



Protecting, Maintaining and Improving the Health of All Minnesotans

Delivered Electronically

November 27, 2017

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Re: In The Matter of the Proposed Rules of the Departments of Agriculture and Health Governing the Minnesota Food Code, *Minnesota Rules*, Chapter 4626; Request for Review and Approval of Notice of Intent to Adopt Rule Amendments With a Public Hearing; Revisor's ID Number 4071

Dear Librarian:

The Minnesota Departments of Agriculture and Health intend to adopt rules Governing the Minnesota Food Code, *Minnesota Rules*, 4626. We plan to publish a Notice of Intent to Adopt Rule Amendments With a Public Hearing in the November 27, 2017 State Register.

The Departments have prepared a Statement of Need and Reasonableness. As required by Minnesota Statutes, sections 14.131 and 14.23, the Department is sending the Library an electronic copy of the Statement of Need and Reasonableness at the same time we are mailing our Notice of Intent to Adopt Rule Amendments With a Public Hearing.

If you have questions, please contact me by either phone at 651-201-5792 or by email at linda.prail@state.mn.us.

Yours very truly,

/s/

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Enclosure: Statement of Need and Reasonableness

Statement of Need and Reasonableness

PROPOSED RULES GOVERNING THE MINNESOTA FOOD CODE,
MINNESOTA RULES, CHAPTER 4626; REVISOR'S ID 4071;
DOCKET NO. - 82-9000-34708

Statement of Need and Reasonableness

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ALTERNATIVE FORMAT

If you would like this document in an alternative format, please contact the
Minnesota Department of Health at 651-201-4500.

ACRONYMS AND ABBREVIATIONS

CFP: Council for Food Protection

Code: Minnesota Food Code, *Minnesota Rules*, Chapter 4626

FDA Code: United States Food and Drug Administration (USFDA or FDA) Food Code

HACCP: Hazard Analysis Critical Control Point

LRFE: Licensed Retail Food Establishment or Establishments

MDA: Minnesota Department of Agriculture

MDH: Minnesota Department of Health

INTRODUCTION

The Minnesota Department of Health (MDH) and the Minnesota Department of Agriculture (MDA) are proposing to amend the Minnesota Food Code (Code), *Minnesota Rules*, Chapter 4626, which the two departments jointly administer. This rulemaking is a major revision of the entire chapter that will bring the Code up to date and in substantial alignment with the 2013 United States Food and Drug Administration (USFDA or FDA) Food Code (FDA Code) and the 2015 supplement to the 2013 FDA Code. This rule regulates almost all licensed retail food establishments (LRFE) in Minnesota. First adopted in 1998, this Code underwent minor amendments in 1999 and none since then. Thus, it is very outdated, and significant revisions are needed to protect consumers of retail food.

For the past 100 years, many federal, state, and local agencies have adopted statutes, regulations, rules, ordinances, and policies dealing with food safety. Minnesota possesses its own collection of statutes and rules regulating food safety. Some are for the front end: the growing, producing and manufacturing of food. Others are for retail food operations where food is prepared, served, or stored. The FDA Code provides the basis for LRFE rules in most states, including Minnesota, to provide rules consistent with national food safety standards.

STATUTORY AUTHORITY

Minnesota Statutes, sections 31.11 and 31.101 authorize MDA and *Minnesota Statutes*, sections 144.07 and 157.011 authorize MDH to adopt rules for food safety and sanitation standards.

Under these statutes, the departments have the necessary statutory authority to adopt the proposed rules.

Delegated Agencies: *Minnesota Statutes*, section 145A.07, subdivision 1, authorizes MDH to enter into an agreement that delegates these duties to local units of government. *Minnesota Statutes*, sections 28A.075 and 28A.0752 authorize MDA to enter into an agreement to delegate these duties to local units of government. MDH delegates to thirty-one agencies and MDA to seven. Delegated local governments ordinances cannot be less strict than the Code, but they may be more strict. Attachment A lists the delegated agencies.

Most delegated agencies will need to revise their ordinances based on the adopted rule language. The departments will set an effective date to allow adequate time after the effective date of the rule to allow for ordinance revision and adoption.

FOODBORNE ILLNESS AND FOOD SAFETY

Foodborne illness is any illness caused by ingesting contaminated food. The food may be contaminated by bacteria, viruses, parasites, and natural or human-made chemicals. Foodborne illness (sometimes called "foodborne disease," "foodborne infection", or "food poisoning") is a common public health problem.

In the United States foodborne illness, including injury is a major cause of both personal distress and preventable illness and death. It is also an economic burden. Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year. This means that one in six people in the United States will suffer from a foodborne illness during a one-year period. Further, foodborne illness is very costly with the annual cost estimated to be \$10–83 billion, including medical costs and reduced productivity.

Foodborne disease can be quite severe, leading to hospitalization and even death; but even when they are relatively mild, they lead to missed days of work. The United States Department of Agriculture Economic Research Service estimates the annual cost (when taking into consideration medical costs, productivity loss, and premature death) of norovirus to be \$2,255,827,318, STEC: \$298,783,251, *Cryptosporidium parvum*: \$51,813,651.77, and Scharff (2012) estimates the mean annual cost of *Giardia intestinalis* to be about \$185,000,000. In addition to medical costs and productivity loss costs, an outbreak caused by an infected food worker is extremely costly to the LRF (loss of food, loss of customers, media attention, lawsuits).

Scientists have described more than 250 foodborne illnesses caused by many different microbes, or pathogens that can contaminate foods. In addition, poisonous chemicals or other harmful substances can cause foodborne diseases if they are present in food. Causative agents for foodborne illness fall into three categories:

- Biological, such as bacteria, viruses, parasites;
- Chemical, such as cleaners, sanitizers, pesticides; and
- Physical, such as glass, nails, animal bones.

If these agents get into food and then into a person's body, they can cause serious illness, injury or death. Nausea, vomiting, abdominal cramps, and diarrhea are common symptoms of many foodborne diseases. The top five pathogens causing the most illness, hospitalizations, and deaths are norovirus, *Salmonella*, nontyphi, *Clostridium perfringens*, *Campylobacter* spp., and *Staphylococcus aureus*.

In Minnesota, norovirus accounted for 57% of the confirmed foodborne outbreaks from 1999 through 2014. During the same period, *Salmonella* accounted for 14%, bacterial intoxications accounted for 10%, and *E. coli* O157:H7 for 5% of outbreaks. (Please see Attachments B, C, &

D.)

Three factors are associated with foodborne disease transmission:

- Contamination: The presence of unwanted substances in foods (chemical, physical, biological, radiological). When unsafe levels of any of them are reached in a final product, adulteration occurs.
- Growth: The proliferation of bacteria. The three intrinsic factors that affect bacterial growth are nutrient content, moisture, and pH. There are three external factors: temperature, time, and atmosphere.
- Survival: The ability of microorganisms to adjust to changes in the environment and to continue to infect in an environmental niche.

In the retail food world, infected food service workers can contaminate food or food can be contaminated with another raw food product. Some examples are:

- An infected food service worker does not wash his or her hands. *Shigella* spp. bacteria, hepatitis A virus, and norovirus can be transferred to food this way.
- Microbes can be transferred from one contaminated food to another uncontaminated food by a food service worker who uses the same knife, cutting board, or other utensil to prepare both, without washing the surface or utensil in between.
- A food that is fully cooked can become re-contaminated if it touches another raw contaminated food or drippings from raw foods containing pathogens, or if it is cooled improperly.
- Animal bones can be incorporated accidentally into a food before being served to a customer, causing choking, or injury to the digestive system.

Outbreak data identifies five major risk factors from employee behaviors and preparation practices in LRFEs that contribute to foodborne illness:

- Improper holding temperatures.
- Inadequate cooking of foods, such as undercooking eggs.
- Contaminated equipment.
- Food from unsafe sources.
- Poor personal hygiene.

A majority of foodborne illnesses can be prevented by following basic food safety. Five key public health interventions can protect consumer health:

- Knowledge: Food handlers know the food safety basics.
- Employee health: Food service workers do not work when sick.
- Hand hygiene: Food handlers adequately and correctly wash their hands and do not contact ready-to-eat foods with bare hands.
- Time and temperature parameters: Food servers keep hot foods hot, cold foods cold and follow correct cooling and reheating procedures.
- Consumer advisories: LRFE owner and operators let customers know the risks of eating raw or undercooked food.

In addition to the five key interventions, the correct design, construction, and maintenance of LRFEs is critical for safely preparing, serving, and storing food.

Federal, state, local, and tribal governments have laws, rules, regulations, ordinances, and procedures governing the retail food industry.

HISTORY AND CONTEXT

U.S. society decided long ago that the safety of food served to the public must be regulated. MDA and MDH do not have the scientific resources to create a brand new food code from scratch. We have used and are continuing to use the FDA Code as a starting point for this iteration.

The Code, first adopted in 1998, has not been updated significantly since then. It was based on the U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration 2005 Model Food Code. Therefore, the Minnesota Code is very outdated. The retail food industry and food industry in general, by comparison, have undergone huge changes in the past twenty years. These changes include:

- More LRFEs,
- More people eating out more often,
- Different types of LRFEs, such as food trucks and pop-up restaurants,
- More types of food available from all over the world,
- New developments in food processing and preparing technologies, and
- Increased consumer interest and concern about where food comes from and how it is prepared.

The U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration 2013 Food Code (FDA Code) is the basis for these proposed rules. The FDA Code is published every four years with a supplement published every two years. It is a model. It is not federal law or federal regulation. States and other governmental bodies may adopt any number of provisions of the FDA Code and may add other provisions as needed.

The departments proposed rules that are very similar to the FDA Code. The FDA Code does not have the force of law. Throughout the Code, the two agencies have not included provisions of the FDA Code that are not enforceable.

Where there are applicable or preemptive national controls, such as the national Safe Drinking Water Act or federal labeling standards, the Code is consistent with and usually directly refers to the national standards.

These proposed rules continue a shift in emphasis toward those food sanitation and safety measures critical to preventing foodborne disease. The shift is away from built-in protection such as requirements for specific types of materials and construction and installation methods for floors, walls, and ceilings toward improving employee personal health habits and hygiene, and owner and operator knowledge about food safety, especially temperature

controls, and industry self-policing.

PROCESS

FDA Code Development Process

Between the every-four-year publications of the FDA Code versions, the agency collects ideas, concerns, and information from a wide variety of sources. These ideas come from governmental bodies, industry, academia, trade organizations, among others. One major source is the Conference for Food Protection.

The Conference for Food Protection (CFP)

CFP is a non-profit organization founded in 1971. The Conference's structure is a representative and equitable partnership among regulators, industry, academia, professional organizations, and consumers. This mixed constituency allows CFP to identify problems, formulate recommendations, and develop and implement practices to ensure food safety.

New rapidly developing food technologies and marketing innovations challenge all groups involved in food production and monitoring to work together to enhance the quality of our food supply. CFP meets at least biennially to provide the forum.

At the meetings, CFP members review, discuss and approve or disapprove proposals from participants and others. CFP staff forward approved proposals to the FDA (or other appropriate federal agencies such as USDA and Center of Disease Control and Prevention (CDC)).

Code Consensus Committee II (CCC II)

Over ten years ago, the CCC II was an early effort by the departments to revise the Code. The membership was a mixture of regulators (MDA, MDH, and delegated agencies) and regulated establishment trade associations (restaurants and grocers) and others interested in food safety. The CCC II created a side-by-side analysis of the existing Code and the 2005 FDA Code with recommendations on what should be included in a revised Code. It also reviewed the 2007 FDA Code and recommended a few items to be included in any Code revision.

Minnesota Food Code Rule Revision Advisory Committee

In Minnesota's rulemaking process, agencies often form advisory committees consisting of representatives of potentially affected groups. These diverse members recommend and advise a department about a new rule or the revision or updating of an existing rule. It is neither legally required nor a decision-making body, nor do its members write the rule language.

For this rule revision, the agencies published a "Request for Comments," the first official step in rulemaking, on December 21, 2009. This notice announced the intended formation of a Food Code Rule Revision Advisory Committee (Committee) and solicited members. The departments planned a Committee with between 20 and 25 members representing as many interested and affected parties as possible.

MDH and MDA also directly contacted organizations that represent persons potentially affected

by the revision and asked for volunteers or nominees to serve on the Committee. In addition, we held a kick-off meeting on January 20, 2010 to inform people about the process to update the Code and announce the Committee formation.

More volunteers and nominees appeared than were needed, so the departments selected a representative and complementary group, listed on Attachment E. The membership was very stable with only one member resigning. Michael Meyer of MHC Culinary Group replaced John Schiltz. In 2014, in order to represent other groups not previously on the Committee, such as farmers markets and assisted living facilities, the departments added a few new members.

A significant number of members attended a majority of meetings. Committee members and other interested people were able to attend the meetings at various locations around the state via video-conferencing.

Meetings and Review Process

The Advisory Committee first met on March 18, 2010. MDA and MDH staff outlined basic rulemaking procedures and the Advisory Committee process. Committee members participated in a brainstorming exercise to identify and prioritize critical issues for update; the results are listed in Attachment F. The Committee discussed the higher-ranked issues during the early Committee meetings.

From time to time, the Committee created subcommittees to work on a particular issue. They were:

- 1) Risk-Based, Science-Based and Hazard Analysis Critical Control Point (HACCP)-Based Subcommittee (*Chair – Peter Snyder*)
- 2) Three-Tier Subcommittee (*Chair – Jeff Luedeman, not an Advisory Committee member*)
- 3) Allergens Subcommittee (*Chair – Nona Narveaz*)
- 4) Person-In-Charge, Certified Food Manager and Active Manager Control Subcommittee (*Chair – Ken Schelper*)
- 5) Food Worker Training and Card Subcommittee (*Chair – Tim Jenkins*).

The subcommittee members worked on the assigned, specific issues and parts of the Minnesota Code and brought their recommendations to the full Committee for discussion and action.

The Committee held 17 meetings from March 18, 2010 to September 27, 2011. It reviewed and deliberated the CCC II recommendations and considered significant changes from the USFDA 2005/2007 Model Food Code compared to the USFDA 2009 Model Food Code. After full discussion, the Committee took formal action by resolution on recommendations. During this time, the FDA released a 2011 Supplement to the Model Code. The departments solicited comments on the content of this document from the committee via e-mail. The Committee made no comments on this Supplement.

The Committee was on hiatus until January 23, 2014 while MDH and MDA staff worked on draft rule language. To better reflect the diversity of Minnesota's LRFEs, meetings resumed with some new members. Joining the Committee were representatives from the assisted living and

housing with service industry, farmers markets, and small LRFEs. The Committee met to review the 2013 US FDA Food Code (FDA dropped the word “Model” from the title) over 10 meetings during 2014. Attachment G lists the meeting dates and locations. Meeting agendas are included as Attachment H.

Managers and supervisors from MDA and MDH reviewed each Committee recommendation individually and decided whether to accept it. The departments’ decisions are included in Attachment I. While not all of the Committee’s recommendations are included in the revisions, the Committee’s collective views and deliberations greatly helped the two departments understand current LRFE and regulatory agency concerns and practices.

Throughout the rulemaking process, many people contacted MDH about the section of the existing Code regulating mushrooms. The departments facilitated a “Mushroom Subcommittee,” which made two recommendations. The departments included those recommendations as modified in the revised language. The full report of the subcommittee is included in Attachment J.

As the revised language was developed, MDH posted various drafts on its website. If the Committee was meeting, it considered any comments received about a posted draft. The Committee determined whether to recommend in corporation of comments in the draft. The departments then decided which revisions to make.

Most Committee members urged that the Code be as close to the FDA Code as possible. Although members agreed with most of the departments proposed changes, disagreement remained on some matters, especially changes to requirements for equipment and food contact surfaces stated in Minnesota Rule, part 4626.0506. The Committee neither approved nor disapproved the draft rule revision placed on public notice.

GENERAL EDITORIAL CHANGES

This rule revision is very large and complicated. We expect its length will be approximately 70 pages longer than the existing rule it revises. Further, we made editorial corrections as outlined below.

The departments do not discuss the following basic changes in the Rule-By-Rule Analysis. These changes are:

Correct basic grammar problems

We corrected many word usage and verb tense errors. A grammatically correct rule is easier for the user to understand and use. Correcting the errors is reasonable.

Change from Potentially Hazardous Food (PHF) to Time/Temperature Control for Safety Food (TCS)

In 2005, the Council for Food Protection Temperature Control for Safety Implementation Committee surveyed industry and regulators about changing the term “potentially hazardous food” (PHF) to “time/temperature control for safety” (TCS). The majority of respondents

preferred using TCS. This switch to “time/temperature control for safety” is necessary because it explicitly points to the obvious public health risks that those food products pose that must be controlled. Time and temperature are the two most relevant control methods for preventing pathogen growth in food. Therefore making an easy-to-understand reference to these common public health risk control methods for food products with the greatest risk of pathogen growth is reasonable.

The term “lavatory” is replaced with the more common term “sink”

The word “lavatories” is replaced with the word “sinks” because it is more commonly used and understood. It is a term used throughout this Code. It is reasonable to use plain language that is commonly understood by the public.

Relocation of the FDA Code reference number

We have moved the FDA Code reference number to the end of the part title because having the Minnesota Code rule part number close to the FDA Code reference number causes problems for computer search engines. Correcting this problem requires a universal change. A reasonable solution is to retain the FDA number but move it away from the rule number.

Changes to the use of the words “shall,” “must,” and “may”

The departments reviewed the proposed Code to ensure “shall,” “must,” and “may,” are used appropriately and consistent with the Office of the State Revisor (Revisor) construction of rule language:

- “Shall” is used when the subject of the verb is animate such as a person or group of people. It designates the requirement as mandatory.
- “Must” is used when the subject of the verb is inanimate such as a restaurant, water or food. It designates the requirement as mandatory.
- “May” is used in both cases (whether the subject of the verb is animate or inanimate). It is permissive, giving the regulated party the flexibility to comply or not.

Complying with the Revisor’s Office standards is self-explanatory as the Revisor is charged with maintaining consistent language in Minnesota statutes and rules.

Relocation of exception clauses to the end of sentences

The FDA Code often begins its sections with the exceptions to the then-following requirement. We think it is needed, reasonable, logical, and simply makes more sense to state the requirement first and then the exceptions. The requirement rather than the exceptions will affect more people and LRFEs.

Revisor Word Change

The Minnesota Food Code is not the only code in the State (building codes, electric code, etc.), so the Revisor changed “the Code” to “this Code” wherever it appears. We agree.

Temperatures and other measurements

We need to write a Food Code as simply and clearly as possible for those who use it. The departments have tried to simplify some of the language of the FDA Code. To that end, we simplified the nomenclature for temperatures and other measurements, such as length, width, and

depth. The FDA Code lists Celsius temperatures first and then the corresponding Fahrenheit value in parenthesis. It also lists metric measurements first followed by the English values. The departments found that many Minnesota LRFE owners, operators, and food workers remain more familiar with Fahrenheit temperature than Celsius temperatures and English values rather than metric values. Thus, we adhered to those preferences and reversed the values. These changes also conform to the Governor's Plain Language Initiative.

Arabic numbers

We have used mostly Arabic numbers throughout the Code rather than numbers written as words ("1" not "one"). Again, this change addresses the need to use plainer and simpler language in government documents, including rules. Using Arabic numbers is reasonable because people's greater ability to read them at a glance make these familiar characters easier to read and understand.

Reassignment of the priority ranking designation of items

The requirements of the Code are many and complex. Since some requirements are more critical to food safety than others are, we need a system that designates each item's priority. The FDA Code introduced a "three tier system" in 2009, which the departments have chosen to strictly follow for assigning priority to items in the revised Code. Please see the information under Minnesota Rules, part 4626.0020, subparts 65A, 65B, and 65C for the discussion of need and reasonableness for the priority ranking terms and their use. Using the same priority assignment scheme as FDA is reasonable because it is the product of the CFP and FDA review. The Committee did not object. The selected priority terms appear as subscripts at the end of the appropriate sections.

Changes to most rule part titles

Many of the FDA Code section titles are not descriptive, making it hard for people to find the applicable requirements. We have changed many titles to reflect accurately the contents of the rule parts. We need these changes to make the Code easier for LRFE owners and operators and others in the food safety arena to use. This is a reasonable approach to make a very long and complicated rule a little simpler.

"Including but not limited to"

This phrase was removed from the proposed Code because it would give the Departments unlimited discretion.

REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out eight factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (8) below quote these factors and then give the departments' response.

“(1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule”

The following will *benefit* from the proposed amendments:

- All persons consuming retail food in Minnesota because overall, the retail food will be safer.
- Some LRFEs will benefit because some of the new requirements are less stringent than existing ones. One example is contained in the proposed Minnesota Rules, parts 4626.0505 and 4525.0506. The departments propose to delete the requirement that all equipment and food-contact surfaces used in LRFEs be certified by a national certification agency. Only 10 types of equipment and food-contact surfaces would require certification.
- Some LRFEs will benefit because the revised Code will be essentially the same as the most recent FDA Code and therefore will be consistent with other state and city codes. This makes employee training, equipment purchases, and operating-procedure development and implementation easier and more cost-effective. This is especially true for national chain restaurants operating in Minnesota.

Some LRFEs may bear costs because they will have to comply with new requirements such as no bare-hand contact with ready-to-eat foods. These costs will be discussed under (5) below.

The MDA, MDH, and delegated agencies will bear costs to prepare for and implement the new requirements.

“(2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues”

Both the MDA and MDH will incur additional costs to prepare for and implement the new requirements.

MDH has estimated \$260,000 for the costs for the time between the adoption and the effective date of the rule and estimated \$183,000 for the preparation costs for the one-year period after the effective date of the rule. Attachment K is a spreadsheet showing the breakdown of these costs.

MDA has estimated for \$98,800 for the costs for the period between the adoption and the effective date of the rule and \$68,700 for the one-year period after the effective date. Attachment L is a spreadsheet showing the breakdown of these costs.

The costs will be borne within the existing departments’ budgets. Any effect on state revenues will be neutral

Some other state agencies own and operate LRFEs. The probable costs to these agencies will be discussed in (5) below.

“(3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule”

The departments’ managers, staff, and the Committee discussed many of the new requirements of the FDA Code at length. It found no less costly or less intrusive methods. The following details some of their considerations.

The option of reducing rules was rejected because these rules are minimum standards to protect public health. Allowing LRFEs to operate without appropriate, up-to-date food safety rules or with significantly fewer requirements would leave the retail-food-consuming public open to suffering foodborne illness with corresponding costly consequences from medical expenses and lost work or education time.

During the last Chapter 4626 revision, there was discussion of requiring all LRFEs to have Hazard Analysis and Critical Point (HACCP) plans. A HACCP plan means a written document delineating the formal procedures for HACCP principles developed by The National Advisory Committee in Microbiological Criteria for Foods. The departments concluded then that requiring HACCP plans for all LRFEs was too costly and not cost-effective. Attachment M contains the pages from the earlier SONAR discussing this issue. The departments reached the same conclusion with this revision.

The Advisory Committee discussed drafting a Code based on the concept of “active managerial control.” The term active managerial control describes industry’s responsibility for developing and implementing food safety management systems to prevent, eliminate, or reduce foodborne illness risk factors from occurring. Active managerial control means that industry management purposefully incorporates specific actions or procedures into their business operations to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety by a continuous monitoring and verification system. A majority of Committee members and both departments view the existing Code and the 2013 FDA Code as based on the concepts of active managerial control and urge the proposed amendments to strengthen that basis.

“(4) a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule”

The departments decided to base the proposed Code on the FDA Code when it initiated the first Chapter 4626 rulemaking. Since then, the departments’ food safety experts have learned nothing that prompts them to change course and no significant opposition to continuing that course has emerged.

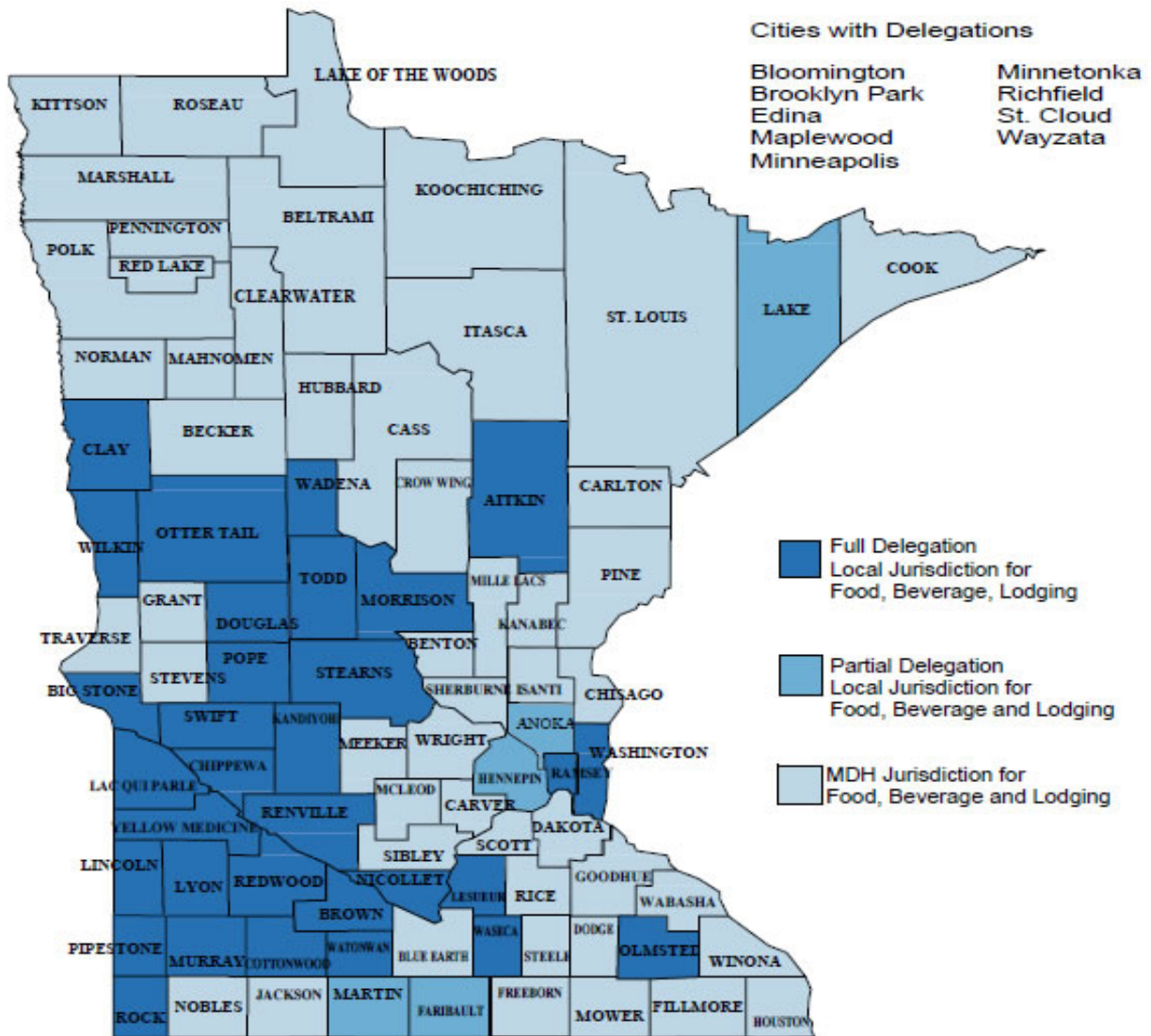
“(5) the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals”

Local unit of government agencies

This portion of the cost analysis is split into two parts. First, there are local units of government that are delegated to administer the food safety program. Second, there are local units of government that own and operate LRFEs.

Delegated agencies

The Commissioner of Health has delegated the authority to administer the MDH retail food safety program to 31 local agencies. Similarly, the Commissioner of Agriculture has delegated the authority to seven agencies to administer the MDA retail food safety program. The departments worked with agency representatives to estimate the implementation costs for the new Food Code. The Committee discussed costs during several of its meetings.



A small group of agency Advisory Committee members developed a draft spreadsheet to begin collecting cost information, which MDH staff refined. Some agency members of the Advisory Committee reviewed the revised spreadsheet via a conference call, which led to modifications. The survey was emailed to all delegated agency members of the Advisory Committee with a request to complete the form and return it to MDH. Seventeen agencies returned the form.

The spreadsheet form proved to be too unwieldy, so the departments developed a VOVICI/Verint survey to collect the information (Attachment N). This survey was emailed to all of the delegated agencies. Fifteen agencies returned a survey, all of which were complete.

None of the delegated agencies are part of a city, county or multi-jurisdictional entity with less than 10 full-time employees. Several people filling out the survey misinterpreted the question

asking for number of employees and replied with the number of employees for the food program, instead of the entire jurisdiction. The departments verified the total employee numbers for each delegated agency.

This chart shows the projected costs organized by number of LRFEs by the agency.

Number of delegated LRFEs	Total Cost for the 6-Month Period after the Adoption of the Revised Rules (\$)	Total Cost for the 12-Month Period after the Effective Date of the Revised Rules (\$)	TOTAL Costs (\$)
130	5,400	2,900	8,300
160	5,300	6,900	12,200
180	3,200	Not stated	3,200
239	5,500	3,400	8,900
250	15,500	12,500	28,000
283	14,500	3,200	17,700
332	9,550	16,900	26,450
465	14,100	5,600	19,700
480	12,500	6,000	18,500
560	29,890	15,000	44,890
775	13,710	750	14,460
835	14,500	6,500	21,000
1100	51,800	41,800	93,600
1800	7,000	13,000	20,000
3700	182,900	319,200	502,100

Based on the cost information from returned surveys, total costs for delegated agencies to implement the new rule ranged from \$3,200 to \$502,100. The costs varied depending on the size and number of food establishments licensed by the agency. Attachment O shows more information about the projected costs.

State and local units of government that own and operate LRFEs

Other state agencies own LRFEs. The Department of Corrections and the Schools for the Deaf and Blind are two examples. The MDH licensing database contains 14 LRFEs owned and operated by a state agency other than the MDA or MDH. Some agencies contract out the food service to private companies. The cost effect on this arrangement would be no different from any other private LRFE. If the contractor currently is in compliance with the Code, there should be minimal costs associated with complying with the revised requirements. The same would be true of state agencies that operate their LRFEs.

Some local units of government, mostly cities and counties own LRFEs. Municipal liquor stores, correctional institutions, campgrounds, pools and parks are examples. Based on rough counts of state LRFEs, discussions with state inspectors and information from delegated agencies, we estimate that approximately 2 – 5% of LRFEs are owned by local units of government. For example, one delegated agency that covers four counties has only 12 city or county owned and operated LRFEs. Hennepin County has reported only two city or county owned LRFEs. All of these entities were included in the regulated LRFEs cost survey discussed below.

Regulated establishments

The cost to the regulated parties of complying with and implementing the new rule is impossible to calculate due to the different affected classes and the range of LRFEs in each class. The departments regulate LRFEs that range from special event stands serving a limited menu of hot dogs and canned pop to large 24-hour full-service restaurants offering over 100 different menu items. These amendments will affect these various types of LRFEs differently. In addition, many larger LRFEs and national chain restaurants have already adopted many or most of the FDA Code's most recent requirements.

Advisory Committee Information

The departments relied on the Advisory Committee members as the primary source for cost information. Members representing regulated establishments attempted to estimate the costs the various types of LRFEs would incur but could not reach firm conclusions due to the complexity of the LRFEs field. Looking at the various possibilities they could imagine, the Committee members' did not reach the threshold amount of \$25,000. Thus, their consensus was that it was unlikely any LRFE currently in compliance with the Code would have to spend more than \$25,000 to meet the revised Code.

Department staff met with representatives of various stakeholder trade associations. They met with Hospitality Minnesota, the umbrella trade organization for food and lodging establishments in Minnesota (Members include LRFEs ranging from small diners to national chain restaurants.): the Minnesota Grocers Association (Members include small to large grocery stores and convenience shops), LeadingAge Minnesota (Members include assisted living and memory care facilities and nursing homes.), and Care Providers of Minnesota (Members include assisted living and memory care facilities and nursing homes.) to discuss possible costs in more detail. In cooperation with these organizations, the departments designed a survey to collect cost information from LRFEs.

Survey

The survey was designed to collect the probable cost of complying with the proposed rule from LRFEs across the state and drive engagement with our regulated parties. The departments sent the survey utilizing an electronic communications platform called GovDelivery. This electronic platform connects people with accessible, relevant, and important government information. A copy of the survey report is included as Attachment P.

The survey was sent on March 13, 2016 to 13,098 LRFE contacts and other people interested in retail food safety. In addition, the survey was posted on the MDH website and remained posted until August 15, 2016. Many retail food organizations also advertised this survey on their web pages or in their newsletters.

The GovDelivery survey successfully reached 11,502 or 88 % of the 13,098-targeted audience. 4495 recipients or 43% opened the survey within the first 120 minutes of the department sending the survey. Of those reached, 255 recipients responded to the survey. Moreover, of that number, 240 or 2% of the total recipients reached completely filled out the survey.

In this good-faith attempt to gather cost information the departments received comments back from LRFE owners and operators, especially those of small LRFEs stating they do not have the time to follow the Code revisions and, in many cases, do not understand the proposed changes. Some respondents based their estimates on an incomplete understanding of the proposed revisions or misinformation. A couple of respondents appear to be simply venting their ire against state government in general. Attachment Q is a copy of the survey results.

Out of the 255 survey responses received, 199 said they had 49 or fewer employees. Of the 199, only 53 (27%) said they would have costs exceeding \$25,000. The departments carefully looked at the categories where these respondents allocated these costs, and found these costs were driven by confusion over equipment and Certified Food Protection Manager (CFPM) requirements. As explained in detail below, we determined these estimates were unfounded. Further, we cannot come up with a scenario that requires a business with less than 50 employees to spend more than the \$25,000 threshold.

Regulated LRFEs Cost Survey Responses:

Total Responses	255
Total Complete Responses	240
Total with 49 or Fewer Employees	199
Total of Responses Stating Costs will Exceed \$25,000	*53

Total Responses	255
Percent of Responses with 49 or Fewer Employees and Stating Costs will Exceed \$25,000	*27%

*see discussion below under Response Analysis

Response Analysis:

Equipment costs were a big concern. There is confusion over the proposed changes to Minnesota Rules, parts 4616.0505 and the new 4626.0506. The existing 4626.0505, item B requires that equipment and food-contact surfaces used in LRFEs must be determined by NSF International or an American National Standards Institute (ANSI) Z34.1 accredited independent entity.

4626.0505, item B is being repealed. The proposed new 4626.0506, item A, requires only 10 types of equipment and food-contact surface must be certified or classified for sanitation by an American National Standards Institute (ANSI) accredited certification program for food service equipment. Some LRFE owners and operator incorrectly believe that they will have to replace all of their NSF-certified equipment with American National Standards Institute (ANSI)-certified equipment. That is not true. Conversely, the proposed changes limit the types of equipment that must be certified for safety and enlarge the universe of possible certifying companies. These changes give owners and operators more choice and flexibility in purchasing equipment. The departments have been working with Hospitality Minnesota, the Minnesota Grocers Association, LeadingAge Minnesota, and Care Providers of Minnesota, and individual LRFE owners and operators to clarify these proposed changes.

The cost to reprint menus and supply table cards to contain the proposed required consumer advisory was another area of concern. There will be costs associated with this requirement. There are ways of minimizing the costs by using stickers or insertions on existing menus and combining the consumer advisory with other information on a table tent.

Certified Food Protection Manager (CFPM)

Certified Food Protection Manager (CFPM) name change was an area of concern and confusion. The name change led some to think they had to have both a CFM and CFPM in their LRFEs. The departments have been working with Hospitality Minnesota, the Minnesota Grocers Association, LeadingAge Minnesota, and Care Providers of Minnesota, and individual LRFE owners and operators to provide clarification regarding the name change.

Because of the concern over cost especially for small establishments, the departments are providing additional cost information for the new CFPM requirements below. The departments are proposing to associate the CFPM requirement to risk categories as described by Minnesota Statutes, 157.20, Subd. 2a - c. These risk categories are listed below.

LRFE Risk Categories.

(a) High-risk establishment. "High-risk establishment" means a public pool, or any food and beverage service establishment, hotel, motel, lodging establishment, or resort that:

- (1) serves potentially hazardous foods that require extensive processing on the premises, including manual handling, cooling, reheating, or holding for service;
- (2) prepares foods several hours or days before service;
- (3) serves menu items that epidemiologic experience has demonstrated to be common vehicles of food-borne illness;
- (4) has a public swimming pool; or
- (5) draws its drinking water from a surface water supply.

(b) Medium-risk establishment. "Medium-risk establishment" means a food and beverage service establishment, hotel, motel, lodging establishment, or resort that:

- (1) serves potentially hazardous foods but with minimal holding between preparation and service; or
- (2) serves foods, such as pizza, that require extensive handling followed by heat treatment.

(c) Low-risk establishment. "Low-risk establishment" means a food and beverage service establishment, hotel, motel, lodging establishment, or resort that is not a high-risk or medium-risk establishment.

All LRFEs designated as "low risk" will be exempt from having a CFPM. Additional exemptions are listed in 4626.0033, item B. These types of LRFEs have menus and procedures that pose little or no risk to public health.

All LRFEs designated as "medium risk" and "high risk" would be required to employ one full-time CFPM. Requiring a CFPM for LRFEs categorized as "medium risk" and "high risk" decreases the public health risk by ensuring LRFEs with more complex food preparation methods are properly trained to eliminate the hazards and risks associated with more complex food preparation methods.

Below is a chart indicating a six-year cost analysis of LRFEs that may be affected by the proposed language. Under the existing language, these LRFEs are not required to employ one full-time CFPM per establishment. With the departments proposed language these LRFE types may be required to employ one full-time CFPM depending on the establishment's method of food preparation. The information below is a snapshot in time and was obtained from the Minnesota Department of Health licensing database in June 2017. This information does not include LRFEs licensed by the department of Agriculture or those licensed by delegated agencies.

LRFE Types	Number of MDH LRFEs	Number of LRFEs Required to Obtain a CFPM	First 3 Year Cost initial training and exam (\$165) plus state certification (\$35)	The Following 4 - 6 year Cost renewal training (\$50 - \$75) plus state certification (\$35)
Seasonal Temporary Food Stands	400	Unknown at this time. Evaluation of food preparation methods will be evaluated upon inspection.	\$200	\$110
Seasonal Permanent Food Stands	260	Unknown at this time. Evaluation of food preparation methods will be evaluated upon inspection.	\$200	\$110
Food Carts	67	21 or 31%	\$200	\$110
Mobile Food Units	625	Unknown at this time. Evaluation of food preparation methods will be evaluated upon inspection.		
Schools with satellite or catered feeding locations	828	7 or 2%	\$200	\$110
Boarding and Lodging Establishments	819	626 or 76%	\$200	\$110
Bed & Breakfast where food is prepared for 18 or fewer persons per meal time	76	23 or 30%	\$200	\$110

Associating the CFPM requirement to risk categories focuses food safety training and certification requirements on LRFEs based on established foodborne illness risk factors as described by the FDA and promotes a more consistent application of the requirement across the state. The proposed requirements benefits outweigh the cost and ensures that LRFE operators preparing food with increased food safety risks will have better food safety knowledge and practices.

“(6) the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals”

By not adopting the rule, there may be increased costs to individuals and society due to foodborne illness and death that the proposed revisions could prevent.

Regulators would continue to incur costs for processing variances for equipment and processes that the proposed revisions would now permit.

LRFEs would continue to incur expense for equipment and processes the existing Code requires that the revisions do not.

“(7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference”

As previously stated the FDA Code is not federal law. Minnesota has chosen to place its licensure policy into state statute, but to base its rule on the FDA Code, which moves the state’s laws toward consistency with national trends. Where there are applicable or preemptive national controls, such as the national Safe Drinking Water Act or federal labeling standards, the proposed Code is consistent with and usually directly refers to the national law or regulation.

“(8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule. . . Cumulative effect’ means the impact that result from incremental impact of the proposed rule in addition to other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time.”

The Code is the only state rule directly governing LRFEs in Minnesota. As stated previously, the federal government does not directly regulate retail food establishments.

RULE AMENDMENTS EFFECT ON FARMING OPERATIONS

Minnesota Stat. § 14.111 requires agencies to send a copy of any proposed rule that affect farming operations to the Commissioner of Agriculture no later than 30-days prior to publication of the proposed rule in the State Register. MDA jointly administers this Code with MDH and has been involved in all aspects of the rule revision process. The proposed amendments do not

regulate the production of food on farms so the proposed amendments will not affect farming operations.

PERFORMANCE-BASED RULES

Minnesota Statutes, sections 14.002 and 14.131 require the departments to describe how in developing these proposed rule amendments; they considered and possibly incorporate performance-based standards in the amendments. (The performance-based standards must emphasize superior achievement in meeting the regulatory objectives and maximum flexibility for the regulated party and department in meeting those goals.)

A true performance-based rule would establish specific outcomes and the regulated party would be able to select the approach or manner to achieve the outcomes. In much of public health regulation, the methods are well-settled safety techniques that must be adhered to. Thus, the departments rejected methods that would not be possible without endangering the public's health. Where possible, these proposed rule amendments do move the requirements to be more process-driven rather than floors, walls, and ceilings as described in the rule-by-rule analysis below.

ADDITIONAL NOTICE PLAN

MDH and MDA designed a dedicated website at the beginning of this rulemaking process and consistently updated it throughout the process

(<http://www.health.state.mn.us/divs/eh/food/code/2009revision/index.html>). All Advisory Committee meetings were open to the public and video conferenced to MDH district offices.

Both the first and second Requests for Comments (RFC) were posted on the MDH website. In addition, the departments either mailed (via the United States Post Office) or emailed both RFCs utilizing an electronic communications platform called GovDelivery. Currently there are over 12,000 subscribers. This electronic platform connects people with accessible, relevant, and important government information. The RFC's were sent to the following groups:

- both departments' official rulemaking lists (Attachment R),
- all of the local units of government delegated to administer the licensing and inspection of food establishments,
- trade organizations such as Hospitality MN and the MN Grocers Association; and
- email lists of people who had expressed an interest in retail food safety.

The Food Code rule revision process and progress were presented and discussed at many Regulators Breakfast meetings. (Attendees at these meetings include MDH and MDA inspectors and regulatory staff from the local units of government delegated to administer the licensing and inspection of food establishments.)

This Code revision was discussed at most of the meetings of the Food Safety Partnership (FSP). (The FSP is a consortium of environmental health professionals, industry partners, and other stakeholders working together to protect the public health in the area of food safety. The goal of the Food Safety Partnership is to create a unified program for food safety in the State of

Minnesota.)

The revision process was presented at several Food Safety and Defense Task Force (FSDTF) meetings. The FSDTF was established to advise the commissioner and the legislature on food issues and food safety.

The quarterly Food, Pools, and Lodging Services (FPLS) Section newsletter published articles about the Code rule revision.

Our Additional Notice Plan also includes giving all of the notice required by statute. We will mail the rule amendments and Notice of Intent to Adopt With a Public Hearing (Notice) to everyone who has registered to be on either departments' rulemaking mailing list under *Minnesota Statutes*, section 14.14, subdivision 1a.

We also will email the Notice to the following groups utilizing an electronic communications platform called GovDelivery. Currently there are over 11,500 subscribers.

- all of the local units of government delegated by either department to administer the licensing and inspection of retail food establishments
- all LRFEs for which MDA, MDH and the delegated agencies have email addresses,
- 520 certified food protection manager trainers for whom we have current email addresses,
- 328 registered Environmental Health Specialists/Sanitarians for whom we have current email addresses,
- trade organizations such as Hospitality MN, Minnesota Grocers Association, LeadingAge Minnesota, Care Providers of Minnesota, and Minnesota Farmers Market Association,
- Minnesota Food Truck Association (MFTA)
We have had difficulty reaching this organization. We will be emailing all persons associated with MFTA and also reaching members through mailing to all LRFE and direct contact by our field staff.
- Minnesota League of Cities, Association of Minnesota Counties and Minnesota Association of Townships,
- National Association of Catering and Events and other like organizations, and
- Others who have expressed an interest in receiving information about food safety.

If we do not have email addresses for any of the above listed persons or organizations, we will mail the Notice to them via USPS.

The Notice, the draft proposed rule amendments, and Statement of Need and Reasonableness (SONAR) will be posted on the dedicated Food Code Rule Revision website.

MDA will post the Notice and links to the draft proposed rule and SONAR on its website.

The departments will present and discuss the amendments, SONAR and Notice of Intent to Adopt at:

- one or more Regulatory Breakfast meetings.
- a Food Safety Partnership meeting.

- a FSDTF meeting.

We will ask and encourage other organizations to publicize the public hearing on their websites and in their print newsletters.

We will give notice to the Legislature per *Minnesota Statutes*, section 14.116. Our Notice Plan does not include notifying the Commissioner of Agriculture because MDA and MDH both administer this rule and MDA has participated in all parts of the rulemaking.

CONSULTATION WITH MMB ON LOCAL GOVERNMENT IMPACT

As required by *Minnesota Statutes*, section 14.131, the departments have consulted with Minnesota Management and Budget (MMB). Before publishing the Notice of Intent to Adopt, we sent to MMB the Governor's Office Proposed Rule and SONAR Form; the proposed rules; and the SONAR. A copy of the cover correspondence and MMB's response is included as Attachment S.

DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION

The departments have determined that a majority of local units of governments delegated to administer the food safety program will need to revise their ordinances to reflect the revisions to the Code. Therefore, the effective date of the revisions will be either January 1st, June 1st or a later date pursuant to *Minnesota Statutes*, section 14.128.

COST OF COMPLYING FOR SMALL BUSINESS OR CITY

The probable costs due to these amendments has been discussed in (5) above. In compliance with *Minnesota Statutes*, section 14.127, based on the information collected from discussions at Committee meetings, the regulated parties cost survey and during the comment periods, we do not know of any situation evolving from these revisions where a small business or city will have a cost of more than \$25,000. Please see the discussion in (5) above for a more detailed analysis of costs.

GENERAL NEED AND REASONABLENESS ANALYSIS

The universal need for safe food to sustain life is self-evident. Some food can be dangerous for humans in its natural state. Problems arise when food is improperly grown, produced, processed, manufactured, prepared, served, or stored. Humans can safely eat most food, if grown, processed, and prepared properly. (The nutritional value of food is outside of the scope of this rule revision.)

Retail food safety is a primary concern for all Minnesotans because they buy groceries, eat at restaurants, and enjoy the rich diversity of cuisine available in the state. Also good and interesting food is an important reason visitors come to Minnesota. Foodborne illness in the United States is a major cause of personal suffering, preventable death, and avoidable economic

burden. CDC estimates each year roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized and 3,000 die of foodborne diseases.

AGENCY WITNESSES

There will be a hearing for this rule revision. Steven Diaz, Section Manager, Food, Pools and Lodging Services Section, MDH and Jeff Luedeman, Retail Food Program Manager, Food and Feed Safety Division, MDA will testify.

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ACRONYMS AND ABBREVIATIONS

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RULE-BY-RULE ANALYSIS

- Please note: When the only change(s) in a part are the ones discussed in “General Editorial Changes” section, we list them under the appropriate part in the Rule-by-Rule Analysis. If there are other revisions to a part, we do not list or discuss the General Editorial Changes included in that part of the rule.
- We use the terms licensee, owner, and operator interchangeably throughout this analysis.

Chapter 1, Purpose and Definitions

4626.0010 FOOD CODE. 1-101.10

The departments rewrote the sentence to clarify that the name of this Code is the “Food Code.” We removed the reference to the current rule parts, as it is no longer correct.

4626.0015 FOOD SAFETY, ILLNESS PREVENTION, AND HONEST PRESENTATION. 1-102.10

This Code needed a clear statement placed at the beginning of the document so everyone can read and understand this Code’s purpose. Having such a statement in a prominent position at its beginning so everyone understands this Code’s purpose is reasonable.

4626.0017 SCOPE. 1-103.10

The departments changed this section from “Applicability” to “Scope” to list the basic subjects covered by this Code and what this Code does.

There needs to be a clear overview of what subjects this Code covers and to what licensed retail food establishments (LRFEs), individuals, and companies this Code applies. Confusion and misunderstandings have occurred in the past, especially in its applicability. Listing the subjects and what they govern clearly on the first page so readers see it before any other Code sections is reasonable.

4626.0018 RESTRICTION OF FOOD TYPE AND PREPARATION METHOD.

The departments added this part because the regulatory authorities sometimes need to prohibit a LRFE from offering certain menu items and doing certain processes that lack the correct

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equipment. This situation often happens with mobile and temporary food establishments that have limited space. For example, a small food truck may not have all the equipment it needs to safely prepare, serve, store a wide range of food, such as a 3-compartment sink, a food prep sink, a handwashing sink, hot holding equipment and adequately sized refrigeration. The departments, which have the regulatory authority to stop hazardous food from being served to the public, chose to state this basic authority at the beginning of the Code, so licensees and operators are alerted immediately to this authority.

4626.0020 STATEMENT OF APPLICATION AND DEFINITIONS. 1-201.10

The departments added many newly defined terms because it has been a long time since this Code has been revised. In that time, LRFEs have developed new food preparation processes and the body of this rule contains many new requirements that address these changes. New terms and definitions are needed to establish a common vocabulary for everyone to understand and implement the new requirements.

Many changes to this section are a plain language improvement. Changing from "listing of terms" to "definitions" switches to a commonly used word. Thus, this section will be clearer for the average reader to read. Using language that is easy to understand is self-explanatory.

Subpart. 1. Applicability.

The departments' revised "applicability" to clearly explain that the following definitions apply to all of this Code. This change is needed and reasonable because it alerts the reader, in the beginning of this Code, to the fact that the definitions apply throughout this Code.

Subp. 2. Additive.

Items A and B simply update references to Code of Federal Regulations citations that apply to food additives. Intent and other language do not change. This revision is self-explanatory.

Subp. 3. Adulterated.

Citations corrections.

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Subp. 4a. Asymptomatic.

“Asymptomatic” is a word used in public health to refer to infected food service employees who can spread foodborne illness.

The departments added a definition of "asymptomatic" to ensure regulators, licensees, and operators understand what the term means and know about this category of ill employees. Common meaning and terminology is needed to better ensure that individuals who are likely capable of passing on an illness do not return to handling food and so that regulators and operators can effectively communicate using the same terminology when referring to control of risk factors related to employee illness.

Asymptomatic employees pose a particular concern because they have no symptoms (vomiting and diarrhea) yet they remain capable of transmitting foodborne illness pathogens through improper food handling practices. The only possible way to ensure such infected employees do not endanger public health is to limit them to non-food handling activities until they are no longer infectious. Therefore, this category of ill employee must be clearly defined and accounted for when developing employee illness policies.

Subp. 5. A_w.

This water activity definition was expanded to include a description. The expanded definition of “A_w” informs the reader of how water activity is calculated.

Water activity is one of two characteristics most commonly used to determine if a food is potentially hazardous. It is often controlled to render the food safe at any temperature (the other is the acidity of the food or pH). Just like human cells, bacteria and microbes need enough water to survive and grow. Most foods have a water activity at or above a level that will provide sufficient moisture to support the growth of bacteria, yeasts, and mold. The amount of available moisture can be reduced to a point that will inhibit the growth of the foodborne illness causing organisms.

Limiting available moisture in a food product is one of the most effective ways controlling microbes that can cause foodborne illness (food dehydration is an example). Expanding the definition of water activity is necessary to provide operators and regulators knowledge about

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what food products are innately potentially hazardous and what type of food processing is needed to make a food product non-potentially hazardous. In addition, the definition of Time/Temperature Control for Safety Foods (TCS) added to this Code is based partially on the water activity of the food product. The definition of water activity and explanation of how it is calculated are needed to support the understanding of what is a Time/Temperature Control for Safety Food.

This change is reasonable because it will allow a clearer understanding between operators and regulatory authorities when making decisions about safe handling of potentially hazardous foods. In addition, it is reasonable because LRFE licensees may desire to formulate a food product that is safe at any temperature. Their understanding of how to test a food product to determine the water activity will allow them greater flexibility to produce these types of food products and to do so with confidence.

Subp. 5a. Balut.

"Balut" is a food that must be handled properly to ensure food safety. As the cultural diversity of Minnesota's population increases, this Code must address foods that were previously uncommon but are now popular among different ethnic groups throughout the state. Baluts, which are fertilized eggs, are neither an egg nor a meat product and they must have time / temperature control for safety. People often eat them without cooking them; therefore, guidance for this specific type of food product becomes necessary to avert the public health risk they pose to the individuals consuming them.

Having a definition that informs operators and regulators what the rule expects is both reasonable and necessary. Balut is considered a delicacy among Philippine, Vietnamese, and other Asian populations. There is a specific incubation period for the fertilized egg and cooking parameters that must be met to ensure food safety. Providing new definitions of new and emerging food products in order to protect the health of Minnesotans is reasonable and necessary.

Subp. 9. C.

The departments deleted the abbreviation "C" from this Code. This abbreviation is commonly understood without defining its use. It is reasonable to delete obsolete or unnecessary terms from this Code.

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Subp. 10a. Certified food protection manager or CFPM.

This Code needs a clear definition of what a “Certified Food Protection Manager or (CFPM)” is and how to obtain a valid certification. Adding this definition to this Code addresses that need.

Food protection managers play an important role in formulating policies, verifying food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. A Center for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study indicates that a certified food protection manager’s presence reduces a LRFEs risk of having a foodborne illness outbreak and serves as a distinguishing factor between LRFEs that experienced a foodborne illness outbreak and those that had not. Having one definition to make it clear to operators what the rule requires is reasonable.

Subp. 11. CIP.

The departments revised the "CIP" (clean-in-place) definition to make it easier for operators and regulatory authorities to understand what type of equipment that they are permitted to clean in place. The existing rule’s intent and meaning of the definition has not changed but the new version is much easier for operators and regulators to understand and eliminates confusion between “CIP” and “in-place, manual cleaning” which are similar terms but have separate meanings. CIP applies to closed-loop systems and other self-contained food equipment that have manufacturer’s instructions for cleaning internal components. In contrast, in-place, manual cleaning applies to large pieces of equipment that must be warewashed (defined below) outside of a warewashing machine or sink due to their size but can be accessed externally for washing, rinsing, and sanitizing.

Including a clear definition of CIP is reasonable to ensure that the requirements of this Code are met by operators.

Subp. 11a. Clean.

The departments deleted the definition of “clean” because there are different standards of what constitutes “clean” within this Code. The existing definition does not specify in detail or clarify

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what is generally meant by and understood to be clean and only caused confusion to the operators and regulators. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 12. Commercial game animal.

The departments deleted the definition of “commercial game animal” from this Code because the term is not used within this Code and it is not defined in Minnesota Statute. The term has been replaced in this Code by language such as “Game animals commercially raised for food...” (part 4626.0160, item A). It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 12a. Commingle.

The departments added a definition of “commingle” so that operators and regulators understand that there is an increased public health risk when shellstock from different containers are mixed together because there is no way to tell which container a particular shellstock item came from. This Code prohibits commingling shellstock entirely to ensure shellstock sale or service does not exceed a risk level that would jeopardize the health of consumers purchasing or eating these products. Therefore, defining the term “commingle” is important.

Having one definition eliminates confusion for operators’ compliance. Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. We need proper identification for tracing the origin and determining conditions of shellfish processing and shipment. If lots are “commingled” at retail, traceability is undermined and the root of the problem may remain undetected.

Subp. 13. Comminuted.

The departments changed this definition for readability and clarity without changing the meaning to make it easier for operators to understand. Increased understanding of this term is needed because “comminuted” meat products pose a greater risk to public health than intact, whole-muscle cuts of meat, which is reflected in cooking temperature requirements in other sections of this Code.

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Subp. 13a. Commissioner.

Both MDA and MDH administer jointly the Code and there has been confusion about which “commissioner” is referred to in various sections, therefore a definition is needed. It is reasonable to identify the Commissioner of MDH as commissioner because that position has specific authorities outlined in this Code. The Commissioner of MDA does not.

Subp. 14. Common dining area.

The departments deleted the definition of “common dining area” from this Code because the term is commonly understood to refer to common areas in institutions and residences where people dine. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 14a. Conditional employee.

The departments added a new definition of “conditional employee” to ensure compliance with the Americans with Disabilities Act, United States Code, title 42, Chapter 126.

A conditional employee is a candidate to whom a job offer has been made conditioned on responses to subsequent medical questions and examinations. The questions or examinations are designed to identify potential food employees who might be suffering from a disease that can be transmitted through food. Other parts of this Code require that when a conditional employee reports a listed diagnosis or symptom the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met. When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee, the conditional employee may then begin working as a food employee.

Adding this definition dispels confusion. The Code needs clarity so operators understand what is required when extending a job offer to a potential employee.

Subp. 17. Cook and chill.

The departments deleted the definition of “cook and chill” because the term is a specific type of reduced oxygen packaging method; therefore, “cook and chill” has been added as a sub-definition under Subp. 68. “Reduced Oxygen Packaging.” Continuing to define “cook and chill”

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separately from “Reduced Oxygen Packaging” could cause confusion. Individuals may believe that it is something separate from reduced oxygen packaging. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 18a. Counter-mounted equipment.

LRFE operators who cannot adequately or effectively clean areas under equipment could create a situation that could attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food. Cleaning effectiveness is directly affected by the ability to access all areas to clean fixed equipment. If that is not possible, sealing the inaccessible areas to prevent contamination is required. The definition of “counter-mounted equipment” is needed and reasonable for operators and regulators to clearly identify this type of equipment.

Subp. 19a. Critical limit.

“Critical Limit” is a term used for controlling hazards to food safety. A critical limit distinguishes between safe and unsafe operating conditions at a crucial or “critical” control point. Critical limits may be based upon factors like temperature, time, moisture level, water activity, or pH. They must be scientifically based and measurable.

Critical limit is a prescribed parameter that must be met to ensure that food safety hazards are controlled at each critical control point. It is reasonable to have one definition to make the concept clear to operators. The Code needs this definition to identify and explain what a critical limit is to operators that are dealing with these types of foods and processes. It is reasonable to have one definition to make the concept clear.

Subp. 19b. Cross-contamination.

A new definition of “cross-contamination” was added for clarity. The departments received many requests from the public to provide a definition to eliminate confusion about the meaning of this term. Cross-contamination of food can lead to serious health risks such as food poisoning or unintended exposure to food allergens. This term is a critical element of food safety.

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Subp. 20. Critical item.

The departments deleted the definition of “critical item” because the term is outdated. Violations have differing severity levels. Some are more likely to result in foodborne illness or injury, while others are more likely to be indirect causes of foodborne illness. The language that is used to refer to the severity level must be clear for everyone to understand.

The existing Code uses two tiers of severity, “critical items” and non-critical items.” These designations were used to assist the LRFE in prioritizing corrections. Assigning severity to the violation helps the operator recognize which provisions in this Code are the most important to prevent or control to provide safe food. This term, as well as the term non-critical has been replaced by a three-tiered severity system, “Priority 1,” “Priority 2,” and “Priority 3.” These three tiers allow more flexibility in determining the severity of a violation and much clearer direction for priorities.

Since the term is not used in the proposed version of this Code its removal is self-explanatory. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 20a. Cut leafy greens or leafy greens.

The definition of “Cut leafy greens or leafy greens” is needed in this Code because certain leafy greens have been implicated in multi-state outbreaks of foodborne disease involving highly pathogenic bacteria, and therefore need time/temperature control to protect public health. These items are commonly sold at retail and used in LRFEs. This definition clarifies for the industry and regulatory what constitutes a cut leafy green or leafy green. It is reasonable to define these terms, so regulators and operators know what the rule requires for time/temperature control in order to protect public health.

Subp. 20b. Dealer.

A definition of "dealer" is needed for operators and regulators to know and understand the shellfish labeling requirements. A dealer must be listed on the label for tracing back investigations during foodborne outbreaks.

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Subp. 20c. Disclosure.

“Disclosure” is a new definition and requirement as part of the broader consumer advisory requirements in this Code. Disclosure requires a LRFE to inform consumers of any products that have not been treated to eliminate pathogens. The disclosure allows individuals to avoid eating foods that may contain pathogens that can cause foodborne illness. This definition clearly describes the essential components of a disclosure.

Subp. 22. Dry storage area.

The definition for “dry storage area” needed some minor clarification so operators and regulators would understand what types of food and single-service items can be stored in such a storage area. Pathogens can contaminate and grow in food that is not stored properly. There is no scientific data showing different outcomes for dry storage of bulk and non-bulk items so allowing storage of packaged and containerized food that does not need time/temperature control frees operators from an unnecessary limitation. Not unduly limiting what can be stored in a dry storage area to bulk items is self-explanatory.

Subp. 24. Easily movable.

The changes to this definition are needed to remove the language regulating the weight of “easily movable” equipment. The design of equipment and the use of aids such as casters, rollers, and gliders are the determining factors of whether something is easily movable, not weight. It is reasonable to allow for greater flexibility in what is defined as “easily movable” equipment.

Subp. 24a. Egg.

This Code needs a definition of “egg” to identify the eggs the departments regulate among the many different varieties of eggs that the public consumes.

Eggs are avian species’ shell eggs known to be commercially marketed in the United States. Thus, this simple definition gives operators a clear understanding of what they can label as an egg in their LRFEs.

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Subp. 24b. Egg product.

The departments need a definition for “egg product” to explain a different physical state of eggs that operators often use in their LRFEs. Egg product contains shell eggs that have been separated from the shell and processed to be free of *Salmonella* spp. microorganisms. Thus, this product is a safe alternative to using shell eggs, particularly for operators that serve highly susceptible populations. It is reasonable and necessary to have one agreed-upon definition so operators and regulators alike know what the rule expects.

Subp. 25. Employee.

This addition of food employee corrects an omission in the existing Code. We should have included it in the existing Code. The term “food employee” must be included in the definition of “employee” because food employees work in LRFEs and are required to comply with this Code. It is reasonable to correct this error.

Subp. 26. Equipment.

The departments revised “equipment” for clarity in the context of this Code. We added more example items that do and those that do not qualify as equipment in a LRFE. The revised definition is also more consistent with other definitions in the Code.

Additional examples make it easier for operators to understand how their equipment commonly encountered in LRFEs fits into the regulatory scheme. Less common items have been excluded or removed.

Subp. 26a. Exclude.

“Exclude” is a specific action that LRFE operators take if they must prohibit an employee from working due to a possible foodborne illness. The definition is needed so operators and regulatory authorities all understand what the prescribed action is.

This Code provides exclusion guidelines for employees that have been identified as a carrier of a foodborne illness or a person that has been exposed to foodborne illness. By excluding the employee, the probability of further transmission is reduced. Defining the term provides clarity and minimizes confusion over what the term means.

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Subp. 27. Extensive remodeling.

The departments deleted the definition of “extensive remodeling” because the term is used only twice within this Code and is used exclusively concerning plan review. The definition was originally in this Code to clarify what types of remodeling projects were considered extensive and thus required department review. Plan review is now required in all situations, regardless of extensiveness, making the term obsolete. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 28. “F” means Fahrenheit.

The departments deleted the definition of “F” because commonly understood abbreviation “F” for “Fahrenheit” was defined as such. Since “F” is used as an abbreviation only after a numerical temperature, its meaning is apparent and this definition is superfluous. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 28a. FDA.

The need for an antecedent for the acronym “FDA” in this Code is self-explanatory.

Subp. 29. Fish.

The definition of fish has been changed to make it easier for readers to understand what varieties of seafood are included when the term “fish” is used in this Code. The change is needed since multitudes of types of seafood are available, with specific rules and food safety concerns applicable to specific types. We have updated the language for clarity.

We also removed mollusks, which are included in the definitions for “molluscan shellfish” and “shellstock.”

Subp. 32. Food cart.

The addition of a more detailed definition of a food cart is needed for operators and regulators to clearly understand what rules pertain to these types of foodservice operations. A “single, self-contained unit” differentiates a food cart from a mobile food unit or seasonal temporary food stand.

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Food carts have the current definition in *Minnesota Statute 157.15*, Subd. 6: "Food cart" means a food and beverage service establishment that is a non-motorized vehicle, self-propelled by the operator. Differentiating food carts from other types of mobile or temporary foodservice operations as a "single, self-contained unit" is reasonable and consistent with this definition.

Subp. 32a. Food catering.

The departments need a definition of "food catering" in this Code because this revision addresses an important area that previous iterations have not: namely; the food service operators' common practice of preparing food that is eaten immediately on or off -site. This definition provides for both foodservice operators and regulators.

Licensing bodies generally evaluate LRFEs based on where food is *prepared* rather than where it is *served*. For example, LRFEs that manufacture food for packaging and delivery to grocery stores are typically evaluated and licensed differently from LRFEs that prepare food for immediate consumption on-site. To accommodate consumer demands, LRFEs that typically prepare food for immediate consumption on-site might also package food for take-out or delivery, or other types of off-site service. Further examples are wedding receptions, private parties, alumni reunions or other events not open to the public. Many businesses specialize in such events, without maintaining a permanent dining area for walk-in customers. Food catering requires additional food safety considerations beyond those that might affect manufactured or on-site foodservice operations. Food often must be protected from contamination and be kept either hot or cold during transportation or service.

The term "catering" has been used in a variety of ways in the foodservice industry for some time. This definition clearly states what "catering" is regardless of the location of service, a definition that applies from the time it is prepared until the time it is served and consumed.

Subp. 35. Food establishment.

The departments revised the definition of "food establishment" to describe and clarify operations and elements of operations that are retail and are therefore subject to this Code without focusing on types or examples of establishments as they can become complex. For example, a single food establishment may include retail operations as well as wholesale or manufacturing operations. This code applies for retail operations and not wholesale or manufacturing operations. The

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revised definition identifies retail establishments that are not subject to this Code based on licensing exemptions or exclusions in *Minnesota Statutes* 157 and 28A. This revised definition clarifies for the industry and regulatory when this Code does and does not apply.

It is reasonable for the industry and regulatory to clearly recognize when and where the provision of this Code apply, and when and where they do not, as in the case of wholesale and manufacturing operations, or where licensing exclusions or exemptions are provided for in *Minnesota Statutes* 157 and 28A.

Subp. 36. Food processing plant.

The departments updated the definition of a “food processing plant” to clarify how a food processing plant differs from other types of food businesses.

The proposed change is reasonable because it more clearly aligns the definition with what is commonly known regarding food processing plants, the plants that manufacture food or provide food to other types of food businesses for additional processing, preparation, or service. Food processing plants have unique food safety considerations that must be evaluated to protect public health.

Subp. 37. Game animal.

The revised definition of game animal is needed in order to add the regulatory references (Code of Federal Regulations, title 9, section 301.02; *Minnesota Statutes*, section 31A.02; *Minnesota Statutes*, section 97A.015, *Minnesota Statutes*, sections 17.452, 17.453, and 17.455) used to determine what defines a game animal for the purposes of this Code. This revision deletes lists or examples of animals and refers to what has been established in Minnesota Statute or the Code of Federal Regulations, title 9. It is important to clearly define game animal as this Code sets standards for cooking time and temperature, and USDA inspection for game animals.

It is reasonable to add clarifying language for industry and regulatory entities that demonstrates the regulatory basis for what defines a game animal. Further, the definition of game animal establishes the framework for public health protections afforded in USDA inspection and cooking time and temperatures.

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Subp. 38. General use pesticide.

The departments added “US” to the title of the federal Environmental Protection Agency (EPA) to make it clear that the Code refers to the US EPA. The US EPA sets standards for “general use pesticides” used in this Code and a precise reference is necessary.

Subp. 38a. Grade A standards.

The Code needs a definition for “Grade A milk standards” that apply to certain products made from milk. The definition is consistent with that of the Food and Drug Administration (FDA), which is used for pasteurized milk. Liquid eggs, fluid milk, and milk products provide an especially good growth media for many types of bacteria. Pasteurization uses heat to kill or inactivate bacteria and other harmful microorganisms likely to exist in these time/temperature control for safety (TCS) foods. Using pasteurized milk products reduces the risk of foodborne illness.

Subp. 39. Group residence.

The departments deleted the definition of “group residence” because the language is outdated. In the existing version of this Code, the definition refers to a type of establishment. The proposed new definition of “food establishment” has been changed to include more food operations including a group residence. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 40. HACCP plan.

This definition has been updated for grammatical clarity. The acronym “HACCP” is correctly stated as “hazard analysis and critical control point.”

Subp. 40a. Handwashing sink.

The definition of “handwashing sink” is needed to ensure that operators understand what type of sink is required in a LRFE.

Hands, which can become contaminated during routine operations, are a common vehicle for transmitting pathogens to food in an LRFE. Handwashing serves as an important intervention for

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controlling foodborne illness. Sufficient handwashing sinks must be available to make handwashing not only possible, but also likely to occur at appropriate times and places. The proposed rule is reasonable as it clearly identifies the type of sink that operators must have as well as its intended purpose.

Subp. 42a. Highly susceptible population.

There is a need to define “highly susceptible population” to ensure operators and regulators know that a facility might be preparing food that will be served to people that are more likely to contract and succumb to a foodborne illness. The term also appears in other areas of the proposed rule. Therefore, a definition is needed.

Certain food safety measures might be needed when serving highly susceptible populations, due to their increased vulnerability to foodborne illness. The proposed rule is consistent with the working definition currently used by health care providers and other organizations that frequently work with these groups of individuals, thus it is reasonable.

Subp. 44. Injected.

The departments modified the definition for "injected" for clarity. The existing definition is unclear and includes language describing what the unintended outcome of the process might be, rather than simply defining the process.

Injecting meats is a common practice in manufacturing and LRFEs that can affect the required final cooking temperature of the products. This change is easier to understand and will allow for effective communication between operators and regulators about meat processing.

Subp. 44a. Juice.

The departments added this definition of “juice” to correspond to a new part added as juice has become a product category of its own within LRFEs. We need a clear definition so operators and regulators know what this Code covers.

Explaining the difference between a juice product and a puree product that highly susceptible populations might consume is both necessary and reasonable for enforcing this Code.

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Subp. 48. Linens.

This definition change for “linens” expands its scope by stating that the list consists of representative examples used for food related work and service. It is reasonable not to limit linen varieties.

Subp. 48a. Major food allergen.

Food allergens have become a significant concern for public health as contaminated food products can lead to serious illness or death. We need a definition for "major food allergen" to explain its scope when this term is used in other areas of the proposed rule. The language includes descriptions of items that are included and excluded from this definition. There are new requirements related to food allergens included in the revisions.

The term, used for the first time, appears several times in the new requirements related to food allergens in the revised Code. The proposed definition is consistent with those used within the food industry and other regulatory agencies throughout the U.S.

Subp. 49. Mass gathering.

The departments deleted the definition of “mass gathering” because it is no longer needed in this Code. Removing unnecessary language from this Code makes it easier for operators to understand. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 50. Meat.

The departments modified the definition of meat to clarify that fish, poultry, and wild animals defined in *Minnesota Statutes*, section 97A.015, Subdivision 55 are not considered meat, to include wild animals lawfully taken and transferred by gift according to *Minnesota Rules*, part 6230.1500 and *Minnesota Statutes*, section 97A.505, or donated to a charitable organization registered under *Minnesota Statutes*, chapter 309.

The departments also removed language that limited the definition of meat to the flesh of animals used as food that is offered for human consumption. Limiting the definition of meat by

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the intended use of the product does not ensure reduced human health risk, and the language is not needed in this Code.

It is reasonable to define meat in a manner generally understood, to clarify what animals are not considered meat, and to remove unnecessary language from this Code. It is also reasonable to expect that meat could be used for human food or pet food, and that product labeling would specify the intended use without unnecessarily limiting the definition of meat in this Code.

Subp. 50a. Mechanically tenderized.

The departments propose to define "mechanically tenderized" in this Code because it is a new common method of preparing meat that fundamentally changes the meat product's characteristics, and with the changes the potential hazards to food safety. Mechanically tenderized meat is a food safety concern because the knives or needles can carry contaminants from the surface of the meat deep into the flesh, potentially contaminating the interior of the meat. This would then directly affect the meat's necessary final cooking temperature to adequately destroy pathogens.

The definition gives operators and regulators a clear description of what happens when meat is mechanically tenderized and the hazards that it poses. This process differs from "injection" of meat and requires a unique definition. Having one definition to make it clear to operators what the rule governs alleviates confusion. It is important to define the process' scope so that the risks are clear.

Subp. 52a. Noncritical item.

The departments deleted the definition of "noncritical item" because it is obsolete. The term is not part of the new three-tiered system for determining the severity level of a violation. Minnesota changed to a three-tiered system, which allows more flexibility in determining the severity of a violation. It is reasonable to delete obsolete or unnecessary terms from this Code. See also Subp. 20. above and Subp. 65a. - c. below.

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Subp. 52b. Mushrooms.

The departments need this definition to clearly define and differentiate “mushrooms” in this Code since operators are more widely using them. There are wild and cultivated mushrooms and this definition provides clarity for operators and regulators.

Having one definition that makes it clear to everyone which items are regulated is reasonable. It is also reasonable to expect that operators may obtain "wild" or cultivated mushrooms to use in their LRFEs. There are over 5,000 species of fleshy mushrooms that grow naturally in North America, making it difficult for regulatory authorities to regulate wild harvested mushrooms. Having a clear definition of mushrooms will foster clear communication between regulators and operators when examining mushrooms at LRFEs.

Subp. 52c. Neighborhood kitchen.

This term “neighborhood kitchen” has become common terminology when referring to kitchens outside of the main kitchen in a senior living facility. The term incorporates that meaning in context.

This definition is needed because it is used elsewhere in this Code. Our aging population has generated an expansion of housing and food service options for residents. Along with this, the industry has developed terms to refer to different types of facilities. Both industry and regulators statewide understand the term to mean a kitchen outside of the main kitchen in these circumstances.

A work group of industry representatives, trade associations, MDH Health Regulations Division representatives and state and local regulators met over several months to discuss the terms used and the minimum requirements for these kitchens. This work group determined that the use of the term neighborhood kitchen was best because it was already common language for all of the groups involved. Since “neighborhood kitchen” is generally regarded as the most appropriate term for the given definition by concerned stakeholders, it is reasonable to use it here.

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Subp. 52d. Noncontinuous cooking.

To allow operators additional flexibility, this Code acknowledges and accepts “noncontinuous cooking,” a method for cooking food in distinct stages that has gained acceptance since the last food code revision.

Some LRFEs partially cook a food item by searing a steak or chicken breast on a char-broiler earlier in the day, for example, and deferring the final cooking and other preparation until it is closer to serving time. LRFEs that are catering an event will commonly use this cooking method to enable them to serve a large number of people in a short amount of time. Therefore, we need this definition to identify this method. This will distinguish it from undercooking food or failing to reheat food properly, which are safety threats subject to enforcement sanctions. Having this process defined allows LRFEs using this desired flexibility and provides regulators with clear boundaries of what it entails.

During the rule development, several industry representatives stated that including provisions for noncontinuous cooking in this Code is important. For clarity and consistency, the departments have used the same language that is in the FDA Food Code.

Subp. 52e. Nonpublic Water System.

The definition of “nonpublic water system” was added to distinguish this type of water supply system from a public water system, which is also defined in this Code. Nonpublic water systems encompass all systems that do not meet the definition of a public water system. This Code establishes water quality standards that must be met by both public and nonpublic water systems to ensure safe water for use in food preparation, handwashing, dishwashing, and consumption in a LRFE. Defining this term is important because it is used with specific meaning and requirements in the following parts of this Code: 4626.0980, 4626.1005, and 4626.1030.

It is reasonable to provide this definition because it promotes an understanding about this specific type of water supply system and clarifies that there are specific requirements for this type of water supply system. Without this definition, operators and regulators may be confused about a particular type of water supply system that might not meet the definition of a public water supply but needs to be constructed and maintained to specific standards to protect public health.

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Subp. 53. Packaged.

“Packaged” has specific meaning beyond its common meaning when used in this Code, especially within the context of labeling provisions. Some food products must be fully labeled, while others do not. The definition was changed to make it easier to understand what the term packaged does and does not include. The term securely was deleted, as in securely bagged or securely packaged, because the term is vague, undefined and does not impact whether or not a product is considered packaged. Eliminating securely also aligns the process of bagging or wrapping to the same standards for other types of packaging such as bottled, canned and cartoned.

The departments considered using the FDA Food Code definition, but rejected it as not being clear enough. The existing language and the language in the FDA Food Code were rewritten to make it easier to understand. Compliance depends on operators being able to understand requirements.

Subp. 54. Person.

The departments removed unnecessary language from the definition of “person.” Simplifying this definition is needed and reasonable because it creates clarity for operators.

Subp. 56. Personal care item.

“Personal care item” carries specific meaning when used in this Code. The proposed language makes the list of personal care items less limiting and more inclusive. The change makes the language more understandable.

Subp. 57. pH.

The departments deleted unnecessary information from the definition. The deleted language described the pH scale but not the pH itself.

Subp. 58. Physical facility.

This revision modified the existing definition of “physical facility” by rearranging the word sequence to make the definition easier to understand. It leads with “accessories” and

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“attachments” before their respective examples rather than just tacking “other accessories” and “other attachments” at the end of their respective clauses.

Subp. 61. Poisonous or toxic material.

Food safety requires proper use and storage of “poisonous or toxic materials.” The departments revised this definition to fix the grammar and to provide lists of inclusive examples rather than limiting ones. Making the definition easier to understand is reasonable.

We also added an exception for sanitizers that was not previously in this Code. Sanitizers are a chemical product that have a specific use identified throughout this Code. The existing definition language provides room for interpretation that sanitizers require the same restrictions as poisonous or toxic materials, which would limit their use required by other parts of this Code. Excluding sanitizers to eliminate possible contradictions between requirements of this Code is important. The departments used the language in the FDA Food Code for this definition because the definition is used across the nation to promote consistent communication about food safety among food service professionals.

Subp. 63. Poultry.

“Poultry” is a common term that carries specific meaning in this Code. The definition, which we changed for clarity, now includes more examples of what poultry is without making it a limited list. We also incorporated Code of Federal Regulations definitions by references for simplicity and consistency with the FDA Food Code.

Subp. 64. Premises.

The departments made changes to “premises” for clarity. Some LRFEs are very large and may share space with other businesses. If this definition is not revised, certain portions of a LRFE may not be considered part of the LRFE when it actually is part of the LRFE operation. The definition is also revised to provide examples of types of premises rather than having a limited list of types of premises.

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It is reasonable to make the changes to the definition so there is a clear understanding of what a premises means as it is used in this Code. It is also reasonable to use this language to be consistent with the FDA Food Code.

Subp. 64a. Prepare.

“Prepare” has specific meaning when used in this Code, which is important for food safety and consistent application. When food is prepared, it triggers numerous additional requirements in the Code based on the risk associated with the preparation of food items.

The departments developed a lengthy nonexclusive list that includes different types of food preparation practices conducted in LRFEs to avoid confusion and inconsistencies in interpretation or application of this Code.

Subp. 65. Primal cut.

The departments expanded the definition of “primal cut” to provide examples of what primal cuts are. It is important to clearly define primal cut and provide examples because it is a term used with specific purpose later in this Code. Without expanding the definition, confusion could result in a non-primal cut of meat handled improperly due to the misinterpretation that it is a primal cut. The consequence could increase the risk to public health.

Subp. 65a. Priority 1 item or p1.

Subp. 65b. Priority 2 item or p2.

Subp. 65c. Priority 3 item.

These three defined priority levels form the linchpin of enforcing this Code by assigning different levels of severity to the violations that inspectors find. These levels, 1, 2, and 3, with 1 being the highest priority and 3 the lowest correspond to the respective violations, based on whether they are more likely to result in foodborne illness or injury. Other violations, which are separate infractions, are elements of the more severe items. So that everyone understands which violations should be corrected immediately, the departments have adopted the FDA Food Code’s new system for assigning severity to the violations. This system prompts an operator to recognize which provisions in this Code are the most important to prevent foodborne illness or

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provide safe food. Defining these terms according to their respective priorities also allows regulators throughout the state to apply the severity levels consistently.

Including definitions that are easily understandable for the respective severity levels in this Code is reasonable. The departments considered using the FDA’s current violation-severity designations, “Priority,” “Priority Foundation,” and “Core,” but rejected them as unreasonable and confusing. The Food Code Advisory Committee, which considered assigning the severity to code provisions as one of their important charges, devised the Priority 1, 2, and 3 terms. In addition, MDH surveyed LRFEs to determine whether the terms Priority 1, Priority 2 or Priority 3 or the language used in the FDA Food Code was understandable. The survey revealed that industry members could easily understand the new terms with the definitions that were given to them. Only 4% of the survey respondents indicated that they could easily understand the FDA Food Code severity designations. The FDA’s terms were not as easy to understand, especially to those persons whose first language is not English, compared to using the word “priority” with a 1, 2, or a 3 assigned to the violation.

The departments opted to use its own system despite the fact that some Food Code Advisory Committee members felt that the departments should choose terms that are consistent with the FDA Food Code terms. They believed that since we were proposing to change the terms that the FDA Food Code terms should be used for the designation.

Subp. 66. Public water system.

The departments revised the definition of a “public water system” as it is used in this Code for clarity and by using language of the Code of Federal Regulations. We also corrected the citation.

Subp. 66a. Ratite.

“Ratite” is the generic name for flightless birds raised as livestock. The distinction between birds that are ratite and those that are poultry is important because there are different Code requirements for each respective type of animal. The sale and service of ratite products have increased since the existing Code adoption. Ratite meats can safely be cooked to a lower temperature than poultry products, and therefore distinguishing the two animal types is important. This language is used in the FDA Food Code and nationwide when communicating about this particular animal product.

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Subp. 67. Ready-to-eat food.

Since the original Code was adopted, “ready-to-eat” food has proliferated. The definition of ready-to-eat (RTE) food has been extensively expanded here to catch up with industry and cultural changes.

Defining what is considered RTE food is important for food safety. The original definition did not include very many examples of what a RTE food is and did not include all the sections of this Code that apply or refer to this definition. Expanding the definition to specifically identify new types of RTE foods will help consumers, industry, and regulators fully understand the concept of what RTE food is and will help them apply other parts of this Code regarding the handling of RTE foods.

This definition includes references to new language that is used throughout this Code. It includes references to consumer advisory for raw or undercooked animal foods ordered at consumer request (eggs, steaks, sushi, etc.) and Time/temp Control for Safety (TCS) foods.

Because the existing language is limited and does not refer to other applicable parts of this Code, changing the language is reasonable. Likewise, including specific categories of ready-to-eat foods to help the consumer, industry, and regulators fully understand what is considered ready-to-eat food is reasonable.

Subp. 68. Reduced oxygen packaging.

“Reduced oxygen packaging” is another definition that the departments have overhauled to meet current LRFE practices.

Food processing has changed significantly since the existing language was written for reduced-oxygen packaging (ROP). LRFEs are using ROP more often because it can extend the shelf life of food, lead to improved quality, and make it easier to prepare large batches of food. In addition, equipment for conducting ROP has become increasingly affordable and available for LRFEs. Due to food safety concerns with ROP, it is imperative that everyone fully understands what ROP means so the food safety requirements are followed. The new definition includes specific types of ROP processes and the microbiological hazards that need to be controlled for that process. It also includes the different types of packaging that are considered to be ROP and

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defines each of these rather than vaguely describing what is not ROP, as is the case with the existing language in this section. The changes in this definition are also needed to make the language easier to understand and to emphasize that there are particular points of concern for controlling the growth of specific pathogens.

It is reasonable to modify this definition so ROP is clearly defined. ROP methods are being used more frequently in LRFEs. Illness and death could result if ROP is not fully understood.

Subp. 70a. Reminder.

Some LRFEs serve food that is raw or not fully cooked at consumer request. “Reminder” is a disclosure statement that is used to refresh consumers’ memory that they might become sick from eating food that is raw or not fully cooked.

Adding this definition is important and reasonable because it is used elsewhere in this Code for food safety. The general public might forget or not understand the risk of eating raw or undercooked animal foods so it is reasonable to inform them of the risk when they are ordering it.

Subp. 70b. Re-service.

This Code contains specific instances when food can be re-served. Having the definition of “re-service” in this Code will dispel confusion as to what “re-service” means. When the last Code was adopted in Minnesota, this term was not included. The FDA added the term to the 2005 FDA Food Code.

It is reasonable to include this definition now so it is clear when this Code refers to re-service. It will also promote consistent application of this Code in Minnesota.

Subp. 70c. Restrict.

“Restrict” means to limit sick LRFE employees’ activities. Having this definition is necessary so it is clear what this Code means as it relates to food employees who are sick or have been recently ill. Otherwise, what it means to restrict a food employee could be unclear and those who are working with food when they should not be can pass their illness to others. Some operators might think it is OK to have ill employees still working in their facility just not handling food.

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This definition clearly includes handling not only food but also equipment, utensils, linens or unwrapped single service/use articles.

It is reasonable to include this definition to help prevent foodborne illness by indicating exactly what it means to restrict an ill employee.

Subp. 70d. Restricted egg.

The departments added the definition of “restricted egg” because it is referenced in part 4626.0175 of this Code. Clearly defining a restricted egg is important for food safety so such eggs are not used incorrectly for food, which might cause illness or death.

Including this definition is reasonable because provisions for use of restricted eggs appear in this Code. Further, clear language that is easily understandable is important for informing consumers, industry, and regulators what a restricted egg is. If an operator does not know what a restricted egg is, he or she might use them for food production.

The language in this definition also incorporates the definition of “egg” as it appears in Code of Federal Regulations in to this Code’s definition for clarity and consistency.

Subp. 71. Restricted use pesticide.

This definition removes a redundant and unnecessary reference to the Federal Insecticide, Fungicide, and Rodenticide Act. The reference to the Code of Federal Regulations, Title 40, Section 152.175 is adequate to define the criteria of a restricted-use pesticide. The definition also changes the term “commercial applicator” to “licensed applicator.” This is needed to clearly declare that a license is required to apply restricted-use pesticide. The term “commercial” does not convey the definite restriction that “licensed” means, which that the law imposes a certain level of training, expertise, and regulatory oversight which is imperative for using and handling of a restricted use pesticide.

Subp. 72. Retail bakery.

The departments deleted the definition of “retail bakery” because MDA does not use it. Thus, the license category is no longer included in the definition of a food establishment. It is reasonable to delete obsolete or unnecessary terms from this Code.

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Subp. 73a. Risk.

“Risk” is used throughout this Code in relation to factors that may result in foodborne illness. Since there are many interpretations of what risk means in general terms, a specific definition for food-related illness is warranted. Risk differs from “hazard” in that hazard describes the damage or negative impact to an individual’s health in the case of an exposure, and risk describes the likelihood that exposure will occur. Something that is extremely hazardous might be very unlikely, and thus not necessarily a risk; and something that is a minor hazard but very likely to occur might therefore be considered a risk. The goal of food safety is to eliminate risk or reduce risk to a safe level by controlling the likelihood that a particular hazard will occur.

It is reasonable to include this definition since using a generic dictionary definition of risk is not adequate to explain what risk is for the purposes of this Code.

Subp. 74. Safe material.

The revision slightly rewords Part A of this definition to better define how a “safe material” is something that ultimately might not result in becoming a component of or otherwise affecting any food. The old definition simply stated a safe material might not affect food. The change indicates that an additive could eventually affect food later down the line. This change might not be known at the time it is added but might develop later as the food sits on the shelf or in storage. Changing this definition allows the regulatory authority to restrict additive use that might affect food long after production.

It is reasonable to change the language in this definition to lend more flexibility to the regulatory authority when identifying a safe material and restricting the use of a material that was once considered safe but eventually affected the food.

Subp. 75. Sanitization.

The departments revised the definition of “sanitization” to clarify the parameters of the amount of time it takes a substance to reduce disease microorganism numbers to a specific level. The existing definition does not provide a time frame for the disease microorganism reduction needed to be sanitized. Adding the time frame is important because products that would be insufficient as sanitizers might achieve an equivalent reduction of disease microorganism numbers over a

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much longer time period. The one-minute time period is important because it is a short enough time to accommodate a LRFE where food quickly contacts surfaces and utensils after cleaning them. If the time period were longer, a risk might exist that the disease microorganism numbers would remain high enough to cause illness if the surface or utensil were used with food despite cleaning.

Clarifying the maximum allowable time period that it takes to inactivate disease microorganisms is reasonable to account for the realistic need of LRFEs have for using surfaces and utensils quickly after washing. Providing this definition preserves public health while eliminating confusion about what makes a substance effective for sanitizing.

Subp. 76a. Service animal.

In general, animals are not allowed in LRFEs. There are certain allowances, however for “service animals”. Defining service animal is important so that consumers, industry, and the regulatory authority know when allowing an animal in a LRFE is acceptable. Otherwise, animals present in a LRFE might pass on pathogens that could cause people to become sick. LRFE workers could handle these animals and contaminate their work areas with these pathogens. This definition is necessary since the term “Support Animal” will no longer be in this Code.

It is reasonable to clearly identify what types of animals are allowed in LRFEs.

Subp. 77. Servicing area.

This revision expands the existing definition of a “servicing area” from applying only to mobile food establishments to any temporary food establishment. Therefore, food carts, retail food vehicles, portable structures, carts, or special event food stands are now included. This change aligns the Code with current licensing categories for temporary food establishments.

This change also adds the phrase “such things as vehicle and equipment cleaning,” which expands the idea of what the servicing area is used for to explain that LRFEs may have more reasons to use the servicing area than the former narrow definition describes.

It is reasonable to modify the definition to clearly identify what types of temporary establishments may make use of a servicing area. It is reasonable to align the definition with current license categories and not to limit what the servicing area may be used for.

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Subp. 78a. Shellfish.

The departments deleted the “shellfish” definition because this Code has replaced the term with the more descriptive “molluscan shellfish.” The molluscan shellfish definition includes the aquatic animals of the Mollusca phylum that were previously included in this definition.

Subp. 78b. Shellfish control authority.

The departments added, “shellfish control authority” because it appears in this Code. The definition identifies the regulatory authorities who oversee molluscan shellfish food safety by certifying harvesters and dealers. In addition, their labels identify shellfish sources. Using molluscan shellfish that have been harvested by approved companies is important to protect the public. Molluscan shellfish that are not harvested and handled properly can cause people to become sick or maybe even die. If there are illnesses or other problems related to shellfish, the shellfish control authority assists in investigations trace the shellfish back to its sources or to adequately respond to complaints.

This Code needs a precise definition so consumers, industry, and the regulatory authority know who the shellfish control authorities are and what role they play in maintaining shellfish safety.

Subp. 79a. Shiga toxin-producing *Escherichia coli* or STEC.

“Shiga toxin-producing *Escherichia coli* or STEC” is used in this Code when referring to specific foodborne illness pathogens. There are many different types of *Escherichia coli* bacteria, many of which are found ubiquitously in humans, but not all of them cause foodborne illness. STEC are typically found only in individuals experiencing foodborne illness symptoms such as diarrhea. This definition is important for accurate food safety communication to make it clear that this Code refers to specific strains of *Escherichia coli* bacteria that cause food borne illness, and not all types of *Escherichia coli*. This distinction will prevent food handlers from being unnecessarily restricted or excluded from work because they have types of *Escherichia coli* that do not cause illness.

Subp. 80. Shucked shellfish.

Changing “one” to “1” for readability is needed and reasonable.

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Subp. 81. Single-service articles.

The departments revised the existing definition of “single-service articles” for clarity. The item, which is intended to be used one time by one person, must then be discarded for food safety. This revision adds the requirement that it be discarded to emphasize its single use. If this definition were not clear, LRFEs might use single-service articles again, which might cause people to become sick. This definition contains non-exclusive list examples of single-service articles rather than limiting them to a specific list.

It is reasonable to change the language for this definition to indicate that the single-service article is to be discarded after one use and to broaden the scope of what could be considered a single service article.

Subp. 82. Single-use article.

The departments revised only the second part of the existing definition of “single-use article.” We added language to clarify that the items listed in the definition do not include everything that may be considered a single-use article. This definition contains examples rather than limiting the definition to a specific list.

Subp. 83. Slacking.

The change in the definition to “slacking” replaces the word “including” with “such as” to indicate the temperatures referred to for slacking are just examples and slacking is not limited to those temperature parameters. The change also includes an example of food undergoing this method as an illustration.

Subp. 84. Smooth.

The departments made only minimal changes to the definition of “smooth” for clarity. Removing some words and re-wording parts. We did this to indicate that Parts A – food contact surfaces, B - non-food contact surfaces and C – floors, ceilings, walls are inherently smooth and have the characteristics spelled out in the definition. This change makes it easier to identify surfaces that are no longer smooth and thus can no longer be easily cleaned.

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Subp. 86. Support animal.

The departments deleted the definition of “support animal” because the term has been replaced with “service animal” in this Code. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 87. Table-mounted equipment.

The departments deleted the definition of “table-mounted equipment” because the term is no longer used in this Code. The term has been replaced with “counter-mounted equipment.”

Subp. 88. Tableware.

The departments deleted the definition of “tableware” because the term is commonly used and understood. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 90a. Time/temperature control for safety food (TCS).

This definition replaces the term “potentially hazardous food” that formerly defined food that required temperature control to keep it safe. The departments added the definition of “time/temperature control for safety food (TCS)” to establish a fundamental and necessary change in how food that supports pathogen growth or toxin formation is to be considered or assessed for the purpose of time/temperature control. By its name, this term and definition clearly communicates which foods require time/temperature control to be kept safe for human consumption to the industry and regulators.

It incorporates foods that have been implicated recently as vehicles or sources of contamination in outbreaks of foodborne disease involving pathogens such as *Salmonella* spp. and *E. coli* O157:H7 that formerly were not thought to be potentially hazardous, or that are in need of temperature control.

This definition introduces the concept of pH and water activity interactions that allows product assessments to determine if a food item requires temperature control to keep it safe for consumption. Under this concept, some foods that formerly required temperature control would no longer need it to prevent the growth of pathogens or toxin formation. Tables A and B contain

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the information that a licensee or operator would need in order to determine whether a food qualifies as TCS.

It is reasonable to add this definition to this Code to replace the definition of potentially hazardous foods because it more specifically and clearly conveys what foods require time/temperature control to prevent pathogen growth or toxin formation. It recognizes that interactions between pH and water activity exist that naturally establish barriers to pathogen growth or toxin formation, and it allows for product assessments based on these interactions to determine if temperature control is necessary.

Subp. 90b. USDA.

The term “USDA” is used in this Code when referring to eggs, meat, and poultry. Adding it is self-explanatory.

Subp. 91. Utensil.

The departments revised the definition of “utensil” to include the different types of probes in the definition so they are properly handled, cleaned, and sanitized as other utensils are. If probes are improperly handled and not cleaned and sanitized, they can transfer bacteria and viruses from one food item to another, which can cause illness.

It is reasonable to add these changes to the definition so that temperature probes and other probe-type devices are treated as utensils.

Subp. 92. Vending machine.

The departments added language to the definition of “vending machine” to address the increasing numbers of vending machines that operate “on your honor” or without some form of payment or key. In addition, increasing are automatic convenience store operations that are considered vending machines but allow customers to purchase products in a non-staffed convenience store-like setting. The inherent food safety risks of vending machines do not change based on whether payment or a key are required for distributing the food. If this language is not added, these types of vending machines might not be regulated under this Code like other types of vending machines. If they are not operated properly, foodborne illness might result.

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It is reasonable to modify the definition to include vending machines that are operated without inserting a form of payment or a key so food dispensed from these vending machines is safe.

Subp. 93. Vending machine location.

The departments changed the definition of “vending machine location” to remove the term “servicing area” since the definition for a “servicing area” that is now in this Code does not apply to vending machines. We made small editorial changes for clarity.

Subp. 94. Warewashing.

The departments re-ordered the wording of the definition of “warewashing” for clarity. We chose to make it clearer that the entire utensil must be cleaned and sanitized, not just the food contact surface of the utensil.

It is reasonable to alter this definition because there could be a difference in the methods for cleaning and sanitizing the food contact surfaces of equipment versus entire utensils.

Subp. 94a. Whole-muscle, intact beef.

The departments added the definition of “whole-muscle, intact beef” which does not appear in the existing Code, to correspond to the language in the 2013 FDA Code when referring to approved sources of food in section 3-201.11, Part (E); cooking raw animal foods section 3-401.11, Parts (C) and (D). This definition is needed to help distinguish cooking requirements for different forms of raw meat.

Proper cooking temperatures are determined based on the potential amount of bacterial contamination. Whole-muscle, intact beef can be cooked to a lower temperature since contamination is assumed to be on the outside of the beef. Moreover, exposure to heat on the exterior surface of the meat will adequately destroy pathogens. Other types of beef, such as hamburger or mechanically tenderized beef can have the contaminants mixed throughout. It therefore must be cooked to a higher temperature to kill the bacteria in the interior portions of the product. The definition for whole-muscle, intact beef is necessary to prevent misinterpretation by operators regarding what products need to be cooked to specific temperatures to adequately destroy pathogens.

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It is reasonable to include this definition because it is referenced in other parts of this Code and it is reasonable to identify different cooking requirements for various forms of raw meat.

Subp. 95. Water activity.

The departments deleted the definition of “water activity” because the information that was included in this definition is now contained within the definition for “A_w.” The words “water activity” has been replaced by A_w so they no longer appear in this Code. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 96. Wild game animal.

The departments deleted the definition for “wild game animal” because wild game animals such as lions, tigers, leopards, elephants, camel, antelopes, anteaters, kangaroos, water buffalo, ankoles, gayals, and yaks are now contained within the definition for “game animal.” It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 97. *.

The departments deleted the definition of what an “*” signifies in this Code because it corresponded to terminology that this Code is replacing. An asterisk was used to designate “critical” items. This Code contains new terminology to designate the severity of a violation. It is reasonable to delete obsolete or unnecessary terms from this Code.

Subp. 98. N.

The departments deleted the definition of what an “N” meant in this Code. Items in this Code are no longer designated with an “N” if they are “non-critical.” New terminology is now being used to designate the severity of a violation. It is reasonable to delete obsolete or unnecessary terms from this Code.

4626.0024 RESPONSIBILITY TO MEET STANDARDS.

The departments added this part to state explicitly what the existing Code merely implies—the licensee is the person responsible for meeting all standards in this Code. The licensee must do this directly or indirectly by ensuring that other entities subject to the licensee’s control or

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direction do so. The licensee bears the responsibility for complying and for acts and omissions of its employees, vendors, and subcontractors with respect to this Code. The departments are charged in their respective statutes with enforcing this lengthy Code's standards and procedures. Making it very clear that the licensee carries the responsibility and civil liability for meeting the terms of this Code is both necessary and reasonable.

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Chapter 2 Management and Personnel

4626.0025 ASSIGNMENT OF PERSON IN CHARGE. 2-101.11

The departments added the phrase “of person in charge” to the title to clarify the topic of this part.

4626.0030 DEMONSTRATION OF KNOWLEDGE BY PERSON IN CHARGE. 2-102.11

The person in charge (PIC) must be properly trained in all aspects of this Code to recognize the importance of conditions that may contribute to foodborne illnesses, such as cross contamination, employee illness, food allergies, etc. The departments clarified this part with minor revisions. We added two additional areas of knowledge.

The departments added item I because allergic reactions from certain foods may cause health consequences that are even more severe than those from bacterial infection. A PIC must know the major food allergens to train staff to control any cross-contamination and so they can assist customers in choosing non-allergenic foods.

The departments added item Q because we are proposing new employee health requirements in Chapter 2. An employee working when ill is a major cause of food-borne illness. The PIC must not only know the requirements for excluding or restricting an ill employee to prevent food borne illness from spreading to other employees or customers, but also train the employees on these requirements.

4626.0033 CERTIFIED FOOD PROTECTION MANAGER (CFPM) REQUIREMENTS FOR FOOD ESTABLISHMENTS.

This Code continues the existing requirement that food establishments have a certified food protection manager (CFPM). We have further strengthened this critical health-protection measure by requiring food establishments to also have persons in charge (PIC as stated in part 4626.0025. This part spells out the details that food establishments must comply with for licensing.

The departments developed this part by moving most of Chapter 9, *Minnesota Rules*, parts 4626.2000–4626.2525 (1999) here. At present, this crucial regulation appears at the end of the

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document (parts 4626.2000 - 4626.2525), and consequently is frequently overlooked. (As stated in part 4626.0020, Subp. 10a, the term “Certified Food Manager” (CFM) has become “Certified Food Protection Manager” (CFPM) for clarity).

Food establishments’ need for fully trained CFPMs to protect members of the public from foodborne hazards remains as strong as ever. This Code supplements CFPMs’ oversight by requiring that food establishment also have competent, knowledgeable persons in charge (PIC) of food establishments. This means food-establishment supervisors are continuously present to safeguard food safety whenever the food establishment is operating. This added measure is reasonable and necessary.

Although this part appears to be entirely new, a majority it comes from the existing Code. The departments revamped the original requirements to make them more explicit. Because the simplest food-handling mistakes can cause a foodborne illness, such details are critical. Properly trained CFPMs can correct common practices that risk foodborne illness and thus preventing outbreaks. PICs can also carry out these necessary corrections. We address these changes below.

Item A is similar to the existing part 4626.2010, subpart 1. The departments replaced the confusing phrase “except for a satellite or catered feeding location” by referring to exceptions stated in item B. This change makes it clear that licensed food establishments must have a CFPM.

In addition, we added an explicit CFPM requirement for a LRFE that reheats TCS food for hot holding. We did this because this food-handling process is one of the most critical. If the reheated food does not reach the correct temperature, and is not kept there until the food is served, the LRFE will fail to kill the bacteria and viruses, leading to foodborne illness.

In item B the departments dropped the existing Code’s exemptions for satellite or catered feeding locations such as senior citizen lunch programs, from having one full-time CFPM. Instead, we are requiring that all LRFEs have a CFPM, unless the satellite or catered feeding location meets the definition of “low risk” as stated in *Minnesota Statutes*, section 147.20, subdivision 2a. We did this because this Code, in adopting another performance-based requirement, will base exemptions on the degree of health risk posed. Many satellite or catered feeding locations prepare, heat, cool, and store food—activities that require CFPMs trained in food safety to ensure food establishments follow proper procedures. The departments replaced existing exemptions with those based on the degree of health risk. We also combined all new exemptions

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into one item for clarity. More specifically, the following explanations provide details about item B's subitems:

In item B, subitem (1) low-risk food establishments, as their label suggests, present little to no risk to the public. These LRFEs do not use complex food handling processes, so the food offered will have little chance of containing harmful bacteria or viruses. Accordingly, we have decided CFPM training and certification would not benefit either the LRFE or the public.

In item B, subitem (2) special event food stands are exempt from having a CFPM in the existing rule and would remain exempt in the proposed rule because these types of establishments present little to no risk to the public. These LRFEs do not use complex food handling processes, so the food offered will have little chance of containing harmful bacteria or viruses. Accordingly, we have decided CFPM training and certification would not benefit either the LRFE or the public.

In item B, subitem (3) retail food vehicles, portable structures, or carts as defined in part 5626.0020, subpart 73, are exempt from having a CFPM in the existing rule and would remain exempt in the proposed rule because these types of establishments present little to no risk to the public. These LRFEs do not use complex food handling processes, so the food offered will have little chance of containing harmful bacteria or viruses. Accordingly, we have decided CFPM training and certification would not benefit either the LRFE or the public.

In item B, subitem (4), unit (a) and (c) the departments exempted the type of precooked or prepackaged products listed in units (a) and (c) because their composition does not allow or their handling does not modify them so that pathogenic microorganisms can grow or form toxins. Thus, any risks are negligible.

In item B, subitem (4), unit (b) processing raw meat, poultry, fish, or game animals intended for consumer to cook referred to here does not pose a high risk. Cooking will eliminate the risk.

In item C, subitems (1) and (2) the departments changed the existing rule to allow a licensee an additional 60 days to obtain certification when opening, remodeling, or reopening a LRFE. Since the LRFE must have one full-time employee who can provide proof that the employee has passed an approved exam, this change simply lessens the burden on licensees who are opening, reopening, or remodeling a LRFE by allowing an additional 60 days to comply.

In item D the departments added the words "current CFPM original certificate or duplicate current CFPM original certificate" to clarify that a LRFEs must post an authentic certificate, which can be met only by posting either the original certificate or a duplicate original certificate.

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Posting a current authentic CFPM certificate provides regulators or the public an easy way to verify that the LRFE is validly certified under health regulations. A photocopy of a CFPM certificate is not valid because fake certificates can easily be generated and placed in many different LRFEs at one time.

In item E, the existing rule requires LRFEs that cease to employ a CFPM to comply within 30, 45, or 90 days. The departments simplified this varied schedule to one 60-day compliance period, which benefits both the regulators and the public.

In item F the departments reorganized the CFPM's duties by rewriting part 4626.2010, subpart 5, into this item F for clarity without changing meaning or requirements. Also, the departments rewrote each duty to clearly identify the specific actions the the CFPM must carry out or ensure that someone under the CFPM carries them out. This clarifies the expectations for both the LRFE and regulatory authorities about what the CRPM must do.

Item G states that to become a CFPM in Minnesota, an individual must complete training in food safety, pass a recognized examination, and submit certain identifying information plus a fee to the commissioner.

In item G, subitem (1) the departments relocated and combined existing part 4626.2015, subparts 1 and 2, into item G, subitem (1). The existing rule allows an individual up to 36 months after passing the required exam to apply for certification.

The proposed change shortens that time to six months. The proposed rule also corrects an existing gap that certifies individuals for up to seven years (84 months) after only one exam. (36 months to apply after taking the exam, the three years the certificate is valid, and a one-year grace period after the certificate expires). Limiting the initial application to a six-month time frame means newly certified CFPMs have more current training in the essential food safety principles that are critical to public health protection than the existing rule requires. Reducing the time between examination and initial application could shift costs forward for a small number of businesses or individuals if they did not apply within a timely fashion. Any additional cost, however, for obtaining or maintaining certification is minimal and outweighed by the importance of having competent CFPMs protecting food safety.

In item G, subitem (2) the departments relocated part 4626.2015, subpart 3, of the existing Code to the proposed Code's part 4626.0033, item G, subitem (2), units (a), (b), and (c). The

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departments reorganized the subject matter and added new details for clarity (listed below) without changing meaning or responsibilities.

In item G, subitem (2), unit (a) we required applicants provide the commissioner with an email address to simplify and update communication methods for and with applicants.

Item G, subitem (2), unit (b) no changes were made.

In item G, subitem (3), unit (c) the departments removed the specific certification fee amount and replaced it with a reference to *Minnesota Statutes*, section 157.16, which stipulates fees for food establishment licenses. In Minnesota, the legislature sets fees in statute. The departments could include them in rule for the parties' convenience but confusion could arise if the fees changed, leaving the rules with conflicting amounts. A reference to the correct statute eliminates the possibility for confusion

In item H the departments replaced the trademarked exam names that appear in the existing Code with a reference to the Conference for Food Protection (CFP). CFP, the nonprofit organization that holds the trademarks, has served as the departments' only recognized source of accreditation standards for food-protection-manager-certification programs since 1971. It remains the only accepted source of exams in the proposed revisions. Removing the trademarked names and identifying the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs by reference eliminates confusion caused by trademarked names, especially when the names change, or CFP develops new exams. Consequently, this rule will remain up to date as it automatically accommodates CFP's changes. This revision is both necessary and reasonable.

Items I and J govern certification renewal and continuing education accreditation. The department kept part of the existing part 4626.2015, subpart 6 and transferred it here to part 4626.0033, items I and J. We also reorganized the contents into a chronological order for clarity. As required under the existing Code, an individual must submit the renewal application with the fee and proof of approved continuing education to maintain CFPM certification. The rule changes are discussed specifically below.

In item I, subitem (1) the departments removed the phrase, "36 months directly preceding submittal of the renewal application" from the existing part 4626.2015, subpart 6, item C and replaced it with "the effective dates of the valid certificate." The existing rule is ambiguous because the 36-month period does not make it clear that the applicant must submit the renewal

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application by the the certificate's expiration date. The revision clearly states when the the applicant-CFPM must complete the continuing education.

Item I, subitem (2), unit (a) we added a requirement for email address to simplify communication with applicants.

In item I, subitem (2), unit (b) the departments revised these requirements without changing or meaning or adding responsibilities.

In item I, subitem (2), unit (c) the departments replaced the stated certification fee amount with a reference to *Minnesota Statutes*, section 157.16, the statute that specifies fees for food establishment licenses. This change is needed to recognize that fees are declared in statute. This change also keeps the rule current by preventing the rule from unceremoniously having an obsolete rule if the statutory amount were to change. Eliminating this possible conflict between fees stated in rule and statute is necessary and reasonable. Total cost of obtaining or maintaining certification does not change.

In item I, subitem (3) the departments relocated existing provisions from part 4626.2015, subpart 8, and revised them to provide a dual system to allow a grace period for currently certified individuals. Those whose certification expires before the proposed change would take effect would have one year to comply with existing part 4626.2015, subpart 8. This will assist thousands of certified food managers whose certification will expire in the one-year period when the proposed rule would take effect. Providing a temporary dual-renewal system is reasonable to accommodate the potentially large number of certificate holders that would be affected. Accommodating them treats them fairly during the transition without jeopardizing public safety.

Also, item I, subitem (3) shortens the grace period for individuals to submit the required renewal application and materials from one year to six months. This applies to those certified individuals whose certification expires after the effective date of the new rule. This grace period eases the transition to the more stringent requirements of the new rules, while simultaneously requiring prompt application, thus protecting the public by ensuring that CFPMs participate in continuing education courses at intervals of 3 ½ years (42 months) at most. Reducing the grace period could shift costs forward for a small number of businesses or individuals if they allowed their state certificate to expire without having attended training within 6 months after the expiration date. Total cost of obtaining or maintaining certification does not change.

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Continuing education is readily available throughout the state and can be completed in many classroom settings and approved online formats. As of July 2015, the MDH Certified Food Manager website lists over 100 face-to-face training courses and 33 approved online trainers. Thus, requesting an individual whose certificate has expired to attend training within 6 months after the expiration date is reasonable.

In item J the departments made no changes to the meaning and content of the existing rule except revising item J, subitem (2) described below.

In item J, subitem (1) the departments added the requirement that documentation of a continuing education certificate contain the applicant's name. Requiring an instructor to add the applicants name to a continuing education certificate is reasonable.

In item J, subitem (2) the departments dropped the requirement that applicants submit an agenda and course outline with their renewal documentation. Instead, the applicants need only list the the training course title from the course completion certificate prepared by the instructor. Since the instructor is required to obtain pre-approval of their qualifications and course content in items K and L, applicants need only identify the course taken on the application. This change is reasonable and necessary to lessen the documentation requirements for both applicants to submit and the departments for application review. The departments retain oversight because they can verify titles or request additional information from applicants if questions arise.

In item J, subitem (3) the departments made no change in the proposed language that documentation of continuing education course must include the number of approved contact hours.

In item J, subitem (4) the departments made no change in the proposed language that documentation of a continuing education course must include the course date.

In item J, subitem (5) the departments made no change in the proposed language that documentation of a continuing education course must include the instructor's name.

In item J, subitem (6) the department added email addresses in addition to telephone numbers as an option for reaching instructors. With email now ubiquitous and commonly accepted for official business communication, this change is necessary and reasonable. This is especially so with agencies moving increasingly toward automated licensing systems.

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Items K, and L address the continuing education course requirements for CFPMs. The departments developed these two items by adapting and expanding existing part 4626.2015, subpart 7, into more comprehensive, cohesive regulations. We are simultaneously simplifying these requirements and making them more explicit, so that all parties can comply with them. Item K spells out the requirements for a continuing education course. Item L contains the duties course instructors must carry out.

Item K, subitems (1) – (3) come from the existing Code part 4626.2015, subpart 7, item A.

In item K, subitem (1) the departments expanded the scope of the existing list of specific course topics to include the broader “food safety and sanitation topics in this Code” because the existing list does not cover the full range of areas CFPMs must keep up with to remain current to protect public health. This broader category is sufficient since the departments accept training materials and exams only from accredited companies. The Conference for Food Protection (CFP), in conjunction with the American National Standards Institute (ANSI), govern these qualifying exam companies. The departments recognize that CFP has identified the essential components of a nationally recognized Food Protection Manager Certification Program and established a mechanism to determine if certification organizations meet these standards. Training materials provided by these exam companies contain content specific to the corresponding exams; and therefore this rule need not state them in additional detail.

In item K, subitem (2) the departments will now require that the MDH commissioner preapprove courses before offering the courses to CFPMs or making changes to approved courses. This new responsibility to review course format, content, and instructor qualifications verifies that courses provide appropriate training, that continuing education courses offered support improved food safety knowledge, skills and abilities. These measures both protect applicants’ time and money and provide reasonable and necessary oversight so that applicants can achieve their required training efficiently amid the great variety of existing courses, formats, and instructors. Preapproval means that MDH staff can quickly identify the approved course on an applicant’s renewal application, streamlining the renewal process. The proposed change also brings the rule up to date with current business practice and states it more clearly and understandably.

In item K, subitem (3) the departments explicitly require that the mandatory courses have an “interactive format.” While courses can take place in conventional classroom settings, which provide well-understood interaction opportunities for instructors and individuals, the departments will also approve online courses to offer training opportunities that are not restricted

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to a particular time and place. The departments need online training opportunities to expand opportunities for small businesses. Small businesses often cannot spare employee time for leaving the workplace to attend a classroom-style course. Those in remote locations find travel to be a too-costly obstacle. Either option, classroom or online, must assess the participants' knowledge to assure that the training is effective. These changes are needed and reasonable.

Item K, subitem (4) repeats part 4626.2015, subpart 7, item B without change.

In item K, subitem (5) the departments propose requiring the commissioner reconsider course content from time to time, which is needed as course content, instructor contact information, and other details about an approved course can change over time. Periodic review of course content is reasonable to ensure that the materials being taught remain adequate to protect public health.

In item K, subitem (6) the departments also propose to have MDH audit existing course content for accuracy and instructor qualifications for competence to address public concerns about course content, and course length. Having MDH audit course content and instructor qualifications for adequacy are reasonable measures to keep up with changes in food safety needs. MDH staff can ask exam companies for details to confirm or retract approval.

In item L, subitem (1) the departments added this subitem to require continuing education course instructors to be certified as CFPMs. Requiring that an instructor hold a CFPM certificate sets a minimum qualification allowed for teaching. The department needs this requirement to protect the public by ensuring proper and correct training for CFPMs.

Persons who have received training from certain instructors have conveyed concerns about instructors receiving money for food safety courses and then neither providing the service nor refunding the money. Also some instructors have taken trainees certification fees promising to send them to MDH and not doing so. The addition of this requirement would provide the department with the power to revoke an instructor's CFPM certificate if the departments' investigation reveals that the instructor has been engaging in unethical practices, consequently disqualifying the instructor from teaching food safety courses in Minnesota.

Item L, subitem (2), comes from existing Code part 4626.2015, item E. The departments omitted words for clarity without significantly changing the the requirement's intent.

In item L, subitem (3) the departments revised the records standard to require that instructors maintain course records in addition to attendance records they keep currently. This revision ensures that the course providers have ready access to their students' course-completion

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certificates. CFPMs are permitted to complete a renewal course any time between the individuals' three-year certification's effective and expiration dates; they then must submit course completion certificates at renewal time. Course providers need to maintain proper records for producing or replacing the course completion certificates as proof for two reasons: providers must prove they have given the training, and supply their students with needed evidence for the students' own use. Requiring course providers to maintain course records is therefore necessary and reasonable.

The departments relocated existing part 4626.2015, subpart 4 to part 4626.033, item M with no changes.

In item N the departments kept the intent and meaning of existing part 4626.2015, subpart 5 and transferred it to part 4626.0033, item N, subitems (1), (2), and (3); they revised it for clarity to clearly and concisely describe the CFPM certificate's validity.

Each certificate must include a printed "effective date," which matches the date an individual passed the required certification exam. CFPM certificates are valid for three years. When a CFPM renews, the new certificate is valid for the next three years, without gaps or overlaps. Having a clear and concise description prevents confusion for both the operators and regulatory authorities.

Item N, subitem (4) restates, without change, the declaration that certificates are not transferable,.

In item O the departments transferred the requirements in part 4626.2015, subpart 9, to part 4626.0033, item O, and added the word "damaged" because the department receives frequent calls requesting a duplicate certificate for certificates that are not lost or destroyed but damaged. This simple change clarifies that the department will supply the replacement for the cost of the duplicate.

In addition, we replaced the certification fee amount with a reference to *Minnesota Statutes*, section 157.16, which states the food establishment license fees to dispel confusion because the fees are set by statute.

4626.0035 DUTIES OF PERSON IN CHARGE. 2-103.11

The person in charge has the primary responsibility for ensuring compliance with this Code when he or she is at the LRFE. See *Minnesota Rules*, part 4626.0030 for further statements of

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need and reasonableness related to this part. The departments modified “Duties of Person in Charge” to align with the FDA Food Code, made small grammatical changes, and added a few subject areas essential for running a safe food operation. The departments made minor grammatical changes and Code reference updates for increased understanding and readability in items A, B, C, D, E, H, K, and L.

The departments added item F to make the person in charge responsible for ensuring proper receiving of delivered food-products. Food delivery often occurs during hours when LRFEs are not operating. Sometimes these deliveries occur without any of the LRFE’s employees present. This can cause a public health risk from the food either left in areas with potential contamination sources or lacking temperature control. Therefore, this requirement ensures that someone at the LRFE is responsible to prevent the improper deliveries and the resulting public health risks. Adding this additional responsibility is reasonable because the LRFE is ultimately responsible for protecting food safety.

The departments clarified item G to specify the appropriate method for verifying cooking temperatures and expanded it to require that the food workers verify food temperatures using proper measuring devices. The previous item did not refer to the equipment needed to verify cooking temperatures, leaving room for misinterpretation by persons in charge. The revised item makes it clear that only properly scaled temperature measuring devices are acceptable for verifying temperatures, making citation to parts 4626.0555 and 4626.0820 necessary.

The departments revised item H for clarity.

The departments added language in item I so that the person in charge makes sure that employees monitor hot and cold holding temperatures. Proper holding temperatures are necessary to prevent bacteria growth or toxin development that can harm public health.

This proposed revision is reasonable because it assigns direct responsibility for ensuring the requirements from other parts in this Code for holding hot or cold food at specific temperatures. This revision does not prescribe how the food establishments verify the temperatures so operators will have flexibility regarding options for compliance.

Item J is new. This item assigns the responsibility to the person in charge to ensure the disclosure of which food products have not been properly cooked, so that the LRFE informs its consumers

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about the potential health risks from eating these raw or undercooked foods. It acknowledges the increased popularity in sale or service of uncooked potentially hazardous foods and new requirements in *Minnesota Rules*, part 4626.0442. Including this responsibility under *Minnesota Rules*, part 4626.0035 also makes it clear that the required disclosure is a high priority for effectively controlling public health risks from serving raw or undercooked food products.

The departments revised items K and L for clarity.

The departments added item M to clarify that the person in charge must ensure that employees are complying with the ban on bare-hand contact with ready-to-eat food. See further information in the section on part 4626.0225. It is critical that food handlers do not touch ready-to-eat food products with bare hands. The departments' experience shows that LRFEs need to supervise their employees to correct improper bare-hand contact behavior. This item is thus necessary and reasonable.

The departments added item N to emphasize the role the person in charge has to communicate food safety principles, especially those related to food allergies. Allergic reactions to food items can be as severe as or even more severe as those caused by foodborne infections or intoxications. This revision makes it clear that the person in charge must train employees under their supervision or have them trained so they understand their role in food safety.

This addition is flexible by not requiring the person in charge to train all of the employees personally; it clearly allows LRFEs to satisfy the requirement by using an outside training provider. In addition, by having the training that is required be specific to the food handler's assigned duties, the training does not need to be as comprehensive as the training required for a Certified Food Protection Manager or person in charge. Finally, this Code does not require an assessment or examination to verify training so operators may train employees or have them trained in whatever method works for their particular operation.

The departments added item O to address illness-reporting responsibilities. By tasking the person in charge with the responsibility for informing both groups of employees that they must report symptoms that they might have to the person in charge, the person in charge can oversee and manage sick employees to prevent spread of the illness to other employees or consumers. Setting

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clear duties for the person in charge and food employees so that employees who are ill, or might be ill, are restricted or excluded provide important protection measures.

Item P is all new language. It assigns the duty to ensure the maintenance and implementation of procedures and plans to the person in charge. The underlying rationale is that that the required plans and procedures create a permanent path to success for a LRFE for food safety, and that controlling the public health risks from food handling is not a random event. Written procedures and plans avert the risk of inconsistent execution of food safety procedures. In addition, written procedures provide documents that regulators can review when assessing a LRFEs compliance with this Code. The person in charge of the LRFE is the logical person to task with ensuring these procedures and plans are being maintained and implemented. In addition, accurate record-keeping allows a LRFE to maintain food safety practices regardless of employee turnover and serves as a good communication tool for documenting compliance.

4626.0040 RESPONSIBILITY OF LICENSEE; PERSON IN CHARGE; FOOD EMPLOYEES AND CONDITIONAL EMPLOYEES. 2-201.11

In item A, the departments substituted the new term, “conditional employee” defined in section 4626.0020, subpart 14a, for “food employee applicants to whom a conditional offer of employment is made.” The new definition makes it clearer and easier to understand that anyone who is accepts a position at the LRFE contingent on having no foodborne diseases must report symptoms to the person in charge.

In item A, the departments also added explicit requirements that employees must report information that allows the person in charge to reduce the risk of foodborne disease transmission, such as the date of onset of symptoms. The person in charge needs specific information to determine whether to exclude or restrict the employee from working in the LRFE to prevent illness transmission.

Requiring all employees to report their symptoms and health is necessary and reasonable to prevent foodborne illness.

In item A, subitem (1), units (a)-(c) and (e), the departments reformatted existing symptoms for added clarity (i.e., listing vomiting, diarrhea, jaundice, lesions).

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In item A, subitem (1), unit (d), the departments added “sore throat with fever” to the list. These symptoms indicate that the person might be infected with *Streptococcus pyogenes*. *Streptococcus pyogenes* causes a common infection otherwise known as “streptococcal sore throat” or “strep throat.” Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Reporting sore throat with fever is consistent with the 2013 FDA Food Code. Since *Streptococcus pyogenes* caused foodborne outbreaks, and sore throat with fever is a common symptom, to identify infected persons and prevent transmission via food is reasonable.

The departments added new language in item A, subitem (2), units (a)-(f): that require employees who receive a diagnosis of one of the listed specific infectious diseases or having a known food borne illness report that diagnosis or illness to the person in charge. The departments changed the formatting for added clarity (i.e., listing *Salmonella* spp., *Shigella* spp., hepatitis A virus) and brought the list up to date. The list of reportable diseases has been reordered for readability.

In item A, subitem (2), unit (a), the departments added norovirus as a reportable illness. Norovirus is the most common cause of foodborne outbreaks in Minnesota, causing 57% of foodborne outbreaks. The majority of those outbreaks occur in LRFEs. LRFEs can prevent norovirus transmission by two methods: 1) excluding ill employees from working until they have recovered and 2) practicing good personal hygiene: handwashing and not touching ready-to-eat foods with bare-hands.

The Centers for Disease Control and Prevention (CDC) estimates that norovirus is the leading cause of foodborne illness in the United States and results annually in 5,461,731 cases of illness, 540,711 doctor visits, 14,663 hospitalizations, and 149 deaths. Transmission of norovirus occurs most commonly through the fecal-oral route, with contaminated food being a common vehicle of transmission. Norovirus also spreads by airborne transmission when people are in close proximity to a vomiting infected person. Therefore, an infected individual vomiting in a food facility increases the risk of infecting employees and consumers.

The person in charge must intervene by excluding food employees who are vomiting or reporting vomiting or diarrhea to keep norovirus from infecting patrons. In addition, norovirus also has a high secondary attack rate (> 50%) via person-to-person contact, so if one food worker is ill it is likely that another will also become ill.

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In item A, subitem (2), unit (e), the departments changed “*Escherichia coli* O157:H7” to Shiga toxin-producing *Escherichia coli*: Since we last revised this Code, diagnostic testing methods for bacterial pathogens, specifically *E.coli*, have changed. Historically, we were only able to detect infections caused by *E. coli* O157:H7, the most common of many Shiga toxin-producing *Escherichia coli* (STEC). In the last decade, we have been able to detect infections caused by other types of STEC that can cause severe illness comparable to *E. coli* O157:H7. STEC are zoonotic diseases, diseases that are derived from cattle and other ruminants. However, *E. coli* O157:H7 and other STEC are also transmitted from person-to-person. So contaminated raw ingredients and ill food employees can both be foodborne disease sources. Individuals with STEC infections may not show symptoms but bloody diarrhea is a classic symptom in those that do. Infected people also can have severe complications like hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). The United States Department of Agriculture Economic Research Service estimates that there are 63,153 cases, 2,138 hospitalizations, and 30 deaths annually due to O157 STEC and 112,752 cases and 271 hospitalizations due to non-O157 STEC.

The departments modified “other enteric bacterial pathogens” to “other enteric bacteria, viral, or parasitic pathogens” in item A, subitem (2), unit (f): Since we last revised this Code, new viruses such as sapovirus have been identified as the cause of foodborne outbreaks and we have new diagnostic tests to identify sapovirus infections. Sapovirus symptoms and modes of transmission are nearly identical to those of norovirus. This virus is highly transmissible from an infected person via the fecal-oral route, and therefore, food and food workers transmit it. In addition, parasites such as *Cryptosporidium* and *Giardia* can also be transmitted by contaminated food and water, or by food that has been contaminated by an infected person. The United States Department of Agriculture Economic Research Service estimates that there are 57,616 cases, 210 hospitalizations and 4 deaths annually due to *Cryptosporidium parvum*.

As diagnostic testing methods continue to improve, it is very likely that new bacterial, viral, and parasitic pathogens transmissible by infected persons to food will be more easily identified. Using “other enteric bacterial pathogens” allows flexibility for food establishment and regulatory authorities to quickly respond to protect the public’s health. The format changes also add clarity making it easier to see which illnesses need to be reported.

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The scientific evidence that STEC, norovirus, and other viral, bacterial, and parasitic pathogens are transmissible from infected persons via food is ample.

The departments added the language in item A, subitem (3) because food employees commonly quit, or stop going to work without resigning, during outbreak investigations and then start a new position at another LRFE. In addition, LRFEs tend to have high staff turnover, and many LRFE employees work at more than one LRFE. An employee exposed to an outbreak may be infected with the pathogen that is associated with that outbreak. It is important that a person exposed to an outbreak or who is a suspected source of an outbreak (ill or asymptomatic) notifies management of their exposure to prevent an outbreak at another LRFE.

This language is similar to the 2013 FDA Food Code requirements. This is a very simple step that a person in charge can easily implement to prevent further transmission during an outbreak to patrons, other LRFEs, and the employees at those LRFEs. The 30-day requirement covers the lengthy durations of illnesses such as hepatitis A virus and *Salmonella*, food workers may not fully recover from these pathogens for weeks after illness appears and could potentially be shedding live bacterial or virus particles, or in other words, still be contagious. This timeframe helps ensure that the person in charge knows if workers have been involved in an outbreak within the last 30 days and can put appropriate restrictions and exclusions in place if the worker is still exhibiting symptoms.

Persons may be afraid of the repercussions of reporting that they have been exposed to or are part of an outbreak. They might be limited in their work duties at a different setting or might not be offered employment until the symptoms resolve and the outbreak subsides. However, the consequences to the public of easily prevented transmission cannot be understated, and the protection of the public is crucial. The person in charge must be notified of an employee being exposed or a part of an outbreak to protect their customers.

In item B, the departments moved language from part 4626.0060 to 4626.0040 so that the person in charge's responsibilities are all listed in one Code citation. Some of the proposed changes are simply changes in formatting for added clarity (i.e., listing *Salmonella* spp., *Shigella* spp., hepatitis A virus).

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Requiring the person in charge to notify regulatory authority of food employees with certain infectious diseases is essential to prevent transmission to LRFE patrons and other employees. It is important for the person in charge to notify the regulatory authority if an employee has been diagnosed with one of these infections. This requirement provides a “heads-up” of possible foodborne infections to regulatory authorities. The regulatory authority may be able to link this illness to other illnesses. The regulatory authority can provide recommendations on proper exclusion or restrictions of the employee to prevent transmitting the infection to other employees or patrons. In addition, the regulatory authority can identify if an outbreak is occurring at the LRFE and provide guidance on how to control the situation and put interventions in place to stop further transmission.

In item B, subitem (1), units (5) - (6), the departments added these specific pathogens to the list. For additional information, see Statement of Need and Reasonableness for language changes covering norovirus, STEC, and other enteric bacteria, viral, or parasitic pathogens located in item A.

In item C, the departments moved language from part 4626.0060 to 4626.0040 so that the person in charge’s responsibilities are all listed in one Code citation. Requiring the person in charge to record all reports of vomiting and diarrhea by employees and to provide this information to the regulatory authority when requested in order to prevent transmission to LRFE patrons and other employees. Furthermore, requiring the person in charge to record incidents of vomiting and diarrhea is an active way for business management and the regulatory authority to monitor illness symptoms in staff to determine if exclusions or restrictions are needed. All personal information and data that the regulatory authority collects will be maintained as private, in accordance with the Minnesota Government Data Privacy Act, *Minnesota Statute*, 13.05.

The departments moved this language in item D from part 4626.0060 to this part so that reporting requirements for the person in charge are all listed in one Code citation.

Some of the proposed changes are simply changes in formatting for added clarity (i.e., listing *Salmonella* spp., *Shigella* spp., hepatitis A virus).

It is important for the person in charge to notify the regulatory authority when a consumer reports having vomiting, diarrhea, and/or a possible pathogen transmissible through food. The

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regulatory authority can determine if the consumer is part of a foodborne outbreak that is occurring at the LRFE and help provide guidance to the LRFE on how to control the situation and put interventions in place to stop further illness transmission to patrons.

Some persons may view the reporting of consumer symptoms or diagnoses as a data privacy issue, however, all personal information and data that is collected by the regulatory authority will be maintained as private, in accordance with the Minnesota Government Data Privacy Act, (*Minnesota Statutes*, 13.05). The collection of this information can help control an outbreak situation and prevent further illness transmission, protecting the health of the public.

In item D, subitems (1) – (7) the departments added specific pathogens to the list. For additional information, see Statement of Need and Reasonableness for language changes/additions covering norovirus, STEC, and other enteric bacteria, viral, or parasitic pathogens located in the sections above.

In Item E, the departments moved the language from part 4626.0060 to this part so that reporting requirements for the PIC and employees are all listed in one Code citation.

Moving the language under one “reporting” citation is reasonable as it helps outline employee reporting requirements and make employee duties more clear and concise.

4626.0045 EXCLUSIONS AND RESTRICTIONS. 2-201.12

The departments revised this part to clarify the requirements that person in charge must follow requirements that are already in this Code. We also added more pathogens that require employees be restricted or excluded to the list of infections that can be transmitted by infected food workers via food.

This part differs from the FDA Food Code to accommodate Minnesota statutes and rules that govern MDH’s outbreak to a response.

In item B, the departments changed language from “restrict” to “exclude.” The existing Code requires that the person in charge restrict the ill employee until MDH and the licensing regulatory agency assessed the situation. The existing language does not specify what would happen after MDH and the regulatory agency assessed the situation. MDH and the regulatory

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agency could remove the restriction, exclude the food employee, or require additional testing or treatment. The proposed language of “exclude” will protect the public from becoming ill due to eating food contaminated by an infected food employee. Excluding the food employee from work, rather than restricting their duties, eliminates the possibility of the food employee handling food from the time the person in charge becomes aware of the food employee’s infection until MDH and the licensing regulatory agency evaluate the potential for transmission.

The change from restriction to exclusion may be opposed by food employees, since it may affect their income. It may also be opposed by employers since they may be short-staffed when excluding an employee from work. However, it is necessary in ensuring that workers in the LRFE are not working while ill and is a key component of preventing illness transmission to patrons.

Additionally, the existing language only addresses bacterial pathogens, and specifically listed *Salmonella* spp., *Shigella* spp., and *E. coli* O157:H7. The language was updated to include viral and parasitic pathogens, and added norovirus, hepatitis A virus and changed *E. coli* O157:H7 to Shiga toxin-producing *E. coli* (STEC). These newly included enteric pathogens are transmissible by food; making the exclusion consistent based on risk of transmission, and easier to implement, since the person in charge will not have to assess if the pathogen is bacterial, viral or parasitic.

In item C, the departments changed the word “applicant” to “conditional food employee. The existing language with the term “applicant” means anyone who applies for a position at the LRFE rather than those who are actually employed at the LRFE. The proposed language will apply only to employees and conditional employees who could actually pose a risk of transmission to LRFE patrons via food. Applicants do not actually work for the LRFE, so they cannot really be restricted from job duties.

The departments have added new language in item D. Food employees are required to cover pus-containing skin lesions such as a boil or infected wound. Wounds that are open, draining, and not properly covered, could potentially contaminate food and lead to foodborne illness. It is necessary to provide clear guidance to the person in charge about what to do if an employee has an open and draining wound that could easily contaminate food. The addition of this language makes it clear that the person in charge is responsible for restricting that employee’s work duties to prevent contamination of food.

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4626.0050 REMOVAL, ADJUSTMENT, OR RETENTION OF EXCLUSIONS AND RESTRICTIONS. 2-201.13

The departments modified this part to align the authority to lift or remove an employee exclusion or restriction with current best practices.

Excluding employees for 24 hours after their last symptoms of diarrhea and vomiting has long been common guidance for the person in charge, but the existing Code did not contain this direction. The departments added new language that explicitly states this 24-hour guidance after last symptoms. This is a reference to part 4626.0045. The statement of need and reasonableness is within part 4626.0045.

The existing Code requires that an employee restriction remain in place until the "...regulatory authority complete[s] an investigation of the confirmed disease outbreak and determines that there is no longer a risk of foodborne disease transmission." This provision requires the regulatory authority to release the employee's restriction only when there is no risk, which is not possible. The risk associated with employees cannot be eliminated without restricting the employee, because there is an inherent risk associated with employees. The most the commissioner or regulatory authority can do is "determine that the risk of foodborne disease transmission has been adequately mitigated." The proposed language in this section reflects this correction.

Also, a proposed editorial change substitutes "Commissioner of Health" for the "Department of Health," which the existing Code designates to determine whether risk has been mitigated. This change simply conforms this part to the rest of this Code for consistency when referring to agency responsibilities.

4626.0055 2-201.14 RESPONSIBILITY OF FOOD EMPLOYEE OR APPLICANT TO REPORT TO PERSON IN CHARGE.

The departments deleted part 4626.0055 because we have added the "responsibility of Food Employee or Applicant to Report to Person in Charge" requirements to part 4626.0040.

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4626.0060 REPORTING BY PERSON IN CHARGE. 2-201.15

The departments deleted part 4626.0060 because the “Reporting by Person in Charge” requirements have been added to part 4626.0040, item B.

4626.0065 CLEAN HANDS. 2-301.11

The departments added the word “hands” to the title to clarify the topic of this part.

4626.0070 CLEANING PROCEDURE. 2-301.12

The departments strengthened the handwashing requirements by spelling out correct handwashing procedures based on current best practices that are essential to food safety.

Improper hand washing will leave pathogenic organisms on the hands that can be transmitted to clean utensils, gloves, and food, resulting in illness. Handwashing done properly can result in a 2-3 log reduction of transient bacteria and a 2 log reduction in transient viruses and protozoa on hands. (**Log Reduction** stands for a 10-fold (one decimal) or 90% **reduction** in numbers of live bacteria. In other words: 1-**Log Reduction** would reduce the number of bacteria 90%. For example, 100 bacteria would be reduced to 10, or 10 reduced to 1.

(<http://www.healthyfacilitiesinstitute.com/documents/hfi-log-reduction-chart.pdf>)

The need for reducing the risk of transferring pathogens to customers’ food is a long-established tenet of food safety and thus is reasonable.

In item A, the departments added “surrogate prosthetic devices” to the exposed portions of arms that must be washed. These devices present as much risk as hands during food handling and therefore need to be kept clean and free of contaminants to protect public health. Including them here is both necessary and reasonable.

Item B describes the required cleaning procedure. The proposed revision significantly expands the prescribed washing procedure. Expanding the prescribed washing procedure is necessary to clarify what standards apply for proper handwashing using the scientifically valid handwashing instructions as adopted in the FDA Code. These standards eliminate surface contaminants sufficiently to reach an acceptable level. We have referred to other parts in this Code related to

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hand-washing sink equipment, which is necessary to describe the minimum equipment required to properly wash hands. Providing this level of detail is reasonable because it eliminates confusion for persons in charge and food employees about what properly washing hands means. These changes also shorten the acceptable time required for handwashing from 20 seconds in the existing Code to 10-15 seconds. This time reduction will save food employees time and encourage handwashing when necessary, while still adequately protecting public health. These changes are necessary and reasonable.

The departments added item C, describing how the sink faucet must be turned off after handwashing. It addresses a common problem of hands being re-contaminated. An employee touches a faucet with dirty hands to turn the faucet on; contaminating it, then re-contaminates his or her clean hands when turning the faucet off. This change is reasonable because it protects public health from hands inadvertently re-soiled immediately after washing. In addition, food establishments can easily comply because there are ample, affordable, hand-washing sink devices on the market that allow users to turn on water without having to physically turn faucet knobs or levers. Foot-operated switches and motion sensors are common place-devices already used to reduce the extra single-use towels needed to turn off a faucet after handwashing. The requirements are reasonable and necessary.

The departments added Item D to allow for the new technology of automatic handwashing facilities. Food workers can efficiently and effectively clean their hands by simply inserting their hands into an automatic hand-washing device. Permitting LRFE operators to take advantage of available new technology by using automatic hand-washing facilities is reasonable. Although this technology is currently costly, it is used throughout the country in many different settings, including food service. This is especially advantageous in food-processing facilities where frequent handwashing is needed. Bringing the rules up to date and allowing operators to adopt automatic hand-washing instead of a traditional hand-washing set up is necessary and reasonable.

4626.0075 WHEN TO WASH HANDS. 2-301.14

The change to the first sentence in this part makes it clear that food employees with prosthetic devices must clean them as they clean their hands and arms. This change accommodates

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technological advances that have created more vocational opportunities within food service for those who use prosthetic devices.

Even though much of the language in this part appears to be new language, most of it is not. The departments reorganized this part to more clearly list the specific times handwashing must occur and rewrote this part using simpler words.

Item A is a reorganized version of some of the language in the existing item F.

Item B contains language from the existing item A.

Item C contains language from the existing item B. We removed the unneeded requirement that the handwashing must be done at a lavatory sink in the toilet room. That requirement is unnecessarily prescriptive and burdensome.

In item D, the term “support animal” was replaced by the term “service animal,” which is more accurate. Please refer to part 4626.0020, subpart 76 for the discussion of the need and reasonableness. In addition, the departments added “aquatic animals” because many LRFEs prepare and serve aquatic animals such as fish, molluscan shellfish, or crustacea and we need to make sure licensees know that their employees must wash their hands after handling fish, molluscan shellfish, or crustacea.

Item E is the language from the existing item D with a clarification phrase added so it does not conflict with the language in part 4626.0105 that does allow eating, drinking, and using tobacco under certain conditions.

Item F is the existing item E. The departments moved some of the language in the existing item F to new item A.

The language in the new item G is language from the existing item H.

The language in the new item H is language from the existing item I.

Item I is a new requirement that requires handwashing before donning gloves. If employees do not wash their hand before donning gloves, contamination from their hand will transfer to the gloves. This contamination of the gloves could cause a foodborne illness.

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Item I was added to acknowledge the increased use of gloves since the existing Code was adopted. The safety that gloves offer, however, can be defeated by the act of donning them. Single-use gloves are packed into boxes that require users to touch the gloves' exterior with their hands when pulling them out of the box. Thus, the glove could become contaminated while putting them on. Handwashing before donning gloves reduces this risk. The proposed language specifically requires that workers must wash their hands before putting gloves on to prevent contaminating the exterior surface of single-use gloves.

Item J is re-lettered from I to J.

4626.0080 WHERE TO WASH HANDS. 2-301.15

Some LRFEs now use automatic hand-washing facilities. The departments have updated this Code to include these automatic hand-washing facilities as appropriate hand-washing places. Recognizing new technology in this Code is important.

We made other changes for clarity without changing the content.

4626.0085 HAND ANTISEPTICS. 2-301.16

The departments rewrote the requirements for hand antiseptics, which food workers may use after washing their hands under the existing Code. Since chemical residue remains after use, the chemical must be safe for incidental food contact and safe for the hands. The changes clarify the rule and update it to reflect acceptable current standards.

In Item A, the departments replaced the word "sanitizer" with "antiseptics" to eliminate confusion between a sanitizer as defined in this Code, and a hand antiseptic. The rule needs to distinguish between antiseptics that are appropriate for food server use and the common hand antiseptic products called "hand sanitizers" that are now in widespread use, not all of which are acceptable. Food establishments use many sanitizers for various reasons, but some of them are not appropriate to use on the hands. We have provided explicit references to the federal CFRs for the needed standards for enforcement.

Item B contains the requirements for use of hand antiseptics that do not meet CFR requirements. Food workers must rinse their hands after using them. This gives operators the flexibility to use

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products that they choose that might not be CFR compliant. Such flexibility is a reasonable measure because the operators may choose for business reasons. Requiring handwashing is necessary to prevent food being served to patrons from contamination.

Item C is simply language that was relocated from the existing item B.

4626.0090 FINGERNAIL MAINTENANCE. 2-302.11

Long or unkempt fingernails can harbor pathogenic organisms and fecal matter.

In item A, the departments deleted the prohibition of nail polish and added item B in order to more clearly address the requirements for both fingernail polish and artificial nails. The wearing of fingernail polish had been prohibited with no exceptions. We are now providing more flexibility by having the no polish requirement apply only when a food employee is working with exposed foods. In addition, we are allowing a polish-wearing employee to work with exposed foods if gloves are worn.

Item B also addresses the trendy use of artificial nails. Artificial nails pose the same health risks as unkempt natural fingernails and are a physical hazard if they fall off into the food. We are placing the same requirements on food employees who wear artificial nails as those who wear nail polish.

Relaxing these requirements provides flexibility and encourages glove use.

4626.0095 JEWELRY PROHIBITION. 2-303.11

The departments made three changes to this part. First, we rewrote it for clarity, which does not change the content.

Second, we specifically prohibit employees from wearing medical information jewelry, a type of jewelry that was not explicitly prohibited in the existing Code. The proposed Code prohibits employees from wearing jewelry.

However, food handlers often assume that medical information jewelry is exempt from such restrictions. These items, however, present contamination risks similar to regular bracelets and

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watches when worn while preparing food. Further, other options for communicating medical information, such as necklaces, do not present a contamination risk.

Third, we described some smooth jewelry that does not act as a source of contamination and thus is allowable. Jewelry may still be worn elsewhere on the body as long as it does not cause a potential for contamination of the food.

These revisions are needed to eliminate confusion; they are reasonable because they protect the public and apply only when food is being prepared.

4626.0100 CLOTHING; CLEAN CONDITION. 2-304.11

The departments made two changes to this part. First, we eliminated a provision specific to a type of cross-contamination from soiled clothing when the employee moves from handling raw animal foods to ready-to-eat foods. Focusing on this one type of cross-contamination neglects a wide variety of common issues from a food employee wearing soiled clothing. Second, we simply stated that a food employee must wear clean outer clothing to address the wider potential problems brought on by soiled clothing. This part now states the rationale as “to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.”

The existing Code already prohibits dirty outer clothing so these changes more directly express what is prohibited in terms of preventing contamination from soiled clothing. These changes are thus necessary and reasonable.

4626.0105 EATING, DRINKING, OR USING TOBACCO. 2-401.11

The departments moved the FDA number to the end of title.

4626.0110 DISCHARGES FROM EYES, NOSE, AND MOUTH. 2-401.12

The departments moved the FDA number to the end of title.

4626.0115 HAIR RESTRAINTS. 2-402.11

The departments made minor editorial changes to this part for clarity without changing its content.

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4626.0120 ANIMAL HANDLING PROHIBITION. 2-403.11

The existing Code prohibits a food employee from handling dogs, cats and other animals that might harbor pathogens that are transmissible through food. The departments revised this part for clarity by making three changes.

First, the departments updated terms without changing the rule’s meaning. We replaced “support animal” with “service animal.”

Secondly, the departments revised the list of the types of animals that a food worker can care for within a LRFE to include fish, molluscan shellfish, or Crustacea display tanks. Since the LRFE may permit animals in the LRFE, allowing a food worker to care for and handle the animal is reasonable, as long as the food worker properly washes his or her hands.

Thirdly, the departments eliminated a redundant list of items that require handwashing before the food worker is permitted to handle. This restriction is already covered in part 4626.0070.

4626.0123 CLEAN UP OF VOMITING AND DIARRHEAL EVENTS. 2-501.11

The departments added new language to protect food handlers and patrons from exposure to pathogens in vomit or diarrhea that occurs in a food establishment. Vomit and diarrhea can and do carry pathogens in large quantities, creating a very high risk of infection. Moreover, pathogens can survive for long periods of time if proper cleaning procedures are not used. Thus, food establishments must put procedures in place to ensure that disease is not transmitted.

A food employee cleaning up after an incident is a high-risk activity. If the employee is not properly protected or does not adequately clean all contaminated surfaces, an outbreak of foodborne illness could result. Therefore, the departments added this part to require LRFEs develop and use proper clean-up procedures that reliably control the risk. This performance-based measure leaves the details to the operators to establish and carry out proper cleaning procedures for consistency during clean up and eliminating the possibility of disease transmission. The LRFEs also bear the responsibility for training their employees to learn and use these procedures.

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Preventing the spread of disease within the LRFE is imperative. These performance-based measures are reasonable.

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4626.0125 SAFE AND NOT ADULTERATED. 3-101.11

The departments rewrote this part to express the condition food must be in more accurately and emphasize that it must be “safe.” This is an editorial change, not a substantive one. “Safe food” which differs from “unadulterated food,” because safety refers to a particular food’s inherent risk level, while “adulteration” refers to contaminating or misbranding a food product during the processing of that food. Both safety and adulteration are discrete terms that are essential for describing the condition of a particular food. The changes are necessary for accuracy and reasonable because they do not add further requirements on regulated parties.

The departments also updated the rule to cite *Minnesota Statutes*, section 34A.02, which covers food adulteration. We deleted the unnecessary reference to part 4626.0430 because it addresses the requirements for “honestly presented.

4626.0130 COMPLIANCE WITH FOOD LAW. 3-201.11

The departments revised item A because numerous rules and regulations on both the state and federal levels have changed over time. This revision makes the language more inclusive and up to date by citing the applicable law with broad references. Using this plain language is reasonable because these citations will remain up to date over time.

Item B was reconfigured for clarity.

The departments updated the citations in item C.

Consumption of raw and undercooked fish and shellfish may lead to foodborne illness. In item D, the departments needed to add the word “undercooked” to correct an oversight in the existing Code. In addition, we clarified that this requirement applies regardless of if the fish is sold in a grocery store, served in a restaurant, or given out as a sample. The risk of illness or infection is the same whether the fish or shellfish is raw or undercooked and does not vary based on the mode of sale of service. The rule change provides additional protection for consumers of fish and shellfish.

The departments added item E to address undercooked whole-muscle steaks, which carry an elevated risk of illness, especially if these intact beef cuts are mechanically tenderized.

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Mechanically tenderizing as defined in part 4625.0020, subpart 50a, these cuts can introduce pathogens and subsequent handling can increase the likelihood of supporting pathogen growth. Pathogens that are not destroyed during cooking can make food consumers ill. This revision requires LRFEs to handle these undercooked products accordingly.

This revision also specifies the labeling required to comply with updated changes to federal regulations, which provide food seller and food purchaser accountability during sale and distribution of meat products. These changes are necessary and reasonable to protect the public from food-borne illness.

The departments incorporated, the USDA requirement for safe handling labeling of packaged not ready to eat meat and poultry in item F. The requirement to label these packages with safe handling instructions is needed to remind the purchaser and consumer of specific preparation processes to avoid foodborne illness.

The USDA changed rules that require safe-food-handling instructions on packaged eggs. This revision to item G brings this Code up-to-date. This change is needed so food consumers can clearly distinguish which raw eggs may contain *Salmonella* from those eggs that are pasteurized to destroy pathogens, and thus can be used in an uncooked or undercooked form without presenting a risk of foodborne illness. These changes are necessary because many food products require eggs in an uncooked or undercooked form and adding proper handling instructions is a minimal and reasonable solution.

4626.0135 FOOD IN HERMETICALLY SEALED CONTAINER; SOURCES. 3-201.12

The departments changed “shall” to “must.”

4626.0140 FLUID MILK AND MILK PRODUCTS; SOURCES. 3-201.13

The departments simplified and shortened the existing rule language for consistency with *Minnesota Statutes*, chapter 32. Dry milk, ice cream, and similar products previously listed in rule language are all defined as dairy products in *Minnesota Statutes*, chapter 32. This change reduces unnecessary product listings in the rule while still referencing the chapter containing the definition of milk products. These changes are necessary and reasonable.

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4626.0145 FISH. 3-201.14

Code of Federal Regulations, title 21, section 123 regulates fish and fishery products. We need to add this citation in order to provide the most up-to-date citations.

We need this revision to accurately reference federal requirements related to catching and harvesting fish and to ensure that food handlers receive regulatory approval before selling or serving fish to prevent offering fish for sale or service which may have been illegally harvested.

4626.0150 MOLLUSCAN SHELLFISH. 3-201.15

The departments added and corrected references to federal documents regulating molluscan shellfish. Code of Federal Regulations, title 21, section 123 regulates molluscan shellfish. There is no change in the requirements.

4626.0155 WILD MUSHROOMS. 3-201.16

The departments need specific requirements for consumer disclosure and records retention to regulate LRFEs that purchase wild mushrooms from harvesters for sale or service to consumers. Existing Code language does not provide adequate detail to express what the rule requires for operators and consumers or for regulators to enforce the rule. The changes here are essential for regulatory agencies to trace this food product back to its origin during any potential illness outbreak or poisoning investigation and for suppliers to disclose to food consumers pertinent information about the food they eat.

The revision of item A restates item A of the existing Code and does not alter its intent.

The departments added item B to institute specific new record-keeping requirements for the LRFE-buyer when purchasing wild mushrooms. The LRFE-buyer must retain these records for 90 days, a period of time that LRFE-buyers are accustomed to from existing requirements for shell-stock records retention. Essential data about the mushrooms include information about the mushroom species, date of sale, quantity by weight, identification statement, name and address of harvester, and a copy of harvester's accredited education. All are items necessary for regulatory authorities to trace the mushrooms backwards properly during a food-illness

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investigation. The existing Code does not require LRFE-buyers to retain these records, which hampered regulatory authorities investigating foodborne illness that implicated mushrooms.

Item C's proposed requirements complement the new requirements in item B and are specific to a harvester-seller selling wild mushrooms. Information regarding the mushroom species, location and date of harvest, locations of LRFE-buyers buying the mushrooms, date of sale to LRFE-buyers, and quantity sold are vital pieces of information that are necessary to trace products forward to potential LRFE-buyers involved in a possible foodborne illness outbreak. Without these key pieces of information, regulatory authorities who know about a harvester-seller distributing unsafe species of mushrooms might be thwarted from preventing diners from consuming wild mushrooms that might cause foodborne illness.

The departments added item D, which requires LRFE-buyers to inform customers that mushrooms come from a source that has not been inspected. Consumers need to know that eating this species of mushrooms still poses a risk to the consumer's health. Wild mushroom harvesting takes place in forests, fields, and other settings, various environments that lack consistency in the growing conditions and surrounding environment. Thus, it is important for LRFE-buyers to disclose to consumers that the variability inherent to wild harvest may pose a risk from consuming the mushrooms. This revision is reasonable because it does not prohibit wild mushroom service altogether, but instead allows consumers to decide the level of risk they are willing to take when choosing their foods.

Item E does not conflict with the existing Code. Commercial harvesting operations that are regularly inspected and approved by the regulatory agency will retain their existing exemptions from this part of the rule.

4626.0156 CERTIFIED WILD MUSHROOM HARVESTER.

Wild-mushroom harvesters' ability to properly identify wild mushrooms is paramount for consumer safety. The departments added this part to specify and clarify the educational and certification requirements that harvesters must meet. At a minimum, a harvester must have completed a training program through an accredited college or university or state mycological society; the program must train its students to identify physical specimens of mushroom species. The harvester must also provide the Commissioner of Agriculture with a document naming the specific mushrooms that he or she is trained to identify. We have added language to clarify the

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responsibilities of the Department of Agriculture for administering this certification program. The existing Code does not clearly state these responsibilities. It is reasonable to expect that harvesters accurately identify wild mushroom species, and that they provide documentation that verifies their identification training in the interest of protecting public health.

4626.0160 GAME ANIMALS. 3-201.17

This revision removes a specific cooking-temperature requirement for wild-animal meat to eliminate redundancy. Cooking temperatures for wild-animal meat are specified under part 4626.0340.

4626.0165 FOOD TEMPERATURES; RECEIVING. 3-202.11

Certain foods need to be received from suppliers at or below specific temperatures. LRFEs must receive TCS foods at the proper temperatures stated in this part to ensure that pathogenic and spoilage bacteria cannot multiply to a significant level that will cause illness in consumers. For ready-to-eat foods, temperature control may be the only method to prevent pathogen growth.

The departments revised item A by adding a reference to item C that is all new language. We revised item B to delete references to unneeded statute, rule, and federal-manual citations. Item C is needed to specify the maximum temperature that eggs need to be for LRFEs receiving them according to *Minnesota Statutes*, section 29.23. Citing the required temperature for receiving eggs here is reasonable because LRFEs are likely to look for this information here with the information in the rules, and provides an easy access to the information and does not change any requirement in statute or federal rule.

4626.0170 FOOD ADDITIVES. 3-202.12

The departments changed “shall” to “must” along with citation corrections.

4626.0175 EGGS. 3-202.13

The departments revised this part to reference the most up-to-date shell egg requirements set by USDA. It does not create any additional requirements for food handlers.

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4626.0177 EGG AND MILK PRODUCTS; PASTEURIZED. 3-202.14

The departments combined parts 4626.0140, 4626.0175, 4626.0180, and 4626.0185 into part 4626.0177. Both eggs and milk products require pasteurization by state law. We updated the statute reference. The existing Code language does not change.

4626.0180 3-202.14 EGGS AND EGG PRODUCTS.

The departments repealed this part because we moved the requirement for eggs and egg products to part 4626.0177. This repealed language has now been combined with the requirement for pasteurized fluid milk and milk products.

4626.0185 3-202.15 MILK AND MILK PRODUCTS.

The departments repealed this part because we moved the requirement for pasteurized milk and milk products to part 4626.0177. This repealed language has now been combined with the requirement for LRFEs to obtain pasteurized egg and egg products.

4626.0190 PACKAGE INTEGRITY. 3-202.15

The departments changed “shall” to “must.”

4626.0195 ICE. 3-202.16

The departments changed “shall” to “must.”

4626.0200 SHUCKED SHELLFISH; PACKAGING AND IDENTIFICATION. 3-202.17

The departments added the term “best if used by” to item A, subitem (2) because “sell by” and “best if used by” are used interchangeably by industry and consumers. This addition does not change the requirement.

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4626.0202 SHELLSTOCK IDENTIFICATION. 3-202.18

The departments relocated this part from part 4626.0205 and restructured it for readability. We also added the word “label” in two places because the words “tag” and “label” are synonymous and used interchangeably in the industry. We also updated one citation in item B.

4626.0205 SHELLSTOCK IDENTIFICATION. 3-202.19

The departments repealed this part and replaced it with part 4626.0202.

4626.0210 SHELLSTOCK; CONDITION. 3-202.19

The departments changed “shall” to “must.”

4626.0215 MOLLUSCAN SHELLFISH AND SHELLSTOCK; ORIGINAL CONTAINER. 3-203.11

Molluscan shellfish and shellstock (raw, in-shell molluscan shellfish, e.g. clams, mussels, and oysters) need to be stored properly with required labeling. In addition to maintaining the stock at correct temperature and condition, proper storage means both separating the mollusks and shellstock by its source and labeling it to precisely identify the geographical location that harvesters collected the shellstock from. Segregating this inventory by its source is critical for regulatory authorities to isolate shellfish implicated in illness outbreaks and tracing them back to their source waters. The container tags or labels would provide vital, necessary information in conducting a trace-back investigation to help determine the source and extent of the outbreak.

The departments added “For Display Purposes” in item B. This is necessary to limit the removal of shellstock from original containers and to eliminate this practice from taking place in other situations.

The additional language in item D provides needed allowances and specific details related to customer self-service of shellstock that has been repackaged. Repackaging shellstock risks losing the tracking information sent with the bulk stock of product; the added language in item D provides specific labeling requirements to control that risk.

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These rule revisions allow food establishments the flexibility to remove shellstock from original containers for ordinary commercial purposes, such as offering a customer a choice of product. The revisions thus are reasonable. At the same time, the revisions require that food handlers provide self-service packages with the same trace-back information essential for tracking foodborne illness outbreaks. Ensuring that regulatory authorities can effectively investigate and respond to outbreaks protects public health, which is essential.

4626.0220 SHELLSTOCK; MAINTAINING IDENTIFICATION. 3-203.12

The departments updated the citation references in item A.

The departments revised item B. LRFEs must maintain accurate shellstock records so that the records can be easily matched to the product on hand or to verify that a specific lot of shellfish has already been sold. Allowing for a quick trace back of shellfish implicated in an outbreak to its source waters is necessary to determine whether to close the area to harvest due to contamination. We need to clarify record keeping by adding the word “label” and requiring the last date of sale to be marked on the tag or label as a required practice.

This rule revision is reasonable because the recording keeping practices allow the regulatory authorities to conduct a foodborne illness investigation and trace back food products if necessary. At the same time, the revision provides operators flexibility for choosing both the record-keeping system to use and how to store, sell, or repackage shellstock. In addition, adding the word label is reasonable for eliminating confusion between labels and tags.

4626.0225 PREVENTING CONTAMINATION FROM HANDS (ALSO SEE PART 4626.0070). 3-301.11

Hands may be a vehicle of contamination.

The departments need this revision because the existing Code contains inconsistent standards and enforcement for employees using bare hands to handle ready-to-eat foods. The transfer of pathogens from food workers hands to ready-to-eat food is one major causes of foodborne illness. The new language adequately protects these food products by prohibiting food employees from using bare hands to handle ready-to-eat foods, except for certain specific situations when using specific procedures that reduce the food-contamination risk.

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Item A clearly prohibits touching ready-to-eat-food with bare hands. There has been confusion in the past about if and when bare hands could touch ready-to-eat foods. Item A is very clear on the requirement. This item also provides two exceptions to the bare hand no contact requirement. These exceptions are contained in items C and D.

Item B requires food employees to minimize bare hand contact with not in a ready-to eat form. While not as critical, bare hand contact with not ready-to-eat food still could cause illness. As a precaution, food employees should not touch not ready-to-eat foods with their bare hands because pathogens could be transmitted to the food. Washing, heating or cooling might kill some or all of these pathogens but others may remain in or on the food. For example, a food employee handles raw chicken with his or her bare hands. The chicken is cooked to the required temperature killing all or most to the pathogens. Without washing his or her hands, using a utensil or donning gloves, the same employees handles raw beef. The beef is allowed to cooked to a lower temperature than the chicken which may allow pathogens to survive and cause an illness.

Item C provides an exemption that allows food employees to use bare hands to touch ready-to-eat food if that food will combined with other food(s) and cooked to the required temperature. Cooking the entire combined food to the required temperature will kill the pathogens in all of combined food product.

All new language under item D is necessary to specify important documentation for a LRFE to demonstrate that it is adequately protecting public health. The existing Code language does not provide a clear standard for when and how employees may handle ready-to-eat food using bare hands. This proposed language clarifies those practices and makes the need for compliance documentation with alternative public health protections that would make bare-hand contact acceptable obvious.

Clarifying bare-hand contact procedures for inspectors and operators is reasonable because it adequately protects public health from one of the most common sources of contamination and illness transmission, bare hands of ill food workers. This revision provides operators flexibility to allow bare-hand contact when applying certain controls to prevent the spread of pathogens. At the same time, it reasonably prevents employees from using bare hands to handle ready-to-eat food by LRFEs that serve a highly susceptible population (i.e., schools and day care facilities).

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4626.0230 PREVENTING CONTAMINATION WHEN TASTING. 3-301.12

The FDA number was moved to the end of the title.

4626.0235 PREVENTING CROSS CONTAMINATION. 3-302.11

The departments revised this part to add requirements needed to prevent workers from transmitting pathogens present on raw animal foods to other raw foods or to foods that are ready to eat. Cross-contamination can occur during storage, preparation, and service. This revision also is needed to clarify existing Code language about storing other raw ready-to-eat foods, such as fruit.

Preventing pathogen transmission among food items by properly separating certain foods during storage, preparation, holding, and display and to prevent contamination of foods that will be served raw without a cooking step are all reasonable measures. Furthermore, it is also reasonable to exempt LRFEs handling frozen foods from following these steps, since we now know that stacking packaged food in a freezer, whether ready to eat or not, does not increase the risk of foodborne illness.

4626.0240 FOOD STORAGE CONTAINERS; IDENTIFIED WITH COMMON NAME OF FOOD. 3-302.12

The departments changed “including” to “such as” and “shall” to “must.”

4626.0245 PASTEURIZED EGGS; SUBSTITUTE FOR RAW EGGS. 3-302.13

The existing Code requires pasteurized eggs to be used in uncooked food products such as certain dressings or sauces. Raw eggs may contain *Salmonella* Enteritidis. The departments removed the word "shell" because it is no longer commonly used when referring to eggs. We removed the existing item B because Tom and Jerry batter is already covered under part 4626.0177. We added in the phrase “foods such as” to clarify that the list of foods does not include all of the possible food containing raw eggs. These are minor and reasonable revisions to clarify the existing requirement.

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4626.0250 PROTECTION FROM UNAPPROVED ADDITIVES. (SEE ALSO 4626.0170) 3-302.14

The departments changed “shall to “must in item A and deleted redundant language in item B, subitem (1) because it is covered in part 4626.0130, item A.

4626.0255 WASHING FRUITS AND VEGETABLES. 3-302.15

The departments revised item A to include the option of washing raw fruits and vegetables with chemicals. This practice has been shown to be safe. Allowing this practice is reasonable because LRFE are using it or want to use it. It might reduce costs.

We also clarified the requirements about fruits and vegetables that the LRFE intend that the consumer will wash.

The departments added item B to require LRFEs using devices that generate chemicals on-site use them according to the manufacturer’s instruction. Misusing these devices may result in the LRFE using too much or too little chemical. Both situations could harm the consumer. Requiring that these chemicals are used properly is a way to protect consumers from chemical illness or injury is needed and reasonable.

We removed unnecessary language from item B, subitem (2), which is self-explanatory.

4626.0260 ICE USED AS EXTERIOR COOLANT; PROHIBITED AS INGREDIENT. 3-303.11

The departments rewrote this part to emphasize that ice that is used to cool the exterior of some foods must not be consumed as a food afterward. This requirement was lost at the end of existing sentence, so we placed it in a more prominent spot. We changed out the word “including” to “such as” clarifying that we are not listing all possible foods; rather we are giving some examples.

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4626.0265 FOOD IN CONTACT WITH WATER OR ICE. 3-303.12

The departments revised item C to delete the phrase “Other than for direct retail sale.” Since packaging foods in containers with water, such as tofu and celery, and selling them directly to the consumer is safe, the phrase is not needed.

In item C, the departments clarified that cut, not whole potatoes can be packaged and sold under this requirement.

We replaced “chicken” with “poultry” in item D because all poultry may be stored safely in this manner.

4626.0270 FOOD CONTACT WITH EQUIPMENT AND UTENSILS. 3-304.11

The departments rewrote this part to clarify the equipment and utensils that food can come in contact with. Rephrasing this part in terms of what is allowable is simpler than trying to list all of the unacceptable situations. This reasonable approach is easier for licensees and operators to understand.

Items A, B and C requires the equipment, utensils and linens be cleaned or cleaned and sanitized as the Code requires before contacting food with them. Item B clarifies that single-service and single-use articles can contact food, because, these articles, if stored and maintained as required in this Code cannot contaminate other food, equipment, or utensils.

4626.0275 IN-USE UTENSILS; BETWEEN-USE STORAGE. 3-304.12

The departments revised this part to clarify the specific requirements for storing utensils between uses. Minor revisions were made to items A, B, D, and E.

The departments revised item C to clarify that acceptable storage of utensils that are being used on a clean portion of food preparation table or cooking equipment depends on whether the surface is being regularly cleaned and sanitized. The sentence structure of the existing provision is confusing, leading to a misinterpretation. The surface where the utensil is stored does *not* need to be cleaned and sanitized *after* the utensil has contacted the surfaces; instead, the surface where a utensil is stored needs to be cleaned and sanitized *before* the utensil can be stored there.

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The new language in item F recognizes the scientific evidence that water of a temperature of 135 degrees F or higher is sufficiently hot enough to control microbial growth and prevent pathogens from proliferating. This revision is reasonable because it protects public health while allowing increased flexibility for operators when storing the utensils that are being used. This revision provides increased flexibility because water helps keep sticky food debris from adhering to the utensils but existing language in this part of this Code limits storage of utensils in water to situations where constantly running water is used for flushing of food debris. Having a dipper well to provide the constantly running water is cost prohibitive due to the price of installation and the extra charges to a water bill if used with regularity. Allowing the utensils to be kept in hot water that does not need to be constantly running controls public health risks while giving operators a method to store utensils in a way that is not cost prohibitive compared to what is currently allowed by this Code.

The departments added item G to recognize that customer self-service bulk-food utensils are regulated separately from this Code under Minnesota Statutes, section 31.84. Regulation and enforcement of those requirements fall exclusively under the purview of the Commissioner of Agriculture and his or her designated employees.

4626.0280 LINENS AND NAPKINS; USE LIMITATION. 3-304.13

The departments added the phrase “such as cloth” to clarify the sort of linens that this requirement applies to. The term “linens” is becoming less familiar to the public.

4626.0285 WIPING CLOTHS; USE LIMITATION. 3-304.14

The department has changed this part’s title from “used for one purpose” to “use limitation” to more accurately describe the scope of use for wiping cloths. This is important since we regulate various ways that wiping cloths are used under this provision.

The department separated requirements for dry and wet wiping clothes and their respective uses to make the specific requirements easy to find. Specifics for dry wiping cloths are now located in item A. LRFEs use dry cloths to remove crumbs and other food debris that is left behind when serving portions are dished out of serving containers to enhance the aesthetics of food presentation. Acknowledging food establishment’s need for attractive presentation is reasonable. To control microbial growth, dry wiping cloths must not become moist. Using wiping clothes

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contaminated with microbes to remove crumbs or debris would obviously risk public health, making these requirements necessary.

We revised item B to make the item specific to moist-state wiping cloths. We added “on counters and other equipment.” LRFEs must keep these cloths in an approved sanitizer solution that controls microbial growth.

The department also added language to subitem (2) to reference corresponding laundering requirements for moist wiping cloths that appear elsewhere in the Code. Linking the use with laundering is important for clear communication about proper use of wiping cloths. Thus these changes are necessary for the users of this Code to have a more logical and comprehensive understanding of moist wiping cloth use.

The department simplified item C to clarify the instructions for wiping cloths that contact raw animal foods. Separating these cloths from other cloth types is the most effective way to protect food from cross-contamination with pathogens; keeping these types of wiping cloths in the sanitizer solution referenced in item B (part 4626.0805) does not adequately eliminate pathogens after the cloth is used with raw animal foods. Therefore, the departments have deleted this unnecessary requirement from item C.

We have added item D because food debris and visible soil in sanitizer solutions inhibits the chemical-sanitizer compounds’ effectiveness, negating the requirements in item B above. This item is necessary and preserves the effectiveness of the sanitizer solutions where wiping cloths are stored.

The departments also added item E to make it clear operators must use sanitizer solutions as prescribed by this Code. Improper use makes the sanitizers a source of chemical contamination. Some food handlers incorrectly store utensils in sanitizer solutions used for wiping cloths or store sanitizer solution buckets in inappropriate locations due to misunderstanding the purpose and safety of the sanitizer solution.

Item F has been added because food service professionals have been using single-use disposable sanitizer wipes increasingly since the publication of the existing Code. Adding this language in item F is necessary to clarify that these EPA-approved products are acceptable.

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The changes in this section are reasonable because they do not establish new or burdensome requirements for operators, but instead clarify existing requirements and add logical associations to other parts of this Code, both of which will increase compliance and public health protection.

4626.0287 GLOVES; USE LIMITATION. 3-304.15

The departments changed “shall” to “must” and “one to “1.”

We revised “including” to “such as” to show we were giving examples and not trying to show all types of a particular activity or items.

We also updated citations.

4626.0290 USING CLEAN TABLEWARE FOR SECOND PORTIONS AND REFILLS. 3-304.16

The departments revised item A for clarity. The one specific instance when refilling a customer’s drinking cup or other utensil is appropriate when the action can be done without contaminating the dispensing source. Food servers can refill drinking cups and containers using pitchers and drink dispensers such as taps, soda guns, and soda fountains. Using such dispensing equipment refills the vessel without the dispenser contacting the place on the container where the consumer’s lip contacts it. Therefore, refilling drinking cups or containers does not risk contaminating the dispensing equipment. The department also changed “employee” to “employees” and rearranged the location of the word “tableware” to improve this item’s grammar and readability. We also added the word “including” clarifying that the examples provided for tableware is not an exhaustive list and could include other examples of tableware not specifically listed in this item.

Item B was changed slightly for the grammatical and readability purposes described above.

We added the word “Drinking” and changed “glasses” to “containers” in item C for clarity and to provide consistency with item A.

The changes made by the department are reasonable because they ease restrictions for tableware reuse, maintain adequate public health protection from potential sources of contamination, and clarify provisions to improve understanding by operators and regulators.

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4626.0295 REFILLING RETURNABLES. 3-304.17

The department replaced this part with all new provisions for refilling returnables at a LRFE.

Item A allows customers to return containers for refilling when it poses no threat to public health. For a classic example, customers buy beer or milk at a retail outlet, and usually pay a deposit for the bottles upon purchase, with the understanding that they will return the empty containers to the retail outlet to receive their deposits back. These retail outlets then return the containers to the original food processing plant for cleaning and sanitizing before refilling them with fresh product. Regulations covering manufacturers and food processors distinct from this Code ensures that the processing plant maintains public health protections during washing and sanitizing.

Item B is new. It addresses food containers that the customer returns to a LRFE, which washes and sanitizes the containers before refilling them. Businesses and college campuses that are reducing single-service and single-use utensils and thus mitigating their waste-stream prompt the need for this provision. The departments are protecting public health by safeguards found in subitems (1), (2), and (3). Subitem (1) ensures that the take-home food containers meet the same standards that multiple-use utensils used in a LRFE must meet through references to parts 4626.0450, 4626.0505, and 4626.0515. Subitem (2) ensures that the refillable take-home food containers are made for this purpose by requiring that the LRFE provide them. That way, consumers cannot bring in random containers that might not meet the utensil characteristics required by subitem (1). Subitem (3) ensures that the LRFE washes, rinses, sanitizes, and inspects the take-home food containers before they are refilled.

The departments added item C to restrict situations such as refilling growlers at breweries and taprooms while still allowing them. Refilling such containers is becoming increasingly popular throughout Minnesota and uniform standards will better protect public health. Subitems (1) through (5) of this provision spell out the needed clear and consistent instructions for operators and regulators regarding refilling these types of containers. These limitations are reasonable because they do not unduly restrict the practice while providing necessary restrictions on how the practices are carried out.

Item D is a rewritten version of part 4626.0295, item C in the existing Code. The departments made no substantive changes to this item.

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The departments added item E to clarify that consumers can refill their own containers from a water-vending machine or system. This is not clear in the existing Code. Water from water-vending machines or systems is also typically of neutral pH and thus the water does not present the same potential hazards to beverage containers that soft drinks or beer do from their typically acidic properties that could degrade the container being refilled. Requiring consumers to use containers that are food-specific for water would be unnecessarily burdensome, provides no additional public health protection, and would be difficult to enforce as many water vending machines or systems when dispensing water are not monitored.

All of these changes are reasonable because they provide additional flexibility for patrons and businesses by creating options for refilling returnable containers with food and beverages, while simultaneously providing necessary restrictions to protect public health.

4626.0300 FOOD STORAGE. 3-305.11

The departments made a minor change to item C to show that examples listed are not inclusive. We changed “shall” to “must.”

4626.0305 FOOD STORAGE; PROHIBITED AREAS. 3-305.12

Food establishments must not store food in specific areas that are likely sources of contamination. The departments changed each of the prohibited food storage areas from singular to plural to make it clear that this prohibition applies to all similar areas. This change adds clarity and improves readability without adding new requirements.

4626.0310 VENDED TCS FOOD; ORIGINAL CONTAINER. 3-305.13

The departments made a grammatical change to enhance readability.

4626.0315 UNPACKAGED FOOD; PROTECTION FROM CONTAMINATION. 3-305.14

The departments changed “shall” to “must.”

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4626.0320 FOOD DISPLAY; PROTECTION FROM CONTAMINATION. 3-306.11

The departments made minor changes in item A.

We moved the language in item B from part 4626.1860, item O of the Code. This requirement applies to all LRFE but it was listed as a requirement only for mobile food establishments, seasonal temporary food stands and seasonal permanent food stands. This was a significant error in the existing Code.

4626.0325 CONDIMENTS; PROTECTION. 3-306.12

The departments changed “shall” to “must” and “including” to “such as.”

4626.0330 CONSUMER SELF-SERVICE OPERATIONS. 3-306.13

With some exceptions, raw animal foods cannot be offered for consumer self-service. Trained employees must monitor buffets and salad bars that include such raw foods.

The departments subdivided the list of excluded foods in item A into subitems and made minor revisions to sentence structure to improve readability. Allowing raw frozen, shell-on shrimp or lobster, and raw shell eggs to be offered at self-service is reasonable because these items have been shown not to cause an increased public health risk.

Because consumers of ready-to-eat foods from self-service operations also provide a contamination risk, the departments need to require oversight of buffets, salad bars, and similar food service models. The departments modified this part to allow a wider range of business plans for self-service models than the existing Code offers, while requiring food-safety monitoring as a basic requirement to protect the public. LRFEs should be able to comply with this necessary and reasonable measure by following sound management practices such as employee training and assignment of food-safety duties. These practices support compliance with many other requirements in this Code, and most businesses already comply with this new requirement. It is thus necessary and reasonable.

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4626.0335 RETURNED FOOD; RE-SERVICE OF FOOD. 3-306.14

Offering foods that have been previously served to or returned by the consumer is prohibited, except under the limited exceptions spelled out in this part. The departments revised the existing part by adding more examples of food to illustrate the types that can be re-served. Steak sauce and wine, which are not TCS foods, do not negatively affect public health protection. Many LRFEs with foods such as those listed already engage in this practice. Therefore, expanding the foods which can be re-served under the conditions specified in this part is reasonable because it allows operators more latitude, while limiting the practice so that it does not pose an increased public health risk is necessary.

The departments added the reference to part 4626.0447 in item B to re-emphasize the prohibitions for serving certain foods to highly susceptible populations. This addition is needed and reasonable because LRFEs need to be aware that there is an additional part related to re-service of food.

4626.0337 MISCELLANEOUS SOURCES OF CONTAMINATION. 3-307.11

LRFEs must protect customers from all sources of contamination under the LRFEs' control, both the most common sources specified in this Code and those that are unspecified. Consequently, the departments added this part as a safety net to address potential contamination sources not specifically identified. Because of the seemingly limitless variety of business plans for food operations, anticipating all the ways food might become contaminated is virtually impossible. Requiring basic protection from miscellaneous contamination sources is a reasonable way to provide robust public health protection for all consumers, while providing the regulatory flexibility needed to address future contamination sources without having to revise this Code further.

4626.0340 COOKING RAW ANIMAL FOODS. 3-401.11

The department expanded item A's references to include items B, C, and the newly added D, which applies to ready-to-eat undercooked or raw animal proteins. The departments' other changes in item A are limited to providing increased readability and proper grammar: and changing the word "including" to "such as" and moving the word "meat" within the sentence. Under subitem (1), unit (a) the word "shell" has been removed, because "egg" and "egg product"

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are now defined in this Code, making the word shell unnecessary here. We needed to change unit (b), under subitem (1), to provide a reference to item C of part 4626.0340, and to refer to game animals under voluntary inspection programs specified in part 4626.0160; this provides clarity about cooking temperatures for this type of raw animal protein.

The departments added “mechanically tenderized” to subitem (2) because this Code defines this type of meat product, which differs from “injected” meats. We have also added reference to part 4626.0160 in subitem (2) to accurately describe cooking temperatures for this game animal meat in a comminuted form. We have added “baluts,” which are a form of poultry carrying the same public health risks as raw chicken and turkey and are becoming an increasingly popular menu item, specifically in LRFEs serving ethnic food products. These changes are reasonable to address our changing food operations and corresponding consumer demand; they are necessary for the departments to regulate them.

The departments needed to add the reference to part 4626.0160, item C, to subitem (3) to make it clear that hunted wild game carries increased public health risks compared to commercially raised game animals. To counter these risks, therefore LRFEs need to cook wild hunted game to a higher temperature.

The departments expanded item B to include other types of whole meat roasts (lamb, pork, and cured pork) that carry the same public health risks as beef roasts listed in the existing version of this Code. This is necessary to eliminate any confusion by regulatory or industry professionals about proper cooking temperatures for these types of roasts. The departments edited subitem (2) in two ways. First, the time-and-temperature parameters for cooking roasts were put into an easy-to-read table format. Second, new pathogen-related data was incorporated into the table, data that indicates different times and temperatures that pathogens are adequately reduced during cooking from the times and temperatures that are listed in the existing Code.

We changed item C because undercooking whole-muscle, intact beefsteak, a practice very common in LRFEs, needed addressing in this Code. Adequate public health protection is achieved by cooking the exterior surfaces of whole-muscle, intact beefsteak to 145 degrees F, because the interior of the meat is free of pathogens if it has not been injected or mechanically tenderized. The departments also limited serving this undercooked whole-muscle, intact beefsteak to LRFEs that are *not* serving highly susceptible populations to ensure public health protection of this vulnerable group of people.

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As the departments did in item C above, they added subitem (1) to protect highly susceptible populations from potential pathogen exposure by prohibiting raw food service to this vulnerable group of people.

The departments added subitem (2) to ensure that children are not exposed to the riskiest of raw animal foods which would be raw animal foods in a comminuted form (such as ground beef or sausage).

The departments added subitem (3) to add a cross-reference to a new requirement in this Code, part 4626.0442, which requires that LRFEs provide consumers with notice of raw or undercooked animal food products, which is related to this particular part of the Code.

The department needed to create a new item D to expand into more specific instructions for serving undercooked or raw animal food. Minimizing risk to the public is important as the popularity of these foods grows.

Language in item D, subitem (4), units (a) to (c) are unchanged from the existing Code.

These changes are reasonable because they:

- add specificity for safely cooking and serving raw-animal foods,
- protect highly susceptible populations from potential adverse health exposures to undercooked animal foods, and
- reduce the stringency for food establishment operators by adding updated scientifically based cooking temperatures for animal food that destroy pathogens (such as allowing pork roasts to be cooked similar to beef roasts, or allowing beef steaks to just be cooked on the surfaces).

All of these changes provide similar or increased public health protection from pathogens found in raw animal foods compared to the existing Code.

4626.0345 MICROWAVE COOKING. 3-401.12

The departments changed “shall” to “must” and “Fahrenheit” to “Celsius” along with “two” to “2.”

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4626.0347 PLANT FOOD; COOKING FOR HOT HOLDING. 3-401.13

The departments added this new language to require that food establishments cook raw fruits and vegetables to a temperature of 135 degrees F (57 degrees C) if the fruits and vegetables will be placed in hot holding. This will reduce, inhibit, or eliminate potential biological hazards (e.g. bacterial pathogens) while allowing for a practical food temperature that is low enough to maintain food quality. This requirement is reasonable because fruits and vegetables are ready to eat at any temperature and do not require the same level of microorganism destruction as do raw animal foods. Cooking to the hot holding temperature of 135 degrees F (57 degrees C) prevents the growth of pathogenic bacteria that may be present in or on these foods.

4626.0349 NONCONTINUOUS COOKING OF RAW ANIMAL FOODS. 3-401.14

The departments added this entirely new part to address noncontinuous cooking of raw animal foods, a food production practice common in catering operations that serve crowds of people at banquets or other large events.

Items A and B work together. Safely cooking noncontinuously requires the operators to heat the food initially for 60 minutes or less (item A) and cool the food for a limited cooling time (item B). This procedure adequately controls *Clostridium perfringens*, *Clostridium botulinum*, and other spore-forming toxigenic bacteria. A longer heating period creates an environment conducive for these bacteria to grow and produce toxins that the final cooking period would not necessarily eliminate. Protecting public health requires the departments to specify 60 minutes in item A followed by the cooling period stated in item B, which refers to standards stated elsewhere in this Code.

The departments added item C to deal with the food that has been cooled. Holding the food cold at or below 41 degrees F is the only way to control microbial growth. Item C states the cold holding standard by citing part 4626.0385, item A. Since this form of food production must use the cooling methods used in part 4626.0385, item A, leading to an identical temperature, citing to this item for the cold holding standard is logical and avoids confusion.

In item D, the departments require that the LRFE bring noncontinuously cooked food up to the temperature stated in part 4626.0340 before selling or serving it. Raw animal food that was initially heated and cooled as described in items A to C, is not safe to eat unless it is cooked to a

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sufficient final temperature prescribed by part 4626.0340, to eliminate any pathogenic microbes that the initial heating of the food did not destroy. By limiting the references to part 4626.0340, items A to C, which intentionally omits item D, the departments are making it clear that operators must not serve *undercooked* noncontinuously cooked raw animal food, regardless of customer request. This is necessary to avoid the public health risk inherent to raw animal foods that have already been undercooked and cooled.

The departments added item E to address the public health risks from food that has been heated twice, which, despite erroneous belief to the contrary, carries the same risks as other TCS foods. In item E, we have provided instructions stating that reheated food must be either: properly cooled again after final heating if it was not served, hot held, or kept under a time-as-a-public-health-control plan for a limited amount of time before discarding—all according to the standards referred to in item E.

Item F requires that LRFEs have and follow written procedures for their methods for noncontinuous cooking of raw animal foods. Because these methods increase public health risks over those of traditional cooking methods, countering these additional risks is necessary. Subitems (1) through (5) are the standards that ensure that operators operate safely. These subitems require that operators:

- receive regulatory approval before using noncontinuous cooking methods;
- maintain records for regulators to review; and
- plan how to monitor this cooking process, keep the food separate from other foods to prevent cross-contamination, and mark the partially heated food clearly to show that it still needs to be fully cooked.

The departments need to meet the increased public health risks by requiring that operators seek and receive approval in advance, so that only competent operators do this type of cooking. Fulfilling these requirements accomplish this goal.

This new part, which addresses methods that the existing Code currently does not permit, is necessary because it safeguards the public before licensees and operators start using it. It is also reasonable because new requirements allow LRFE's the flexibility to offer their customers food cooked this way, while still controlling public health risks. Complying with the existing Code may compromise the quality of raw animal foods prepared in large quantities by caterers and

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banquet venues by requiring it be fully cooked, cooled, and fully reheated—an unappealing prospect. Allowing for noncontinuous cooking means that operators may maintain better food quality (moisture, taste, appearance, etc.) while not risking customer health. This new part is thus both necessary and reasonable.

4626.0350 PARASITE DESTRUCTION. 3-402.11

We reworded item A for clarity. The departments added the word “minimum” to item A, subitem (1) to clear up a misunderstanding that LRFEs could store the fish referred to for no longer than 168 hours. LRFEs are permitted to store the fish for longer periods of time.

In item B, the departments listed the types of food that do not need to be handled according to item A’s requirements. This structure makes it easier to read. In addition, we added new foods that recent food science has found not to need the handling that item A requires.

The departments added new item C because of the increase in aquaculture-raised fish and other seafood means we need additional requirements for reducing parasites. The new standards for fish-freezing temperatures and times are critical for properly destroying the parasite eggs found in the flesh of some fish. Furthermore, we need to specify the type of feed and raising standards for fresh fish to ensure that aquaculture-raised fish products that are consumed raw are not exposed to parasites during development. These specific standards allow food establishments to sell or serve these types of products to consumers without freezing them in advance.

These revisions, which provide clear and understandable instructions for how to freeze fish intended for raw consumption, are reasonable because they require simple practices that destroy dangerous parasites. The revisions also clearly identify the fish products that do not need freezing to destroy pathogens. They state the standards fresh fish must be raised under to ensure they are parasite-free and can be served raw or undercooked. Furthermore, these revisions bring this Code up to date by recognizing businesses’ interest in expanding their food-offering options by rewriting the public health protections to accommodate serving consumer’s raw or undercooked foods. We have included adequate control of parasites in fish products by incorporating the practices that have been considered the industry norm over the past several years.

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4626.0355 PARASITE DESTRUCTION; RECORDS. 3-402.12

LFREs currently must keep records confirming that they have met specific minimum freezing times and temperatures, or that certain fish were raised according to this Code. LRFEs must keep the records on-site for 90 days.

The departments added item C to also require that records be maintained to verify that the critical limits required for parasite control in raw fish products are being met. Records provide a check for both the operator and the regulator for determining that monitoring and corrective actions have taken place. Item C specifies the records that must be maintained from the supplier or aquaculturist to document safety of aquacultured fish.

The changes add requirements specific for fish that have not been frozen but raised in a parasite-free environment. These records must be accompanied by a letter from the supplier or aquaculturists verifying that both the food fed to the fish and environment the fish was raised in meet these standards. This records requirement is necessary so that operators and inspectors can verify that each particular food product's source and quality are safe and unadulterated. As stated above, this is essential for controlling potential consumer exposure to parasites because operators are not required to freeze these fish products as outlined in part 4626.0350.

These are practices recognized as industry norms over the past several years. This new requirement is reasonable because it provides a science-based measurement to ensure public health protection while allowing LRFE operators increased business model flexibility.

4626.0357 FOODS PREPARED FOR IMMEDIATE SERVICE. 3-403.10

The departments added this part for food that is already cooked and refrigerated. LRFEs prepare such food to serve on an individual-order basis. Under these circumstances, the food may be served at any temperature. Foods reheated for immediate service do not require the same level of heat for microorganism destruction as foods that will be hot held. There is not enough time for hazards from pathogenic bacteria or viruses to develop. Therefore, departments revised this part to clarify that reheating for immediate service is a food quality issue, rather than a control for food safety.

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This standard is consistent with the industry norm for the past several years. This new requirement is reasonable because it provides a science-based rationale to ensure public health protection, while also allowing LRFE operators increased business and menu flexibility.

4626.0360 REHEATING FOR HOT HOLDING. 3-403.11

When LRFEs reheat foods that will be held hot, there are certain temperature and time parameters, as well as procedures that they must follow.

The departments revised item C to use plain language. The departments reduced the minimum reheating temperature from 140 degrees F to 135 degrees F for ready-to-eat Time/Temperature Control for Safety Foods (TCS) that comes from a commercially processed package. Because the minimum hot holding temperature of 135 degrees F required in part 4626.0395 provides adequate public health protection, there is no need to require a higher reheating temperature for commercially processed foods.

We re-worded item D for clarity. We specified that LRFEs must reheat food described in subitems (A) to (C) quickly so that it reaches the required temperatures in less than two hours from a starting point of 41 degrees F. This is a food-safety issue. Reheating food too slowly so that it hovers from a temperature above 41 degrees F for more than two hours before reaching the necessary temperature could promote pathogen growth, which may increase the risk of the foodborne illness from pathogens.

Changes to item E are necessary to be consistent with revisions to part 4626.0340.

Because the changes to this part are consistent with reasonable changes to parts 4626.0340 and 4626.0395, it is reasonable to incorporate those changes in requirements into this part. It is also reasonable to specify when reheating begins for the purposes of instruction and understanding by inspectors and food handlers.

4626.0365 3-403.12 REHEATING FOR IMMEDIATE SERVICE.

This part has been repealed and language has been moved to part 4626.0357.

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4626.0367 TREATING JUICE. 3-404.11

LRFEs that package juice must process the juice using proper methods to kill potential pathogens or specifically label the products otherwise.

The departments added this new part to address an FDA regulation that the existing version of the Code does not cover. Requirements for pasteurizing juice are necessary to prevent foodborne illness and deaths from juice containing pathogenic bacteria. In the alternative, clear labeling that indicates the risks from unpasteurized juices is essential for consumers to make informed decisions on whether to purchase and consume such juice products.

This part adds flexibility to this Code by giving operators two options. LRFEs may either process juice to ensure a sufficient pathogen reduction in item A, or label packaged juice with the required warning statement provided in item B, subitem (2). These revisions are necessary for safety because both options are in demand commercially.

This Code defines “juice” in part 4626.0020, subpart 44a, which includes pureed fruits and vegetables, foods that are commonly prepared for serving highly susceptible populations. This revision prohibits LRFEs that serve a highly susceptible population from serving prepackaged juice that bears the warning label. Instead, they are permitted to serve only pasteurized juice. This requirement is necessary to protect the population at greatest risk of illness from consuming unpasteurized juice products, while still reasonably providing operators an option for serving juice to consumers.

Further, Minnesota regulators are already enforcing FDA CFR 21 Part 120, as required by the FDA and state. Including it here is self-explanatory.

4626.0368 JUICE; TREATED. 3-202.110

A LRFE must obtain the prepackaged juice that it serves from a processor who complies with applicable federal regulations.

We added this new language to address an FDA regulation that the current version of this Code does not cover. Requirements for pasteurization of juice under a Hazard Analysis Control Plan (HACCP) plan are necessary to help prevent foodborne illness and deaths from juice containing pathogenic bacteria.

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Minnesota regulators are already enforcing FDA CFR 21 Part 120, as required by the FDA and state. Including it here is self-explanatory.

4626.0370 FROZEN FOOD. 3-501.11

The departments changed “shall” to “must.”

4626.0375 SLACKING TCS FOOD. 3-501.12

The departments moved the word “mechanical” for clarity.

4626.0380 THAWING. 3-501.13

The departments brought the requirements about thawing TCS food up-to-date in several ways. First, we added the word “mechanical” to item A for clarity because LRFE operators commonly misinterpret refrigeration to mean non-mechanical forms of refrigeration, such as using ice baths or even putting food outdoors in the winter in Minnesota. Part 4626.0395 requires that operators use mechanical refrigeration for cold holding of time-temperature control for safety foods to control pathogen growth.

Second, we restated a provision previously contained as (b) under subitem (3) under item B as a new subitem (4). Because subitem (4) is specific to raw animal food products, which have different thawing requirements than the ready-to-eat food requirements described in subitem (3), separating this provision from subitem (3) makes sense.

We revised item D for clarity. We removed the word “approved” to prevent LRFE operators and inspectors from interpreting it to mean that they must seek prior approval before using the procedures, which the departments never intended.

We added the new item E for thawing fish in reduced-oxygen packaging (vacuum packaging). The departments need to control how these frozen fish are thawed because vacuum packaged fish pose a risk to public health from containing *Clostridium botulinum*. The pathogenic bacteria are controlled when the product is in a frozen state, but are not adequately controlled when the product moves from the frozen to refrigerated state. The vacuum packaging’s low oxygen environment is what allows *Clostridium botulinum* to survive and proliferate. Simply opening

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the package and allowing oxygen to enter inactivates the pathogen and thus ends the threat of potential catastrophe from fatal or life-long injury to consumers.

These changes by the department are necessary to close gaps in the existing thawing requirements. The changes improve public health protection by addressing the accompanying threats from improperly thawed foods, especially by controlling *Clostridium botulinum* in reduced oxygen packaged fish. The changes are reasonable because they do not significantly change the thawing practices that LRFEs already use.

4626.0385 COOLING REQUIREMENTS. 3-501.14

The departments updated this part with the new required cooling temperatures and times based on current science. We have changed the hot holding temperature to 135 degrees F as required in part 4626.0395, item A.

These new standards are also incorporated elsewhere, where applicable, in various parts throughout the Code. Item A of this part requires food be cooled from 135 degrees F to 41 degrees F in six hours, with cooling from 135 degrees F to 70 degrees F in two hours. The six-hour cooling parameter, with an initial 2-hour rapid cool, is needed and reasonable because it allows for greater flexibility in meeting the Code while sufficiently controlling bacterial growth rates.

The initial two-hour cooling period is the critical element for protecting food safety according to the most current scientific evidence and remains unchanged. What the proposed Code language changes is the focus by recognizing a six-hour total cooling process, which encourages operators to focus on the entire process. This change increases the likelihood that operators will complete the initial two-hour process more quickly than happens when operators cool food in two separate phases, which the existing Code emphasizes. The changes are reasonable because this shifted emphasis does not increase operators' burden for complying with cooling process requirements while continuing the same or increased level of public health protection.

4626.0390 COOLING METHODS. 3-501.15

The departments changed “shall” to “must.”

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4626.0395 TCS FOOD; HOT AND COLD HOLDING. 3-501.16

The departments revised item A to reduce the required hot holding temperature from 140 degrees F to 135 degrees F, a practice in line with the FDA hot holding temperature requirement. This will allow operators to hold foods at a lower temperature and still safely serve them, a benefit especially to operators that have food on buffets or are serving a group at a catering event. Multiple advisory groups have recommended that 135 degrees F is sufficient to limit pathogen growth and is an effective measure for preventing foodborne illness. Reducing the temperature here is reasonable because it addresses operators' frequent concern about food quality degraded by dehydration. Operators often attribute this reason for not complying with the existing hot holding temperature. The proposed temperature change adequately controls potential pathogen growth while promoting greater compliance among the industry.

In adding item B, the departments specifically require eggs that have not been treated to destroy *Salmonellae* be kept at 45 degrees F or less under mechanical refrigeration. The FDA reviewed research that shows proper temperature control will reduce the risk of *Salmonella* Enteritidis. The USDA has an upper temperature limit of 45 degrees F when transporting shell eggs. If shell eggs are not kept in continuous refrigeration, by the time the eggs are cooked, *Salmonella* Enteritidis will have had an opportunity to grow.

By making 45 degrees F the upper temperature limit for shell eggs in this Code, it will be easier for operators to maintain the necessary temperature of shell eggs from delivery to preparation. This temperature requirement will also allow operators more flexibility. For example, in a restaurant busy preparing breakfasts it can be hard to keep shell eggs below 41 degrees F due to heat from the cooking equipment. Now operators can use the eggs as long as they stay at 45 degrees F or below. This revision is reasonable because the temperature requirement of 45 degrees F for eggs provides public health protection and offers flexibility to the industry, as well as vendors who offer eggs for sale at events such as farmers' markets.

The departments added item C to accommodate liquid foods if operators keep them in specially designed equipment that maintains an aseptic food condition. For example, a milk or juice dispenser commonly found in hotels serving a continental breakfast. The equipment must both maintain a temperature that is either below 41 degrees F or above 135 degrees F and meet the requirements in part 4626.0575. This is reasonable because it permits operators to dispense food

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without temperature control using specialized dispensing methods while protecting food safety due to the aseptic environment inside the dispensing equipment.

The departments relocated requirements for using dry ice or cold packs instead of a mechanical refrigerator from the existing Code to here in item D. Temporary and portable food establishments, when holding food for four hours or less, are permitted to use dry ice or cold packs as long as operators keep the food at the proper food temperatures. Item D does not change current law. (US Public Health Service Food Code Annexes 2013, College Park Maryland, US FDA 2013, pages 445-450)

4626.0400 DATE MARKING; READY-TO-EAT TCS FOOD. 3-501.17

The departments rewrote the requirements for putting dates or “date marking,” on ready-to-eat TCS food. There are two types of TCS foods in most establishments. There are foods the establishment makes from scratch. An example is a potato salad made on site. Establishments also buy some TCS foods. An example is a ham that is sliced for service. Both types of TCS foods need to be date marked to ensure safety to the public. This practice allows the manager to actively control the TCS food.

Seven days are the maximum amount of time the TCS foods food can be used to limit the growth of *Listeria monocytogenes*. The revisions in items A through E spell out the specific food categories to make it clear that both types of food must be date marked. There are TCS foods from processing plants that do not need to be date marked when opened. The list of what TCS foods from processing plants that do not need date making is clear and easy for operators to review.

The revision makes explicit requirements for foods prepared from a combination of ready-to-eat ingredients. When an establishment is preparing a TCS product such as potato salad, it is combining multiple TCS ingredients into one dish. It is imperative the ingredients are all within the 7-day requirements. The oldest ingredient will limit how long a shelf life the product can have. For example, if the hard-boiled eggs going into the potato salad are 3 days old then the salad will only have a 4-day shelf life. That is because 3 days of the 7 total days have already been used. These revisions are reasonable because the explicit, detailed requirements are much easier to understand and read than the existing Code. This regulation strengthens public health

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control while providing industry more precise direction about the length of time they may keep products.

Item F clarifies that LRFE's do not need to date mark shellstock. Although *Listeria monocytogenes* has been isolated from shellstock, there have been no reported Listeriosis cases linked to consuming this product at retail. Shellstock naturally inhibit *Listeria monocytogenes* from growing to harmful levels because of competitive microflora present in and on the shellstock. Therefore, making shellstock exempt from date marking is reasonable and necessary.

The departments also added item G, subitems (1) through (5) to identify specific foods that are exempt from date-marking requirements because they meet established standards. Evidence shows that these foods prevent, inhibit, or limit the growth of *Listeria monocytogenes* when manufactured according to the standards in Code of Federal Regulations, title 21. Examples are deli salads prepared and packaged in a food processing plant, hard and semi-soft cheeses, cultured dairy products, and preserved fish products. In addition, the departments included shelf-stable products identified in subitems (6) and (7) as also exempt.

These revisions are necessary because the departments have a duty to clearly distinguish what they need to regulate to protect public safety. Clarifying which types of foods are exempt is reasonable because it makes it easier for LRFE operators and regulatory authorities to comply with the law.

4626.0405 READY-TO-EAT, TCS FOOD; DISPOSITION. 3-501.18

Minor changes improve clarity and consistency by restructuring the sentences within this part. Items and subitems have been renumbered for better organization and references have been updated as needed. Item A, subitems (1) and (2) include requirements that are moved from part 4626.0400.

Item B includes a new requirement for discarding ready-to-eat TCS food dispensed through a vending machine that exceeds the requirements of part 4626.0400. To ensure public health protection for consumers, this requirement needs to be expanded to include foods that may support the growth of *Listeria monocytogenes* that are sold through vending machines.

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These additions are reasonable because they limit the time that TCS foods can be held at refrigeration temperatures in vending machines to what is consistent with science-based criteria and similar to requirements already in place at other types of LRFEs.

4626.0408 TIME AS PUBLIC HEALTH CONTROL. 3-501.19

Laboratory studies show that Time as Public Health Control (TPHC) can be used to adequately limit pathogens growth or toxin formation in time/temperature control for safety (TCS) food and prevent foodborne illness. TPHC refers to using time only (4 or 6 hours) instead of time and temperature control to prevent the growth of pathogens or toxin formation.

The departments added item A because there are times when adequate refrigeration or heating is not available for TCS foods that LRFEs are displaying or holding for sale or service. Different types of foods and the thickness of the food can mean the food changes temperature at different rates. For example, a broth-based soup will cool faster than a thick soup.

Item A, subitem (1) was added because operators need an option and requirements for how to hold foods when they are not able to mechanically keep the food hot or cold. Food will warm or cool as it equilibrates to the surrounding air temperature if it is held without temperature control. An example would be a catering event being held at a different location than a LRFE.

The departments added item A, subitem (2), requiring written procedures on how the TCS foods will be handled when only time is used as a public health control. The written procedures must be prepared in advance so they are clear and readily available when needed. This is not an area of food handling where relying on memory is a good idea. Requiring the LRFEs make the procedures available to the regulatory authority upon request is needed to ensure they are actually in the LRFE and are correct.

By allowing operators the option of holding foods outside of the temperature parameters, the departments are providing a reasonable amount of flexibility to operators. The requirements detailed for the operators to follow ensure that the food is not going to be abused and harm the public.

Item B requires a 4-hour time limit on TCS if time only rather than in conjunction with temperature control is taking place. The USDA Pathogen Modeling Program (USDA-PMP) has

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conducted controlled studies that show the growth of pathogens and toxin producing organisms is minimal with the 4-hour time constraint. The 4-hour time limit is a conservative choice that allows for a margin of safety if the environment temperature is higher than 75 degrees F. This could happen in a situation where TCS foods are being served outside in the summer. The 4-hour time limit will minimize the risk of illness to the public as long as the following parameters are followed. It is reasonable to expect operators to follow item B, subitems (1) – (4) in order to have the flexibility to serve foods outside of normal operations.

In item B, subitem (1) the food must be either below 41degrees F or above 135 degrees F when it is removed from temperature control. This will ensure the food is not producing pathogens before being removed from temperature control. If the food is not at the proper temperatures initially, there is a greater chance of risk to the public. Cold holding of foods below 41degrees F and hot holding of foods above 135degrees F are well established principles. The operators must know these requirements, which are necessary and reasonable to make sure food reaches the proper temperature initially.

Item B, subitem (2) requires food to be marked or otherwise identified to indicate the time it is removed from temperature control. This is needed so it is easy to see how long the food has been out of refrigeration. If food is left out too long, it can lead to foodborne illness among the public. Operators can accomplish this by either marking the pans or maintaining a log. The method of indication is left up to the operators. The operators are responsible for properly marking and clearly identifying when the food needs to be discarded.

Item B, subitem (3) requires that the food must be cooked and served within the 4-hour time limit. The foods can reach any temperature when held at ambient temperatures as long as they are discarded or consumed within the 4 hours. This will ensure pathogen growth is minimized and ensure public safety. See item B for additional information on control of pathogen growth.

Item B, subitem (4) was added because if TCS foods are not marked with a time they are removed from temperature control, they must be discarded. If foods exceed the 4-hour limit marked, they too must be discarded. If food is not marked, there is no way to know how long the food has been out of temperature control and the TCS food could have been out of temperature control for longer than 4 hours and therefore a danger to the public. The operators must control the food. Likewise, if the time marked for the TCS food is longer than 4 hours, then there is a risk of pathogen growth. Discarding the foods either that are not marked or exceed the 4-hour

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time limit will ensure the food being served to the public is safe for consumption. It is reasonable and necessary to require operators to discard food that is no longer safe to eat.

The departments added item C for food that time is the only control because data produced during the USDA-PMP program shows that food can be safely held for up to 6 hours outside of temperature control if the food does not exceed 70 degrees F. This allows operators the flexibility to serve food that is outside of the existing Code's requirements. It is imperative to require that operators comply with the departments requirements to hold food outside of temperature control for 6 hours.

Item C, subitem (1) was added to set both initial and final temperatures for this 6-hour period to ensure that the food is safe for public consumption. The initial temperature of 41 degrees F or less when removed from temperature control is appropriate because it is well established that keeping foods below 41 degrees F reduces pathogen growth. The food must not exceed 70 degrees F during the maximum of 6 hours it is out of temperature control to ensure pathogen growth is not sufficient enough to cause illness. Thus, this temperature range will ensure the safety of the food before having it outside of temperature control during a 6-hour time limit.

The departments added item C, subitem (2), requiring operators monitor the food so the warmest part does not exceed the maximum temperature. Because pathogen growth in foods kept at 70 degrees F or below for a limited amount of time is negligible, the food is safe for the public to consume. The food, however, must be monitored at its warmest portion to ensure its temperature does not exceed 70 degrees F during the 6- hour period. The operator would meet this requirement by taking an internal temperature, using an appropriate thermometer to measure it. Requiring operators to use a thermometer make sure the food is kept at proper temperatures is a simple measure, both necessary and reasonable.

Item C, subitems (3) and (4) were added because TCS must be marked or identified to show when the food is removed from cold holding. The TCS must be marked to show when the 6-hour time limit is reached. Both of these will indicate clearly, when the food was placed outside of temperature control and when the food must be discarded. This will ensure the operators know the exact time parameter and do not serve foods that are not safe.

The departments added item C, subitem (4), unit (a) because food must be discarded if the temperature exceeds 70 degrees F. The USDA-PMP study determined that food is no longer safe

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for consumption due to pathogen growth at this limit. The operator must monitor the food temperatures and discard food that is outside the allowable temperature limits.

Item C, subitem (4), unit (b) was added because TCS can be held for 6 hours if the temperature does not exceed 70 degrees F. During the 6-hour time limit, the food can be cooked and served. TCS foods that are ready to eat can be served at any temperature if it is within the maximum 6-hour time limit and stays below 70 degrees F. This will allow operators to cook and serve foods that are being held outside of refrigeration as long as the time and temperature parameters are being met. This will give operators more flexibility with their cooking methods. An example is a busy restaurant that may keep a TCS food next to the grill in continuous use, making it impossible to keep the item refrigerated. As long as the food is marked with the time it is removed from refrigeration and a discard time, the rules will not require the food to be refrigerated or kept hot. The operator will be responsible for monitoring the food temperature and discarding it if it exceeds 70 degrees F. Giving the operators the needed flexibility is reasonable as long as control measures are in place.

Item C, subitem (5) was added as the final step required in disposing of TCS foods that do not meet the regulations. Food not marked with a time they are removed from temperature control must be discarded. Foods that are marked with a time that exceed the 6-hour limit must also be discarded. The operators must control the food. Discarding the foods either that are not marked or exceed the 6-hour time limit will ensure the food being served to the public is safe to eat.

The departments added item D as special consideration for LRFEs that serve highly susceptible populations. Such LRFEs may not use time as a temperature control for raw eggs. Raw shell eggs can be contaminated with *Salmonella* Enteritidis. To protect against the increased risk of illness and possible serious consequences, including death for certain people from temperature-abused raw shell eggs, the departments are not permitting operators to serve them to highly susceptible populations. This prohibition minimizes the risk of illness or death. It is thus necessary and reasonable to not allow temperature abused raw shell eggs to be served to highly susceptible populations.

4626.0410 TIME AS PUBLIC HEALTH CONTROL. 3-501.19

As required by the Revisor, the departments repealed and replaced this part with the requirements in part 4626.0408 to reflect both the departments' significant changes to make this

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Code clearer and eliminate potential confusion. In addition, the Rule Advisory Committee reached a consensus to support this change. These changes are therefore necessary and reasonable.

4626.0415 SPECIALIZED PROCESSING VARIANCE REQUIREMENTS.

3-502.11

The departments added requirements to allow LRFEs to prepare food using methods that the existing Code does not otherwise allow. Increasingly, new types of foods are available to meet public demand due to cultural and dietary differences. Specific food processes, however, have historically resulted in more foodborne illnesses than standard processes. To balance this demand with health risks, the departments are allowing LRFEs the flexibility to prepare foods using alternative methods by acquiring specific, formal variances to ensure that LRFEs operate under strict operational procedures. Allowing LRFEs to obtain variances will allow for needed additional diversity in the food service business, while at the same time ensuring the LRFEs meet public safety.

Item A was added because smoking foods to preserve them rather than to enhance flavor can result in pathogen growth. A variance is needed to allow the operator to preserve the food outside Code restriction. The department's review of the variance ensures the LRFE is following the necessary steps to limit pathogen growth. LRFEs are responsible for following the steps required in the variance when smoking foods.

The departments added item B, curing foods, because adding salt and nitrites will inhibit the growth of *Clostridium botulinum*, but must be done by following specialized processes to prevent contamination. A variance will allow them to cure foods following the strict operational procedures. This will produce a cured product that is safe for public consumption.

The departments added item C because food additives, substances that become a component of the food, alter the food's characteristics that shift the food's classification into a different category. Some types of foods require such food additives. Done improperly, these techniques lead to risk. The departments address two such changes in the subitems below.

Item C, subitem (1) addresses additives used to preserve foods. An example is making pickles. Making pickles safely requires food establishment to follow all steps properly and that the food

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is preserved and is safe to eat. An approved variance allows the operator to preserve foods using additives.

Item C, subitem (2) addresses using additives to make TCS foods no longer TCS. For example, a LRFE could use additives to make meat into beef jerky, a product that limits pathogen growth. A variance allows the LRFE to use the method, provided it handles the food correctly.

For these reasons, the departments require a variance when LRFEs apply additives to foods to ensure the resulting food is safe to eat. It is reasonable for the departments to allow operators to expand their capabilities, but necessary to require they obtain a variance when using additives.

The departments added item D because packaging food using reduced oxygen packaging (ROP) is becoming popular in many LRFEs, but risks public health when not done safely. Certain ROP items must have a HACCP plan as defined in proposed part 4626.0420. All other products that are being packaged using ROP must operate under a variance, using techniques that ensure the pathogens are limited. For example, packaging soup in a reduced-oxygen packaging material offers the LRFE the flexibility to prepare menu items in bulk and preserve them to serve in the future. A variance in place means that food will be packaged according to guidelines that ensure the product is safe for consumption.

Item E was added to require that LRFEs obtain a variance to use a display tank for keeping molluscan shellfish alive. At present, there is a large public demand for such shellfish. Due to possible foodborne illnesses that can result from molluscan shellfish, however, it is imperative that the shellfish come from a safe source and the LRFE properly monitors the tank. A carefully crafted variance will allow the LRFE to use the tank but specify the necessary controls that an establishment must follow. Thus, a variance will limit the possibility of a foodborne illness outbreak from the food being consumed from these tanks. It is reasonable and necessary to allow operators to use the tanks under the restrictions that a variance requires to use molluscan shellfish life-support systems.

Item F adds “custom processing animals for personal use” as another special process that requires a variance. This provision allows custom processors to process animals that will not be sold to the general public. An example is a farmer butchering a calf solely for personal food. A variance for this practice adds flexibility. It permits the LRFE to offer its services because risk to the public is reduced by the product being sold to one person. This single sale eliminates the regulatory problem of a recall and trace back of product due to a foodborne illness when the product is sold to only one person.

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Item G was added because sprouts are a TCS food that have been linked to multiple foodborne illness outbreaks. For setting variance terms, the departments rely on the Sprout Safety Alliance (SSA), a public-private alliance for sprout guidance. The SSA is developing educational programs to promote best sprout-safety practices for producers and related stakeholders. SSA is also contributing to the final rule on produce-safety standards, which the FDA Food Safety Modernization Act (FSMA) requires. LRFEs that wish to serve sprouted greens can do so safely by following these standards. A variance will require operators to grow the sprouts safely for human consumption, therefore protecting public health.

Item H was added to cover any other food preparation methods that do not comply with this Code. To use such a method, the operator must acquire a variance. Specifying the specific terms of the variance supplies the oversight mechanism for the departments to oversee operators, making sure they prepare foods in a safe manner when guidelines are not readily available. Operators might wish to adopt new processes that emerge before this Code can be revised again. Including this requirement ensures that regulations are flexible for both operators and regulatory authorities to accommodate consumer demand and protect public health.

4626.0420 REDUCED OXYGEN PACKAGING WITHOUT A VARIANCE; CRITERIA. 3-502.12

This section outlines how operators can use reduced oxygen packaging of time/temperature control for safety (TCS) food safely without a variance.

The departments' changes improve clarity and consistency by using a defined term and restructuring the title and sentences within this part. We have restructured this part to create a more logical organization and references have been updated as needed. Foods that are not TCS food do not support the growth of *C. botulinum* and *L. monocytogenes*. Therefore, the reduced-oxygen packaging HACCP requirements of parts 4626.0415 and this part apply only to TCS foods. We have clarified this application limitation throughout this part.

Packaging TCS food is a way that reduces the oxygen in the package, and if not done properly, can result in illness and even death. The departments added the requirements of item A calling for reduced-oxygen packaging (ROP) processing and holding parameters that control *Listeria monocytogenes* and *Clostridium botulinum* growth and toxin formation. These foodborne pathogens are anaerobes or facultative anaerobes that are able to multiply under either aerobic or anaerobic conditions. Therefore, special controls are necessary to control their growth.

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Refrigerated storage temperatures of 41 degrees F may be adequate to prevent growth and toxin production of some pathogenic microorganisms; but non-proteolytic *C. botulinum* and *L. monocytogenes* are able to multiply well below 41 degrees F. For this reason, *C. botulinum* and *L. monocytogenes* are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

The departments added item B because when followed as written, the ROP methods in this section controls the growth and toxin production of *C. botulinum* and *L. monocytogenes* without a variance. Because business models for LRFEs in Minnesota widely vary, this Code needs safe alternative methods for ROP. Using ROP methods in LRFEs extends the shelf life to many foods because it inhibits spoilage organisms that are typically aerobic. ROP may also offer benefits for time and labor savings, portion control, and quality retention. The methods in this section have been proven to be safe, so obtaining a variance is not necessary as long as ROP methods meet these requirements.

Item B, subitems (1) - (6), describes the specific labeling requirements for ROP food. This part requires ROP foods processed without a variance to have a double barrier, including at least one of the characteristics listed in subitem (2) and a time/temperature control. The department's revised subitem (3) (a) to emphasize that ROP food must be kept at 41 degrees F or below.

The existing 14-day shelf-life limitation for ROP food is unnecessarily restrictive. Scientific studies have shown that ROP food processed according to parameters in this part do not support growth or toxin formation of *C. botulinum* or growth of *L. monocytogenes*. Most foodborne pathogens do not compete well with other microorganisms. Therefore, foods that have a high level of spoilage organisms or lactic acid bacteria that grow under ROP conditions can safely be packaged using ROP and held for up to 30 days at 41 degrees F.

The departments list the requirements in Item C for LRFE to properly package and thaw ROP fish. LRFEs are permitted to package only frozen fish using ROP methods. The fish must remain frozen until either used or removed from the packaging for thawing. This procedure is consistent with fish-handling requirements that appear in part 4626.0380, item E. Stating it explicitly is important because ROP fish that is thawing and then stored under refrigeration carries the risk of supporting *C. botulinum* growth or toxin formation.

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Item D specifies the technical requirements for LRFEs that use the cook-chill and sous vide processes. Some foods already have built-in secondary barriers that prevent the growth of *C. botulinum* and *L. monocytogenes*. Examples are: aw, pH, and nitrite-in-cured-meat products, high levels of competing microorganisms, or intrinsic factors in certain cheeses. When LRFEs package these foods using a reduced-oxygen packaging process, time/temperature becomes critical to control *C. botulinum* and *L. monocytogenes* growth. Non-proteolytic *C. botulinum* spores can germinate and produce toxin at temperatures down to 38 degrees F. Therefore, holding ROP foods at 38 degrees F or less is necessary to prevent the formation of *C. botulinum* toxin. *L. monocytogenes* can grow, although very slowly, at temperatures down to 30 degrees F. Both pathogens proliferate more quickly as the storage temperature increases. Item D addresses cook-chill processing, where food is cooked and then sealed in a barrier bag while still hot. Item D also addresses sous vide processing, where food is sealed in a barrier bag and then cooked. Both depend on time/temperature alone to prevent pathogenic growth. Therefore, having LRFEs monitoring critical limits is essential to make sure the temperatures are adequate to inhibit growth and/or toxin production of any surviving pathogens. The specified limits in item D cover those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures. The food-safety hazard posed if these requirements are not met cannot be overstated. These requirements are thus necessary and included in this revision.

Item D, subitem (2), unit (e) provides three separate time/temperature options for holding ROP cook-chill or sous vide food after it has been safely cooled from 135 degrees F to 41 degrees F or below. Option (i) requires further cooling to 34 degrees F within 48 hours, and allows the ROP cook-chill or sous vide product to be held at 34 degrees F up to 30 days. This change provides a safe option for those businesses that choose to invest in the necessary equipment to maintain storage temperatures of 34 degrees F or less. Options (ii) and (iii) specify time/temperature limits, which are consistent with requirements for ready-to-eat foods provided elsewhere in this Code.

Other requirements stated in item D are measures designed to reinforce cooking temperatures and times, prevent cross-contamination, and set safe-cooling and date-marking parameters provided elsewhere in this Code. We need these requirements to ensure LRFE licensees and operators do not adopt ROP cook-chill or sous vide processes without continuing to observe fundamental food safety control measures, which remain vital for public safety.

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Item E spells out the requirements and limitations for ROP of cheese. The departments moved these requirements from part 4626.0415, item B, subitem (2), unit (c), and have been rewritten for clarity and accuracy.

Item F provides a safe alternative for a LRFE that conducts ROP methods without either a HACCP plan or a variance. When LRFEs observe the limitations in item F, no significant additional public health risks exist from LRFEs' holding their TCS foods in the ROP environment for 48 hours or less. These requirements specify the date and production time labeling that ensure food employees can accurately determine when the 48-hour limit is reached. It is also necessary to specify that these restrictions no longer apply if the ROP package is opened. Lifting the restriction at this point is important to prevent unnecessary waste of ROP product prepared without a HACCP plan that is not served within 48 hours. Food removed from the ROP package can then be held an additional five days, in compliance with date marking requirements found in part 4626.0400. This item strikes a reasonable balance between protecting the public and preserving operators' economic concerns where possible.

4626.0425 PACKAGED FOOD; STANDARDS OF IDENTITY. 3-601.11

The departments revised this part to bring outdated references up-to-date.

4626.0430 FOOD HONESTLY PRESENTED. 3-601.12

The departments changed "shall" to "must."

4626.0435 FOOD LABELS. 3-602.11

The department rewrote this part to update the references to cite the most recent federal government labeling requirements and add specific requirements for enforcement purposes.

Item A now contains the references to the most recent federal government labeling requirements, which are mandatory. They remain here, as in the existing Code, for the convenience of the regulated parties.

To supplement these federal regulations, the departments added item B. The departments need these additional requirements for enforcement purposes. The regulatory authorities must investigate foodborne illness outbreaks to stop further disease spread and otherwise protect

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public health. Such investigations require that the regulatory authorities determine the identity of the food, its origin and composition of food.

Therefore, requiring clear labels for packaged food is reasonable. Food labels are a primary means for consumers to make informed decisions when choosing their food. Federal law has long required that packaged food have clear labels.

The departments added item B to set current, more specific standards for packaged-food labels to inform consumers of what they are buying.

In item B, unit (1) we added the requirement that labels must have the common name of the product or a descriptive statement to identify what consumers are buying. This is a basic requirement of labeling packaged foods.

The departments added in item B, unit (2) a requirement that labels must have a list of ingredients in descending order of predominance. This alerts consumers to the ingredients, sub-ingredients, artificial color or flavor, and chemical preservatives present, information that is important for making an informed decision about what they are buying.

The requirement that labels must accurately declare the quantity of contents so the consumers know how much they are purchasing was added as item B, unit (3). It is especially important to know the package contains multiple servings.

In item B, unit (4), we added the requirement that labels must state the manufacturer, packer, or distributor's name and place of business. This information is necessary for tracing back contaminated foods if there is a foodborne illness outbreak related to a particular product. Knowing where the food is coming from is essential for recalling unsafe products.

The requirement that labels must alert consumers to potential allergens found in the product by providing the food source's name on the label was added in Item B, unit (5). This will prevent an inadvertent exposure to allergens that could be harmful or deadly to a consumer.

In item B, unit (6) we added the requirement that labels must contain other nutritional information required by law. The law, however, contains exemptions to this nutritional labeling. The departments included these references to where they can be found in this section to assist operators to comply with these regulations.

We added item B, unit (7) that requires labels to declare when the color additives canthaxanthin and astaxanthin are present in salmonid fish. Producers may have fed aquacultured fish feed that

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contains these color additives. The bulk container of fish or the retail counter must be labeled with this color additive. Labeling the fish with the color additive allows the consumer to make an informed choice about what they are consuming. It is reasonable to provide this information on the label, as additives are an ingredient in the fish.

All requirements listed in the respective units of item B above address important consumer information about the food they eat. The importance and necessity for including this information is self-evident. Consumers need to know what the food contains to make informed choices what to eat and avoid allergens that can induce dangerous reactions. These requirements are thus necessary and reasonable.

The departments added item C to make sure that bulk foods available for consumer self-dispensing have prominent labels to know exactly what they are buying. Bulk self-dispensing is now very common in retail grocery stores. It is reasonable and necessary for consumers to have this information.

Item C, unit (1): LRFEs must display the manufacturer or processor's label that is provided with the food in plain view.

Item C, unit (2): The bulk container must be labeled with a sign or card that gives the food's common name and ingredients in descending order of predominance. These labels will have the ingredient and allergen information that is relevant to consumers.

To set the necessary limits on certain bulk, unpackaged foods that do not require labeling, the departments added item D. For example, bakery products and unpackaged foods that are portioned to consumer specifications do not require individual labeling as long as the conditions of item D are met.

Item D, unit (1): If a health, nutritional content, or other claim is not being made, then a label is not required. In the absence of a nutritional claim, the public does not need the protection of a label to justify what that claim would provide. It is reasonable to not require a label in this instance.

Item D, unit (2): Certain Code sections exempt foods from labeling requirements. The departments specified where this information appears in the law for operators' convenience. We updated the statute reference.

Item D, unit (3): foods made on the premises or at a facility owned by the same person do not require labels. The agency that has jurisdiction over a facility where the food is made regulates

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the facility. An example is a café that sells pie by the slice. Requiring a LRFE to label each slice of pie is unreasonable because staff are available to answer any questions about ingredients or potential allergens. This is a fair exemption to the Code's labeling requirements.

4626.0440 OTHER FORMS OF INFORMATION. 3-602.12

As the departments did in part 4626.0435 above, we likewise simplified this part without changing LRFEs' requirements. Both the FDA and USDA require warning statements that are spread through different United States Code sections. We removed unneeded citations here in favor of the proposed generic rule to ensure that we captured all written consumer warnings. We simplified the prohibition against altering dating information to a simple statement. We moved item C to part 4626.0435.

4626.0442 CONSUMER ADVISORY; DISCLOSURE. 3-603.11

Consumers must be informed of menu items containing raw or partially cooked animal foods. The LRFE must identify those foods and describe public health risks associated with consumption of raw or undercooked animal foods.

The departments are requiring a consumer advisory in item A because LRFEs must inform consumers about the increased risk of eating certain foods. The advisory informs the consumer about the risks associated with eating raw or partially-cooked animal foods. Certain LRFEs serve foods that need this advisory such as raw oysters in the half shell. Undercooked or raw foods may contain biological agents that cause foodborne illness. It is necessary to deliver a message to the consumer in a meaningful manner that is likely to affect behavior. The information in the consumer advisory alerts the consumer to the options available in the LRFE. The advisory must include both a disclosure and a reminder for the consumer. It is reasonable to expect LRFE inform consumers in an effective written manner as to products that may cause illness or death if consumed.

The departments added item B because there are multiple items that must be included on the disclosure. A disclosure reveals what can be viewed as "hidden ingredients" to the consumer. An example is if a particular menu item contains raw egg. An example is of Caesar salad dressings, which can be made with raw egg. This is necessary so all the required information is accessible to the consumer. It is reasonable to expect operators to disclose this information.

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Item B, subitems (1) and (2) requires a clear description of the animal-derived foods has to be included in the disclosure. Identifying the animal-derived food by asterisking them to a footnote statement is also required. Both of these are needed to give a clear description of the product that is being sold raw or undercooked to the consumer. It is reasonable to expect operators to share this information with their consumers. By providing this disclosure there is clear communication about the food being served. It now is the consumers' choice whether they want to eat or drink the product in question.

The departments added item (C) to ensure a reminder is included in the asterisked footnote. A reminder is a notice about the relationship between food safety and cooking products thoroughly. A reminder is needed to inform the public about how properly cooking products is necessary for food safety. It is reasonable to expect an LRFE to provide a reminder that eating undercooked or raw animal-derived products is hazardous.

Item C, subitem (1) requires that the footnote must tell people that written information is available to consumers upon request. This is needed to give the consumers a more detailed description of the hazards of consuming undercooked or raw products. It allows them to review the potential hazards of consuming raw or undercooked product. It is reasonable for an operator to provide this information.

Both requirements within item C, subitems (2) and (3) inform the consumer that a potential foodborne illness is possible by consuming the product asterisked. It is necessary to provide this information to people that may not realize consuming these products is hazardous to their health. This especially holds true for people with certain medical conditions. It is reasonable for operators to inform the consumers of certain products that may cause harm due to a potential foodborne illness.

4626.0445 UNSAFE, ADULTERATED, OR CONTAMINATED FOOD.

3-701.11

Minor changes to sentence structure are needed to improve clarity of requirements and references.

Within item A the departments add the word “unsafe” to provide a more accurate description of foods which could require remediation under this part and to increase consistency with part 4626.0125 which incorporates the word “safe.” For example, food that has been temperature-abused is unsafe, and this Code needs to specify required actions by the LRFE to protect the

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health of the consumer. Also in item A, the phrase “not honestly presented” replaces the term “misbranded.” Examples of food not honestly presented are indicating “walleye” on the menu but serving some other kind of fish instead, or using red lights to make meat look fresher. This change in wording is needed to provide consistency with the description in part 4626.0125 and part 4626.0430 and to discourage food fraud.

In Items C and D, the word “contaminated” replaces “adulterated.” Contamination of food by an ill foodworker, consumers, or other persons is not included in the definition of “adulteration” found in *Minnesota Statutes*, chapter 34A.02. Changes that improve consistency and clarity of this Code are reasonable because they facilitate better communication between and among regulators, operators, and the public.

4626.0447 FOOD SERVED TO A HIGHLY SUSCEPTIBLE POPULATION. 3-801.11

LRFE that serve food to highly susceptible populations must take special food safety precautions to protect their consumers. This part addresses the requirements for serving certain foods to people who are more at risk of getting sick or that may have more serious health problems when they do get sick.

Item A subitems (1) – (3) provide a safeguard against the risk of contracting foodborne illness from juice by requiring that prepackaged juice be obtained either pasteurized or packaged in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of a “juice” means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. Many documented foodborne-illness cases throughout the United States have been associated with consuming various unpasteurized juice products contaminated with microorganisms such as *Cryptosporidium*, Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*.

Items B, E and F are needed because *Salmonella* often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986, investigators traced a large multistate outbreak of *Salmonella* Enteritidis to stuffed pasta made with raw eggs and labeled “fully cooked.” Eggs remain a major source of these infections,

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causing large outbreaks when they are combined and undercooked as in the 1986 outbreak. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Item C, subitems (1) and (2) are needed because consuming raw or partially cooked animal foods significantly increases the risk of foodborne illness and death, especially in those in susceptible populations. Item C, subitem (3) is needed because, since 1995, raw seed sprouts have emerged as a major recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until intervention methods are in place to improve the safety of these products.

Item D specifies that bare-hand contact with ready-to-eat foods is never allowed for a LRFE serving a highly susceptible population. Traditional methods of preventing the spread of foodborne disease include excluding ill food workers and thorough and frequent handwashing. These two methods alone are not adequate to protect highly susceptible populations from extremely contagious pathogens that may cause greater complications during infection such as norovirus. This Code revision is needed to prohibit LRFEs that serve highly susceptible populations from contacting ready-to-eat foods with bare hands under any circumstances.

Adding necessary protections for persons at greater risk of contracting foodborne illness however, while not unnecessarily restricting food service to the general population, for LRFE operators is reasonable. The need to take extra precautions to avoid sickening the most sensitive members of the population is well recognized by industry and the majority of LRFE operators are already taking similar actions to protect the health of the population at greatest risk of contracting foodborne illness.

Item G clarifies when LRFEs are permitted to re-serve food to a highly susceptible population.

Items G and H address two issues concerning persons in isolation: The “isolation or quarantine” terminology in this Code refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers.

To protect others outside the facility from contamination from an isolated patient, item H, subitem (1) applies. LRFEs are not permitted to re-serve any food. This restriction includes

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unopened, original, intact packages in sound condition, of non-temperature controlled for safety food from a person in isolation or quarantine to anyone else (other patients, clients, or consumers). Food packages that come to a contact isolation room must stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, the LRFE must discard them.

To protect a patient in a “protective environment” isolation setting, which protects the patient from contacting pathogens that other persons bring from outside into the patient’s room, packages of food from any patients, clients or other consumers must not be re-served to such protected patients.

Precautions similar to the isolation setting apply to this setting; i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food must be delivered to this patient each time.

To summarize the key difference between the two scenarios:

Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.

Patients in protective environments should not be re-served food packages from other patients because of the potential for disease transmission to the protective environment patient.

Limiting re-serving of foods based on the status of the patients or clients in medical isolation or quarantine, or a protective environment is reasonable because the staff serving them will already be aware of their status. This additional protection is a reasonable addition to other healthcare safeguards already in place for these persons and those in contact with them. Another option to stop the spread of bacteria and viruses from one person to another is to not allow the re-service of food at any time. This would not be reasonable because there are times when some foods can be re-served safely.

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Chapter 4, Equipment, Utensils and Linens

4626.0450 FOOD CONTACT SURFACES; CHARACTERISTICS AND MATERIALS. 4-101.11

The departments modified the title to make it clear that it pertains to materials and characteristics of food-contact surfaces, not characteristics of other things. It does not establish an additional requirement.

4626.0455 CAST IRON; USE LIMITATION. 4-101.12

The departments changed “shall” to “must.”

4626.0460 LEAD USE LIMITATION. 4-101.13

The departments updated this part to prevent health complications caused by lead poisoning. Lead exposure causes harmful physical and mental conditions in infants, children, and adults. Complications from exposure to high levels of lead can include seizures, nervous system and kidney damage, and even death in both children and adults.

In addition, LRFEs must comply with the lead requirements when purchasing dishes and utensils that their food establishments use.

Pewter is a metal-alloy usually consisting of a high percentage of tin with varying amounts of antimony, copper, and lead. A malleable metal, pewter is used for making tableware.

Manufacturers use solder, a fusible metal alloy, often consisting of tin, lead, and copper, to join metallic parts. The same concerns about heavy metals and lead leaching from brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter and solder.

The departments established maximum lead levels for utensils based on how frequently a utensil is used, the type, and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs, and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach.

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Requiring utensils that are lead-free or that do not exceed the maximum lead levels shown in the chart is necessary to protect public health and is reasonable because such utensils are readily available for purchase.

4626.0465 COPPER; USE LIMITATION. 4-101.14

The departments edited this part slightly with no change to rule meaning to make it easier to understand.

4626.0470 GALVANIZED METAL; USE LIMITATION. 4-101.15

Galvanized metals are iron or steel coated with zinc. Zinc may leach from galvanized food-contact surfaces and, in the presence of acidic foods, is converted into zinc salts. The human body readily absorbs zinc salts. Although zinc is a required mineral, ingesting large quantities causes zinc poisoning. Symptoms may include nausea, vomiting, lethargy, and epigastric pain.

The departments revised this part to prohibit LRFEs from using galvanized metals as utensils and food-contact surfaces of equipment to protect their consumers' health. Because utensils and equipment made of non-galvanized metals are readily available, this restriction is reasonable. Further, prohibiting the use of galvanized metals as food-contact surfaces with high-acid foods to limit the risk of a zinc poisoning outbreaks from happening at LRFEs is also necessary and reasonable.

In addition, the departments removed specific examples of foods that galvanized metal should not come in contact and rewrote the part to make this rule more general to avoid ruling out similar foods not specifically mentioned. Thus, this change simplifies this rule and accounts for types of utensils that are not listed in existing language.

4626.0475 SPONGES; USE LIMITATION. 4-101.16

The departments changed "shall" to "must."

4626.0480 4-101.17 PEWTER; USE LIMITATION.

The departments deleted this redundant part because part 4626.0460, which regulates lead use in food contact surfaces, sufficiently encompasses pewter too. This is true because lead toxicity is

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the primary concern regarding pewter and pewter alloys. Therefore repealing this part from this Code is reasonable.

4626.0485 4-101.18 SOLDER AND FLUX; USE LIMITATION.

The departments deleted this part because part 4626.0460, which regulates lead use in food contact surfaces, sufficiently covers solder and flux. Lead toxicity is the primary concern for solder and flux.

4626.0490 WOOD; USE LIMITATION. 4-101.17

The departments reworded this part to improve clarity and make it easier to read.

4626.0493 NONSTICK COATINGS; USE LIMITATIONS. 4-101.18

The departments revised this part to specify that LRFE are permitted to clean this type of equipment only using non-scouring and non-scratching cleaning equipment. This measure is necessary to prevent potential contamination. Repeatedly scouring and scraping nonstick-coated kitchen equipment and utensils can cause the coating to flake off and potentially contaminate food.

4626.0495 NON-FOOD-CONTACT SURFACES; CHARACTERISTICS. 4-101.19

The departments changed “shall” to “must.”

4626.0500 SINGLE-SERVICE AND SINGLE-USE ARTICLES; CHARACTERISTICS. 4-102.11

The departments changed “shall” to “must.”

4626.0505 EQUIPMENT AND UTENSILS. 4-201.11

The departments deleted most of this very outdated part. We retained item A and deleted items B through K in this part. We added part 4626.0506 to the Code to address specific food equipment

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standards. See need and reasonableness analysis below for part 4626.0506, which addresses this modification.

Of these deleted items, one warrants a specific explanation. Deleting item J, which exempts specific operations serving ten or fewer individuals, is necessary because the existing Code provision confused operators and regulators. In addition, it was based on an arbitrary number of persons. These exempted operations frequently experience variation in the number of individuals they served over time, which switches between their status from being exempt and not being exempt from year to year. This result is incongruous because the scientific reasoning for equipment standards does not change based on the number of individuals exposed. In fact, the types of operations currently exempted from equipment standards (daycares, residential care homes, supervised living facilities) often serve highly susceptible populations that most need safe and durable equipment to control pathogens and prevent contamination. LRFE that were subject to this deleted item will be regulated as any other establishment. Any further exemptions for food equipment standards in this Code will be based on an assessment of menu and operational risk, and not on the number of patrons.

4626.0506 EQUIPMENT.

The departments created a new rule version, but not a new requirement, that replaces the items deleted in part 4626.0505. This rewritten part reflects a compromise among MDH, MDA, delegated agencies, organizations representing licensed food establishments, and other food industry professionals. The department convened several stakeholder meetings to develop this proposed revision, which represents the consensus reached to balance the disparate views of the industry, regulatory authorities, and consumers.

Critical public health protection requires that food equipment properly control temperature to: prevent pathogen growth; prevent refuge of pathogens, insects, and rodents; prevent leaching of harmful substances; and enable effective cleaning and disinfection. It must be safe, durable, and easily cleanable. To meet these specific needs, the departments have long required food equipment to be designed, constructed, and certified to meet uniform, accredited standards. Operators and regulatory authorities look to third-party organizations accredited by the American National Standards Institute (ANSI) to certify that equipment meets these uniform standards. For

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brevity in the rest of this SONAR, the departments will refer to such ANSI-accredited third-party standard development organizations as “SDOs” or “ANSI-accredited independent entities.”

The rewritten part is reasonable because it merely carries forward long-standing methods of assuring food-equipment safety standards. These standards, which the departments specifically apply to food equipment used for food preparation, storage, and cleaning and disinfection, the very processes that present the highest risk to public health. The part neither establishes new requirements nor creates an additional cost for the industry or regulatory authorities.

The rewritten part is reasonable because it merely carries forward long-standing methods of assuring food-equipment safety standards.

On the other hand, the proposal departs from existing standards and provides flexibility for regulated parties by reducing the types of equipment that must meet SDO design and construction standards. In addition, the new part removes the requirement that certain other types of equipment (i.e., water heaters, refuse and garbage compactors, and smaller, more commonly replaced pieces such as toasters and microwave ovens) meet the stringent uniform design and construction standards. The stakeholders have determined that food establishments can operate under these lessened restrictions without compromising public safety.

Similarly, the revision authorizes any ANSI-accredited SDO for food service equipment to certify food equipment, in addition to the National Sanitation Foundation International (NSF), which currently is the exclusive body for such certification. This change opens a greater range of compliant-equipment options to operators. In addition, this revision recognizes that other independent accredited third-party entities that classify equipment to ANSI-accredited food equipment standards (i.e., Underwriter Laboratories (UL), Edison Testing Laboratories (ETL), NSF, Canadian Standards Association (CSA), etc.) provide acceptable assurances for food equipment safety.

Relaxing the existing code requirements where public safety does not require such stringency is reasonable. Likewise, retaining more stringent requirements for food equipment used for purposes that pose the highest risk to food safety is also reasonable.

To make these changes, the departments have grouped the equipment by their respective types to reflect the standards that food establishments must meet. The departments listed the types of

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food equipment that must meet ANSI-accredited standards individually because of the essential role they play in protecting public health during food handling processes.

Industry and regulatory professionals agree that equipment covered by the less restricted standard present a very low risk to public health. They agree too that the increased equipment costs due to certifying these lower risk items can make compliance unaffordable for some operators. Operators often cited certified equipment's higher cost as the reason those items are not replaced. The revised part will reduce the number of operators requesting variances and allow operators to focus their limited funds on purchasing equipment that have the greatest impact on protecting public health.

The departments added item B to clarify and emphasize to operators that existing and proposed rules apply to exhaust hoods. It does not impose additional requirements. Exhaust hoods maintain air quality in a food service operation by removing excess condensation, smoke, and grease-laden vapors, depending on the type of hood. In addition, some hoods provide a new supply of fresh air, otherwise known as make-up air, to replace the air it has removed. The need for this is self-evident.

Item C addresses vending machines. MDA's standard practice is to recognize vending equipment that the National Automated Merchandising Association (NAMA) approves. Item C retains the requirements of part 4626.0505, item B, but was modified to include NAMA and any standards development organization accredited by ANSI for food equipment, not just NSF. Maintaining this practice is reasonable because it retains department oversight without adding regulatory burdens.

Item D is identical to part 4626.0505, item D. It does not impose additional requirements.

The departments added item E to cover those new and unique types of equipment that manufacturers often introduce into the food service industry without having been evaluated by a ANSI-accredited standards developer. Therefore, these minimum standards apply to such pieces of equipment to make sure they support safe food handling practices. Custom-fabricated equipment serves the same purpose as prefabricated equipment and presents the same public health risks, therefore custom-fabricated equipment should meet the same ANSI-accredited food equipment standards. Requiring custom-fabricated equipment to meet ANSI-accredited food equipment standards is necessary and reasonable to protect food safety.

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Items F and G were added to exempt care centers and boarding establishments from having to have ANSI- accredited food equipment because these kitchens do not conduct high-risk food-handling activities. Therefore, the risk of foodborne illness outbreaks caused by using equipment not meeting those standards is low. Most neighborhood kitchens are typically used for low-risk activities for the residents to participate in (e.g., popping popcorn, baking cookies, etc.) and for service of meals prepared in the facilities primary kitchen. Lowering requirements when the risk to public health is low is reasonable and provides the least restrictive requirement for regulated parties.

In addition, the departments added items H and I to exempt other operations that are not high-risk, which also carry correspondingly low risk of foodborne illness outbreaks from equipment not meeting ANSI-accredited food equipment standards. Furthermore, item I is consistent with the current provisions specific to retail food vehicles, portable structures or carts in part 4626.1870, item A. Excluding special event food stands from the provisions in item A follows the current standard allowing non-certified equipment use due to the limited operations of a special event food stand.

4626.0510 FOOD TEMPERATURE MEASURING DEVICES. 4-201.12

The departments restructured this part to make it easier to read and provide an example of a food temperature-measuring device.

4626.0515 MULTIUSE FOOD-CONTACT SURFACES; CHARACTERISTICS. 4-201.11

The departments revised this part for clarity.

Item B refers to enclosed food contact surfaces. Because of their purpose and nature, these surfaces are not exposed to the same hazards that other food contact surfaces in a LRFE are. Since these items have different cleaning requirements and frequencies, they need not have the same composition or characteristics.

4626.0520 CIP EQUIPMENT. 4-202.12

The departments changed “shall” to “must.”

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4626.0525 "V" THREADS; USE LIMITATION. 4-202.13

The departments rearranged this part for clarity. The requirements do not change.

4626.0530 HOT OIL FILTERING EQUIPMENT. 4-202.14

The departments made a minor grammatical change. The requirement does not change.

4626.0535 CAN OPENERS. 4-202.15

The departments made a minor grammatical change. The requirement does not change.

4626.0540 NON-FOOD-CONTACT SURFACES. 4-202.16

The departments changed “shall” to “must.”

4626.0545 KICK PLATES, REMOVABLE; ENCLOSED HOLLOW BASES. 4-202.17

The departments made a citation change to include the correct reference number.

4626.0550 VENTILATION HOOD SYSTEMS; FILTERS. 4-202.18

The departments changed “shall” to “must.”

4626.0555 TEMPERATURE MEASURING DEVICES; FOOD. 4-203.11

The departments revised this part to deal with the inherent limitations of thermometers, which have a limited range for accurate calibration. This means they vary in accuracy depending on the environmental conditions and temperatures where the LRFEs use them. The departments therefore require that LRFEs use temperature-measuring devices that are accurate for a range of temperatures that are both above and below whatever the specific safe temperature is that operators must achieve. We call this their “intended range of use.” Using a device calibrated to this targeted range specific to the products and processes they are using is reasonable to make sure that operators receive the most accurate temperature readings possible. In addition, this

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temperature range will cover those temperatures that operators and regulatory authorities need to verify for cooking and cold holding temperatures to control pathogen growth.

4626.0560 TEMPERATURE MEASURING DEVICES; AMBIENT AIR AND WATER. 4-203.12

As described for part 4626.0560, the departments revised this part to require that operators deal with the inherent limitations of thermometers by using temperature-measuring devices that are calibrated to be accurate “in the intended range of use” for ambient air and water as well as food.

4626.0563 PRESSURE MEASURING DEVICES; MECHANICAL WAREWASHING EQUIPMENT. 4-203.13

The departments added the phrase “indicated on the manufacturer’s data plate” to this part to identify where the pressure range for the warewashing equipment can be found. This clarification simplifies the operator’s understanding of this requirement.

4626.0565 VENTILATION HOOD SYSTEMS; DRIP PREVENTION. 4-204.11

The departments changed “shall” to “must.”

4626.0570 EQUIPMENT OPENINGS, CLOSURES, AND DEFLECTORS. 4-204.12

The departments reworded the language of this part to improve readability. Making this change provides clarity.

4626.0575 DISPENSING EQUIPMENT; PROTECTION OF EQUIPMENT AND FOOD. 4-204.13

The departments rearranged and reworded the language within this part to improve readability and clarity.

The departments also added “liquid food or ice in unpackaged form” in item C to clarify the type of food product this rule addresses. Adding this language to show the precise rule expectations is reasonable to show the scope of this regulation.

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The new item E provides specific requirements for equipment that dispenses TCS foods, which the existing Code does not address. Adding these requirements is reasonable because many LRFE operators now use such dispensing equipment daily so we need standards for ensuring that the equipment is safe and used properly. Under subitem (1) the equipment must maintain the packaged food's sterility for the specific time required. Subitem (2) requires that the equipment meet ANSI standards. This addition will prevent foodborne illnesses associated with contaminated dispensing equipment and food dispensed. It is both necessary and reasonable.

4626.0580 VENDING MACHINE; VENDING STAGE CLOSURE. 4-204.14

The departments restructured this part to improve readability and to indicate that the products provided in this part are only examples of product types that are vended. Without this change, this part may be misconstrued and give the impression that only chips, party mixes, and pretzels are products applicable to this regulation. Making this change for clarity is necessary and reasonable.

4626.0585 BEARINGS AND GEAR BOXES; LEAKPROOF. 4-204.15

The departments changed "shall" to "must."

4626.0590 BEVERAGE TUBING; SEPARATION. 4-204.16

The departments reworded the language to improve readability.

4626.0595 ICE UNITS; SEPARATION OF DRAINS. 4-204.17

The departments changed "shall" to "must."

4626.0600 CONDENSER UNIT; SEPARATION. 4-204.18

The departments changed "shall" to "must."

4626.0605 CAN OPENERS ON VENDING MACHINES. 4-204.19

The departments changed "shall" to "must."

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4626.0610 MOLLUSCAN SHELLFISH TANKS. 4-204.110

The departments revised this part to prevent confusion. Code references for HACCP plans need to align with changes in other areas of this Code.

4626.0615 VENDING MACHINES; AUTOMATIC SHUTOFF. 4-204.111

The departments revised this part for clarity and to bring it up-to-date with the change from “potentially hazardous food (PHF)” to “temperature control for safety food (TCS).” We also included the citations that address cold- and hot-holding temperature requirements. This language does not institute a new requirement. Clarifying and updating the language to be consistent with applicable parts of this Code is self-explanatory.

The revision to item A provides a more accurate reference to risk factor controls outlined in other parts of this Code. The existing Code cites a broad range of references that did not necessarily apply to automatic shutoff features of vending machines.

The revision to item B adds clarity and a reference to cold- and hot-holding temperatures that have been updated within other parts of this Code. 45 degrees F has been changed to 41 degrees F and 140 degrees F has been changed to 135 degrees F because these are the most scientifically accurate cold- and hot-holding temperatures, respectively, to effectively control pathogenic microbial growth.

4626.0620 AMBIENT AIR TEMPERATURE MEASURING DEVICES. 4-204.112

The departments’ revised this part to allow operators to store temperature-measuring devices in a simulated food product, which provides a more constant temperature reading than ambient air temperatures because internal temperatures of foods and liquids do not fluctuate as readily as air. Adding the simulated food product option to the rule provides just as accurate and reliable a reading as ambient air. Allowing simulated-food-product monitoring provides the operator more options than before.

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4626.0625 WAREWASHING MACHINES; DATA PLATE OPERATING SPECIFICATIONS. 4-204.113

The departments changed “shall” to “must.”

4626.0630 WAREWASHING MACHINES; INTERNAL BAFFLES. 4-204.114

The departments changed “shall” to “must.”

4626.0635 WAREWASHING MACHINES; TEMPERATURE MEASURING DEVICES. 4-204.115

The departments changed “shall” to “must.”

4626.0640 MANUAL WAREWASHING EQUIPMENT; HEATERS AND BASKETS. 4-204.116

The departments changed “shall” to “must” and “Fahrenheit” and “Celsius.”

4626.0643 WAREWASHING MACHINES; AUTOMATIC DISPENSING OF DETERGENTS AND SANITIZERS. 4-204.117

The departments revised this requirement to require that detergent and sanitizer feed automatically into the warewashing machine. It also requires that the machine be equipped with a visual or audible signal that the detergent and sanitizer is not delivered during the respective cycles. The need for ensuring detergent and sanitizer delivery is obvious. Adequate sanitizer levels and monitoring are also required by this Code and needed to properly sanitize dishes.

The requirement is reasonable because warewashing machines and add-on alarm systems are readily available and alternative warewashing methods are permitted by this Code for operators who prefer to use a manual warewashing sink or who choose to use hot water in lieu of chemicals to sanitize equipment. These changes are necessary and reasonable.

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4626.0645 WAREWASHING MACHINES; FLOW PRESSURE DEVICE. 4-204.118

The departments restructured this part to change the order in a list of examples; we made no change to rule meaning. Improving readability and clarity is reasonable.

4626.0650 WAREWASHING SINKS AND DRAINBOARDS; SELF-DRAINING. 4-204.119

The departments changed “shall” to “must.”

4626.0655 EQUIPMENT; DRAINAGE. 4-204.120

The departments reordered a list of examples and added the term “such as” to the list of examples to make it obvious that the list of examples is not necessarily all-inclusive of possible conditions requiring draining. We did not change the rule requirements.

4626.0660 VENDING MACHINES; LIQUID WASTE PRODUCTS. 4-204.121

The departments revised this part to improve readability and clarity. We made no changes to the requirements.

4626.0665 CASE LOT HANDLING APPARATUSES; MOVEABILITY. 4-204.122

The departments reordered the list of examples without changing rule meaning. We also added the word “apparatuses” to encompass all devices used similarly to dollies, pallets, racks, and skids to distinguish this category from the word “equipment,” which is used in a different context throughout this Code.

4626.0670 VENDING MACHINE DOORS AND OPENINGS. 4-204.123

The departments revised this part for clarity.

4626.0675 COOLING, HEATING, AND HOLDING CAPACITIES. 4-301.11

The departments updated the Code citations.

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4626.0680 MANUAL WAREWASHING; SINK COMPARTMENT REQUIREMENTS. 4-301.12

In item C, the departments added references to parts 4626.0875 and 4626.0880 to clarify that the alternative manual warewashing equipment must meet the minimum standard for cleaning equipment food contact surfaces. This change does not add new requirements.

The departments added item D to allow LRFEs to use mechanical warewashing equipment in lieu of the manual equipment required in this part. The existing version of the rule requires manual warewashing equipment even if an establishment had installed mechanical warewashing equipment. The departments need to eliminate the unnecessary requirement that food establishments have both manual and mechanical warewashing equipment.

Having one method of cleaning and sanitizing available for food equipment and utensils is necessary but burdening operators with a requirement to have both manual and mechanical equipment is not.

Item E allows food cart operators that do not have manual warewashing equipment to do their warewashing at a separate licensed facility or by agreement with a licensed facility. This item is restated from the existing Code. It is not a new regulation. In addition, the departments are consolidating and moving all warewashing equipment requirements from parts 4626.1850 to 4626.1860 from the existing Code into items F through I. These requirements apply to food carts, special event food stands, mobile food establishments, seasonal temporary food stands, and seasonal permanent food stands. Having one part that addresses manual warewashing requirements increases clarity.

4626.0685 DRAINBOARDS. 4-301.13

The departments changed “shall” to “must.”

4626.0690 VENTILATION HOOD SYSTEMS; ADEQUACY. 4-301.14

The departments changed “shall” to “must.”

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4626.0695 CLOTHES WASHERS AND DRYERS. 4-301.15

The departments changed “shall” to “must.”

4626.0700 UTENSILS; CONSUMER SELF-SERVICE. 4-302.11

The departments restructured this part for clarity.

4626.0705 FOOD TEMPERATURE MEASURING DEVICES REQUIRED. 4-302.12

The departments updated the Code references in this part.

The departments added item B to require that LRFEs use properly designed temperature-measuring devices for measuring thin-food temperatures. Such a thin mass requires a temperature-measuring device with a small diameter probe. Since obtaining an accurate food temperature measurement is vital to preventing foodborne illnesses, it is critical that operators use temperature-measuring devices that match the quantity of food they are measuring. Obviously, using a too-large probe on thin foods may result in a false reading, which would increase public health risk due to undercooking the food. Furthermore, this provision specifically requires using small-diameter probes because a thin diameter probe thermometer can safely measure thick foods. Therefore, an operator can still purchase a single thermometer to measure internal food temperatures if it is a small diameter probe.

4626.0710 TEMPERATURE MEASURING DEVICES; WAREWASHING. 4-302.13

The departments added item B to require that mechanical hot-water sanitizing warewashing machines have an irreversible registering temperature indicator. Types of irreversible registering temperature indicators include thermal labels or thermal tape that change color when a certain temperature is reached or minimum/maximum registering thermometers that report the minimum and maximum temperature the thermometer has registered between resets. Measuring the water temperature at the dish surface level instead of the water’s initial dispensing temperature is important. Manual warewashing operations and hot water mechanical warewashing operations can vary greatly so the departments need to ensure that the dish-surface temperature reaches the

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required minimum temperature to prevent disease-causing pathogens from surviving the warewashing process through improperly sanitized dishes and utensils. In addition, LRFE operators use their warewashing machines daily. They must know what the dish surface temperature is to ensure the temperature meets the minimum requirement or repair the machine if not. This requirement is equivalent to requiring chemical sanitizing warewashing machines be tested with a chemical test strip to verify sanitizer concentration as is already required by this Code.

Providing a more effective means for monitoring the effectiveness for hot-water sanitizing warewashing machines is necessary and reasonable. Aligning hot water monitoring with the requirement in place for operators with chemical warewashing machines is also reasonable.

4626.0715 SANITIZING SOLUTIONS; TESTING DEVICES. 4-302.14

The departments changed “shall” to “must.”

4626.0720 EQUIPMENT, CLOTHES WASHERS AND DRYERS, AND STORAGE CABINETS; CONTAMINATION PREVENTION. 4-401.11

The departments deleted this part because contamination and storage concerns for food, equipment, utensils, linens, and single-use and single-service articles are addressed in parts 4626.0300, 4626.0305, 4626.0955, and 4626.0960.

4626.0721 CLEANING AGENTS AND SANITIZERS; AVAILABILITY. 4-303.11

The departments added this part to specify that LRFEs have on hand the cleaning agents that are necessary to properly clean food service equipment, dishes, and utensils. As stated throughout this Code, LRFE operators are required to properly clean their food service equipment, dishes, and utensils. Obviously, they must provide the necessary supplies to meet these requirements.

4626.0725 FIXED EQUIPMENT; SPACING OR SEALING. 4-402.11

The departments replaced “unit” and “table” references within this part to simplify how the rule reads and make it more relevant to current LRFE operations provides clarity to the rule.

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In addition, the departments deleted item C because carbon dioxide and other bottled gas used in LRFEs pose little risk of foodborne illness when not secured. Most bottled gas used in such facilities comes equipped with gas-connection-nozzle guard to prevent injury caused by a damaged under-pressure nozzle. Gas cylinder safety is the responsibility of occupational health agencies and is not a sanitation concern.

4626.0730 FIXED EQUIPMENT; ELEVATION OR SEALING. 4-402.12

The departments revised this part to make it more precise. We deleted the phrases “of a retail food store” from “fixed equipment; elevation or sealing” because other LRFEs use display units, not just retail settings. This change thus applies the rule to both retail food and nonretail food establishment operations.

In addition, replacing the word “table” with “counter” simplifies the rule and makes it more relevant to current LRFE operations.

4626.0735 EQUIPMENT; GOOD REPAIR AND PROPER ADJUSTMENT. 4-501.11

The departments deleted the word “specified” in item A and rearranged item B for clarity.

4626.0740 CUTTING SURFACES. 4-501.12

The departments added language to this part to improve readability.

4626.0745 MICROWAVE OVENS. 4-501.13

The departments deleted the word “specified” for clarity.

4626.0750 WAREWASHING EQUIPMENT AND FOOD PREPARATION SINKS; CLEANING FREQUENCY. 4-501.14

The departments deleted the word “once” to improve readability.

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4626.0755 WAREWASHING MACHINE; MANUFACTURER'S OPERATING INSTRUCTIONS. 4-501.15

The departments changed “shall” to “must.”

4626.0760 WAREWASHING SINKS; USE LIMITATION. 4-501.16

The departments updated Code citations.

4626.0765 WAREWASHING EQUIPMENT; CLEANING AGENTS. 4-501.17

The departments restructured for clarity.

4626.0770 WAREWASHING EQUIPMENT; CLEAN SOLUTIONS. 4-501.18

The departments changed “shall” to “must.”

4626.0775 MANUAL WAREWASHING EQUIPMENT; WASH SOLUTION TEMPERATURE. 4-501.19

The departments changed “Fahrenheit” and “Celsius.”

4626.0780 FOOD PREPARATION SINKS.

The departments updated this part to make it easier for operators to understand what is required for food preparation sinks. The reorganizing of this section clarifies what the departments expectations are for a LRFE.

The departments added the requirement of item A because an establishment that is washing or thawing products need to have a separate food preparation sink. This will ensure the food is not contaminated when it is being cleaned or thawed for use. An example would be a restaurant that is washing tomatoes. The departments want to ensure the tomatoes do not become contaminated either in the warewashing sinks or the hand sink where there is bacteria and pathogens. Washing the tomatoes in a separate dedicated food prep sink will help minimize the risk of contamination and possible illness. In some cases, an establishment will be thawing food for use. One approved method of thawing is by placing the product under a steady stream of cool running water. Having a separate food preparation sink will allow an establishment to correctly thaw foods. It is

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reasonable to have establishments provide a separate food preparation sink to limit the risk of illness to the public.

Item B was added because adding a food preparation sink to an establishment is needed if there is a menu change or a remodel to the building. If an establishment decides it wants to create a new menu and start using fresh product instead of prepackaged they will need a way to clean the products. It is reasonable for the departments to require a separate food preparation sink when there are changes to the menu or building structure. This will ensure the food being prepared is safe for public consumption.

The departments added item C because a food preparation sink can only be used for food. It is not allowed to be used as a hand washing sink or a sink to clean dishes. It is common to see pans soaking in a sink. Operators need to understand that the food preparation sink can only be used for food and not cleaning. This will ensure that bacteria and pathogens are not present in the sink when it is being used for cleaning products. It is reasonable for the departments to require a food preparation sink that is only used for food in an establishment.

4626.0785 MECHANICAL WAREWASHING EQUIPMENT; WASH SOLUTION TEMPERATURE. 4-501.110

Wash cycle temperatures for mechanical warewashing machines are based on the manufacturer's instructions for proper use and the type of machine. The departments rewrote this part to clarify which temperatures are required for each type of washer (i.e., stationary rack, conveyor, or other). These changes will make it easier for LRFE owners and operators to know how to operate their warewashing equipment.

4626.0790 MANUAL WAREWASHING EQUIPMENT; HOT WATER SANITIZATION TEMPERATURES. 4-501.111

The departments changed "Fahrenheit" and "Celsius."

4626.0795 MECHANICAL WAREWASHING EQUIPMENT; HOT WATER SANITIZATION TEMPERATURES. 4-501.112

The departments replaced the word "provided" with "specified" in this part to ensure consistency with language used throughout this Code, which improves clarity.

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In addition, the word “including” was replaced with “such as” for consistency and clarity.

4626.0800. MECHANICAL WAREWASHING EQUIPMENT; SANITIZATION RINSE PRESSURE. 4-501.113

The departments updated this part to lower the minimum rinse-cycle-flow pressure required in a hot water sanitizing warewashing machine and raise the maximum flow pressure allowed. The revised part also limits the warewashing machine flow pressure to the range specified on the manufacturer’s data plate, which is mounted on the machine. The departments need to recognize this expanded range because effective sanitization still occurs throughout this span of differing flow pressures in a hot water sanitizing warewashing machines. Furthermore, warewashing machine manufacturers’ recommendations differ based on the range that works best for their particular model. Performance-based regulations must reasonably accommodate differing manufacturer recommendations and not unnecessarily constrain effective water pressures that warewashing machines operate under. This change is therefore necessary and reasonable.

4626.0805. MANUAL AND MECHANICAL WAREWASHING EQUIPMENT; CHEMICAL SANITIZATION, TEMPERATURE, PH, CONCENTRATION, AND HARDNESS. 4-501.114

The departments modified this part to align the language with the shift in responsibility for chemical hard surface sanitizers from the FDA to the EPA and from 21 CFR to 40 CFR. The requirements regarding pH, temperature, and water hardness remain, as 21 CFR and 40 CFR do not address these items.

The departments modified item A to clarify that the federal agency referenced is the US EPA and not a state or foreign environmental protection agency. Because the US EPA sets standards for chemical sanitizers, the need to identify the proponent agency and its authority is self-explanatory.

The departments moved provisions about visual or audible warning systems in item D to part 4626.0643 (4-204.117), Warewashing Machines; Automatic Dispensing of Detergents and Sanitizers. Consolidating like provisions for ease of use by the regulatory authorities and operators is necessary and reasonable.

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The departments also modified item D to specify that any sanitizer other than one of the three most common sanitizers (chlorine, iodine, and quaternary ammonium) must be used according to instructions in the product label, which should be EPA-registered.

The departments modified item E to allow LRFEs to use sanitizers other than the most common varieties while promoting proper use by referring to the EPA-registered label. If the product does not have an EPA-registered label, it is probably not listed or approved for use as a sanitizer in a LRFE. Directing operators to a product label to make sure the product is EPA-registered is reasonable and not a burden to the regulated party. It is also reasonable to make operators aware of the requirement to follow label instructions, especially if the product is not among the most common three types of sanitizers (chlorine, iodine, quaternary ammonium).

The departments added item F and subitems to allow LRFEs to use on-site chemical sanitizer generation devices. This change allows them to use “activated water” machines, “ionized salt water” machines, and similar devices, if they are EPA-registered and produce an approved sanitizing solution. Item F allows flexibility for operators because on-site generated sanitizer can be just as effective as a purchased sanitizer.

Thus, new item F reasonably gives the operator more options. In addition, the equipment for on-site sanitizer generation is becoming readily available and increasingly affordable.

4626.0810 MANUAL WAREWASHING EQUIPMENT; CHEMICAL SANITIZATION USING DETERGENT-SANITIZERS. 4-501.115

The departments revised this part in order to clarify that in situations where a detergent-sanitizer is used with no distinct rinse cycle the agent applied in the sanitizing step must be the same as used in the washing step. There has been confusion about this requirement and the language in the existing Code is not clear.

4626.0815 WAREWASHING EQUIPMENT TEST KIT. 4-501.116

The departments changed “shall” to “must.”

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4626.0820 UTENSILS AND TEMPERATURE MEASURING DEVICES; GOOD REPAIR AND PROPER CALIBRATION. 4-502.11

The departments clarified item B by adding the word “food.” This Code contains requirements that are specific to “water temperature measuring devices,” which differ from “food temperature measuring devices.” Clarification alleviates misunderstanding for both operators and regulators.

The departments added item C because maintaining temperature-measuring devices in good repair is necessary to ensure that the readings made by the devices are accurate enough to rely on to prevent the risks that inadequate temperatures and pressure would pose. In addition, the inherent properties measuring devices listed in Item C mean that they are not necessarily capable of being calibrated. Therefore, these particular devices must be addressed separately from food-temperature measuring devices that can and need to be calibrated frequently to be reliable.

Requiring that these devices be maintained in good repair so the operators can detect a problem during routine use, or conversely, do not take corrective action unnecessarily is reasonable. It is also reasonable to require calibrated devices be accurate in their range of use.

4626.0825 SINGLE-SERVICE AND SINGLE-USE ARTICLES; REQUIRED USE. 4-502.12

The departments changed “shall” to “must.”

4626.0830 SINGLE-SERVICE AND SINGLE-USE ARTICLES; RE-USE LIMITATION. 4-502.13

The departments changed “shall” to “must.”

4626.0833 BULK MILK CONTAINERS.

The departments changed “shall” to “must.”

4626.0835 SHELLS; USE LIMITATION. 4-502.14

The departments corrected vocabulary by changing “Molluscan” to Mollusk” for clarity and precision. Enforcement requires correct terminology. Correcting this error is necessary.

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4626.0840 EQUIPMENT, FOOD-CONTACT SURFACES, NON-FOOD-CONTACT SURFACES, AND UTENSILS. 4-601.11

The department changed “shall” to “must.”

4626.0845 EQUIPMENT; FOOD-CONTACT SURFACES, AND UTENSILS. 4-602.11

The departments made changes to items B, D and E to clarify the departments’ expectations for cleaning utensils and equipment. The changes will make it easier for operators to understand what is expected of them at their establishments. The changes also include a chart for operators to reference so they know how frequently utensils and equipment used in refrigerated rooms need to be cleaned.

Item B was changed because it is not always necessary to clean a food-contact surface or utensil between different raw animal foods. Animal foods have different final cooking temperatures. For example, pork has a final cooking temperature of 145 degrees F and chicken has a final cooking temperature of 165 degrees F. It is acceptable for an operator to be cutting pork on a food-contact surface and then switch to cutting chicken. It is reasonable that any microbes from the pork will be killed in the cooking step of the chicken as it is cooked to a higher final cooking temperature. This will allow operators the flexibility to work faster while preparing foods and still ensure public health. As long as an operator is following the proper order of raw animal products it is reasonable for them to use the same food-contact surface without cleaning between different raw animal foods.

The departments updated references in item D, subitem (1) to be as specific as possible regarding which food storage containers may be cleaned less frequently based on the temperatures the food and container are held at. The food storage containers must be cleaned when they are empty. The change in this subitem points to a reference of one section of code, hot and cold holding. This makes it easier for operators to ensure they are maintaining safe food. It is reasonable to expect operators to know the proper hot and cold holding temperatures or to be able to reference them if needed.

Item D, subitem (2) was changed because food is sometimes prepared in a refrigerated room. Bacterial pathogens do not grow as rapidly in a refrigerated temperature environment. There are various cleaning requirements for the utensils and equipment based on the temperature of the

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room. An example is a LRFE that prepares deli salads in a refrigerated room. If the temperature in the room is 45-50 degrees F they will need to clean all utensils and equipment every 16 hours. If the LRFE lowers the temperature of the room to 41 degrees F or less then they only need to clean utensils and equipment every 24 hours. This allows operators the flexibility to determine at what temperature they want to operate a refrigerated room and still provide the public safe foods. It is necessary and reasonable to provide this information to operators in an easy to read format.

The chart in item D, subitem (2), unit (a) provides the cleaning frequency of utensils and equipment in a manner that is easy to understand. This is needed so operators will be able to review the cleaning frequency and follow the code requirements. Cleaning the utensils and equipment must happen at the frequency described in the chart. It is reasonable to present this information in a chart which is easy to understand.

Item D, subitem (2), unit (b) was added because LRFEs need to document the ambient air temperature of the refrigerated room. It is necessary to know the temperature of the room before determining how often to clean the utensils and equipment. It is reasonable for the departments to require an establishment to document the ambient air temperature.

Item D, subitem (3) was added to allow flexibility to the operator. TCS foods can be held in containers for service in places like salad bars. The temperature of the food must be maintained according to the hot and cold holding specifications in part 4626.0395. As long as the food stays within the temperature parameters the containers only need to be cleaned every 24 hours. This allows establishments to refill containers during service. An example is a university cafeteria. In order to feed a large amount of people in a short time period the containers are refilled during service. As long as the hot or cold holding equipment keeps the containers and food at the proper temperature there is not a risk of the public getting sick. It is reasonable to allow operators the flexibility to serve TCS foods without requiring the container to be cleaned in between each refill as long as the food and by extension the container are held at safe temperatures.

Item D, subitem (4) was changed to provide examples of when temperature measuring devices would be allowed to be cleaned less frequently than four hours. Much like other containers and utensils, temperature measuring devices stored in food that is maintained at the hot and cold holding temperatures specified in part 4626.0395 pose no risk to public health if they are washed less frequently. It is reasonable to allow temperature measuring devices to meet the same standards as other equipment and utensils in this part.

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Changes were made to item D, subitem (5) was rewritten for readability and “including” was replaced with “such as” to signify that this is not a requirement that applies only to reach-in refrigerator utensils.

The departments made the addition in item D, subitem (7) because water that is maintained at a temperature of 135 degrees F or above inhibits bacterial proliferation. As a result, in-use utensils may be stored in water at this temperature and cleaned once every 24 hours while posing no risk to public health. It is reasonable to align the time and temperature parameters for cleaning utensils stored in this manner with the other time and temperature combinations found elsewhere in this part. This allows greater flexibility to operators. An establishment may not have the ability to install a running water system for in-use utensil storage. It is not practical to expect an operator to wash a scoop every time they use it.

The list of equipment and utensils in item E, subitems (2) and (3) were reordered for readability. “Such as” was also added to these subitems to make it clear that these are examples and not all inclusive lists.

The departments added additional language to item E, subitem (4) because cleaning food contact equipment on a routine basis is needed to prevent the growth of microorganisms. More examples were added for clarity and “such as” was added before the listing of examples to signify that these are some examples and not a specific list.

4626.0850 COOKING AND BAKING EQUIPMENT. 4-602.12

The departments deleted the word “once” to improve readability.

4626.0855 NON-FOOD-CONTACT SURFACES; CLEANING FREQUENCY. 4-602.13

The departments changed “shall” to “must.”

4626.0860 DRY CLEANING. 4-603.11

The departments changed the order of a list of examples for clarity but did not otherwise change the rule meaning.

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4626.0865 PRECLEANING. 4-603.12

The departments corrected a spelling error of “scrapped” to scraped.”

For clarity, we deleted the term “scupper.” This is an old term that is no longer used.

4626.0870 LOADING OF SOILED ITEMS; WAREWASHING MACHINES. 4-601.13

The departments changed “shall” to “must.”

4626.0875 WET CLEANING. 4-603.14

The departments modified for clarity.

4626.0880 WASHING; PROCEDURES FOR ALTERNATIVE MANUAL WAREWASHING EQUIPMENT. 4-603.15

The departments revised this part for clarity without altering its meaning.

In addition, we corrected the misspelled word “scraped.”

4626.0885 UTENSILS AND EQUIPMENT; RINSING PROCEDURES. 4-603.16

The departments revised the first sentence of this part to make it clear that operators must remove abrasives. They must also remove or dilute cleaning chemicals. The existing language has confused many users of the Code.

The departments deleted outdated item C because this Code does not allow for a two-compartment-sink operation.

4626.0890 4-603.17 RETURNABLES; CLEANING FOR REFILLING.

The departments deleted this part because this requirement is addressed in part 4626.0295, “Take Home Food Container Re-Use.”

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4626.0895 4-701.11 FOOD-CONTACT SURFACES AND UTENSILS.

The departments deleted this part because the requirement is addressed in part 4626.0900.

4626.0900 BEFORE USE AFTER CLEANING. 4-702.11

The departments changed “shall” to “must.”

4626.0905 HOT WATER AND CHEMICAL SANITIZATION. 4-703.11

The departments added the phrase “Contact times must be consistent with EPA-registered label use instructions...” to item C. Sanitizing chemicals differ. Each sanitizing chemical may vary in the contact time it requires to be effective. This is especially true for chlorine sanitizers, which vary in effectiveness depending on temperature and pH condition. We therefore added subitems (1) and (2) describing contact times for chlorine sanitizer specific for varying pH and temperatures. These changes are necessary and reasonable.

4626.0910 CLEAN LINENS. 4-801.11

The departments changed “soil” to “soiled matter” to make it clear that this rule refers to any substance, not just dirt that may befoul linens.

4626.0915 LINENS, CLOTH GLOVES, AND WIPING CLOTHS; FREQUENCY OF LAUNDERING. 4-802.11

The departments revised items A and B for clarity.

In addition, changes made to item D provide a more relaxed requirement regarding the laundering of in-use wiping cloths. Reusing wet wiping cloths from a used cleanser or sanitizing solution to a fresh cleanser or sanitizing solution poses no significant risk for cross-contamination or foodborne illness because the fresh sanitizer or cleanser solution will inactivate microbial pathogens of concern. Making this change is reasonable because LRFEs are required to use cleanser and sanitizing solution with wiping cloths during periods of operation on a daily basis so this requirement pertains to all LRFE operators and provides them the ability to use cloths for longer periods between laundering.

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4626.0920 STORAGE OF SOILED LINENS. 4-803.11

The departments changed “shall” to “must.”

4626.0925 LINENS; MECHANICAL WASHING. 4-803.12

The departments removed “or food preparation” in item B because cleaning wiping cloths in food preparation sinks is now prohibited per part 4626.0780, item C.

4626.0930 LAUNDRY FACILITIES; USE LIMITATIONS. 4-803.13

The departments changed “shall” to “must.”

4626.0935 EQUIPMENT AND UTENSILS; AIR-DRYING REQUIRED. 4-901.11

The departments reworded and restructured the language within this part to improve clarity.

Item A informs the operator that equipment and utensils must be air-dried. Informing the operator of a requirement they must follow rather than a particular task that should not be performed provides clarity to this part.

The language of item B was moved from item C to improve clarity.

We added to item C to clearly require adequate draining to ensure all sanitizer is removed from equipment and utensils before contact with food. The reference to CFR was added for additional clarity.

4626.0940 WIPING CLOTHS; AIR-DRYING LOCATIONS. 4-901.12

The departments changed “shall” to “must.”

4626.0945 LUBRICANTS; FOOD-CONTACT SURFACES. 4-902.11

The departments added the reference “as specified in part 4626.1640” to connect this part to the relevant rule for lubricants.

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4626.0950 EQUIPMENT REASSEMBLY. 4-902.12

The departments changed “shall” to “must.”

4626.0955 EQUIPMENT, UTENSILS, LINENS, AND SINGLE-SERVICE AND SINGLE-USE ARTICLES; STORAGE. 4-903.11

The departments replaced the word “permits” with “allows” in item B, subitem (1) and “provided” with “specified” in item D for clarity and consistency with the rest of this Code.

4626.0960 STORAGE PROHIBITIONS. 4-903.12

The departments revised items A and B for clarity.

Item C’s contents, which were previously contained in now-deleted part 4626.0720, are relocated here. Combining similar requirements for improved Code clarity and conciseness is reasonable.

4626.0965 KITCHENWARE AND TABLEWARE. 4-904.11

The departments restructured language to improve readability.

4626.0970 SOILED TABLEWARE. 4-904.12

The departments changed “shall” to “must.”

4626.0975 PRESET TABLEWARE. 4-904.13

The departments revised this part to make it easier to read.

4626.0977 RINSING EQUIPMENT AND UTENSILS AFTER CLEANING AND SANITIZING. 4-904.14

The departments added proper rinsing procedures for equipment and utensils that have been cleaned and sanitized. Rinsing equipment and utensils after cleaning and sanitizing may contaminate them, depending on the process or water source used. LRFEs that improperly handle utensils that have been warewashed, either completely or incompletely, but not sanitized pose

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another risk of contamination. Therefore, these new restrictions are necessary. The warewashing equipment must directly apply rinse water from a drinking water supply; and the rinse water must be applied after the equipment and utensils have already been sanitized.

Establishing minimum standards for rinsing equipment and utensils after cleaning and sanitizing them is reasonable, provided that LRFE operators are permitted to choose their preferred rinsing method. At the same time, the LRFEs must carry out their chosen method properly to prevent contamination. This proposed revision therefore protects public health while providing LRFEs with operational flexibility.

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Chapter 5 Water, Plumbing and Waste

4626.0980 DRINKING WATER APPROVED SOURCE. 5-101.11

Water, unless it comes from a safe supply, may contaminate food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmitting disease organisms. Natural or manufactured chemicals can also contaminate water. Therefore, to protect consumers and employees, food establishments must obtain water from a source regulated by law and must use, transport, and dispense it in a sanitary manner.

The departments revised this part to require clearly that food establishment operators must use drinking water from “an approved source” in a LRFE. Approved source is a concept used frequently in this rule when referring to sources of both food and water.

4626.0985 DRINKING WATER SYSTEM FLUSHING AND DISINFECTION. 5-101.12

Microbes from soil can contaminate water systems because the pipes are installed underground. Floods and other incidents can also cause water to become contaminated. Chemicals can contaminate, when soldering and welding take place during construction, repair, or modification. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before placed into service.

The departments added references to current versions of *Minnesota Rules*, chapters 4714, 4720, and 4725 to ensure that the food establishment operator or water system installer flushes and disinfects both public and nonpublic water systems to minimum standards. The departments added flooding as an example of an emergency that requires system flushing and disinfection because contaminated floodwaters might infiltrate into the drinking water system.

Drinking water system requirements change over time, and so the departments added language that makes it clear that these systems must meet all federal and state requirements. Flushing and disinfecting a drinking water system after an emergency is necessary for providing safe water to the public.

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4626.0990 BOTTLED DRINKING WATER. 5-101.13

Bottlers obtain their water from a public water system or from a private source such as a spring or well. To protect consumers adequately, public health law must control the means of production. The language added here alerts licensees and operators that other applicable state and federal laws could regulate bottled drinking water, depending on the source of the water and the situation. This clarification ensures that licensees comply with all regulations and the public is protected appropriately.

4626.0995 DRINKING WATER STANDARDS. 5-102.11

Our laws contain bacteriological and chemical standards that drinking water supplies must meet. The departments clarified this part to emphasize these standards for safe drinking water for both public and nonpublic water systems, which are the same water quality standards previously established in this Code. To item A, we added the reference to the exception in part 4626.1000 to make it easier for licensees and operators to read and apply the exception.

Minnesota Rules, chapters 4714, 4720, and 4725 alone do not provide clear and sufficient guidance on drinking water quality standards for nonpublic water systems that LRFEs use. Thus, we have incorporated one that is already in rule, which is also the least restrictive standard for public water systems. We propose that nonpublic water systems used by LRFEs meet the same water quality standards as noncommunity transient (public) water systems.

4626.1000 NONDRINKING WATER. 5-102.12

The departments revised this part to clarify when LRFE may use a nondrinking water supply in their operation. Nondrinking water is not monitored for bacteriological and chemical quality or safety; the lack of testing makes the water not fit for human consumption.

The rule directly addresses the need for clear direction. The change elaborates on a general definition of when nondrinking water can be used for non-culinary purposes by giving specific examples of non-culinary purposes such as air conditioning and fire protection. The revised changes are reasonable because they do not prohibit the use of nondrinking water outright but interject a flexible performance standard to explain the parameters to licensees and operators instead.

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4626.1005 WATER SAMPLING. 5-102.13

Faulty equipment or environmental ground water contaminants may contaminate water supplies. The law requires periodic sampling to monitor the water safety and to detect any changes in safety. We added Item A to refer to an existing rule requiring sampling and testing of public water supplies.

The departments added item B to clarify that LRFE that have nonpublic water systems supplying drinking water must be sampled to ensure the systems meet the same requirements as noncommunity transient public water systems. Sampling requirements in *Minnesota Rules*, chapter 4720, do not specify testing requirements for nonpublic water supplies. Therefore, this specific requirement is needed in this Code to establish the standards that the samples must meet.

Frequency and quality standards related to water sampling are clearer for public water systems. Nonpublic water systems supplying foodservice operations are expected to be safe for use and free of contaminants. Regular testing ensures these requirements are met and the priority designation makes it clear that this requirement is important for public health.

Providing a uniform set of standards for both public and nonpublic water supplies serving LRFEs is needed and reasonable.

4626.1010 WATER SAMPLE REPORT; NOTIFICATION AND RETENTION. 5-102.14

The departments revised this part to add missing detail about LRFEs requirements for using nonpublic water supplies. This part now states when LRFEs must notify regulatory authorities and how long they must retain water sample reports. As outlined in the statement of need and reasonableness for part 4626.1005, only public water supplies fall under the jurisdiction of *Minnesota Rules*, chapter 4720 in Minnesota. LRFEs that are using a nonpublic water source would not fall under the jurisdiction of *Minnesota Rules*, chapter 4720.

Therefore, this Code needs to address potential situations where public health might be compromised by using unsafe water coming from nonpublic sources in LRFEs. The requirements specified in the proposed language in items A and B of this part are identical to

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those required by *Minnesota Rules*, chapter 4720 for public drinking water supplies (which adopt by reference 40 CFR Part 141, the National Primary Drinking Water Regulations).

Providing uniform sets of standards for sampling-result notification and records retention for both public and nonpublic water supplies simplifies both compliance and enforcement. It is reasonable.

4626.1015 WATER SYSTEM CAPACITY. 5-103.11

The departments revised this part to clarify the water system capacity requirement. Proper sanitation within a LRFE requires sufficient water during all hours of operation, including periodic fluctuations in use throughout the day. Without sufficient safe water, a LRFE cannot properly clean equipment and utensils. Food workers cannot clean their hands.

Furthermore, hot water must be available to meet demand during peak periods of use. Booster heaters for warewashers that use hot water for sanitizing equipment and utensils are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization cannot be reached.

The departments also relocated the requirement for sufficient hot water generation in item B from part 4626.1025 (repealed) to this part. Peak water demands occur when an LRFE is busiest. Operators must design their LRFE in anticipation of these demands. Manual washing of food equipment and utensils is most effective when hot water is used and many detergents and sanitizers have minimum water temperature requirements to ensure proper cleaning and sanitization.

The requirements in this part ensure proper sanitation can take place any time a LRFE is operating. Combining the two requirements into this part enhances clarity for the public as well as the regulatory authority. Priority designations make it clear that these requirements are important.

4626.1020 WATER PRESSURE. 5-103.12

We needed to alter the language in this part to make it clear that seasonal temporary and special event food stands are not required to have water under pressure. This part has not changed in

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substance but its application has now been made more explicit in providing an exception for these temporary food operations which are disassembled and moved from place to place. The reference to part 4626.1035 is no longer needed because the terms “seasonal temporary food stand” and “special event food stand” have been added to that part of this Code as well so both 4626.1020 and 4626.1035 are clearly referencing these types of portable LRFEs.

The temporary and portable nature of these food stands requires flexibility in what is required for them. Water for handwashing, dishwashing, and other essential needs must still be provided, but the allowance for that water to not be provided under pressure is reasonable because there is not necessarily going to be an easily accessible drinking water supply connection located near these operations. In actuality, water supplied from a tank in these food stands does provide enough pressure from gravity to adequately rinse hands, equipment, and utensils. These types of LRFEs are limited in the number of days they can operate by Minnesota Statute, Chapter 157 and they must obtain licensure specifically for the events at which they are operating so allowing flexibility regarding this type requirement is reasonable.

4626.1025 5-103.13 HOT WATER.

The departments deleted this part because we added the hot water requirements to part 4626.1015 as a water capacity requirement. This part is no longer needed.

4626.1030 WATER SYSTEM. 5-104.11

As stated before, inadequate water systems may serve as vehicles for contaminating food or food contact surfaces. The departments revised this part to address water delivery. Water for LRFEs must be delivered by systems that are designed, constructed, and maintained to provide safe water.

The department’s revisions clarify the types of water distribution and transportation systems that are approved for LRFEs and updates out-of-date references to other rules.

We added the word “hoses” to item B, subitem (1) to make it clear that hoses are part of the water system and to eliminate confusion about this topic. Public water mains must continue to meet the requirements in *Minnesota Rules*, chapter 4720.

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We updated the terms “water hauler” and “water tank” in item B to align with the terminology used in *Minnesota Rules*, chapter 4720 to avoid confusion. The NSF International Standard No. 51 requirement for hoses has been removed from item B, subitem (3), as requirements for hoses are now incorporated into part 4626.1140 (5-302.16) Drinking Water Hose; Construction and Identification of this Code.

These changes align terms, update references to regulations and relocate some provisions to provide better clarity and readability for licensees, operators and regulators.

4626.1035 ALTERNATIVE WATER SUPPLY. 5-104.12

To ensure safety, alternative water supplies and conveyance systems must meet requirements similar to those for conventional water supplies and distribution systems. Improperly constructed or maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in otherwise safe water being contaminated and used.

The departments deleted the reference to part 4626.1025 as we consolidated this requirement into part 4626.1020 Water System Capacity. We deleted the term mobile establishment since it is now included in the broader term “temporary food establishment,” which is defined in this code, and is therefore redundant. We added the word “for” for clarity. Adding the Code of Federal Regulations (CFR), title 21, section 129 (Processing and Bottling of Bottled Drinking Water) requirement in item A ensures that bottled water meets federal standards, as well as *Minnesota Rules*, chapter 1550. Water vending machines have also been included as an approved alternative supply when existing requirements in *Minnesota Rules*, chapter 1550 are met.

We deleted the old NSF Standard No. 51 because it is not needed. These revisions, along with priority designations, are reasonable additions for clarity and consistency.

4626.1040 PLUMBING SYSTEM; APPROVED MATERIALS, INSTALLATION AND MAINTENANCE 5-201.11

The departments revised and consolidated existing Code requirements for plumbing systems and devices used for distributing water. Water systems must be properly built and maintained to prevent the resulting health hazards that defects pose from contaminated water. Proper materials

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are smooth, durable, nonabsorbent, and corrosion-resistant. Properly designed and constructed water filters protect a system from contamination.

To bring this part up to date, the departments elaborated on existing rule language, which states that plumbing systems must be properly constructed and repaired. The new version also states that they be designed and installed properly. The departments also specify that, in addition to being built with approved materials, plumbing systems must be built with approved equipment and devices, giving regulatory authorities oversight before construction. All of this must be done according to Minnesota law. The departments also added an explicit statement that systems must be maintained in good repair. These changes make explicit what a reasonable interpretation of existing rule would require.

The departments also streamlined the Code by consolidating the plumbing-system requirements by focusing on enforcement authority. Since the department of labor and industry and local building officials enforce *Minnesota Rules*, chapter 4714 (the plumbing code), the departments left intact the existing requirement that a plumbing system simply comply with the plumbing code. They removed standards that are either outdated or incongruent with other Minnesota rules from both this part and other parts dispersed throughout Chapter 5 of this Code. Consequently, the following parts of this Code have been repealed and are now partially or entirely consolidated under the revision to this part: 4626.1045, 4626.1055, 4626.1060, 4626.1105, and 4626.1130.

As a result, food establishments need only comply with the plumbing code as enforced by the department of labor and industry. Health authorities that enforce this Code are relieved from enforcing plumbing standard because myriad plumbing requirements no longer appear in this Code. Food establishment benefit from a simpler food code and simpler dealings with regulatory authorities, thus a lightened regulatory burden.

4626.1045 5-202.11 APPROVED SYSTEM AND CLEANABLE FIXTURES.

The departments deleted this part to eliminate redundancy. Item A has been relocated to part 4626.1040 and item B has been relocated to part 4626.1075. Relocating these items makes this Code more concise by including the requirements with other related, more applicable, requirements in this Code.

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4626.1050 HANDWASHING SINK; INSTALLATION. 5-202.12

For handwashing to be effective, workers need to wash their hands for at least 15 seconds. LRFEs must provide either a mixing valve or combination faucet to supply properly tempered water for handwashing so that food employees can maintain handwashing for at least the requisite 15 seconds. This Code does not allow steam-mixing valves because they are difficult to control and pose a hazard from scalding injuries.

In light of the language that requires a temperature appropriate to allow handwashing for at least 15 seconds, the departments also removed the required minimum water temperature for a handwashing sink. Current research indicates that time, friction, and surfactants are the variables that determine handwashing effectiveness, water temperature does not. Water temperature can be a barrier to handwashing. Depending on the food establishment's ambient temperature, 110 degrees F water may seem too hot for employees to use for the required time.

In addition, automatic handwashing facilities have become commonplace in kitchens and restrooms. Installation according to manufacturer's instructions is necessary to ensure that this equipment functions as intended.

4626.1055 5-202.13 BACKFLOW PREVENTION; AIR GAP.

The departments deleted this part because the requirement for an air-gap backflow prevention is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714, making this reference an unnecessary requirement.

4626.1060 5-202.14 BACKFLOW PREVENTION DEVICE; DESIGN STANDARD.

The departments deleted this part because the requirement for backflow prevention devices is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714. See the Statement of Need and Reasonableness for part 4626.1040 above for more information about deleting these obsolete or unnecessary requirements from this Code.

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4626.1065 WATER CONDITIONING DEVICE; DESIGN. 5-202.15

The departments revised this part for clarity. The existing Code provides that a water-conditioning device must be designed for periodic cleaning and servicing. This revision simply requires that such devices also be installed in a location that makes such maintenance convenient. We also clarified that the water filter must be a replaceable *type of device*. This change has the practical effect of increasing the probability that cleaning and maintenance will occur so the device will serve its intended purpose.

4626.1070 HANDWASHING SINKS; NUMBERS AND CAPACITY. 5-203.11

Handwashing is critical to control foodborne illness and therefore food workers need sufficient handwashing sinks available to make it not only possible, but likely that the workers will wash their hands at all appropriate times and places outlined in this Code. An analysis of 816 reported infected worker-associated outbreaks from 1927-2006 showed that over 61% of these outbreaks came from food service facilities and catered events, and another 11% of them were attributed to schools, day care centers and health care institutions.

We added a reference to item A to include the exceptions to the sink requirement that appear in items B and C.

The departments changed the word of “lavatories” to “sinks” in item B.

Item C incorporates language for special event and seasonal temporary food stands moved from Chapter 9. Relocating existing requirements into this part, more accurately groups rules by topic and increases conciseness of this Code is therefore reasonable.

4626.1075 TOILETS AND URINALS. 5-203.12

Food establishments must have adequate, sanitary toilet facilities to properly dispose of human waste, which carries pathogenic microorganisms, and so that flies and other insects are prevented from spreading disease after contact with such waste. The departments revised this part to clarify the number of toilets and urinals required in a LRFE, as well as the exemption of toilet requirements for various mobile food operations.

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The Minnesota Building Code ensures that the minimum number of toilet facilities are provided in all permanent LRFEs, regardless of type, while the exemption was previously stated in another area of this Code and was relocated here for clarity. Proper sanitation's role in improving and preserving public health is well known and needs no further elaboration.

Existing language from part 4626.1045 specifying that plumbing fixtures be cleanable within the meaning of this Code has been moved here to arrange group requirement categories more logically and in one place.

Item C was added to account for a part in this Code that has now been repealed and relocated under this part for consolidation purposes.

4626.1080 SERVICE SINK. 5-203.13

Mop water and similar liquid wastes that are contaminated with microorganisms, dirt, and debris must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

The departments updated item A of and eliminated the requirement that food establishment provide a faucet for drinking water at the service sink. We also clarified that the service sink must not be used for any other purpose. Using a service sink for only one purpose has been standard practice in the industry for some time as it reduces possible cross contamination concerns in cleaning areas. The revisions make it clear what the requirements are for a service sink.

Item B addresses an issue that inspectors have found at LRFEs that the existing Code has not specifically addressed. Disposing mop water into a toilet or urinal can lead to clogs and possible damage to the plumbing system, as these facilities are not designed for this purpose. Service sinks have screens in place to prevent the entrance of solid waste into the sanitary sewer system, and are designed with larger basins to protect against spills and the contamination of the surrounding floor and walls. In addition, contact with toilets may result in mop equipment being contaminated by fecal contamination.

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Item C, an exemption from having a service sink for mobile food establishments, has been relocated from another section of this Code so that requirements and exemptions for service sinks can now be found in the same place.

4626.1085 BACKFLOW PREVENTION DEVICE; WHEN REQUIRED. 5-203.14

The departments replaced existing language with a general reference to the Minnesota plumbing code (*Minnesota Rules*, 4714) and specific sections of the Uniform Plumbing Code. In addition, language previously found in part 4626.1100 concerning backflow prevention device location has been relocated to this part preventing any conflicting requirements between this Code and the plumbing code. This revision is reasonable in that it reduces confusion and increases the likelihood of compliance on the part of operators. The intent of this part is maintained by making reference to the prevailing regulations concerning plumbing for LRFEs.

Backflow prevention devices are only effective if being properly maintained. The departments added the requirement in item B to ensure backflow preventers are located in an area that allows for maintenance to eliminate any ambiguity regarding the need for maintenance.

4626.1090 5-203.15 BACKFLOW PREVENTION DEVICE; CARBONATOR.

The departments deleted this part because the requirement for carbonator backflow prevention devices is provided in parts 4626.1040 and 4626.1085 by reference to the *Minnesota Rules*, chapter 4714.

4626.1095 HANDWASHING SINKS. 5-204.11

A properly located handwashing sink is one that is available to food employees who are working in food preparation, food dispensing, and warewashing areas. Convenient placement of handwashing sinks facilitates encourages frequent handwashing by food employees in all work areas.

In addition, item B allows a sink to be placed immediately adjacent to a toilet room, providing operators with the opportunity to configure restrooms in a manner that allows for convenient handwashing. These updates clarify the requirement for handwashing sink placement, without placing additional burdens on LRFE operators.

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4626.1100 5-204.12 BACKFLOW PREVENTION DEVICE; LOCATION.

The departments deleted this part and relocated the requirement as item B under part 4626.1085. The language and intent of the existing version of this requirement remains unchanged. We relocated it for consistency and logical arrangement of requirement topics throughout this Code.

4626.1105 WATER CONDITIONING DEVICE; LOCATION. 5-204.13

The departments deleted this part because the requirement for the location of water condition devices is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714. See the Statement of Need and Reasonableness for part 4626.1040 above for more information, making this an unnecessary requirement in this Code.

4626.1110 USING HANDWASHING SINKS. 5-205.11

The departments made minor language changes to the requirements that food establishments maintain handwashing sinks in a condition that promotes handwashing and restrict them for that use only. The departments changed “shall” to “must” and replaced the term “lavatory” with the more common term “sink.”

Item C has also been added to address automatic handwashing facilities that may now be in use in certain types of food service operations. Requiring their use according to manufacturer’s instructions is consistent with equipment requirements in other areas of this Code.

4626.1115 CROSS-CONNECTIONS PROHIBITED. 5-205.12

The departments removed an exception to cross-connection for firefighting. This exception is not relevant to LRFE operators and does not affect the way firefighters may use the water supply in the course of their duties. The departments also changed “shall” to “must.”

4626.1120 SCHEDULING INSPECTION AND SERVICE FOR A WATER SYSTEM DEVICE. 5-205.13

The departments revised this part for clarity, as well as adding a record keeping requirement for maintenance and service of these devices. Regulating authorities need to verify that food

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establishments are complying with this Code. Records provide important evidence that operators are properly maintaining equipment that is in contact with the water supply and having it serviced by individuals trained and licensed to do this work at all times, in accordance with this Code. Backflow preventers are water system devices and must be treated in a similar manner and have been incorporated into item A for this purpose.

4626.1125 WATER RESERVOIR OF FOGGING DEVICES; CLEANING. 5-205.14

This change offers operators more flexibility without lessening the protection required to safeguard public health from respiratory pathogens such as *Legionella pneumophila*.

The departments changed “shall” to “must” and replaced a very specific sanitizing solution with “an effective sanitizing chemical per the manufacturer’s recommendations.” The departments recognize that limiting operators to only a specified concentration of bleach for sanitizing fogging devices is no longer necessary. A variety of approved products are now in regular use in the industry, and newer products may be developed or preferred by equipment manufacturers in the future.

4626.1130 5-205.15 SYSTEM MAINTAINED IN GOOD REPAIR.

The departments deleted this part because the requirement for plumbing system maintenance is provided in part 4626.1040 by reference to the *Minnesota Rules*, chapter 4714. See the Statement of Need and Reasonableness for part 4626.1040 above for more information. Thus, this deletion removes an obsolete or unnecessary requirements from this Code.

4626.1135 WATER TANKS; APPROVED. 5-301.11

The departments deleted the word mobile because freestanding, non-mobile water tanks can be utilized. In addition, the departments updated the citations in items B and C.

4626.1140 DRINKING WATER HOSE; CONSTRUCTION AND IDENTIFICATION. 5-302.16

To prevent drinking water contamination, hoses used to fill clean drinking water tanks need to be used for that purpose only and labeled as such. Hoses that are not designed and maintained

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appropriately can be a source of contamination. The departments revised this part for clarity and added reasonable requirements that mirror the requirement for surfaces that contact food or beverages used in other areas of this Code. This revision ensures that hoses meet the same minimum requirements as other food-contact surfaces.

4626.1145 FILTER; COMPRESSED AIR. 5-303.11

The departments changed “shall” to “must.”

4626.1150 WATER INLET, OUTLET, AND HOSES; PROTECTIVE COVER OR DEVICE. 5-303.12

Operators must protect water supply openings to prevent contamination, which may occur if the supply is exposed to the environment, i.e., at water inlets, outlets, or the ends of transfer hoses. The departments revised this part for clarity and ease of understanding, as well as explicitly stating that the protection is only required when the equipment is not in use. This specificity prevents confusion about a cover requirement and how an inlet or outlet could be used while covered.

4626.1155 MOBILE FOOD ESTABLISHMENT WATER TANK INLET. 5-303.13

The departments changed “shall” to “must” and metric numbers to Arabic numbers.

4626.1160 WATER SYSTEM FLUSHING AND SANITIZATION. 5-304.11

The departments changed “shall” to “must.”

4626.1165 WATER TANK, PUMP, AND HOSE; BACKFLOW PREVENTION. 5-304.12

The departments added the phrase “water tank, pump” to the title to clarify the topic of this part.

4626.1170 PROTECTING INLET, OUTLET, AND HOSE FITTING. 5-304.13

The departments deleted this part because it has been incorporated in part 4626.1150, making this part obsolete or unnecessary.

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4626.1175 WATER TANK, PUMP, AND HOSE; DEDICATION. 5-304.14

Under the existing Code hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. The departments revised this part for grammar and clarity. The departments did modify a requirement by replacing the phrase “after each use” with “before they are used to convey water.” This means that foodservice operators must clean and sanitize hoses *before* using the hose for water, rather than after every use. This change means that the operators remove contamination that may have occurred during storage. This change in operating procedure adds additional public protection with little if any increase in burden on the regulated parties.

4626.1180 SEWAGE HOLDING TANK CAPACITY AND DRAINAGE. 5-401.11

The departments revised item A for clarity. We also made this language consistent with that used in *Minnesota Statute 157* for “mobile food units” and “seasonal temporary food” establishments.

We added item B to prohibit any LRFEs from discharging sewage onto the ground, which creates a very high risk that wastewater containing pathogenic microorganisms will transmit illness. Containing sewage in a vessel to prevent contact with humans or pests that could bodily carry the sewage around the food establishment is imperative. This addition is obviously reasonable when the very high risk to public health from transmitting illness is weighed against readily available and affordable technologies for proper sewage containment.

The departments also added item C to allow the regulatory authority to approve an alternative to waste holding tank requirements. The food establishments and regulatory authorities need this option for flexibility in instances when the foodservice’s nature of operation, its location, or other unforeseen circumstances make waste holding tanks either not practical or possible. Public health remains protected because alternative measures must meet all federal and state standards. This revision is reasonable because it provides operators with flexibility without requiring a variance and it still protects the public.

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4626.1185 5-402.11 ESTABLISHMENT DRAINAGE SYSTEM.

The departments deleted this part. LRFEs plumbing systems, including drainage systems, must be installed in accordance with the Minnesota Plumbing Code as required in part 4626.1140. This repeal removes redundant language and makes this Code more concise and understandable.

4626.1190 BACKFLOW PREVENTION. 5-402.11

The departments updated references and added an exemption to item A for floor drains that originate in refrigerated spaces constructed as an integral part of the building. Some refrigerated spaces, such as meat cutting rooms and food preparation rooms, are required by the plumbing code to have floor drains. This exemption ensures that these permanent portions of a building are not included in the prohibition found in item A.

4626.1195 GREASE TRAP. 5-402.12

The departments changed “shall” to “must.”

4626.1200 CONVEYING SEWAGE. 5-402.13

The departments changed “shall” to “must” and corrected a citation.

4626.1205 REMOVING TEMPORARY FOOD ESTABLISHMENT WASTES. 5-402.14

The departments replaced “mobile food establishments” with “temporary food stands, food carts, special event food stands, retail food vehicles, and portable structures or carts,” into the existing requirement for removing sewage and waste. This makes it clear that all these food establishment forms must comply with the same minimum standards so that a public health hazard is not created.

These revisions incorporate language consistent with *Minnesota Statutes*, chapter 157 for all types of temporary food establishments.

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4626.1210 FLUSHING WASTE RETENTION TANK. 5-402.15

The departments changed “shall” to “must.”

4626.1215 APPROVED SEWAGE DISPOSAL SYSTEM. 5-403.11

The departments added a reference to *Minnesota Rules*, chapter 7081 (Midsized Subsurface Sewage Treatment Systems) to include waste disposal requirements not already covered in *Minnesota Rules*, chapter 7080 (Individual Subsurface Sewage Treatment Systems). Broadening this rule makes it consistent with other parts of this Code and ensures all waste disposal systems meet state requirements.

4626.1220 OTHER LIQUID WASTES AND RAINWATER. 5-403.12

The departments added *Minnesota Rules*, chapters 7081 (Midsized Subsurface Sewage Treatment Systems) and 7083 (Subsurface Sewage Treatment System Credentialing and Product Registration) to existing rule to include waste disposal requirements not already covered in *Minnesota Rules*, chapter 7080 (Individual Subsurface Sewage Treatment Systems). This is consistent with other parts of this Code and ensures all waste disposal systems meet state requirements.

4626.1225 REFUSE; INDOOR STORAGE AREA. 5-501.10

The departments changed “shall” to “must.”

4626.1230 REFUSE; OUTDOOR STORAGE SURFACE. 5-501.11

The departments reordered language to improve readability.

4626.1235 REFUSE; OUTDOOR ENCLOSURE. 5-501.12

The departments changed “shall” to “must.”

4626.1240 REFUSE; RECEPTACLES. 5-501.13

The departments changed “shall” to “must.”

Chapter 5

ACRONYMS AND ABBREVIATIONS

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The word within was added in order to clarify requirement.

4626.1245 REFUSE; RECEPTACLES IN VENDING MACHINES. 5-501.14

The departments changed “shall” to “must.”

4626.1250 REFUSE; OUTSIDE RECEPTACLES. 5-501.15

The departments changed “shall” to “must” also changed “including” to “such as.”

4626.1255 REFUSE; STORAGE AREAS, ROOMS, AND RECEPTACLES; CAPACITY AND AVAILABILITY. 5-501.16

The departments changed “shall” to “must” and “lavatory” to “sink.”

4626.1260 REFUSE; TOILET ROOM RECEPTACLE; COVERED. 5-501.17

The departments changed “shall” to “must.”

4626.1265 REFUSE; CLEANING IMPLEMENT AND SUPPLIES. 5-501.18

The departments replaced the word “equipment” with “implement” because 4626.0020, subpart 26 defines the word “equipment” with a meaning specific to food handling. Using the word “implement” prevents possible confusion.

4626.1270 REFUSE; STORAGE AREAS, REDEEMING MACHINES, EQUIPMENT, AND RECEPTACLES; LOCATION. 5-501.19

The departments changed “shall” to “must.”

4626.1275 STORING REFUSE, RECYCLABLES, AND RETURNABLES; INSECT AND RODENT CONTROL. 5-501.110

The departments changed “shall” to “must.”

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4626.1280 AREAS, ENCLOSURES, AND RECEPTACLES; GOOD REPAIR.

5-501.111

The departments changed “shall” to “must.”

4626.1285 OUTSIDE STORAGE PROHIBITIONS. 5-501.112

The departments changed “shall” to “must.”

4626.1290 COVERING RECEPTACLES. 5-501.113

The departments changed “shall” to “must.”

4626.1295 USING DRAIN PLUGS. 5-501.114

The departments changed “shall” to “must.”

4626.1300 MAINTAINING REFUSE AREAS AND ENCLOSURES. 5-501.115

The departments changed “shall” to “must.”

4626.1305 CLEANING RECEPTACLES. 5-501.116

The departments updated the citations in item A. In item B, we removed the word “soiled” because it is not defined and can be subject to differing interpretations. One person’s “soiled is another person’s “mostly clean.” We want all receptacles to be clean at a set frequency.

4626.1310 REFUSE, RECYCLABLES, AND RETURNABLES; REMOVAL FREQUENCY. 5-502.11

The departments changed “shall” to “must.”

4626.1315 RECEPTACLES OR VEHICLES. 5-502.12

The departments updated the citations because *Minnesota Statutes*, chapter 115A is not the only statute or rule governing solid waste.

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4626.1320 SOLID WASTE COMMUNITY OR INDIVIDUAL FACILITY. 5-503.11

Alternative solid waste disposal requirements in this part were also limited previously to those outlined in *Minnesota Statutes*, chapter 115A (Waste Management) and section 473.803. The proposed update to alternative solid waste disposal requirements described in current state laws and rules is needed to ensure that all solid waste is handled, treated, and disposed of properly by LRFEs.

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Chapter 6, Physical Facilities

4626.1325 FLOORS, WALLS, AND CEILINGS; CHARACTERISTICS, INDOOR AREAS AND MATERIALS. 6-101.11

In item A, subitem (2), the departments replaced the phrase “where carpeting is permitted” with “for all carpeted areas.” The proposed change requires that all carpeted areas, not just permitted carpeted areas, must have carpeting that is closely woven and easily cleanable. This is an oversight in the existing Code. All floor surfaces in a LRFE need to be cleanable in order not to harbor bacteria and viruses.

The departments have rewritten item A, subitem (3), to broadly describe the category of areas where nonabsorbent materials are essential to prevent mold growth, facilitate cleaning, and prevent conditions that allow harmful bacteria to grow. The critical areas are generally subject to heavy food preparation and require routine cleaning. Using the term “such as” to introduce examples of general food facility areas, rather than trying to list all of the specific areas that require nonabsorbent materials, focuses more clearly on the harm the Code seeks to alleviate. At the same time, it maintains flexibility for operators and regulatory authorities. These changes, which streamline this provision and eliminate potential confusion, are thus necessary and reasonable.

The departments needed to clarify that the language in item B is specific to LRFEs that are not permanent. We made changes that are consistent with the existing part 4626.0020, subpart 90. Adding the word “any” shows that this Code applies to all temporary food establishments and not to a particular or specific temporary food establishment. The word “cart” includes food operations currently regulated by MDA. Clarifying language without changing the meaning provides consistency with other parts of this Code. It is necessary and reasonable.

The departments revised item B, subitem (2) to focus the function that “walls and ceilings” must provide. By requiring that walls and ceiling protect the interior food preparation areas from weather and windblown dust and debris at all times, we are stating the standard that LRFES must meet without qualification. Wind-blown dirt, leaves, molds, insects, bird-and-animal fecal droppings, and contaminated litter are environmental sources of contamination for these types of food establishments. Protecting the food preparation areas from contaminants of all sorts is

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essential. To accurately reflect food establishment responsibilities to protect public health, these Code revisions are necessary and reasonable.

4626.1330 OUTDOOR SURFACES; CHARACTERISTICS AND MATERIALS. 6-102.11

In item A, the departments replaced “exterior” with “outdoor” because it more clearly describes areas regulated in this part. Using plain language that is consistent and easy to understand is necessary and reasonable.

We deleted item C because it only referred people to other parts of the Code and added no value to this part.

4626.1335 FLOORS, WALLS, AND CEILINGS; CLEANABILITY. 6-201.11

The departments repealed item B, which duplicated part 4626.1515 and not needed here.

We deleted the prohibition of vinyl flooring in item C. Industry has advanced in the design and manufacture of vinyl flooring so that LRFEs can sanitize and maintain them. Removing outdated restrictions provides flexibility to the regulated industry to use new and advanced materials.

Item D was renamed as B.

4626.1340 FLOORS, WALLS, AND CEILINGS; UTILITY LINES. 6-201.12

The departments changed “shall” to “must.”

The departments added the word “horizontal” in item C to clarify that exposed utility service lines and pipes cannot be installed horizontally on the floor. These are safety issues. Dirt and debris that collect in crevices between such lines and pipes and the floor, making cleaning difficult and can attract unwanted pests. Foot and equipment traffic can damage the conduit and create an electrical or plumbing hazard. Thus, this change is necessary and reasonable.

Further, we deleted “walls” from item C because horizontal utility lines on walls are not subject to the type of damage that similar lines installed on floors may suffer. It is reasonable to delete an unnecessary requirement.

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Language referring to quick disconnect gas hoses, and flexible hoses and caps for cooking equipment in subitems (1) and (2) were removed to provide clarity and eliminate confusion between fixed utility line installation and equipment specific hoses and cords. These types of hoses can be removed to allow for proper cleaning.

4626.1345 FLOOR AND WALL JUNCTURES; COVED AND ENCLOSED OR SEALED. 6-201.13

The departments changed “shall” to “must” and metric numbers to Arabic numbers,

4626.1350 FLOOR CARPETING; RESTRICTIONS AND INSTALLATION. 6-201.14

The departments currently prohibit carpeting in areas where the floor is likely to get wet. So we chose to emphasize that circumstance by adding the phrase “where the floor is” to alert the reader immediately to this fact. The departments replaced the term “lavatory” with the more common term “sink” for ease of understanding. Emphasizing requirements using plain language helps the public understand both our rationale as well as our requirements. These revisions are therefore reasonable.

4626.1355 FLOOR COVERING; MATS AND DUCKBOARDS. 6-201.15

The departments realized that mats and duckboards made of materials that can be moved and are easy to clean will ensure regular and effective cleaning and prevent the accumulation of dirt and waste. Therefore, a simpler requirement to that effect that will adequately protect public health accomplishes that goal, without changing the requirement’s intent. Combining requirements into one part improves clarity while still allowing for use of mats and duckboards.

4626.1360 WALL AND CEILING COVERINGS AND COATINGS. 6-201.16

The departments changed “shall” to “must.”

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4626.1365 WALLS AND CEILINGS; ATTACHMENTS. 6-201.17

LRFE layouts and designs can be complex, especially for wall and ceiling attachments. The departments revised and rearranged items currently listed to follow the words “such as.” This change makes it clear that the rule provides examples rather than an all-inclusive list. It also adds more flexibility in this Code because it covers similarly functioning items that are not listed.

This revision is reasonable because it makes this Code clearer and more understandable.

4626.1370 WALLS AND CEILINGS; STUDS, JOISTS, AND RAFTERS. 6-201.18

The existing rule unnecessarily restricts the items that can be stored in areas with exposed studs, joists and rafters, and therefore unnecessarily limits business licensees in how they manage storage space. The real problem is moisture. Areas subject to moisture must be properly constructed to ensure that surfaces can be easily cleaned and food and equipment stored in these areas are protected from contamination. Prohibiting exposed studs, joists, and rafters that would be exposed to moisture effectively protects public health by controlling mold growth, and still gives operators flexibility when organizing storage areas that are not subject to moisture.

The departments made these revisions to more accurately address the real hazard, which gives operators increased flexibility and maintains public health protection.

4626.1375 LIGHT BULBS; PROTECTIVE SHIELDING. 6-202.11

The departments changed “shall” to “must.”

4626.1380 HEATING, VENTILATING, AND AIR CONDITIONING SYSTEM VENTS. 6-202.12

The departments replaced “food preparation” with “food-contact,” which is a more comprehensive, defined term in this Code. Consistent use of defined terms improves the accuracy of this Code.

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4626.1385 INSECT CONTROL DEVICES; DESIGN AND INSTALLATION. 6-202.13

The departments revised this part to ensure that insect-zapping devices collect dead and stunned insects, as well as insect fragments, within the control device to prevent them from contaminating nearby equipment and food product. Insects, including their fragments, can contain microbial pathogens. This restriction, which allows LRFEs to use the devices, is reasonable and necessary to protect public health.

4626.1390 TOILET ROOMS; ENCLOSED. 6-202.14

The departments reorganized the enclosed-restrooms rule for clarity by adding a reference to part 4626.1555, which helps operators identify all requirements for bathrooms without duplicating the specific regulations.

This change to makes this requirement more useful.

4626.1395 OUTER OPENINGS; PROTECTED. 6-202.15

The departments re-wrote items A and B to make them easier to read. We expanded item C to provide criteria for certain infrequently used doors such as fire exits and delivery doors that no longer need to be self-closing. Closed, tight-fitting doors properly protect public health by preventing insects and other pests from entering the LRFEs. Existing items B and C were reorganized as items D, E, and F for clarity and readability.

4626.1400 EXTERIOR WALLS AND ROOFS; PROTECTIVE BARRIER. 6-202.16

The departments added a phrase that clearly refers to the new item B as the exception to item A, which already requires the walls and roofs of a food establishment to shut out weather and vermin.

As the exception to item A, item B requires food operations that do not take place in a permanent building to protect food and equipment from environmental contamination. Such operations are often located outdoors, without permanent walls or ceilings. Awnings, tents, or umbrellas often commonly provide temporary protection. Nevertheless, rain, wind, or flooding may contaminate

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food and food-contact surfaces. Protecting health requires that temporary food establishments, food carts, special event food stands, and retail food vehicles, portable structures, or carts operate only with adequate protection.

Requiring the operation to simply cease if protection fails, allows the operator to select the type and style of protection that suits the operation's business plan, and is therefore reasonable. The operator thus has the flexibility to balance initial protection costs against benefits of operating in inclement weather, while protecting public health. In addition, item B now concisely covers the requirements for walls and roofs of portable establishments previously addressed by the now-repealed Chapter 9.

4626.1405 OUTDOOR FOOD VENDING AREAS; OVERHEAD PROTECTION. 6-202.17

The departments changed "shall to must."

4626.1410 OUTDOOR SERVICING AREAS; OVERHEAD PROTECTION. 6-202.17

The departments changed "shall to must."

4626.1415 OUTDOOR WALKING AND DRIVING SURFACES; GRADED TO DRAIN. 6-202.19

The departments removed the superfluous phrase "food establishment." That this Code applies to a food establishment is implicit.

4626.1420 OUTDOOR REFUSE AREAS; CURBED AND GRADED TO DRAIN. 6- 202.110

The departments changed "shall" to "must."

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4626.1425 PRIVATE HOMES AND LIVING OR SLEEPING QUARTERS; USE PROHIBITION. 6-202.111

The departments changed “shall” to “must.”

4626.1430 LIVING OR SLEEPING QUARTERS; SEPARATION. 6-202.112

The departments changed “shall” to “must.”

4626.1435 6-301.10 MINIMUM NUMBER.

The departments deleted this part because part 4626.1070 addresses the minimum number of handwashing sinks. Deleting obsolete or unnecessary requirements is reasonable.

4626.1440 HANDWASHING SOAP; AVAILABILITY. 6-301.11

The departments simplified this part about soap at handwashing sinks without changing its meaning.

We also deleted the requirement that an operator have a nailbrush at sinks used by employees because we now know that nailbrushes cause more harm than good. This is especially so when a brush is shared among a large group of people, presenting a food safety hazard. Nailbrushes’ small pockets at the base of the bristles create a moist place for pathogens to live and grow.

In addition, employees use nailbrushes improperly and do not maintain them throughout the day, allowing a pathogen reservoir to form. Employees can remove dirt from under fingernails effectively if they generate the proper friction for adequate handwashing time. Even worse, regulators observe employees incorrectly use nailbrushes in contact with exposed food, such as scrubbing produce items during washing. Simply removing the nailbrush requirement is a better alternative for protecting public health compared to the existing rule. For these reasons, removing the nailbrush requirement is reasonable and necessary.

4626.1445 HAND DRYING PROVISION. 6-301.12

The departments brought the hand-drying methods up to date by deleting one requirement and adding another option.

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In the existing Code, item C allows LRFEs to provide employees with a heated-air hand dryer at sinks in food preparation and warewashing areas, so long as the heated-air hand dryer is not the only device provided. The departments have since dropped this condition because they have determined requiring additional hand drying methods when using heated-air hand dryers is unnecessary.

Wet hands can transfer up to 1000 times more pathogens than dry hands. When properly used, heated-air hand dryers eliminate moisture on hands, thus reducing pathogen transmission to food and food-contact surfaces accordingly. Regulatory authorities frequently find paper towel dispensers empty during inspections, meaning that food workers have no available method of hand drying.

Heated-air hand dryers alone provide proper hand hygiene for foodservice employees. In addition, operators can reduce cost, maintenance, and waste so that a cleaner, hands-free environment exists. This increases the likelihood that workers will wash their hands. Thus, removing the additional requirement for heated-air hand drying devices is reasonable because it is cost effective for licensees and operators and reflects current practice that effectively protects public health.

The departments added an option in new item D that allows LRFE to use air-knife technology for hand drying. Data reviewed by the Food and Drug Administration demonstrates that this technology in hand dryers is equivalent to the hand-drying treatment in existing heated-air devices.

A recent information conclusively provides new evidence for what the existing Code already promotes—effective hand drying prevents pathogens from being transferred from hands to the next surfaces touched. Industry continues to develop and enhance hygienic hand-drying practices. For example, the ultra-rapid Airblade™ hand dryer, with its short, ten-second drying time using HEPA-filtered air, was shown to be superior to the warm-air dryers for reducing pathogens.

These desirable innovations, coupled with eliminating paper waste, will encourage greater compliance with hand drying and reduce the spread of infectious agents by the hand-borne route. Accommodating new emerging trends and technology used in the food industry, while still protecting public health risks from improperly dried hands, is reasonable.

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4626.1450 DISPOSABLE TOWELS; WASTE RECEPTACLE. 6-301-20

The departments changed “shall” to must” and updated the citation reference.

4626.1455 HANDWASHING AIDS AND DEVICES; USE RESTRICTIONS. 6-301.13

The departments changed “shall” to must” and “lavatory” to “sink.”

4626.1457 HANDWASHING SIGNAGE. 6-301.14

The departments added this new part about “handwashing signage” because research has shown that food workers wash their hands more frequently when LRFEs provide signs or posters to remind them, making it an intervention that has measurable success.

Handwashing is a critical factor in reducing transmission of pathogens to food and many employees do not wash their hands as often as necessary. Because posting a handwashing sign is already common practice in the majority of LRFEs, many LRFEs already comply with this requirement.

Also, regulatory agencies frequently provide handwashing signs at no cost to operators. Thus, there is little added burden. In conclusion, since signs or posters provide a visual reminder that increases handwashing behavior, requiring LRFEs to provide them is reasonable and necessary.

4626.1460 6-302.10 TOILETS AND URINALS; MINIMUM NUMBER.

The departments deleted this part because part 4626.1075 addresses the requirement, making it superfluous here.

4626.1465 TOILET TISSUE; AVAILABILITY. 6-302.11

The departments changed “shall” to “must.”

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4626.1470 LIGHTING INTENSITY. 6-303.11

In item B, subitems (1) and (2) and item C, the departments replaced the word “including” with the words “such as,” which serves to introduce the examples following it. Using such examples clarifies the departments’ intent of what this Code permits.

Employees need to see dirty hands, utensils, equipment, and surfaces to properly clean them, actions that are essential to avoid contaminating food and food contact surfaces. Therefore, the departments added the words “handwashing” and “warewashing” in item B, subitem (3) other parts of this Code do not address the food establishment’s need for adequate light. We also specified the minimum lighting intensity for cleaning utensils, equipment, and surfaces.

The departments are removing subitem (4) because lighting requirements in items A, B and C of this part apply to areas behind the bar and the activities conducted there. Therefore, subitem (4) is unnecessary.

4626.1475 VENTILATION; MECHANICAL. 6-304.11

The departments changed the ventilation requirements to do two things: require that all passive airflow systems have mechanical systems that circulate the air properly, and mandate that LRFEs prevent grease from accumulating in their ventilation system and rooms.

In item A, we now require mechanical ventilation so that passive airflow systems achieve sufficient make-up air that other existing state standards require. Passive airflow systems that do not mechanically move air may be inconsistent and ineffective when eliminating grease, heat, steam, etc. A ventilation system that does not supply mechanical make-up air will create a negative pressure situation in the building, which will decrease the ventilation system’s performance.

LRFEs must prevent grease from building up in the system and rooms, so it can operate efficiently in the rooms. Grease is a by-product of the cooking process of foods containing fats that escape as particles into the air and can congeal on surfaces, making surfaces harder to clean, and providing a flammable substance which may cause health and safety hazards.

We also referred to existing state standards for simplicity and to avoid confusion by duplicating or creating new standards is reasonable because it simplifies this Code and improves clarity.

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4626.1480 DRESSING ROOMS AND LOCKERS; DISIGNATION. 6-305-11

The departments changed “shall” to “must.”

4626.1485 6-306.10 SERVICE SINK; AVAILABILITY.

The departments deleted this part because the requirement is addressed in part 4626.1080. Repeating the requirements is unnecessary and duplicate requirements in multiple locations may cause confusion. It is reasonable to delete obsolete or unnecessary requirements from this Code.

4626.1490 6-401.10 HANDWASHING LAVATORIES; CONVENIENTLY LOCATED.

The departments deleted this part because the requirement is addressed in part 4626.1095. Repeating the requirements is unnecessary and duplicate requirements in multiple locations may cause confusion. It is reasonable to delete obsolete or unnecessary requirements from this Code.

4626.1495 TOILET ROOMS; CONVENIENCE AND ACCESSIBILITY. 6-402.11

The departments changed “shall” to “must.”

4626.1500 EMPLOYEE BREAK AREAS, LOCKERS; LOCATION. 6-403.11

The departments changed “shall” to “must.”

4626.1505 RETURNED PRODUCTS; SEGREGATION AND LOCATION. 6-404.11

The departments changed “shall” to “must.”

4626.1510 6-405.10 EQUIPMENT, RECEPTACLES, AND DESIGNATED STORAGE AREA.

The departments deleted this part because the requirement is addressed in part 4626.1270. Repeating the requirements is unnecessary and duplicate requirements in multiple locations may cause confusion. It is reasonable to delete obsolete or unnecessary requirements from this Code.

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4626.1515 PHYSICAL FACILITIES; GOOD REPAIR. 6-501.11

The departments changed the word “shall” to “must.”

4626.1520 PHYSICAL FACILITIES; CLEANING FREQUENCY AND RESTRICTIONS. 6-501.12

The departments changed “shall” to “must.”

4626.1525 CLEANING FLOORS; DUSTLESS METHODS. 6-501.13

LRFEs must use dustless methods of cleaning to prevent food, equipment, utensils, linens, and single-service and single-use articles from being contaminated. The departments have modified item A and item B, subitem (2) to provide examples rather than an all-inclusive list to make this Code more flexible.

4626.1530 CLEANING VENTILATION SYSTEMS; NUISANCE AND DISCHARGE PROHIBITION. 6-501.14

The departments changed “shall” to “must.”

4626.1535 CLEANING MAINTENANCE TOOLS; PREVENTING CONTAMINATION. 6-501.15

The departments replaced “lavatories” with “sinks” because the new term is more commonly used and easier to understand. This part’s intent remains unchanged. The changes are necessary and reasonable.

4626.1540 DRYING MOPS. 6-501.16

The departments changed “shall” to “must.”

4626.1545 ABSORBENT MATERIALS ON FLOORS; USE LIMITATION. 6-501.17

The departments changed “shall” to “must.”

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4626.1550 CLEANING OF PLUMBING FIXTURES. 6-501.18

The departments expanded the existing requirement for handwashing lavatories to all plumbing fixtures and added examples of fixtures, which are not addressed elsewhere in this Code. These changes are needed because cleaning these fixtures will prevent contamination from employees to food and food contact surfaces.

For example, people ill with the highly infectious norovirus shed the virus in high numbers in vomit and feces. In studies on norovirus transmission via fingers, cloths, and contact surfaces, the epidemiological evidence suggests that the virus spreads through the environment from an infected person by aerosol particles. Splash from vomit or toilet flushing creates the aerosol particles, which settle on contact surfaces such as toilet seats or handles. People who touch these contaminated surface can then spread the virus with their hands.

Adding cleaning requirements for additional plumbing fixtures is a necessary and reasonable preventative measure to keep pathogens from spreading. The reference to part 4626.1110 is not relevant to the plumbing-fixture cleaning required here in this Code. The departments have deleted it.

4626.1555 CLOSING TOILET ROOM DOORS. 6-501.19

The existing Code requires that the food establishment keep toilet room doors closed. The departments have added exemptions for cleaning and maintenance operations and so that toilet rooms designed without doors are allowed. This change is needed to reflect current industry practices. This design does not pose any public health issues.

4626.1560 USING DRESSING ROOMS AND LOCKERS. 6-501.110

The departments changed “shall” to “must.”

4626.1565 6-501.111 CONTROLLING PESTS. 6-501.111

The department added an affirmative duty in item A for LRFEs to keep the premises free from insects, rodents, and other pests. The existing Code requires operators and owners to eliminate

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the pests. By this change, the departments are requiring pest prevention and elimination. Pest control needs no explanation.

In addition, the departments replaced the word “minimize” with the word “eliminate,” because there is no tolerable amount of pests or insects in a LRFE. Requiring LRFEs to both prevent and eliminate pests is both necessary and reasonable.

The departments reorganized item C to provide examples rather than an all-inclusive list makes this Code more flexible. Making it clear that other similar circumstances are violations of this Code is reasonable because it makes this Code more understandable and strengthens enforcement.

4626.1570 REMOVING DEAD OR TRAPPED BIRDS, INSECTS, RODENTS, AND OTHER PESTS. 6-501.112

The departments changed “shall” to “must.”

4626.1575 STORING MAINTENANCE TOOLS. 6-501.113

The departments revised the introductory phrase of this part to emphasize the point that this part refers to maintenance tools for buildings and equipment, as opposed to equipment used with food. Providing examples rather than an all-inclusive list emphasizes the harm the departments are addressing and allows for more flexibility in this Code. Making this Code clearer and more understandable is both necessary and reasonable.

4626.1580 MAINTAINING PREMISES; UNNECESSARY ITEMS AND LITTER. 6-501.114

The department streamlined this part by deleting the superfluous words “food establishment,” since food establishments are the subject of this Code.

The departments deleted the word “including” and replaced it with “such as” in item A to provide examples instead of being restricted to the listed items provided in this part. Providing examples adds flexibility in this Code and makes enforcing this Code clearer.

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4626.1585 PROHIBITING ANIMALS. 6-501.115

The departments revised this part, which prohibits live animals from LRFEs, for clarity. This Code already contains restrictions to protect all customers from the health or safety hazards that live animals create. Minimizing direct or indirect contamination of food and food-contact surfaces from animal-carried pathogens remains paramount. The departments updated existing protections that are already in place to make it clearer what situations are allowed and what are not.

In item B, the word “cannot” does not make sense, so the departments replaced it with “does not,” restating the requirement in terms of a food establishment’s responsibility to prevent contamination. This change does not affect intent.

The departments revised item B, subitem (3), that applies to what existing Code calls “support animals,” to instead use the terms “service” and “disabled.” We did this to conform with terms used in the Code of Federal Regulations, which adopted rules under the Americans with Disabilities Act (ADA) of 1990. Using terms provided in other standards that are applicable to regulated parties is reasonable because it provides clarity and consistency.

In addition, the departments revised subitem (3) to identify the customer areas where service animals are allowed and provide examples. Adding language and providing examples is reasonable because it makes this Code clearer and protects public health and safety.

The departments made a similar change for clarity in item B, subitem (4) by adding the words “institutional care facilities.” This broader term identifies the category better than the existing “group residences.”

New language is added and examples are provided in item B, subitem (5) about other situations where animals may be displayed. The revision is needed because it clarifies that animals that are confined or caged cannot be in the food preparation, storage, sales, display, or dining areas. Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. Adding language for caged or confined animals and providing examples is reasonable because it was not addressed in this Code and the requirement protects public health and safety.

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In item C the restrictions apply to the storage of live or dead fish bait because these animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food contact surfaces. The word “fish” is being added to clarify bait is used for fishing as opposed to other types of bait that may be used for hunting purposes and which may be a greater risk to public health than fish bait. The words “food preparation areas” are being deleted because these areas are already addressed in this item. The words “allowed if separately” are being deleted because they do not add to the content of this requirement. Bait must be stored so that contamination of food, clean equipment, utensils and linens; and unwrapped single-use articles cannot result. It is reasonable to add and delete language because it simplifies and clarifies this Code without changing the meaning.

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Chapter 7, Poisonous or Toxic Materials

4626.1590 POISONOUS OR TOXIC MATERIALS; IDENTIFYING INFORMATION 7-101.11

The departments changed “shall” to “must.”

4626.1595 POISONOUS OR TOXIC MATERIALS; COMMON NAME. 7-102.11

The departments refined the language to clarify that all poisonous and toxic materials must be labeled with a common name. The requirement remains the same as existing rule.

4626.1600 POISONOUS OR TOXIC MATERIALS; STORAGE. 7-201.11

The departments changed “shall” to “must.”

4626.1605 POISONOUS OR TOXIC MATERIALS; RESTRICTION. 7-202.11

The departments made minor changes for clarity.

4626.1610 POISONOUS OR TOXIC MATERIALS; CONDITIONS OF USE. 7-202.12

The departments corrected statute and rule references.

In addition, the departments revised “certified” to “licensed” so that this Code and *Minnesota Statutes*, chapter 18B are consistent.

4626.1615 POISONOUS OR TOXIC MATERIAL CONTAINERS. 7-203.11

The departments changed “shall” to “must.”

4626.1620 SANITIZERS; CRITERIA. 7-204.11

LRFEs customarily generate their own sanitizers by mixing chemicals with water. The departments clarified this part to dispel confusion by making it explicit that these requirements

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for sanitizers include those generated on site. We also brought the Code of Federal Regulation (CFR) citations up to date to include the current federal requirements.

4626.1625 CHEMICALS FOR WASHING, TREATMENT, STORAGE AND PROCESSING; FRUITS AND VEGETABLES; CRITERIA. 7-204.12

The departments revised this part to include the relevant federal requirements adopted since Minnesota last revised the existing Code. We listed all requirements for chemical washing, treatment, processing, and storage of fruits and vegetables in this single part of the Code. Citing all of the requirements here will enhance compliance because it allows operators and regulators to have ready access to the information without referring to other documents.

This Code limits LRFEs to using chemicals used to those that the federal government has approved as safe. Obviously, unsafe chemicals may cause illness, injury, or death, whether caused by accidentally applying a chemical to food or due to chemical residues that remain on equipment and utensils. Only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior sanctioned, or exempted by the threshold of regulation process can be used.

The departments added the reference to the complete 21 CFR 173 “Secondary Direct Food Additives Permitted in Food for Human Consumption,” which includes several provisions permitting certain food additives to be used for washing fruits and vegetables. Including all of 21 CFR 173, makes it clear that other permitted food additives are allowed. The program called “Generally Recognized As Safe” (GRAS) also approves antimicrobial agents for washing fruits and vegetables. In addition, the Food Contact Notification Program allows food establishments to use food contact substances that the Program has identified as safe.

We also added the provision that all chemicals used for washing or peeling whole fruits and vegetables must comply with 40 CFR 156 which requires: Human Hazard and Precautionary Statements, Environmental Hazard and Precautionary Statements, Container Labeling, and Worker Protection Statements (§§ 156.200–156.212)

LRFEs using ozone with fruits and vegetables must also comply with specific federal requirements. The departments added this item to include these requirements here too.

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4626.1630 BOILER WATER ADDITIVES; CRITERIA. 7-204.13

The departments changed “shall to “must” and clarified the CFR citation.

4626.1635 DRYING AGENTS; CRITERIA. 7-204.14

The departments updated this part to include all federal requirements for drying agents used in LRFEs because residues might remain from drying agents used. If the chemical used contains unsafe components, illness might result. This is why only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior-sanctioned, or exempted by the threshold of the regulation process can be used. This change conforms this Code to federal law.

4626.1640 LUBRICANTS; INCIDENTAL FOOD CONTACT; CRITERIA. 7-205.11

The departments changed “shall to “must” and clarified the CFR citation.

4626.1645 RESTRICTED USE PESTICIDES; CRITERIA. 7-206.11

The departments changed “shall to “must” and clarified the CFR citation.

4626.1650 RODENT BAIT STATIONS. 7-206.12

The departments changed “shall to “must.”

4626.1655 TRACKING POWDERS; PEST CONTROL AND MONITORING. 7-206.13

The departments clarified the type of pest tracking powders that are allowed in LRFEs. Some pest tracking powders are toxic to humans. The changes make it clear that licensees and operators may use only non-toxic tracking powders, which they cannot permit to contaminate the LRFE. Examples are included but the language does not limit usage to those examples. The new language provides clear requirements. It is reasonable and necessary to protect public health.

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4626.1660 EMPLOYEE MEDICINES; RESTRICTION AND STORAGE. 7-207.11

The departments changed the word “shall” to “may” in item A to better express the licensee and operator’s duty to limit substances on the premises under its control.

The departments determined that the language in existing item B is too limiting. Employee medication stored in any LRFE, not just day care and board and lodging facilities is subject to accidental or malicious use. This change addresses this hazard by limiting storage of medication at LRFEs. It also specifies the labeling requirements for storing necessary medications to prevent misuse or otherwise contaminating food or food-contact surfaces. Such personal medications must be labeled and stored according to the requirements that apply for poisonous or toxic materials. Proper labeling and storage of medications is necessary to ensure that they are not accidentally misused. These requirements are reasonable.

4626.1665 REFRIGERATED MEDICINES; STORAGE. 7-207.12

The departments changed “shall” to” must.”

4626.1670 FIRST AID STORAGE. 7-208.11

The departments changed “shall” to” must.”

4626.1675 PERSONAL CARE ITEMS; STORAGE. 7-209.11

The departments revised this language to clarify the location of approved employee storage of personal items, as required in this Code. Proper storage of employee personal care items is necessary and reasonable to ensure they do not contaminate food, food equipment, or food contact surfaces.

4626.1680 POISONOUS OR TOXIC MATERIALS; SEPARATION. 7-301.11

The departments changed “shall” to “must.”

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Chapter 8, Compliance and Enforcement

4626.1685 PUBLIC HEALTH PROTECTION. 8-101.10

The revisions to this part accomplish three things:

- Remove a superfluous restatement of this Code's purpose;
- Add a reference to part 4626.0506; and
- Add a requirement that deferred equipment replacement be spelled out in written agreements.

The departments deleted the restatement of the intended purpose and applicability of this Code because this information already appears in part 4626.0015 so as to avoid confusion from having duplicative language.

Because we deleted "A," this section has been re-lettered.

This Code carries over provisions from the existing Code that allow LRFEs to continue using older equipment within limits. To that end, the departments added a reference to part 4626.0506, which is a new part listing the 10 types of equipment or food contact surfaces that must be certified or classified to ANSI sanitation standards. Compliance with part 4626.0506 is critical to ensuring safe food. Please refer to the need and reasonableness discussion for the part 4626.0506 requirements.

Adding this citation alerts operators or reminds them of all criteria the regulatory authority use to assess facilities and equipment in service before September 8, 1998. Listing all assessment criteria in one place is a reasonable approach.

Formal agreements for correction of existing equipment and facility deficiencies provide a definite record of what regulated parties and regulatory agencies have agreed to and spell out how facilities and equipment will be brought into compliance. Such compliance agreements between the regulatory authority and the operator are a needed and reasonable protective measure that allow operator flexibility while postponing corrective action that does not pose an imminent public health hazard. A written agreement for replacement of non-compliant equipment provides a timeline for compliance and a basis for further enforcement action if the agreement is not fulfilled.

Allowing regulated parties to use certain commonly available equipment when it has been demonstrated as safe and sanitary is reasonable to allow. It is reasonable to also acknowledge compliance-agreement use between the regulatory authority and the operator to gain compliance over a period of time.

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4626.1690 VARIANCE REQUEST; PROCEDURES. 8-103.11

The departments changed the term “party” to “person” throughout this part upon the Revisor's advice. The word “person” is a term used in statutes and other rules and has a specific legal meaning. This modification is both needed and reasonable to ensure correct usage and consistency with statutes and other rules.

We also corrected rule references. These changes are self-explanatory so we will not describe each one that appears after this explanation.

So that regulated persons and regulatory agencies stay current about variance terms, a person that is granted a variance must keep current approval documents in its files to ensure compliance. The regulated person needs to know, and have readily available, any approvals for deviation from the public health protections specified in this Code to ensure compliance.

Maintaining records on-site also provides easy access to that LRFEs modified requirements and allows the regulated person to maintain control over the documentation. Requiring that the regulated person maintain and bear responsibility for maintaining current approval records for their LRFE is reasonable.

If a variance requires a HACCP plan, the LRFE must submit it with the variance request. Because some specialized processes, such as curing and reduced oxygen packaging, need unique risk controls, HACCP plans are required. The HACCP plan contains the information that shows public health protection from identified hazards; it might show procedures that are contrary to or augment the interventions that this Code prescribes. The specialized processes are identified and HACCP plan requirements are spelled out in other parts of this Code. Required HACCP plans need to be submitted to the regulatory authority for the authority to carry out a comprehensive review of a variance request.

Requiring a variance applicant to submit all the information relevant for the comprehensive review of a request is obviously necessary and reasonable.

4626.1695 VARIANCE REQUEST; CRITERIA FOR DECISION.

The departments added the phrase “variance request” to the title to clarify the topic of this part.

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4626.1700 VARIANCE CONDITIONS; HACCP; NOTIFICATION OF DECISION. 8-103.12

A variance is a legal agreement between the regulatory authority and regulated person. We added item D, which declares that variances cannot be transferred from the original person receiving the variance to a new licensee or operator. When ownership changes, that agreement is no longer valid. Current practice is to declare the non-transferable nature as a condition of the variance approval. Adding this provision in this Code strengthens the departments' policies by making it a regulatory provision and thus law instead of a conditional measure the agencies must include each time. Adopting this measure as a rule meets the purpose of the Administrative Procedure Act.

4626.1705 VARIANCES; EFFECT OF ALTERNATIVE MEASURES OR CONDITIONS. 8-103.13

For the discussion of the change from "party" to "person," please see part 4626.1690.

4626.1710 RENEWAL OF VARIANCE.

For the discussion of the change from "party" to "person," please see part 4626.1690.

4626.1715 VARIANCE DENIAL, REVOCATION, OR REFUSAL TO RENEW; APPEALS.

For the discussion of the change from "party" to "person," please see part 4626.1690.

4626.1720 PLANS; REVIEW REQUIRED. 8-201.11

This Code makes it clear that a firm acting on behalf of a regulated party may submit a plan review application. Many LRFE licensees hire consultants, architects, or contractors to submit plans. This change reflects current practice that happens in approximately 50% of submitted plans. Business partners may provide expertise in construction, equipment selection and installation, or specialized processing. Granting plan-submitting authority to them supplies a reasonable support that eases the process for everyone.

The departments revised item A, which addresses the approval step necessary to prevent regulated persons from treating the application as the end of their obligations. The licensee must wait until the regulatory authority approves its plan before starting construction. Adding this language is needed because persons have started construction before the plans were approved

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and suffered expense and delay because of having to tear out and redo parts of the construction—very undesirable consequences. Adding this approval language at the beginning of the section is reasonable to add emphasis and we hope, will avoid future problems.

Item B adds necessary detail about the location of the plan review applications fee schedule location. We deleted obsolete rule and statutory references and added the correct statutory requirement. These changes are self-explanatory.

We added item F to clearly state the regulatory authority's right to halt construction when it has determined that the work in progress will lead to noncompliance. If a regulated party were to continue work when significant problems are identified, the regulatory authority's ability to further observe and verify compliance with the law as the construction and installation is completed may be hindered. Thus, the regulatory authority needs to be able to stop the work until the regulated party modifies its plans and the regulatory authority approves them, which will assure that this Code's requirements are being met and the regulated party will avoid costs associated with correction.

4626.1725 CONTENTS OF PLANS AND SPECIFICATIONS. 8-201.12

The departments revised this part to require that plans submitted for review include a project description.

Having a project description creates efficiency by allowing the regulating authority to see immediately which of a variety of possible reasons that a plan is being submitted for approval. The submitted plan might include existing conditions mixed with intended modifications. Obviously, a regulatory authority that has this information clearly in front of it without having to discern for itself what the scope of the project is will speed the review. The authority can focus then on the proposed changes related to the scope of work.

Having plan submitters provide a summary statement that describes a project will avoid assumptions and misidentification of the scope of work is therefore reasonable. This will also assist in the communication between the regulated party and the regulatory authority.

Item C adds the requirement that regulated persons submit one set of plans drawn to scale. This standard is needed to evaluate traffic patterns, process flows, and the accessibility of support equipment and facilities. For example, determining the convenience for washing hands is difficult if the measured size of the room and the physical obstacles present are not reflected specifically on paper so the reviewer can see them. Equipment placement has a significant

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impact on food safety, especially handwashing and equipment cleaning areas. These necessary standards are reasonable.

Item C also contains new clarifying language about finish schedules to include in the plan. Not submitting finish schedules has been a problem for many projects. Such an omission has delayed reviews and resulted in costly corrections when the wrong type of flooring or wall surface has been installed. The regulating authorities must see this information because each area in a LRFE has specific floor, wall, and ceiling surface requirements that ensure these surfaces are capable of being maintained in a safe and sanitary condition depending on the specific environmental stresses of the area. Adding this requirement to plans makes it clear that it is a requirement for plan review so those submitting the plans can comply efficiently when submitting their scale drawings. This too is a reasonable change.

New language was needed in item D to clarify that the required information needs to be included on the layout, not as separate documents. Reviewing plans is difficult if all necessary information is scattered among different documents. This change is necessary and reasonable to save time during the review and give the reviewer a better understanding of the project.

We added language in item E requiring a HACCP plan be submitted as part of the plan review when applicable. The combined steps of the regulated person submitting the plan and the regulatory authority reviewing it present an expeditious opportunity to lay a solid food safety foundation for the proposed operation. Regulatory agency staff and business licensees and operators can collaborate to establish and maintain a plan for compliance with this Code. A HACCP plan, a document describing procedures the LRFE will follow to protect public health by controlling scientifically identified hazards, is required for certain specialized food processes identified in this Code. Regulatory plan reviewers need the information provided in the HACCP plan to work with licensees and operators to ensure that they possess the requisite knowledge and equipment for proposed specialized processes adequate to protect the public from foodborne illness.

Having a required HACCP plan be submitted with other required elements of plans is reasonable. Evaluating the HACCP plan is an integral part of the plan review and helps both plan reviewer and operator assess the full scope of the operation.

Item F requires that counter and cabinetry shop drawings must be included in the submitted plan. Surfaces in LRFEs are usually exposed to splash, spillage, and other food soiling and thus are cleaned frequently. These surfaces need to be corrosion-resistant, nonabsorbent, and smooth to keep these surfaces sanitary and safe. Voids and spaces that may allow entry of insects, rodents,

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and other pests must be minimized. Regulatory agency staff need to review shop drawings as a part of plan approval to prevent conditions that promote sanitation problems. The departments moved the requirement to submit a set of elevations and drawings for custom fabricated equipment from item D to item F for logical consistency.

Item G relates to a LRFEs need to have an adequate supply of safe drinking water to safely store, prepare, and serve food and beverages to the public. The LRFEs evidence for satisfying this plan and specification requirement is supplying its unique well number and individual sewage treatment system certificate of compliance for individual sewage disposal systems.

The LRFEs water supply must be protected from contamination, including the waste disposal system the LRFE uses itself. A LRFE may be served by either public or private water and sewer systems. Well design standards and routine testing for bacteria and nitrates are typical for these non-community water supplies and the identifying information allows the regulating authority to verify the correctness of the LRFEs information.

Privately constructed and maintained sewage systems that include septic treatment systems must meet compliance standards that a variety of regulatory entities (MPCA, counties, and cities) have jurisdiction over. The regulatory authority needs to review documentation that shows the system is properly installed and maintained as part of its plan review.

It is both necessary and reasonable for the regulatory authority to verify during plan review that water supply and waste disposal systems associated with a LRFE comply with applicable laws under their respective jurisdictions. In this way, the persons assure public health.

Item H requires that an operator also submit a copy of the zoning approval or building permit with the plans and specifications. New construction or remodeling of food and beverage LRFEs requires approval from several authorities. This requirement makes sure that LRFE licensees, operators, and contractors to have met their obligations for multiple approvals, and the regulatory authority carries the responsibility of verifying it. Requiring an operator to prove to the regulatory authority through public record a building or installation plan is reasonable. Making sure that an operator has satisfied the different responsibilities for ensuring health, safety, and public welfare carried by the various regulatory authorities is extremely important.

Item I removes the superfluous descriptive word "proper" from the review description for additional information submitted. The word proper does not add to the content requirement for a plan review. Removing this word does not change the meaning of this Code provision.

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Item B was deleted. Item B referred to the Chapter 8 requirement that the regulatory authority approve used equipment before the regulated party used them.

Equipment standards are addressed in Chapter 4 of this Code. Repeating the requirements here is unnecessary and might cause confusion. Removing equipment requirements from this part of this Code to improve readability and clarity is reasonable.

4626.1730 WHEN A HACCP PLAN IS REQUIRED. 8-201.13

The departments deleted old language because it was out of date and confusing.

Before engaging in certain food processes that require special steps for the control of public health risks, LRFEs must submit their HACCP plans and variance requests to regulatory authorities. When a HACCP plan will be required by this Code, the license applicant or licensee must submit that plan before beginning HACCP operations. The addition of language in this part is necessary to outline the conditions which would require a HACCP plan submission.

Item A and subitems 1 and 2 provide specific details related to variance approvals and their relation to HACCP plan submission requirements. This is needed to clarify that a variance request and approval by itself does not replace the need to have a HACCP plan reviewed and approved prior to implementing certain food handling processes.

Subitem 1 specifically addresses variances issued for cooking raw animal products to a temperature that is lower than prescribed in other parts of this Code. This deviation from specific times and temperatures must be evaluated to determine if an equivalent bacterial load reduction happens at a lower temperature or reduced amount of time so that risks of infection are adequately controlled. Additionally, it addresses life support tanks for molluscan shellfish which are susceptible to introducing sources of contamination into the shellfish because they are filter feeder organisms which readily absorb items from their surrounding environment.

Subitem 1 also needs to reference special food processing which involve acidification, smoking for preservation, and other food handling techniques that would allow a food to be stored at a temperature or length of time outside of normal parameters which would require a variance. A HACCP plan is required for these special processes to ensure the specific element of the particular food processes that control pathogenic bacteria are guaranteed and acceptable steps are taken to monitor the food processes and take corrective action should a protocol deviation occur.

Many times operators are unaware that a particular food process or use of a specific piece of equipment or ingredient requires a HACCP plan. Language in subitem 2 is needed so that there

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is a check point in place for submission of a HACCP plan when inspection staff or plan reviewers identify equipment commonly used with special processes. An example of this would be identifying a vacuum packaging machine used for reduced oxygen packaging during a routine inspection or when plans are submitted. Because the inventory of equipment within a LRFE is fluid and can change between inspections it is necessary that HACCP plan submission be required if a specific piece of equipment is identified by the regulatory authority during inspections or when plans for construction are submitted.

The language we added to item B is necessary because there are now instances allowed by the Code where a variance is not required for reduced oxygen packaging because there is no deviation from time, temperature, or date marking requirements. However, there is still a distinct risk for dangerous pathogen growth when the oxygen composition is altered in this type of packaging. Because it may not be obvious without a variance request and approval, the language in this item needs to be added so that it is clear to operators and the regulatory authority that extraordinary risks must be controlled through a properly developed and implemented HACCP plan.

We also removed a provision that applied to LRFEs who were conducting HACCP operations before January 26, 2000. Because HACCP has been required for over 15 years, and because HACCP plans are verified annually, this provision is now obsolete.

These revisions are reasonable because they consolidate information previously spread throughout this Code into a concise section detailing when a HACCP plan must be submitted and how the requirements for a HACCP plan submission related to instances where a variance may be issued. This will provide better understanding of and compliance with HACCP requirements and will expedite the HACCP plan submission process because of increased awareness on the part of both operators and the regulatory authority.

4626.1735 CONTENTS OF HACCP PLAN. (See also part 4626.0420) 8-201.14

This part identifies the information required when submitting a HACCP plan.

Information required when submitting a HACCP plan needs to be the same for HACCP plans prepared due to variance requirement and HACCP plans for reduced oxygen packaging (ROP) without a variance. There is no need to separate the requirements for these two types of plans. New language does not limit public health protection, and is clearly aligned with accepted national standards for HACCP plan contents. The new language is also not significantly more burdensome for LRFEs conducting reduced oxygen packaging when compared to other special

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processing methods requiring a HACCP plan. The U. S. Food and Drug Administration approved these standards and they have been widely adopted by industry over the previous decades. Using these standards streamlines Minnesota's process for submitting and approving them and provides consistency for LRFEs operating nationwide.

Incorporating accepted national standards for HACCP plans is reasonable because it provides a clearer path for the time-consuming and technical work of writing a HACCP plan. Multi-state food businesses that operate in Minnesota will find developing and submitting HACCP plans for Minnesota jurisdictions more efficient when our requirements match the national standard. This will also reduce time and resources regulatory agencies dedicate to individual HACCP plan reviews.

The departments deleted item B, which is redundant because it states requirements that already appear in part 4626.1730. This deletion of this language is reasonable because the contents of a HACCP plan are now uniform across all special food processing types and in alignment with requirements for reduced oxygen packaging. The deleted language provided two tracks for HACCP plan content where some information required for special processes was not required for reduced oxygen packaging. This made for a confusing plan submission on the part of operators and for increased review time on the part of regulatory agencies.

Submitting general identifying information about the license applicant or licensee and LRFE, as required in item A, in the HACCP plan, is needed to identify which LRFE is submitting the plan. The new language we have added is simple and easy to understand and provides vital information for correspondence with the LRFE submitting the plan.

In item B, foods covered by the HACCP plan must be identified by category in the submitted HACCP plan. A HACCP plan does not need to list all the TCS foods on the menu because most TCS foods do not require HACCP. When HACCP is required, the LRFE must submit a separate HACCP plan for each food category type. Each submittal need only list the specific foods or food categories covered by that plan.

The new language in Item B is necessary to reflect current HACCP plan submission and review practices used throughout the country and many of the local jurisdictions within Minnesota. Identifying only those foods or food categories covered by the submitted HACCP plan makes it easier for both those preparing and those reviewing the plan to focus on relevant food safety hazards and controls.

Item C requires that HACCP plans include a detailed food flow diagram or chart for each specific food or category covered by the HACCP process so that both food employees and

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regulators correctly identify and address the potential hazards involved. Specifying hazards and controls at each point of the food flow matches the science of food safety hazards with the LRFEs actions to control the hazards. For example, when the bacterial hazard *Listeria monocytogenes* is identified at the cold storage step in an ROP (reduced-oxygen packaging) cook-chill food flow, the HACCP plan must include date marking as the process-specific associated control measure.

The food flow information required will help to identify any deficiencies or shortcomings with the process or facilities that the LRFE needs to address to ensure food product safety.

Requiring a firm submitting a HACCP plan to submit the flow of food in each HACCP process and identify the critical control points necessary to control public health risks for each process is reasonable.

Under item D, a submitted HACCP plan must also summarize for each CCP, the associated critical limits, procedures for monitoring and controlling hazards, how routine operations are verified, and appropriate corrective actions when critical limits are not met. This language is identical to the previous language under this part which and has not changed.

Operators must include adequate supporting documents listed in item E to demonstrate how the operators will protect public health. At a minimum, HACCP plans must include a training plan for food employees and their supervisors. Special food processes that are unique to the operation require customized training that is relevant to the LRFE and its designated employees. Requiring a training plan is reasonable for the comprehensive review and regulatory assistance to LRFEs that must have an enhanced food safety plan.

It is imperative that firms document certain aspects of the HACCP plan (such as critical control point temperatures or times) that are necessary to prove that public health risks are being controlled. Requiring firms to submit examples of forms used for this purpose is reasonable.

HACCP plans must also include any additional scientific information that may be pertinent to a special process or recipe. For example, a firm wishing to hold acidified rice at room temperature for an extended time period must provide scientific data based on their specific recipe that shows the rice has been rendered safe by achieving a pH of 4.1 or below. The LRFE must hold this acid level to control the bacteria *Clostridium Botulinum's* growth. The operator can achieve his information only by having a scientific study performed. Including this information in the HACCP submission then is reasonable, so that firms and regulators have the data necessary for making food safety decisions.

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Item F reflects the fact that the science of food safety and food technology are constantly changing and evolving, as is demonstrated by every revised FDA Food Code. Including a statement in the HACCP Plan requirements that gives the regulatory authority the flexibility to respond to new science and technology not specifically addressed by this Code is reasonable.

4626.1740 TRADE SECRETS. 8-202.10

This part corrects a mistake in citing Minnesota Statute. The correct section is 13.02.

4626.1745 PREOPERATIONAL INSPECTIONS. 8-203.10

The existing Code already requires preoperational inspections to verify that the LRFE has complied with its approved plans. The revisions here remove superfluous language because the preoperational inspections are sufficient to demonstrate compliance with this Code.

4626.1750 NOTICE OF OPENING.

The departments added the phrase “licensee” to clarify the responsible person for providing notification of opening.

4626.1755 LICENSE REQUIRED. 8-301.11

The LRFE must have a valid license and post it conspicuously. The license is not transferrable and must be surrendered when no longer valid.

Revisions to this part clarify requirements by consolidating and strengthening language for possessing and displaying the license. New language requiring that the license be posted is needed for transparency between the business licensee and the public. Consumers have the right to make an informed decision about where they purchase food, and ready access to license information is self-explanatory. The departments moved language prohibiting transfer of a license from part 4626.1780 and expanded it here. New language clarifies that “transfer” refers to persons, places, or types of operation. Language requiring surrender of a void license has been moved from part 4626.1780 with no changes.

Business licensees commonly post the food establishment license and other licenses or certifications where customers can see them. State law requires posting a liquor license and this Code requires that the food protection manager certificate be posted. It is reasonable to specify

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that a required license be readily available for review, not only by the regulatory authority but also by customers. Liquor licenses are required to be posted in a public area and thus requiring equal access to other applicable licenses is reasonable. Consolidating this language pertaining to licenses is reasonable because it makes requirements easier to find and understand.

4626.1760 LICENSE APPLICATION. 8-302.11

This part requires that an applicant who wishes to operate a food business must submit written information to the regulatory authority for review. The words "written" and "on a form provided by the regulatory authority" clarify current procedures and practices of designated forms being used for a food establishment application process. Specifying that the application is for a food establishment is redundant information when addressing licenses in this Code. The repealed language from part 4626.1765 is incorporated into this part. Redundant language is removed. Combining application requirements into one part provides clarity and is therefore reasonable.

4626.1765 8-302.12 FORM OF SUBMISSION.

The departments combined this part with part 4626.1760 for clarity and reduction of redundancy. Combining the application and form of submission language into one part to avoid duplicated language and make a more readable Code is necessary and reasonable.

4626.1770 QUALIFICATIONS AND RESPONSIBILITIES OF APPLICANTS. 8-302.13

The departments added the word "food" to item A, to match the defined term "food establishment." Because inspections and access to the LRFE are required under *Minnesota Statutes*, chapter 157, the additional language included as item C serves a prominent reminder that license applicants must allow and cooperate during inspections. The additional language also identifies who is authorized to access a building and business according to the Statute and Rule. It is reasonable to alert an applicant by citation to the authority public officials hold to enter the LRFE premises.

4626.1775 8-302.14 CONTENTS OF APPLICATION.

The departments moved the requirement for license applications to be submitted to part 4626.1760. Moving and refining the language does not negatively impact public health

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protection and provides a clearer and more concise requirement. The prescribed application process can be efficiently addressed under the existing application section of this Code.

It is reasonable to move the requirement for an application to be on a form prescribed by the regulatory authority to the application section. It is reasonable to not restrict or open the contents of the application form to debate.

4626.1777 DENIAL OF APPLICATION FOR LICENSE; NOTICE. 8-303.30

If the regulatory authority denies an application for license to operate, the regulatory authority shall notify the applicant, and explain its reasoning and the appeal process. The regulatory authority needs to follow a fair and defined process for notifying the applicant. The new language incorporates current practice and will promote uniformity in how regulatory agencies across the state respond to license application deficiencies. Creating a formalized set of requirements for denial notification will improve the relationship between regulated parties and the regulatory agencies.

It is reasonable to protect applicant rights to ensure the applicant is informed of the decisions made during the review and the options for making appeals. Adding a description of a fair and legal procedure when an application for license is denied is reasonable and expected.

4626.1780 8-304.20 LICENSE NOT TRANSFERABLE.

Provisions included in this part have been moved to part 4626.1755, items C and D. Consolidating this language pertaining to licenses is reasonable because it makes requirements easier to find and understand.

4626.1785 INSPECTION. 8-401.10

References to Minnesota Statutes have been updated to reflect current numbering changes. Regulators and regulated persons rely on this Code to provide accurate information, so including updated references is reasonable.

4626.1787 PERFORMANCE AND RISK-BASED INSPECTIONS. 8-401.20

When certain conditions exist that increase risk to the public health, the regulating authorities will inspect food establishments more frequently than the minimum that the statute requires.

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Regulatory authorities need to intervene when there is an increased risk to public health. New provisions in this part identify three reasons this increased risk might exist.

First, certain foods carry a higher food safety risk, for example, shell eggs are associated with *Salmonella*, and thus conducting more frequent risk-based inspections to verify compliance with this Code is reasonable to protect the public. Second, if a particular operator or LRFE has demonstrated a history of noncompliance with priority 1 or 2 items in this Code, increased inspection frequency is both necessary and reasonable. Inspecting more frequently can provide more comprehensive reviews of operation, plus increase opportunities for food-safety education. Thirdly, when an LRFE is following specialized processes under a HACCP plan, but failing to follow its plan's requirements, inspecting more frequently is reasonable to ensure that all aspects of HACCP operations, including record-keeping, validation, and verification, are conducted and maintained as this Code requires.

Regulatory authorities must intervene when they determine that non-conformance is habitual, violations are routinely repeated, complaint conditions persist, and when additional risks associated with the menu are known. When food preparation procedures are known to be problematic or when immunocompromised populations are intended as customers, regulatory authorities may especially need to intervene to ensure safety and protect public health. While these additional regulatory interventions most often resemble additional inspections, these measures effectively elicit compliance from operators and licensees.

Providing the regulated community with examples of when an LRFE will be subject to additional inspections is reasonable and necessary. It is also reasonable to add further risk controls and public health interventions to be implemented instead of focusing on the rote calendar day count between inspections.

4626.1790 ALLOWED AT REASONABLE TIMES AFTER DUE NOTICE.

8-402.11

These minor revisions clarify the rule part to make it more explicit that the person in charge of the food establishment must give the regulatory authority access for inspection. This is especially important for businesses that are operating LRFEs and other businesses at the same location.

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4626.1791 DOCUMENTING INFORMATION AND OBSERVATIONS. 8-403.10

This new part puts standard practice for documentation into rule by listing the basic elements that the regulatory authority must record for documentation accuracy and regulatory consistency. Standard practice requires that the regulatory authority "paint the picture" of environmental health conditions during LRFE inspection. This picture must be factual and complete. A complete report reasonably requires that who, when, where, what conditions and the regulatory agency's legal authority to require corrections are all identified in the inspection report.

Regulatory authorities need a base of LRFE information, such as type of establishment, location, and legal ownership to enforce this Code against a specific business entity. The certain information listed as examples, personnel certificates and source of water supply and sewage disposal, focus the inspection on the environmental health conditions for which that the operator has responsibility. Including this standard practice as an explicit requirement for state and local regulatory agencies statewide is thus necessary and reasonable.

4626.1792 ISSUING A REPORT. 8-403.30

The requirement that the regulatory agency provide operators with completed inspection reports and notices of corrections is self-explanatory.

4626.1795 CEASING OPERATIONS AND EMERGENCY REPORTING. 8-404.11

The departments rewrote this part to require that LRFEs cease operating when they know that severe conditions exist. The rule lists examples: fire, flood, loss of power, loss of water, sewer backup, toxic chemical exposure, or foodborne illness outbreak—each an imminent health risk or endangerment to public health. Currently, operators are only required to notify the regulatory authority. The proposed language further clarifies that if the environmental health threat is localized, the operator may continue operating during the emergency those portions of a LRFE that are separate from the affected portion.

LRFE operators are responsible for maintaining food safety in their establishments and they must to immediately discontinue operations whenever an emergency compromises food safety. Operators often have multiple food and beverage preparation and support areas, such as a separate bar or bakery. This separate area may be unaffected by the emergency and allowing this area to continue operating, after the person in charge has evaluated the risk and deemed it

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insignificant, is reasonable. Discontinuing operations under emergency conditions is common practice and an important, effective public health intervention. It is necessary and reasonable to include this new requirement.

4626.1797 RESUMPTION OF OPERATIONS. 8-404.12

Resuming operations after an emergency shutdown requires that both operators and regulatory authorities assure the public that the LRFE can operate again safely. The problem must be resolved. Thus, protecting public health means that operators and regulatory authorities collaborate as partners to accomplish these mutual goals. This new rule part addresses that collaboration and requires that the parties document risk controls and public health interventions. It may require that the regulatory authority inspect the LRFE before operations resume and the opportunity to verify that the abatement and corrections are completed.

4626.1800 FOOD SAMPLES.

The departments changed “the Code” to “this Code.”

4626.1805 EMBARGO.

The departments changed “the Code” to “this Code.”

4626.1810 CONDEMNATION.

The departments changed “the Code” to “this Code.”

4626.1820 MINNESOTA CLEAN INDOOR AIR ACT.

“Minnesota Clean Indoor Air Act” is retained at the end of Chapter 8 after 4626.1810. The departments changed from “shall” to “must.”

Chapter 9

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Chapter 9

The departments are deleting the entire chapter. The departments removed outdated contents and relocated provisions to more logical and relevant places, as described below

4626.1825.

“Emergency First Aid for Choking” is deleted. The departments required LRFEs to display a poster illustrating first aid for choking when procedures for helping choking victims were not well known. Now, many people know what to do and many LRFEs train their employees in the procedure. The departments and the Advisory Committee determined that the requirement is not needed in this Code.

4626.1830 – .1835 and .1845 – .1870.

These parts contained special requirements for temporary and portable food establishments. Experience has shown that people who want to own and operate one of these establishments read only these specialized sections of this Code, thinking that these are the only requirements that these types of food establishments must meet. Since they do not read the rest of the code, licensees erroneously believing that they are in compliance when they are not. This has caused problems.

To mitigate this confusion and emphasize that this Code applies to all licensees, the departments placed the additional requirements or exemptions to requirements in the appropriate chapter. References concerning temporary and portable food establishments are now located in the following parts within this Code: 4626.0033, 4626.0680, 4626.1135, 4626.1155, 4626.1180, and 4626.1330.

4626.1840.

This part concerning mass gatherings was included in error. MDA, MDH and delegated authorities do not license and inspect mass gatherings as a whole for food regulations. They license and inspect the LRFE operating at the mass gatherings. All information contained in this part is located elsewhere. In the past, this part has caused confusion. Deleting will lessen confusion for vendors at mass gatherings.

4626.2000 – .2025.

These parts contain the requirements for Certified Food Manager (now being called Certified Food Protection Manager), which have been moved to Chapter 2, part 4626.0033. The CFM/CFPM program is a very important part of retail food safety, which correlates to better food safety outcomes. These requirements were lost at the very end of the rule and need to be

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placed more prominently in this Code near other requirements relating to the management and personnel of LRFEs. Placing these requirements in the same area as the requirements for the “Person in Charge (PIC)” is reasonable, especially because in many cases the PIC is a CFPM. The “Rule-by-Rule” analysis for 4626.0033 contain more information about what language was moved to that part and what language has been deleted permanently.

LIST OF ATTACHMENTS

A	Delegated Agency Lists for MDA and MDH
B	Outbreak Graph
C	Outbreak Graph
D	Outbreak Graph
E	Minnesota Food Code Rule Revision Advisory Committee Member Lists
F	Brainstorming Exercise
G	2014 Advisory Committee Meeting Dates and Locations
H	2014 Advisory Committee Meeting Agendas
I	Advisory Committee Recommendations
J	Wild Mushroom Subcommittee Report
K	MDA Cost Breakdown
L	MDH Cost Breakdown
M	HACCP Plan Cost Discussion
N	Delegated Agency Cost Survey
O	Responses to Delegated Agency Survey
P	Business Cost Survey
Q	Business Cost Survey Results
R	MDA and MDH Rulemaking List
S	Consultation with MMB on Local Government Impact Letter

LIST OF EXHIBITS

1	FDA Food Code
2	Supplement

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CONCLUSION - MDA

Based on the foregoing, the proposed rules are both needed and reasonable.

David Frederickson
Commissioner
Minnesota Department of Agriculture

November 16, 2017

Chapter 9

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CONCLUSION - MDH

Based on the foregoing, the proposed rules are both needed and reasonable.

Edward P. Ehlinger, M.D., M.S.P.H.
Commissioner
Minnesota Department of Health

November 20, 2017

MDH Delegation Agreements:

Aitkin County

Anoka County

City of Bloomington

City of Brooklyn Park

Brown, Nicollet, Counties

Cottonwood County

Watonwan County

P4H (Clay, Wilkin, Ottertail)

Countryside Public Health (Big Stone, Swift, Chippewa, LaC Qui Parle, Yellow Medicine Counties)

City of Edina

Faribault-Martin Counties

Hennepin County

Douglas County

Pope County

Kandiyohi-Renville Counties

Lake County

LeSueur-Waseca Counties

City of Maplewood

City of Minneapolis

City of Minnetonka

Morrison County

Todd County

Olmsted County

Ramsey County (not including the City of St. Paul)

City of Richfield

City of St. Cloud

Stearns County

South West Health and Human Services (Lincoln, Lyon, Murray, Pipestone, Redwood, Rock Counties)

Wadena County

Washington County

City of Wayzata

MDA Delegation Agreements:

Hennepin County

Ramsey County

City of Bloomington

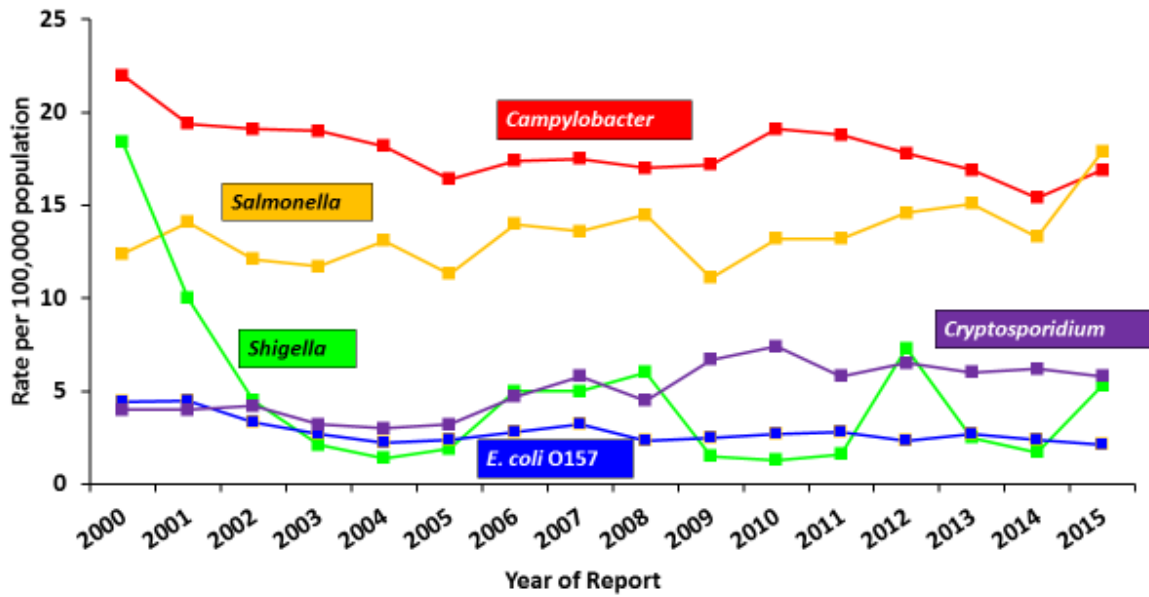
City of Brooklyn Park

City of Minneapolis

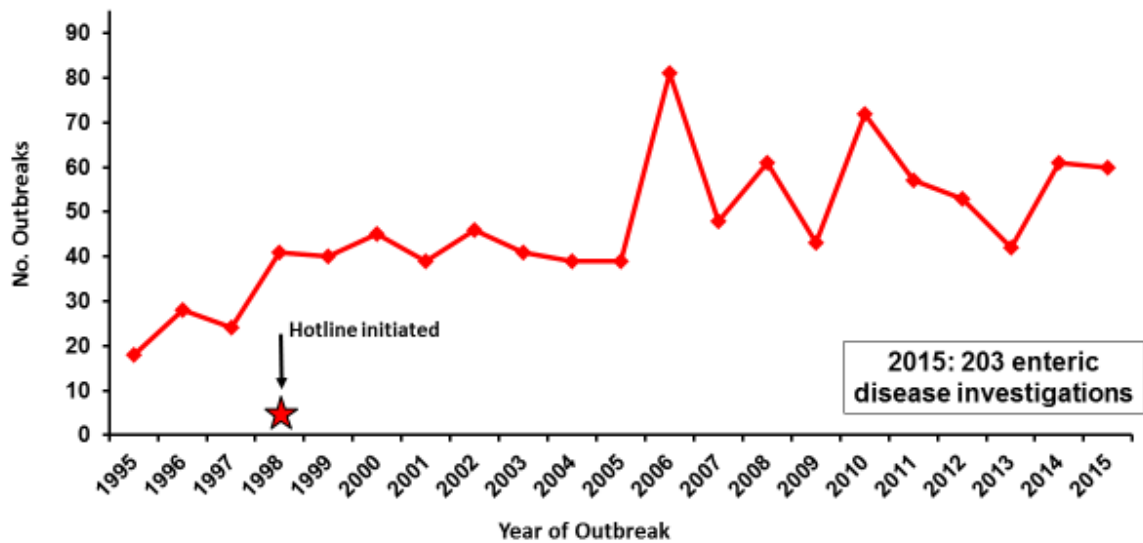
City of Minnetonka

City of Saint Cloud

Selected Enteric Pathogens Reported to MDH, 2000-2015

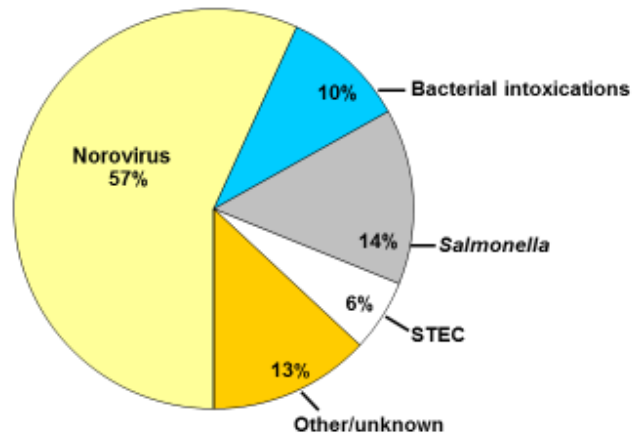


Confirmed Foodborne Outbreaks, Minnesota, 1995-2015

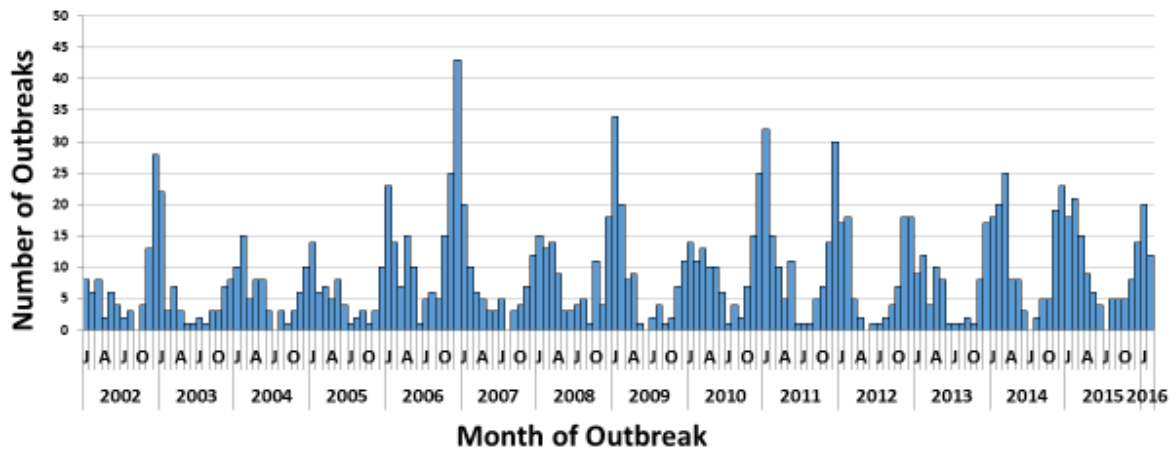


Attachment C

**Confirmed Foodborne Outbreaks by Etiology,
Minnesota, 1999-2015 (n=872)**



Norovirus Outbreaks by Month, Minnesota, 2002 - 2016



Confirmed and suspected norovirus outbreaks, all transmission routes

MINNESOTA FOOD CODE RULE REVISION ADVISORY COMMITTEE MEMBERSHIP

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Jon Christensen , Minnesota Association of Meat Processors	Ruth Petran , ECOLAB/University of Minnesota Ph.D. Candidate
Arlene Coco , Prairie Kitchen Food Safety Training	Jamie Pfuhl , Minnesota Grocers Association
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Chris Gindorff , Lund Food Holdings	John Schiltz , Lake Elmo Inn
Ed Gorman , Gorman's Restaurant	O. Peter Snyder , Hospitality Institute of Technology and Management
Bill Gunther , City of St. Paul	Ken Schelper , Davanni's
Tim Jenkins , City of Minneapolis	Karen Swenson , Brown-Nicollet Environmental Health
Jill Johnson , Local Public Health Association Representative	John Tracy , Stearns County
Kristofer Keller , Washington County	John Weinand , City of Minnetonka Health Division
Nona Narvaez , Anaphylaxis and Food Allergy Association	Angie Wheeler , Minnesota Environmental Health Association (MEHA)
Jim Olson , McDonald's (Franchisee)	Dale Yamnik , YUM Brands, Inc.
Greg Abel , U.S. Food and Drug Administration – <i>Ex officio</i>	<i>State Community Health Services Advisory Committee (SCHSAC) – to be determined</i>

03/01/2010

2014 - 2015 Food Code Rule Revision Advisory Committee Member List

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Greg Abel	FDA	greg.abel@fda.hhs.gov	Ex Officio

*shared seat

Brainstorming Exercise of March 18, 2010 Food Code Advisory Committee Meeting

Committee members were given five post-it notes to use to vote on their top five issues.

Top five* interest areas are:

Votes	Interest
16	Consistency with FDA
16	Bare hand contact
16	Science/Risk based code
12	Categories of three-tiered violations
7	Allergens

*This includes grouping "like" issues from all small groups. All of issues and their respective rankings are listed below.

Other Issues Identified During the Small Group Brainstorming

Votes	Interest
5	Front-line food worker training (compliance with PIC duty expectations – results)
4	For cleaning – allowing room for new technologies
4	CFM duties and clarifications in retail food environment
3	Concern of food code and "ma and pa" restaurants (certain language lost)
3	Address buying local foods
2	Enforceability – technical vs. simple
1	Follow HACCP outline
1	Performance standard based
1	Use of hand sanitizers (in place of hand washing)
1	Norovirus as reportable illness
1	Define/Comply with GMPs
1	Glove issues
1	Certification renewal – measure of learning
1	More public awareness of Code
0	Definition of PHFs
0	Vagueness of direction for grease traps vs. plumbing code
0	2007 Code or 2009 Code
0	Food code needs to be easy to modify
0	Flexibility?
0	Processed produce washing
0	Verification of time/temp (i.e. 165 degrees for 15 seconds)
0	Cabinet surfaces need clarity in guidelines. For example, Formica, sheet vinyl, poured floors in walk-ins, etc. – when is it acceptable? (Health vs. Ag definition)
0	Structured approach
0	Measureable
0	Food code needs to be easy to modify
0	Flexibility?



Minnesota Food Code Rule Revision Advisory Committee Meeting

January 23, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls, Mankato,
Marshall, Rochester, St. Cloud

Agenda:

1. Welcome
2. Status of the Advisory Committee
3. Status of the Rule Revision Effort
4. [FDA 2013 Model Food Code](#)
<http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf>
5. New Issues
6. Next Steps
7. Adjourn

If you should have any questions or concerns, please contact Linda Prail, MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500

**2014 Minnesota Food Code Advisory Committee
Videoconference/Meeting Dates**

Food Code Advisory Committee Videoconference/Meeting Dates	Host Site	Time	Participating DO Sites
January 23, 2014	Freeman B107	12:30PM- 3:00 PM	Bemidji, Duluth, Fergus Falls, Mankato, Marshall, Rochester, St. Cloud
February 25, 2014	Freeman B107	12:30 PM-3:00 PM	Bemidji, Duluth, Fergus Falls, Mankato, Marshall, Rochester, St. Cloud
April 29, 2014	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall
May 27, 2014	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall
June 24, 2014	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall
July 22, 2014	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall
August 26, 2014	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall
September 23, 2014	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall
November 4, 2014 – Canceled	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall
November 25, 2014 – Canceled and Rescheduled for December 8, 2014	Freeman B107	12:30 PM – 3:00 PM	Mankato, Duluth, Rochester, Bemidji, St. Cloud, Fergus Falls, Marshall



Minnesota Food Code Rule Revision Advisory Committee Meeting

February 25, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls, Mankato,
Marshall, Rochester, St. Cloud

Agenda:

1. Welcome
2. Introductions
3. Update on the Rule Revision Process
4. NSF Requirement
5. New 2013 FDA Food Code Language
6. Status of the Committee Membership
7. Subcommittees
8. Next Steps/Next Meeting
9. Adjourn

If you should have any questions or concerns, please contact Linda Prail, MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500



Minnesota Food Code Rule Revision Advisory Committee Meeting

April 29, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls, Mankato,
Marshall, Rochester, St. Cloud

Agenda:

1. Welcome
2. Introductions of New Members
3. Suggestions For Other New Members
4. Subcommittees
5. 2013 Food Code Changes
6. Other Proposed Changes
7. Next Steps
8. Chapter 4

If you should have any questions or concerns, please contact Linda Prail, MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500



Minnesota Food Code Rule Revision Advisory Committee Meeting

May 27, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls, Mankato,
Marshall, Rochester, St. Cloud

Agenda:

1. Welcome
2. New Member Introductions (alternates?)
3. Possible Additional Members
4. Rule Revision Status Update
5. Council for Food Protection Meeting Re-Cap
6. Legislative Session Re-Cap
7. Equipment, Finishes and Utensil Requirements (Chapter 4)
 - a. MEHA Survey Results
 - b. Assisted Living Comments
 - c. Minnesota Farmers' Market Association
8. Food Storage Areas (4626.1370 and 4626.1360, FDA 6-201.16 and 6-201.18)
9. Three Compartment Sinks - Olmsted County
10. Subcommittees
 - a. Cost of Revisions
 - b. Outreach
11. Next Steps

If you should have any questions or concerns, please contact Linda Prail, MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500



Minnesota Food Code Rule Revision Advisory Committee Meeting

June 24, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls,
Mankato, Marshall, Rochester, St. Cloud

Agenda: **Please read the materials for the bolded items (6 & 8)**

1. Welcome
2. Introduction of New Members
3. Possible Additional Members
4. Subcommittees
5. Rule Revision Status Update
- 6. Chapter 4 Language: Equipment, Utensils and Finishes (current code
and FDA 2013 code)**
7. Handwashing: Water Under Pressure
- 8. FDA 3-301.11**
9. Sinks
10. Next Steps
11. Adjourn

If you should have any questions or concerns, please contact Linda Prail,
MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500



Minnesota Food Code Rule Revision Advisory Committee Meeting

July 22, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls,
Mankato, Marshall, Rochester, St. Cloud

Agenda:

1. Welcome
2. Announcements
3. New Members
4. EH Continuous Improvement Board—Tom Hogan, Division Director, Environmental Health Division (EHD)
5. FDA [4-602.11](#) (pg. 171) — Greg Abel, USFDA
6. Barehand Contact (see attached proposal)
7. Sinks (FDA [4-501.16 B](#), (pg. 165) [5-205.11](#), (pg. 191), MN [4626.0760](#) and [4626.0780](#))
8. Subcommittees
9. Cost Calculations
10. Other issues
11. Next step
12. Adjourn

If you should have any questions or concerns, please contact Linda Prail, MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500



Minnesota Food Code Rule Revision Advisory Committee Meeting

August 26, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls,
Mankato, Marshall, Rochester, St. Cloud

Agenda:

1. Welcome
2. Updates & Announcements
 - a. Hawk Letter
3. Sinks, 3-Comp./Scrap-Cleaning & Sanitizing (attached)
4. Long-Term Care Imperative's Recommendations (attached)
5. Other Food Code Issues
 - a. Food Worker Training Subcommittee Recommendation (attached)
6. Who is affected by the Revisions?
7. Cost of Revisions
8. Next step
9. Adjourn

If you should have any questions or concerns, please contact Linda Prail, MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500



Food Code Advisory Committee Meeting

Date: December 8, 2014

Time: 12:30 pm – 3:00 pm

Host: Linda Prail, MDH

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls, Freeman, Mankato, Marshall, Rochester, St. Cloud

Agenda

1. Welcome and Introductions
2. Updates – Steven Diaz, MDH
3. Food Charter – Tim Jenkins, MDH
4. Financial Information for SONAR
5. Next Steps

If you should have any questions or concerns, please contact Linda Prail, MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.



Minnesota Food Code Rule Revision Advisory Committee Meeting

September 23, 2014

12:30 pm - 3:00 pm

Host – O.L. Freeman Building – Room B107

District Office Videoconference Locations: Bemidji, Duluth, Fergus Falls,
Mankato, Marshall, Rochester, St. Cloud

Agenda:

1. Welcome & Announcements
2. Hand Contamination from Public Restroom Doors (attached)
3. Updates
 - a. Minnesota Food Charter Update
 - b. Food Code Rule Revision Status
4. Who is Affected by the Revisions: Review of List (attached)
5. Work on Cost Estimates (attached)
6. Adjourn

If you should have any questions or concerns, please contact Linda Prail,
MDH by email at linda.prail@state.mn.us or by phone at 651-201-5792.

MDH
EH Division – FPLS Section
651-201-4500

Recommendations				
<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>1) 4626.0070 (2-301.12) Cleaning Procedures</p>	<p>Take out word "warm" B. (1) rinse under clean, running warm water; (4) thoroughly rinse under clean, running warm water; and</p>	<p>Do not accept recommendation; use FDA Language</p>	<p>Do not accept recommendation; use FDA Language</p>	<p>Even though warm or hot water may not assist in the cleaning process, warm water is more comfortable for most people and this may encourage more and longer handwashing.</p>
<p>2) 4626.0070 (2-301.13) Special Hand Wash Procedures</p>	<p>Do not accept CCC II language which would keep the following language: 2-301.13 Special Handwash Procedures.* A. A nail brush shall be used: —— (a) upon reporting to work, —— (b) after using the toilet room, and —— (c) after other gross contamination of the hands occur. B. A double handwash is required after using the toilet.</p>	<p>Accept recommendation; use FDA Language</p>	<p>Accept recommendation; use FDA Language</p>	<p>We want to wait and see what CFP and USFDA decides on this issue before making accepting any language on special handwash procedures.</p>

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>3) 4626.0075 (2-301.14) When to Wash & 4626.0080 (2-301.15) Where to Wash</p>	<p>Accept CCCII proposed language; highlighted language is significant new language from the FDA Model Code. 4626.0075 2-301.14 WHEN TO WASH. Food employees shall clean their hands and exposed portions of their arms as specified in part 4626.0070 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles and: A. after touching bare human body parts other than clean hands and clean, exposed portions of arms; B. after using the toilet; C. after caring for or handling service animals or aquatic animals as specified in 4626.0120; D. Except as specified in 4626.0105(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; E. after handling soiled equipment or utensils; F. during food preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks; G. when switching between working with raw foods and working with ready-to-eat foods; ¹H. before donning gloves for working with food; and I. after engaging in other activities that contaminate the hands. 4626.0080 2-301.15 WHERE TO WASH. Food employees shall clean their hands in a handwashing sink or approved automatic handwashing facility and may not clean their hands in a sink used for food preparation or warewashing, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.</p>	<p>Accept with one small addition to B. after using toilet room.</p>	<p>Accept</p>	<p>NA</p>

¹ Advisory Committee thought the highlighted part was very important.

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>4) 4626.0020 Subp. 32 (FDA) Easily Cleanable</p>	<p>Accept CCCII recommended language Easily cleanable. A. "Easily cleanable" means a characteristic of a surface that: (1) allows effective removal of soil by normal cleaning methods; (2) is dependent on the material, design, construction, and installation of the surface; and (3) varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use. B. "Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in Subparagraph (1) of this definition to different situations in which varying degrees of clean ability are required such as: (1) the appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or (2) the need for a different degree of clean ability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.</p>	<p>Accept recommendation; use FDA 2009 language which is the same as CCCII</p>	<p>Accept recommendation; use FDA language which is the same as CCCII</p>	<p>NA</p>

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>5) 4626.2010 Subp. 5 Certified Food Protection Manager Requirements For Food Establishments -Duties of Certified Food Manager</p>	<p>Move this to Subpart 4626.0035 (2-103.11) Person in Charge Subp. 5. Duties of certified food manager. An owner or operator, through the certified food manager, is responsible for ensuring that:</p> <ul style="list-style-type: none"> A. hazards in the day-to-day operation of the food establishment are identified; B. policies and procedures to prevent foodborne illness are developed and implemented; C. employees are trained to ensure that there is at least one trained individual present at all times food preparation activities are conducted who can demonstrate the knowledge required in the Code; D. food preparation activities are directed and corrective action is taken, as needed, to protect the health of the consumer; and E. in-house self-inspections of daily operations are conducted on a periodic basis to ensure that food safety policies and procedures are followed. 	Rescinded	Rescinded	Rescinded

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>6) 4626.0340 (3-401.14) Non-Continuous Cooking of Raw Animal Foods</p>	<p>Recommend the following language</p> <p>(A) Raw animal foods shall not be cooked using non-continuous cooking process unless the food establishment has submitted a HACCP plan to the regulatory authority and the regulatory authority has approved the HACCP plan.</p> <p>(B) Raw animal FOODS that are cooked using a NON-CONTINUOUS COOKING process shall be:</p> <p>(1) Subject to an initial heating process that is no longer than sixty minutes in duration; ^P</p> <p>(2) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME /TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A); ^P</p> <p>(3) After cooling, held frozen or cold, as specified for POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.16(A)(2); ^P</p> <p>(4) Prior to sale or service, cooked using a process as specified in 3-401.11;</p> <p>(5) Cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME /TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A) if not either hot held as specified under ¶3-501.16(A), served immediately, or held using time as a public health control as specified under § 3-501.19 after complete cooking; ^P and</p> <p>(6) Prepared and stored according to written procedures that:</p>	<p>Accepted; use Advisory Committee language</p>	<p>Accepted; use Advisory Committee language</p>	<p>NA</p>

(a) Are maintained in the FOOD ESTABLISHMENT and are available to the REGULATORY AUTHORITY upon request;^{Pf}

(b) Describe how the requirements specified under ¶ (A)-(E) of this Section are to be monitored and documented by the PERMIT HOLDER and the corrective actions to be taken if the requirements are not met;^{Pf}

(c) Describe how the FOODS, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as FOODS that must be cooked as specified under ¶ (D) of this section prior to being offered for sale or service;^{Pf} and

(d) Describe how the FOODS, after initial heating but prior to cooking as specified under ¶(D) of this section, are to be separated from READY-TO-EAT FOODS as specified under ¶ 3-302.11 (D).^{Pf}

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>7) 4626.0225 (3-301.11 D (5)) Preventing Contamination from Hands</p>	<p>Recommends the following language: (5) Documentation that food employees contacting ready-to-eat foods with bare hands comply with the control measure in paragraph (a) below and at least one additional control measure listed in paragraphs (b), (c), and (d) to provide additional safeguards to hazards associated with bare hand contact:</p> <ul style="list-style-type: none"> (a) After using the toilet or when coming to work, using a double handwash procedure which uses a nail brush on the fingertips during the first wash, followed by a second wash as specified in 4626.0070 2-301.12.B, and (b) Using a hand antiseptic after handwashing as specified in part 4626.0085, or (c) Programs to encourage food employees not to work when they are ill, or (d) Other control measures approved by the regulatory authority; and (e) Documentation that corrective action is taken when subparagraphs (D) (1)-(5) of this section are not followed. 	<p>Accept</p> <p>(5) (b) drop “Using”</p>	<p>Accept</p>	<p>NA</p>
<p>8) 4626.0805 4-501.114 (B) Manual and Mechanical Warewashing Equipment; Chemical Sanitization, Temperature, Ph, Concentration, and Hardness</p>	<p>Recommends changing to 20° C (proposed FDA language) (B) An iodine solution shall have a: (1) Minimum temperature of 20°C (68°F),</p>	<p>Accepted; Advisory Committee language</p>	<p>Accepted; Advisory Committee language</p>	<p>NA</p>

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
9) 4626.1555 (6-501.19) Closing Toilet Room Doors	Add Language: Toilet rooms designed without door(s) but with a zig-zag entrance do not need to comply with this provision. (Linda’s attempt at language)	Accept recommendation; use 2 nd Part: “A toilet room entry designed without doors as specified by Minnesota building code does not need to comply with this provision.”	Accept concept	NA
10) 4626.1635 (7-204.14) Drying Agents; Criteria	Add as paragraphs 6 & 7- (6) Generally recognized as safe as determined by a GRAS panel of experts as specified in 21 CFR 170.30 or, (7) Subject of a Food Contact Notification (FCN) for use as a component of a drying agent; and	Accept Advisory Committee language	Accept Advisory Committee language	NA
11) CCCII Chapters 1-8	Motion to accept CCCII Chapters 1-8 (with changes)	NA	NA	On hold pending completion of first draft

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>12) 4626.1440 (6-301.11) Handwashing Cleanser, Availability</p>	<p>To eliminate the nail brush except when an alternative procedure for handwashing was used when handling ready-to-eat foods.</p> <p>A. Each handwashing sink or group of two adjacent sinks shall be provided with a supply of hand cleaning liquid, powder, or bar soap. B. When bare hand contact with ready-to-eat foods is allowed as specified in 4626.0225, a nailbrush must be provided at all handwashing sinks located in a food preparation area.</p>	<p>Accept</p>	<p>Accept</p>	

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>13) 4626.0020 (1-201.10) Statement of Application and Listing of Terms Major Food Allergen</p>	<p>Adopt recommendations of allergens subcommittee.</p> <p>Draft Language: (a) Milk, egg, fish (freshwater or saltwater finfish such as, but not limited to bass, cod, flounder, or tuna), Crustacean shellfish (such as, but not limited to crab, lobster, or shrimp), tree nuts (such as, but not limited to almond, filbert/hazelnuts, lychee/lichee, pecans, or walnuts), wheat, peanuts, and soybeans</p> <p>Subcommittee recommendation to keep the intent maintaining the major 8 allergens.</p> <p>Subcommittee recommendation to leave out language to other references.</p>	<p>Accept</p>	<p>Accept</p>	<p>NA</p>
<p>14) 4626.0435 (3-602.11) (5) Food Labels</p>	<p>The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient (Effective January 1, 2006)</p> <p>Subcommittee recommendation is to keep 2009 Model Food Code language as is.</p>	<p>Accept</p>	<p>Accept</p>	<p>NA</p>
<p>15) 4626.0035 (2-103.11) (L) Person In Charge</p>	<p>Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties</p> <p>Subcommittee recommendation is to keep 2009 Model Food Code language as is.</p>	<p>Accept</p>	<p>Accept</p>	<p>NA</p>

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>16) Three Tier System</p>	<p>Recommendation: Accept FDA Priority/Priority Foundation/Core Three Tier System, including deliberate process for educating regulators first and then the customers as to this terminology.</p>	<p>Not accepted; Accepted three-tier concept; use Priority 1, Priority 2, Priority 3</p>	<p>Not accepted; Accepted three-tier concept, use Priority 1, Priority 2, Priority 3 terminology</p>	<p>We thank the Three Tier Subcommittee for its work. We do not think the FDA terms are user friendly. We, MDH and MDA, do have the resources to provide training to all of the food establishments we inspect. The survey results overwhelmingly wanted Priority 1, Priority 2, Priority 3.</p>

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>17) 4626.0020 (1-201.10) Statement Of Application And Listing Of Terms</p>	<p>Accept recommendations of Chapter 1and Chapter 5 from HACCP subcommittee.</p> <p>Add back a definition of "Clean" Keep the language of the Minnesota Code: "Clean" means free from insects, vermin, and debris and free from physical, chemical, and microbial substances discernible by ordinary sight or touch.</p> <p>Definition of "Hazard" "A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control." [NACMCF. 1998. Hazard analysis and critical control point principles and application guidelines. J. Food Prot. 61(9):1246-1259. www.cfsan.fda.gov/~comm/nacmcfp.html.</p>	<p>Not accepted; use FDA language for "Hazard"</p>	<p>Not accepted; use FDA language for "Hazard"</p>	<p>We do not think a definition of "clean" is needed or useful. We think the FDA definition of "hazard" is more useful.</p>
<p>18) 4626.1050 (5-202.12) Handwashing Lavatory; Water Temperature And Flow.</p>	<p>Change the wording: The hand wash sink will provide water at a warm to tepid temperature and at a flow rate sufficient to rinse hands. (By saying above 70°F, most sinks where the water pipes have cooled to room temperature will meet the criteria.)</p>	<p>Not accepted; use FDA language</p>	<p>Not accepted; use FDA language</p>	<p>No definition of warm to tepid, everyone would have a different idea.</p>

<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
<p>19) 4626.1830 4626.1845 4626.1850 4626.1855 4626.1860 4626.2010</p>	<p>Adopt the revised language for Chapter 9 as presented by MDH and MDA – See Attachment 8</p>	<p>NA</p>	<p>NA</p>	<p>NA</p>
<p>20) 4626.0020 (1-201.10) Statement of Application and Listing of Terms – Major Food Allergen (1) (b)</p>	<p>Adopt FDA definitions for the 8 U.S. major allergens identified by the FDA: "Definitions in the Food Code Allergen Subcommittee recommendations conform to current FDA definitions." Regarding foods derived from the 8 major allergens as written in the FDA Model Code: (1-201.1)(1)(b) A food ingredient that contains protein derived from a food, as specified in Subparagraph (1)(a) of this definition."</p>	<p>Accepted</p>	<p>Accepted</p>	<p>NA</p>
<p>21) 4626.2010 Subpart. 5 Certified Food Protection Manager Requirements For Food Establishments.</p>	<p>Motion moves to rescind the motion that passed at 8/31/2010 meeting Move 4626.2010 Subpart 5 Certified Food Protection Manager Requirements For Food Establishments to Subpart 4626.0035 (2-103.11) Person in Charge</p>	<p>NA</p>	<p>NA</p>	<p>NA</p>

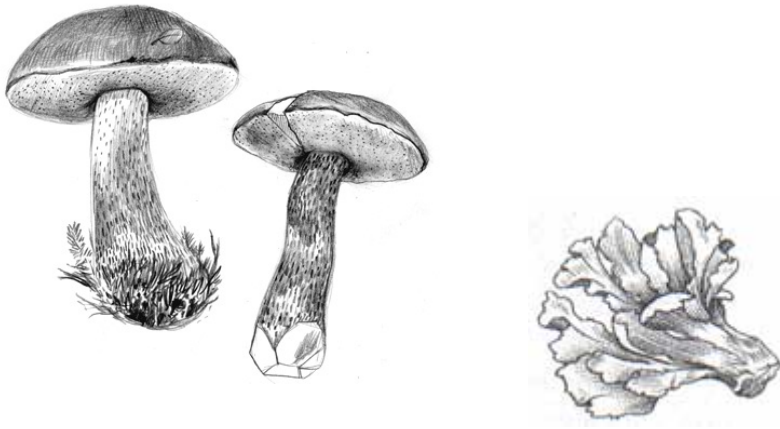
<u>Citation; MN Food Code and FDA Model Food Code</u>	<u>Advisory Committee Approved Motion</u>	<u>MDH Manager and Supervisors Decision</u>	<u>MDA Manager and Supervisors Decision</u>	<u>Reasoning</u>
22) 4626.0505 (4-201.11) (J)(2) Equipment And Utensils	Motion moves to change number of clients from 10 to 12 2. food service or a food operation in a child care center, residential care home, supervised living facility, apartment building with congregate dining, boarding establishment, bed and breakfast, or similar establishment is serving ten or fewer individuals; or	No decision; under discussion	NA	NA
23) 4626.0020 Subpart 30 (1-201.10) Statement Of Application And Listing Of Terms	Add in cut leafy greens/cut tomatoes to MN Food Code. “Cut leafy greens” means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.	Proposed by Departments	Proposed by Departments	NA
	Adopt 2009 FDA with exceptions of any language that has been recommended.	On hold	On hold	On hold until completion of first draft

**2014 Minnesota Food Code Advisory Committee
Motions/Recommendations**

Food Code Advisory Committee Videoconference/Meeting Dates	Motions/Recommendations	Department Action
January 23, 2014	No motions were made.	
February 25, 2014	A vote was taken to keep the NSF Stand in the MN Food Code or to adopt the language from the 2013 FDA Food Code. 5 votes in favor of going with FDA language. 3 votes for mandating ANSI/NSF program 8 votes undecided	
April 29, 2014	A motion was made to accept the 2013 FDA Food Code changes. Motion: Ruth Petran Seconded: Chris Gindorff MSC	
May 27, 2014	No motions were made.	
June 24, 2014	Ken Schelper made a motion to adopt the 2013 FDA Food Code. Dale Yamnik made a friendly amendment to the motion to adopt the 2013 FDA Food Code subpart 4.1 and 4.2 (Design and Construction) in its entirety. The amendment was accepted by Ken and seconded by Kathy Zeman. Motion: Ken Schelper Amended: Dale Yamnik Seconded: Kathy Zeman	

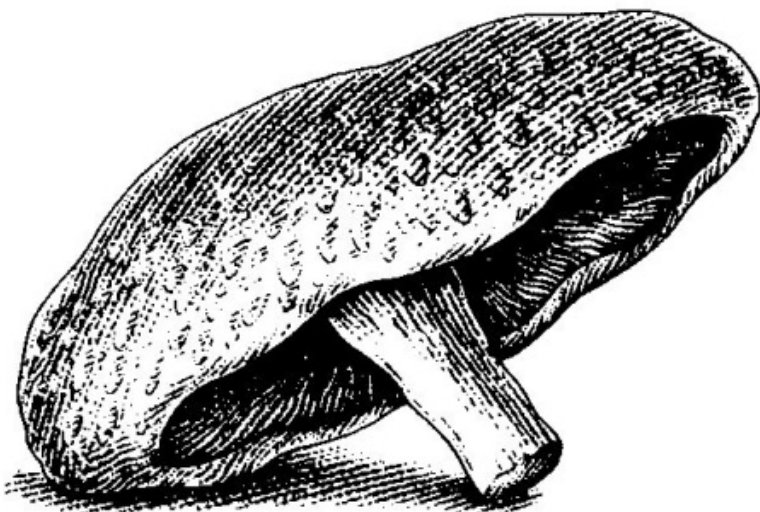
	MSC 11-4	
July 22, 2014	<p>A motion was made to adopt 4-602.11 (B) of the 2009 FDA Food Code rather than the 2013 FDA Food Code.</p> <p>Motion: Dale Yamnik Seconded: Ken Schelper MSC – 17 yes and 0 no’s.</p> <hr/> <p>A motion was made to adopt language as proposed/written below for item (D) (1) of 4626.0225 (3-301.11) :</p> <p>4626.0225 (3-301.11 – page 97) Recommendation: D. Food employees not serving a highly susceptible population may contact exposed, ready-to-eat food with their bare hands if: (1) Before engaging in handling of ready-to-eat foods with bare hands, the permit holder provides written notification to the regulatory authority of their intent to use bare hand contact and that they are in compliance with the requirements of subparagraphs (D) (2) – (7) of this section.</p> <p>Motion: Dale Yamnik Seconded: Ruth Petran MSC: 18 yes, 1 no.</p>	
August 26, 2014	<p>A motion was made to adopt the 2013 FDA language (in reference to 4-501.16) as is.</p> <p>Motion: Dale Yamnik Seconded: Ruth Petran MSC</p>	

	13 in favor 4 not in favor and 2 members abstaining	
September 23, 2014	No motions were made.	
November 25, 2014 Canceled	Meeting canceled.	
December 8, 2014	No motions were made.	



2012

Minnesota Food Code Rule Revision Wild Mushroom Advisory Workgroup



Minnesota Department of Health
Minnesota Department of Agriculture

Minnesota Food Code Rule Revision Wild Mushroom Advisory Workgroup Report

Minnesota Department of Health
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Phone: 651-201-4500

This document is available in alternative formats to individuals with disabilities upon request.

02/06/2013

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The Minnesota Food Code Rule Revision Wild Mushroom Advisory Workgroup

The Minnesota Departments of Health (MDH) and Agriculture (MDA) are revising the Minnesota Food Code, Chapter 4626 (Code). The Departments are considering rule amendments that would bring the Code up to date and into substantial conformance with the 2009 Food and Drug Administration (FDA) Model Food Code and Supplement to the 2009 FDA Model Food Code. To that end, MDH and MDA formed a Minnesota Food Code Rule Revision Advisory Committee (Committee) that advised and provided recommendations on subjects relating to the rule revision to the Departments. Charge to the Minnesota Food Code Rule Revision Wild Mushroom Advisory Workgroup is attached in Appendix 1.

After the Committee completed its review meetings, a number of individuals expressed an interest in reviewing and making recommendations on the section of the code regulating wild mushrooms, Minnesota Rules 4626.0155 WILD MUSHROOMS. In order to be responsive to this interest and to ensure the best possible code, the departments convened a small workgroup.

Text of Minnesota Rules 4626.0155 WILD MUSHROOMS

4626.0155 3-201.16 WILD MUSHROOMS.*

“A. Except as specified in item B, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by a mushroom identification expert whose expertise has been verified and approved by the regulatory authority through the successful completion of a wild mushroom identification course provided by either an accredited college or university or a mycological society. An individual who wants to be approved as a wild mushroom identification expert shall have on file with the regulatory authority a letter from an accredited college or university certifying successful completion of a wild mushroom identification course from an accredited college or university.

B. This part does not apply to:

- (1) cultivated wild mushrooms species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or
- (2) wild mushrooms species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.”

Membership:

The Advisory Workgroup (Workgroup) consisted of 22 people including wild mushroom cultivators and foragers, delegated city and county agencies, MDA and MDH staff and other interested individuals.

A list of Workgroup members is attached in Appendix 2.

MDH and MDA had at least one active member at each meeting and MDH provided staff support for the Workgroup.

Purposes of the Workgroup

The purposes of the Workgroup were:

Represent the various parties who may be affected by 4626.0155 3-201.16 WILD MUSHROOMS.

Assist the Departments in identifying all affected people and organizations and designing ways to let them know about the possible revisions to this section of the rule.

Provide advice and recommendations on 4626.0155 including a final proposal that will be presented to MDH and MDA for a decision.

The Workgroup was a non-voting group. The Workgroup advised and made recommendations. The Commissioners of the Departments of Health and Agriculture will make any final decisions.

Roles and Responsibilities of Mushroom Workgroup Members

- Review, discuss and make recommendations for possible revisions to the Wild Mushroom section of the Code.
- Review information and proposals from MDH/MDA and other interested persons. Listen to and consider input from the public, if offered.
- Provide information about the cost of compliance with any recommended Code changes for small businesses, cities and counties and information on the fiscal impacts and benefits on local units of government.
- Assist the Departments in identifying all interested persons and to design ways to let them know about any recommended changes. This includes both likely supporters and opponents.
- Represent the member's interest group:
 - Act as liaison to the interest group to ensure inclusiveness in the rule revision process.
 - Contact members of interested parties and solicit input on subjects of interest.
 - Speak on behalf of the organizations and constituents that they represent to advise the agencies on the development of the rule amendments.
 - Assist MDH and MDA in communicating the progress of the rule revision to interest group members.
 - Reflect the feedback of their constituents to the discussions of the Workgroup.

Term of Service and Designated Alternates

- Each member will serve for the full duration of the project.
- Each member may designate an alternate to attend meeting(s).
- If a member is unable to attend a meeting, the designated alternate will assume the role of the member at that meeting.
- The public and interested stakeholders are welcome to attend Workgroup meetings.

Role of MDH and MDA

To facilitate the work of the Workgroup, MDH and MDA staff has:

Made arrangements for full Workgroup meetings.

Sent out meeting notices.

Prepared meeting agendas and meeting summaries.

Provided materials for review and consideration.

Provided information through various media to members and other interested parties.

Attended full Workgroup meetings.

Carefully considered all comments and suggestions made by the Workgroup.

Arranged for any final proposals to be reviewed by appropriate MDH and MDA staff.

Workgroup Meetings

The Workgroup meet for the first time on March 19, 2012. Subsequent meetings were held on March 28, April 9 and April 23, 2012. Agendas and minutes for all meetings are attached in Appendix 3. All of the meetings were well attended by both Workgroup members and other interested persons.

Although the Workgroup identified a plethora of issues ranging from training and certification for mushroom harvesters to sustainability of mushroom habitat, the Workgroup was instructed to focus on any needed changes to 4626.0155. After much discussion, the full Workgroup was divided into three small subgroups to work on the following subjects:

1. Specific detailed recommendation for changes to the language of 4626.0155.
2. Mushroom training and certification requirements.
3. Chain of custody requirements for mushrooms.

Recommendations and Work Products

Subgroup 1: Revised Rule Language

Strong agreement was achieved in language change subgroup.

The subgroup's recommendation is to amend the Minnesota Food Code to read as follows:

“4626.0155 3-201.16 WILD MUSHROOMS.

A. Except as specified in item D, wild mushroom species shall be obtained from sources where each mushroom is individually inspected and found to be safe by a certified mushroom harvester whose ability to correctly identify edible wild mushrooms has been verified and approved by the regulatory authority through the successful completion of a wild mushroom identification program provided by an accredited person or organization. A letter issued by the accrediting person or organization certifying the harvester's successful completion of the wild mushroom identification course and specifying the species of wild mushroom the harvester is qualified to identify shall be kept on file with the regulatory authority. The Minnesota Department of Agriculture shall maintain a registry of all certified wild mushroom harvesters.

B. Except as specified in item D, wild mushroom species shall have a written buyer specification which shall be retained by the buyer for 90 days from the date of sale or service.

The written buyer specification shall include all of the following information:

- (1) identification of the mushroom species by the scientific and common name;
- (2) date of sale and quantity by weight of each species sold;
- (3) a statement indicating that the mushroom was identified in its fresh state;
- (4) the name, address and telephone number of the harvester, and
- (5) a statement describing the qualifications and training of the harvester, specifically relating to mushroom identification, including the species that the individual is certified to harvest.

C. Except as specified in item D, the harvester shall retain for 90 days records of wild mushrooms sold to food establishments. The records retained shall include all of the following information:

- (1) identification of the mushrooms by the scientific and common name;
- (2) the state and county locations of harvest;
- (3) the dates of harvest;
- (4) the names of the establishments where wild mushrooms were sold, including dates of sale, and the quantities by weight of each species purchased

D. This section shall not apply to the following:

- (1) cultivated mushroom species that are grown, harvested, and processed in an operation that is licensed and inspected by a food regulatory agency;
- (2) wild mushrooms that are packaged and are the product of a processing plant that is licensed and inspected by a food regulatory agency. Such mushrooms shall be individually inspected by a certified wild mushroom harvester retained by the food processing plant, and labeled with the common name of the mushroom and the name and location of the food processing plant.

Definitions:

Wild mushrooms: Wild mushrooms are edible species of mushrooms that have been harvested from their naturally occurring environment where no human intervention occurred to support their growth.

Cultivated mushrooms: Cultivated mushrooms are edible species of mushrooms that have been cultivated by persons under controlled conditions, outdoors or indoors, on natural or artificial substrate.”

Subgroup 2: Training and Certification Requirements

This subgroup was less successful in achieving consensus. A portion of the group proposed the following:

Public Education Programs

Most mushroom poisonings that occur in the state involve people who have very limited or no knowledge with respect to basic identification of poisonous or edible mushrooms. The following courses are designed to provide people with the fundamental information needed for the safe collection of wild edible mushrooms. Level 1 and level 2 programs are designed to teach identification of wild mushrooms to the general public. Taking these courses will not satisfy requirements for certification nor would they be required for certification. It is the “Certification Program” that is **required** for those wanting Certification. In addition to attending the Certification Program, certification will require demonstrated ability to identify mushrooms and knowledge of the material presented in the above courses through examination by the participating faculty. The examination may require collecting and documenting a predetermined number of fungi; part of the examination may be written or oral.

Level 1. Introduction to Fungi

Lecture:

- Definition of fungi, general ecological attributes diversity of forms, substrates, growth habits.
- How to collect fungi (including basic documentation).

Foray:

- Utilize the techniques learned in lecture.
- Locate fungi (5-10), complete collection slips specifying form, substrate and habitat.

Laboratory:

- Place collections according to the display sign; students talk about their collections.

Demonstrations / displays:

- How to take a spore print.
- Best and popular field guides for identification.

Level 2. Poisonous and Common Edible Mushrooms of Minnesota

Lecture:

- Review collecting and how to take spore prints.
- Demonstrate construction and use of keys for identification.
- Features of mushrooms used in identification (handout provided).
- Major genera of gilled mushrooms and boletes.
- How to complete a documentation form.

Foray:

- Collect a specified number of mushrooms.

Laboratory:

- Set up spore prints
- Prepare documentation.

- Use keys to determine genus and species if possible.
- Use field guides to verify.
- Questions and discussions.

Weekend and / or One Day Forays

Collecting and identifying; everyone is responsible for their own collection; bring books most often used for identification; identify your collection to the extent you can; if time allows, prepare documentation;

Other Programs

1 hour lectures (by invited professionals) dealing with specific groups of fungi; relating to identification or on other mushroom related topic; Symposia on fungi; microscopy workshop; workshops on identification in addition to the above;

Certification Programs

Given as one or two modules a week, or the entire set within one week;
Each module is centered on one group of related edibles;

What is covered;

- Characterization of the group; recent developments in classification.
- Collecting, storage and transportation.
- Edibility concerns.
- Possible health benefits and concerns.
- Mushrooms that may be confused with the subject (look-alikes) and poisoning issues that may be caused by them.

Modules :

1. Policy Considerations

- a. Regulations
 - i. Harvest
 - ii. Commercial activity
- b. Access and tenure
 - i. Private lands
 - ii. Public lands
 1. Federal
 2. State
 3. County
 - iii. Other tenure systems

2. Social Considerations

- a. Other harvesters
- b. Cultural resources
- c. Integrating diverse harvest and use traditions

3. Biological Considerations

- a. Mushrooms and their roles in the ecosystem
- b. Mushroom biology and reproduction
- c. Mushroom habitats

4. Mushroom Identification

- a. Poisonous Mushroom Identification – What you have to know
- b. Advanced Mushroom Identification
- c. General mushroom safety practices

5. Harvest Considerations

- a. General harvest sustainability issues
 - i. What (Fungi anatomy)
 - ii. When (timing and seasonality)
 - iii. How (techniques)
- b. Considerations specific to mushroom harvest
 - i. What (Fungi anatomy)
 - ii. When (timing and seasonality)
 - iii. How (techniques)

6. Market Considerations

- a. Supply assessment
- b. Demand assessment
- c. Scale of commercial operations
- d. Placing your activity in a broader context
- e. Processing and storage

7. Resources and support

- a. Networks
- b. Study materials
- c. Printed materials
- d. Education
- e. Online

Possible Locations for Educational Programs:

- State Parks and Forests
- Eagle Bluff
- Audubon of the North Woods
- Deep Portage
- St. John's University
- Bemidji University
- University of Minnesota/extensions
- Wolf Ridge

Sites that have biology labs could be the ideal places for workshops that require microscopes.

Subgroup 3: Chain of Custody Requirements

This subgroup's recommendations were included in the recommendation for subgroup 1.

Departments' Response to Recommendations and Conclusions

The departments agree in principle with subgroup 1's recommendation.

The Minnesota Department of Agriculture is in agreement with the majority of the proposed language but does not agree with the specific language in the second sentence in section D (2). Specifically, the language is objectionable because this is a proposed revision to the Minnesota Retail Food Code, and the retail food code is not applicable to wholesale manufacturing and distribution facilities; therefore, the Minnesota Retail Food Code cannot contain language requiring any course of action in wholesale facilities. Wholesale facilities are regulated under FDA's Federal Code of

Regulations (CFR), Part 110, Good Manufacturing Practices (GMPs), along with other CFRs.

Section of Concern:

D. This section shall not apply to the following:

(2) wild mushrooms that are packaged and are the product of a processing plant that is licensed and inspected by a food regulatory agency. Such mushrooms shall be individually inspected by a certified wild mushroom harvester retained by the food processing plant, and labeled with the common name of the mushroom and the name and location of the food processing plant.

We will not establish an accreditation program because of the time and money needed to develop and administer such a program. We are planning to establish an advisory committee to establish standards for wild mushroom training classes and to approve submitted classes that meet the standards. The classes must be mushroom type specific, taught by someone well trained in the identification and classification of mushrooms and have a testing component. Upon submission to MDA of evidence of the successful completion of an approved mushroom course, a person will be listed in a database of mushroom harvesters.

The departments do not see the need for their involvement in public education. This type of training is best left to other organizations and groups.

Appendices

Appendix 1: Charge to the Minnesota Food Code Rule Revision Wild Mushroom Advisory Workgroup

Appendix 2: Wild Mushroom Advisory Workgroup Members

Appendix 3: Meeting dates, agenda's and meeting minutes

Appendix 4: Subgroup 1-Revised Rule Language

Appendix 1 - Charge to the Minnesota Food Code Rule Revision Wild Mushroom Advisory Workgroup



**Environmental Health Division
Food, Pools and Lodging Services Section**

Dairy and Food Inspection Division

CHARGE TO THE MINNESOTA FOOD CODE RULE REVISION WILD MUSHROOM ADVISORY WORKGROUP

The Minnesota Departments of Health (MDH) and Agriculture (MDA) are revising the Minnesota Food Code (Chapter 4626). The Departments are considering rule amendments that would bring the Code up to date and into substantial conformance with the 2009 Food and Drug Administration (FDA) Model Food Code and Supplement to the 2009 FDA Model Food Code. To that end, MDH and MDA formed a Minnesota Food Code Rule Revision Advisory Committee that advised and provided recommendations on subjects relating to the rule revision to the Departments.

Recently, a number of individuals have expressed an interest in reviewing and making recommendation(s) on the section of the code regulating wild mushrooms, Minnesota Rules 4626.0155 WILD MUSHROOMS. In order to be responsive to this interest and to ensure the best possible food code rule, the departments are convening a small group to work on this section.

Text of Minnesota Rules 4626.0155 WILD MUSHROOMS.

4626.0155 3-201.16 WILD MUSHROOMS.

“A. Except as specified in item B, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by a mushroom identification expert whose expertise has been verified and approved by the regulatory authority through the successful completion of a wild mushroom identification course provided by either an accredited college or university or a mycological society. An individual who wants to be approved as a wild mushroom identification expert shall have on file with the regulatory authority a letter from an accredited college or university certifying successful completion of a wild mushroom identification course from an accredited college or university.

B. This part does not apply to:

- (1)cultivated wild mushrooms species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or
- (2) wild mushrooms species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.”

Membership: The Advisory Workgroup (Workgroup) will consist of twelve to fourteen people including wild mushroom cultivators and foragers, delegated city and county agencies and other interested individuals. MDH and MDA will have at least one active member at each meeting and will also staff the workgroup.

Purposes of the Workgroup

The purposes of the Wild Mushroom Workgroup (Workgroup) are as follows:

- Represent the various parties who may be affected by 4626.0155 3-201.16 WILD MUSHROOMS.
- Assist the Departments to identify all affected people and organizations and design ways to let them know about the possible revisions to this section of the rule.
- Provide advice and recommendations on 4626.0155 including a final proposal that will be presented to MDH and MDA for a decision.

This Workgroup is a non-voting group. The Workgroup advises and makes recommendations. The Commissioners of the Departments of Health and Agriculture will make any final decisions.

Roles and Responsibilities of Mushroom Workgroup Members

- Review, discuss and make recommendations for possible revisions to the Wild Mushroom section.
- Review information and proposals from MDH/MDA and other interested persons. Listen to and consider input from the public, if offered.
- Provide information about the cost of compliance to MDH and MDA for small businesses, cities and counties and information on the fiscal impacts and benefits on local units of government.
- Assist the Departments in identifying all interested persons and to design ways to let them know about the rules. This includes both likely supporters and opponents of the rules.
- Represent the member’s interest group:
 - Act as liaison to the interest group to ensure inclusiveness in the rule revision process.
 - Contact members of interested parties and solicit input on subjects of interest.

- Speak on behalf of the organizations and constituents that they represent to advise the agencies on the development of the rule amendments.
- Assist MDH and MDA in communicating the progress of the rule revision to interest group members.
- Reflect the feedback of their constituents to the discussions of the Workgroup.

Term of Service and Designated Alternates

- Each member will serve for the full duration of the project.
- Each member may designate an alternate to attend meeting(s).
- If a member is unable to attend a meeting, the designated alternate will assume the role of the member at that meeting.
- The public and interested stakeholders are welcome to attend Workgroup meetings.

Role of MDH and MDA

To facilitate the work of the Workgroup, MDH and MDA staff will:

- Make arrangements for full Workgroup meetings.
- Send out meeting notices.
- Prepare meeting agendas and meeting summaries.
- Provide materials for review and consideration.
- Provide information through various media to members and other interested parties.
- Be present at full Workgroup meetings.
- Carefully consider all comments and suggestions made by the Workgroup.
- Arrange for any final proposals to be reviewed by appropriate MDH and MDA staff.

Appendix 2 - Wild Mushroom Advisory Workgroup Members

Wild Mushroom Advisory Workgroup

Name	Title	Organization
Alan Bergo	Chef	Heartland Restaurant
Kim Carlton	Planner principal	MDH
Kevin Doyle	Owner	Forest Mushrooms
Robert Fulgency	President	North American Mycological Association
Valerie Gamble	Food Inspector II, MS, RS	MDA
Lorna Girard	Supervisor/Dairy & food Inspections	MDA
Bill Gunther	Manager/Department of Safety and Inspections	City of St. Paul
Mike Kempenich	CEO	The Mikeology Store
Brian Krawiecki	Department of Safety and Inspections	City of St. Paul
Katie Lampi	Code Compliance Officer	City of Minneapolis
Lynne Markus	Planner Principal	MDH
Steve Netzman	Past President and Chair	Wild Mushroom Harvesting Committee - MMS
Scott Pampuch	Executive Chef	Minnesota Valley Country Club
Maddy Papermaster	Forager	Minnesota Mycological Society
Linda Prail	Rule Coordinator	MDH
Dave Read	Assistant Director	MDA
Lenny Russo	Owner/Executive Chef	Heartland Restaurant
Pam Steinbach	R.S./Environmental Health Supervisor	MDH
Dan Vassar	Environmental Health	Hennepin County
Ann Walters	Compliance Officer/dairy & Food Inspections	MDA
Dave Wilsey	Assistant Extension Professor	University Extension
Kathy Yerich	Forager	Minnesota Mycological Society

Appendix 3 - Meeting dates, agenda's and meeting minutes

Wild Mushroom Advisory Workgroup Meeting

Monday, March 19, 2012

9:30 – 11:30 @ SOP Bigfork Room

AGENDA

1. Welcome, introductions and housekeeping items
 - Why do you want to participate in this workgroup?
 - What is your experience with wild mushrooms?
2. Review the Workgroup charge
 - Scope and limitations
 - Authority
 - Expected outcome
3. Meeting schedule
 - Four meetings
 - Day
 - Time
4. Notebooks - Materials
5. Brainstorming exercise
 - What is right and what needs to be fixed/changed with the current rule?
6. Next steps

Wild Mushroom Advisory Workgroup Meeting Minutes 03/19/2012

Meeting Date: 03/19/2012

Meeting Owner: Linda D. Prail

Committee Attendees: **Committee Members:** David Wilsey, Brian Krawiecki, Lynne Markus, Angie Cyr, Kevin Doyle, Steve Netzman, Bob Fulgency, Kathy Yerich, Lenny Russo, Dan Vassar, Mike Kempenich, Cynthia Forsberg, Alan B ergo

Staff Members: *MDA Staff:* Lorna Girard, Valerie Gamble *MDH Staff:* Linda Prail, Susan Peterson

Guest Speakers:

Scribe: Susan Peterson

Agenda	Lead	Notes
1) Welcome	Linda Prail	Welcomed attendees. Introductions.
2) Charge – Reason for recommendations		The Minnesota Departments of Health (MDH) and Agriculture (MDA) are revising the Minnesota Food Code (Chapter 4626). The Departments are considering rule amendments that would bring the Code up to date and into substantial conformance

Agenda	Lead	Notes
		with the 2009 Food and Drug Administration (FDA) Model Food Code and Supplement to the 2009 FDA Model Food Code. To that end, MDH and MDA formed a Wild Mushroom Advisory Workgroup that advised and provided recommendations on subjects relating to the wild mushroom rule revision to the Departments.
3) Defines workgroup	Linda Prail	The duties of workgroup, make recommendation and give advice on how to make the rule work, language change and clarification. Need classes for certification.
4) Meeting dates		Planning 4 meetings, agreed to meet on Monday afternoons
5) Brainstorming		Go over MN language - Split in groups of 3 Discussion on what works and doesn't work. Works: exemption 1 works for certification, accredited does work – state agency represents how interrupted. Doesn't work: Loopholes in B-2 may not be an expert available. Who did the mushrooms come from, do they have liability insurance, required to have it. Out of state people, what certification is needed to be licensed as a food wholesaler (license/certification – 2 different things) How many register for than just Morals? Cultivated or wild – which, use same frame as food code as for levels, risks, potential threat. Do we need more regulations and rules? Expert is not much of a statement, use “approved mushroom identifier” There is a contradiction with all agencies, we need to be consistent. Additional ideas on attached sheet.

Decisions / Next Steps

Read information from other states
Make list of mushrooms
Accomplish correct language
Write ideas down you have

Parking Lot

Wild Mushroom Advisory Workgroup Meeting
Wednesday, March 28, 2012

9:30 – 11:30 @ SOP Red River Room

AGENDA

1. Welcome, introductions
2. Workgroup membership finalization
3. New information for notebook
4. Rewriting of the Minnesota rule section
5. Next Steps
6. Adjourn

Wild Mushroom Advisory Workgroup Meeting Minutes 03/28/2012

Meeting Date: 03/28/2012 Snelling Office Park

Meeting Owner: Linda D. Prail

Committee Attendees: **Workgroup Members:** Alan Bergo, Kim Carlton, Kevin Doyle, Bob Fulgency, Bill Gunther, Mike Kempenich, Katie Lampi, Lynne Markus, Steve Netzman, Scott Pampuch, Lenny Russo, Dan Vassar, Ann Walters, Kathy Yerich,

Staff Members: *MDA Staff:* Lorna Girard, Valerie Gamble *MDH Staff:* Linda Prail, Pam Steinbach, Susan Peterson

Guest Speakers: Joellen Feirtag

Scribe: Susan Peterson

Agenda	Lead	Notes
6) Welcome	Linda Prail	Welcomed attendees. Introductions.
7) Overview and chart information from MN Department of Agriculture	Valerie Gamble	Food licensing overview regarding mushrooms. MDA, MDH, county and city health agencies. Licensing exemptions: not from health code, just getting license. Still need certification. When on own land, "part of the farm". Chart: what are regulations direct to consumer? Add additions to chart. Farmers markets: have own/different rules but need to meet the state regulations. Laws: location of land/or regulations. Continue to add information.
8) Handouts		New information for notebook
9) Discussion on new language		Break into groups and discuss new language changes/additions. Review and submit to members.
10) Discussion on Rules for		Start with easiest mushroom (morels).

Agenda	Lead	Notes
Certification		Identification, traceability, food handling Joellen Feirtag to offer course Certification course: UMN St. Paul Campus, April 12th 4 hr. course (may need to have a few courses depending on sign up) What is fee cost? Certification on what course consist of/curriculum Will send more information to MDH/MDA
11) Subcommittee Sign - up		Sign up for 3 different subcommittees: Mushroom List Certification/Course Rule Language
12) Adjourn		
Decisions / Next Steps		
Next meeting April 9, Snelling Office Park		
Parking Lot		

Wild Mushroom Advisory Workgroup Meeting

Monday, April 9, 2012

1:00 – 3:00pm @ SOP Bigfork Room

AGENDA

1. Welcome, introductions
2. Formal composition of workgroup
3. Recap
4. Rule language revision(s)
5. Subcommittees
6. Next Steps

Wild Mushroom Advisory Workgroup Meeting Minutes 04/09/2012

Meeting Date: 04/09/2012 Snelling Office Park**Meeting Owner:** Linda D. Prail

Committee Attendees: **Workgroup Members:** Alan Bergo, Kim Carlton, Kevin Doyle, Bob Fulgency, Bill Gunther, Mike Kempenich, Katie Lampi, Lynne Markus, Steve Netzman, Maddy Papermaster, Lenny Russo, Dan Vassar, Ann Walters, Kathy Yerich,

Staff Members: *MDA Staff:* Lorna Girard, Valerie Gamble *MDH Staff:* Linda Prail, Pam Steinbach, Susan Peterson

Guest Speakers:**Scribe:** Susan Peterson

Agenda	Lead	Notes
13) Welcome	Linda Prail	Welcomed attendees. Introductions.
14) Handouts		Membership list, subcommittee list
15) Update on language	Linda Prail	Both MDH and MDA staff are working on new language.
16) Out of state foragers	Lorna Girard	Update on Wisconsin: Can they sell in Minnesota? Need same qualifications as MN sellers. Source-Who needs to be certified, person that forages or restaurant owner. License and certification are 2 different things.
17) Commonalities/Differences Review	Linda Prail	Linda reviewed the results of the work of the various small groups from the last meeting. Definitions: cultivated and wild mushrooms, recommend wild <u>harvest</u> mushrooms. Approved source: Who is certified, how far back for tracing and what details (documentation), verify wholesomeness. Certification course: what will it consist of, should be state approved. Inspecting: No sampling each mushroom inspected individually. Course/class: conducted by college or university or

Agenda	Lead	Notes
		<p>approved organization</p> <hr/> <p>Mushroom list: concept of list, allowed mushrooms, safe mushrooms only? Traceability: depends on how far back, should be available. Labels: Should there be a mandated label, list common & scientific name. Consumer warning: not needed, list safe directions on package. Buyer/end user certification: Mushrooms should be identified by at least one certified person before consumer purchase.</p>
18) Handouts/Certification		State of Maine, certification course offered by UM Extension
19) Split in Subcommittees		<p>Subcommittees work together: Rule group work on language change, write up new language Certification course: curriculum/topics that have to be covered Traceability:Lynn Markus, Dan Vassar, Kathy Yerich, write up standards for traceability</p>
20) Adjourn		
Decisions / Next Steps		
Next meeting Monday, April 23, Snelling Office Park		
Parking Lot		

Wild Mushroom Advisory Workgroup Meeting

Monday, April 23, 2012

1:00 – 3:00pm @ SOP Mississippi Room

AGENDA

1. Welcome
2. Workgroup Status
3. Report on training class
4. Report from subcommittees
 - a. Rule Language
 - b. Training/certification
 - c. Traceability
5. Next Steps

Wild Mushroom Advisory Workgroup Meeting Minutes 04/23/2012

Meeting Date: 04/23/2012 Snelling Office Park**Meeting Owner:** Linda D. Prail

Committee Attendees: **Workgroup Members:** Alan Bergo, Kim Carlton, Kevin Doyle, Cynthia Forsberg, Bob Fulgency, Mike Kempenich, Katie Lampi, Lynne Markus, Steve Netzman, Maddy Papermaster, Lenny Russo, Ann Walters, Kathy Yerich,

Staff Members: *MDA Staff:* Lorna Girard, Dave Read *MDH Staff:* Linda Prail, Pam Steinbach, Susan Peterson

Guest Speakers:**Scribe:** Susan Peterson

Agenda	Lead	Notes
21) Welcome	Linda Prail	Welcomed attendees
22) Workgroup Status		Discussion on where we are at with language, certification and traceability changes /additions, is "draft" language ready, are we ready to move ahead
23) Report on "draft" CFP Wild Mushroom Guidance document	Pam Steinbach	Language reviewed for guidance document. Questions on MN Mushroom list, should MN have a specific list? Draft copy handed out at meeting
24) Web Page	Susan Peterson	Wild Mushroom Rule Revision information is now posted on food code web page
25) Report on certification class		All classes were full; although some opinions stated it was technical and scientific some work was needed. Agreed 4 hour class was long enough for morals, oysters. Should there be classes for all mushrooms, how long should sessions be?
26) Subcommittee discussion		Broke up in subcommittee groups to work on reports

Agenda	Lead	Notes
27) Subcommittees reports		<p>Rule Language: All agreed to new language. Questions asked: Cultivated-wild, how much human contact to still be called wild? What species of mushrooms must be known and how many should a forager know?</p> <p>Traceability: All agreed to new language on the rule language.</p> <p>Certification: More work needed. Questions asked: how will course be structured, what species were they taught, more emphasis on wild/poison mushrooms. How do you put experiential rules into the certificate?</p>
28) Exercise		Workgroup listed terms used in the rule they “liked” and “disliked” and also were asked what the next steps should be.
29) Adjourn		

Decisions / Next Steps
<p style="text-align: center;">Parking Lot</p>

Appendix 4 - Subgroup 1-Revised Rule Language

4626.0155 3-201.16 WILD MUSHROOMS.

A. Except as specified in item D, wild mushroom species shall be obtained from sources where each mushroom is individually inspected and found to be safe by a certified mushroom harvester whose ability to correctly identify edible wild mushrooms has been verified and approved by the regulatory authority through the successful completion of a wild mushroom identification program provided by an accredited person or organization. A letter issued by the accrediting person or organization certifying the harvester's successful completion of the wild mushroom identification course and specifying the species of wild mushroom the harvester is qualified to identify shall be kept on file with the regulatory authority. The Minnesota Department of Agriculture shall maintain a registry of all certified wild mushroom harvesters.

B. Except as specified in item D, wild mushroom species shall have a written buyer specification which shall be retained by the buyer for 90 days from the date of sale or service. The written buyer specification shall include all of the following information:

- (1) identification of the mushroom species by the scientific and common name;
- (2) date of sale and quantity by weight of each species sold;
- (3) a statement indicating that the mushroom was identified in its fresh state;
- (4) the name, address and telephone number of the harvester, and
- (5) a statement describing the qualifications and training of the harvester, specifically relating to mushroom identification, including the species that the individual is certified to harvest.

C. Except as specified in item D, the harvester shall retain for 90 days records of wild mushrooms sold to food establishments. The records retained shall include all of the following information:

- (1) identification of the mushrooms by the scientific and common name;
- (2) the state and county locations of harvest;
- (3) the dates of harvest;
- (4) the names of the establishments where wild mushrooms were sold, including dates of sale, and the quantities by weight of each species purchased

D. This section shall not apply to the following:

- (1) cultivated mushroom species that are grown, harvested, and processed in an operation that is licensed and inspected by a food regulatory agency;
- (2) wild mushrooms that are packaged and are the product of a processing plant that is licensed and inspected by a food regulatory agency. Such mushrooms shall be individually inspected by a certified wild mushroom harvester retained by the food processing plant, and labeled with the common name of the mushroom and the name and location of the food processing plant.

Definitions:

Wild mushrooms: Wild mushrooms are edible species of mushrooms that have been harvested from their naturally occurring environment where no human intervention occurred to support their growth.

Cultivated mushrooms: Cultivated mushrooms are edible species of mushrooms that have been cultivated by persons under controlled conditions, outdoors or indoors, on natural or artificial substrate.



Minnesota Department of Health
Environmental Health
FPLS Section
651-201-4500

Attachment K 1 of 2

** Please fill in the gray areas on this form

For the Time Between The Adoption Date and The Effective Date						
Agency Name:	Number of licensed food establishments:	Name of person completing this form:		Date Completed:		
MDH	13,000	Dan Disrud		2/25/2016		
COST OF MN FOOD CODE REVISION <small>*from adoption date to effective date</small>	Personel / Staff (Salary, benefits, etc.)	Supplies. Printing, Publication, etc	Training, * not including salary, etc.	Information Technology (including software)	Others, Please specify ...	Cost Total
Activities	Please fill out each field below as acurately as possible. Thank you.					
Revision of Ordinances	\$3,500.00	\$0.00	\$0.00	\$0.00		\$3,500.00
Training, Internal	\$50,000.00	\$3,500.00	\$0.00	\$0.00		\$53,500.00
Training, External	\$50,000.00	\$3,500.00	\$500.00	\$2,000.00		\$56,000.00
Additional Plan Review Time and Equipment Evaluation	\$9,000.00	\$0.00	\$0.00	\$0.00	\$4,000.00	\$13,000.00
Outreach	\$1,500.00	\$14,500.00	\$0.00	\$0.00		\$16,000.00
Updating and Preparing documents	\$2,000.00	\$2,000.00	\$0.00	\$50,000.00		\$54,000.00
Additional inspection time	\$55,000.00	\$9,000.00	\$0.00	\$0.00		\$64,000.00
Overtime, please specify	\$0.00	\$0.00	\$0.00	\$0.00		\$0.00
Total Cost	\$171,000.00	\$32,500.00	\$500.00	\$52,000.00	\$4,000.00	\$260,000.00

* Outside Personnel

** Please fill in the gray areas on this form

For the Year Following the Effective Date						
Agency Name:	Number of licensed food establishments:	Name of person completing this form:		Date Completed:		
MDH	13,000	Dan Disrud		3/29/2016		
COST OF MN FOOD CODE REVISION <small>*from adoption date to effective date</small>	Personel / Staff (Salary, benefits, etc.)	Supplies. Printing, Publication, etc	Training, * not including salary, etc.	Information Technology (including software)	Others, Please specify ...	Cost Total
Activities	Please fill out each field below as acurately as possible. Thank you.					
Revision of Ordinances	\$1,000.00	\$0.00	\$0.00	\$0.00		\$1,000.00
Training, Internal	\$48,000.00	\$0.00	\$0.00	\$0.00		\$48,000.00
Training, External	\$2,000.00	\$1,000.00	\$0.00	\$0.00		\$3,000.00
Additional Plan Review Time and Equipment Evaluation	\$6,000.00	\$0.00	\$0.00	\$0.00	\$4,000.00	\$10,000.00
Outreach	\$1,500.00	\$14,500.00	\$0.00	\$0.00		\$16,000.00
Updating and Preparing documents	\$0.00	\$2,000.00	\$0.00	\$50,000.00		\$52,000.00
Additional inspection time	\$53,000.00	\$0.00	\$0.00	\$0.00		\$53,000.00
Overtime, please specify	\$0.00	\$0.00	\$0.00	\$0.00		\$0.00
Total Cost	\$111,500.00	\$17,500.00	\$0.00	\$50,000.00	\$4,000.00	\$183,000.00

* Outside Personnel

Attachment L 1 of 2

** Please fill in the gray areas on this form

For the Time Between The Adoption Date and The Effective Date						
Agency Name:	Number of licensed food establishments:	Name of person completing this form:		Date Completed:		
MDA	7,000	Jeff Luedeman		5/31/2016		
COST OF MN FOOD CODE REVISION *from adoption date to effective date	Personel / Staff (Salary, benefits, etc.)	Supplies. Printing, Publication, etc	Training, * not including salary, etc.	Information Technology (including software)	Others, Please specify ...	Cost Total
Activities	Please fill out each field below as acurately as possible. Thank you.					
Revision of Ordinances	\$700.00	\$0.00	\$0.00	\$0.00		\$700.00
Training, Internal	\$21,000.00	\$1,500.00	\$0.00	\$0.00		\$22,500.00
Training, External	\$21,000.00	\$0.00	\$0.00	\$0.00		\$21,000.00
Additional Plan Review Time and Equipment Evaluation	\$10,000.00	\$0.00	\$0.00	\$0.00	\$4,000.00	\$14,000.00
Outreach	\$800.00	\$5,000.00	\$0.00	\$0.00		\$5,800.00
Updating and Preparing documents	\$5,500.00	\$800.00	\$0.00	\$10,000.00		\$16,300.00
Additional inspection time	\$15,000.00	\$3,500.00	\$0.00	\$0.00		\$18,500.00
Overtime, please specify	\$0.00	\$0.00	\$0.00	\$0.00		\$0.00
Total Cost	\$74,000.00	\$10,800.00	\$0.00	\$10,000.00	\$4,000.00	\$98,800.00

* Outside Personnel

2. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The main new administrative function for state regulatory agencies will be the review of HACCP plans. The agency administered food inspection programs are fee supported. Costs associated with licensure should remain constant since no significant new inspection responsibilities are enumerated by the code other than the review of HACCP plans where required in existing establishments. Efficiencies may even be realized from having consistent standards between two state agencies such as uniform inspection forms and standardized sanitarian training.

The review of HACCP plans will occur in two places; for existing establishments within the establishment at the time of inspection - for new establishments, at the time of plan review. It is estimated that the review of HACCP plans will take an additional two hours of staff time per plan for review in conjunction with new establishments and one hour for review in existing establishments.

It is estimated that 140 HACCP plans initially will need review statewide in conjunction with inspections in establishments licensed under *Minnesota Statutes*, Chapter 157, in each of the years after HACCP plans are due. Of the 1,000 plans for new establishments that are reviewed annually for establishments licensed under *Minnesota Statutes*, Chapter 157, it is estimated that 50 of them will involve HACCP.

For establishments licensed by the MDA, it is estimated that 1,550 plans will need review initially statewide in conjunction with inspections. Annually another 30 will need review as part of the estimated 700 plans reviewed annually for new establishments.

MnSafe, which is a loose knit partnership of regulatory agencies, industry, food scientists and technologists involving the University of Minnesota, MDH, MDA, industry representatives and the Agricultural Utilization Institute estimates that the average HACCP plan can be reviewed in one to two hours.

The agencies anticipate that the additional time and cost for HACCP plan review over the next two years will be borne by the agencies and will be offset by any efficiencies resulting from the adoption of the statewide food code.

Costs to a local unit of government to inspect establishments through a delegation agreement may result from a need to modify an existing local ordinance. Because the food code is applicable statewide, updating the local ordinance will not be a major undertaking since it requires cross referencing to the revised state rules. A model ordinance will be prepared and available to local jurisdictions. The local agency expense to update any local ordinance to be consistent with the adopted state food code is estimated to be \$1,000 per subdivision. There are 43 counties and 18 cities with agreements with MDH to administer the food, beverage and lodging standards of the state for an estimated total cost to all local jurisdictions of \$61,000.

The proposed rules have no anticipated impact on state revenues because there are no new fees associated with the activities authorized or required by the rules. The additional staff time discussed in the preceding paragraph to review HACCP plans will be incorporated into existing program staffing levels. Therefore, there will be no additional cost to the department or other state agencies.

3. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Comment on agency rule drafts from the Hospitality Institute of Technology and Management recommended a HACCP-based approach to regulation of the state food industry. This approach was discussed by the food code advisory work group and was not recommended for every food establishment or as a substitute for the existing inspection program.

- An inspection-based program is currently specified in state law for both MDH and MDA licensed establishments.
- Inspections of food establishments by government inspectors are recommended by the U.S. FDA in the model code and at a rate more frequent than currently employed by the state agencies.
- An inspection-based program is supported by the national Conference for Food Protection.
- In comment to the agencies by Doug Downs representing meat processors, he estimates processors with less than 10 employees account for 99 percent of the state-licensed plants [not regulated under the food code]. For these plants, he estimates it will cost in the range of \$400 to \$1,000 per product to develop a HACCP plan according to FDA manufacturing plant requirements. A small pilot project was undertaken by the MDA in establishments that do custom meat processing. In this pilot involving three establishments, MDA staff estimated the cost of developing a HACCP plan by the establishment to be from \$50 to \$300. Establishments that currently have good processing control would have relatively few implementation costs, while establishments that have little or no process control would need to spend more for HACCP.

The cost of fees for MDH licensed establishment are set in statutes (*Minnesota Statutes*, section 157.16)

and range between \$130 and \$355 annually per establishment to support an inspection-based program. The fees for MDA establishments are set in *Minnesota Statutes*; section 28A.08. It would not be efficient nor administratively feasible for temporary establishments to have to have HACCP plans. They often have neither the expertise to develop plans nor the permanency to implement them.

No determination has been made as to whether a HACCP plan-based system would be less costly or less intrusive than the existing inspection-based system. The agencies will be closely monitoring those areas where HACCP is being required. Both agencies will be undertaking pilot projects in the next two years using HACCP plans as a foodborne illness control mechanism within some selected establishments.

The cost of foodborne illness to the public is certainly very costly. The investigation of foodborne outbreaks and the potential exclusion of employees can be very intrusive. Such investigations would occur whether the state has an inspection or HACCP-based system in place.

4. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

Throughout the following rule-by-rule justification is additional explanation of alternatives considered in conjunction with each specific provision.

The overall alternative considered by the agencies was put forth in comment on the draft rules and suggested that the agencies require HACCP plans for all food establishments in lieu of inspections. This comment was seriously considered but rejected because state and federal laws govern the state food programs administered by MDH and MDA and require inspections. The alternative option of requiring HACCP plans for all food service operations, not just those with high risk situations like the service of raw animal products, was considered by the rule advisory workgroup. The workgroup concurred with the limitation of the HACCP plan requirement to certain high risk situations at this time. The industry is not trained to develop HACCP plans, though they may be implementing its basic concepts without knowing it. The MDH is in the process of developing rules for food service operation manager certification, the training for which would include HACCP planning. However, that rule is yet to be adopted and compliance would not begin for at least two years. HACCP is a new concept to the retail sector that is being slowly developed and gradually incorporated. At this time the agencies must abide by the statutory requirements to administer an inspection-based regulatory program.

Other major alternatives considered by the state agencies responsible for rule promulgation and the rule advisory work group were mandating a number of additional "built-in" protections such as increasing lighting levels in new and existing establishments, requiring food preparation sinks in all existing establishments, requiring refrigeration lines in salad bars, requiring light colored ceramic tile in kitchens and tile at least eight feet high on the walls in toilet areas, requiring heat boosters under handwashing sinks, requiring thermocouple thermometers; requiring blast chillers and recording thermometers in refrigerators. The mandate of additional built-in mechanisms to achieve food safety were considered and only three proposed. These apply to new or extensively remodeled establishments and include separate food preparation sinks, and solid bases under appliances. The FDA has indicated in the model 1995 food code that most "floor, walls and ceiling" provisions (Chapter 6) are not critical items. There is a link between building condition and food disease, but the emphasis on building factors as a control mechanism is not nearly as critical as behavior factors such as handwashing and the exclusion of ill workers. Because of the emphasis on behavior factors the agencies have chosen not to increase the emphasis on building and equipment controls at this time as much as some local jurisdictions or local health agencies, would like. Where additional building and equipment

requirements have been mandated the applicability has been limited to new facilities or those undergoing extensive remodeling.

Delegated Agency Cost Estimation



Minnesota Department of Health (MDH) and Minnesota Department of Agriculture (MDA) are finalizing the draft revised Minnesota Food Code language and the Statement of Need and Reasonableness (SONAR).

By law, MDH and MDA need to make a determination of the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals and provide the determination and supporting documentation to the Administrative Law Judge (ALJ) [Minnesota Statutes 14.131]

We must determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for any one statutory or home rule charter city that has less than ten full-time employees. Although the statute refers to "city" we want to collect this information from all delegated agencies.

Your participation in this survey is voluntary.

1. Agency Name

2. Name of person completing form

3. Number of employees (For the entire city, county, multi-jurisdiction entity, etc..)

4. Number of licensed food establishments

1. Please enter estimated cost for the following tasks for a six month period of time from the adoption date and the effective date:

A. Revision of Ordinances _____

B. Training of Internal staff _____

C. Training of External People _____

- D. Additional Plan Review Time and Equipment Evaluation _____
- E. Outreach to Persons Outside of your Agency _____
- F. Updating and Preparing Documents _____
- G.. Additional Inspection Time _____
- H. Overtime _____

2. Please enter estimated cost for the following tasks for one year after the effective date of the rule revisions:

- A. Revision of Ordinances _____
- B. Training of Internal Staff _____
- C. Training of External People _____
- D. Additional Plan Review Time and Equipment Evaluation _____
- E. Outreach to Persons Outside of your Agency _____
- F. Updating and Preparing Documents _____
- G. Additional Inspection Time _____
- H. Overtime _____

Thank you for taking the time to complete this survey. We appreciate your willingness to participate and value your feedback.

Minnesota Department of Health
Food, Pools, and Lodging Services
P.O. Box 64975
St. Paul, MN 55164-0975
651-651-4500

Delegated Agency Cost Estimation

		1. Please enter estimated cost for the following tasks for a <u>six month period of time from the adoption date and the effective date:</u>								
Number of employees (For the entire city, county, multi- jurisdiction entity, etc..)	Number of licensed food establishments	A. Revision of Ordinances	B. Training of Internal staff	C. Training of External People	D. Additional Plan Review Time and Equipment Evaluation	E. Outreach to Persons Outside of your Agency	F. Updating and Preparing Documents	G. Additional Inspection Time	H. Overtime	Total Cost
58	239	\$0	\$4,000	\$420	\$0	\$600	\$480	\$0	\$0	\$5,500
450	283	\$2,000	\$2,000	\$1,500	\$1,500	\$2,000	\$500	\$5,000	\$0	\$14,500
1000	1100	\$20,500	\$8,500	\$5,600	\$0	\$8,800	\$8,400	\$0	\$0	\$51,800
3	332	\$2,740	\$2,630	\$1,900	\$380	\$800	\$1,100	\$0	\$0	\$9,550
2317	835	\$500	\$5,000	\$2,000	\$500	\$1,000	\$3,500	\$2,000	\$0	\$14,500
4	465	\$2,300	\$4,500	\$1,300	\$3,000	\$1,000	\$500	\$1,000	\$500	\$14,100
1	130	\$2,300	\$1,000	\$300	\$1,000	\$300	\$200	\$300	\$0	\$5,400
300	775	\$6,100	\$2,930	\$3,080	\$0	\$0	\$1,600	\$0	\$0	\$13,710
	180	\$1,000	\$1,500	\$0	\$0	\$200	\$500	\$0	\$0	\$3,200
1100	560	\$1,860	\$8,340	\$0	\$3,500	\$5,950	\$6,740	\$3,500	\$0	\$29,890
359		\$0	\$150	\$200	\$0	\$250	\$200	\$5,000	\$0	\$5,800
92	250	\$1,000	\$1,000	\$5,000	\$5,000	\$0	\$1,000	\$2,500	\$0	\$15,500
8000	1800	\$1,000	\$2,000	\$500	\$0	\$2,500	\$1,000	\$0	\$0	\$7,000
456	480	\$2,000	\$3,000	\$2,000	\$0	\$500	\$5,000	\$0	\$0	\$12,500
280	160	\$0	\$1,200	\$600	\$500	\$0	\$500	\$2,500	\$0	\$5,300
20	3700	\$22,400	\$56,500	\$18,200	\$8,400	\$4,800	\$7,600	\$65,000	\$0	\$182,900
Agencies Combined Costs		\$65,700	\$104,250	\$42,600	\$23,780	\$28,700	\$38,820	\$86,800	\$500	

Delegated Agency Cost Estimation

2. Please enter estimated cost for the following tasks for one year after the effective date of the rule revisions:

A. Revision of Ordinances	B. Training of Internal Staff	C. Training of External People	D. Additional Plan Review Time and Equipment Evaluation	E. Outreach to Persons Outside of your Agency	F. Updating and Preparing Documents	G. Additional Inspection Time	H. Overtime	Total Cost
\$0	\$800	\$2,000	\$0	\$600	\$0	\$0	\$0	\$3,400
\$0	\$500	\$500	\$500	\$200	\$0	\$1,500	\$0	\$3,200
\$0	\$8,500	\$5,600	\$7,000	\$8,800	\$8,400	\$3,500	\$0	\$41,800
\$2,000	\$500	\$1,900	\$1,500	\$1,000	\$1,000	\$9,000	\$0	\$16,900
\$0	\$0	\$2,000	\$500	\$0	\$0	\$4,000	\$0	\$6,500
\$0	\$1,000	\$300	\$3,000	\$300	\$0	\$1,000	\$0	\$5,600
\$0	\$300	\$300	\$1,000	\$300	\$0	\$1,000	\$0	\$2,900
\$0	\$250	\$250	\$0	\$0	\$250	\$0	\$0	\$750
\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
\$0	\$0	\$5,000	\$0	\$3,000	\$0	\$7,000	\$0	\$15,000
\$0	\$0	\$0	\$0	\$0	\$0	\$12,000	\$0	\$12,000
\$0	\$0	\$5,000	\$5,000	\$0	\$0	\$2,500	\$0	\$12,500
\$1,000	\$1,000	\$500	\$4,000	\$2,500	\$0	\$4,000	\$0	\$13,000
\$0	\$500	\$2,000	\$0	\$1,000	\$2,500	\$0	\$0	\$6,000
\$1,500	\$600	\$500	\$1,300	\$1,500	\$0	\$1,500	\$0	\$6,900
\$11,200	\$56,000	\$11,200	\$42,000	\$11,200	\$12,600	\$175,000	\$0	\$319,200
\$15,700	\$69,950	\$37,050	\$65,800	\$30,400	\$24,750	\$222,000	\$0	

Minnesota Food Code Rule Revision Business Cost Survey



The Minnesota Department of Agriculture (MDA) and the Minnesota Department of Health (MDH) are in the process of revising the Minnesota Food Code, Minnesota Rules, Chapter 4626. A current draft of the proposed revised rule language, a side-by-side comparison of the current rule and the proposed draft language and additional information about the rule revision process can be found at <http://www.health.state.mn.us/divs/eh/food/code/2009revision/index.html>.

As part of the rulemaking process, the Departments are required to try to determine the probable costs of the proposed rule revisions and if the revisions will cost any affected business with 49 or fewer full-time employees more than \$25,000 during the first year the revisions are in effect.

For the purposes of this survey business means a business entity organized for profit or as a non-profit, and includes an individual, partnership, corporation, joint venture, association, or cooperative.

The Departments are asking you to complete this short survey.

This survey is voluntary. No information will be gathered during the survey that could link your answers to you.

If you have any questions, please contact Linda Prail by email at linda.prail@state.mn.us or by phone at 651-201-5792.

1. How many different establishments does your business operate in Minnesota that use requirements found in the Food Code for preserving public health and safety?

For example, if your business operates three restaurants (one each in Lakeville, Roseville and Minneapolis), one congregate dining location in St. Cloud and one grocery store in Maple Grove you would record 5.

2. Does your business have a total of 49 or fewer full-time employees?

- Yes
- No

3. Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code.

Activity: Estimated Cost (*please round to the nearest hundred dollars*)

- Update procedures and design and implement new systems or update existing systems _____
- Training _____
- Certified Food Protection Manager (formerly CFM), if needed _____
- New equipment or new construction or rehabilitation of existing establishment _____
- Supplies, such as new menus or table tents _____
- Additional time with the inspector _____
- Other* (*please indicate the item or activity below*) _____

*Other

4. Will the proposed Minnesota Food Code revisions cost your business more than \$25,000 during the first year the new Code is in effect?

- Yes
- No

On behalf of MDH and MDA, thank you for taking the time to complete this survey.

Minnesota Department of Health
Food, Pools, and Lodging Services
P.O. Box 64975
St. Paul, MN 55164-0975
651-651-4500



Minnesota Food Code Rule Revision Business Cost Survey

Type: Frequency Report

Date: 10/3/2016

Total number of responses collected: 255



1. How many different establishments does your business operate in Minnesota that use requirements found in the Food Code for preserving public health and safety? *For example, if your business operates three restaurants (one each in Lakeville, Roseville and Minneapolis), one congregate dining location in St. Cloud and one grocery store in Maple Grove you would record 5.*

(Respondents were limited to **brief** text responses)

Response	20% 40% 60% 80% 100%	Frequency	Count
0		1.6%	4
1		76.3%	190
2		10.0%	25
3		4.4%	11
4		2.4%	6
5		2.0%	5
8		1.2%	3
Other Responses		2.0%	5
		Valid Responses	249
		Total Responses	249

2. Does your business have a total of 49 or fewer full-time employees?

(Respondents could only choose a **single** response)







Response	20% 40% 60% 80% 100%	Frequency	Count
Yes		82.9%	199
No		17.1%	41
Not Answered			15
Valid Responses			240
Total Responses			255

3. Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code. Activity: Estimated Cost (please round to the nearest hundred dollars)

- **(Update procedures and design and implement new systems or update existing systems)**

(Respondents were limited to **brief** text responses)

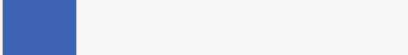
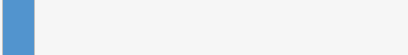
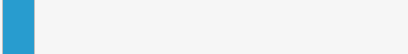
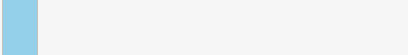
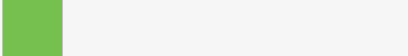
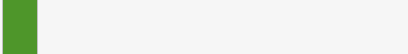
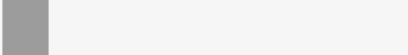

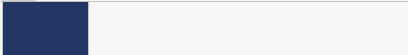

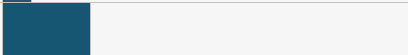
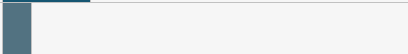
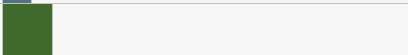
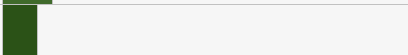
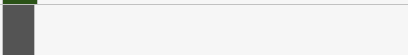
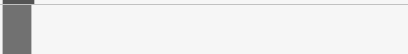
Response	20% 40% 60% 80% 100%	Frequency	Count
0		16.0%	30
1		1.6%	3
100		7.0%	13
200		4.8%	9
250		2.7%	5
300		1.6%	3
500		10.7%	20
1000		13.9%	26
1200		1.1%	2
1500		1.6%	3
1700		1.1%	2
2000		6.4%	12
2500		2.7%	5
3000		4.3%	8
4000		1.1%	2
5000		5.9%	11

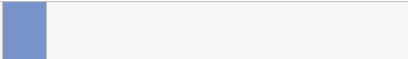
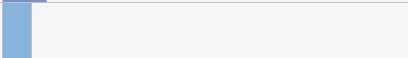
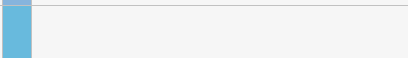
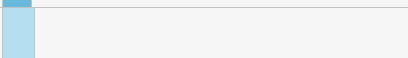
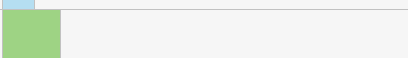
10000		3.2%	6
12000		1.6%	3
15000		1.1%	2
18000		1.6%	3
30000		1.1%	2
Other Responses		9.1%	17
		Valid Responses	187
		Total Responses	187

3.(cont.) Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code. Activity: Estimated Cost (please round to the nearest hundred dollars)

- **(Training)**

(Respondents were limited to **brief** text responses)

Response	20% 40% 60% 80% 100%	Frequency	Count
0		12.7%	24
1		1.6%	3
50		1.6%	3
100		2.6%	5
200		9.0%	17
250		2.6%	5
300		5.3%	10
400		1.6%	3
500		15.9%	30
800		1.1%	2
1000		16.4%	31
1500		1.1%	2
2000		6.3%	12
2500		2.6%	5
3000		1.6%	3
4000		1.1%	2

5000		4.8%	9
6000		1.1%	2
8000		1.1%	2
10000		1.6%	3
Other Responses		8.5%	16
		Valid Responses	189
		Total Responses	189

3.(cont.) Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code. Activity: Estimated Cost (please round to the nearest hundred dollars)

- **(Certified Food Protection Manager (formerly CFM), if needed)**

(Respondents were limited to **brief** text responses)

Response	20% 40% 60% 80% 100%	Frequency	Count
0		22.6%	37
1		1.8%	3
75		1.2%	2
100		6.1%	10
200		9.8%	16
250		5.5%	9
300		7.3%	12
400		5.5%	9
450		1.2%	2
500		11.0%	18
600		2.4%	4
800		4.3%	7
1000		6.1%	10
1500		1.8%	3
3000		1.8%	3
5000		1.8%	3









Other Responses	9.8%	16
Valid Responses		164
Total Responses		164

3.(cont.) Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code. Activity: Estimated Cost (please round to the nearest hundred dollars)

- (New equipment or new construction or rehabilitation of existing establishment)**

(Respondents were limited to **brief** text responses)

Response	20% 40% 60% 80% 100%	Frequency	Count
0		19.3%	34
1		1.1%	2
100		2.8%	5
200		1.1%	2
500		2.8%	5
1000		8.0%	14
1200		4.5%	8
1500		1.1%	2
2000		3.4%	6
2500		3.4%	6
3000		2.3%	4
4000		3.4%	6
5000		8.5%	15
6000		1.1%	2
8000		1.7%	3
10000		5.7%	10


12000		2.3%	4
15000		3.4%	6
18000		1.1%	2
20000		1.1%	2
25000		1.7%	3
30000		3.4%	6
50000		2.3%	4
Other Responses		14.2%	25
		Valid Responses	176
		Total Responses	176

3.(cont.) Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code. Activity: Estimated Cost (please round to the nearest hundred dollars)

- **(Supplies, such as new menus or table tents)**

(Respondents were limited to **brief** text responses)

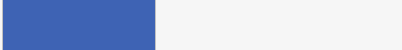













Response	20%	40%	60%	80%	100%	Frequency	Count
0						27.3%	45
1						1.8%	3
10						1.2%	2
100						4.2%	7
150						1.2%	2
200						9.7%	16
250						1.8%	3
300						1.2%	2
400						1.8%	3
500						14.5%	24
600						1.2%	2
1000						12.7%	21
1500						3.6%	6
2500						2.4%	4
3000						2.4%	4
3200						1.2%	2

5000		4.2%	7
Other Responses		7.3%	12
		Valid Responses	165
		Total Responses	165

3.(cont.) Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code. Activity: Estimated Cost (please round to the nearest hundred dollars)

- **(Additional time with the inspector)**





(Respondents were limited to **brief** text responses)

Response	20% 40% 60% 80% 100%	Frequency	Count
0		33.6%	49
1		2.1%	3
50		3.4%	5
100		13.0%	19
150		2.7%	4
200		11.0%	16
250		2.7%	4
300		1.4%	2
500		13.0%	19
1000		6.2%	9
2000		1.4%	2
2500		1.4%	2
3000		2.7%	4
Other Responses		5.5%	8
		Valid Responses	146
		Total Responses	146

3.(cont.) Please complete the table below with the estimated cost your business will spend in each category to incorporate the proposed changes to the Minnesota Food Code. Activity: Estimated Cost (please round to the nearest hundred dollars)

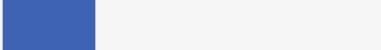

- **(Other* (please indicate the item or activity below))**

(Respondents were limited to **brief** text responses)

Response	20%	40%	60%	80%	100%	Frequency	Count
0						69.4%	34
1						6.1%	3
100						4.1%	2
Other Responses						20.4%	10
Valid Responses							49
Total Responses							49

4. Will the proposed Minnesota Food Code revisions cost your business more than \$25,000 during the first year the new Code is in effect?

(Respondents could only choose a **single** response)

Response	20% 40% 60% 80% 100%	Frequency	Count
Yes		24.2%	53
No		75.8%	166
Not Answered			36
Valid Responses			219
Total Responses			255

Minnesota Department of Health
 Food, Pools, Lodging, Services Section
 PO Box 64975
 St. Paul, Minnesota 55164
 651-201-4500

**MDA Notification List for
Rulemaking**

Administrative Hearings Office
PO Box 64620
St. Paul, MN 55164-0620

Robert M. Hutchinson
Anoka Co Comm. Hlth. & Soc. Serv. Dept.
Courthouse - Fourth Floor
Anoka, MN 55303

Dave Weirens
Association of Minnesota Counties
125 Charles Avenue
St. Paul, MN 55103

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Austin, MN 55912

Gerald G. Splinter, City Manager
City of Brooklyn Center
6301 Shingle Creek Parkway
Brooklyn Center, MN 55444

Norm Erickson
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Rochester, MN 55906

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501 Huron Street SE
Minneapolis, MN 55414

Tom Randgaard
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Box 598, 128 N.W. 15th Street
Faribault, MN 55021

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Flaherty's Happy-Tyme Company
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St. Joseph, MN 56374

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International Ecology Society
1471 Barclay Street
St. Paul, MN 55106

Michael D. Johnson
Box 95
Blue Earth, MN 56013

Joe Kelly
1400 Dean Avenue
Des Moines, IA 50316

Ellen Thomas, Mgr. Regulatory A
Kraft, General Foods, Inc.
801 Waukegan Road
Glenview, IL 60025

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The Land Stewardship Project
821 E. 35th St., Suite 200
Minneapolis, MN 55407

Greg Hubbard
Manitou Ridge Golf Course
3200 McKnight
White Bear Lake, MN 55110

Farmers' Legal Action Group
360 Robert St. N, Suite 500
St. Paul, MN 55101

Vern Ingvalson
Minnesota Farm Bureau Federation
P.O. Box 64370
St. Paul, MN 55164

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Marine on the St. Croix, MN 55047

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Minnesota Government Report
B-12 Press Room, SCB
St. Paul, MN 55101

Abe Rosenthal, President
Minnesota Transport Services Assn.
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St. Paul, MN 55114

Howard Nelson
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Lindstrom, MN 55045

North Country Coop.
425 – 20th Ave. So., Suite 212
Minneapolis, MN 55454-4415

Vincent Snyder, Jr.
O.M. Scott and Sons
14310 Scottslawn Road
Marysville, OH 43041

Peterson-Biddick Company
Wadena, MN 56482

Joseph Hibberd
Ramsey Co. Environmental Health
2785 White Bear Ave. N., Ste 350
Maplewood, MN 55109-1320

Health Director
St. Cloud Health Department
400 South Second Street
St. Cloud, MN 56301

Senoret Chemical Company
566 Leffingwell Avenue
Kirkwood, MO 63122

Julie Smendzuik-O'Brien
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Maplewood, MN 55109

Richard J. Epley
U of M Dept. of Animal Science
1354 Eckles Avenue, 136 ABLMS
St. Paul, MN 55108

L.M. Ferdinandsen
Watkins Products, Inc.
150 Liberty Street
Winona, MN 55987

Colbey Sullivan, House Research
600 State Office Bldg.
100 Rev Martin Luther King Jr. Blvd.
St. Paul, MN 55155

AGENCY NOTIFICATION LIST FOR RULEMAKING

BY MAIL:

TWILA BRASE
CCHF
161 ST. ANTHONY AVENUE, STE 923
ST. PAUL, MN 55103

KIM HUMAN
PHOENIX RESIDENCE
330 MARIE AVENUE EAST
WEST ST PAUL, MN 55118

BY EMAIL:

Michael J. Ahern
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402
ahern.michael@dorsey.com

Bonnie Brueshoff
Dakota County Public Health Dept.
1 Mendota Rd. W, Suite 410
West St. Paul, MN 55118
bonnie.brueshoff@c.dakota.mn.us

Vicki Kunerth
vicki.kunerth@state.mn.us

Minnesota Department of Health

CERTIFICATE OF ACCURACY OF THE MAILING LIST

Proposed Rules Governing [Topic], Minnesota Rules, [citation]

I certify that the list of persons and associations who have requested that their names be placed on the Department of Health rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a, is accurate, complete, and current as of [insert date]. A copy of the mailing list is attached to this Certificate



Cretia Weaver
Legal Secretary



Protecting, Maintaining and Improving the Health of All Minnesotans

October 18, 2017

Chardae Kimber
Executive Budget Officer
Minnesota Management and Budget
658 Cedar St., Suite 400
St. Paul, MN 55155

Re: In the Matter of the Proposed Rules of the Departments of Agriculture and Health Governing Retail Food Safety, *Minnesota Rules*, Chapter 4626; Revisor's ID Number 4071; OAH Docket No. - 82-9000-34708

Dear Ms. Kimber:

On behalf of the Minnesota Departments of Agriculture and Health, we are submitting documents to meet the requirement of *Minnesota Statutes*, section 14.131 that require an agency engaged in rulemaking consult with the Commissioner of Minnesota Management and Budget, "to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."

For your review we have electronically sent you the following documents on proposed rules governing Retail Food Safety.

1. The Governor's Office Proposed Rule and SONAR Form signed by both Commissioner David Frederickson and Commissioner Edward P. Ehlinger.
2. The August 25, 2017 Revisor's draft of the proposed rule.
3. The October 2, 2017 draft of the SONAR.

Copies of these documents are being electronically delivered to the Governor's Office.

If you or any other representative of the Commissioner of Minnesota Management & Budget has questions about the proposed rule, please call me at (651) 201-5792. Please send any correspondence about this matter to me at linda.prail@state.mn.us

Yours very truly,

A handwritten signature in black ink that reads "Linda D. Prail".

Linda D. Prail
Policy and Rule Analyst

Food Code

U.S. Public Health Service



2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

College Park, MD 20740

Food Code

2013 Recommendations of the
United States Public Health Service
Food and Drug Administration



The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.

This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. Alternatives that offer an equivalent level of public health protection to ensure that food at retail and foodservice is safe are recognized in this model.

For public sale by:

U.S. Department of Commerce
National Technical Information Service
5301 Shawnee Road, Alexandria, VA 22312
Phone: 1-800-553-6847
refer to report number **PB2013-110462**

ISBN 978-1-935239-02-4

**Previous Editions of Codes
Recommended by The
United States Public Health Service
for
Regulating Operations Providing Food Directly to the Consumer**

- 1934** - *Restaurant Sanitation Regulations*, Proposed by the U.S. Public Health Service in cooperation with the Conference of State and Territorial Health Officers and the National Restaurant Code Authority
- 1935** - *An Ordinance Regulating Food and Drink Establishments* (Recommended by U.S. Public Health Service), December 1935, Mimeographed
- 1938** - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended by the U.S. Public Health Service*, March 1938, Mimeographed
- 1940** - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended by the U.S. Public Health Service*, June 1940, Mimeographed
- 1943** - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended by the United States Public Health Service*, 1943, FSA, Public Health Bulletin No. 280 (Republished in 1955, DHEW, PHS Publication No. 37)
- 1957** - *The Vending of Foods and Beverages - A Sanitation Ordinance and Code, 1957 Recommendations of the Public Health Service*, DHEW, PHS Publication No. 546
- 1962** - *Food Service Sanitation Manual Including A Model Food Service Sanitation Ordinance and Code, 1962 Recommendations of the Public Health Service*, DHEW, PHS Publication No. 934
- 1965** - *The Vending of Food and Beverages - A Sanitation Ordinance and Code, 1965 Recommendations of the Public Health Service*, DHEW, PHS Publication No. 546
- 1976** - *Food Service Sanitation Manual Including A Model Food Service Sanitation Ordinance, 1976 Recommendations of the Food and Drug Administration*, DHEW/PHS/FDA, DHEW Publication No. (FDA) 78-2091
- 1978** - *The Vending of Food and Beverages Including A Model Sanitation Ordinance, 1978 Recommendations of the Food and Drug Administration*, DHEW/PHS/FDA, DHEW Publication No. (FDA) 78-2091
- 1982** - *Retail Food Store Sanitation Code, 1982 Recommendations of the Association of Food and Drug Officials and U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration*, AFDO/HHS Publication
- 1993** - *Food Code, 1993 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication PB94-113941
- 1995** - *Food Code, 1995 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication PB95-265492

- 1997** - *Food Code, 1997 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication PB97-133656
- 1999** - *Food Code, 1999 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication PB99-115925
- 2001** - *Food Code, 2001 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication PB2002-100819
- 2003** - *Supplement to the 2001 Food Code*, National Technical Information Service Publication PB2003-106843
- 2005** - *Food Code, 2005 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication PB2005-102200
- 2007** - *Supplement to the 2005 Food Code*, National Technical Information Service Publication PB2007-112622
- 2009** - *Food Code, 2009 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication PB2009-112613
- 2011** - *Supplement to the 2009 Food Code*, National Technical Information Service Publication PB2011-114303

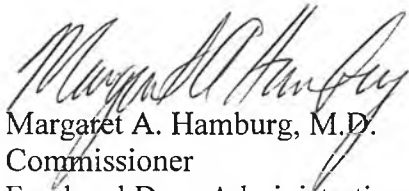
INTRODUCTION to the 2013 FOOD CODE

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) and the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA) are pleased to announce the release of the 2013 and eighth edition of the Food Code. The Food Code is a model code and reference document for state, city, county and tribal agencies that regulate operations such as restaurants, retail food stores, food vendors, and foodservice operations in institutions such as schools, hospitals, assisted living, nursing homes and child care centers. Food safety practices at these facilities play a critical role in preventing foodborne illness. The Food Code establishes practical, science-based guidance for mitigating risk factors that are known to cause or contribute to foodborne illness outbreaks associated with retail and foodservice establishments and is an important part of strengthening our nation's food protection system.

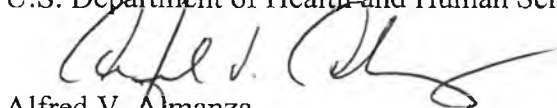
As of 2012, all 50 states and 3 of 6 territories report having retail codes patterned after previous editions of the Food Code. We strongly encourage the adoption and implementation of the 2013 Food Code at all levels of government.

This edition of the Food Code reflects our current understanding of evidenced-based practices for the effective control of microbiological, chemical and physical hazards in food facilities that can cause foodborne illness. Many of the changes to this edition reflect recommendations made at the 2012 biennial meeting of the Conference for Food Protection, a national organization that affords scientists and policy makers from all levels of government, industry, academia and consumers the opportunity to propose and deliberate on improvements to the Food Code.

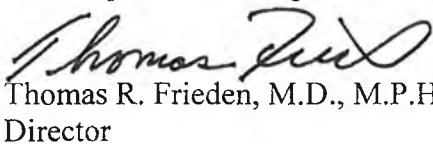
The federal government is committed to enhanced coordination with state, local, and tribal agencies, and the food industry to protect our food supply, and the Food Code is one important element in this strategy. HHS and USDA will continue to take progressive steps to partner with all who have a stake in food safety, and are committed to reducing the incidence of foodborne illness in the United States.



Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services



Alfred V. Amanza
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture



Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Preface

1. **FOODBORNE ILLNESS ESTIMATES, RISK FACTORS, AND INTERVENTIONS**
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1. **FOODBORNE ILLNESS ESTIMATES, RISK FACTORS, AND INTERVENTIONS**

Foodborne illness in the United States is a major cause of personal distress, preventable illness and death, and avoidable economic burden. Scallan et al. (2011a,b) estimated that foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year. The occurrence of approximately 1,000 reported disease outbreaks (local, regional, and national) each year highlights the challenges of preventing these infections.

Most foodborne illnesses occur in persons who are not part of recognized outbreaks. For many victims, foodborne illness results only in discomfort or lost time from the job. For some, especially preschool age children, older adults in health care facilities, and those with impaired immune systems, foodborne illness is more serious and may be life threatening.

The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs are estimated to be \$10 - \$83 billion. As stated by Meade et. al., the nature of food and foodborne illness has changed dramatically in the United States over the last century. While technological advances such as pasteurization and proper canning have all but eliminated some disease, new causes of foodborne illness have been identified. Surveillance of foodborne illness is complicated by several factors. The first is underreporting. Although foodborne illnesses can be severe or even fatal, milder cases are often not detected through routine surveillance. Second, many pathogens transmitted through food are also spread through water or from person to person, thus obscuring the role of foodborne transmission. Finally, pathogens or agents that have not yet been identified and thus cannot be diagnosed cause some proportion of foodborne illness.

Epidemiological outbreak data repeatedly identify five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness:

- Improper holding temperatures,
- Inadequate cooking, such as undercooking raw shell eggs,
- Contaminated equipment,
- Food from unsafe sources, and
- Poor personal hygiene

The Food Code addresses controls for risk factors and further establishes 5 key public health interventions to protect consumer health. Specifically, these interventions are: demonstration of knowledge, employee health controls, controlling hands as a vehicle of contamination, time and temperature parameters for controlling pathogens, and the consumer advisory. The first two interventions are found in Chapter 2 and the last three in Chapter 3.

The Food and Drug Administration (FDA) endeavors to assist the approximately 75 state and territorial agencies and more than 3,000 local departments that assume primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. This industry segment consists of more than one million establishments and employs a work force of over 16 million.

2. PHS MODEL CODES HISTORY, PURPOSE, AND AUTHORITY

(A) History and Purpose

U.S. Public Health Service (PHS) activities in the area of food protection began at the turn of the 20th century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective disease prevention requires the application of comprehensive food sanitation measures from production to consumption.

Additional studies identified and evaluated measures which would most effectively control disease, including work which led to improved processes for pasteurization.

Next, model codes were developed to assist state and local governments in initiating and maintaining effective programs for prevention of foodborne illness. The first of these, which is now titled *Grade A Pasteurized Milk Ordinance – Recommendations of the PHS/FDA*, was initially published in 1924. Subsequently, the PHS published recommended model food codes that address the various components of the retail segment of the food industry. These code editions are listed chronologically on pp. iii and iv. Through the years all states, hundreds of local jurisdictions, and many federal agencies have adopted some edition of model food codes recommended by the PHS.

Today, FDA's purpose in maintaining an updated model food code is to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry. The retail segment includes those establishments or locations in the food distribution chain where the consumer takes possession of the food.

The model Food Code is neither federal law nor federal regulation and is not preemptive. Rather, it represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. Although not federal requirements (until adopted by federal bodies for use within federal jurisdictions), the model Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government. A list of jurisdictions that have reported to FDA their status in adopting the Food Code is available on the FDA CFSAN Web Page at: <http://www.fda.gov/RetailFoodProtection>. The list is self-reported and FDA has not yet evaluated whether all the adopted codes are equivalent to the model Food Code.

Providing model food codes and model code interpretations and opinions is the mechanism through which FDA, as a lead federal food control agency, promotes uniform implementation of national food regulatory policy among the several thousand federal, state, and local agencies and tribes that have primary responsibility for the regulation or oversight of retail level food operations.

(B) Authority

PHS authority for providing assistance to state and local governments is derived from the Public Health Service Act [42 USC 243]. Section 311(a) states in part: "... The Secretary shall ... assist states and their political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid state and local authorities in the enforcement of their ... health regulations and shall advise the several states on matters relating to the preservation and improvement of the public health." Responsibility for carrying out the provisions of the Act relative to food protection was delegated within the PHS to the Commissioner of Food and Drugs in 1968 [21 CFR 5.10(a)(2) and (3)].

Under authority of the Economy Act, June 30, 1932 as amended [31 USC 1535], FDA provides assistance to federal agencies. Assistance provided to local, state, and federal governmental bodies is also based on FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act [21 USC 301].

3. PUBLIC HEALTH AND CONSUMER EXPECTATIONS

It is a shared responsibility of the food industry and the government to ensure that food provided to the consumer is safe and does not become a vehicle in a disease outbreak or in the transmission of communicable disease. This shared responsibility extends to ensuring that consumer expectations are met and that food is unadulterated, prepared in a clean environment, and honestly presented.

Under FDA's 2012 Mission Statement the agency is responsible for:

Protecting the public health by assuring the safety of our nation's food supply...and for advancing the public health by helping the public get accurate, science-based information they need about foods to maintain and improve their health.

Accordingly, the provisions of the Food Code provide a system of prevention and overlapping safeguards designed to minimize foodborne illness; ensure employee health, industry manager knowledge, safe food, nontoxic and cleanable equipment, and acceptable levels of sanitation on food establishment premises; and promote fair dealings with the consumer.

4. ADVANTAGE OF UNIFORM STANDARDS

The advantages of well-written, scientifically sound, and up-to-date model codes have long been recognized by industry and government officials.

Industry conformance with acceptable procedures and practices is far more likely where regulatory officials "speak with one voice" about what is required to protect the public health, why it is important, and which alternatives for compliance may be accepted.

Model codes provide a guide for use in establishing what is required. They are useful to business in that they provide accepted standards that can be applied in training and quality assurance programs. They are helpful to local, state, and federal governmental bodies that are developing or updating their own codes.

The model Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience using earlier model code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

The model Food Code provisions are consistent with, and where appropriate incorporate, federal performance standards for the same products and processes. Federal performance standards in effect define public food safety expectations for the

product, usually in terms of lethality to a pathogenic microorganism of particular concern. Use of performance standards as the measure of regulatory compliance means establishments are free to use innovative approaches in producing safe products, in lieu of adherence to traditional processing approaches, such as specified cooking times and temperatures, that achieve the same end. Federally inspected establishments demonstrate compliance with performance standards by showing that their process adheres to an appropriately designed, validated HACCP plan.

Retail processors may be given the same opportunity as federally-regulated establishments to use innovative techniques in the production of safe foods. Retail establishments may apply to the regulatory authority for a variance to use a specific federal food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in the Food Code. However, to show compliance with the federal performance standard, the retail processor must, like a federally inspected establishment, show that processing controls are in place to ensure that the standard is being met. Thus, a request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record keeping and documented verification being made available to the regulatory authority.

5. MODIFICATIONS AND IMPROVEMENTS IN THIS EDITION

The revisions contained in this edition reflect changes, additions, deletions, and format modifications listed in the Supplement to the 2009 FDA Food Code and recommendations developed during the 2012 Biennial meeting of the Conference for Food Protection. The revisions also reflect input provided by those who have been intimately involved with studying, teaching, and using the earlier editions. Most of these enhancements involve added clarification or new information. Some reflect evolving regulatory policy contained in new or revised federal regulations.

Several of the Tables, Charts, and images were converted throughout the Code to meet web accessibility requirements under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). Section 508 mandates that all federal agencies eliminate the barriers in accessing electronic and information technology. The law helps to ensure that members of the public with disabilities have the ability to access government information and services.

The needed clarifications and missing Code provisions were identified by FDA and others during standardization and certification activities, State Training Team courses, regional food protection seminars, the deliberations of food equipment standards organizations, and the verbal and written requests for clarification received by FDA field and headquarters components.

Changes in provisions related to federal laws and regulations administered by other federal agencies such as the United States Department of Agriculture were jointly developed with those agencies.

In the 2009 FDA Food Code a revised designation system for Code provisions was introduced. In the 2013 edition of the FDA Food Code, Annex 7 Form 3-A Food Establishment Inspection Report and Guide 3-B Instructions for Marking the Food Establishment Inspection Report were updated to reflect the revised designation system.

A Summary of Changes is provided at the end of the Food Code. General enhancements include:

- (1) Added and improved definitions that are more precise and more consistent with terminology and definitions found in related laws and regulations;
- (2) Modified provisions to make them more consistent with national requirements and standards administered by other federal agencies and international bodies; more flexible without compromising public health; and more internally consistent with other Food Code provisions;
- (3) Clarified other provisions regarding their intent, thereby reducing confusion and the potential for inconsistent application;
- (4) Improved user aids contained in the Annexes such as added references and updated public health reasons, model forms, guides, and lists; and
- (5) Expanded the Index with additional terms to assist a broader base of users in finding topics of interest.

6. DISCUSSION OF THE CODE AS A HACCP MODEL AND THE INTENTION TO INCORPORATE OTHER MODELS

It is important to note that preapproval of HACCP plans for food establishments operating pursuant to a variance is provided for under the Food Code, but such a plan preapproval is not a part of another HACCP regulatory model, the Fish and Fishery Products regulation 21 CFR 123, effective December 18, 1997. FDA published the Fish and Fisheries Hazards and Controls Guidance Fourth Edition April 2011. Additionally, there are differences between the two models in the required content of the HACCP plan. For example, the HACCP plans requested by the Food Code must include flow diagrams, product formulations, training plans, and a corrective action plan. Flow diagrams and product formulations are suggested but not mandated components of the Fish and Fishery Products regulation.

These differences are necessitated by differences in the nature of the regulations and the regulatory structure set up to enforce them. HACCP plans developed under the Food Code variance process are provided to the regulatory authority to enable the regulatory authority to assess whether the establishment has designed a system of controls sufficient to ensure the safety of the product. The plans will be reviewed outside the food establishment and, in most cases, in the absence of any historical performance information for the product at that establishment. Therefore, the plan must contain sufficient detail to allow the regulator to fully understand the operations and the intended controls. Products requiring a variance are those which are deemed to be time/temperature control for safety food and for which retail production would otherwise be prohibited.

To assist food establishments in applying HACCP principles at retail, FDA has issued a document entitled: *Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level*. This document is available from FDA and can be found on the FDA Web Page at: <http://www.fda.gov/RetailFoodProtection>.

Under the Fish and Fishery Products regulation, every seafood processor is required to perform a hazard analysis, and must have and implement a written HACCP Plan whenever a hazard analysis reveals a food safety hazard that is reasonably likely to occur. HACCP plans developed pursuant to the Fish and Fishery Products regulation are for all products in the class and are not for products for which production is presently prohibited. Plans will be reviewed on site, with records available to judge, among other things, the adequacy of past corrective actions.

It is intended that the Food Code will be amended to incorporate federal HACCP regulations and guidelines by inclusion in the text of the Food Code, by reference, or through the issuance of interpretations. This will provide alternatives to the preapproval of HACCP plans, such as simplified HACCP plans in line with the Fish and Fishery Products model, if the product is produced under a HACCP plan developed in conformance with such regulation or guideline. In so doing, the need for preapproved plans under the more intensive regimen of the Food Code will be significantly reduced.

HACCP plans are key to the use of performance standards as measures of regulatory compliance. Performance standards issued by the Food Safety and Inspection Service are applicable to a broad range of meat, poultry, and egg products. Federal performance standards are acceptable, equivalent alternatives to the command-and-control provisions that now provide specific times and temperatures for processing various products. Federal performance standards may be used to determine the safety of a product or process under the Food Code if authorized under a variance granted in accord with the Code's variance provisions, and demonstrated by adherence to a validated HACCP plan, consistent with the Code's HACCP provisions.

7. CODE ADOPTION/CERTIFIED COPIES

The model Food Code is provided for use by food regulatory jurisdictions at all levels of government. At the state and local levels the model may be:

- (A) Enacted into statute as an act of the state legislative body;
- (B) Promulgated as a regulation, if the state legislative body has delegated rule-making authority to a governmental administrative agency; or
- (C) Adopted as an ordinance, if the local legislative body has been delegated rule-making authority or regulatory powers.

Typically, code adoption bodies publish a notice of their intent to adopt a code, make copies available for public inspection, and provide an opportunity for public input prior to adoption. This is usually done in one of two ways.

The recommended method is the "short form" or "adoption by reference" approach where a simple statement is published stating that certified copies of the proposed code are on file for public review. This approach may be used by governmental bodies located in states that have enabling laws authorizing the adoption of codes by reference. An advantage to this approach is a substantial reduction in the cost of publishing and printing.

Certified copies of the Food Code for use in adopting the model by reference are available through the FDA Retail Food Protection Team, HFS-320, 5100 Paint Branch Parkway, College Park, MD 20740-3835. Refer to item 2. (A) of this Preface to access a listing of jurisdictions' adoptions.

The alternative method is the "long form" or "section-by-section" approach where the proposed code is published in its entirety.

Both methods of adoption allow for the modification of specific provisions to accommodate existing law, administrative procedure, or regulatory policy. Annex 7 contains model adoption forms for use by governmental bodies who wish to use either of these methods.

8. INFORMATION TO ASSIST THE USER

Many of the improvements contained in the model Food Code, as listed under item 5 of this Preface, are provided to make the document easier to use. Other characteristics of the new edition, if they are understood by the user, make it easier to follow and apply. These include structure, nomenclature, and methodology.

Food Code provisions address essentially four areas: personnel (Chapter 2), food (Chapter 3), equipment/facilities/supplies (Chapters 4, 5, 6, 7), and compliance and enforcement (Chapter 8). A new user will find it helpful to review the Table of Contents together with the Code Reference Sheet (Annex 7, Guide 3-B) in order to quickly gain an understanding of the scope and sequence of subjects included within these four areas. The structural nomenclature of the document is as follows:

Chapter	9
Part	9-1
Subpart	9-101
Section (§)	9-101.11
Paragraph (¶)	9-101.11(A)
Subparagraph	9-101.11(A)(1)

Code provisions are either appropriate for citing and debiting on an inspection report or they are not. Those not intended for citing/debiting are identified by the digits following the decimal point in the numbering system. These “nondebitable” provisions fall into two categories, those that end with two digits after the decimal point and the last digit is a zero, e.g., § 1-201.10; and those that end with three digits after the decimal point and the last 2 digits are zeros, e.g., § 8-805.100.

Two types of internal cross referencing are widely used throughout the Code to eliminate the need for restating provisions.

- A. The first type of cross reference uses phrases that contain the word “under”, e.g., “as specified **under** ... (followed by the relevant portion of the Code).”

The purpose of this type of cross reference is to:

- 1) Alert the reader to relevant information, and
- 2) Provide a system by which each violation is recorded under the one most appropriate provision. This type of cross reference signals to the reader the provision of the Code under which a certain violation is properly cited/debited.

- B. The second type of cross reference uses phrases that contain the word “in,” e.g., “as specified **in**... (followed by the relevant portion of the Code).”

The purpose of this type of cross reference is to:

- 1) Indicate the specific provisions of a separate document such as a federal regulation that are being incorporated by reference in the requirement of the Code, e.g., ¶ 3-201.11(C); or

- 2) Refer the reader to a nondebitable provision of the Code which provides further information for consideration, such as provision for an exception or for an allowance to comply via an alternative method.

For example, ¶ 3-201.16 (A) begins with “Except as specified in ¶ (B)...” and ¶ (B) states the relevant exceptions to ¶ (A). Paragraph 3-201.11(E) states in part, “... as specified *in* ¶ 3-401.11(C)” and ¶ 3-401.11(C) provides for an allowance to serve or sell raw or undercooked, whole-meat, intact beef steaks in a ready-to-eat form.

If you review the exception in ¶ 3-201.16(B) and the allowance in ¶ 3-401.11(C), you will see that exceptions and allowances often contain conditions of compliance, i.e., conditions that must be met in order for the exception or allowance to convey.

Based on the violation being cited, the substance of the text being referred to, and the context in which the reference is made, users of the Code must infer the intent of the cross reference. That is, the user must determine if the cross reference simply alerts the user to additional information about the requirement or if the cross reference:

- sends (via the word “under”) the citing/debiting to another Code provision;
or
- incorporates (via the word “in”) the referenced requirements into the Code provision.

The Food Code presents requirements by principle rather than by subject. For example, equipment requirements are presented under headings such as Materials, Design and Construction, Numbers and Capacities, Location and Installation, and Maintenance and Operation rather than by refrigerators, sinks, and thermometers. In this way provisions need be stated only once rather than repeated for each piece or category of equipment. Where there are special requirements for certain equipment, the requirement is delineated under the appropriate principle (e.g., Design and Construction) and listed separately in the index.

Portions of some sections are written in *italics*. These provisions are not requirements, but are provided to convey relevant information about specific exceptions and alternative means for compliance. Italics are pursuant to a preceding provision that states a requirement, to which the italics offer an exception or another possibility. Italicized sections usually involve the words “except for,” “may”, “need not” or “does not apply.” See ¶ 3-202.18(D).

The former use of “critical” or “non-critical” has been changed in recognition of the need to better identify risk-based controls within the Code’s provisions. Requirements contained in the Food Code are presented as being in one of three categories of importance: PRIORITY ITEM (i.e. a provision in this Code whose application

contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard); PRIORITY FOUNDATION ITEM (i.e., a provision in this Code whose application supports, facilitates or enables one or more PRIORITY ITEMS); and, CORE ITEM (i.e., a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM and that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

A “P” or “Pf” designation after a paragraph or subparagraph indicates that the provision within that section is a PRIORITY ITEM or PRIORITY FOUNDATION ITEM. Any unmarked provisions within a section are CORE ITEMS.

The following conventions are used in the Food Code. “Shall” means the act is imperative, i.e., “shall” constitutes a command. “May not” means absolute prohibition. “May” is permissive and means the act is allowed. The term “means” is followed by a declared fact.

Defined words and terms are in “small caps” in the text of the Food Code chapters to alert the reader to the fact that there is a specific meaning assigned to those words and terms and that the meaning of a provision is to be interpreted in the defined context. A concerted effort was also made to place in “small caps” all forms and combinations of those defined words and terms that were intended to carry the weight of the definition.

The annexes located at the back of the document can provide tremendous assistance to those charged with applying Food Code provisions. No reference is made in the text of a provision to the annexes which support its requirements. This is necessary in order to keep future laws or other requirements based on the model Food Code “clean.” However, the annexes are provided specifically to assist the regulatory authority apply the provisions uniformly and effectively.

It is, therefore, important for users to preview the subject and essence of each of the annexes before using the document. Some of the annexes (e.g., References, Public Health Reasons) are structured to present the information by the specific Food Code item number to which they apply. Other annexes provide information and materials intended to be helpful to the user such as model forms that can be used, a delineation of the principles of HACCP, guidelines for establishment inspection, and criteria for certain food processes for use in evaluating proposed HACCP plans.

9. THE CODE REVISION PROCESS

(A) Food Code Revision and Publication Cycles

FDA is issuing a new edition of the Food Code every 4 years. During the 4-year span of time between editions, FDA may issue supplements to an existing edition. Each new edition will incorporate the changes made in the supplement as well as any new revisions.

(B) Submission of Food Code Change Suggestions

FDA will continue to receive concerns and recommendations for modification of the Food Code from any individual or organization.

Given the purpose of the document as discussed in item 2 of this Preface, the Agency will be especially interested in addressing problems identified by those in government and industry who are responsible for implementing the Food Code. FDA will also be especially responsive to those needed policy and technical changes raised by an organization that uses a democratic process for addressing problems and concerns.

Included are organizations that provide a process that encourages representative participation in deliberations by government, industry, and academic and consumer interests, followed by public health ratification such as a state-by-state vote by officially designated delegates. The Conference for Food Protection (retail food issues), the National Conference on Interstate Milk Shipments (milk and dairy products issues), and the Interstate Shellfish Sanitation Conference (molluscan shellfish issues) are examples of such organizations. These organizations receive problems submitted by any interested individual, but specify the forms on which the issues must be detailed and provide specific time frames during which they may be submitted.

FDA encourages interested individuals to consider raising issues and suggesting solutions involving the federal-state cooperative programs based on FDA's model codes through these organizations.

10. ACKNOWLEDGMENTS

Many individuals devoted considerable time and effort in addressing concerns and developing recommendations that are now reflected in the Food Code. These individuals represent a wide diversity of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations. It is only through the dedicated efforts and contributions of experienced professionals that a scientifically sound, well focused, and up-to-date model code is possible. FDA acknowledges with gratitude the substantial assistance of those who contributed to public health and food safety in the development of the Food Code.

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Chapter

1 Purpose and Definitions

Parts

- 1-1 TITLE, INTENT, SCOPE
- 1-2 DEFINITIONS

1-1 TITLE, INTENT, SCOPE

Subparts

- 1-101 Title
- 1-102 Intent
- 1-103 Scope

Title **1-101.10** **Food Code.**

These provisions shall be known as the Food Code, hereinafter referred to as "this Code."

Intent **1-102.10** **Food Safety, Illness Prevention, and Honest Presentation.**

The purpose of this Code is to safeguard public health and provide to CONSUMERS FOOD that is safe, UNADULTERATED, and honestly presented.

Scope **1-103.10** **Statement.**

This Code establishes definitions; sets standards for management and personnel, FOOD operations, and EQUIPMENT and facilities; and provides for FOOD ESTABLISHMENT plan review, PERMIT issuance, inspection, EMPLOYEE RESTRICTION, and PERMIT suspension.

1-2 DEFINITIONS

Subpart

1-201

Applicability and Terms Defined

***Applicability and
Terms Defined***

1-201.10

**Statement of Application and Listing of
Terms.**

(A) The following definitions shall apply in the interpretation and application of this Code.

(B) Terms Defined. As used in this Code, each of the terms listed in ¶ 1-201.10(B) shall have the meaning stated below.

Accredited Program.

(1) **"Accredited program"** means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

(2) **"Accredited program"** refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(3) **"Accredited program"** *does not refer to training functions or educational programs.*

Additive.

(1) **"Food additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1).

(2) **"Color additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).

"Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

"Approved" means acceptable to the REGULATORY AUTHORITY based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Asymptomatic.

(1) **"Asymptomatic"** means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice.

(2) **"Asymptomatic"** includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

" a_w " means water activity which is a measure of the free moisture in a FOOD, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol A_w .

"Balut" means an embryo inside a fertile EGG that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

"Beverage" means a liquid for drinking, including water.

"Bottled drinking water" means water that is SEALED in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

"Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.

"Certification number" means a unique combination of letters and numbers assigned by a SHELLFISH CONTROL AUTHORITY to a MOLLUSCAN SHELLFISH DEALER according to the provisions of the National Shellfish Sanitation Program.

"CFR" means CODE OF FEDERAL REGULATIONS. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

CIP.

(1) **"CIP"** means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and SANITIZING solution onto or over EQUIPMENT surfaces that require cleaning, such as the method used, in part, to clean and SANITIZE a frozen dessert machine.

(2) **"CIP"** *does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.*

"Commingle" means:

- (1) To combine SHELLSTOCK harvested on different days or from different growing areas as identified on the tag or label, or
- (2) To combine SHUCKED SHELLFISH from containers with different container codes or different shucking dates.

Comminuted.

- (1) **"Comminuted"** means reduced in size by methods including chopping, flaking, grinding, or mincing.
- (2) **"Comminuted"** includes FISH or MEAT products that are reduced in size and restructured or reformulated such as gefilte FISH, gyros, ground beef, and sausage; and a mixture of 2 or more types of MEAT that have been reduced in size and combined, such as sausages made from 2 or more MEATS.

"Conditional employee" means a potential FOOD EMPLOYEE to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential FOOD EMPLOYEES who may be suffering from a disease that can be transmitted through FOOD and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a FOODBORNE DISEASE OUTBREAK in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the FOOD as the source of the illness.

"Consumer" means a PERSON who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale.

Core Item.

- (1) **"Core item"** means a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM.
- (2) **"Core item"** includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

"Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the FOOD to be contacted, the normal use of cleaning compounds and SANITIZING solutions, and other conditions of the use environment.

"Counter-mounted equipment" means EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

"Critical control point" means a point or procedure in a specific FOOD system where loss of control may result in an unacceptable health RISK.

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CRITICAL CONTROL POINT to minimize the RISK that the identified FOOD safety HAZARD may occur.

"Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

"Dealer" means a PERSON who is authorized by a SHELLFISH CONTROL AUTHORITY for the activities of SHELLSTOCK shipper, shucker-packer, repacker, reshipper, or depuration processor of MOLLUSCAN SHELLFISH according to the provisions of the National Shellfish Sanitation Program.

"Disclosure" means a written statement that clearly identifies the animal-derived FOODS which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

Drinking Water.

(1) **"Drinking water"** means water that meets criteria as specified in 40 CFR 141 National Primary Drinking Water Regulations.

(2) **"Drinking water"** is traditionally known as "potable water."

(3) **"Drinking water"** includes the term "water" *except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.*

"Dry storage area" means a room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and dry goods such as SINGLE-SERVICE items.

Easily Cleanable.

- (1) **"Easily cleanable"** means a characteristic of a surface that:
 - (a) Allows effective removal of soil by normal cleaning methods;
 - (b) Is dependent on the material, design, construction, and installation of the surface; and
 - (c) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into FOOD based on the surface's APPROVED placement, purpose, and use.

- (2) **"Easily cleanable"** includes a tiered application of the criteria that qualify the surface as EASILY CLEANABLE as specified in Subparagraph (1) of this definition to different situations in which varying degrees of cleanability are required such as:
 - (a) The appropriateness of stainless steel for a FOOD preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for CONSUMER dining; or
 - (b) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the CONSUMER dining area.

"Easily movable" means:

- (1) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of EQUIPMENT for cleaning; and

- (2) Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the EQUIPMENT to be moved for cleaning of the EQUIPMENT and adjacent area.

Egg.

(1) **"Egg"** means the shell EGG of avian species such as chicken, duck, goose, guinea, quail, RATITES or turkey.

(2) **"Egg"** does not include:

(a) A BALUT;

(b) The egg of reptile species such as alligator; or

(c) An EGG PRODUCT.

Egg Product.

(1) **"Egg Product"** means all, or a portion of, the contents found inside EGGS separated from the shell and pasteurized in a FOOD PROCESSING PLANT, with or without added ingredients, intended for human consumption, such as dried, frozen or liquid eggs.

(2) **"Egg Product"** does not include FOOD which contains EGGS only in a relatively small proportion such as cake mixes.

"Employee" means the PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

"EPA" means the U.S. Environmental Protection Agency.

Equipment.

(1) **"Equipment"** means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

(2) **"Equipment"** does not include apparatuses used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

"Exclude" means to prevent a PERSON from working as an EMPLOYEE in a FOOD ESTABLISHMENT or entering a FOOD ESTABLISHMENT as an EMPLOYEE.

"FDA" means the U.S. Food and Drug Administration.

Fish.

(1) **"Fish"** means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

(2) **"Fish"** includes an edible human FOOD product derived in whole or in part from FISH, including FISH that have been processed in any manner.

"Food" means a raw, cooked, or processed edible substance, ice, BEVERAGE, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

"Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common FOOD.

"Food-contact surface" means:

(1) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or

(2) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip, or splash:

(a) Into a FOOD, or

(b) Onto a surface normally in contact with FOOD.

"Food employee" means an individual working with UNPACKAGED FOOD, FOOD EQUIPMENT OR UTENSILS, OR FOOD-CONTACT SURFACES.

Food Establishment.

- (1) **"Food establishment"** means an operation that:
 - (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and
 - (b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.
- (2) **"Food establishment"** includes:
 - (a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location *unless the vending or feeding location is permitted by the REGULATORY AUTHORITY*; and
 - (b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.
- (3) **"Food establishment"** does not include:
 - (a) *An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;*
 - (b) *A produce stand that only offers whole, uncut fresh fruits and vegetables;*
 - (c) *A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT*
 - (d) *A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;*

(e) *An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;*

(f) *A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or*

(g) *A private home that receives catered or home-delivered FOOD.*

Food Processing Plant.

(1) **"Food processing plant"** means a commercial operation that manufactures, packages, labels, or stores FOOD for human consumption, and provides FOOD for sale or distribution to other business entities such as FOOD PROCESSING PLANTS OR FOOD ESTABLISHMENTS.

(2) **"Food processing plant"** does not include a FOOD ESTABLISHMENT.

Game Animal.

(1) **"Game animal"** means an animal, the products of which are FOOD, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as Poultry, or FISH.

(2) **"Game animal"** includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

(3) **"Game animal"** does not include RATITES.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175 Pesticides classified for restricted use.

"Grade A standards" means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" with which certain fluid and dry milk and milk products comply.

"HACCP plan" means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Handwashing Sink.

(1) **"Handwashing sink"** means a lavatory, a basin or vessel for washing, a wash basin, or a PLUMBING FIXTURE especially placed for use in personal hygiene and designed for the washing of the hands.

(2) **"Handwashing sink"** includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable CONSUMER health RISK.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by LAW, a nurse practitioner, physician assistant, or similar medical professional.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned FOODS, to maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means PERSONS who are more likely than other people in the general population to experience foodborne disease because they are:

(1) Immunocompromised; preschool age children, or older adults; and

(2) Obtaining FOOD at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

"Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(1) The number of potential injuries, and

(2) The nature, severity, and duration of the anticipated injury.

"Injected" means manipulating MEAT to which a solution has been introduced into its interior by processes that are referred to as "injecting," "pump marinating," or "stitch pumping".

Juice.

(1) **"Juice"** means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée.

(2) **"Juice"** *does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as BEVERAGES or ingredients of BEVERAGES.*

"Kitchenware" means FOOD preparation and storage UTENSILS.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

Major Food Allergen.

(1) **"Major food allergen"** means:

(a) Milk, EGG, FISH (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(b) A FOOD ingredient that contains protein derived from a FOOD, as specified in Subparagraph (1)(a) of this definition.

(2) **"Major food allergen"** *does not include:*

(a) *Any highly refined oil derived from a FOOD specified in Subparagraph (1)(a) of this definition and any ingredient derived from such highly refined oil; or*

(b) *Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282).*

"Meat" means the flesh of animals used as FOOD including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, *except FISH, POULTRY, and wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4).*

Mechanically Tenderized.

(1) "**Mechanically tenderized**" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles or any mechanical device.

(2) "**Mechanically tenderized**" does not include processes by which solutions are INJECTED into meat.

"**mg/L**" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"**Molluscan shellfish**" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, *except when the scallop product consists only of the shucked adductor muscle.*

Non-Continuous Cooking.

(1) "**Non-continuous cooking**" means the cooking of FOOD in a FOOD ESTABLISHMENT using a process in which the initial heating of the FOOD is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service.

(2) "**Non-continuous cooking**" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

Packaged.

(1) "**Packaged**" means bottled, canned, cartoned, bagged, or wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.

(2) "**Packaged**" *does not include wrapped or placed in a carry-out container to protect the FOOD during service or delivery to the CONSUMER, by a FOOD EMPLOYEE, upon CONSUMER request.*

"**Permit**" means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

"**Permit holder**" means the entity that:

(1) Is legally responsible for the operation of the FOOD ESTABLISHMENT such as the owner, the owner's agent, or other PERSON; and

(2) Possesses a valid PERMIT to operate a FOOD ESTABLISHMENT.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Person in charge" means the individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection.

Personal Care Items.

(1) **"Personal care items"** means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a PERSON'S health, hygiene, or appearance.

(2) **"Personal care items"** include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

"Physical facilities" means the structure and interior surfaces of a FOOD ESTABLISHMENT including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that:

(1) Is permanently or temporarily connected to the water distribution system of the PREMISES and demands a supply of water from the system; or

(2) Discharges used water, waste materials, or SEWAGE directly or indirectly to the drainage system of the PREMISES.

"Plumbing system" means the water supply and distribution pipes; PLUMBING FIXTURES and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the PREMISES; and water-treating EQUIPMENT.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 4 categories:

- (1) Cleaners and SANITIZERS, which include cleaning and SANITIZING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- (2) Pesticides, *except* SANITIZERS, which include substances such as insecticides and rodenticides;
- (3) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and PERSONAL CARE ITEMS that may be deleterious to health; and
- (4) Substances that are not necessary for the operation and maintenance of the establishment and are on the PREMISES for retail sale, such as petroleum products and paints.

"Poultry" means:

- (1) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, RATITES, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry; and
- (2) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1 Voluntary Poultry Inspection Regulations, Definitions.

"Premises" means:

- (1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or
- (2) The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

"Primal cut" means a basic major cut into which carcasses and sides of MEAT are separated, such as a beef round, pork loin, lamb flank, or veal breast.

Priority Item.

- (1) **"Priority item"** means a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.
- (2) **"Priority item"** includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
- (3) **"Priority item"** is an item that is denoted in this Code with a superscript P^P.

Priority Foundation Item.

- (1) **"Priority foundation item"** means a provision in this Code whose application supports, facilitates or enables one or more PRIORITY ITEMS.
- (2) **"Priority foundation item"** includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and
- (3) **"Priority foundation item"** is an item that is denoted in this Code with a superscript Pf - ^{Pf}.

"Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

Ready-to-Eat Food.

- (1) **"Ready-to-eat food"** means FOOD that:
 - (a) Is in a form that is edible without additional preparation to achieve FOOD safety, as specified under one of the following: ¶ 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in ¶ 3-401.11(C); or
 - (b) Is a raw or partially cooked animal FOOD and the consumer is advised as specified in Subparagraphs 3-401.11(D)(1) and (3); or
 - (c) Is prepared in accordance with a variance that is granted as specified in Subparagraph 3-401.11(D) (4); and

(d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

(2) **"Ready-to-eat food"** includes:

(a) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;

(b) Raw fruits and vegetables that are washed as specified under § 3-302.15;

(c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;

(d) All TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to the temperature and time required for the specific FOOD under Subpart 3-401 and cooled as specified under § 3-501.14;

(e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

(f) Substances derived from plants such as spices, seasonings, and sugar;

(g) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for FOOD safety;

(h) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured MEAT and POULTRY products, such as prosciutto ham, country cured ham, and Parma ham; and dried MEAT and POULTRY products, such as jerky or beef sticks; and

(i) FOODS manufactured as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

Reduced Oxygen Packaging.

(1) **"Reduced oxygen packaging"** means:

(a) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

(b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS *Clostridium botulinum* or *Listeria monocytogenes* require control in the final PACKAGED form.

(2) **"Reduced oxygen packaging"** includes:

(a) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the PACKAGE is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE;

(b) Modified atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the PACKAGING material or the respiration of the FOOD. Modified atmosphere PACKAGING includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

(c) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring FOOD, and impermeable PACKAGING material;

(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

(e) Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

"Refuse" means solid waste not carried by water through the SEWAGE system.

"Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

"Reminder" means a written statement concerning the health RISK of consuming animal FOODS raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Re-service" means the transfer of FOOD that is unused and returned by a CONSUMER after being served or sold and in the possession of the CONSUMER, to another PERSON.

"Restrict" means to limit the activities of a FOOD EMPLOYEE so that there is no RISK of transmitting a disease that is transmissible through FOOD and the FOOD EMPLOYEE does not work with exposed FOOD, clean EQUIPMENT, UTENSILS, LINENS, or unwrapped SINGLE-SERVICE OR SINGLE-USE ARTICLES.

"Restricted egg" means any check, dirty EGG, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.

"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a HAZARD in a FOOD.

"Safe material" means:

- (1) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any FOOD;
- (2) An additive that is used as specified in § 409 of the Federal Food, Drug, and Cosmetic Act; or
- (3) Other materials that are not ADDITIVES and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

"Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

"Servicing area" means an operating base location to which a mobile FOOD ESTABLISHMENT or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding FOOD.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

"Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of MOLLUSCAN SHELLFISH harvesters and DEALERS for interstate commerce.

"Shellstock" means raw, in-shell MOLLUSCAN SHELLFISH.

"Shiga toxin-producing *Escherichia coli*" (STEC) means any *E. coli* capable of producing Shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild non-bloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea), to hemolytic uremic syndrome (HUS - a type of kidney failure). Examples of serotypes of STEC include: *E. coli* O157:H7; *E. coli* O157:NM; *E. coli* O26:H11; *E. coli* O145:NM; *E. coli* O103:H2; and *E. coli* O111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic *E. coli*) or as EHEC (Enterohemorrhagic *E. coli*). EHEC are a subset of STEC which can cause hemorrhagic colitis or HUS.

"Shucked shellfish" means MOLLUSCAN SHELLFISH that have one or both shells removed.

"Single-service articles" means TABLEWARE, carry-out UTENSILS, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one PERSON use after which they are intended for discard.

Single-Use Articles.

(1) **"Single-use articles"** means UTENSILS and bulk FOOD containers designed and constructed to be used once and discarded.

(2) **"Single-use articles"** includes items such as wax paper, butcher paper, plastic wrap, formed aluminum FOOD containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse UTENSILS.

"Slacking" means the process of moderating the temperature of a FOOD such as allowing a FOOD to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen FOOD such as shrimp.

"Smooth" means:

(1) A FOOD-CONTACT SURFACE having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(2) A nonFOOD-CONTACT SURFACE of EQUIPMENT having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(3) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

"Tableware" means eating, drinking, and serving UTENSILS for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of FOOD, air, or water.

"Temporary food establishment" means a FOOD ESTABLISHMENT that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

Time/Temperature Control for Safety Food (formerly “potentially hazardous food” (PHF)).

- (1) **"Time/temperature control for safety food"** means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
- (2) **"Time/temperature control for safety food"** includes:
 - (a) An animal FOOD that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and
 - (b) Except as specified in Subparagraph (3)(d) of this definition, a FOOD that because of the interaction of its A_w and PH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of PH and A_w for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

A_w values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤ 0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

Table B. Interaction of pH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_w values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

(3) **"Time/temperature control for safety food"** does not include:

(a) *An air-cooled hard-boiled EGG with shell intact, or an EGG with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;*

(b) *A FOOD in an unopened HERMETICALLY SEALED CONTAINER that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;*

(c) *A FOOD that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a non-TCS FOOD in Table A or B of this definition;*

(d) *A FOOD that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that FOOD is precluded due to:*

(i) *Intrinsic factors including added or natural characteristics of the FOOD such as preservatives, antimicrobials, humectants, acidulants, or nutrients,*

(ii) *Extrinsic factors including environmental or operational factors that affect the FOOD such as packaging, modified atmosphere such as REDUCED OXYGEN PACKAGING, shelf life and use, or temperature range of storage and use, or*

(iii) *A combination of intrinsic and extrinsic factors; or*

(e) A FOOD that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) - (3)(d) of this definition even though the FOOD may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"USDA" means the U.S. Department of Agriculture.

"Utensil" means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

"Variance" means a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more VENDING MACHINES are installed and operated and includes the storage areas and areas on the PREMISES that are used to service and maintain the VENDING MACHINES.

"Warewashing" means the cleaning and SANITIZING of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Chapter

2

Management and Personnel

Parts

- 2-1 SUPERVISION
- 2-2 EMPLOYEE HEALTH
- 2-3 PERSONAL CLEANLINESS
- 2-4 HYGIENIC PRACTICES
- 2-5 RESPONDING TO CONTAMINATION EVENTS

2-1 SUPERVISION

Subparts

- 2-101 Responsibility
- 2-102 Knowledge
- 2-103 Duties

Responsibility

2-101.11 Assignment.

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall be the PERSON IN CHARGE or shall designate a PERSON IN CHARGE and shall ensure that a PERSON IN CHARGE is present at the FOOD ESTABLISHMENT during all hours of operation.^{Pf}

(B) In a FOOD ESTABLISHMENT with two or more separately PERMITTED departments that are the legal responsibility of the same PERMIT HOLDER and that are located on the same PREMISES, the PERMIT HOLDER may, during specific time periods when food is not being prepared, packaged, or served, designate a single PERSON IN CHARGE who is present on the PREMISES during all hours of operation, and who is responsible for each separately PERMITTED FOOD ESTABLISHMENT on the PREMISES.^{Pf}

Knowledge

2-102.11 Demonstration.

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

(A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection;^{Pf}

(B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM;^{Pf} or

(C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:

(1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;^{Pf}

(2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;^{Pf}

(3) Describing the symptoms associated with the diseases that are transmissible through FOOD;^{Pf}

(4) Explaining the significance of the relationship between maintaining the time and temperature of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and the prevention of foodborne illness;^{Pf}

(5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH;^{Pf}

(6) Stating the required FOOD temperatures and times for safe cooking of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD including MEAT, POULTRY, EGGS, and FISH;^{Pf}

(7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;
Pf

(8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(a) Cross contamination, Pf

(b) Hand contact with READY-TO-EAT FOODS, Pf

(c) Handwashing, Pf and

(d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair; Pf

(9) Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction. Pf

(10) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:

(a) Sufficient in number and capacity, Pf and

(b) Properly designed, constructed, located, installed, operated, maintained, and cleaned; Pf

(11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT; Pf

(12) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; Pf

(13) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW; Pf

(14) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code;^{Pf}

(15) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT;^{Pf}

(16) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(a) FOOD EMPLOYEE,^{Pf}

(b) CONDITIONAL EMPLOYEE,^{Pf}

(c) PERSON IN CHARGE,^{Pf}

(d) REGULATORY AUTHORITY;^{Pf} and

(17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION or RESTRICTION of FOOD EMPLOYEES.^{Pf}

2-102.12 Certified Food Protection Manager

(A) At least one EMPLOYEE that has supervisory and management responsibility and the authority to direct and control FOOD preparation and service shall be a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM.

(B) This section does not apply to certain types of FOOD ESTABLISHMENTS deemed by the REGULATORY AUTHORITY to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of FOOD preparation.

2-102.20 Food Protection Manager Certification.

(A) A PERSON IN CHARGE who demonstrates knowledge by being a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of FOOD Protection Manager Certification Programs is deemed to comply with ¶2-102.11(B).

(B) A FOOD ESTABLISHMENT that has an EMPLOYEE that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of FOOD Protection Manager Certification Programs is deemed to comply with §2-102.12.

Duties

2-103.11 Person in Charge.

The PERSON IN CHARGE shall ensure that:

(A) FOOD ESTABLISHMENT operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under § 6-202.111;^{Pf}

(B) PERSONS unnecessary to the FOOD ESTABLISHMENT operation are not allowed in the FOOD preparation, FOOD storage, or WAREWASHING areas, except that brief visits and tours may be authorized by the PERSON IN CHARGE if steps are taken to ensure that exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination;^{Pf}

(C) EMPLOYEES and other PERSONS such as delivery and maintenance PERSONS and pesticide applicators entering the FOOD preparation, FOOD storage, and WAREWASHING areas comply with this Code;^{Pf}

(D) EMPLOYEES are effectively cleaning their hands, by routinely monitoring the EMPLOYEES' handwashing;^{Pf}

(E) EMPLOYEES are visibly observing FOODS as they are received to determine that they are from APPROVED sources, delivered at the required temperatures, protected from contamination, UNADULTERED, and accurately presented, by routinely monitoring the EMPLOYEES' observations and periodically evaluating FOODS upon their receipt;^{Pf}

(F) EMPLOYEES are verifying that FOODS delivered to the FOOD ESTABLISHMENT during non-operating hours are from APPROVED sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, UNADULTERATED, and accurately presented;^{Pf}

(G) EMPLOYEES are properly cooking TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, being particularly careful in cooking those FOODS known to cause severe foodborne illness and death, such as EGGS and COMMINUTED MEATS, through daily oversight of the EMPLOYEES' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under § 4-203.11 and ¶ 4-502.11(B);^{Pf}

(H) EMPLOYEES are using proper methods to rapidly cool TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are not held hot or are not for consumption within 4 hours, through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures during cooling;^{Pf}

(I) CONSUMERS who order raw; or partially cooked READY-TO-EAT FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety;^{Pf}

(J) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS before they are reused, through routine monitoring of solution temperature and exposure time for hot water SANITIZING, and chemical concentration, pH, temperature, and exposure time for chemical SANITIZING;^{Pf}

(K) CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets as specified under § 3-304.16;^{Pf}

(L) Except when APPROVAL is obtained from the REGULATORY

AUTHORITY as specified in ¶ 3-301.11(E), EMPLOYEES are preventing cross-contamination of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT;^{Pf}

(M) EMPLOYEES are properly trained in FOOD safety, including FOOD allergy awareness, as it relates to their assigned duties;^{Pf}

(N) FOOD EMPLOYEES and CONDITIONAL EMPLOYEES are informed in a verifiable manner of their responsibility to report in accordance with LAW, to the PERSON IN CHARGE, information about their health and activities as they relate to diseases that are transmissible through FOOD, as specified under ¶ 2-201.11(A);^{Pf} and

(O) Written procedures and plans, where specified by this Code and as developed by the FOOD ESTABLISHMENT, are maintained and implemented as required.^{Pf}

2-2 EMPLOYEE HEALTH

Subpart

2-201 Responsibilities of Permit Holder, Person in Employees

Responsibilities and Reporting Symptoms and Diagnosis

2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees.

(A) The PERMIT HOLDER shall require FOOD EMPLOYEES and CONDITIONAL EMPLOYEES to report to the PERSON IN CHARGE information about their health and activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report the information in a manner that allows the PERSON IN CHARGE to reduce the RISK of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE:

reportable symptoms

(1) Has any of the following symptoms:

(a) Vomiting,^P

(b) Diarrhea,^P

(c) Jaundice,^P

(d) Sore throat with fever,^P or

(e) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(i) On the hands or wrists, *unless an impermeable cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the impermeable cover,*^P

(ii) On exposed portions of the arms, *unless the lesion is protected by an impermeable cover,*^P or

(iii) On other parts of the body, *unless the lesion is covered by a dry, durable, tight-fitting bandage,*^P

*reportable
diagnosis*

(2) Has an illness diagnosed by a HEALTH PRACTITIONER due to:

- (a) Norovirus,^P
- (b) Hepatitis A virus,^P
- (c) *Shigella* spp.,^P
- (d) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*,^P
- (e) *Salmonella* Typhi;^P or
- (f) nontyphoidal *Salmonella*;^P

*reportable
past illness*

(3) Had a previous illness, diagnosed by a HEALTH PRACTITIONER, within the past 3 months due to *Salmonella* Typhi, without having received antibiotic therapy, as determined by a HEALTH PRACTITIONER;^P

*reportable
history of exposure*

(4) Has been exposed to, or is the suspected source of, a CONFIRMED DISEASE OUTBREAK, because the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE consumed or prepared FOOD implicated in the outbreak, or consumed FOOD at an event prepared by a PERSON who is infected or ill with:

- (a) Norovirus within the past 48 hours of the last exposure,^P
- (b) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* or *Shigella* spp. within the past 3 days of the last exposure,^P
- (c) *Salmonella* Typhi within the past 14 days of the last exposure,^P or
- (d) Hepatitis A virus within the past 30 days of the last exposure;^P or

*reportable
history of exposure*

(5) Has been exposed by attending or working in a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual who works or attends a setting where there is a CONFIRMED

DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(a) Norovirus within the past 48 hours of the last exposure,^P

(b) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* or *Shigella* spp. within the past 3 days of the last exposure,^P

(c) *Salmonella* Typhi within the past 14 days of the last exposure,^P or

(d) Hepatitis A virus within the past 30 days of the last exposure.^P

responsibility of person in charge to notify the regulatory authority

(B) The PERSON IN CHARGE shall notify the REGULATORY AUTHORITY when a FOOD EMPLOYEE is:

(1) Jaundiced,^{Pf} or

(2) Diagnosed with an illness due to a pathogen as specified under Subparagraphs (A)(2)(a) - (f) of this section.^{Pf}

responsibility of the person in charge to prohibit a conditional employee from becoming a food employee

(C) The PERSON IN CHARGE shall ensure that a CONDITIONAL EMPLOYEE:

(1) Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under Subparagraphs (A)(1) - (3) of this section, is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria for the specific symptoms or diagnosed illness as specified under § 2-201.13;^P and

(2) Who will work as a FOOD EMPLOYEE in a FOOD ESTABLISHMENT that serves as a HIGHLY SUSCEPTIBLE POPULATION and reports a history of exposure as specified under Subparagraphs (A)(4) – (5), is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria as specified under ¶ 2-201.13(I).^P

responsibility of the person in charge to exclude or restrict

(D) The PERSON IN CHARGE shall ensure that a FOOD EMPLOYEE who exhibits or reports a symptom, or who reports a diagnosed illness or a history of exposure as specified under Subparagraphs (A)(1) - (5) of this section is:

(1) EXCLUDED as specified under §§ 2-201.12 (A) - (C), and Subparagraphs (D)(1), (E)(1), (F)(1), (G) or (H)(1) and in compliance with the provisions specified under §§ 2-201.13(A) - (H);^P or

(2) RESTRICTED as specified under Subparagraphs 2-201.12 (D)(2), (E)(2), (F)(2), (H)(2), or §§ 2-201.12(I) or (J) and in compliance with the provisions specified under §§ 2-201.13(D) - (J).^P

responsibility of food employees and conditional employees to report

(E) A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report to the PERSON IN CHARGE the information as specified under § (A) of this section.^{Pf}

responsibility of food employees to comply

(F) A FOOD EMPLOYEE shall:

(1) Comply with an EXCLUSION as specified under §§ 2-201.12(A) - (C) and Subparagraphs 2-201.12(D)(1), (E)(1), (F)(1), (G), or (H)(1) and with the provisions specified under §§ 2-201.13(A) - (H);^P or

(2) Comply with a RESTRICTION as specified under Subparagraphs 2-201.12(D)(2), (E)(2), (F)(2), (G), (H)(2), or §§ 2-201.12 (H), (I), or (J) and comply with the provisions specified under §§ 2-201.13(D) - (J).^P

conditions of exclusion and restriction

2-201.12 Exclusions and Restrictions.

The PERSON IN CHARGE shall EXCLUDE or RESTRICT a FOOD EMPLOYEE from a FOOD ESTABLISHMENT in accordance with the following:

symptomatic with vomiting or diarrhea

(A) *Except when the symptom is from a noninfectious condition*, EXCLUDE a FOOD EMPLOYEE if the FOOD EMPLOYEE is:

(1) Symptomatic with vomiting or diarrhea;^P or

(2) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, *Shigella* spp., nontyphoidal *Salmonella*, or SHIGA TOXIN-PRODUCING *E. COLI*.^P

*jaundiced or
diagnosed with
hepatitis A infection*

(B) EXCLUDE a FOOD EMPLOYEE who is:

(1) Jaundiced and the onset of jaundice occurred within the last 7 calendar days, *unless the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER specifying that the jaundice is not caused by hepatitis A virus or other fecal-orally transmitted infection;*^P

(2) Diagnosed with an infection from hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice;^P or

(3) Diagnosed with an infection from hepatitis A virus without developing symptoms.^P

*diagnosed or reported
previous infection due
to S. Typhi*

(C) EXCLUDE a FOOD EMPLOYEE who is diagnosed with an infection from *Salmonella* Typhi, or reports a previous infection with *Salmonella* Typhi within the past 3 months as specified under Subparagraph 2-201.11(A)(3).^P

*diagnosed with an
asymptomatic
infection from
Norovirus*

(D) If a FOOD EMPLOYEE is diagnosed with an infection from Norovirus and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

*diagnosed with
Shigella spp.
infection and
asymptomatic*

(E) If a FOOD EMPLOYEE is diagnosed with an infection from *Shigella* spp. and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

*diagnosed with **STEC**
and asymptomatic*

(F) If a FOOD EMPLOYEE is diagnosed with an infection from SHIGA TOXIN-PRODUCING *E. COLI*, and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

*diagnosed with
**nontyphoidal
Salmonella** and
asymptomatic*

(G) If a FOOD EMPLOYEE is diagnosed with an infection from nontyphoidal *Salmonella* and is ASYMPTOMATIC, RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION or in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

*symptomatic with **sore
throat with fever***

(H) If a FOOD EMPLOYEE is ill with symptoms of acute onset of sore throat with fever:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

*symptomatic with
**uncovered infected
wound or pustular
boil***

(I) If a FOOD EMPLOYEE is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under Subparagraph 2-201.11(A)(1)(e), RESTRICT the FOOD EMPLOYEE.^P

***exposed to foodborne
pathogen and works in
food establishment
serving HSP***

(J) If a FOOD EMPLOYEE is exposed to a foodborne pathogen as specified under Subparagraphs 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d), RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION.^P

Managing Exclusions and Restrictions

2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.

The PERSON IN CHARGE shall adhere to the following conditions when removing, adjusting, or retaining the EXCLUSION or RESTRICTION of a FOOD EMPLOYEE:

(A) Except when a FOOD EMPLOYEE is diagnosed with an infection from hepatitis A virus or Salmonella Typhi:

removing exclusion for food employee who was symptomatic and not diagnosed

(1) Reinstatement a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(1) if the FOOD EMPLOYEE:

(a) Is ASYMPTOMATIC for at least 24 hours;^P or

(b) Provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the symptom is from a noninfectious condition.^P

Norovirus diagnosis

(2) If a FOOD EMPLOYEE was diagnosed with an infection from Norovirus and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met;^P or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met.^P

***Shigella spp.
diagnosis***

(3) If a FOOD EMPLOYEE was diagnosed with an infection from *Shigella* spp. and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) of this section are met;^P or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) , or (E)(1) and (3)(a) of this section are met.^P

STEC diagnosis

(4) If a FOOD EMPLOYEE was diagnosed with an infection from SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) of this section are met;^P or

retaining exclusion for food employee who was symptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) are met.^P

***Nontyphoidal
Salmonella
diagnosis***

(5) If a FOOD EMPLOYEE was diagnosed with an infection from nontyphoidal *Salmonella* and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

Adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 30 days until conditions for reinstatement as specified under Subparagraphs (G)(1) or (2) of this section are met;^P or

Retaining exclusion for food employee that remains symptomatic

(b) Retain the EXCLUSION for the FOOD EMPLOYEE who is SYMPTOMATIC, until conditions for reinstatement as specified under Paragraphs (G)(1) or (G)(2) of this section are met.^P

hepatitis A virus or jaundice diagnosis - removing exclusions

(B) Reinstatement a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(B) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met;

(1) The FOOD EMPLOYEE has been jaundiced for more than 7 calendar days;^P

(2) The anicteric FOOD EMPLOYEE has been symptomatic with symptoms other than jaundice for more than 14 calendar days;^P or

(3) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a hepatitis A virus infection.^P

S. Typhi diagnosis - removing exclusions

(C) Reinstatement a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(C) if:

(1) The PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY;^P and

(2) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the FOOD EMPLOYEE is free from *S. Typhi* infection.^P

**Norovirus diagnosis
- removing exclusion
or restriction**

(D) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (D)(1) who was RESTRICTED under Subparagraph 2-201.12(D)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a Norovirus infection;^P

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;^P or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 48 hours have passed since the FOOD EMPLOYEE was diagnosed.^P

**Shigella spp.
diagnosis - removing
exclusion or
restriction**

(E) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2-201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella* spp. infection based on test results showing 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics,^P and

(b) At least 24 hours apart;^P

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;^P or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 calendar days have passed since the FOOD EMPLOYEE was diagnosed.^P

**STEC diagnosis -
removing exclusion
or restriction**

(F) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(A)(2) or (F)(1) or who was RESTRICTED under Subparagraph 2-201.12(F)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an infection from SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* based on test results that show 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics;^P and

(b) At least 24 hours apart;^P

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;^P or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 days have passed since the FOOD EMPLOYEE was diagnosed.^P

**nontyphoidal
Salmonella
-removing exclusion
or restriction**

(G) Reinstate a food employee who was EXCLUDED as specified under Subparagraph 2-201.12(A)(2) or who was RESTRICTED as specified under ¶ 2-201.12(G) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY^P and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a nontyphoidal *Salmonella* infection based on test results showing 2 consecutive negative stool specimen cultures that are taken;

(a) Not earlier than 48 hours after discontinuance of antibiotics,^P and

(b) At least 24 hours apart;^P

(2) The FOOD EMPLOYEE was RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;^P or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 30 days have passed since the FOOD EMPLOYEE was diagnosed.^P

sore throat with fever - removing exclusion or restriction

(H) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(H)(1) or (2) if the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE meets one of the following conditions:

(1) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours;^P

(2) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection;^P or

(3) Is otherwise determined by a HEALTH PRACTITIONER to be free of a *Streptococcus pyogenes* infection.^P

uncovered infected wound or pustular boil - removing restriction

(I) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(I) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

(1) An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;^P

(2) An impermeable cover on the arm if the infected wound or pustular boil is on the arm;^P or

(3) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.^P

exposure to foodborne pathogen and works in food establishment serving HSP – removing restriction

(J) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(J) and was exposed to one of the following pathogens as specified under Subparagraph 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d):

Norovirus

(1) Norovirus and one of the following conditions is met:

(a) More than 48 hours have passed since the last day the FOOD EMPLOYEE was potentially exposed;^P or

(b) More than 48 hours have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.^P

Shigella spp. or STEC

(2) *Shigella* spp. or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and one of the following conditions is met:

(a) More than 3 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;^P or

(b) More than 3 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.^P

S. Typhi

(3) *S. Typhi* and one of the following conditions is met:

(a) More than 14 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;^P or

(b) More than 14 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.^P

hepatitis A

(4) Hepatitis A virus and one of the following conditions is met:

(a) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of a prior illness from hepatitis A;^P

(b) The FOOD EMPLOYEE is immune to hepatitis A virus

infection because of vaccination against hepatitis A;^P

(c) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of IgG administration;^P

(d) More than 30 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;^P

(e) More than 30 calendar days have passed since the FOOD EMPLOYEE'S household contact became jaundiced;^P or

(f) The FOOD EMPLOYEE does not use an alternative procedure that allows bare hand contact with READY-TO-EAT FOOD until at least 30 days after the potential exposure, as specified in Subparagraphs (I)(4)(d) and (e) of this section, and the FOOD EMPLOYEE receives additional training about:

(i) Hepatitis A symptoms and preventing the transmission of infection,^P

(ii) Proper handwashing procedures,^P and

(iii) Protecting READY-TO-EAT FOOD from contamination introduced by bare hand contact.^P

2-3 PERSONAL CLEANLINESS

Subparts

2-301	Hands and Arms
2-302	Fingernails
2-303	Jewelry
2-304	Outer Clothing

Hands and Arms

2-301.11 Clean Condition.

FOOD EMPLOYEES shall keep their hands and exposed portions of their arms clean.^P

2-301.12 Cleaning Procedure.

(A) Except as specified in ¶ (D) of this section, FOOD EMPLOYEES shall clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands or arms for at least 20 seconds, using a cleaning compound in a HANDWASHING SINK that is equipped as specified under § 5-202.12 and Subpart 6-301.^P

(B) FOOD EMPLOYEES shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

(1) Rinse under clean, running warm water;^P

(2) Apply an amount of cleaning compound recommended by the cleaning compound manufacturer;^P

(3) Rub together vigorously for at least 10 to 15 seconds while:

(a) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure,^P and

(b) Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;^P

(4) Thoroughly rinse under clean, running warm water;^P and

(5) Immediately follow the cleaning procedure with thorough drying using a method as specified under § 6-301.12.^P

(C) To avoid recontaminating their hands or surrogate prosthetic devices, FOOD EMPLOYEES may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a HANDWASHING SINK or the handle of a restroom door.

(D) If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, an automatic handwashing facility may be used by FOOD EMPLOYEES to clean their hands or surrogate prosthetic devices.

2-301.13 Special Handwash Procedures.

Reserved.

2-301.14 When to Wash.

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES^P and:

(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms;^P

(B) After using the toilet room;^P

(C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in ¶ 2-403.11(B);^P

(D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;^P

(E) After handling soiled EQUIPMENT or UTENSILS;^P

(F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;^P

(G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD;^P

(H) Before donning gloves to initiate a task that involves working with FOOD;^P and

(I) After engaging in other activities that contaminate the hands.^P

2-301.15 Where to Wash.

FOOD EMPLOYEES shall clean their hands in a HANDWASHING SINK or APPROVED automatic handwashing facility and may not clean their hands in a sink used for FOOD preparation or WAREWASHING, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.^{Pf}

2-301.16 Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(a) Be an APPROVED drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an APPROVED drug based on safety and effectiveness;^{Pf} or

(b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash,^{Pf} and

(2) Consist only of components which the intended use of each complies with one of the following:

(a) A threshold of regulation exemption under 21 CFR 170.39 - Threshold of regulation for substances used in FOOD-contact articles;^{Pf} or

(b) 21 CFR 178 - Indirect FOOD Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a FOOD ADDITIVE with conditions of safe use,^{Pf} or

(c) A determination of generally recognized as safe (GRAS). Partial listings of substances with FOOD uses that are GRAS may be found in 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct FOOD Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 – Indirect FOOD Substances Affirmed as Generally Recognized as Safe for use in contact with FOOD, and in FDA's Inventory of GRAS Notices,^{Pf} or

(d) A prior sanction listed under 21 CFR 181 – Prior Sanctioned FOOD Ingredients,^{Pf} or

(e) a FOOD Contact Notification that is effective,^{PF} and

(3) Be applied only to hands that are cleaned as specified under § 2-301.12.^{Pf}

(B) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

(1) Followed by thorough hand rinsing in clean water before hand contact with FOOD or by the use of gloves;^{Pf} or

(2) Limited to situations that involve no direct contact with FOOD by the bare hands.^{Pf}

(C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 MG/L chlorine.^{Pf}

Fingernails

2-302.11 Maintenance.

(A) FOOD EMPLOYEES shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.^{Pf}

(B) *Unless wearing intact gloves in good repair*, a FOOD EMPLOYEE may not wear fingernail polish or artificial fingernails when working with exposed FOOD.^{Pf}

Jewelry

2-303.11 Prohibition.

Except for a *plain ring such as a wedding band*, while preparing FOOD, FOOD EMPLOYEES may not wear jewelry including medical information jewelry on their arms and hands.

Outer Clothing

2-304.11 Clean Condition.

FOOD EMPLOYEES shall wear clean outer clothing to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

2-4 HYGIENIC PRACTICES

Subparts

- 2-401 Food Contamination Prevention**
- 2-402 Hair Restraints**
- 2-403 Animals**

Food Contamination Prevention

2-401.11 Eating, Drinking, or Using Tobacco.

(A) Except as specified in ¶ (B) of this section, an EMPLOYEE shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES; or other items needing protection can not result.

(B) *A FOOD EMPLOYEE may drink from a closed BEVERAGE container if the container is handled to prevent contamination of:*

(1) *The EMPLOYEE'S hands;*

(2) *The container; and*

(3) *Exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.*

2-401.12 Discharges from the Eyes, Nose, and Mouth.

FOOD EMPLOYEES experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

Hair Restraints

2-402.11 Effectiveness.

(A) Except as provided in ¶ (B) of this section, FOOD EMPLOYEES shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *This section does not apply to FOOD EMPLOYEES such as counter staff who only serve BEVERAGES and wrapped or PACKAGED FOODS, hostesses, and wait staff if they present a minimal RISK of contaminating exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.*

Animals

2-403.11 Handling Prohibition.

(A) Except as specified in ¶ (B) of this section, FOOD EMPLOYEES may not care for or handle animals that may be present such as patrol dogs, SERVICE ANIMALS, or pets that are allowed as specified in Subparagraphs 6-501.115(B)(2)-(5).^{Pf}

(B) *FOOD EMPLOYEES with SERVICE ANIMALS may handle or care for their SERVICE ANIMALS and FOOD EMPLOYEES may handle or care for FISH in aquariums or MOLLUSCAN SHELLFISH or crustacea in display tanks if they wash their hands as specified under § 2-301.12 and ¶ 2-301.14(C).*

2-5

RESPONDING TO CONTAMINATION EVENTS

Subpart

2-501

Procedures for Responding

2-501.11 Clean-up of Vomiting and Diarrheal Events.

A FOOD ESTABLISHMENT shall have procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter.^{Pf}

Chapter

3

Food

Parts

- 3-1 CHARACTERISTICS
- 3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS
- 3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING
- 3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN
- 3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN
- 3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING
- 3-7 CONTAMINATED FOOD
- 3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

3-1 CHARACTERISTICS

Subparts

3-101 Condition

Condition

3-101.11 Safe, Unadulterated, and Honestly Presented.

FOOD shall be safe, unADULTERATED, and, as specified under § 3-601.12, honestly presented.^P

3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS

Subparts

3-201	Sources
3-202	Specifications for Receiving
3-203	Original Containers and Records

Sources

3-201.11 Compliance with Food Law.

(A) FOOD shall be obtained from sources that comply with LAW.^P

(B) FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT.^P

(C) PACKAGED FOOD shall be labeled as specified in LAW, including 21 CFR 101 FOOD Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under §§ 3-202.17 and 3-202.18.^{Pf}

(D) FISH, *other than those specified in paragraph 3-402.11(B), that are intended for consumption in raw or undercooked form and allowed as specified in paragraph 3-401.11(D), may be offered for sale or service if they are obtained from a supplier that freezes the FISH as specified under § 3-402.11; or if they are frozen on the PREMISES as specified under § 3-402.11 and records are retained as specified under § 3-402.12.*

(E) WHOLE-MUSCLE, INTACT BEEF steaks that are intended for consumption in an undercooked form without a CONSUMER advisory as specified in ¶ 3-401.11(C) shall be:

(1) Obtained from a FOOD PROCESSING PLANT that, upon request by the purchaser, packages the steaks and labels them, to indicate that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF,^{Pf} or

(2) Deemed acceptable by the REGULATORY AUTHORITY based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF,^{Pf} and

(3) If individually cut in a FOOD ESTABLISHMENT:

(a) Cut from WHOLE-MUSCLE INTACT BEEF that is labeled by a FOOD PROCESSING PLANT as specified in Subparagraph (E)(1) of this section or identified as specified in Subparagraph (E)(2) of this section,^{Pf}

(b) Prepared so they remain intact,^{Pf} and

(c) If PACKAGED for undercooking in a FOOD ESTABLISHMENT, labeled as specified in Subparagraph (E)(1) of this section or identified as specified in (E)(2) of this section.^{Pf}

(F) MEAT and POULTRY that is not a READY-TO-EAT FOOD and is in a PACKAGED form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in LAW, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

(G) EGGS that have not been specifically treated to destroy all viable *Salmonellae* shall be labeled to include safe handling instructions as specified in LAW, including 21 CFR 101.17(h).

3-201.12 Food in a Hermetically Sealed Container.

FOOD in a HERMETICALLY SEALED CONTAINER shall be obtained from a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.^P

3-201.13 Fluid Milk and Milk Products.

Fluid milk and milk products shall be obtained from sources that comply with GRADE A STANDARDS as specified in LAW.^P

3-201.14 Fish.

(A) FISH that are received for sale or service shall be:

(1) Commercially and legally caught or harvested;^P or

(2) APPROVED for sale or service.^P

(B) MOLLUSCAN SHELLFISH that are recreationally caught may not be received for sale or service.^P

3-201.15 Molluscan Shellfish.

(A) MOLLUSCAN SHELLFISH shall be obtained from sources according to LAW and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.^P

(B) MOLLUSCAN SHELLFISH received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.^P

3-201.16 Wild Mushrooms.

(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall not be offered for sale or service by a FOOD ESTABLISHMENT unless the FOOD ESTABLISHMENT has been APPROVED to do so.^P

(B) *This section does not apply to:*

(1) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the FOOD regulatory agency that has jurisdiction over the operation; or

(2) Wild mushroom species if they are in packaged form and are the product of a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.

3-201.17 Game Animals.

(A) If GAME ANIMALS are received for sale or service they shall be:

(1) Commercially raised for FOOD^P and:

(a) Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction,^P or

(b) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction,^P and

(c) Raised, slaughtered, and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program,^P and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee;^P

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and APPROVED" in accordance with 9 CFR 352 Exotic animals; voluntary inspection or rabbits that are "inspected and certified" in accordance with 9 CFR 354 voluntary inspection of rabbits and edible products thereof;^P

(3) As allowed by LAW, for wild GAME ANIMALS that are live-caught:

(a) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction,^P and

(b) Slaughtered and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program,^P and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee;^P or

(4) As allowed by LAW, for field-dressed wild GAME ANIMALS under a routine inspection program that ensures the animals:

(a) Receive a postmortem examination by an APPROVED veterinarian or veterinarian's designee,^P or

(b) Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program,^P and

(c) Are processed according to LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.^P

(B) A GAME ANIMAL may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and threatened wildlife and plants.

Specifications for Receiving

3-202.11 Temperature.

(A) Except as specified in ¶ (B) of this section, refrigerated, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be at a temperature of 5°C (41°F) or below when received.^P

(B) If a temperature other than 5°C (41°F) for a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD is specified in LAW governing its distribution, such as LAWS governing milk and MOLLUSCAN SHELLFISH, the FOOD may be received at the specified temperature.

(C) Raw EGGS shall be received in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.^P

(D) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 57°C (135°F) or above.^P

(E) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen.^{Pf}

(F) Upon receipt, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be free of evidence of previous temperature abuse.^{Pf}

3-202.12 Additives.

FOOD may not contain UNAPPROVED FOOD ADDITIVES or ADDITIVES that exceed amounts specified in 21 CFR 170-180 relating to FOOD ADDITIVES, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR 180 Tolerances for pesticides chemicals in food, and exceptions.^P

3-202.13 Eggs.

EGGS shall be received clean and sound and may not exceed the restricted EGG tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 *et seq.*, administered by the Agricultural Marketing Service of USDA.^P

3-202.14 Eggs and Milk Products, Pasteurized.

(A) EGG PRODUCTS shall be obtained pasteurized.^P

(B) Fluid and dry milk and milk products shall:

(1) Be obtained pasteurized;^P and

(2) Comply with GRADE A STANDARDS as specified in LAW.^P

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135 - Frozen desserts.^P

(D) Cheese shall be obtained pasteurized *unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 - Cheeses and related cheese products, for curing certain cheese varieties.*^P

3-202.15 Package Integrity.

FOOD packages shall be in good condition and protect the integrity of the contents so that the FOOD is not exposed to ADULTERATION or potential contaminants.^{Pf}

3-202.16 Ice.

Ice for use as a FOOD or a cooling medium shall be made from DRINKING WATER.^P

3-202.17 Shucked Shellfish, Packaging and Identification.

(A) Raw SHUCKED SHELLFISH shall be obtained in nonreturnable packages which bear a legible label that identifies the:^{Pf}

(1) Name, address, and CERTIFICATION NUMBER of the shucker, packer or repacker of the MOLLUSCAN SHELLFISH;^{Pf} and

(2) The "sell by" or "best if used by" date for packages with a capacity of less than 1.89 L (one-half gallon) or the date shucked for packages with a capacity of 1.89 L (one-half gallon) or more.^{Pf}

(B) A package of raw SHUCKED SHELLFISH that does not bear a label or which bears a label which does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d) Molluscan shellfish.

3-202.18

Shellstock Identification.

(A) SHELLSTOCK shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or DEALER that depurates, ships, or reships the SHELLSTOCK, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list:^{Pf}

(1) Except as specified under ¶ (C) of this section, on the harvester's tag or label, the following information in the following order:^{Pf}

(a) The harvester's identification number that is assigned by the SHELLFISH CONTROL AUTHORITY,^{Pf}

(b) The date of harvesting,^{Pf}

(c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the SHELLFISH CONTROL AUTHORITY and including the abbreviation of the name of the state or country in which the shellfish are harvested,^{Pf}

(d) The type and quantity of shellfish,^{Pf} and

(e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days";^{Pf} and

(2) Except as specified in ¶ (D) of this section, on each DEALER'S tag or label, the following information in the following order:^{Pf}

(a) The DEALER'S name and address, and the CERTIFICATION NUMBER assigned by the SHELLFISH CONTROL AUTHORITY,^{Pf}

(b) The original shipper's CERTIFICATION NUMBER including the abbreviation of the name of the state or country in which the shellfish are harvested,^{Pf}

(c) The same information as specified for a harvester's tag under Subparagraphs (A)(1)(b)-(d) of this section,^{Pf} and

(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days."^{Pf}

(B) A container of SHELLSTOCK that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

(C) If a place is provided on the harvester's tag or label for a DEALER's name, address, and CERTIFICATION NUMBER, the DEALER's information shall be listed first.

(D) If the harvester's tag or label is designed to accommodate each DEALER's identification as specified under Subparagraphs (A)(2)(a) and (b) of this section, individual DEALER tags or labels need not be provided.

3-202.19 Shellstock, Condition.

When received by a FOOD ESTABLISHMENT, SHELLSTOCK shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or SHELLSTOCK with badly broken shells shall be discarded.

3-202.110 Juice Treated.

Commercially Processed

Pre-PACKAGED JUICE shall:

(A) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120 Hazard Analysis and Critical Control (HACCP) Systems;^{Pf} and

(B) Be obtained pasteurized or otherwise treated to attain a 5-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR Part 120.24 Process Controls.^P

**Original
Containers and
Records**

3-203.11 Molluscan Shellfish, Original Container.

(A) Except as specified in ¶¶ (B) - (D) of this section, MOLLUSCAN SHELLFISH may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(B) For display purposes, SHELLSTOCK may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a CONSUMER may be removed from the display or display container and provided to the CONSUMER if:

(1) The source of the SHELLSTOCK on display is identified as specified under § 3-202.18 and recorded as specified under § 3-203.12; and

(2) The SHELLSTOCK are protected from contamination.

(C) SHUCKED SHELLFISH may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a CONSUMER'S request if:

(1) The labeling information for the shellfish on display as specified under § 3-202.17 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

(2) The shellfish are protected from contamination.

(D) SHUCKED SHELLFISH may be removed from the container in which they were received and repacked in CONSUMER self service containers where allowed by LAW if:

(1) The labeling information for the shellfish is on each CONSUMER self service container as specified under § 3-202.17 and ¶¶ 3-602.11(A) and (B)(1) - (5);

(2) The labeling information as specified under § 3-202.17 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

(3) The labeling information and dates specified under Subparagraph (D)(2) of this section are maintained for 90 days; and

(4) *The shellfish are protected from contamination.*

3-203.12 Shellstock, Maintaining Identification.

(A) Except as specified under Subparagraph (C) (2) of this section, SHELLSTOCK tags or labels shall remain attached to the container in which the SHELLSTOCK are received until the container is empty.^{Pf}

(B) The date when the last SHELLSTOCK from the container is sold or served shall be recorded on the tag or label.^{Pf}

(C) The identity of the source of SHELLSTOCK that are sold or served shall be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under ¶ B of this section, by:^{Pf}

(1) Using an APPROVED record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under ¶ B of this section;^{Pf} and

(2) If SHELLSTOCK are removed from its tagged or labeled container:

(a) Preserving source identification by using a record keeping system as specified under Subparagraph (C)(1) of this section,^{Pf} and

(b) Ensuring that SHELLSTOCK from one tagged or labeled container are not COMMINGLED with SHELLSTOCK from another container with different CERTIFICATION NUMBERS; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the CONSUMER.^{Pf}

3-3**PROTECTION FROM CONTAMINATION AFTER RECEIVING***Subparts*

3-301	Preventing Contamination by Employees
3-302	Preventing Food and Ingredient Contamination
3-303	Preventing Contamination from Ice Used as a Coolant
3-304	Preventing Contamination from Equipment, Utensils, and Linens
3-305	Preventing Contamination from the Premises
3-306	Preventing Contamination by Consumers
3-307	Preventing Contamination from Other Sources

Preventing Contamination by Employees**3-301.11 Preventing Contamination from Hands.**

(A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.

(B) *Except when washing fruits and vegetables as specified under §3-302.15 or as specified in ¶¶ (D) and (E) of this section,* FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT.^P

(C) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form.^{Pf}

(D) *Paragraph (B) of this section does not apply to a FOOD EMPLOYEE that contacts exposed, READY-TO-EAT FOOD with bare hands at the time the READY-TO-EAT FOOD is being added as an ingredient to a FOOD that:*

(1) contains a raw animal FOOD and is to be cooked in the FOOD ESTABLISHMENT to heat all parts of the FOOD to the minimum temperatures specified in ¶¶3-401.11(A)-(B) or §3-401.12; or

(2) does not contain a raw animal FOOD but is to be cooked in the FOOD ESTABLISHMENT to heat all parts of the FOOD to a temperature of at least 63°C (145°F).

(E) FOOD EMPLOYEES not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, READY-TO-EAT FOOD with their bare hands if:

(1) The PERMIT HOLDER obtains prior APPROVAL from the REGULATORY AUTHORITY;

(2) Written procedures are maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that include:

(a) For each bare hand contact procedure, a listing of the specific READY-TO-EAT FOODS that are touched by bare hands,

(b) Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under §§ 5-203.11, 5-204.11, 5-205.11, 6-301.11, 6-301.12, and 6-301.14, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;

(3) A written EMPLOYEE health policy that details how the FOOD ESTABLISHMENT complies with §§ 2-201.11, 2-201.12, and 2-201.13 including:

(a) Documentation that FOOD EMPLOYEES and CONDITIONAL EMPLOYEES acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through FOOD as specified under ¶ 2-201.11(A),

(b) Documentation that FOOD EMPLOYEES and CONDITIONAL EMPLOYEES acknowledge their responsibilities as specified under ¶ 2-201.11(E) and (F), and

(c) Documentation that the PERSON IN CHARGE acknowledges the responsibilities as specified under ¶¶ 2-201.11(B), (C) and (D), and §§ 2-201.12 and 2-201.13;

(4) Documentation that FOOD EMPLOYEES acknowledge that they have received training in:

- (a) *The RISKS of contacting the specific READY-TO-EAT FOODS with bare hands,*
 - (b) *Proper handwashing as specified under § 2-301.12,*
 - (c) *When to wash their hands as specified under § 2-301.14,*
 - (d) *Where to wash their hands as specified under § 2-301.15,*
 - (e) *Proper fingernail maintenance as specified under § 2-302.11,*
 - (f) *Prohibition of jewelry as specified under § 2-303.11, and*
 - (g) *Good hygienic practices as specified under §§2-401.11 and 2-401.12;*
- (5) *Documentation that hands are washed before FOOD preparation and as necessary to prevent cross contamination by FOOD EMPLOYEES as specified under §§ 2-301.11, 2-301.12, 2-301.14, and 2-301.15 during all hours of operation when the specific READY-TO-EAT FOODS are prepared;*
- (6) *Documentation that FOOD EMPLOYEES contacting READY-TO-EAT FOOD with bare hands use two or more of the following control measures to provide additional safeguards to HAZARDS associated with bare hand contact:*
- (a) *Double handwashing,*
 - (b) *Nail brushes,*
 - (c) *A hand antiseptic after handwashing as specified under § 2-301.16,*
 - (d) *Incentive programs such as paid sick leave that assist or encourage FOOD EMPLOYEES not to work when they are ill, or*
 - (e) *Other control measures APPROVED by the REGULATORY AUTHORITY; and*

(7) Documentation that corrective action is taken when Subparagraphs (E)(1) - (6) of this section are not followed.

3-301.12 Preventing Contamination When Tasting.

A FOOD EMPLOYEE may not use a UTENSIL more than once to taste FOOD that is to be sold or served.^P

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

(A) FOOD shall be protected from cross contamination by:

(1) Except as specified in (1)(c) below, separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as fruits and vegetables,^P and

(b) Cooked READY-TO-EAT FOOD;^P

(c) *Frozen, commercially processed and packaged raw animal FOOD may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.*

(2) *Except when combined as ingredients*, separating types of raw animal FOODS from each other such as beef, FISH, lamb, pork, and POULTRY during storage, preparation, holding, and display by:

(a) Using separate EQUIPMENT for each type,^P or

(b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented,^P and

(c) Preparing each type of FOOD at different times or in separate areas;^P

(3) Cleaning EQUIPMENT and UTENSILS as specified under

¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(4) Except as specified under Subparagraph 3-501.15(B)(2) and in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;

(5) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;

(6) Protecting FOOD containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; and

(8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.

(B) *Subparagraph (A)(4) of this section does not apply to:*

(1) Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;

(2) PRIMAL CUTS, quarters, or sides of raw MEAT or slab bacon that are hung on clean, SANITIZED hooks or placed on clean, SANITIZED racks;

(3) Whole, uncut, processed MEATS such as country hams, and smoked or cured sausages that are placed on clean, SANITIZED racks;

(4) FOOD being cooled as specified under Subparagraph 3-501.15(B)(2); or

(5) SHELLSTOCK.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Except for containers holding FOOD that can be readily and unmistakably recognized such as dry pasta, working containers holding FOOD or FOOD ingredients that are removed from their original packages for use in the FOOD ESTABLISHMENT, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the FOOD.

3-302.13 Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes.

Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and EGG-fortified BEVERAGES that are not:^P

(A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2);^P or

(B) Included in ¶ 3-401.11(D).^P

3-302.14 Protection from Unapproved Additives.

(A) FOOD shall be protected from contamination that may result from the addition of, as specified in § 3-202.12:

(1) Unsafe or unAPPROVED FOOD or COLOR ADDITIVES;^P and

(2) Unsafe or unAPPROVED levels of APPROVED FOOD and COLOR ADDITIVES.^P

(B) A FOOD EMPLOYEE may not:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a FOOD considered to be a good source of vitamin B₁;^P or

(2) *Except for grapes,* serve or sell FOOD specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the FOOD ESTABLISHMENT.^P

3-302.15 Washing Fruits and Vegetables.

(A) *Except as specified in ¶ (B) of this section and except for whole, raw fruits and vegetables that are intended for washing by the CONSUMER before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TO-EAT form.*

(B) *Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12.*

(C) Devices used for on-site generation of chemicals meeting the requirements specified in 21 CFR 173.315, Chemicals used in the washing or to assist in the peeling of fruits and vegetables, for the washing of raw, whole fruits and vegetables shall be used in accordance with the manufacturer's instructions.^{Pf}

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

After use as a medium for cooling the exterior surfaces of FOOD such as melons or FISH, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT, ice may not be used as FOOD.^P

3-303.12 Storage or Display of Food in Contact with Water or Ice.

(A) PACKAGED FOOD may not be stored in direct contact with ice or water if the FOOD is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water

(B) Except as specified in ¶¶ (C) and (D) of this section, UNPACKAGED FOOD may not be stored in direct contact with undrained ice.

(C) *Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.*

(D) *Raw poultry and raw FISH that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.*

**Preventing
Contamination
from Equipment,
Utensils, and
Linens**

3-304.11 Food Contact with Equipment and Utensils.

FOOD shall only contact surfaces of:

- (A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code;^P
- (B) SINGLE-SERVICE and SINGLE-USE ARTICLES;^P or
- (C) LINENS, such as cloth napkins, as specified under § 3-304.13 that are laundered as specified under Part 4-8 of this Code.^P

3-304.12 In-Use Utensils, Between-Use Storage.

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:

- (A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;
- (B) In FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;
- (C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;
- (D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;
- (E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not

TIME/TEMPERATURE CONTROL FOR SAFETY FOOD; or

(F) In a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

3-304.13 Linens and Napkins, Use Limitation.

LINENS, such as cloth napkins, may not be used in contact with FOOD *unless they are used to line a container for the service of FOODS and the LINENS and napkins are replaced each time the container is refilled for a new CONSUMER.*

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths in-use for wiping FOOD spills from TABLEWARE and carry-out containers that occur as FOOD is being served shall be:

- (1) Maintained dry; and
- (2) Used for no other purpose.

(B) Cloths in-use for wiping counters and other EQUIPMENT surfaces shall be:

- (1) Held between uses in a chemical sanitizer solution at a concentration specified under § 4-501.114; and
- (2) Laundered daily as specified under ¶ 4-802.11(D).

(C) Cloths in-use for wiping surfaces in contact with raw animal FOODS shall be kept separate from cloths used for other purposes.

(D) Dry wiping cloths and the chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be free of FOOD debris and visible soil.

(E) Containers of chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of FOOD, EQUIPMENT,

UTENSILS, LINENS, SINGLE-SERVICE, OR SINGLE-USE ARTICLES.

(F) SINGLE-USE disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.

3-304.15 Gloves, Use Limitation.

(A) If used, SINGLE-USE gloves shall be used for only one task such as working with READY-TO-EAT FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.^P

(B) Except as specified in ¶ (C) of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with FOOD that is subsequently cooked as specified under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.

(C) Slash-resistant gloves may be used with READY-TO-EAT FOOD that will not be subsequently cooked if the slash-resistant gloves have a SMOOTH, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a SMOOTH, durable, nonabsorbent glove, or a SINGLE-USE glove.

(D) Cloth gloves may not be used in direct contact with FOOD *unless the FOOD is subsequently cooked as required under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.*

3-304.16 Using Clean Tableware for Second Portions and Refills.

(A) Except for refilling a CONSUMER'S drinking cup or container without contact between the pouring UTENSIL and the lip-contact area of the drinking cup or container, FOOD EMPLOYEES may not use TABLEWARE, including SINGLE-SERVICE ARTICLES, soiled by the CONSUMER, to provide second portions or refills.

(B) Except as specified in ¶ (C) of this section, self-service CONSUMERS may not be allowed to use soiled TABLEWARE, including SINGLE-SERVICE ARTICLES, to obtain additional FOOD from the display and serving EQUIPMENT.

(C) Drinking cups and containers may be reused by self-service

CONSUMERS if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D).

3-304.17 Refilling Returnables.

(A) Except as specified in ¶¶ (B) - (E) of this section, empty containers returned to a FOOD ESTABLISHMENT for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT.^P

(B) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:

(1) Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-2;^P

(2) One that was initially provided by the FOOD ESTABLISHMENT to the CONSUMER, either empty or filled with FOOD by the FOOD ESTABLISHMENT, for the purpose of being returned for reuse;

(3) Returned to the FOOD ESTABLISHMENT by the CONSUMER after use;

(4) Subject to the following steps before being refilled with FOOD:

(a) Cleaned as specified under Part 4-6 of this Code,

(b) Sanitized as specified under Part 4-7 of this Code;^P

(c) Visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified under Part 4-1 and 4-2;^P and

(C) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with BEVERAGE if:

(1) The BEVERAGE is not a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;

(2) The design of the container and of the rinsing EQUIPMENT and the nature of the BEVERAGE, when considered together,

allow effective cleaning at home or in the FOOD ESTABLISHMENT;

(3) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

(4) The CONSUMER-owned container returned to the FOOD ESTABLISHMENT for refilling is refilled for sale or service only to the same CONSUMER; and

(5) The container is refilled by:

(a) An EMPLOYEE of the FOOD ESTABLISHMENT, or

(b) The owner of the container if the BEVERAGE system includes a contamination-free transfer process as specified under ¶¶ 4-204.13(A), (B), and (D).that cannot be bypassed by the container owner.

(D) Consumer-owned, personal take-out BEVERAGE containers, such as thermally insulated bottles, nonspill coffee cups, and promotional BEVERAGE glasses, may be refilled by EMPLOYEES or the CONSUMER if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D).

(E) CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE or system.

Preventing Contamination from the Premises

3-305.11 Food Storage.

(A) Except as specified in ¶¶ (B) and (C) of this section, FOOD shall be protected from contamination by storing the FOOD:

(1) In a clean, dry location;

(2) Where it is not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) *FOOD in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling EQUIPMENT as specified under § 4-204.122.*

(C) Pressurized BEVERAGE containers, cased FOOD in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

- (A) In locker rooms;
- (B) In toilet rooms;
- (C) In dressing rooms;
- (D) In garbage rooms;
- (E) In mechanical rooms;
- (F) Under sewer lines that are not shielded to intercept potential drips;
- (G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
- (H) Under open stairwells; or
- (I) Under other sources of contamination.

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

TIME/TEMPERATURE CONTROL FOR SAFETY FOOD dispensed through a VENDING MACHINE shall be in the PACKAGE in which it was placed at the FOOD ESTABLISHMENT or FOOD PROCESSING PLANT at which it was prepared.

3-305.14 Food Preparation.

During preparation, UNPACKAGED FOOD shall be protected from environmental sources of contamination.

**Preventing
Contamination
by Consumers**

3-306.11 Food Display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER before consumption, FOOD on display shall be protected from contamination by the use of PACKAGING; counter, service line, or salad bar FOOD guards; display cases; or other effective means.^P

3-306.12 Condiments, Protection.

(A) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected FOOD displays provided with the proper UTENSILS, original containers designed for dispensing, or individual PACKAGES or portions.

(B) Condiments at a VENDING MACHINE LOCATION shall be in individual PACKAGES or provided in dispensers that are filled at an APPROVED location, such as the FOOD ESTABLISHMENT that provides FOOD to the VENDING MACHINE LOCATION, a FOOD PROCESSING PLANT that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the VENDING MACHINE LOCATION.

3-306.13 Consumer Self-Service Operations.

(A) Raw, UNPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service.^P *This paragraph does not apply to:*

(1) CONSUMER self-service of READY-TO-EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish;

(2) Ready-to-cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked MEATS or CONSUMER-selected ingredients for Mongolian barbecue; or

(3) Raw, frozen, shell-on shrimp, or lobster.

(B) CONSUMER self-service operations for READY-TO-EAT FOODS shall be provided with suitable UTENSILS or effective dispensing

methods that protect the FOOD from contamination.^{Pf}

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures.^{Pf}

3-306.14 Returned Food and Re-Service of Food.

(A) Except as specified in ¶ (B) of this section, after being served or sold and in the possession of a CONSUMER, FOOD that is unused or returned by the CONSUMER may not be offered as FOOD for human consumption.^P

(B) Except as specified under ¶ 3-801.11(G), *a container of FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD may be RE-SERVED from one CONSUMER to another if:*

(1) The FOOD is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

(2) The FOOD, such as crackers, salt, or pepper, is in an unopened original PACKAGE and is maintained in sound condition.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

FOOD shall be protected from contamination that may result from a factor or source not specified under Subparts 3-301 - 3-306.

3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

3-401	Cooking
3-402	Freezing
3-403	Reheating
3-404	Other Methods

Cooking

3-401.11 Raw Animal Foods.

(A) Except as specified under ¶ (B) and in ¶¶ (C) and (D) of this section, raw animal FOODS such as EGGS, FISH, MEAT, POULTRY, and FOODS containing these raw animal FOODS, shall be cooked to heat all parts of the FOOD to a temperature and for a time that complies with one of the following methods based on the FOOD that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for: ^P

(a) Raw EGGS that are broken and prepared in response to a CONSUMER'S order and for immediate service, ^P and

(b) Except as specified under Subparagraphs (A)(2) and (A)(3) and ¶ (B), and in ¶ (C) of this section, FISH and MEAT including GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); ^P

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for RATITES, MECHANICALLY TENDERIZED, and INJECTED MEATS; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw EGGS that are not prepared as specified under Subparagraph (A)(1)(a) of this section: ^P

Minimum Temperature °C (°F)	Minimum Time
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

;or

(3) 74°C (165°F) or above for 15 seconds for POULTRY, BALUTS, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed RATITES, or stuffing containing FISH, MEAT, POULTRY, or RATITES.^P

(B) Whole MEAT roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:^{Pf}

Oven Temperature Based on Roast Weight

Oven Type	Less than 4.5 kg (10 lbs)	4.5 kg (10 lbs) or More
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity ¹	121°C (250°F) or less	121°C (250°F) or less

¹Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

; and

(2) As specified in the following chart, to heat all parts of the FOOD to a temperature and for the holding time that corresponds to that temperature:^P

Temperature °C (°F)	Time ¹ in Minutes
54.4 (130)	112
55.0 (131)	89
56.1 (133)	56
57.2 (135)	36
57.8 (136)	28
58.9 (138)	18
60.0 (140)	12
61.1 (142)	8
62.2 (144)	5
62.8 (145)	4

Temperature °C (°F)	Time ¹ in Seconds
63.9 (147)	134
65.0 (149)	85
66.1 (151)	54
67.2 (153)	34
68.3 (155)	22
69.4 (157)	14
70.0 (158)	0

¹Holding time may include postoven heat rise.

(C) A raw or undercooked *WHOLE-MUSCLE, INTACT BEEF* steak may be served or offered for sale in a *READY-TO-EAT* form if:

(1) The *FOOD ESTABLISHMENT* serves a population that is not a *HIGHLY SUSCEPTIBLE POPULATION*,

(2) The steak is labeled to indicate that it meets the definition of "*WHOLE-MUSCLE, INTACT BEEF*" as specified under ¶ 3-201.11(E), and

(3) The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.

(D) A raw animal FOOD such as raw EGG, raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, or steak tartare; or a partially cooked FOOD such as lightly cooked FISH, soft cooked EGGS, or rare MEAT other than WHOLE-MUSCLE, INTACT BEEF steaks as specified in ¶ (C) of this section, may be served or offered for sale upon CONSUMER request or selection in a READY-TO-EAT form if:

(1) As specified under §§ 3-801.11(C)(1) and (2), the FOOD ESTABLISHMENT serves a population that is not a HIGHLY SUSCEPTIBLE POPULATION;

(2) The FOOD, if served or offered for service by CONSUMER selection from a children's menu, does not contain COMMINUTED MEAT;^{Pf} and

(3) The CONSUMER is informed as specified under § 3-603.11 that to ensure its safety, the FOOD should be cooked as specified under ¶ (A) or (B) of this section; or

(4) The REGULATORY AUTHORITY grants a VARIANCE from ¶ (A) or (B) of this section as specified in § 8-103.10 based on a HACCP PLAN that:

(a) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11,

(b) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe FOOD, and

(c) Verifies that EQUIPMENT and procedures for FOOD preparation and training of FOOD EMPLOYEES at the FOOD ESTABLISHMENT meet the conditions of the VARIANCE.

3-401.12 Microwave Cooking.

Raw animal FOODS cooked in a microwave oven shall be:

- (A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
- (B) Covered to retain surface moisture;
- (C) Heated to a temperature of at least 74°C (165°F) in all parts of the FOOD;^P and
- (D) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 57°C (135°F).^{Pf}

3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Raw animal FOODS that are cooked using a NON-CONTINUOUS COOKING process shall be:

- (A) Subject to an initial heating process that is no longer than sixty minutes in duration;^P
- (B) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD under ¶ 3-501.14(A);^P
- (C) After cooling, held frozen or cold, as specified for TIME/TEMPERATURE CONTROL FOR SAFETY FOOD under ¶ 3-501.16(A)(2);^P
- (D) Prior to sale or service, cooked using a process that heats all parts of the FOOD to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C);^P

(E) Cooled according to the time and temperature parameters specified for cooked TIME /TEMPERATURE CONTROL FOR SAFETY FOOD under ¶ 3-501.14(A) if not either hot held as specified under ¶3-501.16(A), served immediately, or held using time as a public health control as specified under §3-501.19 after complete cooking; ^P and

(F) Prepared and stored according to written procedures that:

(1) Have obtained prior APPROVAL from the REGULATORY AUTHORITY; ^{Pf}

(2) Are maintained in the FOOD ESTABLISHMENT and are available to the REGULATORY AUTHORITY upon request; ^{Pf}

(3) Describe how the requirements specified under ¶ (A)-(E) of this Section are to be monitored and documented by the PERMIT HOLDER and the corrective actions to be taken if the requirements are not met; ^{Pf}

(4) Describe how the FOODS, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as FOODS that must be cooked as specified under ¶ (D) of this section prior to being offered for sale or service; ^{Pf} and

(5) Describe how the FOODS, after initial heating but prior to cooking as specified under ¶(D) of this section, are to be separated from READY-TO-EAT FOODS as specified under ¶3-302.11 (A). ^{Pf}

Freezing

3-402.11 Parasite Destruction.

(A) Except as specified in ¶ (B) of this section, before service or sale in READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH shall be:

(1) Frozen and stored at a temperature of -20°C (-4°F) or below for a minimum of 168 hours (7 days) in a freezer; ^P

(2) Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) or below for a minimum of 15 hours; ^P or

(3) Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours. ^P

(B) Paragraph (A) of this section does not apply to:

- (1) MOLLUSCAN SHELLFISH;
- (2) A scallop product consisting only of the shucked adductor muscle;
- (3) Tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern); or
- (4) Aquacultured FISH, such as salmon, that:
 - (a) If raised in open water, are raised in net-pens, or
 - (b) Are raised in land-based operations such as ponds or tanks, and
 - (c) Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured FISH.
- (5) FISH eggs that have been removed from the skein and rinsed.

3-402.12 Records, Creation and Retention.

(A) Except as specified in ¶ 3-402.11(B) and ¶ (B) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, the PERSON IN CHARGE shall record the freezing temperature and time to which the FISH are subjected and shall retain the records of the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH.^{Pf}

(B) If the FISH are frozen by a supplier, a written agreement or statement from the supplier stipulating that the FISH supplied are frozen to a temperature and for a time specified under § 3-402.11 may substitute for the records specified under ¶ (A) of this section.

(C) If raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, and the FISH are raised and fed as specified in Subparagraph

3-402.11(B)(3), a written agreement or statement from the supplier or aquaculturist stipulating that the FISH were raised and fed as specified in Subparagraph 3-402.11(B)(3) shall be obtained by the PERSON IN CHARGE and retained in the records of the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH.^{Pf}

3-403.10 Preparation for Immediate Service.

Cooked and refrigerated FOOD that is prepared for immediate service in response to an individual CONSUMER order, such as a roast beef sandwich au jus, may be served at any temperature.

Reheating

3-403.11 Reheating for Hot Holding.

(A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.^P

(B) Except as specified under ¶ (C) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.^P

(C) READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that has been commercially processed and PACKAGED in a FOOD PROCESSING PLANT that is inspected by the REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) when being reheated for hot holding.^P

(D) Reheating for hot holding as specified under ¶¶ (A) - (C) of this section shall be done rapidly and the time the FOOD is between 5°C (41°F) and the temperatures specified under ¶¶ (A) - (C) of this section may not exceed 2 hours.^P

(E) *Remaining unsliced portions of MEAT roasts that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

Other Methods

3-404.11 Treating Juice.

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in §§ 8-201.14(B) - (E) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance;^P or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance:^{Pf}

(1) As specified under § 3-602.11,^{Pf} and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, JUICES that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."^{Pf}

3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

- 3-501 Temperature and Time Control**
- 3-502 Specialized Processing Methods**

Temperature and Time Control

3-501.11 Frozen Food.

Stored frozen FOODS shall be maintained frozen.

3-501.12 Time/Temperature Control for Safety Food, Slacking.

Frozen TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less; or

(B) At any temperature if the FOOD remains frozen.

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be thawed:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less; or

(B) Completely submerged under running water:

(1) At a water temperature of 21°C (70°F) or below,

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5°C (41°F), or

(4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), for more than 4 hours including:

(a) The time the FOOD is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the FOOD temperature to 5°C (41°F);

(C) As part of a cooking process if the FOOD that is frozen is:

(1) Cooked as specified under ¶¶ 3-401.11(A) or (B) or § 3-401.12, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process; or

(D) *Using any procedure if a portion of frozen READY-TO-EAT*

FOOD is thawed and prepared for immediate service in response to an individual CONSUMER'S order.

(E) REDUCED OXYGEN PACKAGED FISH that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:

(1) Prior to its thawing under refrigeration as specified in ¶(A) of this section; or

(2) Prior to, or Immediately upon completion of, its thawing using procedures specified in ¶ (B) of this section.

3-501.14 Cooling.

(A) Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled:

(1) Within 2 hours from 57°C (135°F) to 21°C (70°F);^P and

(2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less.^P

(B) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5°C (41°F) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.^P

(C) Except as specified under ¶ (D) of this section, a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less.^P

(D) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.^P

3-501.15 Cooling Methods.

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 by using one or more of the following methods based on the type of FOOD being cooled:

- (1) Placing the FOOD in shallow pans; ^{Pf}
- (2) Separating the FOOD into smaller or thinner portions; ^{Pf}
- (3) Using rapid cooling EQUIPMENT; ^{Pf}
- (4) Stirring the FOOD in a container placed in an ice water bath; ^{Pf}
- (5) Using containers that facilitate heat transfer; ^{Pf}
- (6) Adding ice as an ingredient; ^{Pf} or
- (7) Other effective methods. ^{Pf}

(B) When placed in cooling or cold holding EQUIPMENT, FOOD containers in which FOOD is being cooled shall be:

- (1) Arranged in the EQUIPMENT to provide maximum heat transfer through the container walls; and
- (2) Loosely covered, or uncovered if protected from overhead contamination as specified under Subparagraph 3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the FOOD.

3-501.16 Time/Temperature Control for Safety Food, Hot and Cold Holding.

(A) *Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under §3-501.19, and except as specified under ¶ (B) and in ¶ (C) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be maintained:*

- (1) *At 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F) or above; ^P or*
- (2) *At 5°C (41°F) or less. ^P*

(B) EGGS that have not been treated to destroy all viable **Salmonellae** shall be stored in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less. ^P

(C) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in a homogenous liquid form *may be maintained outside of the temperature control requirements, as specified under ¶ (A) of this section, while contained within specially designed EQUIPMENT that complies with the design and construction requirements as specified under ¶ 4-204.13(E).*

on-premises preparation

• *prepare and hold cold*

3-501.17 Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking.

(A) Except when PACKAGING FOOD using a REDUCED OXYGEN PACKAGING method as specified under § 3-502.12, and except as specified in ¶¶ (E) and (F) of this section, refrigerated, READY-TO-EAT, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD prepared and held in a FOOD ESTABLISHMENT for more than 24 hours shall be clearly marked to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded when held at a temperature of 5°C (41°F) or less for a maximum of 7 days. The day of preparation shall be counted as Day 1.^{Pf}

commercially processed food

• *open and hold cold*

(B) Except as specified in ¶¶ (E) - (G) of this section, refrigerated, READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ (A) of this section and:^{Pf}

(1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1;^{Pf} and

(2) The day or date marked by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety.^{Pf}

(C) A refrigerated, READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD ingredient or a portion of a refrigerated, READY-TO-EAT, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is subsequently combined with additional ingredients or portions of FOOD shall retain the date marking of the earliest-prepared or first-prepared ingredient.^{Pf}

(D) *A date marking system that meets the criteria stated in ¶¶ (A) and (B) of this section may include:*

(1) Using a method APPROVED by the REGULATORY AUTHORITY for refrigerated, READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;

(2) Marking the date or day of preparation, with a procedure to discard the FOOD on or before the last date or day by which the FOOD must be consumed on the premises, sold, or discarded as specified under ¶ (A) of this section;

(3) Marking the date or day the original container is opened in a FOOD ESTABLISHMENT, with a procedure to discard the FOOD on or before the last date or day by which the FOOD must be consumed on the premises, sold, or discarded as specified under ¶ (B) of this section; or

(4) Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the REGULATORY AUTHORITY upon request.

(E) Paragraphs (A) and (B) of this section do not apply to individual meal portions served or rePACKAGED for sale from a bulk container upon a consumer's request.

(F) Paragraphs (A) and (B) of this section do not apply to SHELLSTOCK.

(G) Paragraph (B) of this section does not apply to the following FOODS prepared and PACKAGED by a FOOD PROCESSING PLANT inspected by a REGULATORY AUTHORITY:

(1) Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR 110 Current good manufacturing practice in manufacturing, packing, or holding human food;

(2) Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;

(3) *Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;*

(4) *Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;*

(5) *Preserved FISH products, such as pickled herring and dried or salted cod, and other acidified FISH products defined in 21 CFR 114 Acidified foods;*

(6) *Shelf stable, dry fermented sausages, such as pepperoni and Genoa; and*

(7) *Shelf stable salt-cured products such as prosciutto and Parma (ham).*

3-501.18 Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.

(A) A FOOD specified in ¶ 3-501.17(A) or (B) shall be discarded if it:

(1) Exceeds the temperature and time combination specified in ¶ 3-501.17(A), except time that the product is frozen;^P

(2) Is in a container or PACKAGE that does not bear a date or day;^P or

(3) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in ¶ 3-501.17(A).^P

(B) Refrigerated, READY-TO-EAT, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD prepared in a FOOD ESTABLISHMENT and dispensed through a VENDING MACHINE with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in ¶ 3-501.17(A).^P

3-501.19 Time as a Public Health Control.

(A) Except as specified under ¶ (D) of this section, if time without

temperature control is used as the public health control for a working supply of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD before cooking, or for READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is displayed or held for sale or service:

(1) Written procedures shall be prepared in advance, maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that specify: ^{Pf}

(a) Methods of compliance with Subparagraphs (B)(1)-(3) or C)(1)-(5) of this section; ^{Pf} and

(b) Methods of compliance with § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control. ^{Pf}

***Time –
maximum up to 4
hours***

(B) If time without temperature control is used as the public health control up to a maximum of 4 hours:

(1) The FOOD shall have an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; ^P

(2) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control; ^{Pf}

(3) The FOOD shall be cooked and served, served at any temperature if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control; ^P and

(4) The FOOD in unmarked containers or PACKAGES, or marked to exceed a 4-hour limit shall be discarded. ^P

***Time –
maximum up to
6 hours***

(C) If time without temperature control is used as the public health control up to a maximum of 6 hours:

(1) The FOOD shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the FOOD temperature may not exceed 21°C (70°F) within a maximum time period of 6 hours; ^P

(2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 21°C (70°F) during the 6-hour period, *unless an ambient air temperature is maintained that ensures the FOOD does not exceed 21°C (70°F) during the 6-hour holding period;*^{Pf}

(3) The FOOD shall be marked or otherwise identified to indicate:^{Pf}

(a) The time when the FOOD is removed from 5°C (41°F) or less cold holding temperature control;^{Pf} and

(b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control;^{Pf}

(4) The FOOD shall be:

(a) Discarded if the temperature of the FOOD exceeds 21°C (70°F),^P or

(b) Cooked and served, served at any temperature if READY-TO-EAT, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from 5°C (41°F) or less cold holding temperature control;^P and

(5) The FOOD in unmarked containers or PACKAGES, or marked with a time that exceeds the 6-hour limit shall be discarded.^P

(D) A FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION may not use time as specified under ¶¶ (A), (B) or (C) of this section as the public health control for raw EGGS.

Specialized Processing Methods

3-502.11 Variance Requirement.

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before:^{Pf}

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;^{Pf}

(B) Curing FOOD;^{Pt}

(C) Using FOOD ADDITIVES or adding components such as

vinegar: ^{Pf}

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, ^{Pf} or

(2) To render a FOOD so that it is not TIME/TEMPERATURE CONTROL OF SAFETY FOOD; ^{Pf}

(D) Packaging TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method *except where the growth of and toxin formation by **Clostridium botulinum** and the growth of **Listeria monocytogenes** are controlled as specified under § 3-502.12;* ^{Pf}

(E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption; ^{Pf}

(F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; ^{Pf}

(G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; ^{Pf} or

(H) Sprouting seeds or beans. ^{Pf}

***Clostridium
botulinum and
Listeria
monocytogenes
Controls***

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of ***Clostridium botulinum*** and the growth of ***Listeria monocytogenes***. ^P

(B) Except as specified under ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall implement a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (B) and (D) and that: ^{Pf}

(1) Identifies the FOOD to be PACKAGED; ^{Pf}

(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: ^{Pf}

(a) Has an A_w of 0.91 or less, ^{Pf}

(b) Has a PH of 4.6 or less, ^{Pf}

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, ^{Pf} or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables; ^{Pf}

(3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: ^{Pf}

(a) Maintain the FOOD at 5°C (41°F) or below, ^{Pf} and

(b) Discard the FOOD if within 30 calendar days of its PACKAGING if it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption; ^{Pf}

(4) Limits the refrigerated shelf life to no more than 30 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; ^P

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B), ^{Pf}

(b) Identify a designated work area and the method by which: ^{Pf}

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, ^{Pf} and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation,^{Pf} and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES;^{Pf} and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:^{Pf}

(a) Concepts required for a safe operation,^{Pf}

(b) EQUIPMENT and facilities,^{Pf} and

(c) Procedures specified under Subparagraph (B)(5) of this section and ¶¶ 8-201.14 (B) and (D).^{Pf}

(7) Is provided to the REGULATORY AUTHORITY prior to implementation as specified under ¶ 8-201.13(B).

Fish

(C) *Except for FISH that is frozen before, during, and after PACKAGING*, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method.^P

*Cook-Chill or
Sous Vide*

(D) Except as specified under ¶ (C) and ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a cook-chill or sous vide process shall:

(1) Provide to the REGULATORY AUTHORITY prior to implementation, a HACCP PLAN that contains the information as specified under ¶¶ 8-201.14 (B) and (D);^{Pf}

(2) Ensure the FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER,^{Pf}

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under ¶¶ 3-401.11 (A), (B), and (C),^P

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,^P

(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F),^P

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and:^P

(i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;^P

(ii) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded;^P or

(iii) Held frozen with no shelf life restriction while frozen until consumed or used.^P

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,^{Pf}

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation,^{Pf} and

(h) Labeled with the product name and the date PACKAGED;^{Pf} and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:

(a) Make such records available to the REGULATORY AUTHORITY upon request,^{Pf} and

(b) Hold such records for at least 6 months;^{Pf} and

(4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.^{Pf}

Cheese

(E) Except as specified under ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:

(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;^P

(2) Have a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (B) and (D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;^{Pf}

(3) Labels the PACKAGE on the principal display panel with a “use by” date that does not exceed 30 days from its packaging or the original manufacturer’s “sell by” or “use by” date, whichever occurs first;^{Pf} and

(4) Discards the REDUCED OYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.^{Pf}

(F) A HACCP Plan is not required when a FOOD ESTABLISHMENT uses a REDUCED OXYGEN PACKAGING method to PACKAGE TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is always:

(1) Labeled with the production time and date,

(2) Held at 5°C (41°F) or less during refrigerated storage, and

(3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.

3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING

Subparts

3-601	Accurate Representation
3-602	Labeling
3-603	Consumer Advisory

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and standards of identity or composition, and the general requirements in 21 CFR 130 – Food Standards: General and 9 CFR 319 Subpart A – General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the net quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient.^{Pf}

(6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(q)(3) - (5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(7) For any salmonid FISH containing canthaxanthin or astaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (6) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

(1) *A health, nutrient content, or other claim is not made;*

(2) *There are no state or local LAWS requiring labeling; and*

(3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.^{Pf}

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as “oysters on the half shell (raw oysters),” “raw-EGG Caesar salad,” and “hamburgers (can be cooked to order);”^{Pf} or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.^{Pf}

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request;^{Pf}

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness;^{Pf} or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.^{Pf}

3-7 CONTAMINATED FOOD

Subpart

3-701 Disposition

Disposition

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

(A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be discarded or reconditioned according to an APPROVED procedure.^P

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 - .17 shall be discarded.^P

(C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been RESTRICTED or EXCLUDED as specified under § 2-201.12 shall be discarded.^P

(D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded.^P

3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

Subpart

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) The following criteria apply to JUICE:

(1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;

(2) PrePACKAGED JUICE or a prePACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale;^P and

(3) UnPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls.^P

(B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of:^P

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, EGGnog, ice cream, and EGG-fortified BEVERAGES,^P and

(2) Except as specified in ¶ (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined;^P

(C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form:^P

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare,^P

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue;^P and

(3) Raw seed sprouts.^P

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (E).^P

(E) Time only, as the public health control as specified under ¶ 3-501.19(D), may not be used for raw EGGS.^P

(F) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw EGGS are combined immediately before cooking for one CONSUMER'S serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS;*

(2) *The raw EGGS are combined as an ingredient immediately before baking and the EGGS are thoroughly cooked to a READY-TO-EAT form, such as a cake, muffin, or bread; or*

(3) *The preparation of the food is conducted under a HACCP PLAN that:*

(a) *Identifies the FOOD to be prepared,*

(b) *Prohibits contacting READY-TO-EAT FOOD with bare hands,*

(c) *Includes specifications and practices that ensure:*

(i) ***Salmonella Enteritidis*** *growth is controlled before and after cooking, and*

(ii) ***Salmonella Enteritidis*** *is destroyed by cooking the EGGS according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*

(i) *Control cross contamination of READY-TO-EAT FOOD with raw EGGS, and*

(ii) *Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES, and*

(e) *Describes the training program that ensures that the FOOD EMPLOYEE responsible for the preparation of the FOOD understands the procedures to be used.*

Re-service of Food

(G) *Except as specified in paragraph (H) of this section, FOOD may be re-served as specified under Subparagraph 3-306.14(B)(1) and (2).*

Prohibited Re-service of Food

(H) *FOOD may not be re-served under the following conditions:*

(1) *Any FOOD served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.*

(2) *Packages of FOOD from any patients, clients, or other CONSUMERS should not be re-served to PERSONS in protective environment isolation.*

Chapter

4 Equipment, Utensils, and Linens

Parts

- 4-1 MATERIALS FOR CONSTRUCTION AND REPAIR
- 4-2 DESIGN AND CONSTRUCTION
- 4-3 NUMBERS AND CAPACITIES
- 4-4 LOCATION AND INSTALLATION
- 4-5 MAINTENANCE AND OPERATION
- 4-6 CLEANING OF EQUIPMENT AND UTENSILS
- 4-7 SANITIZATION OF EQUIPMENT AND UTENSILS
- 4-8 LAUNDERING
- 4-9 PROTECTION OF CLEAN ITEMS

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

- 4-101 Multiuse
- 4-102 Single-Service and Single-Use

Multiuse

4-101.11 Characteristics.

Materials that are used in the construction of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT may not allow the migration of deleterious substances or impart colors, odors, or tastes to FOOD and under normal use conditions shall be:^P

- (A) Safe;^P
- (B) Durable, CORROSION-RESISTANT, and nonabsorbent;
- (C) Sufficient in weight and thickness to withstand repeated WAREWASHING;

(D) Finished to have a SMOOTH, EASILY CLEANABLE surface; and

(E) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

4-101.12 Cast Iron, Use Limitation.

(A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.

(B) *Cast iron may be used as a surface for cooking.*

(C) *Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.*

4-101.13 Lead, Use Limitation.

(A) Ceramic, china, and crystal UTENSILS, and decorative UTENSILS such as hand painted ceramic or china that are used in contact with FOOD shall be lead-free or contain levels of lead not exceeding the limits of the following UTENSIL categories:^P

UTENSIL Category	Ceramic Article Description	Maximum Lead MG/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls \geq 1.1 Liter (1.16 Quart)	1
Small Hollowware (excluding cups & mugs)	Bowls < 1.1 Liter (1.16 Quart)	2.0
Flat TABLEWARE	Plates, Saucers	3.0

(B) Pewter alloys containing lead in excess of 0.05% may not be used as a FOOD-CONTACT SURFACE.^P

(C) Solder and flux containing lead in excess of 0.2% may not be used as a FOOD-CONTACT SURFACE.

4-101.14 Copper, Use Limitation.

(A) Except as specified in ¶ (B) of this section, copper and copper alloys such as brass may not be used in contact with a FOOD that has a pH below 6 such as vinegar, fruit JUICE, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.^P

(B) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

4-101.15 Galvanized Metal, Use Limitation.

Galvanized metal may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT that are used in contact with acidic FOOD.^P

4-101.16 Sponges, Use Limitation.

Sponges may not be used in contact with cleaned and SANITIZED or in-use FOOD-CONTACT SURFACES.

4-101.17 Wood, Use Limitation.

(A) Except as specified in ¶¶ (B), (C), and (D) of this section, wood and wood wicker may not be used as a FOOD-CONTACT SURFACE.

(B) Hard maple or an equivalently hard, close-grained wood may be used for:

(1) Cutting boards; cutting blocks; bakers' tables; and UTENSILS such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and

(2) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.

(C) Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.

(D) If the nature of the FOOD requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw FOOD may be kept in:

(1) Untreated wood containers; or

(2) Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for wood.

4-101.18 Nonstick Coatings, Use Limitation.

Multiuse KITCHENWARE such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching UTENSILS and cleaning aids.

4-101.19 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of a CORROSION-RESISTANT, nonabsorbent, and SMOOTH material.

Single-Service and Single-Use

4-102.11 Characteristics.

Materials that are used to make SINGLE-SERVICE and SINGLE-USE ARTICLES:

(A) May not:

(1) Allow the migration of deleterious substances,^P or

(2) Impart colors, odors, or tastes to FOOD; and

(B) Shall be:

(1) Safe,^P and

(2) Clean.

4-2 DESIGN AND CONSTRUCTION

Subparts

4-201	Durability and Strength
4-202	Cleanability
4-203	Accuracy
4-204	Functionality
4-205	Acceptability

Durability and Strength

4-201.11 Equipment and Utensils.

EQUIPMENT and UTENSILS shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

4-201.12 Food Temperature Measuring Devices.

FOOD TEMPERATURE MEASURING DEVICES may not have sensors or stems constructed of glass, *except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.*^P

Cleanability

4-202.11 Food-Contact Surfaces.

(A) Multiuse FOOD-CONTACT SURFACES shall be:

(1) SMOOTH;^{Pf}

(2) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections;^{Pf}

(3) Free of sharp internal angles, corners, and crevices;^{Pf}

(4) Finished to have SMOOTH welds and joints;^{Pf} and

(5) Except as specified in ¶ (B) of this section, accessible for cleaning and inspection by one of the following methods:

- (a) Without being disassembled,^{Pf}
- (b) By disassembling without the use of tools,^{Pf} or
- (c) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.^{Pf}

(B) Subparagraph (A)(5) of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or BEVERAGE syrup lines or tubes.

4-202.12 CIP Equipment.

(A) CIP EQUIPMENT shall meet the characteristics specified under § 4-202.11 and shall be designed and constructed so that:

- (1) Cleaning and SANITIZING solutions circulate throughout a fixed system and contact all interior FOOD-CONTACT SURFACES,^{Pf} and
- (2) The system is self-draining or capable of being completely drained of cleaning and SANITIZING solutions; and

(B) CIP EQUIPMENT that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior FOOD-CONTACT SURFACES throughout the fixed system are being effectively cleaned.

4-202.13 "V" Threads, Use Limitation.

Except for hot oil cooking or filtering EQUIPMENT, "V" type threads may not be used on FOOD-CONTACT SURFACES.

4-202.14 Hot Oil Filtering Equipment.

Hot oil filtering EQUIPMENT shall meet the characteristics specified under § 4-202.11 or § 4-202.12 and shall be readily accessible for filter replacement and cleaning of the filter.

4-202.15 Can Openers.

Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

4-202.16 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

4-202.17 Kick Plates, Removable.

Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(A) Removable by one of the methods specified under Subparagraph 4-202.11(A)(5) or capable of being rotated open; and

(B) Removable or capable of being rotated open without unlocking EQUIPMENT doors.

4-202.18 Ventilation Hood Systems, Filters.

Filters or other grease extracting EQUIPMENT shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

Accuracy

4-203.11 Temperature Measuring Devices, Food.

(A) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to $\pm 1^{\circ}\text{C}$ in the intended range of use.^{Pf}

(B) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to $\pm 2^{\circ}\text{F}$ in the intended range of use.^{Pf}

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

(A) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to $\pm 1.5^{\circ}\text{C}$ in the intended range of use.^{Pf}

(B) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to $\pm 3^{\circ}\text{F}$ in the intended range of use.^{Pf}

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Pressure measuring devices that display the pressures in the water supply line for the fresh hot water SANITIZING rinse shall have increments of 7 kilopascals (1 pound per square inch) or smaller and shall be accurate to ± 14 kilopascals (± 2 pounds per square inch) in the range indicated on the manufacturer's data plate.

Functionality

4-204.11 Ventilation Hood Systems, Drip Prevention.

Exhaust ventilation hood systems in FOOD preparation and WAREWASHING areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-204.12 Equipment Openings, Closures and Deflectors.

(A) A cover or lid for EQUIPMENT shall overlap the opening and be sloped to drain.

(B) An opening located within the top of a unit of EQUIPMENT that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (two-tenths of an inch).

(C) Except as specified under ¶ (D) of this section, fixed piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending into EQUIPMENT shall be provided with a watertight joint at the point where the item enters the EQUIPMENT.

(D) If a watertight joint is not provided:

(1) The piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the FOOD; and

(2) The opening shall be flanged as specified under ¶ (B) of this section.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

In EQUIPMENT that dispenses or vends liquid FOOD or ice in UNPACKAGED form:

(A) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the FOOD shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the FOOD;

(B) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

(C) The delivery tube or chute and orifice of EQUIPMENT used to vend liquid FOOD or ice in UNPACKAGED form to self-service CONSUMERS shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the EQUIPMENT is:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain,

windblown debris, insects, rodents, and other contaminants that are present in the environment, or

(2) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE; and

(D) The dispensing EQUIPMENT actuating lever or mechanism and filling device of CONSUMER self-service BEVERAGE dispensing EQUIPMENT shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

(E) Dispensing EQUIPMENT in which TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in a homogenous liquid form is maintained outside of the temperature control requirements as specified under §3-501.16(A) shall:

(1) be specifically designed and equipped to maintain the commercial sterility of aseptically PACKAGED FOOD in a homogenous liquid form for a specified duration from the time of opening the PACKAGING within the EQUIPMENT; ^P and

(2) conform to the requirements for this EQUIPMENT as specified in *NSF/ANSI 18-2006- Manual Food and Beverage Dispensing Equipment*. ^P

4-204.14 Vending Machine, Vending Stage Closure.

The dispensing compartment of a VENDING MACHINE including a machine that is designed to vend prePACKAGED snack FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

(A) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE.

4-204.15 Bearings and Gear Boxes, Leakproof.

EQUIPMENT containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant cannot leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

4-204.16 Beverage Tubing, Separation.

Except for cold plates that are constructed integrally with an ice storage bin, BEVERAGE tubing and cold-plate BEVERAGE cooling devices may not be installed in contact with stored ice.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines may not pass through an ice machine or ice storage bin.

4-204.18 Condenser Unit, Separation.

If a condenser unit is an integral component of EQUIPMENT, the condenser unit shall be separated from the FOOD and FOOD storage space by a dustproof barrier.

4-204.19 Can Openers on Vending Machines.

Cutting or piercing parts of can openers on VENDING MACHINES shall be protected from manual contact, dust, insects, rodents, and other contamination.

4-204.110 Molluscan Shellfish Tanks.

(A) Except as specified under ¶ (B) of this section, MOLLUSCAN SHELLFISH life support system display tanks may not be used to store or display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the CONSUMER that the shellfish are for display only.^P

(B) MOLLUSCAN SHELLFISH life-support system display tanks that are used to store or display shellfish that are offered for human

consumption shall be operated and maintained in accordance with a VARIANCE granted by the REGULATORY AUTHORITY as specified in § 8-103.10 and a HACCP PLAN that:^{Pf}

(1) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11;^{Pf} and

(2) Ensures that:

(a) Water used with FISH other than MOLLUSCAN SHELLFISH does not flow into the molluscan tank,^{Pf}

(b) The safety and quality of the shellfish as they were received are not compromised by the use of the tank,^{Pf} and

(c) The identity of the source of the SHELLSTOCK is retained as specified under § 3-203.12.^{Pf}

4-204.111 Vending Machines, Automatic Shutoff.

(A) A machine vending TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall have an automatic control that prevents the machine from vending FOOD:

(1) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that cannot maintain FOOD temperatures as specified under Chapter 3;^P and

(2) If a condition specified under Subparagraph (A)(1) of this section occurs, until the machine is serviced and restocked with FOOD that has been maintained at temperatures specified under Chapter 3.^P

(B) When the automatic shutoff within a machine vending TIME/TEMPERATURE CONTROL FOR SAFETY FOOD is activated:

(1) In a refrigerated vending machine, the ambient air temperature may not exceed 5°C (41°F) for more than 30 minutes immediately after the machine is filled, serviced, or restocked;^P or

(2) In a hot holding vending machine, the ambient air temperature may not be less than 57°C (135°F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.^P

4-204.112 Temperature Measuring Devices.

(A) In a mechanically refrigerated or hot FOOD storage unit, the sensor of a TEMPERATURE MEASURING DEVICE shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot FOOD storage unit.

(B) Except as specified in ¶ (C) of this section, cold or hot holding EQUIPMENT used for TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be designed to include and shall be equipped with at least one integral or permanently affixed TEMPERATURE MEASURING DEVICE that is located to allow easy viewing of the device's temperature display.

(C) Paragraph (B) of this section does not apply to EQUIPMENT for which the placement of a TEMPERATURE MEASURING DEVICE is not a practical means for measuring the ambient air surrounding the FOOD because of the design, type, and use of the EQUIPMENT, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated FOOD transport containers, and salad bars.

(D) TEMPERATURE MEASURING DEVICES shall be designed to be easily readable.

(E) FOOD TEMPERATURE MEASURING DEVICES and water TEMPERATURE MEASURING DEVICES on WAREWASHING machines shall have a numerical scale, printed record, or digital readout in increments no greater than 1°C or 2°F in the intended range of use.^{Pf}

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

A WAREWASHING machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operation specifications including the:

- (A) Temperatures required for washing, rinsing, and SANITIZING;
- (B) Pressure required for the fresh water SANITIZING rinse *unless the machine is designed to use only a pumped SANITIZING rinse*; and
- (C) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

4-204.114 Warewashing Machines, Internal Baffles.

WAREWASHING machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

A WAREWASHING machine shall be equipped with a TEMPERATURE MEASURING DEVICE that indicates the temperature of the water:

- (A) In each wash and rinse tank;^{Pf} and
- (B) As the water enters the hot water SANITIZING final rinse manifold or in the chemical SANITIZING solution tank.^{Pf}

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

If hot water is used for SANITIZATION in manual WAREWASHING operations, the SANITIZING compartment of the sink shall be:

(A) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F);^{Pf} and

(B) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.^{Pf}

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

A WAREWASHING machine that is installed after adoption of this Code by the REGULATORY AUTHORITY, shall be equipped to:

(A) Automatically dispense detergents and SANITIZERS;^{Pf} and

(B) Incorporate a visual means to verify that detergents and SANITIZERS are delivered or a visual or audible alarm to signal if the detergents and SANITIZERS are not delivered to the respective washing and SANITIZING cycles.^{Pf}

4-204.118 Warewashing Machines, Flow Pressure Device.

(A) WAREWASHING machines that provide a fresh hot water SANITIZING rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the WAREWASHING machine; and

(B) If the flow pressure measuring device is upstream of the fresh hot water SANITIZING rinse control valve, the device shall be mounted in a 6.4 millimeter or one-fourth inch Iron Pipe Size (IPS) valve.

(C) Paragraphs (A) and (B) of this section do not apply to a machine that uses only a pumped or recirculated SANITIZING rinse.

4-204.119 Warewashing Sinks and Drainboards, Self-Draining.

Sinks and drainboards of WAREWASHING sinks and machines shall be self-draining.

4-204.120 Equipment Compartments, Drainage.

EQUIPMENT compartments that are subject to accumulation of moisture due to conditions such as condensation, FOOD or BEVERAGE drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

4-204.121 Vending Machines, Liquid Waste Products.

(A) VENDING MACHINES designed to store BEVERAGES that are PACKAGED in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(B) VENDING MACHINES that dispense liquid FOOD in bulk shall be:

(1) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and

(2) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(C) Shutoff devices specified under Subparagraph (B)(2) of this section shall prevent water or liquid FOOD from continuously running if there is a failure of a flow control device in the water or liquid FOOD system or waste accumulation that could lead to overflow of the waste receptacle.

4-204.122 Case Lot Handling Apparatuses, Moveability.

Apparatuses, such as dollies, pallets, racks, and skids used to store and transport large quantities of PACKAGED FOODS received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available

apparatuses such as hand trucks and forklifts.

4-204.123 Vending Machine Doors and Openings.

(A) VENDING MACHINE doors and access opening covers to FOOD and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than 1.5 millimeters or one-sixteenth inch by:

- (1) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than 1.5 millimeters or one-sixteenth inch. Screening of 12 or more mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement;
- (2) Being effectively gasketed;
- (3) Having interface surfaces that are at least 13 millimeters or one-half inch wide; or
- (4) Jambs or surfaces used to form an L-shaped entry path to the interface.

(B) VENDING MACHINE service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or one-sixteenth inch.

Acceptability

4-205.10 Food Equipment, Certification and Classification.

FOOD EQUIPMENT that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.

4-3 NUMBERS AND CAPACITIES

Subparts

4-301	Equipment
4-302	Utensils, Temperature Measuring Devices, and Testing Devices

Equipment

4-301.11 Cooling, Heating, and Holding Capacities.

EQUIPMENT for cooling and heating FOOD, and holding cold and hot FOOD, shall be sufficient in number and capacity to provide FOOD temperatures as specified under Chapter 3.^{Pf}

4-301.12 Manual Warewashing, Sink Compartment Requirements.

(A) Except as specified in ¶ (C) of this section, a sink with at least 3 compartments shall be provided for manually washing, rinsing, and SANITIZING EQUIPMENT and UTENSILS.^{Pf}

(B) Sink compartments shall be large enough to accommodate immersion of the largest EQUIPMENT and UTENSILS. If EQUIPMENT or UTENSILS are too large for the WAREWASHING sink, a WAREWASHING machine or alternative EQUIPMENT as specified in ¶ (C) of this section shall be used.^{Pf}

(C) *Alternative manual WAREWASHING EQUIPMENT may be used when there are special cleaning needs or constraints and its use is APPROVED. Alternative manual WAREWASHING EQUIPMENT may include:*

- (1) *High-pressure detergent sprayers;*
- (2) *Low- or line-pressure spray detergent foamers;*
- (3) *Other task-specific cleaning EQUIPMENT;*
- (4) *Brushes or other implements;*
- (5) *2-compartment sinks as specified under ¶¶ (D) and (E) of this section; or*

(6) Receptacles that substitute for the compartments of a multicompartment sink.

(D) Before a 2-compartment sink is used:

(1) The PERMIT HOLDER shall have its use APPROVED; and

(2) The PERMIT HOLDER shall limit the number of KITCHENWARE items cleaned and SANITIZED in the 2-compartment sink, and shall limit WAREWASHING to batch operations for cleaning KITCHENWARE such as between cutting one type of raw MEAT and another or cleanup at the end of a shift, and shall:

(a) Make up the cleaning and SANITIZING solutions immediately before use and drain them immediately after use, and

(b) Use a detergent-SANITIZER to SANITIZE and apply the detergent-SANITIZER in accordance with the manufacturer's label instructions and as specified under § 4-501.115, or

(c) Use a hot water SANITIZATION immersion step as specified under ¶ 4-603.16(C).

(E) A 2-compartment sink may not be used for WAREWASHING operations where cleaning and SANITIZING solutions are used for a continuous or intermittent flow of KITCHENWARE or TABLEWARE in an ongoing WAREWASHING process.

4-301.13 Drainboards.

Drainboards, UTENSIL racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary UTENSIL holding before cleaning and after SANITIZING.

4-301.14 Ventilation Hood Systems, Adequacy.

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

4-301.15 Clothes Washers and Dryers.

(A) Except as specified in ¶ (B) of this section, if work clothes or LINENS are laundered on the PREMISES, a mechanical clothes washer and dryer shall be provided and used.

(B) If on-PREMISES laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under § 4-901.12, a mechanical clothes washer and dryer need not be provided.

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

A FOOD dispensing UTENSIL shall be available for each container displayed at a CONSUMER self-service unit such as a buffet or salad bar.^{Pf}

4-302.12 Food Temperature Measuring Devices.

(A) FOOD TEMPERATURE MEASURING DEVICES shall be provided and readily accessible for use in ensuring attainment and maintenance of FOOD temperatures as specified under Chapter 3.^{Pf}

(B) A TEMPERATURE MEASURING DEVICE with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin FOODS such as MEAT patties and FISH filets.^{Pf}

4-302.13 Temperature Measuring Devices, Manual and Mechanical Warewashing.

(A) In manual WAREWASHING operations, a TEMPERATURE MEASURING DEVICE shall be provided and readily accessible for frequently measuring the washing and SANITIZING temperatures.^{Pf}

(B) In hot water mechanical WAREWASHING operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the UTENSIL surface temperature.^{Pf}

4-302.14 Sanitizing Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided.^{Pf}

4-4	LOCATION AND INSTALLATION
	<i>Subparts</i>
	4-401 Location
	4-402 Installation

Location

4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

(A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:

- (1) In locker rooms;
- (2) In toilet rooms;
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) *A storage cabinet used for LINENS or SINGLE-SERVICE or SINGLE-USE ARTICLES may be stored in a locker room.*

(C) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

Installation

4-402.11 Fixed Equipment, Spacing or Sealing.

(A) EQUIPMENT that is fixed because it is not EASILY MOVABLE shall be installed so that it is:

(1) Spaced to allow access for cleaning along the sides, behind, and above the EQUIPMENT;

(2) Spaced from adjoining EQUIPMENT, walls, and ceilings a distance of not more than 1 millimeter or one thirty-second inch; or

(3) SEALED to adjoining EQUIPMENT or walls, if the EQUIPMENT is exposed to spillage or seepage.

(B) COUNTER-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be installed to allow cleaning of the EQUIPMENT and areas underneath and around the EQUIPMENT by being:

(1) SEALED; or

(2) Elevated on legs as specified under ¶ 4-402.12(D).

4-402.12 Fixed Equipment, Elevation or Sealing.

(A) Except as specified in ¶¶ (B) and (C) of this section, floor-mounted EQUIPMENT that is not EASILY MOVABLE shall be SEALED to the floor or elevated on legs that provide at least a 15 centimeter (6 inch) clearance between the floor and the EQUIPMENT.

(B) *If no part of the floor under the floor-mounted EQUIPMENT is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches).*

(C) *This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the CONSUMER shopping areas of a retail FOOD store, if the floor under the units is maintained clean.*

(D) Except as specified in ¶ (E) of this section, COUNTER-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be elevated on legs that provide at least a 10 centimeter (4 inch) clearance between the table and the EQUIPMENT.

(E) *The clearance space between the table and COUNTER-MOUNTED EQUIPMENT may be:*

(1) 7.5 centimeters (3 inches) if the horizontal distance of the table top under the EQUIPMENT is no more than 50 centimeters (20 inches) from the point of access for cleaning; or

(2) 5 centimeters (2 inches) if the horizontal distance of the table top under the EQUIPMENT is no more than 7.5 centimeters (3 inches) from the point of access for cleaning

4-5 MAINTENANCE AND OPERATION

Subparts

4-501	Equipment
4-502	Utensils and Temperature and Pressure Measuring Devices

Equipment

4-501.11 Good Repair and Proper Adjustment.

(A) EQUIPMENT shall be maintained in a state of repair and condition that meets the requirements specified under Parts 4-1 and 4-2.

(B) EQUIPMENT components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

(C) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate FOOD when the container is opened.

4-501.12 Cutting Surfaces.

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and SANITIZED, or discarded if they are not capable of being resurfaced.

4-501.13 Microwave Ovens.

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.

4-501.14 Warewashing Equipment, Cleaning Frequency.

A WAREWASHING machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing EQUIPMENT, UTENSILS, or raw FOODS, or laundering wiping cloths; and drainboards or other EQUIPMENT used to substitute for drainboards as specified under § 4-301.13 shall be cleaned:

(A) Before use;

(B) Throughout the day at a frequency necessary to prevent recontamination of EQUIPMENT and UTENSILS and to ensure that the EQUIPMENT performs its intended function; and

(C) If used, at least every 24 hours.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

(A) A WAREWASHING machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.

(B) A WAREWASHING machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

4-501.16 Warewashing Sinks, Use Limitation.

(A) A WAREWASHING sink may not be used for handwashing as specified under § 2-301.15.

(B) If a WAREWASHING sink is used to wash wiping cloths, wash produce, or thaw FOOD, the sink shall be cleaned as specified under § 4-501.14 before and after each time it is used to wash wiping cloths or wash produce or thaw FOOD. Sinks used to wash or thaw FOOD shall be SANITIZED as specified under Part 4-7 before and after using the sink to wash produce or thaw FOOD.

4-501.17 Warewashing Equipment, Cleaning Agents.

When used for WAREWASHING, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.^{Pf}

4-501.18 Warewashing Equipment, Clean Solutions.

The wash, rinse, and SANITIZE solutions shall be maintained clean.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual WAREWASHING EQUIPMENT shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions.^{Pf}

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

(A) The temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F);^{Pf}

(2) For a stationary rack, dual temperature machine, 66°C (150°F);^{Pf}

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F);^{Pf} or

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F).^{Pf}

(B) The temperature of the wash solution in spray-type warewashers that use chemicals to SANITIZE may not be less than 49°C (120°F).^{Pf}

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.

If immersion in hot water is used for SANITIZING in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above.^P

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(A) Except as specified in ¶ (B) of this section, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C (194°F), or less than: ^{Pf}

(1) For a stationary rack, single temperature machine, 74°C (165°F); ^{Pf} or

(2) For all other machines, 82°C (180°F). ^{Pf}

(B) *The maximum temperature specified under ¶ (A) of this section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and SANITIZING of EQUIPMENT such as meat saws.*

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

The flow pressure of the fresh hot water SANITIZING rinse in a WAREWASHING machine, as measured in the water line immediately downstream or upstream from the fresh hot water SANITIZING rinse control valve, shall be within the range specified on the machine manufacturer's data plate and may not be less than 35 kilopascals (5 pounds per square inch) or more than 200 kilopascals (30 pounds per square inch).

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶4-703.11(C) shall meet the criteria specified under §7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, ^P and shall be used as follows:

(A) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;^P

Concentration Range (MG/L)	Minimum Temperature PH 10 or less		Minimum Temperature PH 8 or less	
	°C	(°F)	°C	(°F)
25 – 49	49	(120)	49	(120)
50 – 99	38	(100)	24	(75)
100	13	(55)	13	(55)

(B) An iodine solution shall have a:

- (1) Minimum temperature of 20°C (68°F),^P
- (2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective,^P and
- (3) Concentration between 12.5 MG/L and 25 MG/L;^P

(C) A quaternary ammonium compound solution shall:

- (1) Have a minimum temperature of 24°C (75°F),^P
- (2) Have a concentration as specified under § 7-204.11 and as indicated by the manufacturer's use directions included in the labeling,^P and
- (3) Be used only in water with 500 MG/L hardness or less or in water having a hardness no greater than specified by the EPA-registered label use instructions;^P

(D) If another solution of a chemical specified under ¶¶ (A) - (C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITIZATION and the use of the solution shall be APPROVED;^P

(E) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions; ^P and

(F) If a chemical SANITIZER is generated by a device located on-site at the FOOD ESTABLISHMENT it shall be used as specified in ¶¶(A) - (D) of this section and shall be produced by a device that:

(1) Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), ^P

(2) Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements, ^P

(3) Displays the EPA device manufacturing facility registration number on the device, ^{Pf} and

(4) Is operated and maintained in accordance with manufacturer's instructions ^{Pf}.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

If a detergent-SANITIZER is used to SANITIZE in a cleaning and SANITIZING procedure where there is no distinct water rinse between the washing and SANITIZING steps, the agent applied in the SANITIZING step shall be the same detergent-SANITIZER that is used in the washing step.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device. ^{Pf}

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

(A) UTENSILS shall be maintained in a state of repair or condition that complies with the requirements specified under Parts 4-1 and 4-2 or shall be discarded.

(B) FOOD TEMPERATURE MEASURING DEVICES shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.^{Pf}

(C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and be accurate within the intended range of use.

4-502.12 Single-Service and Single-Use Articles, Required Use.

A FOOD ESTABLISHMENT without facilities specified under Parts 4-6 and 4-7 for cleaning and SANITIZING KITCHENWARE and TABLEWARE shall provide only SINGLE-USE KITCHENWARE, SINGLE-SERVICE ARTICLES, and SINGLE-USE ARTICLES for use by FOOD EMPLOYEES AND SINGLE-SERVICE ARTICLES for use by CONSUMERS.^P

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES may not be reused.

(B) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells may not be used more than once as serving containers.

4-6 CLEANING OF EQUIPMENT AND UTENSILS

Subparts

4-601	Objective
4-602	Frequency
4-603	Methods

Objective

4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be clean to sight and touch.^{Pf}

(B) The FOOD-CONTACT SURFACES of cooking EQUIPMENT and pans shall be kept free of encrusted grease deposits and other soil accumulations.

(C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.

Frequency

4-602.11 Equipment Food-Contact Surfaces and Utensils.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned:

(1) Except as specified in ¶ (B) of this section, before each use with a different type of raw animal FOOD such as beef, FISH, lamb, pork, or POULTRY;^P

(2) Each time there is a change from working with raw FOODS to working with READY-TO-EAT FOODS;^P

(3) Between uses with raw fruits and vegetables and with TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;^P

(4) Before using or storing a FOOD TEMPERATURE MEASURING DEVICE;^P and

(5) At any time during the operation when contamination may have occurred.^P

(B) *Subparagraph (A)(1) of this section does not apply if the FOOD-CONTACT SURFACE or UTENSIL is in contact with a succession of different types of raw MEAT and POULTRY each requiring a higher cooking temperature as specified under § 3-401.11 than the previous type.*

(C) Except as specified in ¶ (D) of this section, if used with TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned throughout the day at least every 4 hours.^P

(D) *Surfaces of UTENSILS and EQUIPMENT contacting TIME/TEMPERATURE CONTROL FOR SAFETY FOOD may be cleaned less frequently than every 4 hours if:*

(1) *In storage, containers of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;*

(2) *UTENSILS and EQUIPMENT are used to prepare FOOD in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:*

(a) *The UTENSILS and EQUIPMENT are cleaned at the frequency in the following chart that corresponds to the temperature; and*

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C - 7.2°C (>41°F - 45°F)	20 hours
>7.2°C - 10.0°C (>45°F - 50°F)	16 hours
>10.0°C - 12.8°C (>50°F - 55°F)	10 hours

(b) *The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the FOOD ESTABLISHMENT.*

(3) *Containers in serving situations such as salad bars, delis,*

and cafeteria lines hold READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same FOOD that is at the required temperature, and the containers are cleaned at least every 24 hours;

(4) TEMPERATURE MEASURING DEVICES are maintained in contact with FOOD, such as when left in a container of deli FOOD or in a roast, held at temperatures specified under Chapter 3;

(5) EQUIPMENT is used for storage of PACKAGED or UNPACKAGED FOOD such as a reach-in refrigerator and the EQUIPMENT is cleaned at a frequency necessary to preclude accumulation of soil residues;

(6) The cleaning schedule is APPROVED based on consideration of:

(a) Characteristics of the EQUIPMENT and its use,

(b) The type of FOOD involved,

(c) The amount of FOOD residue accumulation, and

(d) The temperature at which the FOOD is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or

(7) In-use UTENSILS are intermittently stored in a container of water in which the water is maintained at 57°C (135°F) or more and the UTENSILS and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(E) Except when dry cleaning methods are used as specified under § 4-603.11, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cleaned:

(1) At any time when contamination may have occurred;

(2) At least every 24 hours for iced tea dispensers and

CONSUMER self-service UTENSILS such as tongs, scoops, or ladles;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers and display containers; and

(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

4-602.12 Cooking and Baking Equipment.

(A) The FOOD-CONTACT SURFACES of cooking and baking EQUIPMENT shall be cleaned at least every 24 hours. *This section does not apply to hot oil cooking and filtering EQUIPMENT if it is cleaned as specified in Subparagraph 4-602.11(D)(6).*

(B) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

4-602.13 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

Methods

4-603.11 Dry Cleaning.

(A) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only SURFACES that are soiled with dry FOOD residues that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD.

(B) Cleaning EQUIPMENT used in dry cleaning FOOD-CONTACT SURFACES may not be used for any other purpose.

4-603.12 Precleaning.

(A) FOOD debris on EQUIPMENT and UTENSILS shall be scraped over a waste disposal unit or garbage receptacle or shall be removed in a WAREWASHING machine with a prewash cycle.

(B) If necessary for effective cleaning, UTENSILS and EQUIPMENT shall be preflushed, presoaked, or scrubbed with abrasives.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Soiled items to be cleaned in a WAREWASHING machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(A) Exposes the items to the unobstructed spray from all cycles; and

(B) Allows the items to drain.

4-603.14 Wet Cleaning.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(B) The washing procedures selected shall be based on the type and purpose of the EQUIPMENT or UTENSIL, and on the type of soil to be removed.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

If washing in sink compartments or a WAREWASHING machine is impractical such as when the EQUIPMENT is fixed or the UTENSILS are too large, washing shall be done by using alternative

manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) in accordance with the following procedures:

- (A) EQUIPMENT shall be disassembled as necessary to allow access of the detergent solution to all parts;
- (B) EQUIPMENT components and UTENSILS shall be scrapped or rough cleaned to remove FOOD particle accumulation; and
- (C) EQUIPMENT and UTENSILS shall be washed as specified under ¶ 4-603.14(A).

4-603.16 Rinsing Procedures.

Washed UTENSILS and EQUIPMENT shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:

(A) Use of a distinct, separate water rinse after washing and before SANITIZING if using:

- (1) A 3-compartment sink,
- (2) Alternative manual WAREWASHING EQUIPMENT equivalent to a 3-compartment sink as specified in ¶ 4-301.12(C), or
- (3) A 3-step washing, rinsing, and SANITIZING procedure in a WAREWASHING system for CIP EQUIPMENT;

(B) Use of a detergent-SANITIZER as specified under § 4-501.115 if using:

- (1) Alternative WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) that is APPROVED for use with a detergent-SANITIZER, or
- (2) A WAREWASHING system for CIP EQUIPMENT;

(C) Use of a nondistinct water rinse that is integrated in the hot water SANITIZATION immersion step of a 2-compartment sink operation;

(D) If using a WAREWASHING machine that does not recycle the SANITIZING solution as specified under ¶ (E) of this section, or alternative manual WAREWASHING EQUIPMENT such as sprayers, use of a nondistinct water rinse that is:

(1) Integrated in the application of the SANITIZING solution, and

(2) Wasted immediately after each application; or

(E) If using a WAREWASHING machine that recycles the SANITIZING solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the SANITIZING solution.

4-7 SANITIZATION OF EQUIPMENT AND UTENSILS

Subparts

4-701	Objective
4-702	Frequency
4-703	Methods

Objective

4-701.10 Food-Contact Surfaces and Utensils.

EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED.

Frequency

4-702.11 Before Use After Cleaning.

UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT shall be SANITIZED before use after cleaning.^P

Methods

4-703.11 Hot Water and Chemical.

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111;^P

(B) Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator;^P or

(C) Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under § 4-501.114. Contact times shall be consistent with those on EPA-registered label use instructions by providing:

(1) Except as specified under Subparagraph (C)(2) of this section, a contact time of at least 10 seconds for a chlorine solution specified under ¶ 4-501.114(A),^P

(2) A contact time of at least 7 seconds for a chlorine solution of 50 MG/L that has a PH of 10 or less and a temperature of at least 38°C (100°F) or a PH of 8 or less and a temperature of at least 24°C (75°F),^P

(3) A contact time of at least 30 seconds for other chemical SANITIZING solutions,^P or

(4) A contact time used in relationship with a combination of temperature, concentration, and PH that, when evaluated for efficacy, yields SANITIZATION as defined in ¶ 1-201.10(B).^P

4-8	LAUNDERING	
	<i>Subparts</i>	
	4-801	Objective
	4-802	Frequency
	4-803	Methods

Objective

4-801.11 Clean Linens.

Clean LINENS shall be free from FOOD residues and other soiling matter.

Frequency

4-802.11 Specifications.

(A) LINENS that do not come in direct contact with FOOD shall be laundered between operations if they become wet, sticky, or visibly soiled.

(B) Cloth gloves used as specified in ¶ 3-304.15(D) shall be laundered before being used with a different type of raw animal FOOD such as beef, FISH, lamb, pork or POULTRY.

(C) LINENS that are used as specified under § 3-304.13 and cloth napkins shall be laundered between each use.

(D) Wet wiping cloths shall be laundered daily.

(E) Dry wiping cloths shall be laundered as necessary to prevent contamination of FOOD and clean serving UTENSILS.

Methods

4-803.11 Storage of Soiled Linens.

Soiled LINENS shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of FOOD, clean EQUIPMENT, clean UTENSILS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-803.12 Mechanical Washing.

(A) Except as specified in ¶ (B) of this section, LINENS shall be mechanically washed.

(B) In FOOD ESTABLISHMENTS in which only wiping cloths are laundered as specified in ¶ 4-301.15(B), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a WAREWASHING or FOOD preparation sink that is cleaned as specified under § 4-501.14.

4-803.13 Use of Laundry Facilities.

(A) Except as specified in ¶ (B) of this section, laundry facilities on the PREMISES of a FOOD ESTABLISHMENT shall be used only for the washing and drying of items used in the operation of the establishment.

(B) *Separate laundry facilities located on the PREMISES for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering FOOD ESTABLISHMENT items.*

4-9 PROTECTION OF CLEAN ITEMS

Subparts

4-901	Drying
4-902	Lubricating and Reassembling
4-903	Storing
4-904	Preventing Contamination

Drying

4-901.11 Equipment and Utensils, Air-Drying Required.

After cleaning and SANITIZING, EQUIPMENT and UTENSILS:

(A) Shall be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface SANITIZING solutions), before contact with FOOD; and

(B) May not be cloth dried *except that UTENSILS that have been air-dried may be polished with cloths that are maintained clean and dry.*

4-901.12 Wiping Cloths, Air-Drying Locations.

Wiping cloths laundered in a FOOD ESTABLISHMENT that does not have a mechanical clothes dryer as specified in ¶ 4-301.15(B) shall be air-dried in a location and in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and the wiping cloths. *This section does not apply if wiping cloths are stored after laundering in a SANITIZING solution as specified under § 4-501.114.*

Lubricating and Reassembling

4-902.11 Food-Contact Surfaces.

Lubricants as specified under § 7-205.11 shall be applied to FOOD-CONTACT SURFACES that require lubrication in a manner that does not contaminate FOOD-CONTACT SURFACES.

4-902.12 Equipment.

EQUIPMENT shall be reassembled so that FOOD-CONTACT SURFACES are not contaminated.

Storing

4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

(A) Except as specified in ¶ (D) of this section, cleaned EQUIPMENT and UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored:

- (1) In a clean, dry location;
- (2) Where they are not exposed to splash, dust, or other contamination; and
- (3) At least 15 cm (6 inches) above the floor.

(B) Clean EQUIPMENT and UTENSILS shall be stored as specified under ¶ (A) of this section and shall be stored:

- (1) In a self-draining position that allows air drying; and
- (2) Covered or inverted.

(C) SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored as specified under ¶ (A) of this section and shall be kept in the original protective PACKAGE or stored by using other means that afford protection from contamination until used.

(D) *Items that are kept in closed PACKAGES may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks, and skids that are designed as specified under § 4-204.122.*

4-903.12 Prohibitions.

(A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:

- (1) In locker rooms;
- (2) In toilet rooms;
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
- (7) Under open stairwells; or
- (8) Under other sources of contamination.

(B) *Laundered LINENS and SINGLE-SERVICE and SINGLE-USE ARTICLES that are PACKAGED or in a facility such as a cabinet may be stored in a locker room.*

Preventing Contamination

4-904.11 Kitchenware and Tableware.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES and cleaned and SANITIZED UTENSILS shall be handled, displayed, and dispensed so that contamination of FOOD- and lip-contact surfaces is prevented.

(B) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by EMPLOYEES and by CONSUMERS if CONSUMER self-service is provided.

(C) Except as specified under ¶ (B) of this section, SINGLE-SERVICE ARTICLES that are intended for FOOD- or lip-contact shall be furnished for CONSUMER self-service with the original individual wrapper intact or from an APPROVED dispenser.

4-904.12 Soiled and Clean Tableware.

Soiled TABLEWARE shall be removed from CONSUMER eating and drinking areas and handled so that clean TABLEWARE is not contaminated.

4-904.13 Preset Tableware.

(A) Except as specified in ¶ (B) of this section, TABLEWARE that is preset shall be protected from contamination by being wrapped, covered, or inverted.

(B) *Preset TABLEWARE may be exposed if:*

(1) Unused settings are removed when a CONSUMER is seated; or

(2) Settings not removed when a CONSUMER is seated are cleaned and SANITIZED before further use.

4-904.14 Rinsing Equipment and Utensils after Cleaning and Sanitizing.

After being cleaned and SANITIZED, EQUIPMENT and UTENSILS shall not be rinsed before air drying or use unless:

(A) The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under Subparts 4-204 and 4-501; and

(B) The rinse is applied only after the EQUIPMENT and UTENSILS have been SANITIZED by the application of hot water or by the application of a chemical SANITIZER solution whose EPA-registered label use instructions call for rinsing off the SANITIZER after it is applied in a commercial WAREWASHING machine.

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Chapter

5

Water, Plumbing, and Waste

Parts

- 5-1 WATER
- 5-2 PLUMBING SYSTEM
- 5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT
WATER TANK
- 5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER
- 5-5 REFUSE, RECYCLABLES, AND RETURNABLES

5-1 WATER

Subparts

- 5-101 Source
- 5-102 Quality
- 5-103 Quantity and Availability
- 5-104 Distribution, Delivery, and Retention

Source

5-101.11 Approved System.

DRINKING WATER shall be obtained from an APPROVED source that is:

(A) A PUBLIC WATER SYSTEM;^P or

(B) A nonPUBLIC WATER SYSTEM that is constructed, maintained, and operated according to LAW.^P

5-101.12 System Flushing and Disinfection.

A DRINKING WATER system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.^P

5-101.13 Bottled Drinking Water.

BOTTLED DRINKING WATER used or sold in a FOOD ESTABLISHMENT shall be obtained from APPROVED sources in accordance with 21 CFR 129 - Processing and Bottling of Bottled DRINKING WATER.^P

Quality

5-102.11 Standards.

Except as specified under § 5-102.12:

(A) Water from a PUBLIC WATER SYSTEM shall meet 40 CFR 141 - National Primary Drinking Water Regulations and state DRINKING WATER quality standards;^P and

(B) Water from a nonPUBLIC WATER SYSTEM shall meet state DRINKING WATER quality standards.^P

5-102.12 Nondrinking Water.

(A) A nonDRINKING WATER supply shall be used only if its use is APPROVED.^P

(B) NonDRINKING WATER shall be used only for nonculinary purposes such as air conditioning, nonFOOD EQUIPMENT cooling, and fire protection.^P

5-102.13 Sampling.

Except when used as specified under § 5-102.12, water from a nonPUBLIC WATER SYSTEM shall be sampled and tested at least annually and as required by state water quality regulations.^{Pf}

5-102.14 Sample Report.

The most recent sample report for the nonPUBLIC WATER SYSTEM shall be retained on file in the FOOD ESTABLISHMENT or the report shall be maintained as specified by state water quality regulations.

Quantity and Availability

5-103.11 Capacity.

(A) The water source and system shall be of sufficient capacity to meet the peak water demands of the FOOD ESTABLISHMENT.^{Pf}

(B) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the FOOD ESTABLISHMENT.^{Pf}

5-103.12 Pressure.

Water under pressure shall be provided to all fixtures, EQUIPMENT, and nonFOOD EQUIPMENT that are required to use water *except that water supplied as specified under ¶¶ 5-104.12(A) and (B) to a TEMPORARY FOOD ESTABLISHMENT or in response to a temporary interruption of a water supply need not be under pressure.*^{Pf}

Distribution, Delivery, and Retention

5-104.11 System.

Water shall be received from the source through the use of:

(A) An APPROVED public water main;^{Pf} or

(B) One or more of the following that shall be constructed, maintained, and operated according to LAW:^{Pf}

(1) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,^{Pf}

(2) Water transport vehicles,^{Pf} or

(3) Water containers.^{Pf}

5-104.12 Alternative Water Supply.

Water meeting the requirements specified under Subparts 5-101, 5-102, and 5-103 shall be made available for a mobile facility, for a TEMPORARY FOOD ESTABLISHMENT without a permanent water supply, and for a FOOD ESTABLISHMENT with a temporary interruption of its water supply through:

- (A) A supply of containers of commercially BOTTLED DRINKING WATER;^{Pf}
- (B) One or more closed portable water containers;^{Pf}
- (C) An enclosed vehicular water tank;^{Pf}
- (D) An on-PREMISES water storage tank;^{Pf} or
- (E) Piping, tubing, or hoses connected to an adjacent APPROVED source.^{Pf}

5-2 PLUMBING SYSTEM

Subparts

5-201	Materials
5-202	Design, Construction, and Installation
5-203	Numbers and Capacities
5-204	Location and Placement
5-205	Operation and Maintenance

Materials

5-201.11 Approved.

(A) A PLUMBING SYSTEM and hoses conveying water shall be constructed and repaired with APPROVED materials according to LAW.^P

(B) A water filter shall be made of SAFE MATERIALS.^P

Design, Construction, and Installation

5-202.11 Approved System and Cleanable Fixtures.

(A) A PLUMBING SYSTEM shall be designed, constructed, and installed according to LAW.^P

(B) A PLUMBING FIXTURE such as a HANDWASHING SINK, toilet, or urinal shall be EASILY CLEANABLE.

5-202.12 Handwashing Sink, Installation.

(A) A HANDWASHING SINK shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet.^{Pf}

(B) A steam mixing valve may not be used at a HANDWASHING SINK.

(C) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

(D) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

5-202.13 Backflow Prevention, Air Gap.

An air gap between the water supply inlet and the flood level rim of the PLUMBING FIXTURE, EQUIPMENT, or nonFOOD EQUIPMENT shall be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch).^P

5-202.14 Backflow Prevention Device, Design Standard.

A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device.^P

5-202.15 Conditioning Device, Design.

A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

Numbers and Capacities

5-203.11 Handwashing Sinks.

(A) Except as specified in ¶¶ (B) and (C) of this section, at least 1 HANDWASHING SINK, a number of HANDWASHING SINKS necessary for their convenient use by EMPLOYEES in areas specified under § 5-204.11, and not fewer than the number of HANDWASHING SINKS required by LAW shall be provided.^{Pf}

(B) If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, automatic handwashing facilities may be substituted for HANDWASHING SINKS in a FOOD ESTABLISHMENT that has at least 1 HANDWASHING SINK.

(C) If APPROVED, when FOOD exposure is limited and HANDWASHING SINKS are not conveniently available, such as in some mobile or TEMPORARY FOOD ESTABLISHMENTS or at some VENDING MACHINE LOCATIONS, EMPLOYEES may use chemically treated towelettes for handwashing.

5-203.12 Toilets and Urinals.

At least 1 toilet and not fewer than the toilets required by LAW shall be provided. If authorized by LAW and urinals are substituted for toilets, the substitution shall be done as specified in LAW.

5-203.13 Service Sink.

(A) At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

(B) Toilets and urinals may not be used as a service sink for the disposal of mop water and similar liquid waste.

5-203.14 Backflow Prevention Device, When Required.

A PLUMBING SYSTEM shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the FOOD ESTABLISHMENT, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by LAW, by:

(A) Providing an air gap as specified under § 5-202.13^P; or

(B) Installing an APPROVED backflow prevention device as specified under § 5-202.14.^P

5-203.15 Backflow Prevention Device, Carbonator.

(A) If not provided with an air gap as specified under §5-202.13, a dual check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4 mm (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.^P

(B) *A dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified under ¶ (A) of this section.*

Location and Placement

5-204.11 Handwashing Sinks.

A HANDWASHING SINK shall be located:

(A) To allow convenient use by EMPLOYEES in FOOD preparation, FOOD dispensing, and WAREWASHING areas;^{Pf} and

(B) In, or immediately adjacent to, toilet rooms.^{Pf}

5-204.12 Backflow Prevention Device, Location.

A backflow prevention device shall be located so that it may be serviced and maintained.

5-204.13 Conditioning Device, Location.

A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

Operation and Maintenance

5-205.11 Using a Handwashing Sink.

(A) A HANDWASHING SINK shall be maintained so that it is accessible at all times for EMPLOYEE use.^{Pf}

(B) A HANDWASHING SINK may not be used for purposes other than handwashing.^{Pf}

(C) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.^{Pf}

5-205.12 Prohibiting a Cross Connection.

(A) A PERSON may not create a cross connection by connecting a pipe or conduit between the DRINKING WATER system and a nonDRINKING WATER system or a water system of unknown quality.^P

(B) The piping of a nonDRINKING WATER system shall be durably identified so that it is readily distinguishable from piping that carries DRINKING WATER.^{Pf}

5-205.13 Scheduling Inspection and Service for a Water System Device.

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the PERSON IN CHARGE.^{Pf}

5-205.14 Water Reservoir of Fogging Devices, Cleaning.

(A) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(1) Maintained in accordance with manufacturer's specifications;^P and

(2) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under ¶ (B) of this section, whichever is more stringent.^P

(B) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(1) Draining and complete disassembly of the water and aerosol contact parts;^P

(2) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;^P

(3) Flushing the complete system with water to remove the detergent solution and particulate accumulation;^P and

(4) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 MG/L hypochlorite solution.^P

5-205.15 System Maintained in Good Repair.

A PLUMBING SYSTEM shall be:

(A) Repaired according to LAW;^P and

(B) Maintained in good repair.

5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK

Subparts

5-301	Materials
5-302	Design and Construction
5-303	Numbers and Capacities
5-304	Operation and Maintenance

Materials

5-301.11 Approved.

Materials that are used in the construction of a mobile water tank, mobile FOOD ESTABLISHMENT water tank, and appurtenances shall be:

(A) Safe;^P

(B) Durable, CORROSION-RESISTANT, and nonabsorbent; and

(C) Finished to have a SMOOTH, EASILY CLEANABLE surface.

**Design and
Construction**

5-302.11 Enclosed System, Sloped to Drain.

A mobile water tank shall be:

- (A) Enclosed from the filling inlet to the discharge outlet; and
- (B) Sloped to an outlet that allows complete drainage of the tank.

5-302.12 Inspection and Cleaning Port, Protected and Secured.

If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

- (A) Flanged upward at least 13 mm (one-half inch); and
- (B) Equipped with a port cover assembly that is:
 - (1) Provided with a gasket and a device for securing the cover in place, and
 - (2) Flanged to overlap the opening and sloped to drain.

5-302.13 "V" Type Threads, Use Limitation.

A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

5-302.14 Tank Vent, Protected.

If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

- (A) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or
- (B) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

5-302.15 Inlet and Outlet, Sloped to Drain.

(A) A water tank and its inlet and outlet shall be sloped to drain.

(B) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

5-302.16 Hose, Construction and Identification.

A hose used for conveying DRINKING WATER from a water tank shall be:

- (A) Safe;^P
- (B) Durable, CORROSION-RESISTANT, and nonabsorbent;
- (C) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
- (D) Finished with a SMOOTH interior surface; and
- (E) Clearly and durably identified as to its use if not permanently attached.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and DRINKING WATER system when compressed air is used to pressurize the water tank system.^P

5-303.12 Protective Cover or Device.

A cap and keeper chain, closed cabinet, closed storage tube, or other APPROVED protective cover or device shall be provided for a water inlet, outlet, and hose.

5-303.13 Mobile Food Establishment Tank Inlet.

A mobile FOOD ESTABLISHMENT'S water tank inlet shall be:

- (A) 19.1 mm (three-fourths inch) in inner diameter or less; and

(B) Provided with a hose connection of a size or type that will prevent its use for any other service.

**Operation and
Maintenance**

5-304.11 System Flushing and Sanitization.

A water tank, pump, and hoses shall be flushed and SANITIZED before being placed in service after construction, repair, modification, and periods of nonuse.^P

5-304.12 Using a Pump and Hoses, Backflow Prevention.

A PERSON shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under § 5-303.12.

5-304.14 Tank, Pump, and Hoses, Dedication.

(A) Except as specified in ¶ (B) of this section, a water tank, pump, and hoses used for conveying DRINKING WATER shall be used for no other purpose.^P

(B) *Water tanks, pumps, and hoses APPROVED for liquid FOODS may be used for conveying DRINKING WATER if they are cleaned and SANITIZED before they are used to convey water.*

5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER

Subparts

- 5-401 Mobile Holding Tank**
- 5-402 Retention, Drainage, and Delivery**
- 5-403 Disposal Facility**

Mobile Holding Tank

5-401.11 Capacity and Drainage.

A SEWAGE holding tank in a mobile FOOD ESTABLISHMENT shall be:

- (A) Sized 15 percent larger in capacity than the water supply tank; and
- (B) Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

Retention, Drainage, and Delivery

5-402.10 Establishment Drainage System.

design, construction, and installation

FOOD ESTABLISHMENT drainage systems, including grease traps, that convey SEWAGE shall be designed and installed as specified under ¶ 5-202.11(A).

5-402.11 Backflow Prevention.

(A) Except as specified in ¶¶ (B), (C), and (D) of this section, a direct connection may not exist between the SEWAGE system and a drain originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILS are placed.^P

(B) *Paragraph (A) of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.*

(C) *If allowed by LAW, a WAREWASHING machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.*

(D) If allowed by LAW, a WAREWASHING or culinary sink may have a direct connection.

location and placement

5-402.12 Grease Trap.

If used, a grease trap shall be located to be easily accessible for cleaning.

operation and maintenance

5-402.13 Conveying Sewage.

SEWAGE shall be conveyed to the point of disposal through an APPROVED sanitary SEWAGE system or other system, including use of SEWAGE transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to LAW.^P

5-402.14 Removing Mobile Food Establishment Wastes.

SEWAGE and other liquid wastes shall be removed from a mobile FOOD ESTABLISHMENT at an APPROVED waste SERVICING AREA or by a SEWAGE transport vehicle in such a way that a public health HAZARD or nuisance is not created.^{Pf}

5-402.15 Flushing a Waste Retention Tank.

A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

Disposal Facility

5-403.11 Approved Sewage Disposal System.

design and construction

SEWAGE shall be disposed through an APPROVED facility that is:

(A) A public SEWAGE treatment plant;^P or

(B) An individual SEWAGE disposal system that is sized, constructed, maintained, and operated according to LAW.^P

5-403.12 Other Liquid Wastes and Rainwater.

Condensate drainage and other nonSEWAGE liquids and rainwater shall be drained from point of discharge to disposal according to LAW.

5-5 REFUSE, RECYCLABLES, AND RETURNABLES

Subparts

- 5-501 Facilities on the Premises**
- 5-502 Removal**
- 5-503 Facilities for Disposal and Recycling**

Facilities on the Premises

materials, design, construction, and installation

5-501.10 Indoor Storage Area.

If located within the FOOD ESTABLISHMENT, a storage area for REFUSE, recyclables, and returnables shall meet the requirements specified under §§ 6-101.11, 6-201.11 - 6-201.18, 6-202.15, and 6-202.16.

5-501.11 Outdoor Storage Surface.

An outdoor storage surface for REFUSE, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be SMOOTH, durable, and sloped to drain.

5-501.12 Outdoor Enclosure.

If used, an outdoor enclosure for REFUSE, recyclables, and returnables shall be constructed of durable and cleanable materials.

5-501.13 Receptacles.

(A) Except as specified in ¶ (B) of this section, receptacles and waste handling units for REFUSE, recyclables, and returnables and for use with materials containing FOOD residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.

(B) *Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the FOOD ESTABLISHMENT, or within closed outside receptacles.*

5-501.14 Receptacles in Vending Machines.

Except for a receptacle for BEVERAGE bottle crown closures, a REFUSE receptacle may not be located within a VENDING MACHINE.

5-501.15 Outside Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables used with materials containing FOOD residue and used outside the FOOD ESTABLISHMENT shall be designed and constructed to have tight-fitting lids, doors, or covers.

(B) Receptacles and waste handling units for REFUSE and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

numbers and capacities

5-501.16 Storage Areas, Rooms, and Receptacles, Capacity and Availability.

(A) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold REFUSE, recyclables, and returnables that accumulate.

(B) A receptacle shall be provided in each area of the FOOD ESTABLISHMENT or PREMISES where REFUSE is generated or commonly discarded, or where recyclables or returnables are placed.

(C) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

5-501.17 Toilet Room Receptacle, Covered.

A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

5-501.18 Cleaning Implements and Supplies.

(A) Except as specified in ¶ (B) of this section, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for REFUSE, recyclables, and returnables.

(B) If APPROVED, off-PREMISES-based cleaning services may be used if on-PREMISES cleaning implements and supplies are not provided.

location and placement

5-501.19 Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.

(A) An area designated for REFUSE, recyclables, returnables, and, except as specified in ¶ (B) of this section, a redeeming machine for recyclables or returnables shall be located so that it is separate from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and a public health HAZARD or nuisance is not created.

(B) A redeeming machine may be located in the PACKAGED FOOD storage area or CONSUMER area of a FOOD ESTABLISHMENT if FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are not subject to contamination from the machines and a public health HAZARD or nuisance is not created.

(C) The location of receptacles and waste handling units for REFUSE, recyclables, and returnables may not create a public health HAZARD or nuisance or interfere with the cleaning of adjacent space.

5-501.110 Storing Refuse, Recyclables, and Returnables.

REFUSE, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

5-501.111 Areas, Enclosures, and Receptacles, Good Repair.

Storage areas, enclosures, and receptacles for REFUSE, recyclables, and returnables shall be maintained in good repair.

5-501.112 Outside Storage Prohibitions.

(A) Except as specified in ¶ (B) of this section, REFUSE receptacles not meeting the requirements specified under ¶ 5-501.13(A) such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with FOOD residue may not be stored outside.

(B) Cardboard or other packaging material that does not contain FOOD residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.

5-501.113 Covering Receptacles.

Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be kept covered:

(A) Inside the FOOD ESTABLISHMENT if the receptacles and units:

(1) Contain FOOD residue and are not in continuous use;
or

(2) After they are filled; and

(B) With tight-fitting lids or doors if kept outside the FOOD ESTABLISHMENT.

5-501.114 Using Drain Plugs.

Drains in receptacles and waste handling units for REFUSE, recyclables, and returnables shall have drain plugs in place.

5-501.115 Maintaining Refuse Areas and Enclosures.

A storage area and enclosure for REFUSE, recyclables, or returnables shall be maintained free of unnecessary items, as specified under § 6-501.114, and clean.

5-501.116 Cleaning Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES, and waste water shall be disposed of as specified under § 5-402.13.

(B) Soiled receptacles and waste handling units for REFUSE, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

Removal

5-502.11 Frequency.

REFUSE, recyclables, and returnables shall be removed from the PREMISES at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

5-502.12 Receptacles or Vehicles.

REFUSE, recyclables, and returnables shall be removed from the PREMISES by way of:

(A) Portable receptacles that are constructed and maintained according to LAW; or

(B) A transport vehicle that is constructed, maintained, and operated according to LAW.

***Facilities for
Disposal and
Recycling***

5-503.11 Community or Individual Facility.

Solid waste not disposed of through the SEWAGE system such as through grinders and pulpers shall be recycled or disposed of in an APPROVED public or private community recycling or REFUSE facility; or solid waste shall be disposed of in an individual REFUSE facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to LAW.

Physical Facilities

Parts

- 6-1 MATERIALS FOR CONSTRUCTION AND REPAIR
- 6-2 DESIGN, CONSTRUCTION, AND INSTALLATION
- 6-3 NUMBERS AND CAPACITIES
- 6-4 LOCATION AND PLACEMENT
- 6-5 MAINTENANCE AND OPERATION

6-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

- 6-101 Indoor Areas
- 6-102 Outdoor Areas

Indoor Areas

6-101.11 Surface Characteristics.

(A) Except as specified in ¶ (B) of this section, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

- (1) SMOOTH, durable, and EASILY CLEANABLE for areas where FOOD ESTABLISHMENT operations are conducted;
- (2) Closely woven and EASILY CLEANABLE carpet for carpeted areas; and
- (3) Nonabsorbent for areas subject to moisture such as FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet rooms, mobile FOOD ESTABLISHMENT SERVICING AREAS, and areas subject to flushing or spray cleaning methods.

(B) *In a TEMPORARY FOOD ESTABLISHMENT:*

- (1) *If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other APPROVED materials that are effectively treated to control dust and mud; and*

(2) Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.

Outdoor Areas

6-102.11 Surface Characteristics.

(A) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(B) Exterior surfaces of buildings and mobile FOOD ESTABLISHMENTS shall be of weather-resistant materials and shall comply with LAW.

(C) Outdoor storage areas for REFUSE, recyclables, or returnables shall be of materials specified under §§ 5-501.11 and 5-501.12.

6-2	DESIGN, CONSTRUCTION, AND INSTALLATION
	Subparts
	6-201 Cleanability
	6-202 Functionality

Cleanability

6-201.11 Floors, Walls, and Ceilings.

Except as specified under § 6-201.14 and *except for antislip floor coverings or applications that may be used for safety reasons*, floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are SMOOTH and EASILY CLEANABLE.

6-201.12 Floors, Walls, and Ceilings, Utility Lines.

(A) Utility service lines and pipes may not be unnecessarily exposed.

(B) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(C) Exposed horizontal utility service lines and pipes may not be installed on the floor.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

(A) In FOOD ESTABLISHMENTS in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (one thirty-second inch).

(B) The floors in FOOD ESTABLISHMENTS in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and SEALED.

6-201.14 Floor Carpeting, Restrictions and Installation.

(A) A floor covering such as carpeting or similar material may not be installed as a floor covering in FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, REFUSE storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(B) If carpeting is installed as a floor covering in areas other than those specified under ¶ (A) of this section, it shall be:

(1) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(2) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

6-201.15 Floor Covering, Mats and Duckboards.

Mats and duckboards shall be designed to be removable and EASILY CLEANABLE.

6-201.16 Wall and Ceiling Coverings and Coatings.

(A) Wall and ceiling covering materials shall be attached so that they are EASILY CLEANABLE.

(B) *Except in areas used only for dry storage*, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and SEALED to provide a SMOOTH, nonabsorbent, EASILY CLEANABLE surface.

6-201.17 Walls and Ceilings, Attachments.

(A) Except as specified in ¶ (B) of this section, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be EASILY CLEANABLE.

(B) *In a CONSUMER area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.*

6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Except for TEMPORARY FOOD ESTABLISHMENTS, studs, joists, and rafters may not be exposed in areas subject to moisture.

Functionality

6-202.11 Light Bulbs, Protective Shielding.

(A) Except as specified in ¶ (B) of this section, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing FOOD in unopened packages, if:*

(1) *The integrity of the packages cannot be affected by broken glass falling onto them; and*

(2) *The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.*

(C) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of FOOD, FOOD-CONTACT SURFACES, EQUIPMENT, OR UTENSILS.

6-202.13 Insect Control Devices, Design and Installation.

(A) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(B) Insect control devices shall be installed so that:

(1) The devices are not located over a FOOD preparation area; and

(2) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

6-202.14 Toilet Rooms, Enclosed.

Except where a toilet room is located outside a FOOD ESTABLISHMENT and does not open directly into the FOOD ESTABLISHMENT such as a toilet room that is provided by the management of a shopping mall, a toilet room located on the PREMISES shall be completely enclosed and provided with a tight-fitting and self-closing door.

6-202.15 Outer Openings, Protected.

(A) Except as specified in ¶¶ (B), (C), and (E) and under ¶ (D) of this section, outer openings of a FOOD ESTABLISHMENT shall be protected against the entry of insects and rodents by:

- (1) Filling or closing holes and other gaps along floors, walls, and ceilings;
- (2) Closed, tight-fitting windows; and
- (3) Solid, self-closing, tight-fitting doors.

(B) Paragraph (A) of this section does not apply if a FOOD ESTABLISHMENT opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.

(C) Exterior doors used as exits need not be self-closing if they are:

- (1) Solid and tight-fitting;*
- (2) Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the FOOD ESTABLISHMENT; and*
- (3) Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.*

(D) Except as specified in ¶¶ (B) and (E) of this section, if the windows or doors of a FOOD ESTABLISHMENT, or of a larger structure within which a FOOD ESTABLISHMENT is located, are kept open for ventilation or other purposes or a TEMPORARY FOOD ESTABLISHMENT is not provided with windows and doors as specified under ¶ (A) of this section, the openings shall be protected against the entry of insects and rodents by:

- (1) 16 mesh to 25.4 mm (16 mesh to 1 inch) screens;
- (2) Properly designed and installed air curtains to control flying insects; or

(3) Other effective means.

(E) Paragraph (D) of this section does not apply if flying insects and other pests are absent due to the location of the ESTABLISHMENT, the weather, or other limiting condition.

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Perimeter walls and roofs of a FOOD ESTABLISHMENT shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

Except for machines that vend canned BEVERAGES, if located outside, a machine used to vend FOOD shall be provided with overhead protection.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Except for areas used only for the loading of water or the discharge of SEWAGE and other liquid waste, through the use of a closed system of hoses, SERVICING AREAS shall be provided with overhead protection.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

Exterior walking and driving surfaces shall be graded to drain.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

Outdoor REFUSE areas shall be constructed in accordance with LAW and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the REFUSE and from cleaning the area and waste receptacles.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting FOOD ESTABLISHMENT operations.^P

6-202.112 Living or Sleeping Quarters, Separation.

Living or sleeping quarters located on the PREMISES of a FOOD ESTABLISHMENT such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for FOOD ESTABLISHMENT operations by complete partitioning and solid self-closing doors.

6-3	NUMBERS AND CAPACITIES
	<i>Subparts</i>
	6-301 Handwashing Sinks
	6-302 Toilets and Urinals
	6-303 Lighting
	6-304 Ventilation
	6-305 Dressing Areas and Lockers
	6-306 Service Sinks

Handwashing Sinks

6-301.10 Minimum Number.

HANDWASHING SINKS shall be provided as specified under § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Each HANDWASHING SINK or group of 2 adjacent HANDWASHING SINKS shall be provided with a supply of hand cleaning liquid, powder, or bar soap.^{Pf}

6-301.12 Hand Drying Provision.

Each HANDWASHING SINK or group of adjacent HANDWASHING SINKS shall be provided with:

- (A) Individual, disposable towels; ^{Pf}
- (B) A continuous towel system that supplies the user with a clean towel; ^{Pf} or
- (C) A heated-air hand drying device; ^{Pf} or
- (D) A hand drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures. ^{Pf}

6-301.13 Handwashing Aids and Devices, Use Restrictions.

A sink used for FOOD preparation or UTENSIL washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a HANDWASHING SINK as specified under §§ 6-301.11 and 6-301.12 and ¶ 5-501.16(C).

6-301.14 Handwashing Signage.

A sign or poster that notifies FOOD EMPLOYEES to wash their hands shall be provided at all HANDWASHING SINKS used by FOOD EMPLOYEES and shall be clearly visible to FOOD EMPLOYEES.

6-301.20 Disposable Towels, Waste Receptacle.

A HANDWASHING SINK or group of adjacent HANDWASHING SINKS that is provided with disposable towels shall be provided with a waste receptacle as specified under ¶ 5-501.16(C).

Toilets and Urinals

6-302.10 Minimum Number.

Toilets and urinals shall be provided as specified under § 5-203.12.

6-302.11 Toilet Tissue, Availability.

A supply of toilet tissue shall be available at each toilet. ^{Pf}

Lighting

6-303.11 Intensity.

The light intensity shall be:

(A) At least 108 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry FOOD storage areas and in other areas and rooms during periods of cleaning;

(B) At least 215 lux (20 foot candles):

(1) At a surface where FOOD is provided for CONSUMER self-service such as buffets and salad bars or where fresh produce or PACKAGED FOODS are sold or offered for consumption,

(2) Inside EQUIPMENT such as reach-in and under-counter refrigerators; and

(3) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, WAREWASHING, and EQUIPMENT and UTENSIL storage, and in toilet rooms; and

(C) At least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILS or EQUIPMENT such as knives, slicers, grinders, or saws where EMPLOYEE safety is a factor.

Ventilation

6-304.11 Mechanical.

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

Dressing Areas and Lockers

6-305.11 Designation.

(A) Dressing rooms or dressing areas shall be designated if EMPLOYEES routinely change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be provided for the orderly storage of EMPLOYEES' clothing and other possessions.

Service Sinks

6-306.10 Availability.

A service sink or curbed cleaning facility shall be provided as specified under ¶ 5-203.13(A).

6-4	LOCATION AND PLACEMENT
	<i>Subparts</i>
	6-401 Handwashing Sinks
	6-402 Toilet Rooms
	6-403 Employee Accommodations
	6-404 Distressed Merchandise
	6-405 Refuse, Recyclables, and Returnables

Handwashing Sinks

6-401.10 Conveniently Located.

HANDWASHING SINKS shall be conveniently located as specified under § 5-204.11.

Toilet Rooms

6-402.11 Convenience and Accessibility.

Toilet rooms shall be conveniently located and accessible to EMPLOYEES during all hours of operation.

Employee Accommodations

6-403.11 Designated Areas.

(A) Areas designated for EMPLOYEES to eat, drink, and use tobacco shall be located so that FOOD, EQUIPMENT, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination.

(B) Lockers or other suitable facilities shall be located in a designated room or area where contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES can not occur.

Distressed Merchandise

6-404.11 Segregation and Location.

Products that are held by the PERMIT HOLDER for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.^{Pf}

Refuse, Recyclables, and Returnables

6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.

Units, receptacles, and areas designated for storage of REFUSE and recyclable and returnable containers shall be located as specified under § 5-501.19.

6-5	MAINTENANCE AND OPERATION
	Subpart
	6-501 Premises, Structures, Attachments, and Fixtures - Methods

Premises, Structures, Attachments, and Fixtures - Methods

6-501.11 Repairing.

PHYSICAL FACILITIES shall be maintained in good repair.

6-501.12 Cleaning, Frequency and Restrictions.

(A) PHYSICAL FACILITIES shall be cleaned as often as necessary to keep them clean.

(B) *Except for cleaning that is necessary due to a spill or other accident*, cleaning shall be done during periods when the least amount of FOOD is exposed such as after closing.

6-501.13 Cleaning Floors, Dustless Methods.

(A) Except as specified in ¶ (B) of this section, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.

(B) *Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:*

(1) *Without the use of dust-arresting compounds; and*

(2) *In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.*

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

(A) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(B) If vented to the outside, ventilation systems may not create a public health HAZARD or nuisance or unlawful discharge.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.

FOOD preparation sinks, HANDWASHING SINKS, and WAREWASHING EQUIPMENT may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.^{Pf}

6-501.16 Drying Mops.

After use, mops shall be placed in a position that allows them to air-dry without soiling walls, EQUIPMENT, or supplies.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Except as specified in ¶ 6-501.13(B), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

6-501.18 Cleaning of Plumbing Fixtures.

PLUMBING FIXTURES such as HANDWASHING SINKS, toilets, and urinals shall be cleaned as often as necessary to keep them clean.

6-501.19 Closing Toilet Room Doors.

Except during cleaning and maintenance operations, toilet room doors as specified under § 6-202.14 shall be kept closed.

6-501.110 Using Dressing Rooms and Lockers.

(A) Dressing rooms shall be used by EMPLOYEES if the EMPLOYEES regularly change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be used for the orderly storage of EMPLOYEE clothing and other possessions.

6-501.111 Controlling Pests.

The PREMISES shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to eliminate their presence on the PREMISES by:

(A) Routinely inspecting incoming shipments of FOOD and supplies;

(B) Routinely inspecting the PREMISES for evidence of pests;

(C) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under §§ 7-202.12, 7-206.12, and 7-206.13;^{Pf} and

(D) Eliminating harborage conditions.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the PREMISES at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

6-501.113 Storing Maintenance Tools.

Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

(A) Stored so they do not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES; and

(B) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The PREMISES shall be free of:

(A) Items that are unnecessary to the operation or maintenance of the establishment such as EQUIPMENT that is nonfunctional or no longer used; and

(B) Litter.

6-501.115 Prohibiting Animals.

(A) Except as specified in ¶¶ (B) and (C) of this section, live animals may not be allowed on the PREMISES of a FOOD ESTABLISHMENT.^{Pf}

(B) Live animals may be allowed in the following situations if the contamination of FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES can not result:

(1) Edible FISH or decorative FISH in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

(2) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

(3) In areas that are not used for FOOD preparation and that are usually open for customers, such as dining and sales areas, SERVICE ANIMALS that are controlled by the disabled EMPLOYEE or PERSON, if a health or safety HAZARD will not result from the presence or activities of the SERVICE ANIMAL;

(4) Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

(a) Effective partitioning and self-closing doors separate the common dining areas from FOOD storage or FOOD preparation areas,

(b) Condiments, EQUIPMENT, and UTENSILS are stored in enclosed cabinets or removed from the common dining areas when pets are present, and

(c) Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and

(5) In areas that are not used for FOOD preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals.

(C) Live or dead FISH bait may be stored if contamination of FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES can not result.

Chapter

7

Poisonous or Toxic Materials

Parts

- 7-1 LABELING AND IDENTIFICATION
- 7-2 OPERATIONAL SUPPLIES AND APPLICATIONS
- 7-3 STOCK AND RETAIL SALE

7-1 LABELING AND IDENTIFICATION

Subparts

- 7-101 Original Containers
- 7-102 Working Containers

Original Containers

7-101.11 Identifying Information, Prominence.

Containers of POISONOUS OR TOXIC MATERIALS and PERSONAL CARE ITEMS shall bear a legible manufacturer's label. ^{Pf}

Working Containers

7-102.11 Common Name.

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners and SANITIZERS taken from bulk supplies shall be clearly and individually identified with the common name of the material. ^{Pf}

7-2 OPERATIONAL SUPPLIES AND APPLICATIONS

Subparts

7-201	Storage
7-202	Presence and Use
7-203	Container Prohibitions
7-204	Chemicals
7-205	Lubricants
7-206	Pesticides
7-207	Medicines
7-208	First Aid Supplies
7-209	Other Personal Care Items

Storage

7-201.11 Separation.

POISONOUS OR TOXIC MATERIALS shall be stored so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning;^P and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. *This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.*^P

Presence and Use

7-202.11 Restriction.

(A) Only those POISONOUS OR TOXIC MATERIALS that are required for the operation and maintenance of a FOOD ESTABLISHMENT, such as for the cleaning and SANITIZING of EQUIPMENT and UTENSILS and the control of insects and rodents, shall be allowed in a FOOD ESTABLISHMENT.^{Pf}

(B) *Paragraph (A) of this section does not apply to PACKAGED POISONOUS OR TOXIC MATERIALS that are for retail sale.*

7-202.12 Conditions of Use.

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

- (1) LAW and this Code,
- (2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT,^P
- (3) The conditions of certification, if certification is required, for use of the pest control materials,^P and
- (4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

- (1) A HAZARD to EMPLOYEES or other PERSONS is not constituted,^P and
- (2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and for a RESTRICTED USE PESTICIDE, this is achieved by:^P
 - (a) Removing the items,^P
 - (b) Covering the items with impermeable covers,^P or
 - (c) Taking other appropriate preventive actions,^P and
 - (d) Cleaning and SANITIZING EQUIPMENT and UTENSILS after the application.^P

(C) A RESTRICTED USE PESTICIDE shall be applied only by an applicator certified as defined in 7 USC 136 Definitions, (e) Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act, or a PERSON under the direct supervision of a certified applicator.^{Pf}

Container Prohibitions

7-203.11 Poisonous or Toxic Material Containers.

A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense FOOD.^P

Chemicals

7-204.11 Sanitizers, Criteria.

Chemical SANITIZERS, including chemical sanitizing solutions generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall:

- (A) Meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)^P, or
- (B) Meet the requirements as specified in 40 CFR 180.2020 Pesticide Chemicals Not Requiring a Tolerance or Exemption from Tolerance-Non-food determinations.^P

7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.

(A) Chemicals, including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall:

- (1) Be an approved food additive listed for this intended use in 21 CFR 173,^P or
- (2) Be generally recognized as safe (GRAS) for this intended use,^P or
- (3) Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification),^P and
- (4) Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices.^P

(B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a FOOD ESTABLISHMENT shall meet the requirements specified in 21 CFR 173.368 Ozone.^P

7-204.13 Boiler Water Additives, Criteria.

Chemicals used as boiler water ADDITIVES shall meet the requirements specified in 21 CFR 173.310 Boiler water additives.^P

7-204.14 Drying Agents, Criteria.

Drying agents used in conjunction with SANITIZATION shall:

(A) Contain only components that are listed as one of the following:

- (1) Generally recognized as safe for use in FOOD as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe,^P
- (2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,^P
- (3) Generally recognized as safe for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to FOOD as described in 21 CFR 170.30 Eligibility for classification as generally recognized as safe (GRAS),^P
- (4) Subject of an effective Food Contact Notification as described in the Federal Food Drug and Cosmetic Act (FFDCA) Section 409(h),^P
- (5) APPROVED for use as a drying agent under a prior sanction as described in the Federal Food Drug and Cosmetic Act (FFDCA) § 201(s)(4);^P
- (6) Specifically regulated as an indirect FOOD ADDITIVE for use as a drying agent as specified in 21 CFR Parts 174-178,^P or
- (7) APPROVED for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact

articles;^P and

(B) When SANITIZATION is with chemicals, the approval required under Subparagraph (A)(5) or (A)(7) of this section or the regulation as an indirect FOOD ADDITIVE required under Subparagraph (A)(6) of this section, shall be specifically for use with chemical SANITIZING solutions.^P

Lubricants

7-205.11 Incidental Food Contact, Criteria.

Lubricants shall meet the requirements specified in 21 CFR 178.3570 Lubricants with incidental food contact, if they are used on FOOD-CONTACT SURFACES, on bearings and gears located on or within FOOD-CONTACT SURFACES, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.^P

Pesticides

7-206.11 Restricted Use Pesticides, Criteria.

RESTRICTED USE PESTICIDES specified under ¶ 7-202.12(C) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.^P

7-206.12 Rodent Bait Stations.

Rodent bait shall be contained in a covered, tamper-resistant bait station.^P

7-206.13 Tracking Powders, Pest Control and Monitoring.

(A) Except as specified in ¶ (B) of this section, a tracking powder pesticide may not be used in a FOOD ESTABLISHMENT.^P

(B) If used, a nontoxic tracking powder such as talcum or flour may not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

Medicines

7-207.11 Restriction and Storage.

(A) *Except for medicines that are stored or displayed for retail*

sale, only those medicines that are necessary for the health of EMPLOYEES shall be allowed in a FOOD ESTABLISHMENT.^{Pf}

(B) Medicines that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be labeled as specified under § 7-101.11 and located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.^P

7-207.12 Refrigerated Medicines, Storage.

Medicines belonging to EMPLOYEES or to children in a day care center that require refrigeration and are stored in a FOOD refrigerator shall be:

(A) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines;^P and

(B) Located so they are inaccessible to children.^P

First Aid Supplies

7-208.11 Storage.

First aid supplies that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be:

(A) Labeled as specified under § 7-101.11;^{Pf} and

(B) Stored in a kit or a container that is located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, and LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.^P

Other Personal Care Items

7-209.11 Storage.

Except as specified under §§ 7-207.12 and 7-208.11, EMPLOYEES shall store their PERSONAL CARE ITEMS in facilities as specified under ¶ 6-305.11(B).

7-3 STOCK AND RETAIL SALE

Subpart

7-301 Storage and Display

Storage and Display

7-301.11 Separation.

POISONOUS or TOXIC MATERIALS shall be stored and displayed for retail sale so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS or TOXIC MATERIALS by spacing or partitioning;^P and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE OR SINGLE-USE ARTICLES.^P

Chapter

8

Compliance and Enforcement

Parts

- 8-1 CODE APPLICABILITY
- 8-2 PLAN SUBMISSION AND APPROVAL
- 8-3 PERMIT TO OPERATE
- 8-4 INSPECTION AND CORRECTION OF VIOLATIONS
- 8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

8-1 CODE APPLICABILITY

Subparts

- 8-101 Use for Intended Purpose
- 8-102 Additional Requirements
- 8-103 Variances

Use for Intended Purpose

8-101.10 Public Health Protection.

(A) The REGULATORY AUTHORITY shall apply this Code to promote its underlying purpose, as specified in § 1-102.10, of safeguarding public health and ensuring that FOOD is safe, UNADULTERATED, and honestly presented when offered to the CONSUMER.

(B) In enforcing the provisions of this Code, the REGULATORY AUTHORITY shall assess existing facilities or EQUIPMENT that were in use before the effective date of this Code based on the following considerations:

- (1) Whether the facilities or EQUIPMENT are in good repair and capable of being maintained in a sanitary condition;

(2) Whether FOOD-CONTACT SURFACES comply with Subpart 4-101;

(3) Whether the capacities of cooling, heating, and holding EQUIPMENT are sufficient to comply with § 4-301.11; and

(4) The existence of a documented agreement with the PERMIT HOLDER that the facilities or EQUIPMENT will be replaced as specified under ¶ 8-304.11(G).

Additional Requirements

8-102.10 Preventing Health Hazards, Provision for Conditions Not Addressed.

(A) If necessary to protect against public health HAZARDS or nuisances, the REGULATORY AUTHORITY may impose specific requirements in addition to the requirements contained in this Code that are authorized by LAW.

(B) The REGULATORY AUTHORITY shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the PERMIT applicant or PERMIT HOLDER and a copy shall be maintained in the REGULATORY AUTHORITY'S file for the FOOD ESTABLISHMENT.

Variances

8-103.10 Modifications and Waivers.

The REGULATORY AUTHORITY may grant a VARIANCE by modifying or waiving the requirements of this Code if in the opinion of the REGULATORY AUTHORITY a health HAZARD or nuisance will not result from the VARIANCE. If a VARIANCE is granted, the REGULATORY AUTHORITY shall retain the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

8-103.11 Documentation of Proposed Variance and Justification.

Before a VARIANCE from a requirement of this Code is APPROVED, the information that shall be provided by the PERSON requesting the VARIANCE and retained in the REGULATORY AUTHORITY'S file on the FOOD ESTABLISHMENT includes:

(A) A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;^{Pf}

(B) An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal;^{Pf} and

(C) A HACCP PLAN if required as specified under ¶ 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the VARIANCE requested.^{Pf}

8-103.12 Conformance with Approved Procedures.

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANS and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver;^P and

(B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring the CRITICAL CONTROL POINTS,^{Pf}

(2) Monitoring of the CRITICAL CONTROL POINTS,^{Pf}

(3) Verification of the effectiveness of the operation or process,^{Pf} and

(4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT.^{Pf}

8-2 PLAN SUBMISSION AND APPROVAL

Subparts

8-201	Facility and Operating Plans
8-202	Confidentiality
8-203	Construction Inspection and Approval

Facility and Operating Plans

8-201.11 When Plans Are Required.

A PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY properly prepared plans and specifications for review and approval before:

- (A) The construction of a FOOD ESTABLISHMENT;^{Pf}
- (B) The conversion of an existing structure for use as a FOOD ESTABLISHMENT;^{Pf} or
- (C) The remodeling of a FOOD ESTABLISHMENT or a change of type of FOOD ESTABLISHMENT or FOOD operation as specified under ¶ 8-302.14(C) if the REGULATORY AUTHORITY determines that plans and specifications are necessary to ensure compliance with this Code.^{Pf}

8-201.12 Contents of the Plans and Specifications.

The plans and specifications for a FOOD ESTABLISHMENT, including a FOOD ESTABLISHMENT specified under § 8-201.13, shall include, as required by the REGULATORY AUTHORITY based on the type of operation, type of FOOD preparation, and FOODS prepared, the following information to demonstrate conformance with Code provisions:

- (A) Intended menu;
- (B) Anticipated volume of FOOD to be stored, prepared, and sold or served;
- (C) Proposed layout, mechanical schematics, construction materials, and finish schedules;

(D) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;

(E) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed; and

(F) Other information that may be required by the REGULATORY AUTHORITY for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT.

8-201.13 When a HACCP Plan is Required.

(A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:

(1) Submission of a HACCP PLAN is required according to LAW;

(2) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(4), § 3-502.11, or ¶ 4-204.110(B);

(3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.

(B) Before engaging in REDUCED OXYGEN PACKAGING without a VARIANCE as specified under § 3-502.12, a PERMIT applicant or PERMIT HOLDER shall submit a properly prepared HACCP PLAN to the REGULATORY AUTHORITY.

8-201.14 Contents of a HACCP Plan.

For a FOOD ESTABLISHMENT that is required under § 8-201.13 to have a HACCP PLAN, the plan and specifications shall indicate:

(A) A categorization of the types of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are specified in the menu such as soups and sauces, salads, and bulk, solid FOODS such as MEAT roasts, or of other FOODS that are specified by the REGULATORY AUTHORITY;^{Pf}

(B) A flow diagram by specific FOOD or category type identifying CRITICAL CONTROL POINTS and providing information on the following:

(1) Ingredients, materials, and EQUIPMENT used in the preparation of that FOOD,^{Pf} and

(2) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved;^{Pf}

(C) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern;^{Pf}

(D) A statement of standard operating procedures for the plan under consideration including clearly identifying:

(1) Each CRITICAL CONTROL POINT,^{Pf}

(2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,^{Pf}

(3) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the FOOD EMPLOYEE designated by the PERSON IN CHARGE,^{Pf}

(4) The method and frequency for the PERSON IN CHARGE to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS,^{Pf}

(5) Action to be taken by the PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met,^{Pf} and

(6) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed;^{Pf} and

(E) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal.^{Pf}

Confidentiality

8-202.10 Trade Secrets.

The REGULATORY AUTHORITY shall treat as confidential in accordance with LAW, information that meets the criteria specified in LAW for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under §§ 8-201.12 and 8-201.14.

Construction Inspection and Approval

8-203.10 Preoperational Inspections.

The REGULATORY AUTHORITY shall conduct one or more preoperational inspections to verify that the FOOD ESTABLISHMENT is constructed and equipped in accordance with the APPROVED plans and APPROVED modifications of those plans, has established standard operating procedures as specified under ¶ 8-201.12(E), and is in compliance with LAW and this Code.

8-3	PERMIT TO OPERATE
	<i>Subparts</i>
	8-301 Requirement
	8-302 Application Procedure
	8-303 Issuance
	8-304 Conditions of Retention

Requirement

8-301.11 Prerequisite for Operation.

A PERSON may not operate a FOOD ESTABLISHMENT without a valid PERMIT to operate issued by the REGULATORY AUTHORITY.^{Pf}

***Application
Procedure***

**8-302.11 Submission 30 Calendar Days Before
Proposed Opening.**

An applicant shall submit an application for a PERMIT at least 30 calendar days before the date planned for opening a FOOD ESTABLISHMENT or the expiration date of the current PERMIT for an existing facility.

8-302.12 Form of Submission.

A PERSON desiring to operate a FOOD ESTABLISHMENT shall submit to the REGULATORY AUTHORITY a written application for a PERMIT on a form provided by the REGULATORY AUTHORITY.

**8-302.13 Qualifications and Responsibilities of
Applicants.**

To qualify for a PERMIT, an applicant shall:

- (A) Be an owner of the FOOD ESTABLISHMENT or an officer of the legal ownership;
- (B) Comply with the requirements of this Code;
- (C) As specified under § 8-402.11, agree to allow access to the FOOD ESTABLISHMENT and to provide required information; and
- (D) Pay the applicable PERMIT fees at the time the application is submitted.

8-302.14 Contents of the Application.

The application shall include:

- (A) The name, birth date, mailing address, telephone number, and signature of the PERSON applying for the PERMIT and the name, mailing address, and location of the FOOD ESTABLISHMENT;
- (B) Information specifying whether the FOOD ESTABLISHMENT is owned by an association, corporation, individual, partnership, or other legal entity;

(C) A statement specifying whether the FOOD ESTABLISHMENT:

(1) Is mobile or stationary and temporary or permanent, and

(2) Is an operation that includes one or more of the following:

(a) Prepares, offers for sale, or serves TIME/TEMPERATURE CONTROL FOR SAFETY FOOD:

(i) Only to order upon a CONSUMER'S request,

(ii) In advance in quantities based on projected CONSUMER demand and discards FOOD that is not sold or served at an APPROVED frequency, or

(iii) Using time as the public health control as specified under § 3-501.19,

(b) Prepares TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in advance using a FOOD preparation method that involves two or more steps which may include combining TIME/TEMPERATURE CONTROL FOR SAFETY FOOD ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,

(c) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for delivery to and consumption at a location off the PREMISES of the FOOD ESTABLISHMENT where it is prepared,

(d) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for service to a HIGHLY SUSCEPTIBLE POPULATION,

(e) Prepares only FOOD that is not TIME/TEMPERATURE CONTROL OF SAFETY FOOD, or

(f) Does not prepare, but offers for sale only prePACKAGED FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;

(D) The name, title, address, and telephone number of the PERSON directly responsible for the FOOD ESTABLISHMENT;

(E) The name, title, address, and telephone number of the PERSON who functions as the immediate supervisor of the PERSON specified under ¶ (D) of this section such as the zone, district, or regional supervisor;

(F) The names, titles, and addresses of:

(1) The PERSONS comprising the legal ownership as specified under ¶ (B) of this section including the owners and officers, and

(2) The local resident agent if one is required based on the type of legal ownership;

(G) A statement signed by the applicant that:

(1) Attests to the accuracy of the information provided in the application, and

(2) Affirms that the applicant will:

(a) Comply with this Code, and

(b) Allow the REGULATORY AUTHORITY access to the establishment as specified under § 8-402.11 and to the records specified under §§ 3-203.12 and 5-205.13 and Subparagraph 8-201.14(D)(6); and

(H) Other information required by the REGULATORY AUTHORITY.

Issuance

8-303.10 New, Converted, or Remodeled Establishments.

For FOOD ESTABLISHMENTS that are required to submit plans as specified under § 8-201.11 the REGULATORY AUTHORITY shall issue a PERMIT to the applicant after:

(A) A properly completed application is submitted;

(B) The required fee is submitted;

(C) The required plans, specifications, and information are reviewed and APPROVED; and

(D) A preoperational inspection as specified in § 8-203.10 shows that the establishment is built or remodeled in accordance with the APPROVED plans and specifications and that the establishment is in compliance with this Code.

8-303.20 Existing Establishments, Permit Renewal, and Change of Ownership.

The REGULATORY AUTHORITY may renew a PERMIT for an existing FOOD ESTABLISHMENT or may issue a PERMIT to a new owner of an existing FOOD ESTABLISHMENT after a properly completed application is submitted, reviewed, and APPROVED, the fees are paid, and an inspection shows that the establishment is in compliance with this Code.

8-303.30 Denial of Application for Permit, Notice.

If an application for a PERMIT to operate is denied, the REGULATORY AUTHORITY shall provide the applicant with a notice that includes:

- (A) The specific reasons and Code citations for the PERMIT denial;
- (B) The actions, if any, that the applicant must take to qualify for a PERMIT; and
- (C) Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in LAW.

Conditions of Retention

8-304.10 Responsibilities of the Regulatory Authority.

(A) At the time a PERMIT is first issued, the REGULATORY AUTHORITY shall provide to the PERMIT HOLDER a copy of this Code so that the PERMIT HOLDER is notified of the compliance requirements and the conditions of retention, as specified under § 8-304.11, that are applicable to the PERMIT.

(B) Failure to provide the information specified in ¶ (A) of this section does not prevent the REGULATORY AUTHORITY from taking authorized action or seeking remedies if the PERMIT HOLDER fails to comply with this Code or an order, warning, or directive of the REGULATORY AUTHORITY.

8-304.11 Responsibilities of the Permit Holder.

Upon acceptance of the PERMIT issued by the REGULATORY AUTHORITY, the PERMIT HOLDER in order to retain the PERMIT shall:

(A) Post the PERMIT in a location in the FOOD ESTABLISHMENT that is conspicuous to CONSUMERS;

(B) Comply with the provisions of this Code including the conditions of a granted VARIANCE as specified under § 8-103.12, and APPROVED plans as specified under § 8-201.12;

(C) If a FOOD ESTABLISHMENT is required under § 8-201.13 to operate under a HACCP PLAN, comply with the plan as specified under § 8-103.12;

(D) Immediately contact the REGULATORY AUTHORITY to report an illness of a FOOD EMPLOYEE OR CONDITIONAL EMPLOYEE as specified under ¶ 2-201.11(B);

(E) Immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist as specified under § 8-404.11;

(F) Allow representatives of the REGULATORY AUTHORITY access to the FOOD ESTABLISHMENT as specified under § 8-402.11;

(G) Replace existing facilities and EQUIPMENT specified in § 8-101.10 with facilities and EQUIPMENT that comply with this Code if:

(1) The REGULATORY AUTHORITY directs the replacement because the facilities and EQUIPMENT constitute a public health HAZARD or nuisance or no longer comply with the criteria upon which the facilities and EQUIPMENT were accepted,

(2) The REGULATORY AUTHORITY directs the replacement of the facilities and EQUIPMENT because of a change of ownership, or

(3) The facilities and EQUIPMENT are replaced in the normal course of operation;

(H) Comply with directives of the REGULATORY AUTHORITY including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY in regard to the PERMIT HOLDER'S FOOD ESTABLISHMENT or in response to community emergencies;

(I) Accept notices issued and served by the REGULATORY AUTHORITY according to LAW; and

(J) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in LAW for failure to comply with this Code or a directive of the REGULATORY AUTHORITY, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

(K) Notify customers that a copy of the most recent establishment inspection report is available upon request by posting a sign or placard in a location in the food establishment that is conspicuous to customers or by another method acceptable to the REGULATORY AUTHORITY.

8-304.20 Permits Not Transferable.

A PERMIT may not be transferred from one PERSON to another PERSON, from one FOOD ESTABLISHMENT to another, or from one type of operation to another if the FOOD operation changes from the type of operation specified in the application as specified under ¶ 8-302.14(C) and the change in operation is not APPROVED.

8-4**INSPECTION AND CORRECTION OF VIOLATIONS***Subparts*

8-401	Frequency
8-402	Competency and Access
8-403	Report of Findings
8-404	Imminent Health Hazard
8-405	Violation of Priority Item or Priority Foundation Item
8-406	Core Item Violation

*Frequency***8-401.10** **Establishing Inspection Interval.**

(A) Except as specified in ¶¶ (B) and (C) of this section, the REGULATORY AUTHORITY shall inspect a FOOD ESTABLISHMENT at least once every 6 months.

(B) *The REGULATORY AUTHORITY may increase the interval between inspections beyond 6 months if:*

(1) *The FOOD ESTABLISHMENT is fully operating under an APPROVED and validated HACCP PLAN as specified under § 8-201.14 and ¶¶ 8-103.12(A) and (B);*

(2) *The FOOD ESTABLISHMENT is assigned a less frequent inspection frequency based on a written RISK-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every 6 months the establishment is contacted by telephone or other means by the REGULATORY AUTHORITY to ensure that the establishment manager and the nature of FOOD operation are not changed; or*

(3) *The establishment's operation involves only coffee service and other UNPACKAGED or prePACKAGED FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD such as carbonated BEVERAGES and snack FOOD such as chips, nuts, popcorn, and pretzels.*

(C) The REGULATORY AUTHORITY shall periodically inspect throughout its PERMIT period a TEMPORARY FOOD ESTABLISHMENT that prepares, sells, or serves UNPACKAGED TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and that:

(1) Has improvised rather than permanent facilities or EQUIPMENT for accomplishing functions such as handwashing, FOOD preparation and protection, FOOD temperature control, WAREWASHING, providing DRINKING WATER, waste retention and disposal, and insect and rodent control; or

(2) Has inexperienced FOOD EMPLOYEES.

8-401.20 Performance- and Risk-Based.

Within the parameters specified in § 8-401.10, the REGULATORY AUTHORITY shall prioritize, and conduct more frequent inspections based upon its assessment of a FOOD ESTABLISHMENT'S history of compliance with this Code and the establishment's potential as a vector of foodborne illness by evaluating:

(A) Past performance, for nonconformance with Code or HACCP PLAN requirements that are PRIORITY ITEMS or PRIORITY FOUNDATION ITEMS;

(B) Past performance, for numerous or repeat violations of Code or HACCP PLAN requirements that are CORE ITEMS;

(C) Past performance, for complaints investigated and found to be valid;

(D) The HAZARDS associated with the particular FOODS that are prepared, stored, or served;

(E) The type of operation including the methods and extent of FOOD storage, preparation, and service;

(F) The number of people served; and

(G) Whether the population served is a HIGHLY SUSCEPTIBLE POPULATION.

Competency

8-402.10 Competency of Inspectors.

An authorized representative of the REGULATORY AUTHORITY who inspects a FOOD ESTABLISHMENT or conducts plan review for compliance with this Code shall have the knowledge, skills, and ability to adequately perform the required duties.

Access

8-402.11 Allowed at Reasonable Times after Due Notice.

After the REGULATORY AUTHORITY presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the PERSON IN CHARGE shall allow the REGULATORY AUTHORITY to determine if the FOOD ESTABLISHMENT is in compliance with this Code by allowing access to the establishment, allowing inspection, and providing information and records specified in this Code and to which the REGULATORY AUTHORITY is entitled according to LAW, during the FOOD ESTABLISHMENT'S hours of operation and other reasonable times.

8-402.20 Refusal, Notification of Right to Access, and Final Request for Access.

If a PERSON denies access to the REGULATORY AUTHORITY, the REGULATORY AUTHORITY shall:

(A) Inform the PERSON that:

(1) The PERMIT HOLDER is required to allow access to the REGULATORY AUTHORITY as specified under § 8-402.11 of this Code,

(2) Access is a condition of the acceptance and retention of a FOOD ESTABLISHMENT PERMIT to operate as specified under ¶ 8-304.11(F), and

(3) If access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to LAW; and

(B) Make a final request for access.

8-402.30 Refusal, Reporting.

If after the REGULATORY AUTHORITY presents credentials and provides notice as specified under § 8-402.11, explains the authority upon which access is requested, and makes a final request for access as specified in § 8-402.20, the PERSON IN CHARGE continues to REFUSE access, the REGULATORY AUTHORITY shall provide details of the denial of access on an inspection report form.

8-402.40 Inspection Order to Gain Access.

If denied access to a FOOD ESTABLISHMENT for an authorized purpose and after complying with § 8-402.20, the REGULATORY AUTHORITY may issue, or apply for the issuance of, an inspection order to gain access as provided in LAW.

Report of Findings

8-403.10 Documenting Information and Observations.

The REGULATORY AUTHORITY shall document on an inspection report form:

(A) Administrative information about the FOOD ESTABLISHMENT'S legal identity, street and mailing addresses, type of establishment and operation as specified under ¶ 8-302.14(C), inspection date, and other information such as type of water supply and SEWAGE disposal, status of the PERMIT, and personnel certificates that may be required; and

(B) Specific factual observations of violative conditions or other deviations from this Code that require correction by the PERMIT HOLDER including:

(1) Failure of the PERSON IN CHARGE to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Code as specified under § 2-102.11,

(2) Failure of FOOD EMPLOYEES, CONDITIONAL EMPLOYEES, and the PERSON IN CHARGE to report a disease or medical condition as specified under ¶¶ 2-201.11(B) and (D),

(3) Nonconformance with PRIORITY ITEMS OR PRIORITY FOUNDATION ITEMS of this Code,

(4) Failure of the appropriate FOOD EMPLOYEES to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the REGULATORY AUTHORITY as specified under § 8-103.12,

(5) Failure of the PERSON IN CHARGE to provide records required by the REGULATORY AUTHORITY for determining conformance with a HACCP PLAN as specified under Subparagraph 8-201.14(D)(6), and

(6) Nonconformance with CRITICAL LIMITS of a HACCP PLAN.

8-403.20 Specifying Time Frame for Corrections.

The REGULATORY AUTHORITY shall specify on the inspection report form the time frame for correction of the violations as specified under §§ 8-404.11, 8-405.11, and 8-406.11.

8-403.30 Issuing Report and Obtaining Acknowledgment of Receipt.

At the conclusion of the inspection and according to LAW, the REGULATORY AUTHORITY shall provide a copy of the completed inspection report and the notice to correct violations to the PERMIT HOLDER or to the PERSON IN CHARGE, and request a signed acknowledgment of receipt.

8-403.40 Refusal to Sign Acknowledgment.

The REGULATORY AUTHORITY shall:

(A) Inform a PERSON who declines to sign an acknowledgment of receipt of inspectional findings as specified in § 8-403.30 that:

(1) An acknowledgment of receipt is not an agreement with findings,

(2) Refusal to sign an acknowledgment of receipt will not affect the PERMIT HOLDER'S obligation to correct the violations noted in the inspection report within the time frames specified, and

(3) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the REGULATORY AUTHORITY'S historical record for the FOOD ESTABLISHMENT; and

(B) Make a final request that the PERSON IN CHARGE sign an acknowledgment receipt of inspectional findings.

8-403.50 Public Information.

Except as specified in § 8-202.10, the REGULATORY AUTHORITY shall treat the inspection report as a public document and shall make it available for disclosure to a PERSON who requests it as provided in LAW.

Imminent Health Hazard

8-404.11 Ceasing Operations and Reporting.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, SEWAGE backup, misuse of POISONOUS OR TOXIC MATERIALS, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.^P

(B) *A PERMIT HOLDER need not discontinue operations in an area of an establishment that is unaffected by the IMMINENT HEALTH HAZARD.*

8-404.12 Resumption of Operations.

If operations are discontinued as specified under § 8-404.11 or otherwise according to LAW, the PERMIT HOLDER shall obtain approval from the REGULATORY AUTHORITY before resuming operations.

**Violation of
Priority Item or
Priority
Foundation Item**

8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall at the time of inspection correct a violation of a PRIORITY ITEM or PRIORITY FOUNDATION ITEM of this Code and implement corrective actions for a HACCP PLAN provision that is not in compliance with its CRITICAL LIMIT.^{Pf}

(B) Considering the nature of the potential HAZARD involved and the complexity of the corrective action needed, the REGULATORY AUTHORITY may agree to or specify a longer time frame, not to exceed:

(1) 72 hours after the inspection, for the PERMIT HOLDER to correct violations of a PRIORITY ITEM; or

(2) 10 calendar days after the inspection, for the PERMIT HOLDER to correct violations of a PRIORITY FOUNDATION ITEM or HACCP PLAN deviations.

8-405.20 Verification and Documentation of Correction.

(A) After observing at the time of inspection a correction of a violation of a PRIORITY ITEM or PRIORITY FOUNDATION ITEM or a HACCP PLAN deviation, the REGULATORY AUTHORITY shall enter the violation and information about the corrective action on the inspection report.

(B) As specified under ¶ 8-405.11(B), after receiving notification that the PERMIT HOLDER has corrected a violation of a PRIORITY ITEM OR PRIORITY FOUNDATION ITEM or HACCP PLAN deviation, or at the end of the specified period of time, the REGULATORY AUTHORITY shall verify correction of the violation, document the information on an inspection report, and enter the report in the REGULATORY AUTHORITY'S records.

**Core Item
Violation**

8-406.11 Time Frame for Correction.

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall correct CORE ITEMS by a date and time agreed to or specified by the REGULATORY AUTHORITY but no later than 90 calendar days after the inspection.

(B) *The REGULATORY AUTHORITY may approve a compliance schedule that extends beyond the time limits specified under ¶ (A) of this section if a written schedule of compliance is submitted by the PERMIT HOLDER and no health HAZARD exists or will result from allowing an extended schedule for compliance.*

8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

Subpart

8-501

Investigation and Control

Investigation and Control

8-501.10

Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis.

The REGULATORY AUTHORITY shall act when it has reasonable cause to believe that a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through FOOD; may be a carrier of infectious agents that cause a disease that is transmissible through FOOD; or is affected with a boil, an infected wound, or acute respiratory infection, by:

(A) Securing a confidential medical history of the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE suspected of transmitting disease or making other investigations as deemed appropriate; and

(B) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected FOOD EMPLOYEE or CONDITIONAL EMPLOYEE.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

Based on the findings of an investigation related to a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE who is suspected of being infected or diseased, the REGULATORY AUTHORITY may issue an order to the suspected FOOD EMPLOYEE, CONDITIONAL EMPLOYEE or PERMIT HOLDER instituting one or more of the following control measures:

(A) RESTRICTING the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE;

(B) EXCLUDING the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE; or

(C) Closing the FOOD ESTABLISHMENT by summarily suspending a PERMIT to operate in accordance with LAW.

8-501.30 Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order.

Based on the findings of the investigation as specified in § 8-501.10 and to control disease transmission, the REGULATORY AUTHORITY may issue an order of RESTRICTION or EXCLUSION to a suspected FOOD EMPLOYEE or the PERMIT HOLDER without prior warning, notice of a hearing, or a hearing if the order:

(A) States the reasons for the RESTRICTION or EXCLUSION that is ordered;

(B) States the evidence that the FOOD EMPLOYEE or PERMIT HOLDER shall provide in order to demonstrate that the reasons for the RESTRICTION or EXCLUSION are eliminated;

(C) States that the suspected FOOD EMPLOYEE or the PERMIT HOLDER may request an appeal hearing by submitting a timely request as provided in LAW; and

(D) Provides the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-501.40 Removal of Exclusions and Restrictions.

The REGULATORY AUTHORITY shall release a FOOD EMPLOYEE, OR CONDITIONAL EMPLOYEE from RESTRICTION or EXCLUSION according to LAW and the conditions specified under § 2-201.13.

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Food Code

U.S. Public Health Service



ANNEXES

2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

College Park, MD 20740

1

Compliance and Enforcement

- 1. PURPOSE
- 2. EXPLANATION
- 3. PRINCIPLE
- 4. RECOMMENDATION
- 5. PARTS
 - 8-6 CONSTITUTIONAL PROTECTION
 - 8-7 AUTHORITY
 - 8-8 NOTICES
 - 8-9 REMEDIES

1. PURPOSE

The purpose of this Annex is to set forth provisions, in codified form, that provide a full array of enforcement mechanisms while recognizing the diverse statutes and regulations that currently govern the operations of the thousands of State and local regulatory agencies.

2. EXPLANATION

State or local statutes, regulations, and ordinances vary in their design, specificity, and degree of comprehensiveness in that they may:

- (A) Contain authorities that provide the basis for certain post-inspection compliance strategies but remain silent with respect to other enforcement mechanisms;
- (B) Include specific requirements that are different from those provided in this Annex; and
- (C) Be structured so that provisions such as administrative procedures are embodied in sections of the law that transcend and are separate from those governing food establishments.

Consequently, in this document a deliberate attempt is made to extract those provisions that could conceptually be adopted as an extension of Chapter 8 if they were compatible with existing, governing State and local statutes. The extracted provisions are numbered to sequentially follow Chapter 8 but are placed in this Annex so that regulatory agencies can revise them to be consistent with their statutes and their needs as discussed in the Recommendation, below.

It is anticipated that adoption of this Code will be facilitated by the fact that:

(A) The compliance provisions of Chapter 8 that should be an integral part of State or local food regulations are part of the text of the Code; and

(B) The administrative and judicial enforcement provisions that are critical to the framework of a food regulatory program, but that may be repetitive or discrepant when compared to State or local statutes, are separated in this Annex.

3. PRINCIPLE

Although the situations necessitating escalated enforcement actions comprise a small percentage of those encountered by the regulator, a full spectrum of enforcement tools must be available where immediate hazards exist, or where compliance is not obtained voluntarily. Thus, a jurisdiction must have in place both the necessary statutory framework that includes a broad-based, well-defined enforcement component and regulations that specify the requirements within those legal authorities. It is imperative that there be clearly stated and legally sound rules that include the criteria for compliance and enforcement, the responsibilities of all parties, sanctions for noncompliance, and due process guarantees.

4. RECOMMENDATION

FDA recommends that agencies assess their statutory provisions that pertain to food establishments in light of this Annex and consider proposing changes to their statutes and regulations where they determine that provisions contained within this Annex will strengthen their programs. Such an assessment may involve reviewing problems encountered in attempts to prosecute under existing State or local provisions; considering comments received by the regulatory authority about its enforcement process; consulting with staff and legal counsel to identify gaps or weaknesses in the provisions; comparing provisions with sister agencies for comprehensiveness, equity, and uniformity; and seeking input from outside sources that have experience in taking, or being the subject of, enforcement actions.

Appropriate wording and cross referencing changes to the provisions in this Annex may be necessary, based on whether they are adopted as statutes or regulations. Modifications to the adoption forms (Forms #2-A and #2-B in Annex 7) may also be necessary based on that decision.

Parts

- 8-6 CONSTITUTIONAL PROTECTION**
- 8-7 AUTHORITY**
- 8-8 NOTICES**
- 8-9 REMEDIES**

8-6	CONSTITUTIONAL PROTECTION
	<i>Subparts</i>
	8-601 Procedural Safeguards
	8-602 Judicial Review

Procedural Safeguards

8-601.10 Preservation of Rights.

The REGULATORY AUTHORITY shall justly apply the remedies according to LAW and this Code, to preserve the rights to equal protection and due process of a PERSON to whom the remedies are applied.

Judicial Review

8-602.10 Rights of Recipients of Orders or Decisions.

A recipient of a REGULATORY AUTHORITY order or decision may file a petition for judicial review in a court of competent jurisdiction after available administrative appeal remedies are exhausted.

8-7 AUTHORITY

Subpart

8-701 Legal Authority

***Legal Authority* 8-701.10 Adoption of Regulations.**

The REGULATORY AUTHORITY shall have the requisite legal authority from the appropriate statute/ordinance making authority to adopt and enforce regulations to carry out the administrative and judicial enforcement provisions of the Code that are critical to the framework of a Food Establishment regulatory program, to include the requirement for the issuance of a Permit.

8-701.11 Implementation of Regulations.

Appropriate modifications to the adoption forms (Form #2-A (Adoption by Reference short form) and #2-B (Adoption by Section-by-Section Reference)) in Annex 7, where used, shall be made consistent with said legal authority to enact regulations and enforce compliance of the Code, whether they are adopted as statutes or regulations.

8-701.20 Basis for Action.

The REGULATORY AUTHORITY shall clearly state and reference within the Code the legally sound basis for compliance and enforcement action, the responsibilities of the parties, sanctions for noncompliance and due process.

8-8 NOTICES

Subpart

8-801 Service of Notice

Service of Notice 8-801.10 Proper Methods.

(Note: Adoption of this section provides the basis for serving notice of inspectional findings as specified in § 8-403.30 and would be cited there.)

A notice issued in accordance with this Code shall be considered to be properly served if it is served by one of the following methods:

(A) The notice is personally served by the REGULATORY AUTHORITY, a LAW enforcement officer, or a PERSON authorized to serve a civil process to the PERMIT HOLDER, the PERSON IN CHARGE, or PERSON operating a FOOD ESTABLISHMENT without a PERMIT;

(B) The notice is sent by the REGULATORY AUTHORITY to the last known address of the PERMIT HOLDER or the PERSON operating a FOOD ESTABLISHMENT without a PERMIT, by registered or certified mail or by other public means so that a written acknowledgment of receipt may be acquired; or

(C) The notice is provided by the REGULATORY AUTHORITY in accordance with another manner of service authorized in LAW.

8-801.20 Restriction or Exclusion Order, Hold Order or Summary Suspension.

An EMPLOYEE RESTRICTION or EXCLUSION order, an order to hold and not distribute FOOD, such as a hold, detention, embargo, or seizure order which is hereinafter referred to as a hold order, or a summary suspension order shall be:

(A) Served as specified in ¶ 8-801.10(A); or

(B) Clearly posted by the REGULATORY AUTHORITY at a public entrance to the FOOD ESTABLISHMENT and a copy of the notice sent by first class mail to the PERMIT HOLDER or to the owner or custodian of the FOOD, as appropriate.

8-801.30 When Notice is Effective.

Service is effective at the time of the notice's receipt or if service is made as specified in ¶ 8-801.20(B), at the time of the notice's posting.

8-801.40 Proof of Proper Service.

Proof of proper service may be made by affidavit of the PERSON making service or by admission of the receipt signed by the PERMIT HOLDER, the PERSON operating a FOOD ESTABLISHMENT without a PERMIT to operate, or an authorized agent.

8-9 REMEDIES

Subparts

8-901 Criteria for Seeking Remedies

Administrative

- 8-902 Inspection Orders**
- 8-903 Holding, Examination, and Destruction of Food**
- 8-904 Summary Permit Suspension**
- 8-905 Hearings Administration**
- 8-906 Hearing Officer, Purpose, Qualifications, Appointment, and Powers**
- 8-907 Rights of Parties and Evidence**
- 8-908 Settlement**

Judicial

- 8-909 Inspection Orders**
- 8-910 Means of Instituting Judicial Enforcement Proceedings**
- 8-911 Criminal Proceedings**
- 8-912 Injunctive Proceedings**
- 8-913 Civil Proceedings**

Criteria for Seeking Remedies

8-901.10 Conditions Warranting Remedy.

The REGULATORY AUTHORITY may seek an administrative or judicial remedy to achieve compliance with the provisions of this Code if a PERSON operating a FOOD ESTABLISHMENT OR EMPLOYEE:

- (A) Fails to have a valid PERMIT to operate a FOOD ESTABLISHMENT as specified under § 8-301.11;
- (B) Violates any term or condition of a PERMIT as specified under § 8-304.11;
- (C) Allows serious or repeated code violations to remain uncorrected beyond time frames for correction APPROVED, directed, or ordered by the REGULATORY AUTHORITY under ¶¶ 8-405.11(A) and (B), and ¶¶ 8-406.11(A) and (B);

(D) Fails to comply with a REGULATORY AUTHORITY order issued as specified in § 8-501.20 concerning an EMPLOYEE or CONDITIONAL EMPLOYEE suspected of having a disease transmissible through FOOD by infected PERSONS;

(E) Fails to comply with a hold order as specified in § 8-903.10;

(F) Fails to comply with an order issued as a result of a hearing for an administrative remedy as specified in § 8-906.40; or

(G) Fails to comply with a summary suspension order issued by the REGULATORY AUTHORITY as specified in §§ 8-801.20 and 8-904.10.

Administrative

Inspection Orders

8-902.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may order access for one or more of the following purposes, subject to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-902.20 Contents of Inspection Order.

The REGULATORY AUTHORITY'S inspection order shall:

(A) Stipulate that access be allowed on or to the described PREMISES, FOOD, or records under the order's provisions;

(B) Provide a description that specifies the PREMISES, FOOD, or records subject to the order; and

(C) Specify areas to be accessed and activities to be performed.

***Holding,
 Examination,
 and Destruction
 of Food***

8-903.10 Hold Order, Justifying Conditions and Removal of Food.

(Note: Adoption of this section provides the basis for ¶ 3-202.18(B) and would be cited there.)

(A) According to time limits imposed by LAW, the REGULATORY AUTHORITY may place a hold order on a FOOD that:

- (1) Originated from an UNAPPROVED source;
- (2) May be unsafe, ADULTERATED, or not honestly presented;
- (3) Is not labeled according to LAW, or, if raw MOLLUSCAN SHELLFISH, is not tagged or labeled according to LAW; or
- (4) Is otherwise not in compliance with this Code.

(B) If the REGULATORY AUTHORITY has reasonable cause to believe that the hold order will be violated, or finds that the order is violated, the REGULATORY AUTHORITY may remove the FOOD that is subject to the order to a place of safekeeping.

8-903.20 Hold Order, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified in § 8-903.10, without prior warning, notice of a hearing, or a hearing on the hold order.

8-903.30 Hold Order, Contents.

The hold order notice shall:

- (A) State that FOOD subject to the order may not be used, sold, moved from the FOOD ESTABLISHMENT, or destroyed without a written release of the order from the REGULATORY AUTHORITY;

(B) State the specific reasons for placing the FOOD under the hold order with reference to the applicable provisions of this Code and the HAZARD or adverse effect created by the observed condition;

(C) Completely identify the FOOD subject to the hold order by the common name, the label information, a container description, the quantity, REGULATORY AUTHORITY'S tag or identification information, and location;

(D) State that the PERMIT HOLDER has the right to an appeal hearing and may request a hearing by submitting a timely request as specified in §§ 8-905.10 and 8-905.20;

(E) State that the REGULATORY AUTHORITY may order the destruction of the FOOD if a timely request for an appeal hearing is not received; and

(F) Provide the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-903.40 Hold Order, Official Tagging of Food.

(A) The REGULATORY AUTHORITY shall securely place an official tag or label on the FOOD or containers or otherwise conspicuously identify FOOD subject to the hold order.

(B) The tag or other method used to identify a FOOD that is the subject of a hold order shall include a summary of the provisions specified in § 8-903.30 and shall be signed and dated by the REGULATORY AUTHORITY.

8-903.51 Hold Order, Food May Not Be Used or Moved.

(A) Except as specified in ¶ (B) of this section, a FOOD placed under a hold order may not be used, sold, served, or moved from the establishment by any PERSON.

(B) The REGULATORY AUTHORITY may allow the PERMIT HOLDER the opportunity to store the FOOD in an area of the FOOD ESTABLISHMENT if the FOOD is protected from subsequent deterioration and the storage does not restrict operations of the establishment.

8-903.60 Examining, Sampling, and Testing Food.

The REGULATORY AUTHORITY may examine, sample, and test FOOD in order to determine its compliance with this Code.

8-903.70 Hold Order, Removing the Official Tag.

Only the REGULATORY AUTHORITY may remove hold order tags, labels, or other identification from FOOD subject to a hold order.

8-903.80 Destroying or Denaturing Food.

If a hold order is sustained upon appeal or if a timely request for an appeal hearing is not filed, the REGULATORY AUTHORITY may order the PERMIT HOLDER or other PERSON who owns or has custody of the FOOD to bring the FOOD into compliance with this Code or to destroy or denature the FOOD under the REGULATORY AUTHORITY'S supervision.

8-903.90 Releasing Food from Hold Order.

The REGULATORY AUTHORITY shall issue a notice of release from a hold order and shall remove hold tags, labels, or other identification from the FOOD if the hold order is vacated.

**Summary
Permit
Suspension**

8-904.10 Conditions Warranting Action.

The REGULATORY AUTHORITY may summarily suspend a PERMIT to operate a FOOD ESTABLISHMENT if it determines through inspection, or examination of EMPLOYEES, FOOD, records, or other means as specified in this Code, that an IMMINENT HEALTH HAZARD exists.

8-904.20 Summary Suspension, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may summarily suspend a PERSON'S PERMIT as specified in § 8-904.10 by providing written notice as specified in § 8-801.20 of the summary suspension to the PERMIT HOLDER or PERSON IN CHARGE, without prior warning, notice of a hearing, or a hearing.

8-904.30 Contents of the Notice.

A summary suspension notice shall state:

- (A) That the FOOD ESTABLISHMENT PERMIT is immediately suspended and that all FOOD operations shall immediately cease;
- (B) The reasons for summary suspension with reference to the provisions of this Code that are in violation;
- (C) The name and address of the REGULATORY AUTHORITY representative to whom a written request for reinspection may be made and who may certify that reasons for the suspension are eliminated; and
- (D) That the PERMIT HOLDER may request an appeal hearing by submitting a timely request as specified in §§ 8-905.10 and 8-905.20.

8-904.40 Time Frame for Reinspection.

After receiving a written request from the PERMIT HOLDER stating that the conditions cited in the summary suspension order no longer exist, the REGULATORY AUTHORITY shall conduct a reinspection of the FOOD ESTABLISHMENT for which the PERMIT was summarily suspended within 2 business days, which means 2 days during which the REGULATORY AUTHORITY'S office is open to the public.

8-904.50 Term of Suspension, Reinstatement of Permit.

(A) A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and their elimination has been confirmed by the REGULATORY AUTHORITY through reinspection and other means as appropriate.

(B) The suspended PERMIT shall be reinstated immediately if the REGULATORY AUTHORITY determines that the public health HAZARD or nuisance no longer exists. A notice of reinstatement shall be provided to the PERMIT HOLDER or PERSON IN CHARGE.

**Hearings
Administration**

8-905.10 Response to Notice of Hearing or Request for Hearing, Basis and Time Frame.

(Note: Adoption of this section provides the basis for §§ 8-303.30(C) and 8-501.30(C). §§ 8-905.10(C) and (D) would be cited there.)

(A) A PERSON who receives a notice of hearing for an administrative remedy as specified in Part 8-8, § 8-901.10, or § 8-905.30(A) and elects to respond to the notice shall file a response to notice as specified in § 8-905.20 within 7 calendar days after service.

(B) A PERMIT applicant may request a hearing regarding the disposition of an application for a new or revised PERMIT if the REGULATORY AUTHORITY does not issue or deny the PERMIT within the time frame specified in LAW.

(C) A PERMIT HOLDER may request a hearing to address concerns about the REGULATORY AUTHORITY'S denial of application for a PERMIT or request for a VARIANCE, or compliance actions, except that a hearing request does not stay the REGULATORY AUTHORITY'S restriction or exclusion of EMPLOYEES specified in §§ 8-501.10 - 8-501.40, a hold order specified in § 8-903.10, or the imposition of a summary suspension specified in § 8-904.10.

(D) A PERSON desiring a hearing in response to a denial of an application for PERMIT or an adverse administrative determination shall submit a hearing request to the REGULATORY AUTHORITY within 10 calendar days of the date of the denial, inspection, or compliance action, unless the REGULATORY AUTHORITY specifies in

certain situations that the request shall be submitted within a shorter period of time.

8-905.20 Response to a Notice of Hearing or Request for Hearing, Required Form and Contents.

A response to a hearing notice or a request for hearing as specified in § 8-905.10 shall be in written form and contain the following:

- (A) If a response to notice of hearing,
 - (1) An admission or denial of each allegation of fact;
 - (2) A statement as to whether the respondent waives the right to a hearing; and may also contain
 - (3) A statement of defense, mitigation, or explanation concerning any allegation of fact; and
 - (4) A request to the REGULATORY AUTHORITY for a settlement of the proceeding by consent agreement, if the REGULATORY AUTHORITY will provide this opportunity.
- (B) If a request for hearing,
 - (1) A statement of the issue of fact specified in ¶ 8-905.30(B) for which the hearing is requested; and
 - (2) A statement of defense, mitigation, denial, or explanation concerning each allegation of fact.
- (C) If either a response to notice of hearing or a request for a hearing,
 - (1) A statement indicating whether the presence of witnesses for the REGULATORY AUTHORITY is required; and
 - (2) The name and address of the respondent's or requester's legal counsel, if any.

8-905.30 Provided Upon Request.

The REGULATORY AUTHORITY shall hold hearings according to LAW and the provisions of this Code:

(A) As determined necessary by LAW or the REGULATORY AUTHORITY to accomplish the purpose and intent of this Code specified in § 8-101.10; and

(B) As requested by a PERMIT applicant or a PERMIT HOLDER if:

(1) Requested as specified in § 8-905.10, and

(2) The request demonstrates that there is a genuine and material issue of fact that justifies that a hearing be held.

8-905.40 Provided in Accordance with Law.

Hearings shall be conducted according to LAW, administrative procedures, and this Code.

8-905.50 Timeliness, Appeal Proceeding Within 5 Business Days, Other Proceeding Within 30 Calendar Days.

(A) The REGULATORY AUTHORITY shall afford a hearing:

(1) Except as provided in ¶ (B) of this section, within 5 business days after receiving a written request for an appeal hearing from:

(a) A PERSON who is EXCLUDED by the REGULATORY AUTHORITY from working in a FOOD ESTABLISHMENT as specified in §§ 8-501.10 - 8-501.40,

(b) A PERMIT HOLDER or PERSON whose FOOD is subject to a hold order as specified in Subpart 8-903, or

(c) A PERMIT HOLDER whose PERMIT is summarily suspended as specified in Subpart 8-904; and

(2) Within 30 calendar days but no earlier than 7 calendar days after the service of a hearing notice to consider administrative remedies for other matters as specified in ¶ 8-905.10(C) or for matters as determined necessary by the REGULATORY AUTHORITY.

(B) A PERMIT HOLDER or PERSON who submits a request for a hearing as specified in Subparagraphs (A)(1)(a)-(c) of this section may waive the prompt hearing in the written request to the REGULATORY AUTHORITY.

8-905.60 Notice, Contents.

A notice of hearing shall contain the following information:

(A) Time, date, and place of the hearing;

(B) Purpose of the hearing;

(C) Facts that constitute the basis or reason for the hearing including specific details of violations or allegations;

(D) The rights of the respondent, including the right to be represented by counsel and to present witnesses and evidence on the respondent's behalf as specified in § 8-907.10;

(E) At the REGULATORY AUTHORITY'S discretion, the procedure for the respondent to request an offer from the REGULATORY AUTHORITY to settle the matter;

(F) The consequences of failing to appear at the hearing;

(G) The maximum sanctions or penalties as specified in ¶¶ 8-906.40(B) - (D) that may result from the hearing if the hearing concerns a proposed administrative remedy and if the facts are found to be as alleged;

(H) If the hearing concerns a proposed administrative remedy, a statement specifying the form and time frame for response as specified in § 8-905.10;

(I) Notification that the written response shall include the information specified in § 8-905.20; and

(J) The name and address of the PERSON to whom such written response shall be addressed.

8-905.70 Proceeding Commences Upon Notification.

A hearing proceeding commences at the time the REGULATORY AUTHORITY notifies the respondent of the hearing proceeding.

8-905.80 Procedure, Expeditious and Impartial.

Hearings shall be conducted in an expeditious and impartial manner.

8-905.90 Confidential.

(A) Hearings or portions of hearings may be closed to the public:

(1) If compelling circumstances, such as the need to discuss in the hearing a PERSON'S medical condition or a FOOD ESTABLISHMENT'S trade secrets, indicate that it would be prudent; and

(2) According to LAW, such as an open meetings LAW.

(B) A party to a hearing shall maintain confidentiality of discussions that warrant closing the hearing to the public.

8-905.100 Record of Proceeding.

A complete record of a hearing shall be prepared under the direction of the PERSON conducting the hearing and maintained as part of the REGULATORY AUTHORITY'S records for the FOOD ESTABLISHMENT. *Except as required by LAW, a verbatim transcript of the hearing need not be prepared.*

**Hearing Officer,
Purpose
Qualifications,
Appointment,
and Powers**

8-906.10 Appointment by Regulatory Authority and Purpose.

The REGULATORY AUTHORITY may appoint a PERSON such as an adjudicator, administrative LAW judge, or examiner, hereinafter referred to as a hearing officer, who presides over a proceeding initiated by the REGULATORY AUTHORITY or by a PERSON contesting an action of the REGULATORY AUTHORITY, to perform one or more of the following:

- (A) Hear the facts presented by an applicant or a PERMIT HOLDER;
- (B) Make a decision or recommendation concerning administrative remedies to achieve compliance with this Code; or
- (C) Address other concerns or allegations appropriately raised according to LAW, in the matter before the hearing officer.

8-906.20 Qualifications.

A hearing officer shall be knowledgeable of the provisions of this chapter and the LAW as they relate to hearings, and be:

- (A) A REGULATORY AUTHORITY representative other than the PERSON who inspects the FOOD ESTABLISHMENT or who has any other role in making the decision that is being contested; or
- (B) An individual who is not employed by the REGULATORY AUTHORITY.

8-906.30 Powers, Administration of Hearings.

(A) A hearing officer shall have the following powers in a hearing in which the hearing officer presides:

- (1) Setting and conducting the course of a hearing requested in accordance with or authorized by this Code,

(2) Issuing subpoenas in the name of the REGULATORY AUTHORITY at the request of a party to a hearing, administering oaths and affirmations, examining witnesses, receiving evidence,

(3) Approving a consent agreement on the issues involved in the hearing entered into by the REGULATORY AUTHORITY and the respondent after the respondent receives a hearing notice,

(4) Sustaining, modifying, rescinding, or vacating an order or directive of the REGULATORY AUTHORITY in an appeal hearing proceeding, and if the order or directive is sustained, ordering appropriate measures to execute the REGULATORY AUTHORITY'S order or directive; and

(B) Unless a party appeals to the head of the REGULATORY AUTHORITY within 15 days of the hearing or a lesser number of days specified by the hearing officer:

(1) Rendering a binding decision and final order in a proceeding after conducting a hearing, if the respondent has not waived the right to a hearing, and

(2) Then notifying the respondent of the decision and the order which contains the findings and conclusions of LAW.

8-906.40 Powers, Administrative Remedies.

The hearing officer shall have the following powers in a hearing proceeding concerning an administrative remedy specified in §§ 8-901.10 and 8-905.30:

(A) Issuing orders to abate or correct violations of this Code and establishing a schedule for the abatement or correction of violations;

(B) Making a finding of fact regarding the occurrence of each violation and assessing, levying, and ordering a reasonable civil penalty, according to LAW and not to exceed the amount specified in ¶ 8-913.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-913.10(C);

(C) Suspending, revoking, modifying, or imposing reasonable restrictions or conditions on a PERMIT to operate a FOOD ESTABLISHMENT, or ordering the closure of a FOOD ESTABLISHMENT that is operated without a valid PERMIT as required under § 8-301.11;

(D) Making a finding of fact regarding the occurrence of each violation of the REGULATORY AUTHORITY'S or hearing officer's LAWFUL order issued in accordance with this Code and assessing, levying, and ordering a reasonable civil penalty, in accordance with LAW and not to exceed the amount specified in ¶ 8-913.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-913.10(C);

(E) Deferring or suspending the imposition of a decision or execution of an order, and imposing a probationary period, upon the condition that the respondent comply with the hearing officer's reasonable terms and conditions;

(F) Dismissing the appeal if the matter is settled between the REGULATORY AUTHORITY and the respondent after a hearing notice is served;

(G) Ordering reinspection of a FOOD ESTABLISHMENT to determine compliance with a hearing officer's order;

(H) Suspending or ordering the payment of a fee established by the REGULATORY AUTHORITY for a reinspection that is required to determine compliance and for the reinstatement of a PERMIT after suspension;

(I) Retaining and exercising jurisdiction for a specific period of time not to exceed 90 calendar days after the hearing officer's decision and final order is issued, over a respondent who receives a hearing notice; and

(J) Modifying or setting aside an order by rehearing upon the hearing officer's own motion, the motion of the REGULATORY AUTHORITY, or the motion of the respondent.

***Rights of
Parties and
Evidence***

8-907.10 Rights of Parties.

Parties to a hearing may be represented by counsel, examine and cross examine witnesses, and present evidence in support of their position.

8-907.20 Evidence to be Presented by the Regulatory Authority.

The REGULATORY AUTHORITY shall present at the hearing its evidence, orders, directives, and reports related to the proposed or appealed administrative remedy.

8-907.30 Evidence to be Excluded.

Evidence shall be EXCLUDED:

(A) If it is irrelevant, immaterial, unduly repetitious, or excludable on constitutional or statutory grounds or on the basis of evidentiary privilege recognized by the state's courts; or

(B) Otherwise according to LAW.

8-907.40 Testimony under Oath.

Testimony of parties and witnesses shall be made under oath or affirmation administered by a duly authorized official.

8-907.50 Written Evidence.

Written evidence may be received if it will expedite the hearing without substantial prejudice to a party's interests.

8-907.60 Documentary Evidence.

Documentary evidence may be received in the form of a copy or excerpt.

Settlement

8-908.10 Authorization.

The REGULATORY AUTHORITY may settle a case after a notice of hearing is served by providing a respondent with an opportunity to request a settlement before a hearing commences on the matter and by entering into a consent agreement with the respondent.

8-908.20 Respondent Acceptance of Consent Agreement Is Waiver of Right to Appeal.

Respondents accepting a consent agreement waive their right to a hearing on the matter.

Judicial

Inspection Orders

8-909.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may seek access for one or more of the following purposes, according to LAW for gaining access:

- (A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;
- (B) To examine and sample the FOOD; and
- (C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-909.20 Contents of Court Petition.

In the absence of a specific set of requirements established by LAW, in its petition to the court to compel access the REGULATORY AUTHORITY shall:

- (A) Describe in detail the PREMISES, FOOD, or records on or to which access was denied;
- (B) Detail the legal authority to regulate and to have access

for a specific purpose on or to the PREMISES, FOOD, or records where access was denied; and

(C) Provide information that the FOOD ESTABLISHMENT possesses a valid PERMIT from the REGULATORY AUTHORITY and that it applies to the PREMISES where access was denied; or

(D) Provide information that a PERSON is known to be or suspected of operating a FOOD ESTABLISHMENT without possessing a valid PERMIT as specified in LAW and under this Code.

8-909.30 Sworn Statement of Denied Access.

The REGULATORY AUTHORITY shall demonstrate to the court by affidavit, sworn testimony, or both that:

(A) Access on or to the PREMISES, FOOD, or records was denied after the REGULATORY AUTHORITY acted as specified in §§ 8-402.20 and 8-402.30; or

(B) There is reason to believe that a FOOD ESTABLISHMENT is being operated on the PREMISES and that access was denied or is sought under a REGULATORY AUTHORITY'S reasonable administrative plan to enforce the provisions of this Code.

8-909.40 Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may issue an inspection order that:

(A) Includes the information specified in ¶¶ 8-902.20(A) - (C); and

(B) Orders or authorizes any other identified agencies and persons including LAW enforcement agencies to execute, or assist with the execution of, the order.

8-909.50 Optional Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may further issue an inspection order that:

- (A) Provides a maximum time limit for the order's execution;
- (B) Authorizes LAW enforcement officers who assist in the order's execution to use necessary force against PERSONS or property to execute the order; and
- (C) Requires that the agencies or PERSONS ordered or authorized to execute the order shall report to the court the date and time of the order's execution and the findings reached by the inspection, examination, or sampling conducted under the order.

**Means of
Instituting
Judicial
Enforcement
Proceedings**

8-910.10 Institution of Proceedings.

(A) Proceedings to enforce this Code may be instituted by the REGULATORY AUTHORITY according to LAW by issuing a citation or summons, by filing a misdemeanor complaint affidavit and request for a warrant of arrest with the court of competent jurisdiction, or by referring the complaint to a grand jury for indictment, as appropriate.

(B) The REGULATORY AUTHORITY may designate a representative to issue summons or citations or sign warrants on behalf of the agency.

**Criminal
Proceedings**

8-911.10 Authorities, Methods, Fines, and Sentences.

(A) The REGULATORY AUTHORITY may seek to enforce the provisions of this Code and its orders by instituting criminal proceedings as provided in LAW against the PERMIT HOLDER or other PERSONS who violate its provisions.

(B) A PERSON who violates a provision of this Code shall be guilty of a misdemeanor, punishable by:

- (1) A fine of not more than (designate amount) dollars, or by imprisonment not exceeding 1 year, or both the fine and imprisonment; or
- (2) If the PERSON has been convicted once of violating this Code or if there is an intent to defraud or mislead, a fine not exceeding (designate amount) or imprisonment not exceeding (designate time) year(s) or both.

(C) Each day on which a violation occurs is a separate violation under this section.

***Injunctive
Proceeding***

8-912.10 Petitions for Injunction.

The REGULATORY AUTHORITY may, according to LAW, petition a court of competent jurisdiction for temporary or permanent injunctive relief to achieve compliance with the provisions of this Code or its orders.

***Civil
Proceedings***

8-913.10 Petitions, Penalties, and Continuing Violations.

(A) The REGULATORY AUTHORITY may petition a court of competent jurisdiction to enforce the provisions of this Code or its administrative orders and according to LAW collect penalties and fees for violations.

(B) In addition to any criminal fines and sentences imposed as specified in § 8-911.10, or to being enjoined as specified in § 8-912.10, a PERSON who violates a provision of this Code, any rule or regulation adopted in accordance with LAW related to FOOD ESTABLISHMENTS within the scope of this Code, or to any term, condition, or limitation of a PERMIT issued as specified in §§ 8-303.10 and 8-303.20 is subject to a civil penalty not exceeding (designate amount).

(C) Each day on which a violation occurs is a separate violation under this section.

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References

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS
2. BIBLIOGRAPHY
3. SUPPORTING DOCUMENTS
4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS

The *Food Code* makes frequent reference to federal statutes contained in the United States Code (USC) and the *Code of Federal Regulations* (CFR). Copies of the USC and CFR can be viewed and copied at government depository libraries or may be purchased as follows.

(A) Viewing and Copying the USC or CFR

(1) Federal Depository Library

The USC and CFR are widely available for reference and viewing in some 1300 "depository libraries" located throughout the United States. *A Directory of U.S. Government Depository Libraries* is published by the Joint Committee on Printing of the United States Congress and is available through the Superintendent of Documents, U.S. Government Printing Office. This publication lists all depository libraries by state, city, and congressional district.

Persons may also obtain information about the location of the depository library nearest to them by contacting:

GPO Customer Contact Center, Mail Stop: IDCC
U.S. Government Printing Office
732 North Capitol Street, NW
Washington, DC 20401-0001
(866) 512-1800, Fax (202) 512-2104
Email: ContactCenter@gpo.gov

(2) Internet World Wide Web Information System

The CFRs are available on-line in downloadable form through the Internet World Wide Web information system. The source is:

The National Archives and Records Administration
Copies of Federal Regulations - Retrieve CFR by Citation
Provided through the Government Printing Office Web Site - GPO Inet Services

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1>

(B) Purchasing Portions of the USC or CFR

Persons wishing to purchase relevant portions of the USC or CFR may do so
by writing: or by calling:

Superintendent of Documents (New Orders) U.S. Government Printing Office P.O. Box 371954 Pittsburgh, PA 15250-7954;	(202) 512-1800 from 8:00 a.m. to 5:30 p.m. eastern time, Monday-Friday (except Federal holidays. Orders may be charged to American Express, Discover, MasterCard, or Visa
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Or by emailing: gpo@custhelp.com or at <http://www.gpo.gov/customers/print.htm> .

(C) USC as it Relates to the Code Definition of "Adulterated"

This language has been retyped as accurately as possible and inserted in the Food Code Annex for informational purposes. For legal purposes, use only language taken directly from the United States Code (USC).

21 USC Sec. 342
Title 21 - Food and Drugs
Chapter 9 - Federal Food, Drug and Cosmetic Act
Subchapter IV - Food

ADULTERATED FOOD

Sec. 402 [342]

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.^[1]

(2)

(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a (a) of this title; or

(C) if it is or if it bears or contains

(i) any food additive that is unsafe within the meaning of section 348 of this title; or

(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e (a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is

adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph ^[2] (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) Reoffer of food previously denied admission

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381 (a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

[1] So in or". original. The period probably should be “;

[2] So in original. Probably should be “subparagraph”.

(As amended by Congress, 2002 – Subsec. (h). Pub. L. 107-188 added subsec. (h).)

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2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.

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2-301.12 Cleaning Procedure. (Handwashing)

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2-301.13 Special Handwashing Procedures.

Reserved.

2-301.14 When to Wash.

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2-301.16 Hand Antiseptics.

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2. Code of Federal Regulations, Title 21, Part 170.39 Threshold of Regulation for Substances Used in Food-Contact Articles.
3. Code of Federal Regulations, Title 21, Part 182 Substances Generally Recognized as Safe.
4. Code of Federal Regulations, Title 21, Part 184 Direct Food Substances Affirmed as Generally Recognized as Safe.
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2-302.11 Maintenance. (Fingernails)

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2-303.11 Prohibition. (Jewelry)

2-304.11 Clean Condition. (Outer Clothing)

2-401.11 Eating, Drinking, or Using Tobacco.

2-402.11 Effectiveness. (Hair Restraints)

1. Code of Federal Regulations, Title 21, Sections 110.10 Personnel. (b) (1) "Wearing outer garments suitable to the operation" (4) "Removing all unsecured jewelry" (6) "Wearing, where appropriate, in an effective manner, hair nets, head bands, caps, beard covers, or other effective hair restraints." (8) "Confining...eating food, chewing gum, drinking beverages or using tobacco...." and (9) "Taking other necessary precautions"

2-403.11 Handling Prohibition. (Animals)

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2-501.11 Clean-up of Vomiting and Diarrheal Events.

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Chapter 5 Water, Plumbing, and Waste

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1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions) found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr180.940.pdf

2. Code of Federal Regulations, Title 40 Part 180.2020 Pesticide Chemicals Not Requiring a Tolerance or an Exemption From Tolerance-Non-Food determinations found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr180.2020.pdf

3. Code of Federal Regulations, Title 29 Part 1910.1000 Occupational Safety and Health Standards found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/29cfr1910.1000.pdf

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.

1. Code of Federal Regulations, Title 21, Part 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables.

2. Code of Federal Regulations, Title 21, Part 173.405, Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate.

7-204.13 Boiler Water Additives, Criteria.

1. Code of Federal Regulations, Title 21, Part 173.310, Boiler water additives.

7-204.14 Drying Agents, Criteria.

1. Code of Federal Regulations, Title 21, Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe.

2. Code of Federal Regulations, Title 21, Parts 175, Indirect Food Additives: Adhesives and Components of Coatings.

3. Code of Federal Regulations, Title 21, Parts 178, Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers.

4. Code of Federal Regulations, Title 21, Parts 176, Indirect Food Additives: Paper and Paperboard Components.

5. Code of Federal Regulations, Title 21, Parts 177, Indirect Food Additives: Polymers.

6. Code of Federal Regulations, Title 21, Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe.

7. Code of Federal Regulations, Title 21, Part 181, Prior-Sanctioned Food Ingredients.

8. Code of Federal Regulations, Title 21, Part 182, Substances Generally Recognized as Safe.

9. Code of Federal Regulations, Title 21, Part 170.39, Threshold of regulation for substances used in food-contact articles.

10. Code of Federal Regulations, Title 21, Part 170.30, Eligibility for classification as generally recognized as safe (GRAS)

11. Code of Federal Regulations, Title 21, Part 174, Indirect Food Additives: General.

12. Federal Food Drug and Cosmetic Act, Section, 409 (h),
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/default.htm>

13. Federal Food Drug and Cosmetic Act, Section 201(s)(4)
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/default.htm>

14. Food Contact Notification, Ingredients and Packaging,
<http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm>

7-205.11 Incidental Food Contact, Criteria.

1. Code of Federal Regulations, Title 21, Part 178.3570, Lubricants with incidental food contact.

7-206.11 Restricted use Pesticides, Criteria.

1. Code of Federal Regulations, Title 40, Part 152 Subpart I, Classification of Pesticides.

3. SUPPORTING DOCUMENTS

FDA is providing the following guidance documents for reference. A brief summary for each document is provided.

- A. Voluntary National Retail Food Regulatory Program Standards
- B. FDA Procedures for Standardization and Certification of Retail food Inspection/Training Officers
- C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments
- D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems
- E. Food Establishment Plan Review Guide
- F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)
- G. Growing Sprouts in a Retail Food Establishment
- H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety
- I. Evaluation and Definition of Potentially Hazardous Foods
- J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers" October 28, 2004
- K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

- L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003
- M. Comprehensive Guidelines for Food Recovery Programs
- N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.
- O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens
- P. Employee Health and Personal Hygiene Handbook
- Q. Risk Assessment Process and Spreadsheet to Redesignate Food Code Provisions
- R. Parameters for Determining Inoculated Pack/Challenge Study Protocols
- S. The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response
- T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)

A. Voluntary National Retail Food Regulatory Program Standards

This document can be accessed at the following web site:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm> and was formulated from ideas and input by Federal, State, and local regulatory officials, industry, trade and professional associations, academia, and consumers. The purposes of these standards are:

- To serve as a bench mark to retail food regulatory program managers in the design and management of a retail food program;
- To provide a means of recognition of programs meeting these standards;
- To promote uniformity in retail food programs to reduce the risk factors known to cause foodborne illness;
- To provide a foundation for the food regulatory program that is focused on the risk factors and other factors that may contribute to foodborne illness; and
- To promote, through the management of a retail food regulatory program, the active managerial control in the retail establishment of all the factors that may cause foodborne illness.

Further purposes of these standards are to serve as a guide to regulatory retail food program managers in the design and management of a retail food program and to provide a means of recognition for those programs that meet these standards.

The intent in the development of these standards is to establish a basic foundation in design and management of a retail food program. Program management may add additional requirements to meet individual program needs.

The standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause foodborne illness as well as other factors that may contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness.

B. FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers

This document can be found by accessing the following web site:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/InspectionsQualityAssurance/ucm2006814.htm>. This is a procedure that integrates the assessment of an individual's knowledge, skills, and abilities in a manageable number of inspections while preserving the quality and integrity of the process. At the same time, we continue to learn from our experiences in applying it and remain open to improving these Procedures based on your experiences and feedback.

As they are written, the Procedures address the situation wherein an FDA Standard is assessing a CANDIDATE who is not employed by FDA. For example, Paragraph 3-301(C) mentions but does not require recording citations (i.e., identifying the codified provision that relates to each observed violation). Since jurisdiction's codification systems (numeric or alphanumeric) are usually different from the system in the FDA Food Code, the utility of that practice would be minimal in an FDA-to-jurisdiction field exercise. However, within a jurisdiction where the same Code is in use, the practice could be useful in reinforcing diligence in ensuring that violations listed during inspections are, in fact, soundly based in regulation.

FDA invites and encourages jurisdictions to use these Procedures in their internal Standardization and Certifications and to add dimensions that promote uniformity such as citing codified provisions, as discussed above. With a few language changes, the document can be custom-tailored to fit individual jurisdictions and serve as their procedures. As with other documents provided as guidance for applying regulatory requirements in the retail sector, these Procedures are in the "public domain" and we encourage their duplication and use.

C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

The Operator's Manual can be found by accessing the following web site:

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm>. FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. It recognizes that there are differences between using HACCP at retail and in food manufacturing. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system.

This document is intended to serve as a guide in the writing of a simple plan based on HACCP principles that can be used to manage food safety. It is very important to understand that this Guide is intended to assist industry's voluntary implementation of HACCP principles. It is not meant to stand alone, but instead should be used together with advice from and in consultation with your Federal, State, local, or tribal food safety regulatory authority. The regulatory authority is an important resource for reviewing your food safety management system. Regulatory food safety professionals can provide important information for the public health rationale for controlling a particular hazard. Users of this document also need to consult and use the latest edition of the FDA Food Code since many of its requirements are not reproduced here but constitute a fundamental program that is prerequisite to implementing a HACCP program.

Hazard Analysis Critical Control Point (HACCP) is a common sense technique to control food safety hazards. It is a preventive system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards. HACCP is not a stand alone program but is one part of a larger system of control procedures that must be in place in order for HACCP to function effectively. These control procedures are prerequisite programs and are discussed more in Annex 4.

The success of a HACCP program is dependent upon both people and facilities. Management and employees must be properly motivated and trained if a HACCP program is to successfully reduce the risk of foodborne illness. Education and training in the principles of food safety and management commitment to the implementation of a HACCP system are critical and must be continuously reinforced. Instilling food worker commitment and dealing with problems such as high employee turnover and communication barriers must be considered when designing a HACCP plan.

Successful implementation of a HACCP plan is also dependent upon the design and performance of facilities and equipment. The likelihood of the occurrence of a hazard in a finished product is definitely influenced by facility and equipment design, construction, and installation that play a key role in any preventive strategy.

The Agency recognizes that this document has areas that need to be further clarified and developed with broader input and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

D. **Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems**

The Regulator's Manual can be found by accessing the following website: <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm>. This document provides State, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles to assist them with identifying and assessing control of foodborne illness risk factors. In addition, the manual details intervention strategies that can be developed with retail and food service operators to reduce the occurrence of foodborne illness risk factors. It also provides recommendations for evaluating voluntarily-implemented food safety management systems if invited to do so by industry.

The utilization of voluntary food safety management systems by industry and the incorporation of risk-based methodology into regulatory inspection programs are important elements in reaching the goals established by the Healthy People 2010 health improvement strategy and FDA retail program goals.

In 2004, the Conference for Food Protection (CFP) endorsed both documents with a recommendation that both industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs. The CFP is composed of regulators, industry, academia, professional organizations, and consumers whose purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety.

A Federal Register notice announcing the availability of these documents was published July 21, 2005 (Docket No. 2005D-0274).

E. Food Establishment Plan Review Guide

This document can be found at:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm>. This Food Establishment Plan Review document has been developed for the purpose of assisting both regulatory and industry personnel in achieving greater uniformity in the plan review process. It is the result of a joint effort by FDA and the Conference for Food Protection.

Plan review of food service establishments, retail food stores, and all other food operations, must be maintained as a high priority by all regulatory food agencies for both new and existing facilities.

This document has been developed to serve as a guide in facilitating greater uniformity and ease in conducting plan review whether your position is a regulator or an industry person wishing to build or to expand. You need not be an expert to effectively complete this process.

A good review of plans helps to avoid future problems. By listing and locating equipment on floor plans and diagramming specifications for electrical, mechanical and plumbing systems, potential problems can be spotted while still on paper and modifications made BEFORE costly purchases, installation and construction.

Food establishment plan review is recognized as an important food program component that allows:

- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
- Industry to establish an organized and efficient flow of food.
- Regulatory agencies to eliminate code violations prior to construction.

F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the "FDA Baseline Report." The Baseline Report is available from FDA through the following website: <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf>. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional*

Foodservice, Restaurant, and Retail Food Store Facility Types (2004). This second report is available from FDA through the following website: <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm089696.htm>. An additional data collection project is planned for 2008.

G. Growing Sprouts in a Retail Food Establishment

This document, *Growing Sprouts in a Retail Food Establishment*, can be found at the web site

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ucm078758.htm> .

There were 25 reported outbreaks associated with raw and lightly cooked seed sprouts in the United States between January 1996 and December 2003. No single treatment so far has been shown to completely eliminate pathogens on seeds or sprouts without affecting germination or yield; therefore a combination of factors is used to eliminate and control potential pathogens and assure a safe, ready-to-eat food product. Seeds or beans grown using Good Agricultural Practices (GAPs) and conditioned, transported, and stored according to GMPs reduce the potential for seed to serve as a source of contamination. Retail Sprouting Industry Best Practices help ensure that no further contamination occurs and precautionary measures are taken to prevent high levels of bacteria from growing on the seeds or sprouts. Seeds for sprouting or sprouts should receive a chemical disinfection treatment that has been approved by EPA for reduction of pathogens. Other treatments such as irradiation of seeds [21 CFR 179.26(b)(10)] have been approved. Because no treatments are known to completely eliminate pathogens without adversely affecting germination or yield, microbial testing of spent irrigation water from the sprouting process is also necessary to verify that no pathogens are present. Raw sprouts are considered time/temperature control for safety food (TCS) and therefore, require refrigeration.

H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety

These documents are available for purchase at minimum cost from the Association of Food and Drug Officials (AFDO) at the website <http://www.afdo.org/>. These guides were funded by USDA through the University of Florida in cooperation with Florida A&M University and the Association of Food and Drug Officials and developed by experts from academic, regulatory, and industry areas. Nine guides help retailers and regulatory personnel understand the food safety controls to implement in retail food and food service operations in order to process and sell safe food products. They can also be used as a reference in applying for or reviewing a variance and HACCP Plan, where required, for retail processing of beef jerky, cured and hot smoked sausage, cured and smoked ham, fermented and dried sausage, fresh-cut produce, fresh juice, reduced oxygen packaging (ROP), smoked seafood, and sushi.

Each guide provides a definition of terms, a flow diagram, and a detailed check list for operations including receiving, food storage, preparation, and display. Information in the Appendices helps identify specific food safety hazards associated with that product, necessary equipment calibrations, product labeling, recommended record keeping with sample log sheets, and a daily SOP check list. Authoritative sources are also referenced such as FDA's "Fish and Fisheries Products Hazards & Controls Guidance" and 21 CFR 101 for labeling requirements.

These guides are not intended to replace or duplicate existing regulations within the jurisdictions of the regulatory authority or food establishment but they offer information and references for more uniform practices.

I. Evaluation and Definition of Potentially Hazardous Foods

This document can be found at the web site

<http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm> . The Institute of Food Technologists (IFT) prepared and submitted this report as part of a contract with FDA. It contains responses to various questions posed by FDA about time/temperature control for safety food (TCS food). The IFT reviewed the evolution of the term TCS and recommended a change to time/temperature control for safety (TCS) food as well as a science-based framework for determining the effectiveness of processing technologies that formulate a food so that it is non-TCS.

The IFT Science and Technology Expert Panel reviewed the two protocols used by NSF International and the American Baking Association for determining if a food is a TCS and proposed an alternate approach. The report examines intrinsic factors such as a_w , pH, redox potential, natural and added antimicrobials and competitive microorganisms, and extrinsic factors such as packaging, atmospheres, storage conditions, processing steps, and new preservation technologies that influence microbial growth. The report also analyzes microbial hazards related to time/temperature control of foods for safety.

The IFT developed a framework that could be used to determine whether a food is a TCS food or not. Part of the framework includes two tables that consider the interaction of pH and a_w in a food, whether the food is raw or heat-treated, and whether it is packaged. When further product assessment is required, the application of microbiological challenge testing (inoculation studies) is discussed along with pathogen modeling programs and reformulation of the food. An extensive reference list is included in the report.

- J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, “How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers” October 28, 2004

The guide is designed to assist restaurants and other food service employers in complying with the employment provisions of the Americans with Disabilities Act (ADA). The EEOC worked extensively with the Food and Drug Administration in developing this new publication.

Available online at http://www.eeoc.gov/facts/restaurant_guide.html, http://www.eeoc.gov/facts/restaurant_guide_summary.html, and www.fda.gov, the guide covers such topics as how the FDA Food Code provisions about restricting and excluding sick employees interact with the ADA’s requirements; types of reasonable accommodations, including the use of service animals; and what an employer should do if a charge of discrimination is filed against the employer’s business.

Title I of the ADA, which prohibits employment discrimination against people with disabilities in the private sector and State and local governments, and the Rehabilitation Act’s prohibitions against disability discrimination in the federal government. The EEOC enforces Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race, color, religion, sex, and national origin; the Age Discrimination in Employment Act, which prohibits discrimination against individuals 40 years of age or older; the Equal Pay Act; and sections of the Civil Rights Act of 1991.

- K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for “Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7” at <http://www.fsis.usda.gov/wps/wcm/connect/f5001b3d-defa-4db8-a510-881ca90415ff/ecolio157h7dirguid4-13-04.pdf?MOD=AJPERES>. On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf, in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli* (*E. coli*) O157:H7 contamination.

USDA/FSIS announced in 2002 that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback contaminated product that is in commerce to its source and to remove it from commerce. In the Spring of 2004, FSIS began conducting sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities as well as at import facilities. Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

Additionally, ground beef products have been implicated as a transmission vehicle in foodborne outbreaks of infections with pathogens such as *Escherichia coli* O157:H7 and Salmonella. To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies adulterated ground beef, and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

FSIS recently published “Sanitation Guidance for Beef Grinders” which contains an example of a fresh ground beef production log. The guidance is located at the following website: http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf.

The following information would be used to facilitate traceback of contaminated ground beef products:

- The manufacturer name of source material used for product produced.
- The type of product or description of the purchased or received article(s).
- The establishment information from the label of source product used such as the name, address, and establishment number
- The supplier lot numbers, product code or production or pack date of source materials used.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce such as time of grind, grinder sanitation records and amount (in pounds) and lot/batch numbers, production codes, name and package size of the products produced.

In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).
2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.
3. Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products.
4. Best Practices for Raw Ground Products.
5. FSIS Sanitation Performance Standards Compliance Guide.
6. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 (<http://www.fsis.usda.gov/wps/wcm/connect/f5001b3d-defa-4db8-a510-881ca90415ff/ecolio157h7dirguid4-13-04.pdf?MOD=AJPERES>)

L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003

This document can be found at <http://www.foodprotect.org/guides/>. Permanent Outdoor Cooking Establishments (POCE) include a wide range of facilities from barbecue pits at beach resorts to campfire meals at dude ranches, pig roasts and clam bakes, and multi-menu food service sites in amusement and theme parks. It is essential that the equipment and physical facility requirements be based upon a menu review of the items to be prepared, cooked, held, and served. Many of these POCEs are high risk operations engaging in extensive preparation of raw ingredients: processes that include the cooking, hot and cold holding, and reheating of time/temperature control for safety foods. These guidelines provide the basis on which regulatory authorities can evaluate and permit permanent outdoor cooking establishments.

M. Comprehensive Guidelines for Food Recovery Programs

Food recovery programs collect foods from commercial production and distribution channels and redistribute them to people in need. There are food recovery efforts carried out by public, private, and nonprofit organizations across the country. The primary goal of food recovery programs is to collect safe and wholesome food donated from commercial sources to meet the nutritional needs of the hungry.

With bipartisan support, Congress passed the Bill Emerson Good Samaritan Food Donation Act in 1996. The Act is designed to encourage the donation of food and grocery products to nonprofit organizations such as homeless shelters, soup kitchens, and churches for distribution to hungry individuals. The Bill Emerson Good Samaritan Food Donation Act promotes food recovery by limiting the liability of donors to instances of gross negligence or intentional misconduct.

The *Guidelines* are intended to provide guidance to those who want to participate in food recovery programs as donors and receiving operations as well as to those who oversee standards compliance as regulators or peer inspectors.

The *Guidelines* also give advice on implementing a food recovery program, various ways to contribute to food recovery programs, choosing suitable partners, and laying the foundation for a successful program. This includes food safety provisions in alignment with the FDA Food Code, guidelines for monitoring food recovery programs, and handling of donations of game animals. For simple recordkeeping, the *Guidelines* contain sample forms designed to facilitate the management of a variety of aspects of food recovery programs.

For in-depth information, see the *Comprehensive Guidelines for Food Recovery Programs* available via the Conference for Food Protection web page at <http://www.foodprotect.org/guides/>

N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.

This document can be found at the web site:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm>

The Retail Food Protection Program Information Manual, Storage and Handling of Tomatoes provides safe storage and handling practices for cut tomatoes and additional rationale for including cut tomatoes in the definition of time/temperature control for safety food in the 2005 Food Code. Historically, uncooked fruits and vegetables have been considered non-TCS food unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. Since 1990, at least 12 multi-state foodborne illness outbreaks have been associated with different varieties of tomatoes. From 1998 – 2006, outbreaks associated with tomatoes made up 17% of the produce-related outbreaks reported to FDA. *Salmonella* has been the pathogen of concern most often associated with tomato outbreaks. Recommendations are being offered to prevent contamination in food service facilities and retail food stores and to reduce the growth of pathogenic bacteria when contamination of fresh tomatoes may have already occurred (regardless of the location where the contamination occurred).

O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens.

This document can be found at:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm>.

Following 24 multi-state outbreaks between 1998 and 2008, cut leafy greens was added to the definition of time/temperature for safety food requiring time-temperature control for safety (TCS). The term used in the definition includes a variety of cut lettuces and leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also not considered cut leafy greens. The pH, water activity, available moisture and nutrients of cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41°F (5°C) or less inhibits growth and promotes general die off in some pathogens such as *E. coli* O157:H7, *Salmonella*, *E. coli* O157:H7 and *Listeria monocytogenes*, once attached to the surface or internalized into cut surfaces of leafy greens, are only marginally affected by chemical sanitizers. Recommended handling instructions for leafy greens during purchasing and receiving, storage, food employee handling fresh produce, washing fresh produce, preparation for sale or service and display for sale or service are attached to the document.

P. Employee Health and Personal Hygiene Handbook

This document can be found at:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113827.htm>.

The Employee Health and Personal Hygiene Handbook was developed to encourage practices and behaviors that can help prevent food employees from spreading foodborne pathogens to food. Information is provided in a question-and-answer format and includes easy references to forms and tables that food service and retail food establishments and the public health community may find useful when training staff and addressing employee health and hygiene matters. This handbook highlights a combination of three interventions that can be effective in prevention of the transmission of foodborne viruses and bacteria in food establishments. These interventions include: (a) restricting or excluding ill food employees from working with food; (b) using proper handwashing procedures; and (c) eliminating bare hand contact with foods that are ready-to-eat (RTE). Concurrent use of each intervention will help prevent the transmission of viruses, bacteria and protozoan oocysts from food employees to consumers through contaminated food. **Note that the recommendations provided are not to be construed as medical advice or directions to diagnose a medical condition.**

The person in charge and the food employee always have the option to seek professional medical attention as warranted by the situation at hand.

Q. Risk Assessment Process and Spreadsheet to Redesignate Food Code Provisions

These documents can be found at:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/default.htm>.

FDA developed a set of definitions and a qualitative risk assessment process to redesignate the Food Code provisions and work with the CFP Critical Items Committee of stakeholders for feedback. It changed “critical” and “non-critical” to risk designations which include “priority item,” “priority foundation item” and “core item” to link the provision to hazards associated with foodborne illness or injury. The method used is described in “**Risk Assessment Process to Redesignate Food Code Provisions**” and the decision-making process recorded in the Excel spreadsheet for transparency. The risk assessment decision-making process explained in the instructions provides a science-based rationale for each redesignation. It is internally consistent and consistent with peer-reviewed publications.

The process considered the general and specific hazards that each provision is intended to address. An initial risk designation was made based on the definitions for “priority item,” “priority foundation item”, and “core item”, to show how directly the provision eliminated, prevented or reduced to an acceptable level, the hazards associated with foodborne illness or injury. To further refine the designation, the virulence or severity of the hazard in the absence of control by this Code provision was also examined. Contributing factors (contamination factors, proliferating/amplification factors, survival factors and method of preparation) identified for foodborne outbreaks reported to the Centers for Disease Control and Prevention were also considered. The risk designation was then re-evaluated in terms of meeting the definition, characteristics of the potential hazards, size and/or number of outbreaks caused by the hazard in conjunction with non-application of this Code provision and the contributing factors. The final determination was based on the term which most closely defined that provision, taking into account any weighting due to severity and infectivity of the hazard. Additional comments and references to explain or support this determination were included on the spreadsheet.

R. Parameters for Determining Inoculated Pack/Challenge Study Protocols

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), in response to questions posed by FDA, developed guidelines for conducting challenge studies on pathogen inhibition and inactivation studies in a variety of foods. The guidelines are available at:

http://www.fsis.usda.gov/wps/portal/informational/aboutfsis!/ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdz9TfQLsh0VAfb5Y5I!/?1dmy¤t=true&urile=wcm%3Apath%3A%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Fdata-collection-and-reports%2Fnacmcf%2Fcurrent-subcommittees%2Fparameters-for-inoculated-pack-challenge-study-protocols%2Fct_index9

The document is intended for use by the food industry, including food processors, food service operators and food retailers; federal, state and local food safety regulators; public health officials; food testing laboratories; and process authorities. The document is focused on, and limited to, bacterial inactivation and growth inhibition and does not make specific recommendations with respect to public health. NACMCF concluded that challenge studies should be designed considering the most current advances in methodologies, current thinking on pathogens of concern, and an understanding of the product preparation, variability and storage conditions. Studies should be completed and evaluated under the guidance of an expert microbiologist in a qualified laboratory and should include appropriate statistical design and data analyses.

This document provides guidelines for choice of microorganisms for studies, inoculum preparation, inoculum level, methods of inoculation, incubation temperatures and times, sampling considerations, and interpreting test results. Examples of appropriately designed growth inhibition and inactivation studies are provided. The NACMCF report, through tables and appendices, also provides sources of accepted laboratory methods, considerations for selecting a laboratory, pathogens of concern with control methods for food product categories, relevant Food Code definitions and food product checklists that test the protocol. It also includes recommended minimum expertise for designing, conducting and evaluating microbiological studies; potential pathogens of concern for growth studies based on pH and a_w ; examples of mathematical growth and inactivation models and their application to different foods; pathogen growth ranges used in CommBase and Pathogen Modeling Program models; and limits for growth when other conditions are near optimum.

S. The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response

This document can be found at: <http://www.cifor.us/CIFORGuidelinesProjectMore.cfm>

The Guidelines for Foodborne Outbreak Response describe the overall approach to foodborne disease outbreaks, including preparation, detection, investigation, control and follow-up. The Guidelines also describe the roles of all key organizations in foodborne disease outbreaks. The Guidelines are targeted at local, state and federal agencies that are responsible for preventing and managing foodborne disease.

T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)

In 2009, the Council to Improve Foodborne Outbreak Response (CIFOR) convened a workgroup comprised of representatives from the food industry and local, state and Federal government for the purpose of creating guidelines and tools specific for industry response to foodborne illness. The resulting document, called the *CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)*, was developed as *voluntary* guidance for managers of Food Establishments (“Industry”) to help outline, clarify, and explain Industry’s recommended role in a foodborne illness outbreak investigation. These CIFOR Industry Guidelines:

- Provide a step-by-step approach including Preparation, Illness Complaints, Investigation, Control, and Follow-up
- Describe what to expect when first notified of potential illnesses or outbreak
- Provide Tools to guide Industry through the regulatory investigation process.

This document is available for download at: <http://www.cifor.us/index.cfm>

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to publications from federal regulatory agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest to regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed organization and those listed are up-to-date as of the printing of the 2005 Food Code.

FDA Publications:

These guidance documents identify the kinds of preventive measures that food establishment and food processing operators may take to minimize risks to food under their control, from tampering or other malicious, criminal, or terrorist actions:

- **Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance** at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082751.htm>

- **Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance** at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm>
- **Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance** at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083049.htm>.
- **Importers and Filers: Food Security Preventive Measures Guidance** at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm078978.htm>.
- **The Bioterrorism Act of 2002** at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm>.

USDA Publications:

- **Food Safety and Inspection Service (FSIS) Security Guidelines for Food Processors** at http://www.fsis.usda.gov/wps/portal/searchhelp/sitemap!/ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdx9jfQLsh0VAclLpdM!/ ?1dmy¤t=true&urile=wcm%3Apath%3A%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Ffood-defense-and-emergency-response%2Fpreparation-and-prevention%2Fguidance-documents%2Fguidance-documents
- **FSIS Guidelines “Keep America’s Food Safe”** at http://www.fsis.usda.gov/wps/portal/frame-redirect?url=/wps/wcm/connect/FSIS-Content/fsis-questionable-content/security-guidelines/keep-americas-food-safe/CT_Index.

This guidance is designed to assist transporters, warehouses, distributors, retailers, and restaurants with enhancing their security programs to further protect the food supply from contamination due to criminal or terrorist acts.

- **FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products** at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-and-emergency-response/preparation-and-prevention/guidance-documents/guidance-documents>.

This guidance contains recommendations to ensure the security of food products through all phases of the distribution process.

Additional information on FSIS food security guidance publications is available over the Internet at <http://www.fsis.usda.gov>.

Industry Publications:

- **National Restaurant Association.** Information for restaurants can be found on the National Restaurant Association's web page at <http://www.restaurant.org>.
 - **Food Marketing Institute (FMI) Security Information and Resources** web page at <http://www.fmi.org/foodsafety/> provides access to security information and guidelines targeted specifically to food retailers.
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Guidance on Responding to Food Emergencies:

- Centers for Disease Control and Prevention (CDC) Emergency Preparedness and Response information can be found at <http://www.bt.cdc.gov/>.
- USDA – Food and Nutrition Service food emergency publication, **Responding to a Food Recall** at <http://fsrio.nal.usda.gov/emergency-preparedness-and-management/response/foodservice-and-retail>.

FDA's Office of Emergency Operations at 301-443-1240 for FDA regulated products and FSIS Technical Service Center at 1-800-233-3935 for USDA regulated products.

Food Defense and Emergency Guidance of Interest to Schools:

- **A Biosecurity Checklist for School Foodservice: Developing a Biosecurity Management Plan**

The document is from the USDA – Food and Nutrition Service and provides information for school food service managers. It can be found at <http://fsrio.nal.usda.gov/emergency-preparedness-and-management/prevention-and-preparation/foodservice-and-retail>. The exact link to the checklist is <http://healthymeals.nal.usda.gov/hsmrs/biosecurity.pdf> . Currently the checklist is only available in an electronic format.

- USDA – Food and Nutrition Service food emergency publication, **Emergency Readiness Plan: A Guide for the School Foodservice Operation** at: <http://fsrio.nal.usda.gov/emergency-preparedness-and-management/prevention-and-preparation/foodservice-and-retail>
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Defense Guidance of Interest to Consumers:

- **Food Safety and Security: What Consumers Need to Know**, at <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/emergency-preparedness/food-safety-and-security-what-consumers-need-to-know> .
- **Food Tampering: An Extra Ounce of Caution**, at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079137.htm>

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3 *Public Health Reasons/ Administrative Guidelines*

CHAPTER 1	PURPOSE AND DEFINITIONS
CHAPTER 2	MANAGEMENT AND PERSONNEL
CHAPTER 3	FOOD
CHAPTER 4	EQUIPMENT, UTENSILS, AND LINENS
CHAPTER 5	WATER, PLUMBING, AND WASTE
CHAPTER 6	PHYSICAL FACILITIES
CHAPTER 7	POISONOUS OR TOXIC MATERIALS
CHAPTER 8	COMPLIANCE AND ENFORCEMENT

Chapter 1 Purpose and Definitions

Applicability and Terms Defined	1-201.10	Statement of Application and Listing of Terms.
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(B) *Terms Defined*

The individual definitions in Chapter 1 are not numbered, consistent with current conventions regarding the use of plain language in drafting rules, and with use in national and international standards and some Federal regulations. This facilitates making changes to the definitions as they become necessary in subsequent editions of the Food Code. The intent of the definitions to be binding in terms of the application and interpretation of the Code is clearly stated in Chapter 1.

Accredited Program.

Refer to the definition for Accredited Program in ¶1-201.10 (B)(3).

Food protection manager *certification* occurs when *individuals* demonstrate through a certification program that they have met specified food safety knowledge standards.

Food protection certification program *accreditation* occurs when *certification organizations* demonstrate through an accreditation program that they have met specified program standards.

Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an

accrediting agency based upon the certifying organization's meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection.

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standards for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food Protection, 2792 Miramar Lane, Lincoln, CA 95648 and found at <http://www.foodprotect.org/>

Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Egg.

The definition of egg includes avian species' shell eggs known to be commercially marketed in the United States. Also included are the eggs of quail and ratites such as ostrich.

Not included are baluts. Baluts are considered a delicacy among Philippine and Vietnamese populations. They are derived from fertile eggs, typically duck eggs, subjected to incubation temperatures for a period of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell. Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as eggs under the EPIA.

In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C (108.5°F) in incubators with a relatively high humidity. (Complete development and hatching would take place in 28 days.) Under these conditions, the potential for growth of transovarian *Salmonella* organisms such as *S. Enteritidis* within the shell, and the potential for an increase in pathogenic microflora on the shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may only be 14 days at an incubation temperature of 37°C (99°F). A balut is a time/temperature control for safety food subject to time/temperature management including proper cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator eggs are available for sale in some parts of the southern United States. In restaurants, the menu item “Alligator Eggs” is sometimes made of alligator egg, but other times is simply a fanciful name for a menu item that may include seafood items such as shrimp, but contains no alligator egg.

Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback, Hawksbill, Kemp’s Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

Food establishment and food processing plant.

Food Establishment and a food processing plant located within the same premises of a food establishment

Some food businesses perform operations that provide food directly to consumers as a “Food Establishment,” and also supply food to other business entities as a “Food Processing Plant.” Within such a business, those operations that provide food directly to consumers only should be considered part of a “Food Establishment” for the purposes of applying the Food Code while those operations that supply food to other business entities may be subject to other rules and regulations that apply to “Food Processing Plants”. It is essential that the permit holder and persons in charge be aware that regulatory requirements and the appropriate operational practices for “Food Establishments” may differ from those for “Food Processing Plants.”

Some facilities and functions may be subject to different regulatory requirements depending on whether that facility or function is regulated as a “Food Establishment” or as a “Food Processing Plant”, or both. Those facilities and functions within a business that are shared by both the “Food Establishment” and “Food Processing Plant” operations, e.g., refrigeration units, dressing room and toilet facilities, food equipment, water and waste systems, pest control, might be subject to similar regulatory requirements. The Food Code is intended to apply to “food establishments”.

Packaged.

The definition of “packaged” was revised in (2) to clarify when foods packaged at retail need not be labeled.

Refer to Public Health Reasons for Food Labels §3-602.11.

Time/Temperature Control for Safety Food

Time Temperature Control for Safety Food (TCS) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether slow or rapid.

The definition of TCS food takes into consideration pH, a_w , pH and a_w interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the a_w value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and a_w may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or a_w values are unable to control or eliminate bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting.

In determining if time/temperature control is required, combination products present their own challenge. A combination product is one in which there are two or more distinct food components and an interface between the two components may have a different property than either of the individual components. A determination must be made about whether the food has distinct components such as pie with meringue topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a TCS food.

A well designed inoculation study or other published scientific research should be used to determine whether a food can be held without time/temperature control when:

- process technologies other than heat are applied to destroy foodborne pathogens (e.g., irradiation, high pressure processing, pulsed light, ozonation);
- combination products are prepared; or

- other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt content, antimicrobials) are used to control or eliminate pathogen growth.

Before using Tables A and B in paragraph 1-201.10(B) of the definition for “time/temperature control for safety food” in determining whether a food requires time/temperature control for safety (TCS), answers to the following questions should be considered:

- Is the intent to hold the food without using time or temperature control?
 - If the answer is No, no further action is required. The decision tree later in this Annex is not needed to determine if the item is a TCS food.
- Is the food raw, or is the food heat-treated?
- Does the food already require time/temperature control for safety by definition in paragraph 1-201.10(B)?
- Does a product history with sound scientific rationale exist indicating a safe history of use?
- Is the food processed and packaged so that it no longer requires TCS such as ultra high temperature (UHT) creamers or shelf-stable canned goods?
- What is the pH and a_w of the food in question using an independent laboratory and Association of Official Analytical Chemists (AOAC) methods of analysis?

A food designated as product assessment required (PA), in either table should be considered TCS Food until further study proves otherwise. The PA means that based on the food’s pH and a_w and whether it was raw or heat-treated or packaged, it has to be considered TCS until inoculation studies or some other acceptable evidence shows that the food is a TCS food or not. The Food Code requires a variance request to the regulatory authority with the evidence that the food does not require time/temperature control for safety.

The Food Code definition designates certain raw plant foods as TCS food because they have been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these designations are supported by Tables A and B. For example:

For cut cantaloupe (pH 6.2-7.1, $a_w > 0.99$, not heat-treated), fresh sprouts (pH > 6.5 , $a_w > 0.99$, not heat-treated), and cut tomatoes (pH 4.23 – 5.04, $a_w > 0.99$, not heat-treated), Table B indicates that they are considered TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for TCS food will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor enhancement, a variance is required under ¶ 3-502.11(C). A HACCP plan is required whether the food is a TCS food as in subparagraph 3-502.11(C)(1) or not a TCS food, as in subparagraph 3-502.11(C)(2). A standardized recipe validated by lab testing for pH and a_w would be an appropriate part of the variance request with annual (or other frequency as specified by the regulatory authority) samples tested to verify compliance with the conditions of the variance.

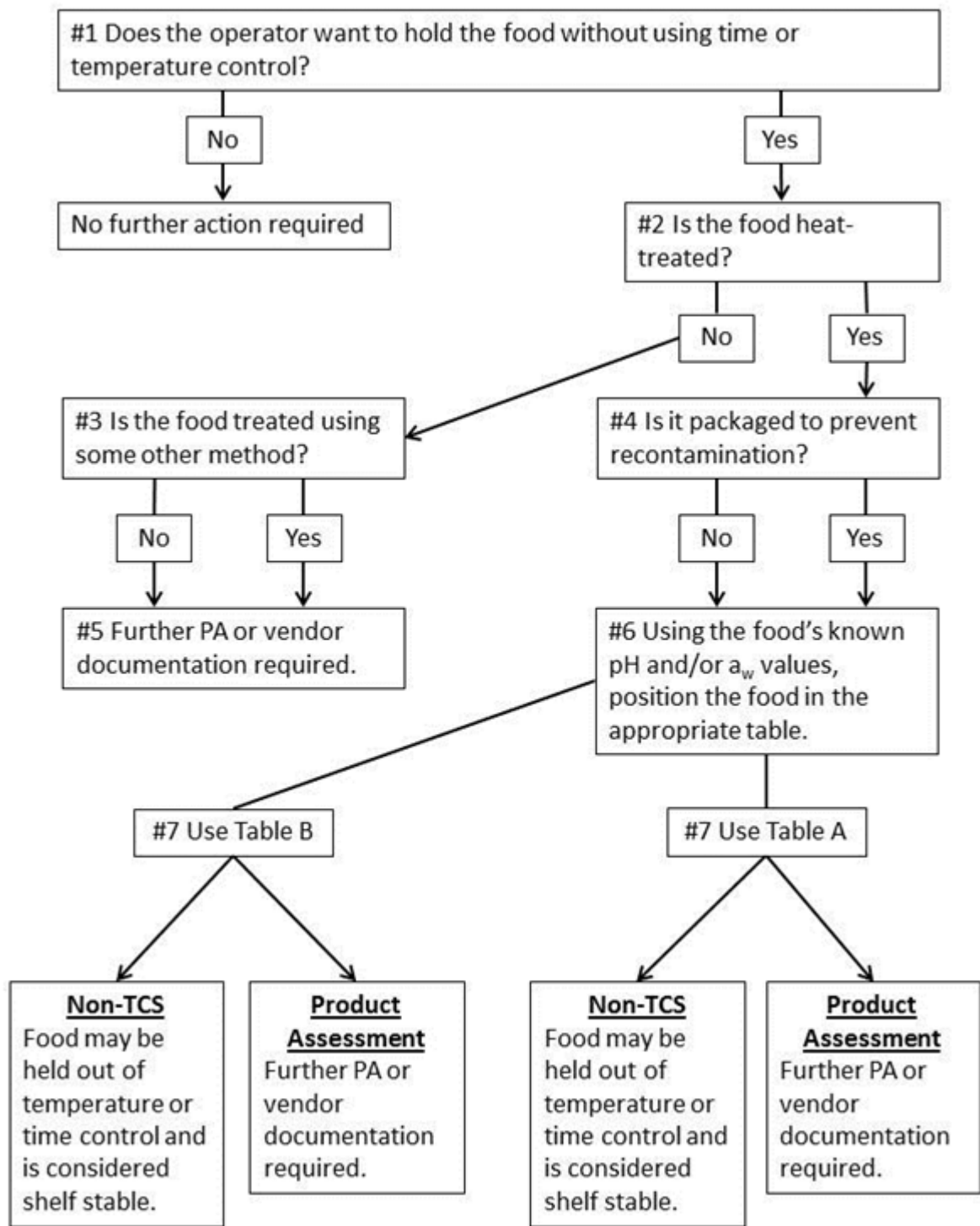
More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at <http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm>

Instructions for using the following Decision Tree and Table A and Table B:

1. Does the operator want to hold the food without using time or temperature control?
 - a. No – Continue holding the food at $\leq 5^{\circ}\text{C}$ (41°F) or $\geq 57^{\circ}\text{C}$ (135°F) for safety and/or quality.
 - b. Yes – Continue using the decision tree to identify which table to use to determine whether time/temperature control for safety (TCS) is required.
2. Is the food heat-treated?
 - a. No – The food is either raw, partially cooked (not cooked to the temperature specified in section 3-401.11 of the Food Code) or treated with some other method other than heat. Proceed to step #3.
 - b. Yes – If the food is heat-treated to the required temperature for that food as specified under section 3-401.11 of the Food Code, vegetative cells will be destroyed although spores will survive. Proceed to step #4.
3. Is the food treated using some other method?
 - a. No – The food is raw or has only received a partial cook allowing vegetative cells and spores to survive. Proceed to step #6.
 - b. Yes – If a method other than heat is used to destroy pathogens such as irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the effectiveness of the process needs to be validated by inoculation studies or other means. Proceed to step #5.
4. Is it packaged to prevent re-contamination?
 - a. No – Re-contamination of the product can occur after heat treatment because it is not packaged. Proceed to step #6.
 - b. Yes – If the food is packaged immediately after heat treatment to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because spore-forming bacteria are the only microbial hazard. Proceed to step #7.
5. Further product assessment or vendor documentation required.
 - a. The vendor of this product may be able to supply documentation that inoculation studies indicate the food can be safely held without time/temperature control for safety.

- b. Food prepared or processed using new technologies may be held without time/temperature control provided the effectiveness of the use of such technologies is based on a validated inoculation study.
6. Using the food's known pH and/or a_w values, position the food in the appropriate table.
 - a. Choose the column under "pH values" that contains the pH value of the food in question.
 - b. Choose the row under " a_w values" that contains the a_w value of the food in question.
 - c. Note where the row and column intersect to identify whether the food is "non-TCS food" and therefore does not require time/temperature control, or whether further product assessment (PA) is required. Other factors such as redox potential, competitive microorganisms, salt content, or processing methods may allow the product to be held without time/temperature control but an inoculation study is required.
7. Use **Table A** for foods that are heat-treated and packaged **OR** use **Table B** for foods that are not heat-treated or heat-treated but not packaged.
8. Determine if the item is non-TCS or needs further product assessment (PA).

1-201.10(B) Decision Tree #1 – Using pH, a_w , or the Interaction of pH and a_w to Determine if a Food Requires Time/Temperature Control for Safety



1-201.10(B) – Table A and Table B

Table A. Interaction of PH and A_w for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

a_w values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤ 0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

Table B. Interaction of PH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_w values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

Chapter 2 Management and Personnel

Responsibility 2-101.11 Assignment.

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

In cases where a food establishment has several departments on the premises (e.g., a grocery store with deli, seafood, and produce departments) and the regulatory authority has permitted those departments individually as separate food establishments, it may be unnecessary from a food safety standpoint to staff each department with a separate Person in Charge during periods when food is not being prepared, packaged or served. While activities such as moving food products from a refrigerated display case to the walk-in refrigerator, cleaning the floors, or doing inventory when the department is not busy, do take place during these times, a designated Person in Charge for multiple departments or the entire facility can oversee these operations and be ready to take corrective actions if necessary.

Knowledge 2-102.11 Demonstration.

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

The Food Code does not require reporting of uninfected cuts or reporting of covered, protected infected cuts/lesions/boils since no bare hand contact with ready-to-eat (RTE) food is a Code requirement.

2-102.12 Certified Food Protection Manager

The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks and other economic, staffing, cultural and behavioral challenges make it imperative that food protection managers know and control the risk factors that impact the safety of the food they sell or serve. Food protection managers have an important role in formulating policies, verifying food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. A Centers for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not.

FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, in different facility types.

There are a number of state and local agencies that currently mandate food protection manager certification. It is appropriate for State and local agencies, by way of codes and ordinances or by policy to establish criteria for what types of permitted establishments could be exempt from the mandatory manager certification requirement and for determining the conditions under which the minimum number of certified food protection managers must be some number greater than one.

Factors to consider when establishing such criteria include:

- the size and scope of the operation;
- the hours of operation;
- the types of foods sold or served;
- the extent to which food is prepared on site;
- the number of staff,
- type of population served, e.g. highly susceptible or not; and
- the number of meals served.

2-102.20 Food Protection Manager Certification.

Many food protection manager certification programs have shared a desire to have the food manager certificates they issue universally recognized and accepted by others – especially by the increasing number of regulatory authorities that require food manager certification.

Needed has been a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and administration.

After a multi-year effort involving a diversity of stakeholder groups, the Conference for Food Protection (CFP) completed work on its **Standards for Accreditation of Food Protection Manager Certification Programs** found at: <http://www.foodprotect.org/manager-certification/>. In 2002 the Conference entered into a cooperative agreement with the American National Standards Institute (ANSI) to provide independent third-party evaluation and accreditation of certification bodies determined to be in conformance with these Conference standards. ANSI published its first listing of accredited certifiers in 2003.

The Acting Commissioner of the Food and Drug Administration, in his address before the 2004 biennial meeting of the Conference for Food Protection, commended this Conference achievement and encouraged universal acceptance based on the CFP/ANSI accreditation program.

Distributed at this meeting was the following letter addressed to the Conference Chair and signed by the Director of FDA's Center for Food Safety and Applied Nutrition. The letter puts forth the Agency's basis for its support of universal acceptance of food protection manager certifications.

"The 2004 biennial meeting of the **Conference for Food Protection** is a fitting occasion for FDA's Center for Food Safety and Applied Nutrition to commend the Conference for its significant achievements in support of State and local food safety programs.

The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection as a voluntary national organization qualified to develop standards to promote food protection. Conference recommendations contribute to improvements in the model FDA Food Code and help jurisdictions justify, adopt and implement its provisions.

Conference mechanisms involving active participation by representatives of diverse stakeholder groups produce consensus standards of the highest quality. An excellent example is the Conference's **Standards for Accreditation of Food Protection Manager Certification Programs**, and its announcement of the new on-line listing of accredited certifiers of industry food protection managers. Many years in their development, these Conference standards identify the essential components necessary for a credible certification program. Components cover a wide range of requirements such as detailed criteria for exam development and administration, and responsibilities of the certification organization to candidates and the public.

FDA applauds the Conference for this significant achievement, and encourages agencies at all levels of government to accept certificates issued by listed certifiers as meeting their jurisdictions' food safety knowledge and certification requirements. The American National Standards Institute (ANSI) has independently evaluated these certification programs under an agreement with the Conference for Food Protection. Governments and industry widely recognize and respect ANSI as an accrediting organization. ANSI has found certifiers it lists as accredited (<http://www.ansi.org/>) under "conformity assessment" – "personnel certification accreditation" to conform to the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs.****

The Food Code states the person in charge of a food establishment is accountable for developing, carrying out, and enforcing procedures aimed at preventing food-borne illness. Section 2-102.11 states that one means by which a person in charge may demonstrate required knowledge of food safety is through certification as a food protection manager by passing an examination that is part of an accredited program.**

FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANSI means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. The procedure provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.

FDA, along with State, local, tribal, and other Federal agencies and the food industry, share the responsibility for ensuring that our food supply is safe. It is anticipated that this new Conference for Food Protection/ANSI program will lead to enhanced consumer protection, improve the overall level of food safety, and be an important component of a seamless national food safety system."

*The ANSI-CFP Accreditation Program list of accredited organizations utilizing the Conference for Food Protection (CFP) Standards may be viewed on-line by going to:
<https://www.ansica.org/wwwversion2/outside/ALLdirectoryListing.asp?menuID=8&prgID=8&status=4>

** Accredited program does not refer to training functions or educational programs.

Duties**2-103.11 Person in Charge.**

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

When food and other purchased goods are delivered and placed into designated locations within the food establishment during non-operating hours, the Person in Charge must make sure food employees inspect such product and verify that it is from the appropriate supplier, is in the desired condition, and was delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately upon arrival to the food establishment. Distributors contracted by the food establishment are often given a key to allow access into the establishment outside of normal working hours. Upon delivery, all food must be appropriately stored in a safe and secure manner within the food establishment. For example, time/temperature control for safety foods must be stored within refrigeration units and held at temperatures of 41°F or below. Likewise, if the food product is frozen, it must be placed into the freezer.

To minimize the potential for access to the food establishment and the food by an unauthorized person, precautions should be applied overall to the food establishment and especially when access to the facility is made under key access deliveries.

Additional information on food defense can be viewed at:

<http://www.fda.gov/Food/FoodDefense/default.htm>

Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans.

Restaurant and retail food service managers need to be aware of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid cross-contact during food preparation and service. The 2008 Conference of Food Protection (CFP) passed Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of the Person in Charge. Accordingly, the Person in Charge's Duties under paragraph (M) were amended to assure the food safety training of employees includes food allergy awareness in order for them to safely perform duties related to food allergies.

Paragraph (M) "EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties" allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

Paragraph (N) emphasizes the important role the Person in Charge (PIC) has in making sure employees properly report certain information about their health status as it relates to diseases that are transmitted by food. In an effort to reinforce dialogue between food employees and the PIC, there must be a way to verify that food employees and conditional employees are informed of their responsibility to report such information. Examples of ways to verify that employees have been appropriately informed include:

- The ability to provide documentation that all food employees and conditional employees are informed of their responsibility to report to management, such as completion of Form 1-B, "Conditional Employees or Food Employees Reporting Agreement" in Annex 7 or other similar state or local forms containing the same information;
- Presenting evidence such as curriculum and attendance rosters documenting that each employee has completed a training program which includes all the information required for reporting in Form 1-B;
- Implementation of an employee health policy that includes a system of employee notification using a combination of training, signs, pocket cards or other means to convey all the required information (Refer to Annex 3, 2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201, for further guidance);

- Other methods that satisfactorily demonstrate that all food employees and conditional employees are informed of their responsibility to report to the PIC information about their health and activities as it relates to diseases that are transmissible through food, as specified under ¶2-201.11 (A)

In various places throughout the Code, it is specified that either written operating procedures or operational plans be developed. The link between management responsibility for developing and implementing the procedures or plans is now established as a new duty for the Person in Charge (PIC). This new provision does not establish new requirements in the development of plans or procedures; rather it emphasizes the importance of the role the PIC plays in ensuring active managerial control of the food establishment with the development and implementation of plans and/or procedures as specified in this Code. Examples of Code provisions that call for the development of plans or procedures can be found in: §2-501.11, ¶¶3-301.11(D) and 3-401.14 (F), §§ 3-501.19, and 5-205.14. Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. There are many tools that industry can use to develop an effective system to achieve active managerial control of foodborne illness risk factors. An important tool in controlling risk factors inherent in a food establishment is the development and implementation of written procedures or plans.

(Also refer to Annex 4 – Management of Food Safety Practices (1) (D) for further information).

2-2 Employee Health

Overall goals

The purpose of this section of the Food Code is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food employees into food. The agents of concern are known to be readily transmissible via food that has been contaminated by ill food employees, and so for that reason, are the primary focus of the Employee Health section of the Food Code. However, there are different levels of risk associated with different levels of clinical illness. The structure of the restrictions and exclusions has, therefore, been designed in a tiered fashion depending on the clinical situation to offer the maximum protection to public health with the minimal disruption to employees and employers.

Four levels of illness or potential illness have been identified with the first level being the highest potential risk to public health and the fourth level being the lowest. The first level relates to employees who have specific symptoms (e.g., vomiting, diarrhea, jaundice) while in the workplace. These symptoms are known to be associated commonly with the agents most likely to be transmitted from infected food employees through contamination of food. The first level also relates to employees who have been diagnosed with typhoid fever or an infection with hepatitis A virus (within 14 days of symptoms). The second level relates to employees who have been diagnosed with the specific agents that are of concern, but who are not exhibiting symptoms of disease because their symptoms have resolved. The third level relates to employees who are diagnosed with the specific agents, but never develop any gastrointestinal symptoms. The fourth level relates to those individuals who are clinically well but who may have been exposed to a listed pathogen and are within the normal incubation period of disease.

The most significant degree of restriction and exclusion applies to the first level of food employee illness. Infected food employees in the first level are likely to be excreting high levels of their infectious pathogen, increasing the chance of transmission to food products, and thus on to those consuming the food. The first level includes food employees who are:

- Experiencing active symptoms of diarrhea or vomiting – with no diagnosis,
- Experiencing jaundice within the last 7 days-- with no diagnosis,
- Diagnosed with typhoid fever,
- Diagnosed with hepatitis A within 7 days of jaundice or 14 days of any symptoms, or
- Experiencing active symptoms of diarrhea or vomiting, and diagnosed with Norovirus, *E. coli* O157:H7 or other Shiga toxin-producing *Escherichia coli* (STEC), *Shigella* spp. infection, or nontyphoidal *Salmonella*.

Diagnosis with typhoid fever or hepatitis A virus is included in level 1 because employees diagnosed with these pathogens are likely to be shedding high levels of the pathogen in their stool without exhibiting gastrointestinal symptoms. Peak levels of hepatitis A viral shedding in the feces typically occurs before symptoms appear. Diarrhea and vomiting are reliable indicators of infection with Norovirus, *E. coli* O157:H7 or other STEC, and *Shigella* spp., but are not typical symptoms of typhoid fever or hepatitis A. For example, employees diagnosed with typhoid fever are more likely to experience constipation, rather than diarrhea. Jaundice is also not always reliable as an indicator of a hepatitis A infection because employees can be infected with hepatitis A virus without experiencing jaundice (anicteric employees). Dark urine and light colored stool may be an indicator of a hepatitis A infection but may go unreported.

Maximum protection to public health requires excluding food employees suffering from typhoid fever, hepatitis A virus, or specific gastrointestinal symptoms associated with diseases identified as likely to be transmitted through contamination of food (See section 2-201.12, Tables 2-201.12 #1a and #1b in this Annex). This situation describes the highest level of risk in transmitting pathogens to food, or what we would find in the first level.

Food employees who have been diagnosed with one of the agents of concern, but are not symptomatic because their symptoms have resolved, are still likely to be carrying the infected agent in their intestinal tract. This makes such employees less likely to spread the agent into food than others who are actually symptomatic, but employees diagnosed with one of the agents of concern still pose an elevated threat to public health. For this reason, there are a series of exclusions (if the employees work in facilities serving highly susceptible populations (HSP)) and restrictions (for non-HSP facilities) depending on the agent involved (See section 2-201.12, Table #2). This situation describes the second level of risk in transmitting pathogens to food.

Diagnosed, asymptomatic food employees who never develop symptoms are typically identified during a foodborne illness outbreak investigation through microbiological testing. If infected and asymptomatic employees are not microbiologically tested, they will remain undetected and could therefore extend the duration of a foodborne illness outbreak through continued contamination of food. The Food Code provides restriction or exclusion guidelines for employees that are identified through microbiological testing with an infection from a listed foodborne pathogen, but are otherwise asymptomatic and clinically well (See section 2-201.12, Table #3). The exclusion or restriction guidelines are applied until the identified food employees no longer present a risk for foodborne pathogen transmission. This situation describes the third level of risk in transmitting pathogens to food.

Some food employees or conditional employees may report a possible exposure to an agent. For example, a food employee may have attended a function at which the food employee ate food that was associated with an outbreak of shigellosis, but the employee remains well. Such individuals fall into the category of having had a potential exposure and present a lower risk to public health than someone who is either symptomatic or who has a definitive diagnosis. They present a level of risk to public health that is greater than if they had not had the exposure. The approach taken in the Food Code to food employees who have had a potential exposure is based on the incubation times (time between exposure and the onset of symptoms) of the various agents. The times chosen for restriction are the upper end of the average incubation periods for the specific agents. The Food Code provides restriction guidelines for food employees working in facilities serving a HSP. The reasoning is that this will restrict food employees only up to the time when it is unlikely they will develop symptoms. As a further protection to public health, it is recommended that such exposed food employees working in facilities not serving a HSP pay particular attention to personal hygiene and report the onset of any symptoms (See section 2-201.12, Table #4). This situation describes the fourth level of risk in transmitting pathogens to food.

This structured approach has linked the degree of exclusion and restriction to the degree of risk that an infected food employee will transmit an agent of concern into food. The approach strikes a balance between protecting public health and the needs of the food employee and employer.

The Food Code provisions related to employee health are aimed at removing highly infectious food employees from the work place. They were developed with recognition of the characteristics of the six important pathogens, and of the risk of disease transmission associated with symptomatic and asymptomatic shedders. The provisions also account for the increased risk associated with serving food to HSP's and the need to provide extra protection to those populations.

The Employee Health section was developed and revised with assistance and input from the Centers for Disease Control and Prevention (CDC) and the U.S. Equal Employment Opportunity Commission (EEOC). The exclusion and restriction criteria are based on communicable disease information, as required by the Americans with Disabilities Act of 1990, in the list of Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens posted on CDC's website, and from the Control of Communicable Diseases Manual, 19th Ed., David L. Heymann, MD, Editor, by the American Public Health Association, Washington D.C., 2008.

2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201

The information provided in Subpart 2-201 is designed to assist food establishment managers and regulatory officials in removing infected food employees when they are at greatest risk of transmitting foodborne pathogens to food. Practical applications of the information in Subpart 2-201 by a food establishment manager may involve using Subpart 2-201 as a basis for obtaining information on the health status of food employees and can also be used as a basis in developing and implementing an effective Employee Health Policy. Regulatory officials can benefit by using the information provided below as a basis for determining compliance with Subpart 2-201 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Subpart 2-201 may help to prevent foodborne illness associated with contamination of food by ill or infected food employees. The person in charge and food employees should be familiar with and able to provide the following information through direct dialogue or other means when interviewed by facility managers or regulatory officials. Compliance must be based, however, on first hand observations or information and cannot be based solely on responses from the person in charge to questions regarding hypothetical situations or knowledge of the Food Code. Also, when designing and implementing an employee health policy, the following information should be considered and addressed:

1. Does the establishment have an Employee Health Policy? If so, are the food employees aware of the employee health policy, and is it available in written format and readily available for food employees? (Note: A written Employee Health Policy is not a Food Code requirement unless the facility is operating under a pre-approved alternative procedure specified under ¶3-301.11(E)).
2. Does the establishment require conditional employees and food employees to report certain illnesses, conditions, symptoms, and exposures?
3. Are the reporting requirements explained to all employees?
4. What are the reporting requirements for conditional employees, food employees, and the food establishment manager?
5. Are conditional employees asked if they are experiencing certain symptoms or illnesses upon offer of employment? If so, which symptoms or illnesses?
6. If a food employee reports a diagnosis with one of the 6 listed pathogens in the Food Code, what questions are asked of the food employee? (The first question every food manager should ask a food employee who reports diagnosis with a listed pathogen is if the employee is currently having any symptoms.)
7. Who does the establishment notify when a food employee reports a diagnosis with one of the listed pathogens?
8. What gastrointestinal symptoms would require exclusion of a food employee from the food establishment?
9. What history of exposure is a conditional employee or food employee required to report?
10. If a food employee reports a gastrointestinal symptom, what criteria are used to allow the employee to return to work?

**Responsibilities
and Reporting
Symptoms and
Diagnosis**

2-201.11

**Responsibility of the Person in Charge, Food
Employees, and Conditional Employees.**

Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a listed pathogen, or exposure to a listed pathogen to the person in charge. The person in charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

A conditional employee is a potential food employee to whom a job offer has been made, conditional on responses to subsequent medical questions or examinations. The questions or examinations are designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990. A conditional employee becomes a food employee as soon as the employee begins working, even if only on a restricted basis. When a conditional employee reports a listed diagnosis or symptom, the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met (as specified under section 2-201.13 of the Food Code). When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee (as specified under section 2-201.13 of the Food Code), the conditional employee may then begin working as a food employee.

Reporting Symptoms:

In order to protect the health of consumers and employees, information concerning the health status of conditional employees and food employees must be disclosed to the person in charge. The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. A food employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

The symptoms of vomiting, diarrhea, or jaundice serve as an indication that an individual may be infected with a fecal-oral route pathogen, and is likely to be excreting high levels of the infectious agent. When a food employee is shedding extremely high numbers of a pathogen through the stool or vomitus, there is greater chance of transmitting the pathogen to food products.

Sore throat with fever serves as an indication that the individual may be infected with *Streptococcus pyogenes*. *Streptococcus pyogenes* causes a common infection otherwise known as “streptococcal sore throat” or “strep throat.” Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Previous foodborne episodes with streptococcus sore throat have occurred in contaminated milk and egg products. Food products can be contaminated by infected food employees hands or from nasal discharges. Untreated individuals in uncomplicated cases can be communicable for 10-21 days, and untreated individuals with purulent discharges may be communicable for weeks or months.

Lesions containing pus that may occur on a food employee’s hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing *Staphylococcus aureus* into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing *Staphylococcus aureus* into food.

If a food employee has an infected cut and bandages it and puts on a glove, the employee does not have to report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is required.

Title I of the Americans with Disabilities Act of 1990 (ADA)

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant’s health status.

The ADA also requires that employers provide reasonable accommodation to qualified applicants and employees with disabilities. A reasonable accommodation is a change in the application process, in the way a job is done, or to other parts of the job that enables a person with a disability to have equal employment opportunities. ADA disabilities are serious, long-term conditions. Most people with diseases resulting from the pathogens listed in the Food Code do not have ADA disabilities because these diseases are usually short-term in duration. In addition, the gastrointestinal symptoms listed in the Food Code usually are not long-term and severe enough, in themselves, to be ADA disabilities. Of course, these symptoms may be linked to other conditions that may be serious enough to be ADA disabilities, like Crohn's disease or cancer.

A food employer may exclude any employee under the Food Code upon initially learning that the employee has *Salmonella* Typhi, or has a gastrointestinal symptom listed in the Food Code. The excluded employee may then ask for an ADA reasonable accommodation instead of the exclusion. In response, the employer's first step should be to ask the employee to establish that the employee is disabled by the disease or symptom (or that the symptom is caused by another ADA disability). If the employee successfully proves that the employee has an ADA disability, then the employer may continue to exclude the employee under the Food Code if:

- there is no reasonable accommodation at work that would eliminate the risk of transmitting the disease while also allowing the employee to work in a food handling position, or
- all reasonable accommodations would pose an undue hardship on the employer's business; and
- there is no vacant position **not involving food handling** for which the employee is qualified and to which the employee can be reassigned.

Example 1: A food employee working in the café of a department store informs the employer that the employee has been diagnosed with a disease caused by *Salmonella* Typhi. The employer immediately excludes the employee under the requirements of the Food Code. The employee then establishes that the disease is an ADA disability because it is severe and long-term and the employee requests reasonable accommodation instead of an exclusion. The employer determines that no reasonable accommodation would eliminate the risk of transmitting *Salmonella* Typhi through food and refuses to remove the exclusion. However, there is a vacant clerical position in another part of the store for which the employee is qualified. Unless the employer can establish that reassigning the employee to this position would be an undue hardship, the employer's failure to make the reassignment instead of continuing the exclusion would be a violation of the ADA.¹

¹ Whether or not the employee in question is an individual with an ADA disability, in those jurisdictions where the Code is adopted, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

Example 2: A food employee has diarrhea and is excluded. The employee establishes that the diarrhea is caused by Crohn's disease. This employee also establishes a serious longstanding history of Crohn's disease and is an individual with an ADA disability. Crohn's disease is not a communicable disease and cannot be transmitted through food. No reasonable accommodation is needed to eliminate the risk of transmitting the disease through the food supply, so the Food Code exclusion should be removed. Of course, the Food Code's provisions on personal cleanliness for hands and arms apply as usual, requiring employees to clean hands and exposed portions of arms after using the toilet room and in other specified circumstances (Subpart 2-301).

Somewhat different rules apply to conditional employees. If a conditional employee reports a disease or symptom listed in the Food Code and shows that the disease or symptom makes the conditional employee an individual with an ADA disability, the employer may withdraw the job offer only if:

- The job involves food handling; and
- The employer determines that either there is no reasonable accommodation that would eliminate the risk of transmitting the disease through food, or any such accommodation would be an undue hardship to the business.
- There is no need to offer the conditional employee a vacant position not involving food handling as a reasonable accommodation.

It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in Annex 2 that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission. See the Equal Employment Opportunity Commission's *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, found at http://www.eeoc.gov/facts/restaurant_guide.html or http://www.eeoc.gov/facts/restaurant_guide_summary.html for detailed information about the interaction between the FDA Food Code and the ADA.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease that can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness. Applicants, to whom a conditional offer of employment is extended, and food employees are required to report their specific history of exposure, medical symptoms, and previous illnesses.

The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

Section 103 (d) of the Americans with Disabilities Act of 1990, Public Law 101–336, requires the Secretary to publish a list of infectious and communicable diseases that are transmitted through handling the food supply and to review and update the list annually. The CDC published on its website in November 2012 a list of Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens. See the list at <http://www.cdc.gov/foodsafety/food-safety-office.html#food>

The final list has been reviewed in light of new information and has been revised as set forth below.

Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens

Some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine or jaundice. The failure of food-handlers to wash hands in certain situations (such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors in the spread of these pathogens.

Some pathogens usually cause disease when food is intrinsically contaminated or cross-contaminated during production, processing or transportation, but may also be contaminated when prepared by infected persons. Bacterial pathogens in this category often cause disease after bacteria have multiplied in food after it has been kept at improper temperatures permitting their multiplication to an infectious dose. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting these pathogens.

The following represent both types of pathogens that may be transmitted by an infected food handler:

Astroviruses

Bacillus cereus

Campylobacter jejuni

Clostridium perfringens

Cryptosporidium species

Entamoeba histolytica

Enterohemorrhagic *E. coli*

Enterotoxigenic *E. coli*

Giardia intestinalis
Hepatitis A virus
Nontyphoidal *Salmonella*
Noroviruses
Rotaviruses
Salmonella Typhi*
Sapoviruses
Shigella species
Staphylococcus aureus
Streptococcus pyogenes
Taenia solium - cysticercosis
Vibrio cholera

Yersinia enterocolitica

* 1. Kauffmann-White scheme for designation of *Salmonella* serotypes

The 6 Listed Pathogens:

The CDC has designated the 6 organisms listed in the Food Code as having high infectivity via contamination of food by infected food employees. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and/ or the severity of the medical consequences to those who become ill.

The following is taken from information provided in the 19th Edition of Control of Communicable Diseases Manual, the CDC website, and the FDA Bad Bug Book, 2nd Edition, and is provided as background information on pathogen virulence, infectivity, and common symptoms exhibited with infection of each of the 6 listed pathogens.

NOROVIRUS

Noroviruses (genus *Norovirus*, family *Caliciviridae*) are small (27-40 nm), round structured, single-stranded RNA, nonenveloped viruses. They are a genetically diverse group classified into at least five genogroups, designated GI-GV, which are further subdivided into at least 35 genotypes. Noroviruses are recognized as the most common cause of epidemic and sporadic gastroenteritis across all age groups worldwide.

Transmission of norovirus occurs primarily through the fecal-oral route, including direct person-to-person contact and indirect transmission through contaminated food, water, or environmental surfaces. Vomitus-oral transmission can also occur through aerosolization followed by direct ingestion or environmental contamination.

Noroviruses are the leading cause of foodborne illness in the United States. Food handler contact with raw or other ready-to-eat foods is the most common scenario resulting in foodborne norovirus outbreaks. Norovirus contamination of produce and shellfish can also occur during production. Secondary household transmission is common.

Noroviruses are environmentally stable, able to survive both freezing and heating (although not thorough cooking), are resistant to many common chemical disinfectants, and can persist on surfaces for up to 2 weeks. Proper hand hygiene and exclusion of food employees exhibiting symptoms of norovirus disease (i.e., diarrhea or vomiting) are critical for norovirus control.

Incubation Period: In volunteer studies, the range is 10-50 hours. In foodborne norovirus outbreaks, the median incubation period is 33 hours.

Symptoms and Complications: Acute-onset of vomiting, watery non-bloody diarrhea, abdominal cramps, and nausea, or a combination of these symptoms. Low grade fever and body aches may also be associated. Symptoms typically last 24 to 72 hours. Norovirus disease is usually self-limited without any serious long-term sequelae. Among the young and the elderly, dehydration is a common complication. Volunteer studies have found that as many as 30% of individuals infected with norovirus are asymptomatic. There is no specific treatment for norovirus disease. Supportive therapy consists of oral or intravenous rehydration solutions to replace fluid loss and electrolytes. Previous exposure does not provide long-term immunity; thus, individuals may be repeatedly infected throughout their lifetimes.

Infectivity: Noroviruses are highly contagious, and it is thought that an inoculum of as few as 18 viral particles may be sufficient to infect an individual. Although pre-symptomatic shedding may occur, shedding usually begins with onset of symptoms, peaks 4 days after exposure, and may persist for 3 weeks after recovery. However the degree of infectivity of prolonged shedding has not been determined and peak contagiousness is during the acute stage of disease. Peak viral loads in both symptomatic and asymptomatic infections (may be as high as 100 billion viral particles/g feces).

NONTYPHOIDAL SALMONELLA

Caused by serotypes **other than** *S. Typhi* and *S. Paratyphi A*.

Unlike previous editions of the FDA Food Code, the 2013 edition requires food employees to report a diagnosis of nontyphoidal *Salmonella* (NTS), prompts the person in charge to exclude food employees with diagnosis of NTS, and provides conditions for reinstatement of a food employee who provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from NTS, and where appropriate, approval from the regulatory authority

Nontyphoidal *Salmonella* (NTS) *enterica* serotypes are among the most common bacterial cause of foodborne illness. NTS are estimated to cause more than one million domestically acquired foodborne illnesses in the United States each year (Scallan et al. 2011), and are the leading cause of hospitalizations and deaths due to foodborne illness in the United States (Barton-Behravesh et al. 2011, CDC 2011). Whereas reductions in incidence have been achieved for many other foodborne pathogens in recent years, no significant change in incidence of NTS infections has occurred since the start of FoodNet surveillance during 1996–1998 (CDC 2011). Therefore, further interventions are needed to reduce the incidence of NTS infections.

Commercial food establishments are an important setting for the transmission of NTS, both in the form of recognized foodborne disease outbreaks as well as sporadic infections. During 1998 to 2002, the 585 *Salmonella enterica* outbreaks reported to the Centers for Disease Control and Prevention accounted for 49% of all bacterial outbreaks (Lynch et al. 2006). Forty-six percent of *Salmonella* outbreaks occurred in restaurant/deli establishments, the most common setting for *Salmonella* outbreaks (Lynch et al. 2006). For the period of 2009-2010, the 243 *Salmonella* outbreaks reported to the CDC accounted for 51% of bacterial foodborne disease outbreaks. Outbreaks of salmonellosis at commercial food establishments frequently involve direct transmission to patrons from fresh produce or undercooked foods of animal origin, or cross contamination from these foods. However, numerous NTS outbreak investigations have implicated food workers as the source of the outbreak or strongly suggested transmission from food workers (Ethelberg et al. 2004; Greig et al. 2007; Hedberg et al. 1991; Hedican et al. 2009; Hundy and Cameron 2002; Khuri-Bulos et al. 1994; Maguire et al. 2000; Medus et al. 2006; Todd et al 2007a, 2007b).

In a study of restaurant-associated salmonellosis outbreaks in Minnesota published by Medus et al. (2006), the importance of infected food workers as a source of contamination in the outbreaks was supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks. Second, food workers infected with NTS were identified in the majority (83%) of the outbreak investigations. Infected food workers who reported a history of illness shed NTS in the stool for a median of 1 month. The authors concluded that regardless of the original source of a *Salmonella* outbreak in a restaurant (e.g., raw meat or eggs), the initial source of a salmonellosis outbreak, food workers frequently serve as reservoirs for NTS and contribute to transmission to patrons. Thus, assessment of food worker history, i.e., symptoms and exposures, testing of stool samples and exclusion or restriction of infected food workers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

In a study of food workers with salmonellosis who were detected through routine surveillance (Medus et al. 2010), 2.2% of identified culture-confirmed *Salmonella* cases were food workers, and identification of these cases were critical to the identification of numerous outbreaks. The authors concluded that the rapid identification and follow-up of food workers among reported cases of salmonellosis is important to the early detection and control of outbreaks in restaurant settings. Importantly, even hostesses, servers, bartenders, and others who theoretically have limited food preparation duties can serve as sentinels of transmission within the restaurant. The authors also stated that food workers should be considered an important source of *Salmonella* transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to *Salmonella*-like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties.

The biology of NTS and the epidemiology of salmonellosis are complex; food workers may be an underappreciated part of that complexity. In order to decrease the incidence of NTS infections in the United States, commercial food establishments should also be targets for more focused prevention measures, and prevention and control efforts should consider food workers as an important source of NTS transmission.

General Description:

Nontyphoidal *Salmonella* (NTS) *enterica* are bacteria that cause a diarrheal illness called salmonellosis. NTS are among the most common and important causes of enteric disease. An estimated 1.2 million cases occur annually in the United States; of these, approximately 42,000 are culture-confirmed cases reported to the Centers for Disease Control and Prevention.

Salmonella lives in the intestines of animals or humans. It can be found in water, food, soil, or surfaces that have been contaminated with the feces of infected animals or humans. People can become infected with *Salmonella* by:

- Eating foods contaminated with the bacteria. Contaminated foods are often of animal origin, such as beef, poultry, unpasteurized milk, or eggs. Fruits and vegetables may also be contaminated. Any food can be contaminated by an infected food handler.
- Contacting farm animals or pets (including reptiles, amphibians, chicks, and ducklings), animal feces, or animal environments.
- Touching contaminated surfaces or objects and then touching ones mouth or putting a contaminated object into ones mouth.
- Drinking contaminated water.

Most infections are thought to be acquired through consumption of contaminated food.

Incubation Period:

Symptoms often begin 12 to 72 hours after being exposed to the bacteria, although it can take up to a week or more for symptoms to develop in some people.

Symptoms and Complications:

Symptoms of salmonellosis include diarrhea, abdominal cramps, and fever. The illness usually lasts 4 to 7 days. Persons with NTS infections usually recover without treatment. However, in approximately 20% of persons, the illness is so severe that hospitalization is required. In these patients the NTS infection may spread from the intestine to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. An estimated 400 fatal cases of salmonellosis occur each year. A small number of persons experience long-term consequences from NTS infections, such as arthritis that can last for months or years.

Antibiotic treatment for salmonellosis is generally not indicated for typical intestinal illness. Antibiotics typically do not shorten the duration of illness or eliminate the carrier state. However, antibiotic treatment is recommended for persons who develop invasive (extraintestinal) infections, infants under 2 months of age, the elderly, or those who have certain underlying medical conditions that predispose them to invasive infection.

Infectivity:

The minimum infectious dose of NTS for humans is generally described as 100 to 1,000 organisms. However, doses of fewer than 10 organisms have caused illness in multiple outbreaks. Persistence of NTS in the stool after the acute phase of illness is a well described consequence of NTS infections. This persistence is often referred to as a temporary carrier state, and the term “shedding” is used to describe the excretion of *Salmonella* in the stool.

Studies have consistently shown that the median duration of shedding in the stool to be 4 to 5 weeks after onset of acute gastroenteritis. Persons who have been exposed to NTS but who never develop symptoms can also be temporary carriers of NTS; these persons shed NTS for a shorter period of time than persons who experienced illness. Carriers of NTS are known to shed the bacteria in the stool intermittently. Treatment with antimicrobials does not eradicate NTS from stool and may actually prolong the duration of shedding.

SALMONELLA TYPHI

Salmonella enterica subspecies *enterica* serovar Typhi (commonly *S. Typhi*) causes a systemic bacterial disease, with humans as the only host. This disease is relatively rare in the United States, with fewer than 500 sporadic cases occurring annually in the U.S. Worldwide, the annual estimated incidence of typhoid fever is about 17 million cases with approximately 600,000 deaths. Currently, most cases of **S. Typhi** in industrialized nations are imported into the country from developing countries. Antibiotic-resistant strains have become prevalent in several areas of the world.

Incubation period: Generally 1 to 3 weeks, but may be as long as 2 months after exposure.

Symptoms and Complications: High fever, from 103° to 104°F; lethargy; gastrointestinal symptoms, including abdominal pains and diarrhea or constipation; headache; achiness; loss of appetite. A rash of flat, rose-colored spots sometimes occurs. Septicemia, with colonization of other tissues and organs; e.g., may lead to endocarditis. Septic arthritis may occur, in which the infection directly affects the joints and may be difficult to treat. Chronic infection of the gallbladder may occur, which may cause the infected person to become a carrier.

Infectivity: The minimal infectious dose is estimated to be less than 1000 bacterial cells. An individual infected with **S. Typhi** is infectious as long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter. About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers.

SHIGA TOXIN-PRODUCING ESCHERICHIA COLI

E. coli O157:H7 is the most commonly identified serotype of Shiga toxin-producing **Escherichia coli** (STEC) as a cause of foodborne illness in the United States. **E. coli** O157:H7 is a zoonotic disease derived from cattle and other ruminants. However, **E. coli** O157:H7 also readily transmits from person-to-person, so contaminated raw ingredients and ill food employees both can be sources of foodborne disease. Other STEC serotypes have been identified as a source of foodborne illness in the United States, however not as frequently as **E. coli** O157:H7. The other serogroups most commonly implicated as a cause of foodborne illness in the United States are O26, O111, O103, O45, and O121.

The Food Code definition of STEC covers all **E. coli** identified in clinical laboratories that produce Shiga toxins. Nearly 200 O:H combinations of **E. coli** have been shown to produce Shiga toxins. The Food Code definition includes all STEC, including those that have not been specifically implicated in human disease such as hemorrhagic colitis (i.e., bloody diarrhea) or hemolytic uremic syndrome (HUS). Infections with STEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). [Note: “enterohemorrhagic” (EHEC) is a subset of STEC that has the capacity to both produce Shiga toxin and cause “attaching and effacing” lesions in the intestine.]

Incubation period: Symptoms usually begin 3 to 4 days after exposure, but the time may range from 1 to 9 days.

Symptoms and Complications: Hemorrhagic colitis is characterized by severe cramping (abdominal pain), nausea or vomiting, and diarrhea that initially is watery, but becomes grossly bloody. In some cases, the diarrhea may be extreme, appearing to consist entirely of blood and occurring every 15 to 30 minutes. Fever typically is low-grade or absent. Infections from EHEC may range from asymptomatic to mild diarrhea to severe, life threatening complications (e.g., hemorrhagic colitis, hemolytic uremic syndrome)). About 3% to 7% STEC infections progress to HUS .

Infectivity: The infective dose of E. coli O157:H7 is estimated to be very low, in the range of 10 to 100 cells. Children under 5 years old are most frequently diagnosed with infection and are at greatest risk of developing HUS. The elderly also experience a greater risk of complications. The duration of excretion of STEC in the stool is typically 1 week or less in adults, but can be up to 3 weeks or longer in one-third of infected children.

SHIGELLA SPP.

Causes an acute bacterial disease, known as shigellosis, and primarily occurs in humans, but also occurs in other primates such as monkeys and chimpanzees. An estimated 300,000 cases of shigellosis occur annually in the U.S. *Shigella* spp. consist of 4 species or serogroups, including *S. flexneri*, *S. boydii*, *S. sonnei*, and *S. dysenteriae*; which all differ in geographical distribution and pathogenicity. *Shigella* spp. are highly infectious and highly virulent. Outbreaks occur in overcrowding conditions, where personal hygiene is poor, including in institutions, such as prisons, mental hospitals, day care centers, and refugee camps, and also among men who have sex with men. Water and RTE foods contaminated by feces, frequently from food employees' hands, are common causes of disease transmission. Multidrug-resistant *Shigella* (including *S. dysenteriae* type 1) have appeared worldwide. Concern over increasing antimicrobial resistance has led to reduced use of antimicrobial therapy in treating shigellosis.

Incubation period: Eight to 50 hours.

Symptoms and Complications: Abdominal pain, diarrhea, fever, nausea, and sometimes vomiting, tenesmus, toxemia, and cramps. The stools typically contain blood, pus, or mucus resulting from mucosal ulcerations. The illness is usually self-limited, with an average duration of 5-7 days. Infections are also associated with rectal bleeding, drastic dehydration, and convulsions in young children. The fatality rate for *Shigella dysenteriae* 1 may be as high as 20% among hospitalized cases. Other complications can also occur, such as reactive arthritis, intestinal perforation, and hemolytic uremic syndrome.

Infectivity: The infectious dose for humans is low, with as few as 10 bacterial cells depending on age and condition of the host. Infectivity occurs during acute infection and until the infectious agent is no longer present in feces, usually within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may persist for months or longer.

HEPATITIS A VIRUS

Hepatitis A virus (HAV) is a 27-nanometer picornavirus (positive strand RNA, non-enveloped virus). The hepatitis A virus has been classified as a member of the family *Picornaviridae*. The exact pathogenesis of HAV infection is not understood, but the virus appears to invade from the intestinal tract and is subsequently transported to the liver. The hepatocytes are the site of viral replication and the virus is thought to be shed via the bile.

HAV is most commonly spread by the fecal-oral route through person-to-person contact. Risk factors for reported cases of hepatitis A include personal or sexual contact with another case, illegal drug use, homosexual male sex contact, and travel to an endemic country. Common source outbreaks also can occur through ingestion of water or food that has fecal contamination. However, the source of infection is not identified for approximately 50% of reported cases.

HAV infection is endemic in developing countries, and less common in industrialized countries with good environmental sanitation and hygienic practices. In the developing world, nearly all HAV infections occur in childhood and are asymptomatic or cause a mild illness. As a result, hepatitis A (symptomatic infection with jaundice) is rarely seen in the developing world. More than 90% of adults born in many developing countries are seropositive.

Children play an important role in the transmission of HAV and serve as a source of infection for others, because most children have asymptomatic infections or mild, unrecognized HAV infections. In the United States, the disease is most common among school-aged children and young adults. After correction for under-reporting and undiagnosed infections, an estimated 61,000 HAV infections (includes cases of hepatitis A as well as asymptomatic infections) occurred in 2003.

HAV Immunization: Immune globulin (IG) can be used to provide passive pre-exposure immunoprophylaxis against hepatitis A. Protection is immediately conferred to an exposed individual following administration of IG, and immunity is provided for 3-5 months following inoculation. IG is effective in preventing HAV infection when given as post-exposure immunoprophylaxis, if given within 14 days of exposure. When a food employee with hepatitis A is identified, IG is often given to co-workers. Active immunoprophylaxis using hepatitis A vaccine (a formalin-inactivated, attenuated strain of HAV) has been shown to provide immunity in > 95% of those immunized, with minimal adverse reactions.

Hepatitis A vaccination of food employee has been advocated, but has not been shown to be cost-effective and generally is not recommended in the United States, although it may be appropriate in some communities.

Incubation period: Average 28-30 days (range 15-50 days).

Symptoms and Complications: Illness usually begins with symptoms such as nausea/vomiting, diarrhea, abdominal pain, fever, headache, and/or fatigue. Jaundice, dark urine or light colored stools might be present at onset, or follow illness symptoms within a few days. HAV infection of older children and adults is more likely to cause clinical illness with jaundice (i.e., hepatitis A); onset of illness is usually abrupt. In young adults, 76-97% have symptoms and 40-70% are jaundiced. Jaundice generally occurs 5-7 days after the onset of gastrointestinal symptoms. For asymptomatic infections, evidence of hepatitis may be detectable only through laboratory tests of liver infections such as alanine aminotransferase (ALT) tests. The disease varies in severity from a mild illness to a fulminant hepatitis, ranging from 1-2 weeks to several months in duration. In up to 10-15% of the reported cases, prolonged, relapsing hepatitis for up to 6 months occurs. The degree of severity often increases with age; however, most cases result in complete recovery, without sequelae or recurrence. The reported case fatality rate is 0.1% - 0.3% and can reach 1.8% for adults over 50 years old.

Diagnosis: Diagnosis of HAV infection requires specific serological testing for IgM anti-HAV. IgM anti-HAV becomes undetectable within 6 months of illness onset for most persons; however, some persons can remain IgM anti-HAV positive for years after acute infection. Total anti-HAV (the only other licensed serologic test) can be detected during acute infection but remains positive after recovery and for the remainder of the person's life.

Infectivity: The infective dose of HAV is presumed to be low (10 to 100 viral particles), although the exact dose is unknown. The viral particles are excreted in the feces of ill people (symptomatic and asymptomatic) at high densities (10^6 to 10^8 /gm) and have been demonstrated to be excreted at these levels for up to 36 days post-infection. Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice. Most cases are probably noninfectious after the first week of jaundice. Chronic shedding of HAV in feces has not been reported. HAV is shed at peak levels in the feces, one to two weeks before onset of symptoms, and shedding diminishes rapidly after liver dysfunction or symptoms appear. Liver dysfunction or symptoms occur at the same time circulating antibodies to HAV first appear. Immunity after infection probably lasts for life; immunity after vaccination is estimated to last for at least 20 years.

Reporting History of Exposure:

The reporting requirements for history of exposure are designed to identify employees who may be incubating an infection due to norovirus, *Shigella* spp., *E. coli* O157:H7 or other STEC, typhoid fever, HAV.

Which employees who report exposure are restricted?

- Employees who work in a food establishment serving a highly susceptible population (HSP) facility, except those employees who are exposed to nontyphoidal *Salmonella* (NTS).

Why don't employees who are exposed to nontyphoidal *Salmonella* (NTS) need to be restricted?

- For those employees who are exposed to nontyphoidal *Salmonella*, exposure alone does not necessitate restriction of the employee based on epidemiologic evidence of no increased risk of employees with only a history of exposure versus employees who were infected and diagnosed.

What constitutes exposure?

- Consuming a food that caused illness in another consumer due to infection with Norovirus, *Shigella* spp., *E. coli* O157:H7 or other STEC, typhoid fever, or HAV.
- Attending an event or working in a setting where there is a known disease outbreak.
- Close contact with a household member who is ill and is diagnosed with a listed pathogen.

Why are other guidelines provided, in addition to restriction for employees serving an HSP who report exposure to hepatitis A virus?

- Employees who have had a hepatitis A illness in the past are most likely protected from infection by life-time immunity to hepatitis A infection.
- Immunity developed through immunization or IgG inoculation prevents hepatitis A infection in exposed employees.
- Our standard definition of HSP doesn't apply very well to HAV. Children under 6 years old who become infected with HAV are generally asymptomatic, and while a higher proportion of susceptible elderly who become infected have serious illness, most institutionalized elderly are protected from HAV by prior infection.

What is the period of restriction?

- The period of restriction begins with the most recent time of foodborne or household member exposure and lasts for the usual incubation period of the pathogen as defined in the Control of Communicable Diseases Manual. This is the time that the employee is most likely to begin shedding the pathogen.
 - For norovirus, 48 hours after the most recent exposure
 - For **Shigella** spp., 3 days after the most recent exposure
 - For **E. coli** O157:H7 or other STEC, 3 days after the most recent exposure
 - For typhoid fever (**S. Typhi**), 14 days after the most recent exposure
 - For HAV, 30 days after the most recent exposure

What is the period of restriction when exposed to a diagnosed, ill household member?

- While the household member is symptomatic with an infection due to Norovirus, **Shigella** spp., **E coli** O157:H7 or other STEC, typhoid fever (**S. Typhi**) or HAV;
- Plus during the usual incubation period of the pathogen of concern:
 - For norovirus, symptomatic period plus 48 hours
 - For **Shigella** spp., symptomatic period plus 3 days
 - For **E. coli** O157:H7 or other STEC, symptomatic period plus 3 days
 - For typhoid fever (**S. Typhi**), symptomatic period plus 14 days
 - For HAV, onset of jaundice plus 30 days

What is the appropriate response to a report of exposure to other food employees?

- Employees who report a history of exposure but who do not work in a HSP facility should be reminded of the requirements for reporting illness, avoidance of bare hand contact with RTE foods, and proper hand washing and personal hygiene.

2-201.12 Exclusions and Restrictions.²

Refer to public health reasons for § 2-201.11 for actions to take with conditional employees.

It is necessary to exclude food employees symptomatic with diarrhea, vomiting, or jaundice, or suffering from a disease likely to be transmitted through contamination of food, because of the increased risk that the food being prepared will be contaminated such as with a pathogenic microorganism. However, if the food employee is suffering from vomiting or diarrhea symptoms, and the condition is from a non-infectious condition, Crohn's disease or an illness during early stages of a pregnancy, the risk of transmitting a pathogenic microorganism is minimal. In this case, the food employee may remain working in a full capacity if they can substantiate that the symptom is from a noninfectious condition. The food employee can substantiate this through providing to the person in charge medical documentation or other documentation proving that the symptom is from a noninfectious condition.

Because of the high infectivity (ability to invade and multiply) and/ or virulence (ability to produce severe disease), of typhoid fever (***Salmonella Typhi***) and hepatitis A virus, a food employee diagnosed with an active case of illness caused by either of these two pathogens, whether asymptomatic or symptomatic, must be excluded from food establishments. The exclusion is based on the high infectivity, and/or the severe medical consequences to individuals infected with these organisms. A food employee diagnosed with an active case of illness caused by norovirus, ***Shigella*** spp., STEC, or nontyphoidal ***Salmonella*** (NTS), is excluded if exhibiting symptoms of vomiting and diarrhea, and then allowed to work as the level of risk of pathogen transmission decreases (See section 2-201.12, Tables #1b, #2 and #3).

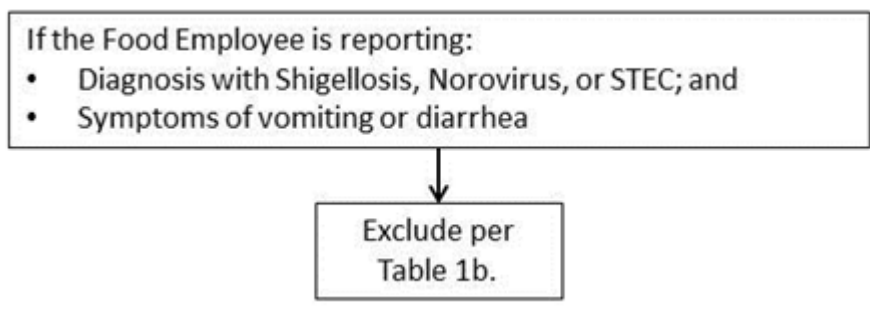
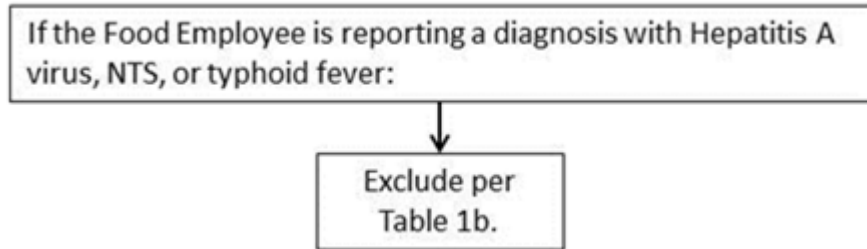
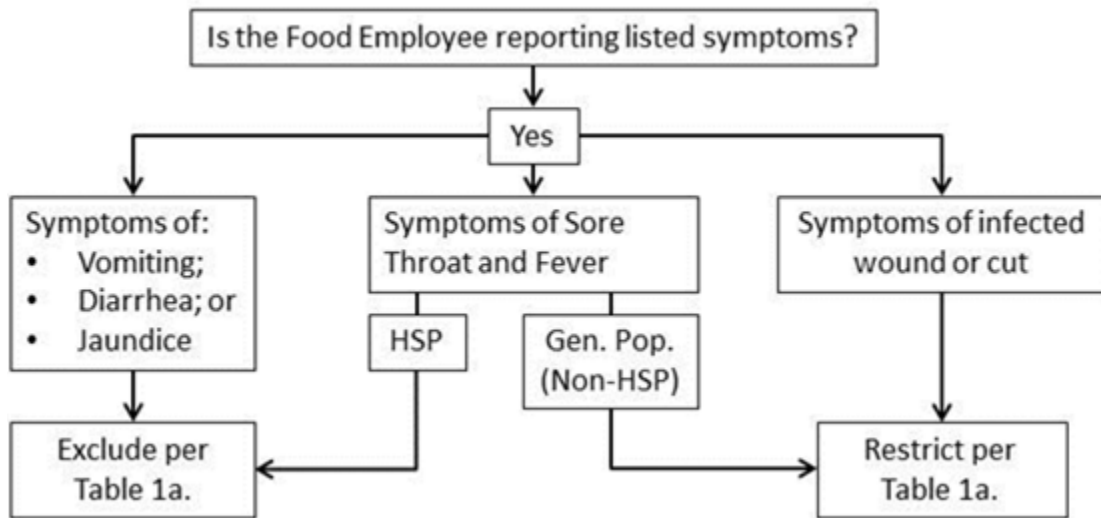
The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed pathogen, but never developed symptoms. The decrease in risk is taken under consideration when excluding and restricting diagnosed food employees and results in a slight difference in the way food employees diagnosed with Norovirus, but asymptomatic with respect to gastrointestinal symptoms are handled (See section 2-201.12, Table #2).

²In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

Restriction of food employees infected with NTS after resolution of symptoms has not been a national standard. However, because of the prolonged duration of shedding of NTS, evidence that food workers have been the source of foodborne outbreaks, evidence that food workers work while ill (Green et al. 2005), and evidence of inadequate hand hygiene practices (Green et al. 2006; US FDA 2004), exclusion or restriction of infected food worker duties is a reasonable public health measure. At a minimum, potential for transmission and how to prevent it should be discussed with the food employee and their manager.

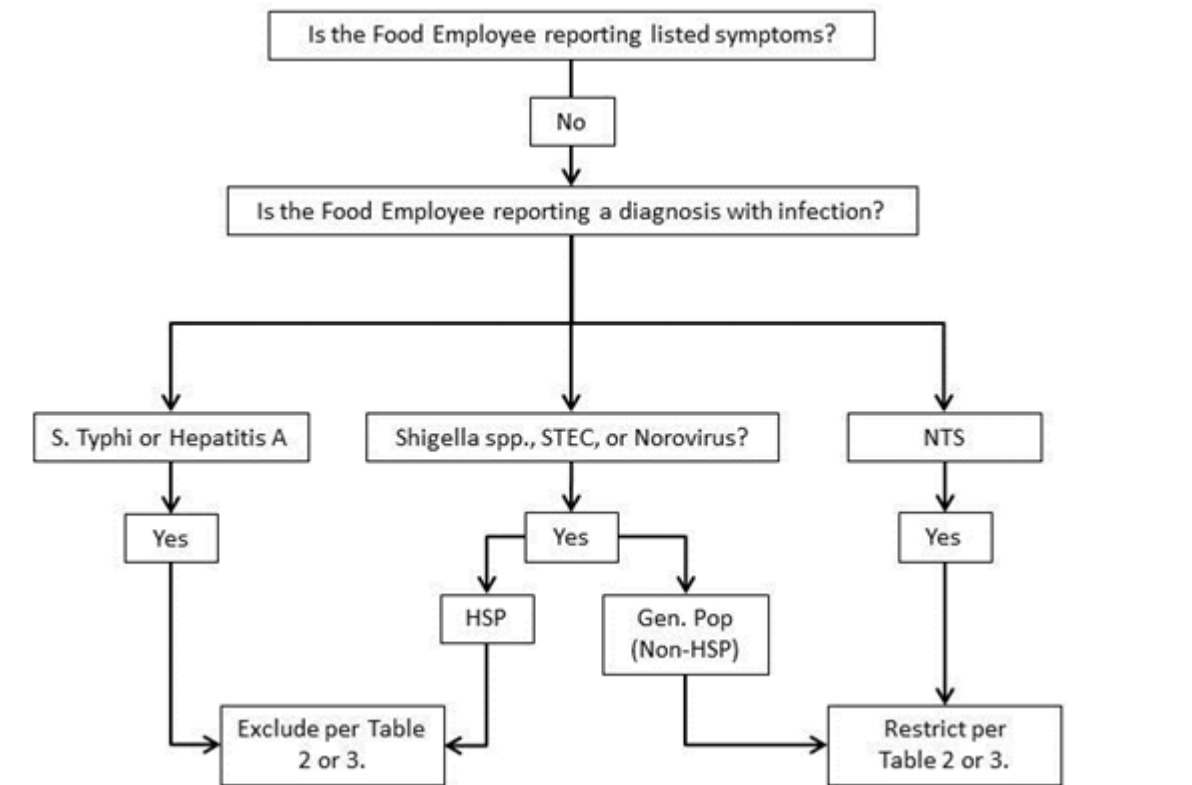
There is no epidemiological evidence of an increased risk of NTS transmission from food employees in highly susceptible populations over the general population. Current evidence suggests that restriction is sufficient in food establishments that serve either highly susceptible populations or the non-highly susceptible populations to control transmission on NTS. Further, events where an infected food handler is involved in nontyphoidal salmonellosis outbreaks in establishments serving highly susceptible populations are much less frequent than those in establishments not serving highly susceptible populations. For example, from 1998-2011, only 41 nontyphoidal salmonellosis outbreaks were reported to CDC that occurred in nursing home facilities and 16 outbreaks in hospitals, compared with 731 outbreaks in restaurants or delis. There are many highly susceptible persons in the general population who eat in regular, non-institutionalized settings. A more restrictive exclusion criteria for establishments serving highly susceptible populations is not warranted at this time.

2-201.11 / 2-201.12 Decision Tree 1. When to Exclude or Restrict a Food Employee Who Reports a Symptom and When to Exclude a Food Employee Who Reports a Diagnosis with Symptoms Under the Food Code



Key: Decision Tree 1
 STEC = Shiga toxin-producing *Escherichia coli*
 HSP = Highly Susceptible Population
 NTS = Nontyphoidal *Salmonella*

2-201.11 / 2-201.12 Decision Tree 2a. When to Exclude or Restrict a Food Employee Who is Asymptomatic and Reports a Listed Diagnosis Under the Food Code



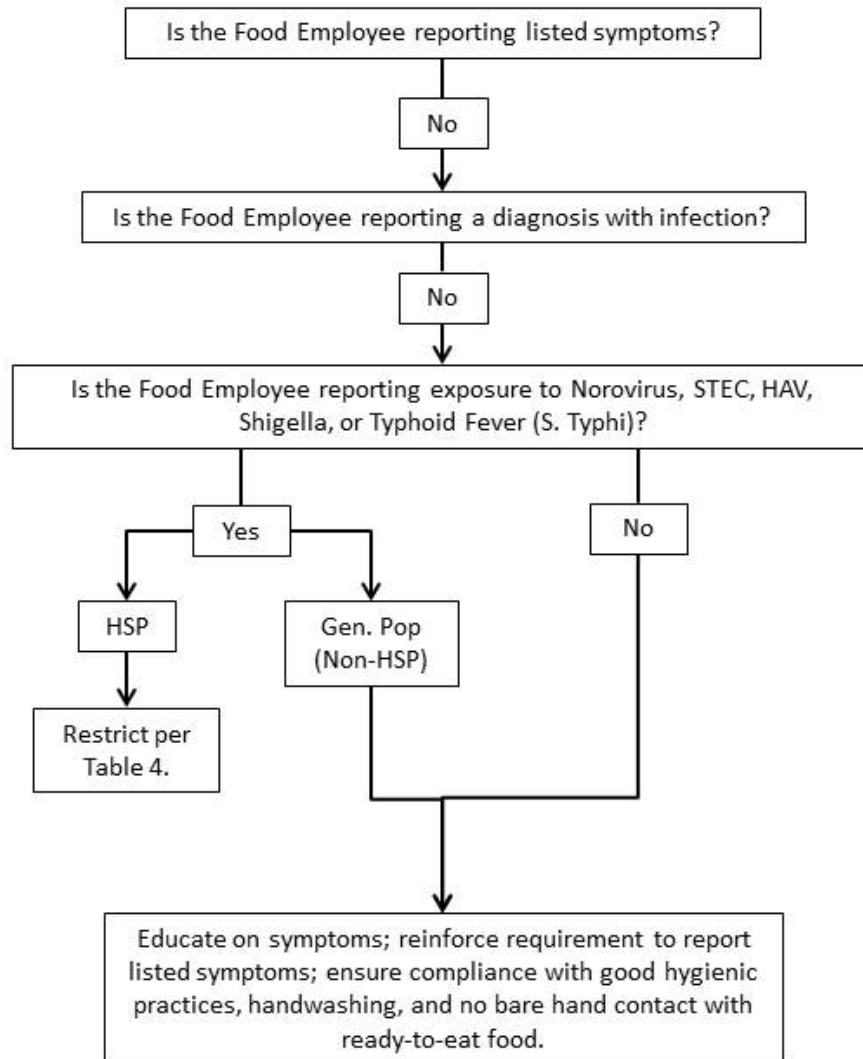
Key: Decision Tree 2a

STEC = Shiga toxin-producing *Escherichia coli*

HSP = Highly Susceptible Population

NTS = Nontyphoidal *Salmonella*

2-201.11 / 2-201.12 Decision Tree 2b. When to Restrict a Food Employee Who Reports a Listed Exposure Under the Food Code



Key: Decision Tree 2b

STEC = Shiga toxin-producing *Escherichia coli*

HAV = Hepatitis A virus

HSP = Highly Susceptible Population

2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Food employees and conditional employees shall report symptoms immediately to the person in charge

The person in charge shall prohibit a conditional employee who reports a listed symptom from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a symptomatic food employee.

Symptom	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not serving an HSP)	Removing Symptomatic Food Employees from Exclusion or Restriction	RA Approval Needed to Return to Work?
Vomiting	EXCLUDE 2-201.12(A)(1)	EXCLUDE 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A)(1). Exceptions: If diagnosed with Norovirus, <i>Shigella</i> spp., STEC, HAV, or typhoid fever (S. Typhi) (see Tables 1b & 2).	No if not diagnosed
Diarrhea	EXCLUDE 2-201.12(A)(1)	EXCLUDE 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A). Exceptions: If Diagnosed with Norovirus, STEC, HAV, or S. Typhi (see Tables 1b & 2).	No if not diagnosed
Jaundice	EXCLUDE 2-201.12(B)(1) if the onset occurred within the last 7 days	EXCLUDE 2-201.12(B)(1) if the onset occurred within the last 7 days	When approval is obtained from the RA 2-201.13 (B), and: <ul style="list-style-type: none"> Food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or Food employee provides medical documentation 2-201.13(B)(3). 	Yes
Sore Throat with Fever	EXCLUDE 2-201.12(G)(1)	RESTRICT 2-201.12(G)(2)	When food employee provides written medical documentation 201.13(G) (1)-(3).	No
Infected wound or pustular boil	RESTRICT 2-201.12(I)	RESTRICT 2-201.12(I)	When the infected wound or boil is properly covered 2-201.13(I)(1)-(3).	No

Key: Table 1a

RA = Regulatory Authority

STEC = Shiga toxin-producing *Escherichia coli*

HAV = Hepatitis A virus

HSP = Highly Susceptible Population

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

Food employees and conditional employees shall report a listed Diagnosis with symptoms immediately to the person in charge

- The person in charge shall notify the RA when a food employee is jaundiced or reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis with symptoms from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed, symptomatic food employee.

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Hepatitis A virus	EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: <ul style="list-style-type: none"> • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (also see Table 2). 	Yes
Typhoid Fever (S. Typhi)	EXCLUDE 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: <ul style="list-style-type: none"> • Food employee provides medical documentation, that states the food employee is free of a S. Typhi infection 2-201.13(C)(2) (also see Table 2). 	Yes (continued)

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Nontyphoidal <i>Salmonella</i>	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	When approval is obtained from the RA 2-201.13(G), and: <ul style="list-style-type: none"> • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal <i>Salmonella</i> infection 2-201.13(G)(1) or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic (2-201.13(G)(2)). 	Yes
STEC	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	<ol style="list-style-type: none"> 1. <u>Serving a non-HSP facility:</u> 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility:</u> 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> <ul style="list-style-type: none"> • Approval is obtained from RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2) (also see Table 2). 	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
<i>Norovirus</i>	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	<ol style="list-style-type: none"> 1. <u>Serving a non-HSP facility:</u> 2-201.13 (A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility:</u> 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> <ul style="list-style-type: none"> • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 2). 	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility (continued)

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
<i>Shigella spp.</i>	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	<ol style="list-style-type: none"> 1. <u>Serving a non-HSP facility:</u> 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility:</u> 2-201.13(A)(3)(b): Remains excluded until meeting the requirements in No. 3. 3. <u>Restriction or Exclusion remains until:</u> <ul style="list-style-type: none"> • Approval is obtained from the RA 2-201.13(E), and • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(E)(2) (also see Table 2). 	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

Key: Table 1b

RA = Regulatory Authority

STEC = Shiga toxin-producing *Escherichia coli*

HAV = Hepatitis A virus

HSP = Highly Susceptible Population

NTS = Nontyphoidal *Salmonella*

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge

- The person in charge shall notify the RA when a food employee reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid fever (S. Typhi) including previous illness with S. Typhi (see 2-201.11 (A)(3))	EXCLUDE 2-201.12(C)	EXCLUDE 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: <ul style="list-style-type: none"> • Food employee provides medical documentation that states the food employee is free of an S. Typhi infection 2-201.13)(C)(2) (also see Table 1b). 	Yes
Nontyphoidal <i>Salmonella</i>	RESTRICT 2-201.12(G)	RESTRICT 2-201.12(G)	When approval is obtained from the RA 2-201.13(G), and: <ul style="list-style-type: none"> • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal <i>Salmonella</i> infection 2-201.13)(G)(1) or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic (2-201.13(G)(2)). 	Yes (continued)

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
<i>Shigella</i> spp.	EXCLUDE 2-201.12(E)(1)	RESTRICT 2-201.12(E)(2)	<ol style="list-style-type: none"> 1. <u>Serving a non-HSP facility:</u> 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility:</u> 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> <ul style="list-style-type: none"> • Approval is obtained from the RA 2-201.13(E), and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 201.13(E)(3)(a) (also see Table 1b). 	<p>Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility</p> <p>(continued)</p>

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Norovirus	EXCLUDE 2-201.12(D)(1)	RESTRICT 2-201.12(D)(2)	<ol style="list-style-type: none"> 1. <u>Serving a non-HSP facility:</u> 2-201.13(A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility:</u> 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> <ul style="list-style-type: none"> • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 1b). 	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
STEC	EXCLUDE 2-201.12(F)(1)	RESTRICT 2-201.12(F)(2)	<ol style="list-style-type: none"> 1. <u>Serving a non-HSP facility:</u> 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility:</u> 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> <ul style="list-style-type: none"> • Approval is obtained from the RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2). 	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility (continued)

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
<i>Hepatitis A virus</i>	EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: <ul style="list-style-type: none"> • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (see also Table 1b). 	Yes

Key: Table 2

RA = Regulatory Authority

STEC = Shiga toxin-producing *Escherichia coli*

HAV = Hepatitis A virus

HSP = Highly Susceptible Population

NTS = Nontyphoidal *Salmonella*

2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge

- The person in charge shall notify the RA when a food employee reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid Fever (S. Typhi) including previous illness with S. Typhi (see 2-201.11 (A)(3))	EXCLUDE 2-201.12(C)	EXCLUDE 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: Food employee provides medical documentation, specifying that the food employee is free of a S. Typhi infection 2-201.13(C)(2).	Yes
Shigella spp.	EXCLUDE 2-201.12(E)(1)	RESTRICT 2-201.12(E)(2)	Remains excluded or restricted until approval is obtained from the RA, and: <ul style="list-style-type: none"> • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee was last diagnosed 2-201.13(E)(3). 	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Nontyphoidal <i>Salmonella</i>	RESTRICT 2-201.12(G)	RESTRICT 2-201.12(G)	When approval is obtained from the RA 2-201.13(G), and: <ul style="list-style-type: none"> • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal <i>Salmonella</i> infection 2-201.13(G)(1) or • Food employee did not develop symptoms and >30 days have passed since the food employee was diagnosed (2-201.13(G)(3)). 	(continued)

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Norovirus	EXCLUDE 2-201.12(D)(1)	RESTRICT 2-201.12(D)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(D), and <ul style="list-style-type: none"> • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee was diagnosed 2-201.13(D)(3). 	Yes to return to an HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
STEC	EXCLUDE 2-201.12(F)(1)	RESTRICT 2-201.12(F)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(F), and: <ul style="list-style-type: none"> • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee was diagnosed 2-201.13(F)(3). 	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	EXCLUDE 2-201.12(B)(3)	EXCLUDE 2-201.12(B)(3)	When approval is obtained from the RA 2-201.13(B), and <ul style="list-style-type: none"> • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3). 	Yes

Key: Table 3

RA = Regulatory Authority

STEC = Shiga toxin-producing *Escherichia coli*

HAV = Hepatitis A virus

HSP = Highly Susceptible Population

NTS = Nontyphoidal *Salmonella*

2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Food employees and conditional employees shall report a listed exposure to the person in charge

- The person in charge shall prohibit a conditional employee who reports a listed exposure from becoming a food employee in a facility serving an HSP until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of an exposed food employee
- The person in charge shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing and no BHC with RTE foods for all food employees that report a listed exposure

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Typhoid Fever (<i>S. Typhi</i>)	RESTRICT 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(3) When 14 calendar days have passed since the last exposure, or more than 14 days has passed since the food employee's household contact became asymptomatic.	No
<i>Shigella</i> spp.	RESTRICT 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 days have passed since the food employee's household contact became asymptomatic.	No
Norovirus	RESTRICT 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(1) When more than 48 hours have passed since the last exposure, or more than 48 hours has passed since the food employee's household contact became asymptomatic.	No
STEC	RESTRICT 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 calendar days has passed since the food employee's household contact became asymptomatic.	No

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Hepatitis A virus	RESTRICT 2-201.12(l)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(l)(2) When any of the following conditions is met: <ul style="list-style-type: none"> • The food employee is immune to HAC infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or • More than 30 calendar days have passed since the last exposure, or since the food employee's household contact became jaundiced; or • The food employee does not use an alternative procedure that allows BHC with RTE food until at least 30 days after the potential exposure, and the employee receives additional training. 	No

Key: Table 4

HSP = Highly Susceptible Population

BHC = Bare Hand Contact

RTE = Ready-To-Eat

GHP = Good Manufacturing Practices

STEC = Shiga toxin-producing *Escherichia coli*

2-201.12 Exclusion and Restrictions (continued)³

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by ***Salmonella Enteritidis***. Over 70% of the deaths in outbreaks attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active gastrointestinal symptoms, followed by diagnosis and history of exposure.

The history of exposure that must be reported applies to Norovirus, Hepatitis A, *Shigella* spp., STEC and *Salmonella* Typhi. It does not include nontyphoidal *Salmonella*.

Upon being notified of the history of exposure, the person in charge should immediately:

1. Discuss the traditional modes of transmission of fecal-oral route pathogens.
2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.
3. Review the symptoms listed in the Code that require immediate exclusion from the food establishment.
4. Remind food employees of their responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.
5. Ensure that the food employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

³In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

A restricted food employee may work in an area of the food establishment that houses packaged food, wrapped single-service or single-use articles, or soiled food equipment or utensils. Examples of activities that a restricted person might do include working at the cash register, seating patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or maintenance capacity consistent with the criteria in the definition of the term “restricted.” A food employee who is restricted from working in one food establishment may not work in an unrestricted capacity in another food establishment, but could work unrestricted in another retail store that is not a food establishment. A restricted food employee may enter a food establishment as a consumer.

An excluded individual may not work as a food employee on the premises of any food establishment.

2-201.13 Removal of Exclusions and Restrictions.⁴

Food employees diagnosed with Norovirus, hepatitis A virus, *Shigella* spp., *E. coli* O157:H7 or other STEC, nontyphoidal *Salmonella* and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or 2-201.12(B)(2). However these symptomatic, diagnosed food employees differ from symptomatic, undiagnosed food employees in the requirements that must be met before returning to work in a full capacity after symptoms resolve.

The person in charge may allow undiagnosed food employees who are initially symptomatic and whose symptoms have resolved to return to work in a full capacity 24 hours after symptoms resolve.

However, diagnosis with a listed pathogen invokes additional requirements before the person in charge may allow diagnosed food employees to return to work in full capacity.

Asymptomatic food employees diagnosed with Norovirus, *Shigella* spp., *E. coli* O157:H7 or other STEC may not return to work in a full capacity for at least 24 hours after symptoms resolve. The person in charge shall only allow these food employees to work on a restricted basis 24 hours after symptoms resolve and they shall only allow this if not in a food establishment that serves a highly susceptible population. These restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction as specified under subparagraphs 2-201.13(D) (1)-(2); 2-201.13(E)(1)-(2); or 2-201.13(F)(1)-(2).

⁴In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code’s exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

In a food establishment that serves a highly susceptible population, food employees who are diagnosed with Norovirus, **Shigella** spp., **E. coli** O157:H7 or other STEC and initially symptomatic with vomiting or diarrhea, shall not work on a restricted basis after being asymptomatic for at least 24 hours. These food employees must remain excluded until they are medically cleared or otherwise meet the criteria for removal from exclusion from a highly susceptible population under subparagraph 2-201.13(D)(1)-(2), 2-201.13(E)(1)-(2), or 2-201.13 (F)(1)-(2).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(4).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(3). A food employee with an anicteric infection with the hepatitis A virus has a mild form of hepatitis A without jaundice. Food employees diagnosed with an anicteric infection with the hepatitis A virus are excluded if they are within 14 days of any symptoms. Anicteric, diagnosed food employees shall be removed from exclusion if more than 14 days have passed since they became symptomatic, or if medically cleared. Asymptomatic food employees diagnosed with an active infection with the hepatitis A virus are also excluded until medically cleared.

Food employees diagnosed with typhoid fever (caused by a **Salmonella Typhi** infection) are always excluded, even without expressing gastrointestinal symptoms, since these symptoms are not typically exhibited with typhoid fever. Outbreaks of foodborne illness involving typhoid fever (**Salmonella Typhi**) have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness. The high virulence combined with the extremely high infectivity of **S. Typhi** warrant exclusion from the food establishment until the food employee has been cleared by a physician or has completed antibiotic therapy.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through diagnosis, or laboratory confirmation of their stools to have Norovirus, or any one of the four bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The risk that food employees who are asymptomatic shedders will transmit a communicable disease varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism. Exclusion in a food establishment that serves a highly susceptible population affords protection to people who are immune-suppressed. Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population provided there is adequate attention to personal hygiene and avoidance of bare-hand contact with RTE foods.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the four bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases Manual."

Hands and Arms 2-301.11 Clean Condition.

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

2-301.12 Cleaning Procedure.

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques.

In the case of a food worker with one hand or a hand-like prosthesis, the Equal Employment Opportunity Commission has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the “subungal space”, has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate. Fingernail brushes, if used properly, have been found to be effective tools in decontaminating this area of the hand. Proper use of single-use fingernail brushes, or designated individual fingernail brushes for each employee, during the handwashing procedure can achieve up to a 5-log reduction in microorganisms on the hands.

There are two different types of microbes on the hands, transient and resident microbes. Transient microbes consist of contaminating pathogens which are loosely attached to the skin surface and do not survive or multiply. A moderate number of these organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin and they are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination in food service.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands and when an antimicrobial soap is used, a minimum of 15 seconds is required. Soap is important for the surfactant effect in removing soil from the hands and a warm water temperature is important in achieving the maximum surfactant effect of the soap.

Every stage in handwashing is equally important and has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the transient microbial load on the hands. It is equally important to avoid recontaminating hands by avoiding direct hand contact with heavily contaminated environmental sources, such as manually operated handwashing sink faucets, paper towel dispensers, and rest room door handles after the handwashing procedure. This can be accomplished by obtaining a paper towel from its dispenser before the handwashing procedure, then, after handwashing, using the paper towel to operate the hand sink faucet handles and restroom door handles.

Handwashing done properly can result in a 2-3 log reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e., $> 10^4$ microbes, as found on hands contaminated with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

2-301.13 Special Handwash Procedures.

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

2-301.14 When to Wash.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately before, during, or after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

2-301.15 Where to Wash.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing sinks are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

2-301.16 Hand Antiseptics.

In the 2005 Food Code, the use of the term “hand sanitizer” was replaced by the term “hand antiseptic” to eliminate confusion with the term “sanitizer,” a defined term in the Food Code, and to more closely reflect the terminology used in the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994.

The term “sanitizer” is typically used to describe control of bacterial contamination of inert objects or articles, or equipment and utensils, and other cleaned food-contact surfaces. The Food Code definition of “sanitizer” requires a minimum microbial reduction of 5 logs, which is equal to a 99.999% reduction. The FDA bases the 5-log reduction on the AOAC International’s “Official Methods of Analysis 2003,” which requires a minimum 5-log reduction in microorganisms to achieve “sanitization.”

Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing microorganisms from human skin is a totally different process and sterilization of human skin is nearly impossible to achieve without damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms than the 5-log reduction required for “sanitization.” Therefore, the effect achieved from using antimicrobial hand agents is not consistent with the definition of “sanitization” in the Food Code.

The word “antiseptic” is a Greek term, meaning “against putrefaction”, and eventually evolved into a second definition, meaning, “a substance used to destroy pathogenic microorganisms.” The term “antiseptic” is often used to describe agents used on skin to prevent infection of the skin.

“Antiseptic” is defined under section 201 (o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 (o)), as: “The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation of a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.”

Section 333.403 of the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994, defines a “health-care antiseptic” as an antiseptic-containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination. An “antiseptic handwash” or “health-care personnel handwash drug product” is defined in Section 333.403 of the Monograph as an antiseptic containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is a broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin.

Replacing the term “hand sanitizer” with the term “hand antiseptic” allows the use of a more scientifically appropriate term that is used to describe reduction of microorganisms on the skin and will improve clarification and regulation of these products.

The provisions of § 2-301.16 are intended to ensure that an antimicrobial product applied to the hands is 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. Because of the need to protect workers and to ensure safe food, hand antiseptics must comply with both the human drug and the food safety provisions of the law. The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

As a Drug Product

There are two means by which a hand antiseptic is considered to be safe and effective when applied to human skin:

1. A hand antiseptic may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. (<http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>). This document is maintained by the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Also known as the “Orange Book,” this document provides “product-specific” listings rather than listings by compound and it is published annually with monthly supplements. However, as of the end of 1998, no hand antiseptics are listed in this publication since no new drug applications have been submitted and approved for these products.
2. A hand antiseptic active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand antiseptic products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are “drugs” under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand antiseptics and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP’s); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975, for hand antiseptic use by food handlers, are being evaluated under the Over-the-Counter (OTC) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2005, a final OTC drug monograph for these products has not been finalized. Therefore, FDA has not made a final determination that any of these products are generally recognized as safe and effective (GRAS/E).

GRAS/E antimicrobial ingredients for hand sanitizer use by food handlers will be identified in a future final monograph issued under the OTC Drug Review. Information about whether a specific product is covered by the proposed monograph may be obtained from the tentative final monograph (TFM) for "Health Care Antiseptic Drug Products for OTC Human Use; Proposed Rule." This TFM, which was published in the ***Federal Register*** of June 17, 1994 (59 FR 31402), describes the inclusion of hand sanitizers in this Review on page 31440 under Comment 28 of Part II. Information about whether a specific product is included in this proposed monograph may also be available from the manufacturer.

Questions regarding acceptability of a hand antiseptic with respect to OTC compliance may be directed to the Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation & Research Food and Drug Administration 10903 New Hampshire Ave., Building 51, 5th Floor, Silver Spring, MD 20993. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

As a Food Additive

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the substances in a hand antiseptic must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the substances in a hand antiseptic are reasonably expected to become a component of food based upon the product's intended use, circumstances under which those substances may be legally used include the following:

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.
2. The intended use of a substance, including substances that contact food such as those in hand antiseptics, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186.

These lists are not exhaustive because the FFDCa allows for independent GRAS determinations.

For the use of a substance to be GRAS within the meaning of the FFDCa, there must be publicly available data that demonstrate that the substance is safe for its intended use. There also must be a basis to conclude that there is a consensus among qualified experts that these publicly available data establish safety. If the use of a substance in food is GRAS, it is not subject to premarket review by FDA. While there is no legal requirement to notify FDA of an independent GRAS determination, a number of firms have chosen to do so with the expectation of receiving a response letter from FDA (see FDA's Inventory of GRAS Notices at (<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm>)). Although such a letter does not affirm the independent GRAS determination, it is an opportunity for the firm to receive comment from FDA regarding the materials supporting its determination.

3. The intended use of a substance may be the subject of a prior sanction, which is an explicit approval by the FDA or the United States Department of Agriculture (USDA) prior to September 6, 1958. All known prior sanctions are published under 21 CFR Part 181.
4. A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCa Section 409 (h). Substances that are the subject of an effective food-contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Food Contact Substance (FCS) Notifications. This list is available on-line at: Inventory of Effective Food Contact Substance (FCS) Notifications (<http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm>). A food-contact substance that is the subject of an effective notification submitted under FFDCa 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer identified in that notification.

The Division of Food Contact Substance Notifications does not certify or provide approvals for specific products. However, if the intended use of a substance in contact with food meets the requirements of 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*, FDA may provide a letter to a firm stating that the intended use of this product is exempt from regulation as a food additive. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of substances in hand antiseptics as food additives may be directed to the Division of Food Contact Substance Notifications, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740. It may be helpful or necessary to provide label/promotional information when inquiring about a specific substance.

Fingernails **2-302.11** **Maintenance.**

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry **2-303.11** **Prohibition.**

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

The term “jewelry” generally refers to the ornaments worn for personal adornment and medical alert bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for transmitting disease-causing organisms to food. If a food worker wears a medical alert or medical information bracelet, the conflict between this need and the Food Code’s requirements can be resolved through reasonable accommodation in accordance with the Americans with Disabilities Act. The person in charge should discuss the Food Code requirement with the employee and together they can work out an acceptable alternative to a bracelet. For example, the medical alert information could be worn in the form of a necklace or anklet to provide the necessary medical information without posing a risk to food. Alternatives to medical alert bracelets are available through a number of different companies (e.g., an internet search using the term “medical alert jewelry” leads to numerous suppliers).

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing **2-304.11** **Clean Condition.**

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Food Contamination Prevention **2-401.11** **Eating, Drinking, or Using Tobacco.**

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

2-401.12 Discharges from the Eyes, Nose, and Mouth.

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

***Hair Restraints* 2-402.11 Effectiveness.**

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

***Animals* 2-403.11 Handling Prohibition.**

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

2-501.11 Clean-up of Vomiting and Diarrheal Events.

When an employee, customer, or other individual vomits or has a diarrheal event in a food establishment, there is a real potential for the spread of harmful pathogens in the establishment. Putting the proper response into action in a timely manner can help reduce the likelihood that food may become contaminated and that others may become ill as a result of the accident.

According to the CDC, Norovirus is the leading cause of foodborne disease outbreaks in the United States. More specifically, Noroviruses are the most common cause of sporadic cases and outbreaks of acute gastroenteritis. Norovirus is the most common cause of gastroenteritis in people of all ages and it is responsible for greater than 50% of all foodborne gastroenteritis outbreaks. CDC estimates that 21 million cases of acute gastroenteritis are due to Norovirus infection.

Noroviruses can be highly contagious, and it is thought that an inoculum of as few as 10-18 viral particles may be sufficient to infect an individual. Transmission occurs via foodborne and person-to-person routes, airborne inhalation of vomitus droplets, and also through contact with contaminated environmental surfaces. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.

In addition, the potential transmission level of Norovirus shed in the feces at levels up to 1 trillion viral particles per gram of feces and one projectile vomiting incident can contaminate the environment with 300,000 viral particles. One study found that employees who reported having cleaned up vomitus were more likely to contract illness than those who did not.

Norovirus causes acute onset of vomiting (often explosive) and diarrhea (also often explosive) which can contaminate surfaces and become airborne increasing the chances of additional infections. A recent study has also shown that the bathroom environment was identified as a major reservoir of human Norovirus, even in the absence of an ill individual on site. Studies have shown that Norovirus can survive on fomite surfaces for up to at least 5 days at room temperature and that routine cleaning, without a disinfectant specifically to address Norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites.

Effective clean up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and disinfecting countertops and floors, such as certain quaternary ammonium compounds, may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration.

Consumers are at risk of contracting Norovirus illness from direct exposure to vomitus or from exposure to airborne Norovirus from vomitus. Additionally, exposed food employees are also at risk of contracting Norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers.

The Food Code specifies that the Person in Charge is to exclude or restrict a food employee who exhibits, or reports a symptom, or who reports a diagnosed illness or a history of exposure to Norovirus. A clean-up and response plan is intended to address situations where a food employee or other individual becomes physically ill in areas where food may be prepared, stored or served. Once such an episode has occurred, timely effective clean-up is imperative.

When developing a plan that addresses the need for the cleaning and disinfection of a vomitus and/or diarrheal contamination event, a food establishment should consider:

- the procedures for containment and removal of any discharges, including airborne particulates;
- the procedure for cleaning, sanitizing, and, as necessary, the disinfection of any surfaces that may have become contaminated;
- the procedures for the evaluation and disposal of any food that may have been exposed to discharges;
- the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and their proper use;
- procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter;
- the circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;
- notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;
- the segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;
- minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code;
- minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and
- the conditions under which the plan will be implemented.

When a food employee has been diagnosed, has recent history or exposure to, or is the suspect source of a confirmed disease outbreak of Norovirus, it must be reported to the person in charge per the FDA Food Code in subparagraphs 2-201.11 (A)(2)(a), 2-201.11(A)(4)(a), 2-201.11(A)(5)(a), and ¶2-201.11(B). If a food employee has been diagnosed with Norovirus it must also be reported to the regulatory authority. Refer to public health reasons for §2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees for more information about appropriate employee health policies.

Chapter 3 Food

Condition	3-101.11	Safe, Unadulterated, and Honestly Presented.
Sources	3-201.11	Compliance with Food Law.

Refer to the public health reason for § 3-401.11.

Source

A primary line of defense in ensuring that food meets the requirements of § 3-101.11 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat treatment nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Fish

Except for raw molluscan shellfish, certain species of large tuna, certain aquacultured fish, and fish eggs that have been removed from the skein and rinsed, if fish are intended for raw or undercooked consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling or other information should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Juice

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices.

On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a single thermal processing step are exempt from the microbial hazard requirements of the HACCP regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such as juice bars) are not required to comply with this regulation.

Rather, the Food Code requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Refer to Chapter 1 for the definition of juice. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations.

Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that bears the warning label and they must serve only pasteurized juice. For juice only, this population includes children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care.

Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore not covered by section 3-603.11) when prepared and served at retail. Usually the juice is served by the glass or in small batches compared to a commercial juice processor. The risk of using "drops" and damaged fruits or vegetables is much less at retail because of buyer specs that provide higher quality produce, meaning that fruits for juicing are less likely to be of a lower quality or damaged.

Additional information is available in the document, "Guidance for Industry: Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Pathogen Reduction; Final Guidance", October 7, 2002 which can be found at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm058962.htm> or obtained from the FDA Office of Nutritional Products Labeling and Dietary Supplements.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by Federal regulation to label the product with safe food handling instructions. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and pre-labeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling Guidance for Irradiated Raw Meat and Meat Products

In December 1999, the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) issued a final regulation to permit the use of ionizing radiation to reduce foodborne pathogens, including *Escherichia coli* O157:H7, and extend the shelf life of raw refrigerated and frozen meat and meat products (Irradiation of Meat Food Products 64 *Federal Register* 72150, December 23, 1999).

The final regulations are published in Title 9 of the Code of Federal Regulations (9 CFR 424.21 Use of food ingredients and sources of radiation and provide that raw refrigerated products may receive a maximum absorbed dose of no more than 4.5 kGy, and that frozen product receive no more than 7.0 kGy, in accordance with the FDA restrictions provided for in Title 21 of the Code of Federal Regulations (21 CFR 179.26(a) Ionizing radiation for the treatment of food, (a) Energy sources). The regulations further require that all irradiated meat and meat products bear labeling that reflects that the product was irradiated, or that the product contains an irradiated meat or poultry product. This labeling requirement is applicable even at retail facilities where irradiated coarse ground beef might be finely ground for retail sale, or in cases where irradiated product is combined with other non-irradiated meat or poultry product for retail sale.

In cases where the entire package of product is irradiated, the labeling must include both a statement and the international symbol, called the radura. Additionally, the product name must include the word "irradiated," or the labeling must bear a disclosure statement such as, "treated with radiation" or "treated by irradiation." If either statement is used, the logo must be placed in conjunction with the statement. If an irradiated meat or meat product is used to formulate a multi-ingredient product with other non-irradiated components, the irradiated meat ingredient must be identified as such in the ingredients statement, but the logo is not required. For example, the ingredients statement for a Chicken and Beef Sausage product that contains irradiated beef would be, Ingredients: chicken, irradiated beef, seasonings (salt, pepper, spice), and the logo would not be required to be present.

All labels for products produced at federally inspected establishments bearing statements about irradiation must be submitted to USDA/FSIS for evaluation and approval prior to use.

Optional labeling statements about the purpose of the irradiation process may be included on the labeling of irradiated products provided they are not false or misleading and have been evaluated first by USDA/FSIS. If such statements indicate a specific benefit from irradiation, such as a reduction of microbial pathogens, such statements must be substantiated by processing documentation and validated through the processing and Hazard Analysis and Critical Control Point (HACCP) system. Such validation and documentation of the HACCP system would only be applicable in federally inspected establishments.

Because irradiation can substantially reduce and, in some situations, eliminate any detectable level of pathogenic bacteria, it is important that the meat products be held at the proper refrigerated temperatures to prevent growth of any pathogens present, and that the packaging is not compromised. Although co-mingling irradiated beef with non-irradiated meat or poultry is not prohibited under the current regulations, USDA/FSIS believes that such a process would decrease the benefit of irradiation by potentially exposing the irradiated product to pathogenic bacteria. While FSIS considers such comingling to be highly unlikely, if it did occur, a statement advising the consumer that the product contains both irradiated and non-irradiated components would be required.

The Radura, International Symbol:



Further information about labeling irradiated raw meat is available through Directive 7700.1, Irradiation of Meat and Poultry Products, on the USDA/FSIS website at <http://www.fsis.usda.gov/wps/wcm/connect/058dd732-7fc8-4787-a283-30ed50d6f7e0/7700.1Rev1.pdf?MOD=AJPERES>. Irradiation Questions & Answers can be found at <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/irradiation-and-food-safety>.

Labeling for Raw Shell Eggs

The Code of Federal Regulations 21 CFR 101.17 **Food Labeling warning, notice, and safe handling statements**, paragraph (h) *Shell* eggs state in subparagraph (1), “The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement: ‘SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.’” Further, in subparagraph (4) it states, “Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (h) of this section.”

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

Refer also to public health reason for § 3-602.11.

3-201.12 Food in a Hermetically Sealed Container.

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of *Clostridium botulinum*, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.13 Fluid Milk and Milk Products.

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Listeria monocytogenes*, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

3-201.14 Fish.

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

RECREATIONALLY CAUGHT FISH

Recreationally caught fish received for sale or service may be approved by the regulatory authority. The EPA recognizes that fish are a healthy part of our diet and recognizes fishing as an all-American recreational pastime, however, they add the cautionary note that some individuals, such as pregnant women and small children, may need to limit their intake of certain noncommercial fish. Recreationally caught fish may contain possible contaminants that may pose health risks. Fish advisories can be found in EPA Listing of Fish Advisories the EPA website at: <http://www.epa.gov/waterscience/fish/>.

States issue fish consumption advisories if elevated concentrations of chemicals such as mercury or dioxin are found in local fish. For most people, the risk from mercury by eating fish is not a health concern. Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. Therefore, the FDA and the EPA recently advised women who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and eat fish and shellfish that are lower in mercury. (<http://www.epa.gov/waterscience/fishadvice/advice.html>).

State-issued advisories apply primarily to non-commercial fish obtained through sport, recreation, and subsistence activities. Each advisory is different; it may recommend unrestricted, limited, or totally restricted consumption; may be targeted to everyone or limited to women, children, or other people at risk; and may apply to certain species or sizes of fish or a specific waterbody.

States may issue safe-eating guidelines in addition to issuing fish advisories. A fish advisory is issued to warn the public of the potential human health risks from chemical contamination of certain species from particular types of waterbodies such as lakes, rivers, and/ or coastal waters within the State. In contrast, a safe-eating guideline is issued to inform the public that fish from specific waterbodies have been tested for chemical contaminants and the fish from these waters are safe to eat without consumption restrictions.

Regulatory authorities are encouraged to monitor and review the National Listing of Fish Advisories (See August 2004 EPA Fact Sheet at <http://www.epa.gov/waterscience/fish/advisories/factsheet.pdf> as well as the local listings, as part of the decision-making process regarding the approval of recreationally caught fish being used in food establishments.

3-201.15 Molluscan Shellfish.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, and *Listeria monocytogenes* that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving Federal and State public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

3-201.16 Wild Mushrooms.

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that includes individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups.

Regulatory authorities have expressed their difficulty in regulating wild harvested mushrooms at retail. There are many different approaches in regulating the sale and service of wild harvested mushrooms. The differences in approach could be due to geography, the type of wild mushrooms that typically grow in a particular region and/or local/state laws that are enforced. The Conference for Food Protection (CFP) has attempted to develop a national model or standards for regulatory programs to address and recognize wild harvested mushroom identification. The difficulty in trying to get consensus on national model/standards lies in the question of what is the best national model/standard available that state/local regulatory authorities can apply in a meaningful way to ensure wild harvested mushrooms sold at retail are obtained from a safe source.

With the change in the codified text, the regulatory authority will have the flexibility to apply their laws and/or policies for wild harvested mushroom identification. At a minimum, when developing a wild harvest mushroom identification program, the following elements should be addressed:

- Developing resources & criteria to select wild mushroom species for service or sale,

- Establishing record-keeping and traceability to assure safety of wild harvested mushrooms,
- Written buyer specifications that include:
 - a. Identification by the scientific name and the common name of the mushroom species,
 - b. A statement that the mushroom was identified while in the fresh states,
 - c. The name and contact information of the person who identified the mushroom and the mushroom seller, and
 - d. A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.
- Development of qualifications and training curriculum that could be used for further training of mushroom identifiers

In addition, the CFP has guidance material titled “Draft Model Guidance for Wild Harvested Mushrooms” posted on their website at www.foodprotect.org so state and local regulatory authorities can use the information to develop and implement their own wild harvested mushroom program. The guidance document is still a work in progress.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.17 Game Animals.

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

***Specifications for Receiving* 3-202.11 Temperature.**

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. USDA published a final rule (63 FR 45663, August 27, 1998 Shell Eggs; Refrigeration and Labeling Requirements) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2°C (45°F).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of *Staphylococcus aureus*). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

3-202.12 Additives.

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

Food and Color additives must be used in compliance with a federal food, or color additive regulation, an effective food-contact notification, or a threshold of regulation exemption. Such regulations, notifications, and exemptions are generally composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use. In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food-contact notifications are listed at <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=fcsListing&displayAll=false&page=17>, and threshold of regulation exemptions are listed at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/ucm093685.htm>.

Other substances that are added to food include those prior sanctioned for use in food by either the FDA or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in Title 21 CFR Parts 181-186, Title 9 CFR Section 424.21(b) and at <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm>. Tolerances and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR Part 180. Substances that are prohibited from use in human food are listed in Title 21 CFR Part 189.

3-202.13 Eggs.

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg may be restricted because it is a/an:

- (i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.
- (ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.
- (iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.
- (iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).
- (v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.
- (vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inapplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs...
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. These rules are one part of a larger farm-to-table approach for ensuring the safety of our nation's egg supply. The public health goal is a 50 percent reduction in all salmonellosis and a 50 percent reduction in **Salmonellae Enteritidis** illnesses by 2010.

3-202.14 Eggs and Milk Products, Pasteurized.

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these time/temperature control for safety foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

3-202.15 Package Integrity.

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as **Clostridium botulinum** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.

Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

3-202.16 Ice.

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

3-202.17 Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

3-202.18 Shellstock Identification.

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

3-202.19 Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

3-202.110 Juice Treated.

Refer to public health reason for § 3-801.11.

***Original Containers and Records* 3-203.11 Molluscan Shellfish, Original Container.**

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

When shucked shellfish are prepackaged in consumer self service containers, the labeling information as specified under section 3-202.17 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

3-203.12 Shellstock, Maintaining Identification.

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product.....	14 days
Incubation period	56 days
Medical diagnosis and confirmation.....	5 days
Reporting	5 days
<u>Epidemiological investigation.....</u>	<u>10 days</u>
Total	90 days

In reality and as stated in the provision, the 90-day “clock” starts at the time the container of shellstock is emptied. Starting from the date of harvest is not correct because the shellstock may be sold/consumed in less than the 14 days of shelf life cited in the chart above. Therefore, the 90 days may expire and the tag discarded before an illness is reported and investigated.

Shellstock could be frozen in the food establishment during the 14-day estimated shelf life period, which would effectively stop the clock on the shelf life. The shellstock could be thawed and consumed past the 14-day shelf life. In this case, the 90 days would expire before consumption if the clock started 90 days from the harvest date.

Freezing shellstock in the food establishment is not usually done because, although oysters-in-the-shell can be frozen with fair results, they do not have the same texture and appearance of a fresh oyster when thawed. Commercially frozen oysters are frozen rapidly to retain product quality.

***Preventing Contamination by Employees* 3-301.11 Preventing Contamination from Hands.**

In November 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill food workers as the first preventative strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing; and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized independently and may not be effective. However, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled. Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as specified in the Food Code, may not be an adequate intervention to prevent the transmission of pathogenic microbes to ready-to-eat foods via hand contact with ready-to-eat foods. Handwashing as specified in the Food Code will reduce microbial contamination of the hands by 2-3 logs.

Food employees and conditional employees infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands combined with a very low infectious dose necessary to cause infection are the reasons that FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for ***Giardia*** and ***Cryptosporidium*** is believed to be as low as 1-10 oocysts, and as few as 10 virus particles can infect an individual with Norovirus or hepatitis A.

The CDC now estimates that Norovirus is the leading cause of foodborne illness in the United States. Contaminated hands are a significant factor in the transmission of enteric viruses, including Norovirus and hepatitis A virus. Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungual space of the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

If a ready-to-eat food is being added as an ingredient to a food item that is subsequently subjected to a pathogen kill step (such as adding cheese or other ready-to-eat toppings to a pizza dough or adding vegetables to a raw meat dish before cooking) then strict prohibition of bare hand contact is not necessary. Cooking foods to the temperatures required in the Food Code will reduce the likelihood of survival of pathogens that might be transferred from an employee's hands to the surface of the ready-to-eat foods. The exception specifically targets bare hand contact with ready-to-eat food at the time it is added as an ingredient to food that will be cooked in the food establishment to the minimum temperatures specified in the Food Code. The exception does not apply when adding ready-to-eat foods as ingredients to foods that will only be lightly heated, melted, or browned rather than cooked to the minimum temperatures specified in this section. Nor does this exception apply when adding ready-to-eat foods as ingredients to foods that are intended for preparation by the consumer offsite. When proper heat treatment is used in combination with the exclusion/restriction of ill food workers and proper handwashing, the proper heat treatment provides an additional means of interrupting disease transmission.

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.14.

3-301.11(E) Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.¹ Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used.

¹Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

Because highly susceptible populations include persons who are immunocompromised, the very young and the elderly, establishments serving these populations may not use alternatives to the no bare hand contact with ready-to-eat food requirement.

Acceptability of an alternative procedure to no bare hand contact requires prior approval from the regulatory authority based on the food establishment having a written employee health policy that details how the establishment complies with management of ill employees as specified under sections 2-201.11 - .13 and management of handwashing practices as specified under Part 2-3 of the Code. The approval should also be based on evidence provided through written procedures and documentation that at least all of the following are addressed:

(A) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in section 2-301.14, including after using the toilet and between tasks that may recontaminate the hands.

(B) **Hygienic Practices** as specified in Part 2-4.

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions**, and

(2) **Exclusions and restrictions**, i.e., that food employees and conditional employees report their health status as specified in section 2-201.11; ill food employees are restricted or excluded as specified in section 2-201.12; and the exclusions and restrictions are removed as specified in section 2-201.13;

(D) **How the alternative practices and procedures will control the hazard through an active managerial control program.** Such a program includes monitoring and verifying the institution of the provisions described in paragraphs A-C above and satisfies the following:

(1) The public health hazard associated with bare hand contact specific to the food establishment operation is identified and understood. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an effective training program for food employees that emphasizes not working when ill with any of the gastrointestinal symptoms listed in the Code, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(E) The alternative procedure should clearly describe monitoring, documentation, and verification actions to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

(F) Documentation of the practices, procedures, and corrective actions related to an alternative to no bare hand contact with ready-to-eat food must be maintained and readily available at the food establishment at all times for use by the person in charge and for review by the regulatory authority.

***Preventing
Food and
Ingredient
Contamination***

**3-302.11 Packaged and Unpackaged Food – Protection
Separation, Packaging, and Segregation.**

It is important to separate foods in a ready-to-eat form from raw animal foods during storage, preparation, holding and display to prevent them from becoming contaminated by pathogens that may be present in or on the raw animal foods. An exception is permitting the storage and display of frozen, commercially packaged raw animal food adjacent to or above frozen, commercially packaged ready-to-eat food. The freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-contamination. Additional product handling, drippage during the freezing process, partial thawing or incomplete seals on the package increase the risk of cross-contamination from these products packaged in-house.

With regard to the storage of different types of raw animal foods as specified under subparagraph 3-302.11(A)(2), it is the intent of this Code to require separation based on anticipated microbial load and raw animal food type (species). Separating different types of raw animal foods from one another during storage, preparation, holding and display will prevent cross-contamination from one to the other. The required separation is based on a succession of cooking temperatures as specified under § 3-401.11 which are based on thermal destruction data and anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are required to be cooked to an internal temperature of 145°F for 15 seconds, shall be stored above or away from raw poultry, which is required to be cooked to an internal temperature of 165°F for 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

**3-302.12 Food Storage Containers, Identified with
Common Name of Food.**

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism ***Salmonella Enteritidis*** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

3-302.14 Protection from Unapproved Additives.

Refer to the public health reason for § 3-202.12.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

3-302.15 Washing Fruits and Vegetables.

Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the majority of organisms and/or chemicals present; however, more recent studies have demonstrated washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water or with chemicals as specified in Section 7-204.12, or both, before eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still important to remove soil and debris first.

Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. It is important to follow practices that minimize pathogens in the water or on the surface of produce. It is important that proper handwashing procedures are followed, in accordance with Section 2-301.12 Cleaning Procedure, before and after handling fresh produce.

Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots, cucumbers or citrus fruits that will not be bruised easily or penetrated by brush bristles. Scrubbing firm produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food. Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label.

Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the package label, and can be used as ready-to-eat without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should not be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered time/temperature control for safety food (TCS) requiring time/temperature control for safety and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm>, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm215053.htm> and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm>

On October 26, 1998 a voluntary guidance document for the produce industry which addresses microbial hazards and good agricultural and management practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents and was updated on August 19, 2003. This “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”, October 26, 1998, is available from FDA’s Food Safety Initiative staff and also on the Internet at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064574.htm>.

Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued “Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,” which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. This guide is available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm>.

On January 11, 2006 FDA/CFSAN published additional safe handling advice on the purchase, storage, and preparation of fresh produce, as well as Q & A’s for consumers on their website at: <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm114299.htm>. This document is available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the cleaning of fresh produce.

Preventing Contamination from Ice Used as a Coolant

3-303.11

Ice Used as Exterior Coolant, Prohibited as Ingredient.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

3-303.12 Storage or Display of Food in Contact with Ice and Water.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens **3-304.11 Food Contact with Equipment and Utensils.**

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

The Food Code defines gloves as a "utensil" and therefore gloves must meet the applicable requirements related to utensil construction, cleaning, and storage.

3-304.12 In-Use Utensils, Between-Use Storage.

Refer to the public health reason for § 3-304.11.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 135°F or above during intermittent use because microbial growth is controlled at such temperatures.

A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to determine if a utensil is improperly designed for the task or whether a food employee is misusing an appropriately designed utensil.

3-304.13 Linens and Napkins, Use Limitation.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

3-304.14 Wiping Cloths, Use Limitation.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution of adequate concentration between uses. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

Wiping down a surface with a reusable wet cloth that has been properly stored in a sanitizer solution is an acceptable practice for wiping up certain types of food spills and wiping down equipment surfaces. However, this practice does not constitute cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

The same is true of the practice of wiping down a surface using dry disposable towels and a spray bottle containing pre-mixed sanitizing solution. This practice is not prohibited, however it alone does not constitute proper cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

Further, for the purpose of wiping up food spills from surfaces in situations where full cleaning and sanitizing is not required (such as when a soft drink overflows onto the side of a cup or onto a countertop) the use of dry cloths and disposable towels is also acceptable as long as the cloth or towel is used for no other purpose. Again, this does not constitute a proper cleaning and sanitizing procedure for a food contact surface, when such is called for in 4-6 and 4-7 of the Food Code.

In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the requirements in Parts 4-6 and 4-7 of the Food Code, the surface must be first cleaned properly to remove organic material. In most cases this requires use of detergents or other cleaners such as described in Section 4-603.14 of the Food Code. After the surface is clean to sight and touch, a sanitizing solution of adequate temperature with the correct chemical concentration should then be applied to the surface. The sanitizing solution must stay on the surface for a specific contact time as specified in this Code and in accordance with the manufacturer's EPA-registered label, as applicable.

3-304.15 Gloves, Use Limitation.

Refer to the public health reason for § 3-304.11.

Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable requirements related to utensil construction, good repair, cleaning, and storage.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food. Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves. Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants enter the inside of the glove.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

Natural Rubber Latex (NRL) Gloves

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2, 3-304.15). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively reviewing its current policy on the use of disposable NRL gloves in food operations in light of the possible transmission of the latex protein via food. To gain additional information regarding allergic reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been collecting reports of such reactions from consumers who have contacted the Agency. Several offices within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and other related efforts will be used to determine if policy changes regarding the use of latex in food operations, based on food safety considerations, are warranted.

The FDA, Office of Food Additive Safety, Division of Food Contact Notification, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components. FDA regulates NRL gloves used for medical purposes only.

FDA is aware of the following information related to occupational hazards (not food safety hazards) associated with the use of NRL gloves:

- The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication number 97-135) which is found at <http://www.cdc.gov/niosh/docs/97-135/>.
- The American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging the routine use of NRL gloves by food handlers. (1997) <http://www.acaai.org/public/physicians/joint.htm>.

The AAAAI provides information on latex allergies on the web at http://www.aaaai.org/patients/allergic_conditions/latex_allergy.stm.

The ACAAI provides information on latex allergies on the web at <http://www.acaai.org/public/facts/latex.htm>.

- An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves for food handling..." (1999) <http://www.latexallergylinks.org/LA-TIB.html>.

OSHA addresses gloves in the following Federal regulation, which can be found at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9788.

OSHA Regulations (Standards - 29 CFR)
Standard Number: 1910.138
Standard Title: Hand Protection.

SubPart Number: I

SubPart Title: Personal Protective Equipment

(a) General requirements. Employers shall select and require employees to use appropriate hand protection when employees' hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes.

(b) Selection. Employers shall base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.

3-304.16 Using Clean Tableware for Second Portions and Refills.

Refer to the public health reason for § 3-304.11.

3-304.17 Refilling Returnables.

Food establishments may provide multi-use to-go containers to consumers with the intention that the containers are to be returned to the food establishment for refilling or reuse. These containers are likely to be soiled when the consumer returns the container to the food establishment. As a result, pathogens may be transferred to food by consumers or employees directly, or indirectly, from used take-home food containers. The existing provisions in the Food Code, specifically the cleaning and sanitization provisions in Parts 4-6 and 4-7, if carried out properly upon return of a used container, are sufficient to ensure that the container is safe to refill or reuse if performed in conjunction with a visual inspection by a food employee to verify that the container still meets the intent of the provisions in Parts 4-1 and 4-2. Reusing single-service and single-use articles is prohibited by the Food Code.

The refilling of consumer-owned, personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, by a consumer or food employee introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned, personal take-out beverage containers is limited to beverages that are not potentially hazardous (time/temperature control for safety) foods. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

**Preventing
Contamination
from the
Premises**

**3-305.11
3-305.12**

**Food Storage.
Food Storage, Prohibited Areas.**

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

3-305.13

**Vended Time/Temperature Control for Safety
Food, Original Container.**

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended time/temperature control for safety food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, time/temperature control for safety foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-305.14

Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips from overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

**Preventing
Contamination
by Consumers**

3-306.11

Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-306.12 Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-306.13 Consumer Self-Service Operations.

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are time/temperature control for safety foods and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Re-Service or Sale.

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not time/temperature control for safety foods and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

***Preventing Contamination from Other Sources* 3-307.11 Miscellaneous Sources of Contamination.**

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Cooking	3-401.11	Raw Animal Foods.
	3-401.12	Microwave Cooking.
	3-401.13	Plant Food Cooking for Hot Holding.

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has reached 62.8°C (145°F). Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, lamb roasts and cooked corned beef can be prepared using one of the time and temperature combinations listed in the chart in § 3-401.11 to meet a 6.5-log₁₀ reduction of Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time. The source of the time and temperature parameters is from the USDA/FSIS Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index>.

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of *Salmonellae*. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods. Part 3-4 includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63°C(145°F), a time span of 15 seconds will provide a 3D reduction of ***Salmonella* Enteritidis** in eggs.

The requirements specified under ¶ 3-401.11(D) acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods.

In consumer self-service operations, such as buffets, salad bars, sushi bars, or display cases, the consumer advisory as specified under section 3-603.11 must be posted or available at the self-service unit where the raw or partially cooked food is held for service and readily accessible to consumers prior to making their food selections. In a catered situation, such as a wedding reception, guests are responsible for making their own requests or selections.

Slow-cooked roasts - Heating Deviations and Slow Come Up Time

(Source: USDA/FSIS Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index>.)

Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even re-cooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of ***Staphylococcus aureus***, are extremely heat stable and are not inactivated by normal re-cooking temperatures.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded 5-logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed. Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, “For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork, and lamb are not included.”

NACMCF comments included, “Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food.”

As reflected in the definition of “whole-muscle, intact beef steak,” marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, *Trichinella spiralis*, *Toxoplasma gondii*, and *Taenia solium*, parasites causing foodborne illness, are inactivated at temperatures below 145°F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145°F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145°F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animal foods because when cooked to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncured Meat Patties (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing *Escherichia coli*. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee on Microbiological Criteria for Foods" (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

“Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157°F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158°F requirement.”

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158°F for less than one second is an adequate cook based on the following:

1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetative enteric pathogens;
2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and
3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C (165°F) or above for 15 seconds yield greater than a 7D reduction.

Children's Menu

The 2005 FDA Food Code Section 3-401.11 (D) "Raw Animal Foods" allows operators to serve raw or partially cooked animal food items on their customer's request, as long as the establishment does not serve a "Highly Susceptible Population" and the customer is informed of the risks associated with consuming undercooked items.

The definition of "Highly Susceptible Population" however, only includes young children who are of pre-school age and who obtain food under custodial care (as from a child daycare center). This definition does not address pre-school and older children eating in retail food establishments (such as restaurants), where it is common practice to offer menu items intended for children (e.g. "Kids Menu").

The Food Code seeks to increase current protection of children beyond custodial care facilities and establish needed safeguards in all retail food establishments. The importance of this issue can be demonstrated for numerous combinations of raw animal foods and associated pathogens. The greatest impact on children however, is undercooked ground beef, where the specific organism of concern is *Escherichia coli* O157:H7.

Children are at relatively high risk for infection with *E. coli* O157:H7. It is possibly the leading cause of acute kidney failure and Hemolytic Uremic Syndrome (HUS) in children [10]. Infection with *E. coli* O157:H7 can result with mild to severe symptoms such as: non-bloody or bloody diarrhea to HUS, which is a condition that includes destruction of red blood cells, problems with blood clotting and kidney failure. About 2% to 20% of patients that are infected with *E. coli* O157:H7 develop HUS [6]. The risk of illness from *E. coli* O157:H7 in ground beef has been shown to be about 2.5 times higher for preschool children and infants than for the rest of the population [6]. The CDC has reported the following *E. coli* O157:H7 infection rates per 100,000 by age range: 8.2 for young children 1-9 years old and 3.0 for older children 10-20 years of age [4].

Precluding undercooked foods from being offered on a children's menu may result in increased protection to children from foodborne illness, particularly *E. coli* O157:H7, which can result in severe consequences in children.

3-401.12 Microwave Cooking.

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Hedderson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 57°C (135°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

3-401.14

Non-Continuous Cooking of Raw Animal Foods.

Close attention must be paid to control of biological hazards when a food establishment cooks raw animal foods using a process in which the food is partially cooked then cooled with the expectation of fully cooking the food at a later date or time. Section 3-401.14 requires that establishments wishing to use a non-continuous process for the cooking of raw animal foods establish and follow a written plan that ensures each stage of the process is completed within time and temperature parameters that adequately prevent pathogen survival and growth. Section 3-401.14 also requires that establishments take special precautions to ensure that raw animal foods that have only been initially heated to temperatures that are not lethal to the pathogens of concern are clearly identified so that they will not be inadvertently sold or served to the consumer in a partially cooked state.

To ensure the food does not dwell for extended periods within temperature ranges that favor pathogen growth, § 3-401.14 establishes limits on the time permitted to initially heat the food (initial “come-up” time) and the time permitted to cool the product to temperatures that are safe for refrigerated storage. Together, these limits should prevent food from remaining at temperatures at which pathogen growth to harmful levels may occur.

The criteria in § 3-401.14 were developed with consideration of the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) *Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips* found in 9 CFR 318.23 and 9 CFR 381.150. (http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr318.23.pdf, http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr381_08.html)

The maximum one hour time limit for the initial heating stage was established based on estimates from predictive microbial modeling. It is intended to limit the cumulative growth of *Clostridium perfringens* that may occur during the come-up time and the subsequent cooling of the product in accordance with the requirements in ¶ 3-501.14(A). Unless properly controlled, processes in which animal foods are heated to sub-lethal temperatures and times and then cooled may create an environment for the growth of *Clostridium perfringens*, *Clostridium botulinum* and other spore forming, toxigenic bacteria.

The product temperature achieved during the initial heating process may not be sufficient to destroy vegetative cells of ***Clostridium botulinum***, ***Clostridium perfringens***, and ***Bacillus cereus***, if present. The concern is the generation of a large number of vegetative cells of ***Clostridium perfringens*** and/or ***Clostridium botulinum*** before the final cooking stage. For ***Clostridium botulinum***, if enough vegetative cells are produced, toxigenesis can occur in the product before the product is fully cooked. The toxin is not destroyed at the minimum required cooking temperatures. For ***Clostridium perfringens***, if a large number of vegetative cells are consumed, illness can result. In either case a high number of vegetative cells may challenge the lethality step of the ultimate cooking process to the extent that it will be unable to completely eliminate all of these vegetative cells. The cumulative growth of these bacterial pathogens must be taken into account during both the initial heating and cooling steps. The hazard may be compounded with an extended initial “come-up” time and/or a prolonged cooling stage. Hence the degree of hazard may be dependent upon the ultimate effect of the initial heating and cooling, as well as the final cooking step.

A full and adequate cook during the final cooking step is of critical importance to ensure destruction of any pathogens that may have survived and proliferated during any initial heating and cooling stages of the non-continuous cooking process. Section 3-401.14 requires that animal foods cooked by a non-continuous cooking process achieve a minimum final cook temperature that heats all parts of the food to a temperature and for a time specified under ¶¶3-401.11 (A)-(C). This requirement also precludes serving animal foods that have undergone non-continuous cooking in an undercooked or raw state. In other words, animal foods cooked using a non-continuous process are not covered in the exceptions provided for in ¶ 3-401.11(D) that allow for serving undercooked animal foods upon consumer request and with an adequate consumer advisory.

Section 3-401.14 requires that an establishment using non-continuous cooking processes also establish procedures for identifying foods that have only been partially cooked and cooled. This is necessary to ensure these foods are not mistaken by food workers for foods that have been fully cooked and therefore ready-to-eat without a full cook. Partially cooked foods may appear to be fully cooked.

Requiring that food establishments obtain prior approval by the regulatory authority before employing non-continuous cooking processes will help to ensure that the establishment has the proper procedures in place, as well as the necessary facilities and capacity to monitor the appropriate cooling, cooking, separation and product identification of the foods. in accordance with the requirements.

Freezing**3-402.11****Parasite Destruction.**

Refer to the public health reason for § 3-201.11.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

The recommended control strategies refer to the ambient air temperature during freezing and to the length of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held after it is solid frozen, whichever is appropriate. The parasite hazard is not considered to be reasonably likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that contains the egg mass) and rinsed.

In response to information provided to the FDA Office of Seafood, the Fish and Fisheries Products Hazards and Controls Guidance lists certain species of tuna as not being susceptible to parasites of concern and therefore exempted from the freezing requirements that apply to other fish species that are consumed raw.

The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food in an aquaculture operation. On the other hand, aquacultured fish that are fed processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most pelleted feeds, should be used.

Additionally, it should be noted that the Fish and Fisheries Products Hazards and Controls Guidance, Edition 4, Tables 3-2 and 3-3 (Chapter 3) lists those species for which FDA has information that a potential parasite hazard exists. Fish species in Tables 3-2 and 3-3 that do not have specific parasite hazards listed are not necessarily safe when consumed raw or undercooked. This is because fish species in Tables 3-2 and 3-3 were not listed with a parasite hazard if the species were generally cooked before consumption. In addition, in some cases, there is insufficient information or data to be able to denote a specific parasite hazard or deem the species as naturally parasite-free. The exemptions to freezing as specified in ¶ 3-402.11(B) of the *Food Code* are inclusive of and in harmony with the information and recommendations provided in the Fish and Fisheries Products Hazards and Controls Guidance.

Based on FDA's current assessment, parasites are not considered a significant hazard in molluscan shellfish or in scallop products consisting only of the shucked abductor muscle. Therefore these products are not required to be subject to the parasite destruction procedures specified under ¶3-402.11(A) prior to sale or service in a raw or partially cooked form.

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3-402.12 Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

While the Country of Origin Labeling requirements, <http://www.ams.usda.gov/COOL/> effective Sept. 30, 2004, mandate identification of wild and farm-raised fish and shellfish, the requirements do not address contents of pelleted feed used in the aquaculture operation. Documentation must be available in the food establishment from the source-through-purchase specifications or labeling that pelleted feed used did not contain fresh fish or plankton. Follow the guidance provided in the Fish and Fisheries Products Hazards and Controls Guidance, Table #3-1 – Potential Vertebrate Species Related Hazards and Table #3-2 – Potential Invertebrate Species Related Hazards.

Reheating 3-403.11 Reheating for Hot Holding.

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly cooled. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held at improper holding temperatures or improperly cooled, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Shelf-stable, commercially prepared ready-to eat foods in hermetically sealed containers will have received a controlled retort process that destroys all bacterial pathogens, both vegetative cells and spores, to provide a commercially sterile product. Refrigerated, commercially processed, ready-to-eat, TCS food will have received controlled thermal processing that destroys vegetative bacterial cells and a controlled cooling process that prevents the germination of any spores present. Packaging prevents recontamination and refrigeration prevents spore germination. Because there is limited risk of contamination in these types of products, reheating such foods to the minimum hot holding temperature of 135°F is considered adequate when reheating for hot holding. This should be the case for product that remains in the container or package after it is opened, provided the proper steps are taken to protect the remaining portions from contamination and they are maintained at the appropriate cold holding temperatures as specified in the Food Code.

Refer also to the public health reason for § 3-401.12.

3-404.11 Treating Juice.

Refer to the public health reason for § 3-801.11.

Temperature and Time Control	3-501.11	Frozen Food.
	3-501.12	Time/Temperature Control for Safety Food, Slacking.
	3-501.13	Thawing.

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

ROP Fish

Retailers should be aware that when a manufacturer packages fish and fishery products a hazard analysis is required under 21 CFR Parts 123 and 1240, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (the Seafood HACCP Rule) to provide for control for nonproteolytic *C. botulinum*. Factors that make formation of *C. botulinum* toxin reasonably likely to occur during finished product storage and distribution are those that may result from the use of a reduced oxygen packaging (ROP) environment in a food that does not contain barriers to growth of *C. botulinum*.

The processing control for *C. botulinum* can be either freezing, refrigeration alone or refrigeration in combination with chemical inhibitors, (e.g. salt, water activity control). The Fish and Fishery Products Hazards and Control Guidance, Fourth Edition, Chapter 13, addresses freezing as a control strategy for frozen product. This control is intended to prevent exposure of the product to conditions conducive to the production of toxin by nonproteolytic strains of *C. botulinum* in the closed ROP package.

If freezing was chosen by the manufacturer as the barrier to control for nonproteolytic strains of *C. botulinum*, then each individual package of the ROP fish should be labeled to be kept frozen and thawed according to the manufacturer's label instructions. Typically ROP fish will come into retail food establishments in a frozen state with a label that indicates to "thaw immediately before use" or indicates that the product needs to be "kept frozen, and thawed under refrigeration immediately before use."

If a "Keep Frozen" label is not present on each individual ROP package unit, it may or may not be acceptable to store under refrigeration, depending in part on whether there are barriers such as pH or water activity to growth of *C. botulinum* in addition to refrigeration.

As an added safeguard to prevent the possibility of *C. botulinum* toxin formation, the Food Code requires that any frozen ROP fish that does not have barriers to growth of *C. botulinum* in addition to refrigeration be completely removed from the ROP environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41°F or less for a prolonged time period and/or selling it as a refrigerated product.

3-501.14 Cooling.

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of time/temperature control for safety foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, time/temperature control for safety foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 52°C (70°F - 125°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

The Food Code provision for cooling provides for cooling from 135°F to 41°F or 45°F in 6 hours, with cooling from 135°F to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Code. The initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might involve cooling from 135°F to 70°F in 1 hour, in which case 5 hours remain for cooling from 70°F to 41°F or 45°F. Conversely, if cooling from 135°F to 41°F or 45°F is achieved in 6 hours, but the initial cooling to 70°F took 3 hours, the food safety hazards may not be adequately controlled.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as ***Clostridium perfringens*** or ***Bacillus cereus*** should be killed or inactivated. However, under substandard sanitary conditions, other pathogens such as ***Salmonella*** or ***Listeria monocytogenes*** may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

Shell Eggs

FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell egg pasteurization requires the egg to have been subjected to a 5-log kill process for ***Salmonella Enteritidis***, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction. Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that ***Salmonella Enteritidis*** will be eliminated in all treated eggs. Further, irradiated eggs must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a time/temperature control for safety food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a time/temperature control for safety food after cooling because pathogens, which may be present in the water, may pass through the egg shell during cooling.

Salmonella Enteritidis has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inapplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs...
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established Federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of ***Clostridium botulinum*** and ***Clostridium perfringens*** and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells can multiply to hazardous levels. The presence of sufficient numbers of ***C. botulinum*** or other spore-forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these organisms will provide the greatest amount of safety.

The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of ***C. botulinum*** and no more than 1 log growth of ***C. perfringens***. The performance standard of no more than 1 log growth of ***C. perfringens*** was based on the following reasons:

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of ***C. perfringens*** per gram as one of the criteria for incriminating ***C. perfringens*** as a causative agent of foodborne illness in finished product. However, foods responsible for ***C. perfringens*** outbreaks were found usually to contain 10^6 vegetative ***C. perfringens*** cells per gram.

In FSIS microbiological raw product surveys, samples were found to contain more than 1000 *C. perfringens* per gram. There is some probability that greater than 10^4 *C. perfringens* per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of *C. perfringens* in the raw product are spores.

2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 *C. perfringens* (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative *C. perfringens* per gram in the product if it is improperly cooled after cooking.
3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than $1 \log_{10}$ growth of *C. perfringens* would be appropriate to ensure that there would be no more than 10^5 *C. perfringens* per gram on the finished product after cooling.
4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of *C. perfringens* to no more than $1 \log_{10}$ would be reasonable and somewhat conservative with respect to product safety. (64 FR 732, January 6, 1999, Performance Standards for the Production of Certain Meat and Meat Products).

The FSIS compliance guideline for the cooling performance standards, which can be found at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index>. Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization), is that product must be cooled from 130°F to 80°F in 1.5 hours and from 80°F to 40°F in 5 hours. This cooling rate can be applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and poultry products. The guideline results in continuous and rapid cooling of the product in the temperature range where the spore-forming organisms can grow rapidly.

The former USDA guideline of cooling from 120°F to 55°F in no more than 6 hours is also included in the new compliance guidelines. In using this guideline, chilling should begin within 90 minutes after the cooking cycle is completed, and cooling should continue until product reaches 40°F. The 6-hour rule begins when the product reaches 120°F, and product should not be shipped until the product reaches 40°F. This older cooling guideline results in a significantly smaller margin of safety, especially if the product is non-intact. In using this older guideline, the establishment has to ensure that cooling is as rapid as possible, especially between 120°F and 80°F, and should monitor the cooling closely to prevent any deviation. If product remains between these temperatures for more than an hour, compliance with the performance standard is less certain.

The FSIS cooling guideline **for meat and poultry products containing 100 ppm added nitrite** is 130°F to 80°F in 5 hours and from 80°F to 45°F in 10 hours, a total of 15 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling deviations, the establishment should assume that their process has exceeded the performance standard for controlling the growth of *C. perfringens*, and should take corrective action. However, the **presence of nitrite** should ensure compliance with the performance standard for *C. botulinum*.

The Food Code provision for cooling is similar, though not identical to the FSIS cooling compliance guidelines. It provides for cooling from 135°F to 70°F in 2 hours and from 135°F to 41°F or 45°F in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Food Code provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the data on safe cooling times for cooked, time/temperature control for safety foods. The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130°F to 45°F can safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the study, continuous cooling of a meat product from 130°F to 45°F in 15 hours permitted about 1 log growth of *C. perfringens*.

In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data referenced in the CFP recommendation do not support a change in the FSIS guidance or the Food Code § 3-501.14 and considered it inadvisable to ask the NACMCF to undertake the task requested for several reasons:

1. The study did not address growth of *C. botulinum*.
2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.
3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other time/temperature control for safety foods.

As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position paper to clarify their joint position on the cooling issues.

3-501.15 Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

3-501.16 Time/Temperature Control for Safety Food, Hot and Cold Holding.

Bacterial growth and/or toxin production can occur if time/temperature control for safety food remains in the temperature "Danger Zone" of 5°C to 57°C (41°F to 135°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Cold Holding

Maintaining TCS foods under the cold temperature control requirements prescribed in this code will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness. All microorganisms have a defined temperature range in which they grow, with a minimum, maximum, and optimum. An understanding of the interplay between time, temperature, and other intrinsic and extrinsic factors is crucial to selecting the proper storage conditions for a food product. Temperature has dramatic impact on both the generation time of an organism and its lag period.

When considering growth rate of microbial pathogens, time and temperature are integral and must be considered together. Increases in storage and/or display temperature will decrease the shelf life of refrigerated foods since the higher the temperature, the more permissive conditions are for growth.

The exception for holding time/temperature control for safety food in specially designed dispensing equipment recognizes technology designs that maintain the safety of aseptically-packaged fluid foods when the equipment is manufactured and operated in conformance with the NSF/ANSI Standard No. 18. NSF/ANSI 18 was revised in 2006, with FDA input, to address the storage of certain types of time/temperature for safety food or beverages in dispensing equipment without temperature control. The key condition for FDA allowing this exemption from 3-501.16 is that the equipment conforms to the requirements as specified in NSF/ANSI 18.

Except for raw shell eggs, control of the growth of *Listeria monocytogenes* (*Lm*) is the basis for the list of cold holding temperature and time combinations in paragraph 3-501.17(A). The list addresses time, in addition to temperature, as a control for the growth of *Lm* in refrigerated, ready-to-eat, time/temperature control for safety food. The Code provisions for cold holding focus on environmental conditions that allow 1 log of growth of *Lm*, and do not set an acceptable number of *Lm* in food. Neither do they imply that *Lm* is in the product.

The times and temperatures in the 1999 Food Code were based on the USDA Pathogen Modeling Program (PMP), which is conservative in estimating how soon *Lm* begins to grow and how fast. The PMP was based largely on observations of microbial growth in broth cultures, but some observations in specific foods were also included. The PMP allows for some variation in temperature, pH, and water activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999 Food Code estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

During 2000, CFSAN researched published literature and compiled a listing of the growth potential of *Lm* in various food commodities using real food data. Based on this information, the 1999 Food Code times and temperatures of 41°F for 7 days and 45°F for 4 days were validated, but the underlying performance standard changed for the commodities studied. The research-based, food-specific times and temperatures allow no more than 1 log of growth instead of the 3 log growth predicted in the PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance standard and the fact that the infectious dose of *Lm* remains unknown.

FDA concluded that the 1999 Code time/temperature criteria hold true and provide both a greater level of safety and a more realistic basis for regulatory requirements without compromising public health protection.

In October 2003, FDA, in cooperation with the USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (risk assessment) at <http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessment/SafetyAssessment/UCM197329.pdf>.

This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

The risk assessment identified several broad factors that affect consumer exposure to *Lm* at the time of food consumption. Two of these factors, refrigerated storage temperature and duration of refrigerated storage before consumption, have a direct bearing on cold holding time/temperature combinations used in food establishments.

FDA continues to have concerns about the potential for growth of *Lm* in refrigerated, ready-to-eat, time/temperature control for safety food, prepared and packaged in a food processing plant and held in a food establishment. Data from the risk assessment (see the following Annex 3, 3-501.16, Table 1) show a significant reduction in the projected cases of listeriosis when refrigerated storage is limited to 41°F. Based on these data and conclusions from the risk assessment, FDA continues to recommend that food establishments limit the cold storage of time/temperature control for safety foods, ready-to-eat foods to a maximum temperature of 41°F.

3-501.16 – Table 1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures*

Maximum Refrigerator Temperature	Cases of Listeriosis ^a		
	Median	55 th Percentile	995 th Percentile
Baseline ^b	2105	3/4 ^c	3/4 ^c
7 °C (45 °F) maximum	656	331	761
5 °C (41 °F) maximum	28	1	126

^aValues for the median, upper and lower uncertainty levels.

^bThe baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.

^cThe baseline number of cases of listeriosis is fixed based on CDC surveillance data.

*The scenario assumed the distribution of storage times is the same for all three temperature sets.

Source: Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003. Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures.

Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998 Refrigeration and Labeling Requirements for Shell Eggs) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7°C (45°F). This regulation, however, does not apply to eggs while held at all retail establishments.

FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of ***Salmonella Enteritidis*** to occur. The agency reviewed research indicating that ***Salmonella Enteritidis*** multiplies at temperatures of 10°C (50°F) and above but can be inhibited at lower temperatures, e.g., 8°C (46°F), 7°C (45°F), and 4°C (39°F). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 7°C (45°F) for eggs stored and displayed at retail establishments. Amended Federal regulations 21 CFR Part 115.50 issued on December 5, 2000 and became effective on June 4, 2001.

Although Congress did not expressly preempt State law in this area, FDA found preemption is needed because State and local laws that are less stringent than the Federal requirements will not support the important public health goals of these regulations. FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will support the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the requirements of these regulations; requirements that are the same as or more stringent than FDA's requirements remain in effect.

Historical Record of Cold Holding Temperature Provisions

The 1976 Food Service Sanitation Manual recommended 45°F as the cold holding temperature. Based on the available science at the time, the 1993 Food Code lowered the cold holding temperature to 41°F.

However, stakeholders raised concerns that many of the refrigerators currently in place in food establishments would not be capable of maintaining food at that temperature. There was also concern that most of the open-top buffet and food prep table-type units being built at the time could not reliably maintain food at 41°F or less. Industry pointed out that operators needed to recover investments in new refrigeration equipment purchased just before or after a state adopted the 41°F provision.

Consequently, the Conference of Food Protection (CFP) recommended the 1997 Food Code incorporate the option of having a 5-year phase-in period for the 41°F requirement to allow for upgrading of existing equipment, and the FDA agreed.

By 2006, many states adopted and implemented the phase-in period, the 5 years had expired and they were requiring cold holding at 41°F or less. In addition, NSF/ANSI Standard 7 was revised in 1997 and again in 1999 to ensure that equipment conforming to the Standard, including open-top and display units, could achieve the desired performance under conditions typically found in the food service and retail environments. Thus, there are mechanisms in place to allow industry flexibility in holding foods out of temperature control and the exemption for holding at 45°F was no longer necessary, given equipment capabilities, existing provisions of the Food Code that could be utilized (e.g., variances, time as a public health control), and the impact on public health. Additionally, the FDA believed this exemption was no longer necessary and perhaps was detrimental to public health protection in light of what had been learned about the growth and survival of *Listeria monocytogenes* (LM) in refrigerated foods.

In 2006, the CFP recommended (CFP Issue 2006-I-033) and FDA agreed that the option of maintaining 45°F as a cold holding temperature be deleted from § 3-501.16. In the Supplement to the 2005 Food Code, the option to maintain 45°F as the cold holding temperature was deleted from the Food Code and 41°F became the standard for cold holding.

Hot Holding

In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended that the minimum hot holding temperature specified in the Food Code:

- Be greater than the upper limit of the range of temperatures at which ***Clostridium perfringens*** and ***Bacillus cereus*** may grow; and
- Provide a margin of safety that accounts for variations in food matrices, variations in temperature throughout a food product, and the capability of hot holding equipment to consistently maintain product at a desired target temperature.

C. perfringens has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than at 52°C (125°F). Studies also suggest that temperatures that preclude the growth of ***C. perfringens*** also preclude the growth of ***B. cereus***.

CDC estimates that approximately 250,000 foodborne illness cases can be attributed to ***C. perfringens*** and ***B. cereus*** each year in the United States. These spore-forming pathogens have been implicated in foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an important public health intervention.

Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food Protection meeting, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure in the prevention of foodborne illness.

- 3-501.17** **Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking.**
- 3-501.18** **Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.**

Refer to Annex 7, Chart 4-C.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as *Listeria monocytogenes*, is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat foods.

Based on a predictive growth curve modeling program for *Listeria monocytogenes*, ready-to-eat, time/temperature control for safety food may be kept at 5°C (41°F) a total of 7 days. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for *Listeria monocytogenes* to multiply, before freezing and after thawing. Time/temperature control for safety refrigerated foods must be consumed, sold or discarded by the expiration date.

Date marking is the mechanism by which the Food Code requires active managerial control of the temperature and time combinations for cold holding. Industry must implement a system of identifying the date or day by which the food must be consumed, sold, or discarded. Date marking requirements apply to containers of processed food that have been opened and to food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers. It is not the intent of the Food Code to require date marking on the labels of consumer size packages.

A date marking system may be used which places information on the food, such as on an overwrap or on the food container, which identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the Regulatory Authority upon request, during inspections.

FDA/USDA/CDC *Listeria monocytogenes* Risk Assessment

In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods at <http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessment/SafetyAssessment/UCM197329.pdf>. This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that 5 factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of a ready-to-eat food; (2) frequency and levels of *L. monocytogenes* in a ready-to-eat food; (3) potential of the food to support growth of the bacterium during refrigeration; (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption.

Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative risk of contamination and growth of *Listeria monocytogenes*. The risk categories used were: very high risk; high risk; moderate risk; low risk; and very low risk.

Impact of the Listeria monocytogenes Risk Assessment on Date Marking

Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on very high and high risk foods, while at the same time, exempting foods that present a very low, or low risk of contamination and growth of *Listeria monocytogenes*. Based on this evaluation, date marking provisions of the Food Code do not apply to the following foods:

Deli Salads Prepared and Packaged in a Food Processing Plant

Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of ***Listeria monocytogenes***. There are estimates that 85% of all deli salads are prepared and packaged in a food processing plant and do not support growth. Based on discussions with deli salad manufacturers and trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli salads to add one or more preservatives that inhibit the growth of ***Listeria monocytogenes***. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of ***Listeria monocytogenes***, all deli salads prepared and packaged in a food processing plant are exempt from date marking. However, all deli salads prepared in a food establishment require date marking.

Hard and Semi-Soft Cheeses

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses (<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113942.htm>), based on the presence of several factors that may control the growth of ***Listeria monocytogenes***. These factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are exempt from date marking.

List of Hard Cheeses Exempt from Date Marking	List of Semi-Soft Cheeses Exempt from Date Marking
Asadero Abertam Appenzeller Asiago medium or old Bra Cheddar Christalina Colby Cotija Anejo Cotija Coon Derby Emmentaler English Dairy Gex (blue veined) Gloucester Gjetost Gruyere Herve Lapland Lorraine Oaxaca Parmesan Pecorino Queso Anejo Queso Chihuahua Queso de Prensa Romanello Romano Reggiano Sapsago Sassenage (blue veined) Stilton (blue veined) Swiss Tignard (blue veined) Vize Wensleydale (blue veined)	Asiago soft Battelmatt Bellelay (blue veined) Blue Brick Camosum Chantelle Edam Fontina Gorgonzola (blue veined) Gouda Havarti Konigskase Limburger Milano Manchego Monterey Muenster Oka Port du Salut Provolone Queso de Bola Queso de la Tierra Robbiole Roquefort (blue veined) Samsoe Tilsiter Trappist

Cultured Dairy Products

Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation. Data from the risk assessment show that *Listeria monocytogenes* does not grow in these foods and therefore, these products are exempt from date marking.

Preserved Fish Products

Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products, manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or acidity of these products does not allow for the growth of *Listeria monocytogenes* and therefore, these products are exempt from date marking. This exemption does not apply to hot or cold smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved on-site, in a food establishment, such as ceviche.

Shellstock

Although *Listeria monocytogenes* has been isolated from shellstock there have been no reported Listeriosis cases linked to the consumption of this product at retail. The competitive microflora present in and on shellstock inhibits the growth of *Listeria monocytogenes* to harmful levels when the product is held under refrigeration at retail. Therefore shellstock are exempt from date marking.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable ready-to-eat meat and poultry products. Shelf stable ready-to-eat meat and poultry products are not required by USDA to be labeled “Keep Refrigerated.” For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label “Keep Refrigerated.” To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Food Code date marking requirements.

Shelf stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham, or Parma ham do not require refrigeration or Food Code date marking. Other salt-cured products include basturma, breasaola, coppa, and capocola.

Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the USDA-required label “Keep Refrigerated.” Examples of these products are cooked bologna, cooked salami, and sliced country ham which are ready-to-eat fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (non-time/temperature control for safety food) sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked.

If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is not required by USDA/FSIS and if applied, would not supercede or replace date marking requirements established by the Food Code or by State/local authorities that apply after the food is opened in a retail establishment.

Manufacturer’s use-by dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages.

Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer’s use-by date is its recommendation for using the product while its quality is at its best. Although it is a guide for quality, it could be based on food safety reasons. It is recommended that food establishments consider the manufacturer’s information as good guidance to follow to maintain the quality (taste, smell, and appearance) and salability of the product. If the product becomes inferior quality-wise due to time in storage, it is possible that safety concerns are not far behind.

It is not the intention of this provision that either the manufacturer’s date or the date marked by the food establishment be placed on consumer packages.

3-501.19 Using Time as a Public Health Control.

The 2000 Conference for Food Protection (CFP) meeting recommended that FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control, section 3-501.19. In response to the CFP recommendation, FDA in consultation with USDA/FSIS, determined that there is sufficient scientific information available to support the current provision in the Food Code without requesting consideration by the NACMCF. As an alternative response, FDA informed the CFP that it would provide the following position paper on using time alone as a public health control.

Position Paper

Food Code section 3-501.19 allows time/temperature control for safety food that is ready-to-eat (RTE) to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed or for up to 6 hours for refrigerated food, if the food is 5°C (41°F) when initially removed from temperature control, and as long as the food temperature does not exceed 21°C (70°F). The following information is provided to explain the reasoning in allowing time alone to be used as a public health control for food safety.

Background Information

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Holding Cold Food Without Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, *Listeria monocytogenes* is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of *L. monocytogenes* warrants concern for time/temperature control for safety foods RTE foods. Although the FDA and USDA have a zero tolerance for *L. monocytogenes* in RTE food, conditions are permitted in the Food Code that would allow *L. monocytogenes* cells 1 log of growth (3.3 generations). *Salmonella* is also a concern especially with products containing eggs. However *L. monocytogenes* grows more rapidly than *Salmonella* at refrigeration and room temperatures. By ensuring minimal *Listeria* growth in food, the threat from *Salmonella* would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow *B. cereus* to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41°F or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of *L. monocytogenes* remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for *L. monocytogenes* in food were not found, however published values at 68°F and 70°F in egg and milk products confirmed slow *L. monocytogenes* growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, *L. monocytogenes* would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly.

Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

It is important to note that time/temperature control for safety foods held without cold holding temperature control for a period of 4 hours do not have any temperature control or monitoring. These foods can reach any temperature when held at ambient air temperatures as long as they are discarded or consumed within the four hours.

Holding Hot Food without Temperature Control

The second scenario for food without temperature control exists when food is cooked according to Food Code recommendations, then kept at room temperature for 4 hours before discarding. Foodborne pathogens of concern for an uncontrolled temperature scenario are sporeformers including *Clostridium perfringens* and *Bacillus cereus*. Food cooked according to Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of *C. perfringens* or *B. cereus* and may actually serve as a heat shock that activates the spores. *B. cereus* is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. *C. perfringens* is found commonly in outbreaks attributed to inadequate hot holding of beef and poultry. Despite the prevalence of both spores in nature, *C. perfringens* cases are estimated to be more numerous than *B. cereus* cases by a factor of 10.

B. cereus can produce emetic toxin in food, and the optimum temperature for the production of toxin is between 77°F and 86°F. However, the time needed to produce the toxin is longer than the time the food will be exposed to any temperature range with a 4-hour holding limit. Both *C. perfringens* and *B. cereus* produce enterotoxin inside the intestine of the infected host if substantial numbers of vegetative cells are present in the food (10^{5-7} CFU/g). Although the reported levels of both spores in raw foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in food.

During the time without temperature control, the temperature of the food could decrease slowly enough to expose spores of both organisms to optimal growth conditions for a significant length of time. Like warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of foods prepared it would be impossible to generalize how fast a typical product loses temperature after cooking. As with warming, it is prudent to imagine a worst-case scenario where heat loss is slowed. A beef roast slow cooked to 130°F for the appropriate time according to the Food Code was used as consideration for possible spore growth. Cooking roast beef to 130°F can create an anaerobic environment in both the meat and gravy. The low internal temperature creates a small temperature differential with the environment (assumed at 75°F), allowing for a slower decrease in the food's temperature.

After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or rolled meat product would lose heat quickly enough to discourage significant growth of either *C. perfringens* or *B. cereus*. If all spores were distributed on the surface of the product by either pre- or post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe. Likewise, products that are stirred or products that lose heat faster than a roast would also be considered safe.

----- End of position paper -----

At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that examined scientific research related to the growth of *Listeria monocytogenes*, and the influence of time and temperature on its growth.

The 2004 CFP report stated that the USDA-PMP program can be used as a tool to estimate time periods for a 1-log increase in growth for *Listeria monocytogenes* in ideal (laboratory media) growth conditions. Using this modeling approach, at 41°F, 45°F, and 50°F, the time for a 1-log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (70°F) a 1-log increase was noted at 5.2 hours and at ideal growth temperatures (95°F), the reported time for a 1-log increase was 3.0 hours. In general, the data from the USDA-PMP program provides very conservative growth data and, in most cases, growth would be expected to be less rapid in a food system. This table does provide comparative information relative to growth rates at different holding temperatures in the event that time was used as a factor in managing food safely.

The report further recommended that food could safely be held for up to 6 hours without external temperature control as long as the food temperature did not exceed 70°F. Based on that report and data from the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003, the Food Code allows time/temperature control for safety food to be stored up to 6 hours without external temperature control provided that the food temperature does not exceed 70°F and the food is discarded or consumed at the end of the 6 hours.

The Safety of the Time as a Public Health Control Provision from Cooking Temperatures (135°F or above) to Ambient

FDA conducted in-house laboratory experiments to test the safety of the existing TPHC provisions of 4 hours without temperature control starting with an initial temperature of 135°F or above. *Clostridium perfringens* was chosen to represent a worst case scenario pathogen for foods allowed to cool from cooking temperatures to ambient without temperature control, because its spores can survive normal cooking procedures, it can grow at relatively high temperatures (>120°F) and it has a short lag period. *C. perfringens* spores were inoculated into foods that were cooked and then cooled to yield a cooling curve that would promote outgrowth as quickly as possible. The growth data suggest that the existing 4-hour TPHC provision will be safe for 6 hours after cooking, with the additional 2-hour margin of safety built-in for consumer handling.

Consumer Handling Practices

An Audits International study was funded in 1999 by FDA to determine the food handling practices of consumers purchasing food at retail and returning home to refrigerate their items. Forty-six (46) states are represented, and the data comprises several food groups purchased from different grocery-store types. The food groups represented were: pre-packaged lunch meat, deli-counter products, seafood, fresh meat, pre-packaged deli product, liquid dairy, semi-solid dairy product, ice cream, frozen entrées, frozen novelties and whipped topping.

The study evaluated information regarding time and food temperature at retail food stores, time to reach home refrigeration, temperature after transport home, location and type of retail establishment where purchase was made and type of product purchased.

For product temperature at retail and after transportation, 5 product categories were used: pre packaged lunch meat, pre packaged deli product, deli counter products, seafood and fresh meat. These categories were considered most applicable to the TPHC recommendations. The temperature ranges for these products at retail and after transport to the home are summarized in Figures 1 and 2 respectively. The data suggest that with current retail refrigeration practices, 25% of items are held above 45°F (Figure 1). The data also show that by the time the product arrives at the home, 98% of products were at 65°F or less (Figure 2).

The time of transport for all food categories from the retail establishment to home refrigeration was also recorded. The data summarized in Figure 3 shows that over 97% of the foods purchased were ready to be placed in refrigeration within 2 hours of purchase. For this histogram, all food categories except for frozen entrées were included. Because all foods end up bagged and transported together, the time each product was transported to the home was considered a valid data point and therefore used. Based on the data, a benchmark was established that TCS foods purchased in a food establishment would be either consumed, or placed under temperature control, within 2 hours.

Figure 1. Temperatures of refrigerated products at retail (Audits International).

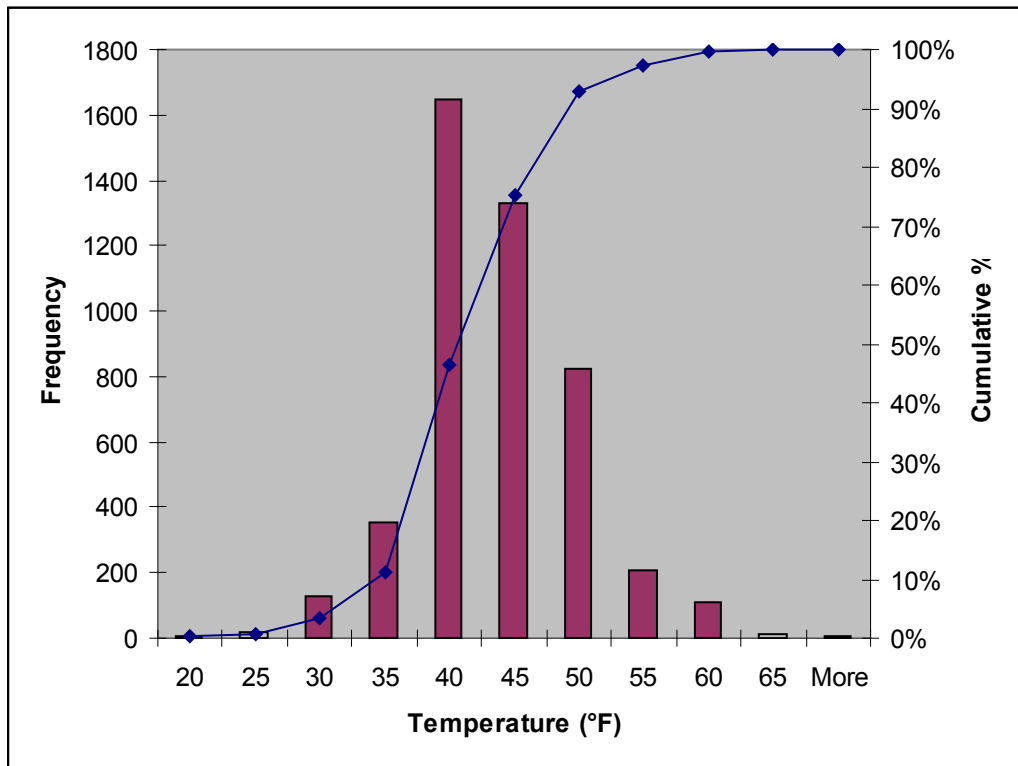


Figure 2. Product temperatures after transport to the home (Audits International).

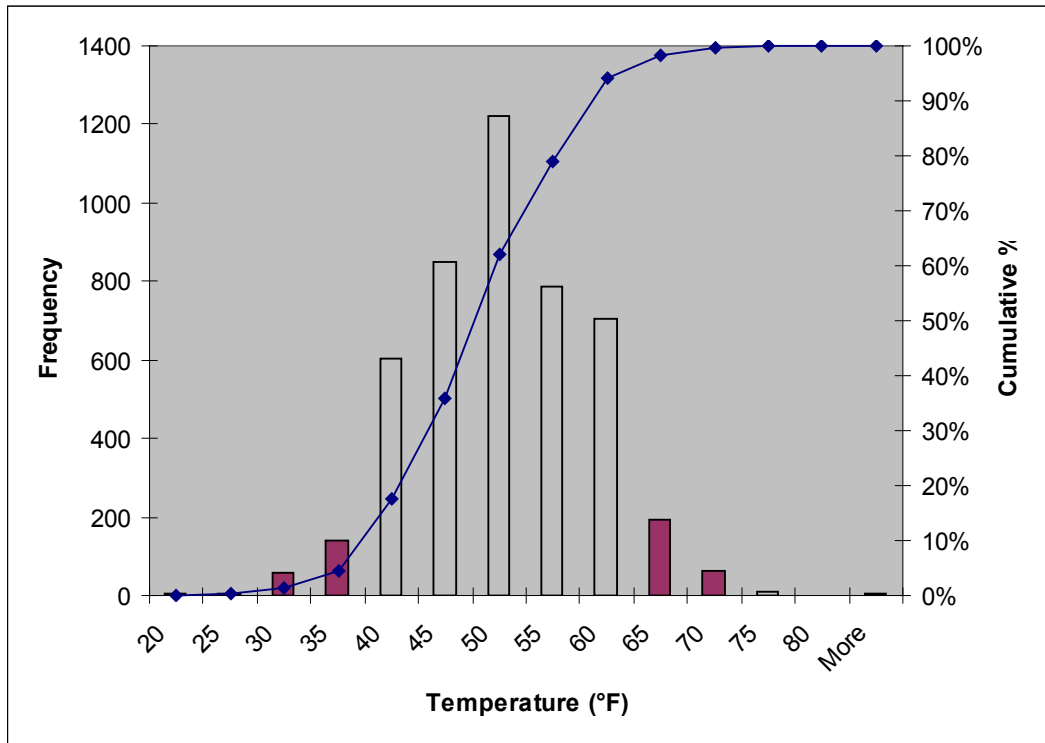
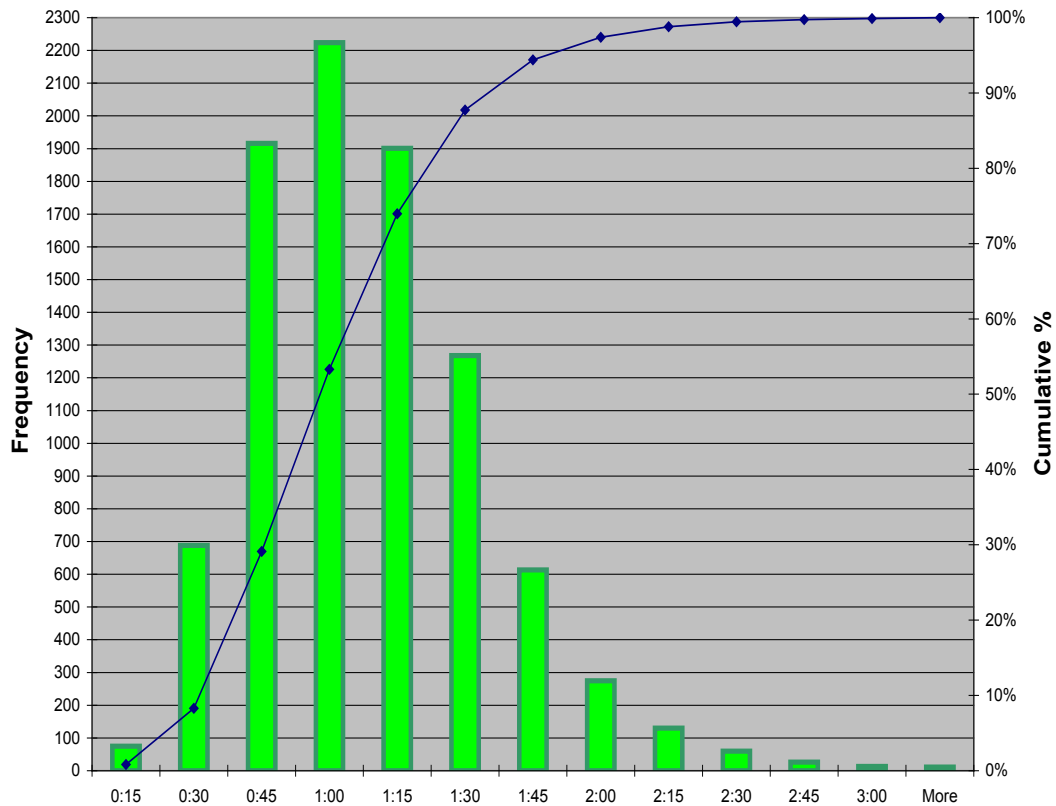


Figure 3. Times reported for transport of grocery items from the retail outlet to the home (Audits International).



The Safety of the Time as a Public Health Control Provision from Refrigeration Temperatures (41°F or less) to Ambient

As noted above, the current TPHC provision has two time provisions. Food can be kept with no temperature stipulations for 4 hours in a food establishment, at which time the food must be cooked and served, served if RTE, or discarded within the four hours. However, if food does not exceed 70°F, it may be held for 6 hours and cooked and served, served if RTE or discarded within the six hours. For foods warming from refrigeration to ambient temperatures, the data from the Audits International study outlined above, along with simulations from the USDA Pathogen Modeling Program (PMP), were used to determine the safety of the existing TPHC recommendations.

Assuming pathogen growth in foods going from refrigeration (41°F or less) to ambient temperature, the following parameters were used for the PMP simulation:

- 65°F was used as the temperature for the entire simulation;
- 2 hours were added to all times (4h or 6h) allowed in the current TPHC recommendation, to factor in transportation time (per the Audits International study outlined above);

- The data were generated from PMP broth models (pH 6.8), with the minimal NaCl and no sodium nitrite.

Table 1 summarizes the predicted growth of *Bacillus cereus* (vegetative), *Escherichia coli*, *Listeria monocytogenes*, *Salmonella* spp., *Shigella flexneri*, and *Staphylococcus aureus*, using the PMP and based on the assumptions discussed above. The data predicted that less than 1-log growth would be seen for each organism, during the 8 hour time period. Thus, the data show that the current 4 and 6 hour TPHC provisions from 41°F or less to ambient, allow minimal growth of a number of pathogens of concern.

Table 1. The USDA Pathogen Modeling Program estimation of growth (Log CFU/g) of several pathogens for 6 hours or 8 hours, at 65°F.

Pathogens	6 Hours	8 hours
<i>B. cereus</i> (vegetative cells)	0.62	0.87
<i>E. coli</i>	0.35	0.52
<i>L. monocytogenes</i>	0.47	0.71
<i>Salmonella Spp.</i>	0.25	0.41
<i>S. flexneri</i>	0.26*	0.34*
<i>S. aureus</i>	0.38*	0.51*

* Model predictions were in 5 hour increments, the 6 and 8 hour data was extrapolated between 5 hour and 10 hour predictions.

References

U.S. Department of Agriculture. 1997. *Pathogen Modeling Program*. USDA Agricultural Research Service, Wyndmoor, PA.

Food and Drug Administration. 2006. Growth of *Clostridium perfringens* inoculated into beef roasts and meatloaf (unpublished data).

----- End of Summary of Consumer Handling Practices study -----

Raw eggs

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with ***Salmonella Enteritidis***, that the use of time as a public health control in institutional settings is not allowed.

**Specialized
Processing
Methods**

3-502.11

Variance Requirement.

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.

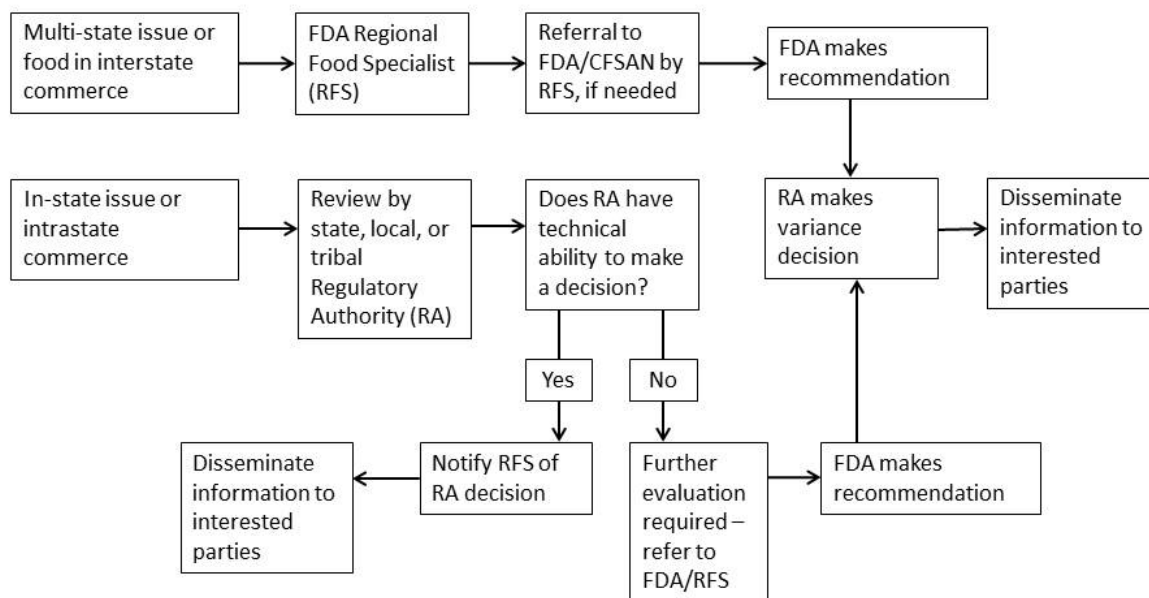
Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.

Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.

FDA recommends that regulatory authorities develop a written administrative process that is consistent with, and addresses the information contained in, Food Code sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.

3-502.11 Chart 1 – A Model Flow Process for State Regulators to Address Variances

Developed by the CFP Variance Committee



Model Administrative Procedures for Regulators to Address Variances

- 1) Designate an agency team and assign a leader to address variance requests.
- 2) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.
- 3) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.
 - a) For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the issue exists. Regulators are encouraged to be consistent with national policies, guidelines, or opinions.
 - b) For variances that address intrastate issues, regulators are also encouraged to determine if other State or national guidance exists, and to stay consistent with it.

- 4) Make the agency's decision. Inform the applicant.
 - a) If the variance request is approved, determine the starting date and document all special provisions with which the applicant must comply.
 - b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.
- 5) Inform other interested parties, including the FDA Regional Food Specialist.
 - a) For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.
 - b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.
- 6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.
- 7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.
- 8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.
- 9) Establish written procedures for withdrawing approval of the variance if it is not successful.

3-502.12

Reduced Oxygen Packaging Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic. ROP may also offer benefits related to time and labor savings, portion control and quality retention. However, ROP can also increase the potential for the growth of certain pathogens in the absence of the growth of competing spoilage organisms. For example, if certain controls are not in place, the formation of ***C. botulinum*** toxin may occur before spoilage renders the product unacceptable to the consumer.

The type of food, the production and packaging methods used, and the packaging material can impact the level of oxygen present within a package and within the food matrix. Combinations of some or all of these variables may result in an oxygen level within a package, or within a food matrix, that is less than 21%. While ROP may involve different foods and different packaging materials, each process is characterized by the deliberate removal of oxygen from or the reduction in the oxygen level in the package or the food matrix at the time of packaging.

Certain foodborne pathogens that are anaerobes or facultative anaerobes are able to multiply under either aerobic or anaerobic conditions. Therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic ***C. botulinum*** and ***L. monocytogenes*** are able to multiply well below 5°C (41°F). For this reason, ***C. botulinum*** and ***L. monocytogenes*** are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

Reduced Oxygen Packaging with Two Barriers

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes*** without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control ***C. botulinum*** and ***L. monocytogenes*** when used in conjunction with a food storage temperature of 5°C (41°F) or less. These barriers are:

- a_w of 0.91 or less;
- pH of 4.6 or less;
- cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or

- high levels of competing microorganisms such as those found on raw meat or raw poultry or raw vegetables.

The barriers described above are effective controls for **C. botulinum** and **L. monocytogenes** in reduced oxygen packaged foods because:

- **C. botulinum** will not produce toxin below an a_w of 0.91, and the minimum a_w for growth of **L. monocytogenes** is 0.92.
- **C. botulinum** will not produce toxin when the pH is 4.6 or below and **L. monocytogenes** will generally not grow at this pH under refrigeration temperatures.
- Nitrite, used in meat and poultry curing, inhibits the outgrowth of **C. botulinum** spores.
- Most foodborne pathogens do not compete well with other microorganisms. Therefore foods that have a high level of spoilage organisms or lactic acid bacteria that grow under ROP conditions can safely be packaged using ROP and held for up to 30 days at 5°C (41°F).

Other intrinsic or extrinsic factors can also control the growth and/or toxin production of **C. botulinum** and **L. monocytogenes**.

Foods that are not time/temperature control for safety food (TCS) should not support the growth of **C. botulinum** and **L. monocytogenes**. Therefore the reduced oxygen packaging HACCP requirements of sections 3-502.11 or 3-502.12, apply only to TCS foods.

Reduced Oxygen Packaging with One Barrier (Cook-Chill and Sous Vide)

Some foods may not have secondary barriers to prevent the growth of **C. botulinum** and **L. monocytogenes**, such as a_w , pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses. When these foods are packaged using a reduced oxygen packaging process, time/temperature becomes the critical controlling factor for growth of **C. botulinum** and **L. monocytogenes**. Non-proteolytic **C. botulinum** spores are able to germinate and produce toxin at temperatures down to 3°C (38°F). Therefore, holding ROP foods at 3°C (38°F) or less should prevent the formation of **C. botulinum** toxin. **L. monocytogenes** is able to grow, although very slowly, at temperatures down to -1°C (30°F). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Three separate options are provided in (D)(2)(e).

These time-temperature combinations will provide equivalent food safety protection without need for a variance. (***L. monocytogenes*** will be eliminated by the cooking procedures specified in ¶¶3-401.11(A), (B) and (C) and recontamination will be prevented by filling the product into the bag while it is still hot (cook-chill) or by cooking in the sealed bag (sous vide). ***C. botulinum*** will not grow under the specified time-temperature combinations.)

Since there may not be other controlling factors for ***C. botulinum*** and ***L. monocytogenes*** in a cook-chill or sous vide packaged product, continuous monitoring of temperature control and visual examination to verify refrigeration temperatures is important. New technology makes it possible to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook-chill and sous vide products at 1°C (34°F) or 5°C (41°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures that can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook-chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Reduced Oxygen Packaging with Cheese

Cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following:

- a lower pH;
- salt (NaCl) added during processing;
- low moisture content;
- added preservatives; and
- live competing cultures.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on the intrinsic factors in these cheeses plus the refrigeration temperature of 41°F or less to maintain safety. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of ***L. monocytogenes*** under modified atmosphere conditions.

Reduced Oxygen Packaging with Fish

Unfrozen raw fish and other seafood are specifically excluded from ROP at retail because of these products' natural association with non-proteolytic *C. botulinum* (primarily type E) which grows at 3°C (37-38°F). ROP of fish and seafood that are frozen before, during and after the ROP packaging process does not present this hazard.

HACCP Plans with Reduced Oxygen Packaging

A Hazard Analysis and Critical Control Point (HACCP) plan is essential when using ROP processing procedures. *C. botulinum* and *L. monocytogenes* are potential hazards which must be controlled in most TCS foods. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used. Developing a HACCP plan and providing a copy to the regulatory authority prior to implementation provides notice to the regulatory authority that the food establishment intends to conduct ROP operations and makes it possible to verify that the appropriate ROP procedures are being followed and that the requirements of §3-502.12 are being met.

When a food establishment intends to conduct ROP and hold the product for more than 48 hours without using one of the secondary barriers defined in section 3-502.12 (the criteria specified in paragraph 3-502.12(D) combined with holding the product at 5°C (41°F) or less, or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), it is important that an application for a variance (under section 3-502.11) provide evidence that the ROP methodology intended for use is safe.

The Relationship Between Time and Reduced Oxygen Packaging

Time is also a factor that must be considered in ROP at retail. The use of date labels on VP, MAP, and CAP products and assuring those dates do not exceed the manufacturer's "sell by" or "use by" date is intended to limit the shelf life to a safe time period (based on a time in which growth will not occur or involves the presence of two barriers to growth). When these ROP products are frozen, there is no longer a restricted shelf life. The shelf life limits for cook-chill and sous-vide foods are based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 1°C (34°F) or less for 30 days or 5°C (41°F) or less for 7 days after packaging, with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook-chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook-chill and sous-vide processes.

3-502.12 (F) exempts refrigerated, ROP foods that are always removed from the package within 48 hours of packaging from the requirements in section 3-502.12 because growth and toxin formation by anaerobic pathogens in that limited time frame is not considered a significant hazard in such foods.

Accurate Representation	3-601.11 3-601.12	Standards of Identity. Honestly Presented.
Labeling	3-602.11 3-602.12	Food Labels. Other Forms of Information.

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness outbreak and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Food Labels and other forms of Information

Food labels serve as a primary means by which consumers can make informed decisions about their food selections. Many items in a food establishment are provided by the food employee to the consumer upon consumer request. When a consumer orders a specific food or specific amount of food from a food employee, that employee may put the food in a wrapper or carry-out container at the time the order is placed. This food is not considered “packaged”, per the Food Code definition; it was merely wrapped or placed in a carry-out container to facilitate service and delivery of the food to the consumer in a protected manner. When food is under the direct control of the operator and provided to the consumer upon consumer request, the consumer has an opportunity to ask about ingredients, nutrients, allergens and weight.

Alternatively, some food items are enclosed in a container or wrapping for use in the display of that item for consumer self-service. In these instances, the label provides an important source of information for consumers to answer questions about ingredients, allergens, weight, and manufacturer.

List of Ingredients

A list of ingredients on the label enables a consumer to make an informed decision about a packaged food product. Therefore it is important that the list of ingredients accurately describe all of the ingredients present in the food. In some instances, an ingredient itself may be composed of two or more ingredients, or sub-ingredients. The 21 CFR 101.4(b)(2), calls for the sub-ingredients to be declared on the label - d. One example includes parenthetically listing the individual sub-ingredients in descending order of predominance after the common or usual name of the main ingredient, as illustrated here:

- Bread pudding: bread (*wheat flour, water, yeast, salt, honey*), milk, eggs, and sugar

Another example is to incorporate the common or usual name of each sub ingredient into the list of ingredients in descending order of predominance in the finished food without listing the ingredient itself, as illustrated here :

- Bread pudding: milk, wheat flour, water, eggs, sugar, yeast, salt, and honey.

Food Allergen Labeling

The Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282) require that all affected packages of food labeled on or after January 1, 2006 identify on the label the names of the food sources of any major food allergens (i.e., the following eight foods and any protein derived from them: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) used as ingredients in the food. Providing the name of the food source on the label of packaged foods alerts consumers to the presence of a major food allergen and may prevent an inadvertent exposure. The names of the food sources are the same as the names of the eight foods that are major food allergens, with the exception that for fish, crustacean shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass, flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the specific types of tree nuts (e.g., almonds, pecans, or walnuts).

Nutrition Labeling

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in the CFR referenced in subparagraph 3-602.11(B)(6) if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

- (1) The food establishment has total annual sales to consumers of no more than \$500,000 (or no more than \$50,000 in food sales alone), and
- (2) The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Nutritional Products Labeling and Dietary Supplements Food Labeling by a small business with less than 100 full-time equivalent employees, or

(2) The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments, and foods sold only in those establishments;

(D) Foods similar to those specified in the preceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:

(1) Ready-to-eat but not necessarily for immediate consumption,

(2) Prepared primarily in the food establishment from which it is sold, and

(3) Not offered for sale outside the food establishment;

(E) Foods of no nutritional significance such as coffee;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

Canthaxanthin and Astaxanthin

Canthaxanthin and Astaxanthin are color additives for salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout, cutthroat trout, and brown trout. These color additives may be in the feed that is fed to aquacultured fish. When those fish are placed into a bulk container for shipment, the bulk container will bear a label declaring the presence of canthaxanthin.

Providing this information on the label of fish packaged and offered for sale at retail will inform the consumer of the presence of these additives

21 CFR 73.75 promulgates requirements for the use of canthaxanthin in salmonid fish. 21 CFR 73.35 promulgates requirements for the use of astaxanthin in salmonid fish. For additional information, see the Federal Register announcement 63 FR 14814, March 27, 1998, Listing of Color Additives Exempt from Certification, Canthaxanthin.

Safe Handling Instructions

Refer to public health reason for § 3-201.11 Labeling for Meat and Poultry.

Consumer Advisory	3-603.11	Consumption of Raw or Undercooked Animal Foods.
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Refer to the public health reason for § 3-401.11.

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior. The following information is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

"FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."

Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for "**disclosure**" of what consumers view as "hidden ingredients," for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a "**reminder**" that consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are provided**, as described in § 3-603.11 of the Code. **Disclosure is** achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such raw or undercooked ingredients. A third option for the consumer "reminder" was added later. The **reminder is** a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. Essential criteria for such written information are available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740. All brochures must meet these essential criteria. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

The information contained in both the disclosure and reminder should be publicly available and readable so that consumers have benefit of the total message (disclosure and reminder) before making their order selections.

It is not possible to anticipate all conceivable situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

The *Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code* (section 3-603.11 in the FDA Model Food Code), is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740.

Locating the Advisory:

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

Educational Messages:

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to § 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the information is being requested by the consumer, it would be expected to play a role in subsequent choices.

Applicability:

Food Establishments:

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

"... Otherwise Processed to Eliminate Pathogens...":

This phrase is included in § 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by § 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in §§ 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

Recognition of Other Processes:

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing ***Vibrio vulnificus*** in oysters to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, "pasteurized to reduce ***Vibrio vulnificus***" or "temperature treated to reduce ***Vibrio vulnificus***." Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not, however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, § 3-603.11. In the insert page for § 3-603.11, the **Reminder** options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words “meat” rather than “beef, lamb, and pork” and “seafood” rather than “fish” are used. Categorical terms like “meat” are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, “milk” is not mentioned in the actual on-site advisory language. The sale or transportation of final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of an official FDA position statement found at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007973.htm>). Nonetheless, approximately 25 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by § 3-603.11 of this Code operates in conjunction with a dairy farm in a State that allows the in-State sale or service of unpasteurized milk, or in the case where a State allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to Consumer Advisory Reminder, paragraph 3-603.11(C), options 2 or 3).

Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from ***Vibrio*** infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

Disposition **3-701.11** **Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.**

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Additional Safeguards **3-801.11** **Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.**

Refer to the public health reason for § 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of a “juice” means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as ***Cryptosporidium***, Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Vibrio cholera***. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly susceptible population.

In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile products (canned juices) are acceptable for service to a highly susceptible population. Persons providing pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food safety.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of **Salmonella Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a **Salmonella Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of **Salmonella Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to **Salmonella Enteritidis**.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. Further information is available at the FDA website, <http://www.fda.gov>, by entering "sprouts" in the search window.

Although the Code's allowance for the Regulatory Authority to grant a variance (refer to §§ 8-103.10 - .12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operating plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 3-801.11(F)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of ***Salmonella Enteritidis***.

3-801.11(G) and (H) Re-service of food

The Food Code addresses two issues concerning persons in isolation:

1. Contamination from an isolated patient to others outside.

The re-service of any food including unopened, original, intact packages in sound condition, of non-temperature controlled for safety food from a person in isolation or quarantine for use by anyone else (other patients, clients, or consumers) is not permitted. The “isolation or quarantine” terminology in the Code text refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers. Once food packages come to a contact isolation room, they stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, they must be discarded.

2. Contamination from the outside into a room with a patient in a “protective environment” isolation setting which protects the patient from contacting pathogens from other patients, healthcare workers, or other persons.

Packages of food from any patients, clients or other consumers should not be re-served to persons in protective environment isolation. Precautions similar to the isolation setting apply to this setting, i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food should be delivered to this patient each time.

To summarize the key difference between the two scenarios:

- Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.
- Patients in protective environments should not be re-served with food packages from other patients because of the potential for disease transmission to the protective environment patient.

Chapter 4 Equipment, Utensils, and Linens

Multiuse 4-101.11 Characteristics.

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4-101.12 Cast Iron, Use Limitation.

Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.

4-101.13 Lead, Use Limitation.

Historically, lead has been used in the formulation or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery (Ceramics); Imported and Domestic – Lead Contamination (CPG 7117.07) for leachable lead in ceramicware, and pieces that exceed these levels are subject to recall or other agency enforcement action. The levels are based on how frequently a piece of ceramicware is used, the type and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs, and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee mug is generally used every day to hold a hot acidic beverage, often several times a day.

The FDA allows use of lead glazes because they're the most durable, but regulates them tightly to ensure their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that keep the lead from leaching during use. Small potters often can't control the firing of lead glazes as well so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

In 21 CFR 109.16, FDA requires high-lead-leaching decorative ceramicware to be permanently labeled that it's not for food use and may poison food. Such items bought outside the United States may not be so labeled, potentially posing serious risk if used for food.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys.

4-101.14 Copper, Use Limitation.

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 22 hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

4-101.15 Galvanized Metal, Use Limitation.

Galvanized means iron or steel coated with zinc. Metals such as iron and steel are coated with zinc to prevent rusting. Under certain conditions, zinc may leach from galvanized food-contact surfaces into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized food-contact surface. On contact with acidic foods and beverages, the zinc may be converted to zinc salts which are readily absorbed by the body

Zinc is generally considered to be non-toxic, and in fact is a required mineral for many processes that occur in the human body. However, zinc is known to be toxic when ingested in large quantities. Symptoms of zinc poisoning include vomiting, nausea, lethargy, fatigue, and epigastric pain. Most reports of zinc poisoning implicate contaminated food that resulted from storage in a galvanized metal container.

Also see <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000082.htm>

4-101.16 Sponges, Use Limitation.

Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

4-101.17 Wood, Use Limitation.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

4-101.18 Nonstick Coatings, Use Limitation.

Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. The Agency has determined that neither the particles that may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched by sharp or rough-edged kitchen tools, the manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided.

4-101.19 Nonfood-Contact Surfaces.

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

***Single-Service and Single-Use* 4-102.11 Characteristics.**

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

Durability and Strength

4-201.11

Equipment and Utensils.

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they can not maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

4-201.12

Food Temperature Measuring Devices.

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

Cleanability

4-202.11

Food-Contact Surfaces.

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

4-202.12

CIP Equipment.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

4-202.13 "V" Threads, Use Limitation.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

4-202.14 Hot Oil Filtering Equipment.

To facilitate and ensure effective cleaning of this equipment, Code requirements, §§ 4-202.11 and 4-202.12 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

4-202.15 Can Openers.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

4-202.16 Nonfood-Contact Surfaces.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

4-202.17 Kick Plates, Removable.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

Accuracy 4-203.11 Temperature Measuring Devices, Food.

The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) requires that all Federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using the Fahrenheit scale for temperature measurement.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) which requires the use of metric values. The $\pm 1.5^{\circ}\text{C}$ requirement is more stringent than the 3°F previously required since $\pm 1.5^{\circ}\text{C}$ is equivalent to $\pm 2.7^{\circ}\text{F}$. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the 3°F requirement applies because of the calibrated intervals of Fahrenheit thermometers.

The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a temperature measuring device that measures from a specified frozen temperature to 20°C (68°F). The device must be accurate to specifications within that use range.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

***Functionality* 4-204.11 Ventilation Hood Systems, Drip Prevention.**

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drizzle are no longer clean.

4-204.12 Equipment Openings, Closures and Deflectors.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects, or rodents. If the equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

NSF/ANSI 18-*Manual Food and Beverage Dispensing Equipment* is the standard for manual food and beverage dispensing equipment which has been designed to maintain the safety of aseptically packaged fluid foods without refrigeration even after the hermetic seal is broken.

NSF/ANSI 18 was revised in 2006 to specifically address dispensing equipment designed to hold time/temperature control for safety food or beverages in a homogeneous liquid form without temperature control. NSF/ANSI 18 requires that such equipment designs include a number of safeguards that prevent the contamination of specially packaged food stored within the dispensing equipment. The Standard also requires that the dispensing equipment have lockout mechanisms that preclude the dispensing of the product if such safeguards fail or if a prescribed duration of storage is exceeded.

The American National Standards Institute (ANSI) recognizes NSF/ANSI 18 as the sole American National Standard for the sanitary design of manual food and beverage dispensers.

4-204.14 Vending Machine, Vending Stage Closure.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4-204.15 Bearings and Gear Boxes, Leakproof.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4-204.16 Beverage Tubing, Separation.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4-204.18 Condenser Unit, Separation.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4-204.19 Can Openers on Vending Machines.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4-204.110 Molluscan Shellfish Tanks.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

4-204.111 Vending Machines, Automatic Shutoff.

Failure to store time/temperature control for safety food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control," provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4-204.112 Temperature Measuring Devices.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all time/temperature control for safety foods are stored at least at the minimum temperature required in Chapter 3.

Installing an air thermometer in some open display refrigerators can be difficult without physically impairing the usability of the case and interfering with cleaning and sanitation. Use of a temperature monitoring system that uses probe-like sensors that are placed in material resembling the density of food is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of this product mimicking method.

A permanent temperature measuring device is required in any unit storing time/temperature control for safety food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining time/temperature control for safety foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4-204.114 Warewashing Machines, Internal Baffles.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

**4-204.117 Warewashing Machines, Automatic
Dispensing of Detergents and Sanitizers.**

The presence of adequate detergents and sanitizers is necessary to effect clean and sanitized utensils and equipment. The automatic dispensing of these chemical agents, plus a method such as a flow indicator, flashing light, buzzer, or visible open air delivery system that alerts the operator that the chemicals are no longer being dispensed, ensures that utensils are subjected to an efficacious cleaning and sanitizing regimen.

**4-204.118 Warewashing Machines, Flow Pressure
Device.**

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for section 4-203.13.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

4-204.121 Vending Machines, Liquid Waste Products.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

4-204.122 Case Lot Handling Equipment, Movability.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

4-204.123 Vending Machine Doors and Openings.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

Acceptability **4-205.10** **Food Equipment, Certification and Classification.**

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Equipment **4-301.11** **Cooling, Heating, and Holding Capacities.**

The ability of equipment to cool, heat, and maintain time/temperature control for safety foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4-301.12 **Manual Warewashing, Sink Compartment Requirements.**

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;
2. Removal of any abrasive and removal or dilution of cleaning chemicals; and
3. Sanitization.

Refer also to the public health reason for § 4-603.16.

4-301.13 Drainboards.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

4-301.14 Ventilation Hood Systems, Adequacy.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for § 4-204.11.

4-301.15 Clothes Washers and Dryers.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for § 4-401.11.

Utensils, Temperature Measuring Devices, and Testing Devices **4-302.11 Utensils, Consumer Self-Service.**

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked time/temperature control for safety food.

4-302.12 Food Temperature Measuring Devices.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

When determining the temperature of thin foods, those having a thickness less than 13 mm (1/2 inch), it is particularly important to use a temperature sensing probe designed for that purpose. Bimetal, bayonet style thermometers are not suitable for accurately measuring the temperature of thin foods such as hamburger patties because of the large diameter of the probe and the inability to accurately sense the temperature at the tip of the probe. However, temperature measurements in thin foods can be accurately determined using a small-diameter probe 1.5 mm (0.059 inch), or less, connected to a device such as thermocouple thermometer.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

Effective mechanical hot water sanitization occurs when the surface temperatures of utensils passing through the warewashing machine meet or exceed the required 71°C(160°F). Parameters such as water temperature, rinse pressure, and time determine whether the appropriate surface temperature is achieved. Although the Food Code requires integral temperature measuring devices and a pressure gauge for hot water mechanical warewashers, the measurements displayed by these devices may not always be sufficient to determine that the surface temperatures of utensils are reaching 71°C(160°F). The regular use of irreversible registering temperature indicators provides a simple method to verify that the hot water mechanical sanitizing operation is effective in achieving a utensil surface temperature of 71°C (160°F).

4-302.14 Sanitizing Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and
2. Too much sanitizer in the final rinse water could be toxic.

Location **4-401.11** **Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.**

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

Installation **4-402.11** **Fixed Equipment, Spacing or Sealing.**

This section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;
2. Ensures that equipment that is subject to moisture is sealed;
3. Prevents the harborage of insects and rodents; and
4. Provides accessibility for the monitoring of pests.

4-402.12 **Fixed Equipment, Elevation or Sealing.**

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

Equipment**4-501.11****Good Repair and Proper Adjustment.**

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding time/temperature control for safety foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Contact time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12**Cutting Surfaces.**

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4-501.13**Microwave Ovens.**

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4-501.14**Warewashing Equipment, Cleaning Frequency.**

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4-501.16 Warewashing Sinks, Use Limitation.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

4-501.17 Warewashing Equipment, Cleaning Agents.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4-501.18 Warewashing Equipment, Clean Solutions.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.

If the temperature during the hot water sanitizing step is less than 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

The temperature of hot water delivered from a warewasher sanitizing rinse manifold must be maintained according to the equipment manufacturer's specifications and temperature limits specified in this section to ensure surfaces of multiuse utensils such as kitchenware and tableware accumulate enough heat to destroy pathogens that may remain on such surfaces after cleaning.

The surface temperature must reach at least 71°C (160°F) as measured by an irreversible registering temperature measuring device to affect sanitization. When the sanitizing rinse temperature exceeds 90°C (194°F) at the manifold, the water becomes volatile and begins to vaporize reducing its ability to convey sufficient heat to utensil surfaces. The lower temperature limits of 74°C (165°F) for a stationary rack, single temperature machine, and 82°C (180°F) for other machines are based on the sanitizing rinse contact time required to achieve the 71°C (160°F) utensil surface temperature.

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, Federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. Provisions for pH, temperature, and water hardness in section 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels. Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and if pH, temperature, and water hardness (for quat) are not included on the label, that the solutions meet the standards required in the Code.

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature minimum levels and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated.

By contrast, paragraph 4-703.11(C) addresses contact time in seconds. For chemical sanitization, this paragraph is only violated when the specified contact time is not met.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940.

EPA sanitizer registration assesses compliance with 40 CFR 180.940, therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. If a sanitarian determined that a solution exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.

To summarize, a sanitizing solution that is too weak would be a violation of section 4-501.114. A solution that is too strong would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use chemical sanitizers.

A variety of hard food contact surface sanitizers such as sodium hypochlorite or hypochlorous acid, can be generated on-site by technologies known as electrolyzed water, electro chemically activated water, and electro activated water in pesticide generating devices. Paragraph 4-501.114(F) addresses the efficacy and use of these on-site generated solutions and Section 4-703.11 requires that the conditions of use yields sanitization as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

Because EPA does not require registration of solutions generated and used on-site, the user of the equipment should look to the device manufacturer for data to validate the efficacy of the solution produced by the device as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site in the food establishment.

Any data used to validate efficacy of on-site generated sanitizer solutions should include validation testing that includes all factors that could impact the efficacy of the sanitizer solution, including water hardness, pH, temperature, and a time element because efficacy can reduce with time. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices. See the EPA web site at <http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html>. According to the web site, "EPA's Good Laboratory Practice Standards (GLPS) compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under FIFRA section 5 of the Toxic Substances Control Act (TSCA), and pursuant to testing consent agreements and test rules issued under section 4 of TSCA."

Verifying the adequacy of chlorine-based solutions can be accomplished on an on-going basis by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using acceptable test methods and equipment.

The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment consistently generates a solution on-site at the necessary concentration to achieve sanitization.

Devices can be used for years to produce chemicals intended for the washing of fruits and vegetables, (e.g., hypochlorous acid, ozone, and chlorine dioxide). Other devices that are capable of producing hard food contact surface cleaning and sanitizing solutions on-site (e.g., chlorine, hypochlorous acid that are generated by processes known as electrolyzed water, electro chemically activated water, and electro activated water).

A device used to generate hard food contact surface sanitizers on-site is considered a pesticide device. The Environmental Protection Agency (EPA) defines a device in 40 CFR 152.500, Requirements for devices, as “(a) A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.”

The EPA does not require the registration of pesticide devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as 40 CFR 152.500 Requirements for Devices and 156.10 Labeling Requirements. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this regulation include, but are not limited to:

- The name, brand, or trademark under which the product is sold
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

Maintaining and cleaning devices used for the on-site generation of sanitizing solutions in accordance with manufacturer's specifications will help to ensure that they continue to generate the sanitizer chemicals in the form and concentration for which their efficacy was assessed.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

***Utensils and
Temperature
and Pressure
Measuring Devices***

4-502.11 Good Repair and Calibration.

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

**4-502.12 Single-Service and Single-Use Articles,
Required Use.**

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

**4-502.13 Single-Service and Single-Use Articles, Use
Limitation.**

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4-502.14 Shells, Use Limitation.

The reuse of mollusk and crustacean shells as multiuse utensils is not allowed in food establishments. This prohibition does not apply to the removal of the oyster or other species from the shell for preparation, then returning the same animal to the same shell for service.

The shell itself may be potentially unsafe for use as a food utensil because of residues from natural and environmental contamination occurring after the mollusk or crustacean is removed. In addition, natural shells are not durable or easily cleanable as specified under section 4-502.13. When mollusk or crustacean shells (from commercial sources) are re-used by filling them with shucked shellfish, the food is considered misleading and not honestly presented.

***Objective* 4-601.11 Equipment, Food-Contact Surfaces, Nonfood-
Contact Surfaces, and Utensils.**

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Frequency**4-602.11****Equipment Food-Contact Surfaces and Utensils.**

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for time/temperature control for safety foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in subparagraph 4-602.11(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41°F or less and 55°F.

Surfaces of utensils and equipment contacting food that is not time/temperature control for safety food such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS does not automatically consider species adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000, Other Consumer Protection Activities). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis.

The 2012 Conference for Food Protection (CFP) requested that FDA amend §4-602.11 of the Food Code to require that equipment food contact surfaces and utensils that have contacted raw animal foods that are major food allergens be cleaned before use with other raw animal foods (Issue 2012-III-024). FDA recognizes that in addition to their intended use as ingredients, the unintended presence of major food allergens in foods may occur through cross-contact. Cross-contact describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient. While most cross-contact can be avoided through control of the environment during food production and preparation, the CFP request only addresses allergen cross-contact from raw animal foods that are major food allergens and therefore, falls short of comprehensive allergen cross-contact control for all eight (8) major food allergens. Although limited in scope, such a change supports the continued efforts of FDA to work in cooperation with the Conference for Food Protection toward control of food allergens in retail food establishments. Therefore, §4-602.11 was amended to require that food contact surfaces of equipment and utensils that have contacted raw animal foods that are major food allergens, such as raw fish, must be cleaned and sanitized prior to contacting other types of raw animal foods.

Refer also to Annex 4 - Management of Food Safety Principles for Food Allergens as Food Safety Hazards.

4-602.12 Cooking and Baking Equipment.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in § 4-602.11.

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Methods 4-603.11 Dry Cleaning.

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not time/temperature control for safety foods. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4-603.12 Precleaning.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

**4-603.13 Loading of Soiled Items, Warewashing
Machines.**

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4-603.14 Wet Cleaning.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

**4-603.15 Washing, Procedures for Alternative Manual
Warewashing Equipment.**

Some pieces of equipment are fixed or too large to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4-603.16 Rinsing Procedures.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

***Objective* 4-701.10 Food-Contact Surfaces and Utensils.**

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

Frequency **4-702.11** **Before Use After Cleaning.**

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Methods **4-703.11** **Hot Water and Chemical.**

Efficacious sanitization depends on warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as rinse pressure, temperature, and chemical concentration are used in combination with time to achieve sanitization.

When surface temperatures of utensils passing through warewashing machines using hot water for sanitizing do not reach the required 71°C (160°F), it is important to understand the factors affecting the decreased surface temperature. A comparison should be made between the machine manufacturer's operating instructions and the machine's actual wash and rinse temperatures and final rinse pressure. The actual temperatures and rinse pressure should be consistent with the machine manufacturer's operating instructions and within limits specified in §§ 4-501.112 and 4-501.113.

If either the temperature or pressure of the final rinse spray is higher than the specified upper limit, spray droplets may disperse and begin to vaporize resulting in less heat delivery to utensil surfaces. Temperatures below the specified limit will not convey the needed heat to surfaces. Pressures below the specified limit will result in incomplete coverage of the heat-conveying sanitizing rinse across utensil surfaces.

Objective **4-801.11** **Clean Linens.**

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency **4-802.11** **Specifications.**

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Methods **4-803.11** **Storage of Soiled Linens.**

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4-803.12 **Mechanical Washing.**

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4-803.13 **Use of Laundry Facilities.**

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

Drying **4-901.11** **Equipment and Utensils, Air-Drying Required.**

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4-901.12 **Wiping Cloths, Air-Drying Locations.**

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

Lubricating and Reassembling **4-902.11** **Food-Contact Surfaces.**

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-902.12 **Equipment.**

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

Storing **4-903.11** **Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.**

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4-903.12 **Prohibitions.**

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

Preventing **4-904.11** **Kitchenware and Tableware.**
Contamination **4-904.12** **Soiled and Clean Tableware.**
 4-904.13 **Preset Tableware.**

The presentation or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

4-904.14 **Rinsing Equipment and Utensils after Cleaning and Sanitizing.**

The rinsing of cleaned and sanitized utensils and equipment in a manner that may contaminate the surfaces before they are used, such as running them under a faucet or by dipping them in a vessel of water, is prohibited. The application of a post-sanitizing rinse is restricted to warewashing machines because there will be little opportunity for contamination of the potable water rinse if applied within the confines of a compliant warewashing machine. Provided the sanitization is achieved before the rinse is applied and as long as any chemical sanitizers are used in accordance with an EPA-registered label, the sanitary state of utensils and equipment should not be altered by applying a potable water rinse after the required final sanitizing rinse within a warewashing machine.

Chapter 5 Water, Plumbing, and Waste

Source **5-101.11** **Approved System.**

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

5-101.12 **System Flushing and Disinfection.**

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

5-101.13 **Bottled Drinking Water.**

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Quality **5-102.11** **Standards.**

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

5-102.12 **Nondrinking Water.**

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological and chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces by nondrinking water. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

Irrigation water used in the cultivation of fresh produce, e.g. herb gardens or other onsite gardens, is another example of nondrinking water. Whenever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination. Water has the potential to be a direct source of contamination and vehicle for spreading contamination. Research has shown that irrigation water can increase the frequency of pathogen contamination of harvested produce, and may contain or convey pathogens, such as *Salmonella* spp. Where used, irrigation water should be adequate and approved for its intended use in accordance with Good Agricultural Practices (GAPs) that minimize the potential for contaminated water to contact the edible portion of the crop. FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruit and Vegetables" provides useful information about GAPs and safely growing, harvesting, washing, sorting, packing and distributing produce. It is available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm>.

5-102.13 Sampling.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

5-102.14 Sample Report.

The most recent water sampling report must be kept on file to document a safe water supply.

Quantity and 5-103.11 Capacity.
Availability

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization can not be reached.

Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-103.12 Pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

***Distribution, Delivery, and Retention* 5-104.11 System.**

Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

5-104.12 Alternative Water Supply.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

***Materials* 5-201.11 Approved.**

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

***Design, Construction, and Installation* 5-202.11 Approved System and Cleanable Fixtures.**

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

5-202.12 Handwashing Facility, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (100 to 108°F).

An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

5-202.13 Backflow Prevention, Air Gap.

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

5-202.14 Backflow Prevention Device, Design Standard.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system. Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative.

To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

5-202.15 Conditioning Device, Design.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

Numbers and 5-203.11 Handwashing Sinks.
Capacities

Because handwashing is such an important intervention in the control of foodborne illness, sufficient handwashing sinks must be available to make handwashing not only possible, but likely to occur at all appropriate times and places as outlined in Sections 2-301.14 and 2-301.15.

According to Greig et al. (July 2007) an analysis of 816 reported outbreaks of infected worker-associated outbreaks from 1927-2006 found that over 61% of these outbreaks came from food service facilities and catered events, and another 11% of them are attributed to schools, day care centers and health care institutions. The two most frequently reported risk factors associated with these implicated food workers was bare hand contact with food, and failure to properly wash hands.

Green et al (JFP, March 2007) found that handwashing was more likely to occur in restaurants whose food workers received food safety training, had more than one handwashing sink, and had a handwashing sink in the observed worker's sight. This suggests that improving food worker hand hygiene requires more than food safety education.

5-203.12 Toilets and Urinals.

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

5-203.13 Service Sink.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

5-203.14 Backflow Prevention Device, When Required.

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

5-203.15 Backflow Prevention Device, Carbonator.

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If carbon dioxide backs up into a copper water line, carbonic acid will dissolve some of the copper. The water containing the dissolved copper will subsequently be used in dispensing soft drinks and the first few customers receiving the drinks are likely to suffer with the symptoms of copper poisoning.

An air gap or a vented backflow prevention device meeting ASSE Standard No. 1022 will prevent this occurrence, thereby reducing incidences of copper poisoning.

***Location and Placement* 5-204.11 Handwashing Sinks.**

Hands are a common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. The transfer of contaminants can be limited by providing food employees with handwashing sinks that are properly equipped and conveniently located.

A handwashing sink that is properly located is one that is available to food employees who are working in food preparation, food dispensing, and warewashing areas. Handwashing sinks that are blocked by portable equipment or stacked full of soiled utensils and other items, are rendered unavailable for employee use. Nothing must block the approach to a handwashing sink thereby discouraging its use, plus it must be kept clean and well stocked with soap and sanitary towels to facilitate frequent use. Therefore, a handwashing sink that is located in the immediate work area, or between work areas that the Code states must be equipped with handwashing sinks, depending upon the size and function of the facility, would be considered properly located. Such placement of handwashing sinks facilitates frequent handwashing by food employees in all work areas.

5-204.12 Backflow Prevention Device, Location.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

5-204.13 Conditioning Device, Location.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

Operation and Maintenance 5-205.11 Using a Handwashing Sink.

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

5-205.12 Prohibiting a Cross Connection.

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

5-205.13 Scheduling Inspection and Service for a Water System Device.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Cleaning **5-205.14** **Water Reservoir of Fogging
Devices, Cleaning.**

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as ***Legionella pneumophila***. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

5-205.15 **System Maintained in Good Repair.**

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Materials **5-301.11** **Approved.**

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Design and **5-302.11** **Enclosed System, Sloped to Drain.**
Construction **5-302.12** **Inspection and Cleaning Port, Protected and
Secured.**

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

5-302.13 "V" Type Threads, Use Limitation.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

5-302.14 Tank Vent, Protected.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

5-302.15 Inlet and Outlet, Sloped to Drain.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

5-302.16 Hose, Construction and Identification.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Numbers and Capacities 5-303.11 Filter, Compressed Air.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

5-303.12 Protective Cover or Device.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

5-303.13 Mobile Food Establishment Tank Inlet.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

**Operation and
Maintenance**

5-304.11

System Flushing and Disinfection.

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

5-304.12

**Using a Pump and Hoses, Backflow
Prevention.**

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system. Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

5-304.13

Protecting Inlet, Outlet, and Hose Fitting.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

5-304.14

Tank, Pump, and Hoses, Dedication.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

**Mobile
Holding
Tank**

5-401.11

Capacity and Drainage.

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

**Retention,
Drainage, and
Delivery**

5-402.10 Establishment Drainage System.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

5-402.11 Backflow Prevention.

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

The exception in paragraph 5-402.11(B) allows for a direct connection to the sanitary sewer system for floor drains originating in refrigerated spaces that are constructed as an integral part of the building structure. Examples of refrigerated spaces that are considered an integral part of the building include refrigerated prep rooms, meat cutting rooms, and refrigerated storage rooms. The exception specifically targets refrigerated spaces that are considered an integral part of the building. It does not apply to prefabricated walk-in refrigerators and freezers with prefabricated floors. It is not intended to apply to pieces of equipment, including those which may be located in a refrigerated room and which indirectly drain to a floor drain within the room. Drainage from equipment is addressed under paragraph 5-402.11(A).

5-402.12 Grease Trap.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

5-402.13 Conveying Sewage.

5-402.14 Removing Mobile Food Establishment Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

5-402.15 Flushing a Waste Retention Tank.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

**Disposal
Facility**

5-403.11

Approved Sewage Disposal System.

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

5-403.12

Other Liquid Waste and Rainwater.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

**Facilities
on
the Premises**

5-501.10

Indoor Storage Area.

5-501.11

Outdoor Storage Surface.

5-501.12

Outdoor Enclosure.

5-501.13

Receptacles.

5-501.14

Receptacles in Vending Machines.

5-501.15

Outside Receptacles.

5-501.16

**Storage Areas, Rooms, and Receptacles,
Capacity and Availability.**

5-501.17

Toilet Room Receptacle, Covered.

5-501.18

Cleaning Implements and Supplies.

5-501.19

**Storage Areas, Redeeming Machines,
Receptacles and Waste Handling Units,
Location.**

5-501.110

**Storage Refuse, Recyclables, and
Returnables.**

5-501.111

**Areas, Enclosures, and Receptacles, Good
Repair.**

5-501.112

Outside Storage Prohibitions.

5-501.113

Covering Receptacles.

5-501.114

Using Drain Plugs.

5-501.115

Maintaining Refuse Areas and Enclosures.

5-501.116

Cleaning Receptacles.

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents. Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Removal **5-502.11** **Frequency.**
 5-502.12 **Receptacles or Vehicles.**

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Facilities **5-503.11** **Community or Individual Facility.**
for Disposal and
Recycling

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Chapter 6 Physical Facilities

Indoor Areas **6-101.11** **Surface Characteristics.**

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

Outdoor Areas 6-102.11 Surface Characteristics.

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Cleanability 6-201.11 Floors, Walls, and Ceilings.
6-201.12 Floors, Walls, and Ceilings, Utility Lines.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, thereby preventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as *Listeria monocytogenes*.

6-201.14 Floor Carpeting, Restrictions and Installation.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

6-201.15 Floor Covering, Mats and Duckboards.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

6-201.16 Wall and Ceiling Coverings and Coatings.
6-201.17 Walls and Ceilings, Attachments.
6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

Functionality 6-202.11 Light Bulbs, Protective Shielding.

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

6-202.13 Insect Control Devices, Design and Installation.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

6-202.14 Toilet Rooms, Enclosed.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

6-202.15 Outer Openings, Protected.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Code, 2009 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of subparagraph 6-202.15(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in ¶ 6-202.15(C).

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibited.

6-202.112 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

***Handwashing Sinks* 6-301.10 Minimum Number.**

Refer to the public health reason for § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

6-301.12 Hand Drying Provision.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

It is known that wet hands transfer bacteria more readily than dry hands. The residual moisture found on the hands after washing allows for bacterial and viral transfer to food or solid surfaces by touch. The method in which hands are dried is a critical factor in reducing chances of cross-contamination by hands to food and environmental surfaces (Patrick et al., (1997)).

With regard to the addition of air knife technology for hand drying, data reviewed by FDA scientists at the FDA's National Center for Food Safety Technology (Moffitt Center) demonstrates that the use of this technology in hand dryers has been found to be equivalent to the hand drying treatment in existing heated-air devices.

While the Food Code does not specifically address the configuration or ergonomic design of hand drying devices, technologies employing air knife systems do not appear to accommodate the drying of one's arms and may not be large enough to accommodate surrogate prosthetic devices for hands and arms to fit within the hand-dryer. In the case where food employees are expected to wash their forearms or are fitted with a surrogate prosthetic device, the food establishment would need to provide an alternate means for drying of the arms and certain prosthetic devices.

6-301.14 Handwashing Signage.

A sign or poster is required to remind food employees to wash their hands.

6-301.20 Disposable Towels, Waste Receptacle.

Waste receptacles at handwashing sinks are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

***Toilets and Urinals* 6-302.10 Minimum Number.**

Refer to the public health reason for § 5-203.12.

6-302.11 Toilet Tissue, Availability.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

***Lighting* 6-303.11 Intensity.**

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up.

Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Ventilation **6-304.11** **Mechanical.**

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

Dressing Areas and Lockers **6-305.11** **Designation.**

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Service Sinks **6-306.10** **Availability.**

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Handwashing Sinks **6-401.10** **Conveniently Located.**

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

Toilet Rooms **6-402.11** **Convenience and Accessibility.**

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

Employee Accommodations **6-403.11** **Designated Areas.**

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Distressed Merchandise **6-404.11** **Segregation and Location.**

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

Refuse, Recyclables, and Returnables **6-405.10** **Receptacles, Waste Handling Units, and Designated Storage Areas.**

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Premises, Structures, Attachments, and Fixtures, - Methods **6-501.11** **Repairing.**

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

6-501.12 **Cleaning, Frequency and Restrictions.**

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

6-501.13 Cleaning Floors, Dustless Methods.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

6-501.16 Drying Mops.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

6-501.18 Cleaning of Plumbing Fixtures.

Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

Refer also to the public health reason for § 5-205.11.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

Hand contact with contaminated surfaces can result in self-inoculation by touching of the nose and mouth. The spread of *Shigella sonnei* in a nursery school has been traced to contaminated toilets. Experiments by Gerba, et al and Barker and Bloomfield have shown that when bacteria and viruses were seeded into a household toilet, the detection of bacteria and viruses in the fallout droplets from the aerosols produced when flushing remain airborne long enough to settle on surfaces throughout the bathroom. Barker and Bloomfield also demonstrated that *Salmonella* Enteritidis could be isolated from the air surrounding a household toilet after flushing the toilet.

Noroviruses which are a major cause of gastroenteritis can be transmitted by fecal-oral, airborne inhalation, person-to-person and environmental-to-person routes. Norovirus, which is highly infectious, is shed in vomitus and stool in high numbers. A study was conducted by J. Barker et al to look at the transmission of norovirus via fingers, cloths and contact surfaces. The results indicated that where fingers come into contact with virus-contaminated toilet tissue, norovirus is consistently transferred via the fingers to a melamine surface and from there to other typical hand-contact surfaces such as taps, door handles and telephone receivers. In this study epidemiological evidence suggests that environmental spread from an infective person occurs by settling of aerosol particles on to contact surfaces. Hands can then spread the virus when they touch toilet seats or flush handles contaminated by splash from vomit or aerosol particles generated during toilet flushing.

6-501.19 Closing Toilet Room Doors.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

6-501.110 Using Dressing Rooms and Lockers.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

6-501.111 Controlling Pests.

Insects and other pests are capable of transmitting disease to humans by contaminating food and food-contact surfaces. Effective measures must be taken to eliminate their presence in food establishments.

**6-501.112 Removing Dead or Trapped Birds, Insects,
Rodents, and Other Pests.**

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

6-501.113 Storing Maintenance Tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

**6-501.114 Maintaining Premises, Unnecessary Items
and Litter.**

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

6-501.115 Prohibiting Animals.

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with service animals are required under § 2-301.14 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for "service animal" is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by "seeing eye dogs"; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with disabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the Federal agency which has the lead in these matters, in documents such as, “Commonly Asked Questions About Service Animals in Places of Business”; “The Americans with Disabilities Act Questions and Answers”; “A Guide to Disability Rights Laws”; and “Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement.” The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is <http://adata.org/>.

Chapter 7 Poisonous or Toxic Materials

Original Containers **7-101.11** **Identifying Information, Prominence.**

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

Working Containers **7-102.11** **Common Name.**

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Storage **7-201.11** **Separation.**

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

Presence and Use **7-202.11** **Restriction.**

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 **Conditions of Use.**

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted use pesticides are applied.

**Container
Prohibitions**

7-203.11

Poisonous or Toxic Material Containers.

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

Chemicals

7-204.11

Sanitizers, Criteria.

See explanation in §4-501.114.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940, Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food contact sanitizing solutions) or 40 CFR 180.2020, Non-food determinations. Because there is no EPA registration of solutions generated and used on-site, the user of the equipment should look to the equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as well as the conditions for use of the solution.

Some sanitizers produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. Occupational Safety and Health Administration (OSHA) limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000, Air contaminants. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.

7-204.12	Chemicals for Washing Fruits and Vegetables, Criteria.
7-204.13	Boiler Water Additives, Criteria.
7-204.14	Drying Agents, Criteria.

If the chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior sanctioned or exempted by the threshold of regulation process can be used. Information regarding food contact substances notification may be found on the FDA website under the Food Topic in Ingredients and Packaging section at: <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm>

Chemicals that are not generally recognized as safe, or not authorized by FDA for these uses may be submitted for review by filing a Food Additive Petition, a Food Contact Notification (FCN), or a request for exemption under the Threshold of Regulation. Wash chemicals, boiler water additives, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR. If the chemicals are hard food-contact sanitizers, or washes for raw agricultural commodities (RACs) that are used on a farm or in a packing house, then this is under the jurisdiction of the EPA.

21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption includes a number of regulations permitting certain food additives to be used for washing fruits and vegetables. In an effort to be consistent with federal law a change was made in Section 7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria to include all of 21 CFR 173 so as not to exclude the use of other permitted food additives. There is also another mechanism for approval of antimicrobial agents for washing fruits and vegetables (i.e., the food contact notification program) as well as GRAS ingredients permitted as antimicrobials or for general food use. This revision allows for the use of ingredients that are GRAS for this use and food contact substances which were the subject of an effective food contact notification for this use. 21 CFR 173 includes permitted food additives such as those listed in 21 CFR 173.315 Chemicals used in the washing or to assist in the peeling of fruits and vegetables. This section specifically identifies some of the chemicals that may be used in washing fruits and vegetables, regardless of whether the chemicals are commercially produced or generated on site. Sodium hypochlorite is listed in 21 CFR 173.315 for use in washing fruits and vegetables at levels not exceeding the minimum amount required to accomplish the intended technical effect. FDA has no objection to the use of calcium hypochlorite in the place of sodium hypochlorite under 21 CFR 173.315.

On December 4, 2012, the FDA amended the food additive regulations to provide for the safe use of sodium dodecylbenzenesulfonate (SDBS) (CAS No. 25155-30-0) as an antimicrobial agent for use in wash water for fruits and vegetables without the requirement of a potable water rinse. 21 CFR Section 173.405 specifically identifies this additive as an antimicrobial agent used in wash water for fruits and vegetables. The additive may be used at a level not to exceed 111 milligrams per kilogram in the wash water. Fruits and vegetables treated by the additive do not require a potable water rinse. Use of this additive is limited to use in commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments and other food service operations in which food is prepared for or served directly to the consumer. To ensure safe use of the additive, refer to the label or labeling of the additive and/or antimicrobial pesticide container for adequate directions. Information on the label is required in accordance to provisions within 21 CFR 173.405 and the Federal Food, Drug and Cosmetic Act. Although the petitioned use of SDBS is regulated under Section 409 of the FD & C Act as a food additive, this intended use of SDBS may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA requirements pertain to EPA registered pesticide products that have uses subject to EPA or both FDA and EPA regulations. Therefore, manufacturers intending to use this food additive for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

Boiler water additives that may be safely used in the preparation of steam that may contact food, and their condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

Lubricants **7-205.11** **Incidental Food Contact, Criteria.**

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Pesticides **7-206.11** **Restricted Use Pesticides, Criteria.**
 7-206.12 **Rodent Bait Stations.**

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 Tracking Powders, Pest Control and Monitoring.

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

Medicines 7-207.11 Restriction and Storage.

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage.

There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

7-207.12 Refrigerated Medicines, Storage.

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

First Aid Supplies 7-208.11 Storage.

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

Other Personal Care Items 7-209.11 Storage.

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

**Storage and
Display**

7-301.11

Separation.

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

Chapter 8 Compliance and Enforcement

**Construction
Inspection and
Approval**

**8-201.12
8-203.10**

**Contents of the Plans and Specifications.
Preoperational Inspections.**

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm>.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operating procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

- (1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,
- (2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Time/temperature control for safety food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with ¶ 2-103.11(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

8-304.11 Responsibility of the Permit Holder

It is important that regulatory agencies comply with applicable laws related to disclosure of public information. Making inspection reports available to the public promotes transparency and allows the public to be better informed about the businesses they patronize and the government agencies that serve the public. The intent is to improve industry and regulatory practices related to food safety at the foodservice and retail level.

8-402.10 Competency of Inspectors.

Regulatory agencies are encouraged to use Standard #2 of the draft *FDA's Recommended National Retail Food Regulatory Program Standards* (<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm>) to ensure employees who inspect food establishments are properly trained. Regulatory inspectors are also encouraged to seek food safety certification through a nationally recognized and accredited program.

8-501.20

**Restriction or Exclusion of Food Employee, or Summary
Suspension of Permit.**

See discussion in Annex 3, § 2-201.12.

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4 Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors

1. ACTIVE MANAGERIAL CONTROL
2. INTRODUCTION TO HACCP
3. THE HACCP PRINCIPLES
4. THE PROCESS APPROACH – A PRACTICAL APPLICATION OF HACCP AT RETAIL TO ACHIEVE ACTIVE MANAGERIAL CONTROL
5. FDA RETAIL HACCP MANUALS
6. ADVANTAGES OF USING THE PRINCIPLES OF HACCP
7. SUMMARY
8. ACKNOWLEDGMENTS
9. RESOURCES AND REFERENCES

1. ACTIVE MANAGERIAL CONTROL

- (A) What is the common goal of operators and regulators of retail food and food service establishments and what is presently being done to achieve this goal?**

The common goal of operators and regulators of retail and food service establishments is to produce safe, quality food for consumers. Since the onset of regulatory oversight of retail and food service operations, regulatory inspections have emphasized the recognition and correction of food safety violations that exist at the time of the inspection. Recurring violations have traditionally been handled through re-inspections or enforcement activities such as fines, suspension of permits, or closures. Operators of retail and food service establishments routinely respond to inspection findings by correcting violations, but often do not implement proactive systems of control to prevent violations from recurring. While this type of inspection and enforcement system has

done a great deal to improve basic sanitation and to upgrade facilities in the United States, it emphasizes reactive rather than preventive measures to food safety. Additional measures must be taken on the part of operators and regulators to better prevent or reduce foodborne illness. Annex 5 of the Food Code provides additional information on conducting risk-based inspections. It should be reviewed in conjunction with the material found in this Annex to better understand the role of the regulator in facilitating active managerial control by the operator.

(B) Who has the ultimate responsibility for providing safe food to the consumer?

The responsibility of providing safe food to the consumer is shared by many people in every stage in the production of food, including consumers, themselves. Since most consumers receive their food from retail and food service establishments, a significant share of the responsibility for providing safe food to the consumer rests with these facilities. Working together with their regulatory authorities, operators of retail and food service establishments can make the greatest impact on food safety.

(C) How can foodborne illness be reduced?

The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne-Disease Outbreaks – United States," identifies the most significant contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors." These five broad categories are:

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene.

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the "FDA Baseline Report." The Baseline Report is available from FDA through the following website: <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf>. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)*. This second report is available from FDA through the following website:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm089696.htm>.

The data collection was repeated again in 2008 and published in a 2009 report. This was followed by a Trend Analysis Report covering 1998-2008 that was published in October 2010. The CDC Surveillance Report and the results from the FDA Risk Factor Studies support the concept that operators of retail and food service establishments must be proactive and implement food safety management systems that will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors. By reducing the occurrence of foodborne illness risk factors, foodborne illness can also be reduced.

(D) How can the occurrence of foodborne illness risk factors be reduced?

To effectively reduce the occurrence of foodborne illness risk factors, operators of retail and food service establishments must focus their efforts on achieving active managerial control. The term “active managerial control” is used to describe industry’s responsibility for developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors.

Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

There are many tools that can be used by industry to provide active managerial control of foodborne illness risk factors. Regulatory inspections and follow-up activities must also be proactive by using an inspection process designed to assess the degree of active managerial control that retail and food service operators have over the foodborne illness risk factors. In addition, regulators must assist operators in developing and implementing voluntary strategies to strengthen existing industry systems to prevent the occurrence of foodborne illness risk factors. Elements of an effective food safety management system may include the following:

- Certified food protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a food preparation process, such as cooling
- Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits, such as final cooking temperatures, that need to be monitored and verified
- Purchase specifications
- Equipment and facility design and maintenance
- Monitoring procedures

- Record keeping
- Employee health policy for restricting or excluding ill employees
- Manager and employee training
- On-going quality control and assurance
- Specific goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors.

A food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles contains many of these elements and provides a comprehensive framework by which an operator can effectively control the occurrence of foodborne illness risk factors.

2. INTRODUCTION TO HACCP

(A) What is HACCP and how can it be used by operators and regulators of retail food and food service establishments?

Hazard Analysis and Critical Control Point (HACCP) is a systematic approach to identifying, evaluating, and controlling food safety hazards. Food safety hazards are biological, chemical, or physical agents that are reasonably likely to cause illness or injury in the absence of their control. Because a HACCP program is designed to ensure that hazards are prevented, eliminated, or reduced to an acceptable level before a food reaches the consumer, it embodies the preventive nature of “active managerial control.”

Active managerial control through the use of HACCP principles is achieved by identifying the food safety hazards attributed to products, determining the necessary steps that will control the identified hazards, and implementing on-going practices or procedures that will ensure safe food.

Like many other quality assurance programs, HACCP provides a common-sense approach to identifying and controlling problems that are likely to exist in an operation. Consequently, many food safety management systems at the retail level already incorporate some, if not all, of the principles of HACCP. Combined with good basic sanitation, a solid employee training program, and other prerequisite programs, a food safety management system based on HACCP principles will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors that lead to out-of-control hazards.

HACCP represents an important tool in food protection that small independent businesses as well as national companies can use to achieve active managerial control of risk factors. The *Food Code* requires a comprehensive HACCP plan when conducting certain specialized processes at retail such as when a variance is granted or

when a reduced oxygen packaging method is used. However, in general, the implementation of HACCP at the retail level is voluntary. FDA endorses the voluntary implementation of food safety management systems based on HACCP principles as an effective means for controlling the occurrence of foodborne illness risk factors that result in out-of-control hazards.

While the operator is responsible for developing and implementing a system of controls to prevent foodborne illness risk factors, the role of the regulator is to assess whether the system the operator has in place is achieving control of foodborne illness risk factors. Using HACCP principles during inspections will enhance the effectiveness of routine inspections by incorporating a risk-based approach. This helps inspectors focus their inspection on evaluating the effectiveness of food safety management systems implemented by industry to control foodborne illness risk factors.

The principles of HACCP are also an integral part of the draft *FDA's Recommended Voluntary National Retail Food Regulatory Program Standards*. For regulatory program managers, the use of risk-based inspection methodology based on HACCP principles is a viable and practical option for evaluating the degree of active managerial control operators have over the foodborne illness risk factors. The complete set of *Program Standards* is available from FDA through the following website:
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm>.

(B) What are the Seven HACCP Principles?

In November 1992, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) defined seven widely accepted HACCP principles that explained the HACCP process in great detail. In 1997, NACMCF reconvened to review the 1992 document and compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. Based on this review, NACMCF again endorsed HACCP and defined HACCP as a systematic approach to the identification, evaluation, and control of food safety. Based on a solid foundation of prerequisite programs to control basic operational and sanitation conditions, the following seven basic principles are used to accomplish this objective:

- Principle 1: Conduct a hazard analysis
- Principle 2: Determine the critical control points (CCPs)
- Principle 3: Establish critical limits
- Principle 4: Establish monitoring procedures
- Principle 5: Establish corrective actions
- Principle 6: Establish verification procedures
- Principle 7: Establish record-keeping and documentation procedures.

This Annex will provide a brief overview of each of the seven principles of HACCP. A more comprehensive discussion of these principles is available from FDA by accessing the NACMCF guidance document on the FDA Web Page at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm>. Following the overview, a practical scheme for applying and implementing the HACCP principles in retail and food service establishments is presented.

(C) What are Prerequisite Programs?

In order for a HACCP system to be effective, a strong foundation of procedures that address the basic operational and sanitation conditions within an operation must first be developed and implemented. These procedures are collectively termed “prerequisite programs.” When prerequisite programs are in place, more attention can be given to controlling hazards associated with the food and its preparation. Prerequisite programs may include such things as:

- Vendor certification programs
- Training programs
- Allergen management
- Buyer specifications
- Recipe/process instructions
- First-In-First-Out (FIFO) procedures
- Other Standard Operating Procedures (SOPs).

Basic prerequisite programs should be in place to:

- Protect products from contamination by biological, chemical, and physical food safety hazards
- Control bacterial growth that can result from temperature abuse
- Maintain equipment.

Additional information about prerequisite programs and the types of activities usually included in them can be found in the FDA’s Retail HACCP manuals discussed later in this Annex or by accessing the NACMCF guidance document on the FDA Web Page.

3. THE HACCP PRINCIPLES

(A) Principle #1: Conduct a Hazard Analysis

(1) What is a food safety hazard?

A hazard is a biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(2) What are biological hazards?

Biological hazards include bacterial, viral, and parasitic microorganisms. See Table 1 in this Annex for a listing of selected biological hazards. Bacterial pathogens comprise the majority of confirmed foodborne disease outbreaks and cases. Although cooking destroys the vegetative cells of foodborne bacteria to acceptable levels, spores of spore-forming bacteria such as *Bacillus cereus*, *Clostridium botulinum*, and *Clostridium perfringens* survive cooking and may germinate and grow if food is not properly cooled or held after cooking. The toxins produced by the vegetative cells of *Bacillus cereus*, *Clostridium botulinum*, and *Staphylococcus aureus* may not be destroyed to safe levels by reheating. Post-cook recontamination with vegetative cells of bacteria such as *Salmonellae* and *Campylobacter jejuni* is also a major concern for operators of retail and food service establishments.

Viruses such as norovirus, hepatitis A, and rotavirus are directly related to contamination from human feces. Recent outbreaks have also shown that these viruses may be transmitted via droplets in the air. In limited cases, foodborne viruses may occur in raw commodities contaminated by human feces (e.g., shellfish harvested from unapproved, polluted waters). In most cases, however, contamination of food by viruses is the result of cross-contamination by ill food employees or unclean equipment and utensils. Unlike bacteria, a virus cannot multiply outside of a living cell. Cooking as a control for viruses may be ineffective because many foodborne viruses seem to exhibit heat resistance exceeding cooking temperature requirements, under laboratory conditions. Obtaining food from approved sources, practicing no bare hand contact with ready-to-eat food as well as proper handwashing, and implementing an employee health policy to restrict or exclude ill employees are important control measures for viruses.

Parasites are most often animal host-specific, but can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross-contamination of ready-to-eat food with raw animal foods, untreated water, or contaminated equipment or utensils. Like viruses, parasites do not grow in food, so control is focused on destroying the parasites and/or preventing their introduction. Adequate cooking destroys parasites. In addition, parasites in fish to be consumed raw or undercooked can also be destroyed by effective freezing techniques. Parasitic

contamination by ill employees can be prevented by proper handwashing, no bare hand contact with ready-to-eat food, and implementation of an employee health policy to restrict or exclude ill employees.

Annex 4, Table 1a – 1c. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures

Annex 4, Table 1a. Selected Bacterial Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
<i>Bacillus cereus</i> (intoxication caused by heat stable, preformed emetic toxin and infection by heat labile, diarrheal toxin)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooking, cooling, cold holding, hot holding
<i>Campylobacter jejuni</i>	Poultry, raw milk	Cooking, handwashing, prevention of cross-contamination
<i>Clostridium botulinum</i>	Vacuum-packed foods, reduced oxygen packaged foods, under-processed canned foods, garlic-in-oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal processing (time + pressure), cooling, cold holding, hot holding, acidification and drying, etc.
<i>Clostridium perfringens</i>	Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies	Cooling, cold holding, reheating, hot holding
<i>E. coli</i> O157:H7 (other shiga toxin-producing <i>E. coli</i>)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing, prevention of cross-contamination, pasteurization or treatment of juice
<i>Listeria monocytogenes</i>	Raw meat and poultry, fresh soft cheese, paté, smoked seafood, deli meats, deli salads	Cooking, date marking, cold holding, handwashing, prevention of cross-contamination
<i>Salmonella spp.</i>	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare hand contact with RTE foods, handwashing, pasteurization or treatment of juice
<i>Shigella spp.</i>	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing
<i>Staphylococcus aureus</i> (preformed heat stable toxin)	RTE TCS foods touched by bare hands after cooking and further time/temperature abused	Cooling, cold holding, hot holding, no bare hand contact with RTE food, handwashing
<i>Vibrio spp.</i>	Seafood, shellfish	Cooking, approved source, prevention of cross-contamination, cold holding

RTE = ready-to-eat

TCS = time/temperature control for safety food

Annex 4, Table 1b. Selected Parasitic Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
<i>Anisakis simplex</i>	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing
<i>Taenia spp.</i>	Beef and pork	Cooking
<i>Trichinella spiralis</i>	Pork, bear, and seal meat	Cooking

RTE = ready-to-eat

TCS = time/temperature control for safety food

Annex 4, Table 1c. Selected Viral Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing
Other Viruses (Rotavirus, Norovirus, Reovirus)	Any food contaminated by infected worker via fecal-oral route	No bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing

RTE = ready-to-eat

TCS = time/temperature control for safety food

(3) What are Chemical Hazards?

Chemical hazards may be naturally occurring or may be added during the processing of food. High levels of toxic chemicals may cause acute cases of foodborne illness, while chronic illness may result from low levels.

The Code of Federal Regulations (<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>), Title 21 Food and Drugs, provides guidance on naturally occurring poisonous or deleterious substances, e.g., 21 CFR Parts 109 Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, and 184 Direct Food Substances Affirmed as Generally Recognized as Safe. The CFR also provide allowable limits for many of the chemicals added during processing, e.g., 21 CFR Part 172 Food Additives Permitted for Direct Addition to Food For Human Consumption.

FDA's Compliance Policy Guidelines also provide information on naturally occurring chemicals

(<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm>). See Chapter 5 – Foods, Colors and Cosmetics. Examples include sections:

- 540.600 Fish, Shellfish, Crustaceans, and Other Aquatic Animals – Fresh, Frozen or Processed – Methyl Mercury,
- 555.400 Foods – Adulteration with Aflatoxin, and
- 570.200 Aflatoxin in Brazil Nuts, .375 Peanuts and Peanut Products, and .500 Pistachio Nuts.

Table 2 of this Annex provides additional examples of chemical hazards, both naturally occurring and added.

(4) Food Allergens As Food Safety Hazards

Recent studies indicate that over 11 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an “allergen.” For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

Many foods, with or without identifiable allergens, have been reported to cause food allergies. However, FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies:

- Milk
- Egg
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans.

Consumers with food allergies rely heavily on information contained on food labels to avoid food allergens. Each year, FDA receives reports from consumers who have experienced an adverse reaction following exposure to a food allergen. Frequently, these reactions occur either because product labeling does not inform the consumer of the presence of the allergenic ingredient in the food or because of the cross-contact of a food with an allergenic substance not intended as an ingredient of the food during processing and preparation.

In August 2004, the Food Allergen Labeling and Consumer Protection Act (Public Law 108-282, Title II) was enacted, which defines the term “major food allergen.” The definition of “major food allergen” adopted for use in the Food Code (see paragraph 1-201.10(B)) is consistent with the definition in the new law. The following requirements are included in the new law:

- For foods labeled on or after January 1, 2006, food manufacturers must identify in plain language on the label of the food any major food allergen used as an ingredient in the food, including a coloring, flavoring, or incidental additive.
- FDA is to conduct inspections to ensure that food facilities comply with practices to reduce or eliminate cross-contact of a food with any major food allergens that are not intentional ingredients of the food.
- Within 18 months of the date of enactment of the new law (i.e., by February 2, 2006), FDA must submit a report to Congress that analyzes the results of its food inspection findings and addresses a number of specific issues related to the production, labeling, and recall of foods that contain an undeclared major food allergen.
- Within 2 years of the date of enactment of the new law (i.e., by August 2, 2006), FDA must issue a proposed rule, and within 4 years of the date of enactment of the new law (i.e., by August 2, 2008), FDA must issue a final rule to define and permit the use of the term “gluten-free” on food labeling.
- FDA is to work in cooperation with the Conference for Food Protection (CFP) to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments.

Annex 4, Table 2a-b. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Annex 4, Table 2a. Naturally Occurring Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Naturally Occurring Chemical Hazards	Associated Foods	Control measures
Scombrototoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; Also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
Ciguatoxin	Reef fin fish from extreme SE US, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught: <ul style="list-style-type: none"> • Purchase fish from approved sources. • Fish should not be harvested from an area that is subject to an adverse advisory.
Tetrodotoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins Aflatoxin Patulin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination. Apple juice products	Check condition at receiving; do not use moldy or decomposed food. Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.

Naturally Occurring Chemical Hazards	Associated Foods	Control measures
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
Shellfish toxins Paralytic shellfish poisoning (PSP) Diarrhetic shellfish poisoning (DSP) Neurotoxin shellfish poisoning (NSP) Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada Molluscan shellfish from Gulf of Mexico Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs and anchovies.	Ensure molluscan shellfish are: <ul style="list-style-type: none"> • from an approved source; and • properly tagged and labeled.
Pyrrolizidine alkaloids	Plants food containing these alkaloids. Most commonly found in members of the Boraginaceae, Compositae, and Leguminosae families.	Do not consume of food or medicinals contaminated with these alkaloids.
Phtyoaemmagglutinin	Raw red kidney beans (Undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
Allergens	Foods containing or contacted by: Milk Egg Fish Crustacean shellfish Tree nuts Wheat Peanuts Soybeans	Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.

Annex 4, Table 2b. Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Added Chemical Hazards	Associated Foods	Control measures
Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
Toxic elements/compounds Mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel and swordfish. Grains treated with mercury based fungicides	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High acid food and beverages	Do not use vessels containing lead.

Added Chemical Hazards	Associated Foods	Control measures
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and Vegetables Shrimp Lobster Wine	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments.
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrites.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints)	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.

(5) What are Physical Hazards?

Illness and injury can result from foreign objects in food. These physical hazards can result from contamination or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment. As establishments develop their food safety management systems, Annex 4, Table 3 can be used to aid in the identification of sources of potential physical hazards to the food being prepared, served, or sold. Annex 4, Table 3 provides some examples of common physical hazards.

Annex 4, Table 3. Main Materials of Concern as Physical Hazards and Common Sources^{a, b}

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

^a Adapted from Corlett (1991).

^b Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

(6) What is the purpose of the hazard analysis principle?

The purpose of hazard analysis is to develop a list of food safety hazards that are reasonably likely to cause illness or injury if not effectively controlled.

(7) How is the hazard analysis conducted?

The process of conducting a hazard analysis involves two stages:

1. Hazard Identification
2. Hazard Evaluation

Hazard identification can be thought of as a brain storming session. This stage focuses on identifying the food safety hazards that might be present in the food given the food preparation process used, the handling of the food, the facility, and general characteristics of the food itself. During this stage, a review is made of the ingredients used in the product, the activities conducted at each step in the process, the equipment

used, the final product, and its method of storage and distribution, as well as the intended use and consumers of the product.

Based on this review, a list of potential biological, chemical, or physical hazards is made at each stage in the food preparation process.

In stage two, the hazard evaluation, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. The purpose of this stage is to determine which of the potential hazards listed in stage one of the hazard analysis warrant control in the HACCP plan. Severity is the seriousness of the consequences of exposure to the hazard. Considerations made when determining the severity of a hazard include understanding the impact of the medical condition caused by the illness, as well as the magnitude and duration of the illness or injury. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Hazards that are not reasonably likely to occur are not considered in a HACCP plan. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage, and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled.

Upon completion of the hazard analysis, a list of significant hazards that must be considered in the HACCP plan is made, along with any measure(s) that can be used to control the hazards. These measures, called control measures, are actions or activities that can be used to prevent, eliminate, or reduce a hazard. Some control measures are not essential to food safety, while others are. Control measures essential to food safety like proper cooking, cooling, and refrigeration of ready-to-eat, time/temperature control for safety foods are usually applied at critical control points (CCPs) in the HACCP plan (discussed later). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. Likewise, more than one hazard may be addressed by a specific control measure (e.g., proper cooking).

(B) Principle #2: Determine Critical Control Points (CCPs)

(1) What is the Critical Control Point (CCP)?

A critical control point (CCP) means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk. Control can be applied at this point and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated, or reduced to acceptable levels. Common examples of CCPs include cooking, cooling, hot holding, and cold holding of ready-to-eat time/temperature control for safety foods. Due to vegetative and spore- and toxin-forming bacteria that are associated with raw animal foods, it is apparent that

the proper execution of control measures at each of these operational steps is essential to prevent or eliminate food safety hazards or reduce them to acceptable levels.

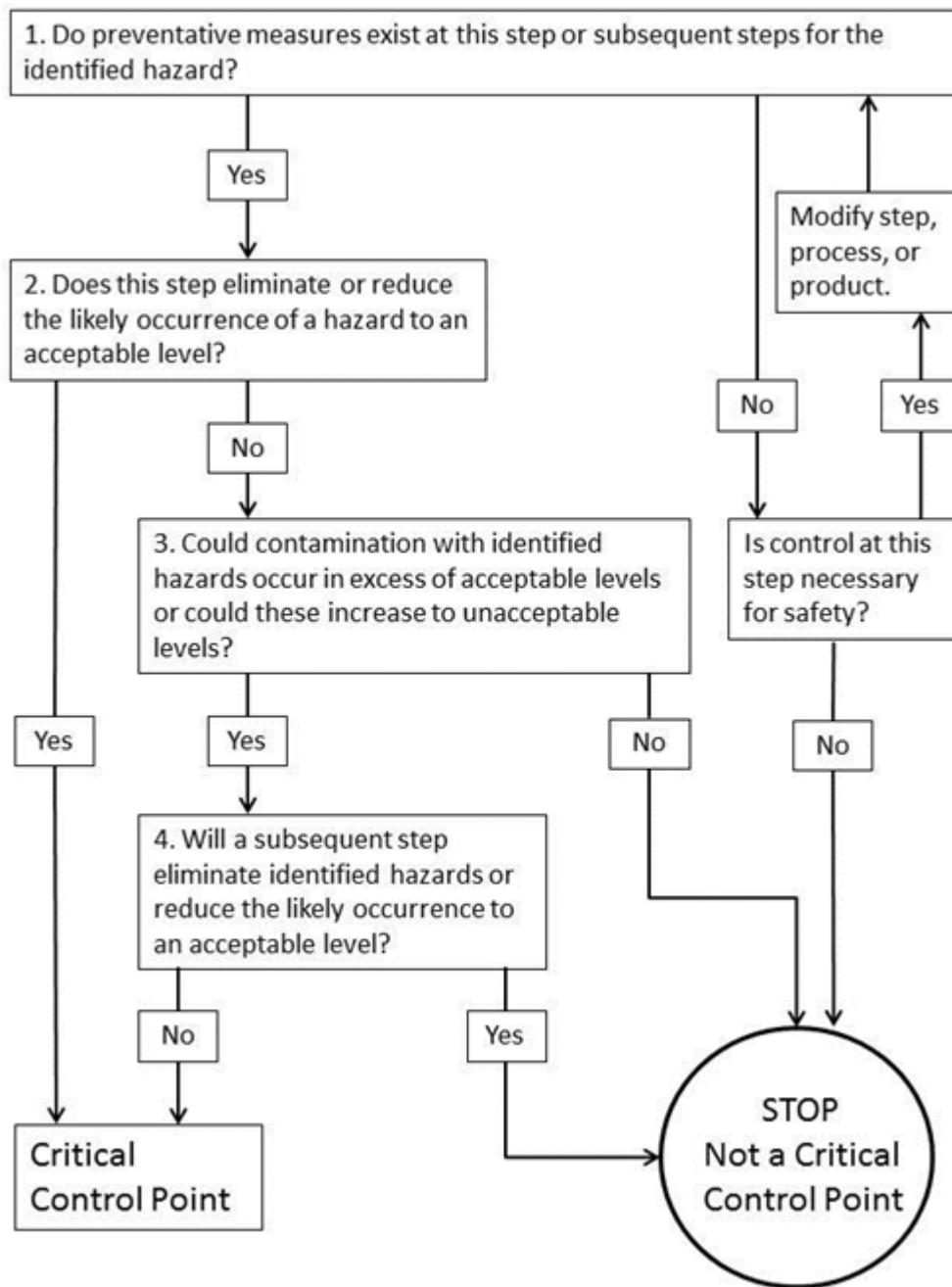
(2) Are quality issues considered when determining CCPs?

CCPs are only used to address issues with product safety. Actions taken on the part of the establishment such as first-in first-out (FIFO) or refrigerating non-time/temperature control for safety foods are to ensure food quality rather than food safety and therefore should not be considered as CCPs unless they serve a dual-purpose of ensuring food safety.

(3) Are the CCPs the same for everyone?

Different facilities preparing similar food items may identify different hazards and the CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, and processes employed. In mandatory HACCP systems, there may be rigid regulatory requirements regarding what must be designated a CCP. In voluntary HACCP systems, hazard control may be accomplished at CCPs or through prerequisite programs. For instance, one facility may decide that it can best manage the hazards associated with cooling through a standardized procedure in its prerequisite programs rather than at a CCP in its HACCP plan. One tool that can be used to assist each facility in the identification of CCPs unique to its operation is a CCP decision tree.

Annex 4 – CCP Decision Tree 1



* Decision tree adapted from NACMCF

(C) Principle #3: Establish Critical Limits

(1) What is a critical limit and what is its purpose?

A critical limit is a prescribed parameter (e.g., minimum and/or maximum value) that must be met to ensure that food safety hazards are controlled at each CCP. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Each control measure at a CCP has one or more associated critical limits. Critical limits may be based upon factors like temperature, time, moisture level, water activity (a_w), or pH. They must be scientifically-based and measurable.

(2) What are examples of critical limits?

Examples of critical limits are the time/temperature parameters for cooking chicken (165 °F for 15 seconds). In this case, the critical limit designates the *minimum* criteria required to eliminate food safety hazards or reduce them to an acceptable level. The critical limit for the acidification of sushi rice, a pH of ≤ 4.6 , sets the *maximum* limit for pH necessary to control the growth of spore- and toxin-forming bacteria. Critical limits may be derived from regulatory standards such as the FDA *Food Code*, other applicable guidelines, performance standards, or experimental results.

(D) Principle #4: Establish Monitoring Procedures

(1) What is the purpose of monitoring?

Monitoring is the act of observing and making measurements to help determine if critical limits are being met and maintained. It is used to determine whether the critical limits that have been established for each CCP are being met.

(2) What are examples of monitoring activities?

Examples of monitoring activities include visual observations and measurements of time, temperature, pH, and water activity. If cooking chicken is determined to be a CCP in an operation, then monitoring the internal temperature of a select number of chicken pieces immediately following the cook step would be an example of a monitoring activity. Alternatively, the temperature of an oven or fryer and the time required to reach an internal temperature of 165 °F could also be monitored.

(3) How is monitoring conducted?

Typically, monitoring activities fall under two broad categories:

- measurements
- observations

Measurements usually involve time and temperature but also include other parameters such as pH. If an operation identifies the acidification of sushi rice as a CCP and the critical limit as the final pH of the product being ≤ 4.6 , then the pH of the product would be measured to ensure that the critical limit is met.

Observations involve visual inspections to monitor the presence or absence of a food safety activity. If date marking is identified as a CCP in a deli operation for controlling *Listeria monocytogenes* in ready-to-eat deli meats, then the monitoring activity could involve making visual inspections of the date marking system to monitor the sell, consume, or discard dates.

(4) How often is monitoring conducted?

Monitoring can be performed on a continuous or intermittent basis. Continuous monitoring is always preferred when feasible as it provides the most complete information regarding the history of a product at a CCP. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts.

If intermittent monitoring is used, the frequency of monitoring should be conducted often enough to make sure that the critical limits are being met.

(5) Who conducts monitoring?

Individuals directly associated with the operation (e.g., the person in charge of the establishment, chefs, and departmental supervisors) are often selected to monitor CCPs. They are usually in the best position to detect deviations and take corrective actions when necessary. These employees should be properly trained in the specific monitoring techniques and procedures used.

(E) Principle #5: Establish Corrective Actions

(1) What are corrective actions?

Corrective actions are activities that are taken by a person whenever a critical limit is not met. Discarding food that may pose an unacceptable food safety risk to consumers is a corrective action. However, other corrective actions such as further cooking or reheating a product can be used provided food safety is not compromised. For example, a restaurant may be able to continue cooking hamburgers that have not reached an internal temperature of 155 °F for 15 seconds until the proper temperature is met. Clear instructions should be developed detailing who is responsible for performing the corrective actions, the procedures to be followed, and when.

(F) Principle #6: Establish Verification Procedures

(1) What is verification?

Verification includes those activities, other than monitoring, that determine the validity of the HACCP plan and show that the system is operating according to the plan.

Validation is a component of verification which focuses on collecting and evaluating scientific and technical information to determine if the HACCP system, when properly implemented, will effectively control the hazards. Clear instructions should be developed detailing who is responsible for conducting verification, the frequency of verification, and the procedures used.

(2) What is the frequency of verification activities? What are some examples of verification activities?

Verification activities are conducted frequently, such as daily, weekly, monthly, and include the following:

- observing the person doing the monitoring and determining whether monitoring is being done as planned
- reviewing the monitoring records to determine if they are completed accurately and consistently
- determining whether the records show that the frequency of monitoring stated in the plan is being followed
- ensuring that corrective action was taken when the person monitoring found and recorded that the critical limit was not met
- validating that the critical limits are achieving the desired results of controlling the identified hazard
- confirming that all equipment, including equipment used for monitoring, is operated, maintained, and calibrated properly.

(G) Principle #7: Establish Record Keeping Procedures

(1) Why are records important?

Maintaining documentation of the activities in a food safety management system can be vital to its success. Records provide documentation that appropriate corrective actions were taken when critical limits were not met. In the event that an establishment is implicated in a foodborne illness, documentation of activities related to monitoring and corrective actions can provide proof that reasonable care was exercised in the operation of the establishment. Documenting activities provides a mechanism for verifying that the activities in the HACCP plan were properly completed. In many cases, records can serve a dual purpose of ensuring quality and food safety.

(2) What types of records are maintained as part of a food safety management system?

There are at least 5 types of records that could be maintained to support a food safety management system:

- records documenting the activities related to the prerequisite programs
- monitoring records
- corrective action records
- verification and validation records
- calibration records.

4. THE PROCESS APPROACH – A PRACTICAL APPLICATION OF HACCP AT RETAIL TO ACHIEVE ACTIVE MANAGERIAL CONTROL

(A) Why Focus on HACCP Principles at Retail and Food Service?

FDA recognizes that there are important differences between using HACCP principles in a food safety management system developed for food manufacturing plants and applying these same principles in food safety management system developed for use in retail and food service establishments.

Since the 1980's, operators and regulators have been exploring the use of the HACCP principles in restaurants, grocery stores, institutional care facilities, and other retail food establishments. During this time, much has been learned about how these principles can be used in these varied operations, collectively referred to as retail food establishments. Most of this exploration has centered around the focal question of how to stay true to the NACMCF definitions of HACCP and still make the principles useful to an industry that encompasses the broadest range of conditions.

Unlike industries such as canning, other food processing, and dairy plants, the retail industry is not easily defined by specific commodities or conditions. Consider the following characteristics that retail food establishments share that set them apart from most food processors:

1. Employee and management turnover is exceptionally high in food establishments, especially for entry level positions. This means the many employees or managers have little experience and food safety training must be continuously provided.
2. Many establishments are start-up businesses operating without benefit of a large corporate support structure and having a relatively low profit margin and perhaps less capital to work with than other segments of the food industry.
3. There is an almost endless number of production techniques, products, menu items, and ingredients used which are not easily adapted to a simple, standardized approach. Changes occur frequently and little preparation time is available.

FDA fully recognizes the diversity of retail and food service establishments and their varying in-house resources to implement HACCP. That recognition is combined with an understanding that the success of such implementation is dependent upon establishing realistic and useful food safety strategies that are customized to the operation.

(B) What is the Process Approach?

When conducting the hazard analysis, food manufacturers usually use food commodities as an organizational tool and follow the flow of each product. This is a very useful approach for producers or processors since they are usually handling one product at a time. By contrast, in retail and food service operations, foods of all types are worked together to produce the final product. This makes a different approach to the hazard analysis necessary. Conducting the hazard analysis by using the food preparation processes common to a specific operation is often more efficient and useful for retail and food service operators. This is called the "process approach" to HACCP.

The process approach can best be described as dividing the many food flows in an establishment into broad categories based on activities or stages in the preparation of the food, then analyzing the hazards, and placing managerial controls on each grouping.

(C) What are the three food preparation processes most often used in retail and food service establishments and how are they determined?

The flow of food in a retail or food service establishment is the path that food follows from receiving through service or sale to the consumer. Several activities or stages make up the flow of food and are called operational steps.

Examples of operational steps include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling, packaging, serving, and selling. The terminology used for operational steps may differ between food service and retail food store operations.

Most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41°F and 135°F:

- **Process 1: Food Preparation with No Cook Step**

Example flow: Receive – Store – Prepare – Hold – Serve

(other food flows are included in this process, but there is no cook step to destroy pathogens)

- **Process 2: Preparation for Same Day Service**

Example flow: Receive – Store – Prepare – Cook – Hold – Serve

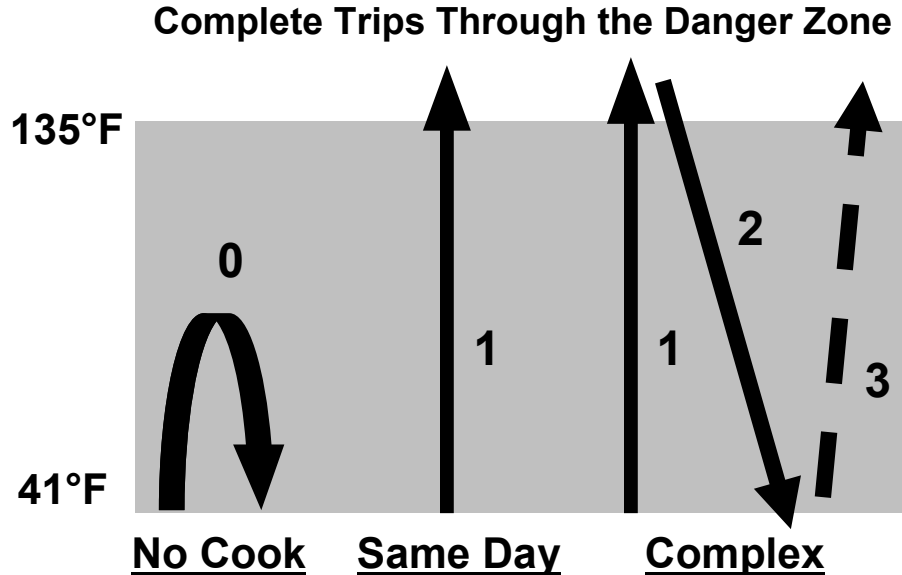
(other food flows are included in this process, but there is only one trip through the temperature danger zone)

- **Process 3: Complex Food Preparation**

Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve

(other food flows are included in this process, but there are always two or more complete trips through the temperature danger zone)

A summary of the three food preparation processes in terms of number of times through the temperature danger zone can be depicted in a Danger Zone diagram. Although foods produced using process 1 may *enter* the danger zone, they do not pass all the way through it. Foods that go through the danger zone only once are classified as Same Day Service, while foods that go through more than once are classified as Complex food preparation.



The three food preparation processes conducted in retail and food service establishments are not intended to be all-inclusive. For instance, quick service facilities may have “cook and serve” processes specific to their operation. These processes are likely to be different from the “Same Day Service” preparation processes in full service restaurants since many of their foods are generally cooked and hot held before service. In addition, in retail food stores, operational steps such as packaging and assembly may be included in all of the food preparation processes before the product is sold to the consumer. It is also very common for a retail or food service operator to use multiple food preparation processes to create a single menu item.

(D) How is a hazard analysis conducted in process HACCP?

In the process approach to HACCP, conducting a hazard analysis on individual food items is time and labor intensive and is generally unnecessary. Identifying and controlling the hazards in each food preparation process achieves the same control of risk factors as preparing a HACCP plan for each individual product.

Example: An establishment has dozens of food items (including baked chicken and baked meatloaf) in the “Preparation for Same Day Service” category. Each of the food items may have unique hazards, but regardless of the individual hazards, control via proper cooking and holding will generally ensure the safety of all of the foods in this category. An illustration of this concept follows:

- Even though they have unique hazards, baked chicken and meatloaf are items frequently grouped in the “Same Day Service” category (Process 2).
- *Salmonella* spp. and *Campylobacter*, as well as spore-formers, such as *Bacillus cereus* and *Clostridium perfringens*, are significant biological hazards in chicken.
- Significant biological hazards in meatloaf include *Salmonella* spp., *E. coli* O157:H7, *Bacillus cereus*, and *Clostridium perfringens*.
- Despite their different hazards, the control measure used to kill pathogens in both these products is cooking to the proper temperature.
- Additionally, if the products are held after cooking, then proper hot holding or time control is also required to prevent the outgrowth of spore-formers that are not destroyed by cooking.

As with product-specific HACCP, critical limits for cooking remain specific to each food item in the process. In the scenario described above, the cooking step for chicken requires a final internal temperature of 165°F for 15 seconds to control the pathogen load for *Salmonella* spp. Meatloaf, on the other hand, is a ground beef product and requires a final internal temperature of 155°F for 15 seconds to control the pathogen load for both *Salmonella* spp. and *E. coli* O157:H7. Some operational steps such as refrigerated storage or hot holding have critical limits that apply to all foods.

Annex 4, Table 4 further illustrates this concept. Note that the only unique control measure applies to the critical limit of the cooking step for each of the products. Other food safety hazards and control measures may exist that are not depicted here:

Annex 4, Table 4: Examples of Hazards and Control Measures for Same Day Service Items

Baked Meatloaf (Process 2: Preparation for Same Day Service)

Example Biological Hazards	Example Control Measures
<i>Salmonella</i> spp.	Refrigeration at 41°F or below
<i>E. coli</i> O157:H7	Cooking at 155°F for 15 seconds
<i>Clostridium perfringens</i>	Hot Holding at 135°F or above OR Time Control
<i>Bacillus cereus</i>	Hot Holding at 135°F or above OR Time Control
Various fecal-oral route pathogens	Good personal hygiene (No bare hand contact with ready-to-eat food, proper handwashing, exclusion/restriction of ill employees)

Baked Chicken (Process 2: Preparation for Same Day Service)

Example Biological Hazards	Example Control Measures
<i>Salmonella</i> spp.	Refrigeration at 41°F or below
<i>Campylobacter</i>	Cooking at 165°F for 15 seconds
<i>Clostridium perfringens</i>	Hot Holding at 135°F or above OR Time Control
<i>Bacillus cereus</i>	Hot Holding at 135°F or above OR Time Control
Various fecal-oral route pathogens	Good personal hygiene (No bare hand contact with ready-to-eat food, proper handwashing, exclusion/restriction of ill employees)

(E) How is the process approach helpful to industry in determining the measures that must be implemented to actively manage the foodborne illness risk factors that result in out-of-control hazards?

Even though variations in foods and in the three food preparation process flows used to prepare them are common, the control measures will generally be the same based on the number of times the food goes through the temperature danger zone. Several of the most common control measures associated with each food preparation process are discussed in this Annex. Retail or food service establishments should use these simple control measures as the core of their food safety management systems; however, there may be other risk factors unique to an operation or process that are not listed here. Each operation should be evaluated independently.

In developing a voluntary food safety management system, active managerial control of risk factors common to each process can be achieved by implementing control measures at certain operational steps designated as critical control points (CCPs) or by implementing prerequisite programs. This is explained in more detail in the Operator's Manual discussed in Part 5 of this Annex.

(F) Facility-wide Considerations

In order to have active managerial control over personal hygiene and cross-contamination, certain control measures must be implemented in all phases of the operation. All of the following control measures should be implemented regardless of the food preparation process used:

- **No bare hand contact with ready-to-eat foods (or use of a pre-approved, alternative procedure)** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Proper handwashing** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Restriction or exclusion of ill employees** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Prevention of cross-contamination** of ready-to-eat food or clean and sanitized food-contact surfaces with soiled cutting boards, utensils, aprons, etc., or raw animal foods.

(G) Food Preparation Process 1 – Food Preparation with No Cook Step

Example Flow: RECEIVE → STORE → PREPARE → HOLD → SERVE

Several food flows are represented by this particular process. Many of these food flows are common to both retail food stores and food service facilities, while others only apply to retail operations. Raw, ready-to-eat food like sashimi, raw oysters, and salads are grouped in this category. Components of these foods are received raw and will not be cooked before consumption.

Foods cooked at the processing level but that undergo no further cooking at the retail level before being consumed are also represented in this category. Examples of these kinds of foods are deli meats, cheeses, and other pasteurized dairy products (such as yogurt). In addition, foods that are received and sold raw but are to be cooked by the consumer after purchase, e.g., hamburger meat, chicken, and steaks, are also included in this category.

All the foods in this category lack a cook step *while at the retail or food service facility*; thus, there are no complete trips through the danger zone. Purchase specifications can be required by the retail or food service establishment to ensure that foods are received as safe as possible. Without a kill step to destroy pathogens, preventing further contamination by ensuring that employees follow good hygienic practices is an important control measure.

Cross-contamination must be prevented by properly storing ready-to-eat food away from raw animal foods and soiled equipment and utensils. Foodborne illness may result from ready-to-eat food being held at unsafe temperatures for long periods of time due to the outgrowth of bacteria.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cold holding or using time alone** to control bacterial growth and toxin production
- **Food source** (e.g., shellfish due to concerns with viruses, natural toxins, and *Vibrio* and for certain marine finfish intended for raw consumption due to concerns with ciguatera toxin)
- **Receiving temperatures** (e.g., certain species of marine finfish due to concerns with scombrototoxin)
- **Date marking** of ready-to-eat TCS food held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Freezing** certain species of fish intended for raw consumption due to parasite concerns

- **Cooling** from ambient temperature to prevent the outgrowth of spore-forming or toxin-forming bacteria.

(H) Food Preparation Process 2 – Preparation for Same Day Service

Example Flow: RECEIVE → STORE → PREPARE → COOK → HOLD → SERVE

In this food preparation process, food passes through the danger zone only once in the retail or food service facility before it is served or sold to the consumer. Food is usually cooked and held hot until served, e.g., fried chicken, but can also be cooked and served immediately. In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cooking** to destroy bacteria and parasites
- **Hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria.

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrototoxin.

(I) Food Preparation Process 3 – Complex Food Preparation

Example Flow: RECEIVE → STORE → PREPARE → COOK → COOL → REHEAT → HOT HOLD → SERVE

Foods prepared in large volumes or in advance for next day service usually follow an extended process flow. These foods pass through the temperature danger zone more than one time; thus, the potential for the growth of spore-forming or toxigenic bacteria is greater in this process. Failure to adequately control food product temperatures is one of the most frequently encountered risk factors contributing to foodborne illness. Food handlers should minimize the time foods are at unsafe temperatures.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cooking** to destroy bacteria and parasites
- **Cooling** to prevent the outgrowth of spore-forming or toxin-forming bacteria
- **Hot and cold holding or using time alone** to control bacterial growth and toxin formation

- **Date marking** of ready-to-eat TCS food held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Reheating** for hot holding, if applicable.

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrototoxin.

5. FDA RETAIL HACCP MANUALS

(A) What guidance has been developed by FDA to assist operators of retail and food service establishments in achieving active managerial control of foodborne illness risk factors?

FDA, in partnership with Federal, State, and local regulators, industry, academia, and consumers, has written a guidance document entitled, *“Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments.”* Commonly referred to as the “Operator’s Manual,” this document is designed to assist operators with developing or enhancing food safety management systems based on the process approach to HACCP. The manual presents a step-by-step procedure for writing and voluntarily implementing a food safety management system based on the principles of HACCP. The desired outcome is an operator who employs a preventive rather than a reactive strategy to food safety.

The Operator’s Manual embodies FDA’s current thinking on the application of HACCP principles at retail. It advocates the voluntary use of HACCP principles using the process approach as a practical and effective means of reducing the occurrence of foodborne illness risk factors leading to out-of-control hazards. The Operator’s Manual is strictly for the voluntary implementation of HACCP principles at retail and should not be used to develop HACCP plans that are required through Federal, State, or local regulations, ordinances, or laws. The document can be found on the FDA Web Page at <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm>.

(B) What guidance has been developed by FDA to assist regulators of retail and food service establishments in assessing industry’s active managerial control of foodborne illness risk factors?

FDA has written a document for regulators of retail and food service establishments entitled, *“Managing Food Safety: A Regulator’s Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems.”* Commonly referred to as the “Regulator’s Manual,” this document was written to provide a risk-based inspectional “roadmap” for evaluating the

degree of active managerial control an operator has over foodborne illness risk factors.

In addition, the manual advocates the use of voluntary intervention strategies, including the development of food safety management systems or risk control plans to bring about a long-term behavior change that will result in a reduction in the occurrence of risk factors. In cases where an operator may want their inspector to provide them with feedback on their voluntarily-implemented food safety management system, the manual provides regulators with information on how to validate and verify an existing system.

The document can be found on the FDA Web Page at:
<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm>.

Annex 5 of the Food Code outlines the basis for conducting successful risk-based inspections and is provided to assist industry in achieving active managerial control of foodborne illness risk factors as outlined in the draft *Recommended National Retail Food Regulatory Program Standards* and the *Regulator's Manual*.

6. ADVANTAGES OF USING THE PRINCIPLES OF HACCP

(A) What advantages does using HACCP principles offer operators of retail and food service establishments?

Rather than relying solely on periodic feedback from inspections by regulatory agencies, an establishment operator who implements a food safety management system based on HACCP principles emphasizes continuous problem solving and prevention. Additionally, HACCP enhances and encourages communication between industry and regulators.

A food safety management system based on HACCP principles offers many other advantages to industry. One advantage is that such a system may provide a method for achieving active managerial control of multiple risk factors associated with an entire operation. Other advantages include:

- Reduction in product loss
- Increase in product quality
- Better inventory control
- Consistency in product preparation
- Increase in profit
- Increased employee awareness and participation in food safety.

(B) What advantages does using HACCP principles offer regulators of retail and food service establishments?

Traditional inspections are relatively resource-intensive, inefficient, and reactive rather than preventive in nature. Using traditional inspection techniques allows for a satisfactory “snapshot” assessment of the requirements of the code at the time of the inspection. Unfortunately, unless an inspector asks questions and inquires about the activities and procedures being utilized by the establishment even at times when the inspector is not there, there is no way to know if an operator is achieving *active* managerial control.

With the limited time often available for conducting inspections, regulators must focus their attention on those areas that clearly have the greatest impact on food safety – foodborne illness risk factors. By knowing that there are only a few control measures that are essential to food safety and focusing on these during the inspection, an inspector can assess the operator’s active managerial control of the foodborne illness risk factors.

Regulators can provide invaluable feedback to an operator through their routine inspections. This is especially useful when utilizing a risk-based approach. By incorporating HACCP principles into routine inspections, an inspector can provide an operator with the constructive input needed to establish the control system necessary to bring the foodborne illness risk factors back under continuous control.

7. SUMMARY

In order to make a positive impact on foodborne illness, retail and food service operators must achieve active managerial control of the risk factors contributing to foodborne illness. Combined with basic sanitation, employee training, and other prerequisite programs, the principles of HACCP provide an effective system for achieving this objective.

The goal in applying HACCP principles in retail and food service is to have the operator take purposeful actions to ensure safe food. The process approach simplifies HACCP principles for use in retail and food service. This practical and effective method of hazard control embodies the concept of active managerial control by providing an on-going system of simple control measures that will reduce the occurrence of risk factors that lead to out-of-control hazards.

The role of retail and food service regulatory professionals is to conduct risk-based inspections using HACCP principles to assess the degree of control industry has over the foodborne illness risk factors. Regulators can assist industry in achieving active managerial control of risk factors by using a risk-based inspection approach to identify strengths and weaknesses and suggesting possible solutions and improvements.

8. ACKNOWLEDGMENTS

Much of this Annex is adapted from the National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point Principles and Guidelines, adopted August 14, 1997.

The physical hazards table (Table 3) was provided courtesy of “Overview of Biological, Chemical, and Physical Hazards” in “HACCP Principles and Applications,” Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992. p. 8-28. Chapman and Hall, New York.

Based on a recommendation from the Retail HACCP Committee of the Conference for Food Protection, the two HACCP Manuals have been endorsed by the Conference.

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U.S. Department of Commerce
703-487-4650.

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<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm252338.htm>

The **Fish and Fishery Products Hazards and Controls Guidance**, Fourth Edition, April 2011 is available electronically at:
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm> . Single copies may be obtained as long as supplies last from FDA district offices and from:

U.S. Food and Drug Administration
Office of Seafood
5100 Paint Branch Parkway
College Park, MD 20740-3835

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5

Conducting Risk-Based Inspections

1. PURPOSE AND SCOPE
2. RISK-BASED ROUTINE INSPECTIONS
3. WHAT IS NEEDED TO PROPERLY CONDUCT A RISK-BASED INSPECTION?
4. RISK-BASED INSPECTION METHODOLOGY
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1. PURPOSE AND SCOPE

This Annex provides regulatory program managers and front-line inspection staff with guidance on planning, scheduling, conducting, and evaluating risk-based inspections. The *FDA's Voluntary National Retail Food Regulatory Program Standards* (Program Standards)

(<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm>) provide additional recommendations to assist regulatory program managers in the planning and development of a risk-based inspection program.

The primary focus of this Annex is to provide inspectors with methods for conducting risk-based inspections. Various strategies that can be used by regulatory professionals to assist operators in achieving active managerial control of foodborne illness risk factors are also included in this Annex.

As presented in Annex 4, the Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne Disease Outbreaks – United States" (<http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm>) identifies the most frequently reported contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors."

These five broad categories are:

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene.

The FDA manual, *Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems* (FDA's Regulator's Manual) (<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm>), provides additional information on conducting risk-based inspections. Annex 4 of the Food Code provides additional information on Hazard Analysis and Critical Control Point (HACCP) principles and the process approach to HACCP. It should be reviewed in conjunction with the material found in this Annex to better prepare for performing risk-based inspections.

The "Retail Food Program Resource Guide," a CD-ROM containing pertinent FDA documents referenced in this Annex, is available for use by federal, state, local, and tribal regulatory agencies. It is produced by and available through FDA Regional Retail Food Specialists or the FDA Division of Federal-State Relations (HFC-150); U.S. Food and Drug Administration; 5600 Fishers Lane, Room 12-07; Rockville, Maryland 20857; PHONE (301) 827-6906; (FAX) (301) 443-2143.

2. RISK-BASED ROUTINE INSPECTIONS

Inspections have been a part of food safety regulatory activities since the earliest days of public health. The term "routine inspection" has been used to describe periodic inspections conducted as part of an on-going regulatory scheme.

Program managers should strive to have adequate staffing and resources to allow all inspectors ample time to thoroughly evaluate establishments and ask as many questions as needed to fully understand establishments' operations. For most jurisdictions, however, inspectors continue to have limited time in which to complete inspections. This does not negate the need to thoroughly identify and assess the control of foodborne illness risk factors during each inspection.

It is a false assumption that inspectors cannot conduct risk-based inspections in a limited timeframe. Even with limited time, inspectors can focus their inspections on assessing the degree of active managerial control an operator has over the foodborne illness risk factors. By focusing inspections on the control of foodborne illness risk factors, inspectors can be assured that they are making a great impact on reducing foodborne illness.

As described in Annex 4, active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their businesses to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors is recommended to achieve active managerial control. Regulatory inspections and follow-up activities must be proactive by using an inspection process designed to evaluate the implementation of Food Code interventions and the degree of active managerial control that retail and foodservice operators have over foodborne illness risk factors. The five Food Code interventions below were new interventions introduced with the 1993 Food Code and they are just as important today as they were in 1993. They encompass a wide-range of control measures specifically designed to protect consumer health:

- Demonstration of Knowledge
- Implementation of Employee Health Policies
- Hands as a Vehicle of Contamination
- Time/Temperature Relationships
- Consumer Advisory.

When Food Code interventions are not being implemented or if behaviors, activities, or procedures likely to cause foodborne illness are observed, inspectors should verify that the operator takes immediate corrective action so that consumers do not become sick or injured. Observations made on the day of the inspection, as well as information gained about the behaviors, activities, and procedures that occur at other times, allow inspectors to assess the strengths and weaknesses of the food safety management system that is in place.

An operator should be made aware of the inspectional findings both during, and at the conclusion of, the inspection and strategies for achieving compliance in the future should be discussed. Corrective actions taken during the inspection and repeat violations should be noted on the inspection report. Repeat violations should trigger further compliance and enforcement actions.

The inspection process is also an opportunity to educate the operator on the public health reasons supporting the Code requirements. If operators are afforded the chance to ask questions about general food safety matters, they may clearly understand the public health significance of non-compliance.

Lastly, if the operator demonstrates a history of violations related to foodborne illness risk factors, the inspection process can be used to assist the operator with implementing long-term control systems to prevent those risk factors from occurring in the future.

3. WHAT IS NEEDED TO PROPERLY CONDUCT A RISK-BASED INSPECTION?

A. Schedule Inspections Based on Risk

Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments. Standard 3 of the Program Standards requires that regulatory jurisdictions develop and use a process that groups food establishments into at least three categories based on potential and inherent food safety risks. In addition, Standard 3 requires that regulatory jurisdictions assign inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk. With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness.

Table 1 of this Annex provides an example of risk categories and assignment of inspection frequency based on risk. In this example, the type of food served, food preparation processes conducted, and history of compliance related to foodborne illness risk factors are used as the basis of categorizing risk. Each jurisdiction is encouraged to develop risk categories tailored to their specific program needs and resources and to reassess the risk categories on an annual basis.

Regardless of the risk category initially assigned to food establishments, regulatory jurisdictions sometimes consider whether the establishment has implemented a voluntary food safety management system like HACCP, to justify a decrease in inspection frequency. Likewise, the following factors are among many that regulatory jurisdictions sometimes use to justify an increase in inspection frequency:

- History of non-compliance with provisions related to foodborne illness risk factors or critical items
- Specialized processes conducted
- Food preparation a day in advance of service
- Large number of people served
- History of foodborne illness and/or complaints
- Highly susceptible population served.

Annex 5, Table 1. Risk Categorization of Food Establishments

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non- time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	1
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.	2
3	An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	3
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

B. Have the Proper Equipment

In order to conduct risk-based inspections, each inspector must be provided with the proper equipment to assess the control of foodborne illness risk factors within food establishments. See Program Standard 8 at

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm> for recommendations of equipment needed by inspectors. At a minimum, each inspector should be provided with the following essential equipment:

- Thermocouple with the appropriate probes for the food being tested
- Alcohol swabs or other suitable equipment for sanitizing probe thermometers
- Chemical test kits for different chemical sanitizer types
- Heat-sensitive tape or maximum registering thermometer
- Flashlight
- Head cover, such as baseball cap, hair net, or equivalent.

Other equipment may be provided to inspectors on an “as needed” basis. While it is desirable for each inspector to have the following equipment, depending on the resources available to the agency, this equipment may be shared in a central office as appropriate:

- Pressure gauge for determining in-line pressure of hot water at injection point of warewashing machine (5-30 psi)
- Light meter
- Measuring device for measuring distances
- Time/temperature data logger
- pH meter
- Water activity meter
- Camera
- Computers with or without an electronic inspection system
- Black light
- Foodborne illness investigation kits
- Sample collection kits
- Cell phones.

C. Provide Adequate Training

Standard 2 of the Program Standards explains that regulatory staff shall have the knowledge, skills, and ability to adequately perform their required duties. Inspectors need the proper training before they can be expected to conduct risk-based inspections. Training includes a combination of classroom training, in-field training, standardization, and continuing education. For specific training recommendations refer to Program Standard 2 at

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm> and its accompanying Appendix B at the aforementioned website.

(1) Classroom Training

The first phase of staff training should provide an orientation to the program with a review of program history, structure, and relationships to other food-related programs. Specific emphasis should be on the program's goals and objectives. The basic training curriculum should include the following components:

- Prevailing statutes, regulations, or ordinances
- Public health principles
- Communication skills
- Epidemiology
- Microbiology
- HACCP.

FDA's ORA-U

(<http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm>)

provides basic curriculum components free of charge to regulators via the internet. This allows state, local, and tribal health departments to conserve their time and funding resources instead of developing their own training courses. It also allows inspectors to access training as needed. Distance learning allows government agencies and industries to cost-effectively disseminate the most current technical and regulatory information on an as-needed basis.

(2) Field Training and Experience

The second phase of training should move the new inspector into the field with a training officer. On-site training should focus on specific inspection tasks such as interviewing, making observations, measuring conditions such as temperatures and sanitizer strength, assessing the control operators have over the foodborne illness risk factors, ensuring implementation of Food Code interventions, and completing the inspection form. If an electronic database is used by the agency, training in its use should be included in this phase.

The evaluation of food safety management systems based on HACCP principles should be part of the field training experience. The trainee and the trainer should review establishment menus, operations, recipes, and standard operating procedures. Inspectors should be able to demonstrate proficiency in gathering information about the food preparation processes, including accurate charting of the food flows and determination of the Critical Control Points (CCPs) and critical limits in an operation. This part of the training should also include a familiarization with the compliance and enforcement protocol in place in the jurisdiction including recommendation of voluntary strategies to prevent risk factor occurrence.

(3) Standardization

The third part of staff training should include standardization. This process improves uniformity in the application and interpretation of applicable regulations, inspection methodology, and report writing. The Program Standards recommend that staff conducting inspections undergo a standardization process similar to the one described in the *FDA Procedures for Standardization and Certification of Retail Food Inspection/ Training Officers* (<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/InspectionsQualityAssurance/ucm2006814.htm>). Standardization should be completed after the trainee completes classroom and field training.

(4) Continuing Education

The training process for inspection staff should be continuous. The final phase of training should include a mechanism to ensure that learning is ongoing and staff is kept abreast of food safety issues and the latest science.

D. Ensure Adequate Program Resources

As indicated in Standard 8 of the Program Standards, regulatory agencies should have adequate funding, staff, and equipment necessary to support a risk-based retail food safety program designed to reduce the occurrence of foodborne illness risk factors. Program management should do everything they can to secure funding and resources to support regulatory food programs.

Standard 8 of the Program Standards also states that the program budget should provide the necessary resources to develop and maintain a retail food safety program that has a staffing level of one full-time equivalent (FTE) devoted to food for every 280 - 320 inspections performed. Inspections, for purposes of this calculation, include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews, and other direct establishment contact time such as on-site training.

4. RISK-BASED INSPECTION METHODOLOGY

A. Focus the Inspection

Conducting a risk-based inspection requires inspectors to focus their efforts on evaluating the degree of active managerial control that operators have over foodborne illness risk factors. In addition, it is essential that the implementation of Food Code interventions also be verified during each inspection. Inspectors need to spend the majority of their time observing the behaviors, practices, and procedures that are likely to lead to out-of-control foodborne illness risk factors and asking management and food employees questions to supplement actual observations.

Retail and food service operators implement “control measures” to ensure food safety. Control measures are actions or activities that are used to prevent, eliminate, or reduce food safety hazards. Inspectors need to determine the control measures that should be implemented to prevent the occurrence of foodborne illness risk factors in each food preparation process. In order to determine the foodborne illness risk factors common to each operation, it is important for inspectors to understand that the food preparation processes and all the associated control measures initiated by a retail or food service operator represent a food safety management system. It will be necessary for inspectors to ask questions in order to gain information about the system already in place. Once the degree of active managerial control is determined, inspectors will be able to assist operators with strengthening their existing food safety management systems.

B. Lead by Example

Nonverbal communication is just as important as verbal communication in relaying important food safety principles to retail and food service operators. By setting the example during inspections, inspectors not only demonstrate competency, but they also relay important food safety information to the person in charge and food employees. The following are ways that inspectors set the example during inspections:

- Washing their hands when entering the food preparation area at the beginning of the inspection and after engaging in any activities that might contaminate their hands
- Not working when they are suffering from symptoms such as diarrhea, fever, vomiting, or jaundice or if they are diagnosed with a disease transmittable by food
- Being careful not to touch ready-to-eat (RTE) food with their bare hands
- Washing and sanitizing their thermocouple probe at the start of the inspection and between foods
- Using a proper hair restraint and practicing good personal hygiene
- Being careful not to contaminate clean and sanitized food contact-surfaces with unclean hands or their inspection equipment.

C. Conduct Inspections at Variable Times

Inspectors should enter the food establishment during hours of operation or at other reasonable times. Inspectors should show identification and provide the permit holder or person in charge with a verbal or written notice of the purpose of the inspection. Procedures outlined in the Food Code and in the jurisdiction’s procedures should be followed if access to conduct an inspection is denied. Refusal should be documented on the inspection report and an administrative or judicial inspection order obtained.

In planning for inspections, inspectors should consider the importance of timing. Several operational steps at retail such as receiving, preparation, and cooling can be evaluated only during limited time periods. In order to properly evaluate critical

processes that occur outside of the normal 8 a.m. to 5 p.m. working hours, an inspector should be allowed the flexibility to conduct inspections early in the morning, late in the evening, and even on weekends.

D. Establish Inspection Priorities and Use Inspection Time Wisely

With the limited time allotted for inspections, inspectors must develop clear priorities to make the most efficient use of their time in each food establishment. Although basic sanitation issues generally do not change during the course of an inspection, critical behaviors, practices, and procedures leading to foodborne illness risk factors may be only observable during limited time periods of the preparation or cooling process. For this reason, assessment of the active managerial control of foodborne illness risk factors should generally be performed before reviewing basic sanitation issues.

To effectively set priorities, the following four activities should be completed early in the inspection:

- (1) Establish an open dialogue with the person in charge
- (2) Review previous inspection records
- (3) Conduct a menu or food list review
- (4) Conduct a quick walk-through.

(1) Establish an Open Dialogue with the Person in Charge

The tone of the inspection is often set during the first few minutes of the inspection. A professional but personable approach is the balance which should be maintained. Genuine interest in the food establishment and the staff translates into good relations which may be helpful in conveying the goal of promoting public health. Having an open dialogue with the person in charge during all phases of the inspection gives inspectors an opportunity to learn important information about the existing food safety management system.

It is important to know both the strengths and weaknesses of the existing food safety management system early in the inspection in order to focus the inspection on weak areas. Questions about practices and procedures related to foodborne illness risk factors and Food Code interventions such as the establishment's employee health policy and consumer advisory notice should be asked during all phases of the inspection. It is important to ask enough questions to fully understand the system being utilized in the food establishment. This is especially true when evaluating whether the employees are adhering to the established no bare hand contact and handwashing policies. Asking the person in charge questions about important activities such as receiving, cooling, and preparation is also important in relaying the importance of out-of-control foodborne illness risk factors.

The person in charge should be encouraged to accompany inspectors during the inspection. This may ultimately save time since violations can be pointed out and

corrected as they are observed. In addition, the importance of violations related to foodborne illness risk factors and Food Code interventions is more apparent if they are pointed out during the inspection rather than waiting until the end. Violations should be marked on the inspection form even if immediate corrective actions are taken. Corrective actions taken should also be recorded on the inspection form. Inspectors can also use this time to share knowledge about critical processes. By communicating the public health rationale behind the regulations, inspectors will leave the person in charge with a clear understanding for why active managerial control of foodborne illness risk factors must be a top priority in the day-to-day operation of the business.

Early in the inspection, inspectors should inquire about activities that are presently occurring. Processes that occur over time like cooling and reheating also need to be assessed over time; thus, inspectors should ask in the beginning of the inspection if any foods are currently being cooled or reheated.

It is important for inspectors to allow the operator a chance to discuss issues related to food safety. One-way communication in which inspectors do all the talking is not conducive to a risk-based philosophy. An effective risk-based inspection is dependent on inspectors' ability to maintain two-way communication in order to properly assess behaviors, processes, and procedures that occur in the food establishment.

(2) Review Previous Inspection Reports

In order to detect trends of out-of-control foodborne illness risk factors, it is important for inspectors to review past inspection reports before conducting an inspection. This can be done in the office or on-site in the food establishment. This activity is especially important in jurisdictions where inspectors rotate from one inspection to the next. If the same foodborne illness risk factor is out-of-control during more than one inspection, it is strongly recommended that the operator develop an intervention strategy to prevent its recurrence. Intervention strategies are discussed later in this Annex.

Knowledge of what has been corrected from the last inspection also gives inspectors an opportunity to provide positive feedback to the operator and allows inspectors to track corrected violations in accordance with their jurisdiction's policies and procedures.

(3) Conduct a Menu/Food List Review

Menus, including all written and verbal lists of foods prepared and offered in a food establishment, can be reviewed in a fairly simple manner. The review can either be done simultaneously with a quick walk-through of the operation or at the beginning of the inspection as a discussion with management. The menu/food list also does not need to be reviewed during every inspection. If a review was done during a recent inspection, inspectors should inquire about new items, seasonal items, substitutions, or changes in preparation since the last menu review was conducted.

A review of the menu/food list allows inspectors to begin to group food items into one of three broad process categories (discussed in Annex 4 of the Food Code and later in this Annex). Mentally grouping products by process assists inspectors in focusing the inspection on the control measures critical to each process. Conducting a review of the menu/food list also allows inspectors to establish inspection priorities by identifying:

- High-risk foods or high-risk food preparation processes
- Operational steps requiring further inquiry such as receiving, preparation, cooking, and cooling.

By identifying high-risk foods or high-risk food preparation processes, inspectors can focus the inspection on those foods or processes that are more likely to cause foodborne illness if uncontrolled. The menu/food list review might be the only time inspectors are made aware of specialized processes such as formulating a food so that it is not time/temperature control for safety food (TCS) or high-risk seasonal menu items such as “raw oysters on the half shell.” Foods such as shellstock and certain fish for raw consumption require documentation that should be reviewed during the inspection. If Caesar salad or hollandaise sauce is served, further inquiry is needed regarding the preparation of these items since they are sometimes prepared with raw or undercooked eggs.

Several operational steps like receiving, preparation, cooking, and cooling may not be inspected as vigorously in retail and food service inspections due, in part, to the hours of the day in which these steps occur. If a food establishment is inspected in the afternoon hours, for example, receiving and food preparation might have already occurred. In order to evaluate the establishment’s active managerial control of foodborne illness risk factors, it is imperative that inspectors ask enough questions to obtain information about the operational steps that they cannot directly observe during the current inspection.

(4) Conduct a Quick Walk-through

As inspectors discuss the menu or food list and establishes open communication with the person in charge, it is suggested that they conduct a quick walk-through of the food establishment to observe what is going on at that time. Conducting a quick walk-through is especially important to observe several activities that might otherwise go unnoticed or unobserved until later in the inspection, including:

- Receiving
- Food preparation and handling
- Cooking
- Cooling
- Reheating.

Speaking directly to the food service employees preparing the food is also an excellent way to assess the effectiveness of the establishment's food safety training and standard operating procedures for critical processes such as cooling. Noting that receiving or food preparation is occurring at the beginning of the inspection allows inspectors an opportunity to take advantage of viewing "real-life" production processes and will help inspectors to obtain a clear picture of the establishment's true practices. Receiving and food preparation only occur during limited times, so inspectors may want to stop and observe these operational steps while they are happening.

Early in the inspection, temperatures of time/temperature control for safety foods (TCS) should be taken. For example, if inspecting in the morning, inspectors should check the temperatures of last night's stored leftovers. If inspecting in the afternoon, inspectors should check the temperatures of foods prepared that morning that are now cooling. Also, inspectors should ask whether any foods are currently being cooked or reheated.

E. Determine Process Flows

Many retail and food service establishments have implemented effective food safety management systems by establishing controls for the food preparation methods and processes common to their operation. Control of food preparation processes rather than individual food items is often called the "process approach" to HACCP. The process approach using the principles of HACCP can best be described as dividing the many food items in an operation into food preparation processes then analyzing the foodborne illness risk factors associated with each process. By placing managerial controls on specific operational steps in the flow of food, foodborne illness can be prevented.

As presented in Annex 4 of the Food Code, most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41° F and 135° F. In conducting risk-based inspections, it is necessary for an inspector to be knowledgeable regarding how food is prepared in the operation. Knowing how products are prepared in an establishment allows inspectors to focus their inspections on the critical procedures and steps in the preparation of those products.

F. Determine Foodborne Illness Risk Factors In Process Flows

Annex 4 of the Food Code details the essential control measures specific to each food preparation process, in addition to essential facility-wide control measures. Inspectors should generally focus their inspections on verifying that operators have implemented control measures to control for foodborne illness risk factors common to the processes conducted in each operation. There may be other foodborne illness risk factors unique to specific operations; thus, inspectors should independently evaluate each operation and food preparation process conducted.

G. Assess Active Managerial Control of Foodborne Illness Risk Factors and Implementation of Food Code Interventions

Although some food establishments have formal HACCP plans, many do not. Even without a HACCP system, every food establishment needs to have active managerial control of foodborne illness risk factors. This may be achieved through several means, such as training programs, manager oversight, or standard operating procedures. For example, some food establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions to achieve active managerial control.

While a person in charge may require the maintenance of in-house written records by employees to ensure that monitoring is being performed using the correct method and at the proper frequency, foodborne illness risk factors may be managed without the use of formal record keeping. Monitoring, whether through direct observations or by taking appropriate measurements, is by far the most important step in ensuring food safety. If an operator is effectively monitoring all critical activities in the food establishment and taking corrective actions when needed, safe food will result. With a few exceptions, maintaining formal records at retail is not required; therefore, records may not be in place for use during the inspection. As a result, it will be necessary to use direct observations and interviewing to determine whether a food establishment is adequately monitoring foodborne illness risk factors in their existing food safety management system.

This section provides a comprehensive discussion of how to assess the active managerial control of each of the foodborne illness risk factors and the implementation of each of the Food Code interventions. Assessment of active managerial control involves more than determining compliance with Food Code provisions. In assessing whether the operator has active managerial control, inspectors should observe whether the operator has established the appropriate control measures and critical limits and whether appropriate monitoring and corrective action procedures are in place and followed. In addition, inspectors should assess whether managers and employees are knowledgeable of food safety principles and critical practices and procedures necessary to prevent foodborne illness. If during the inspection inspectors observe that control measures are not being implemented appropriately to control risk factor occurrence, immediate corrective action must be taken.

(1) Demonstration of Knowledge

It is the responsibility of the person in charge to ensure compliance with the Code. Knowledge and application of Food Code provisions are vital to preventing foodborne illness and injury. Data collected by FDA suggest that having a certified food manager on-site has a positive effect on the occurrence of certain foodborne illness risk factors in the industry.

In order to assess whether the person in charge demonstrates knowledge, inspectors should verify that the person in charge has one or more of the following:

- A valid food protection manager certificate
- No priority item violations during the current inspection
- Correct responses to food safety related questions as presented in ¶ 2-102.11(C) of the Food Code.

(2) Assessing Safe Sources and Receiving Temperatures

The time and day of the inspection is important when assessing whether foods are received from safe sources and in sound condition. Foods may be received in the food establishment on set days. Inspectors should ask questions to ascertain the day or days that deliveries are received and also the receiving procedures in place by the food establishment. Inspections can be scheduled at times when it is known that products will be received by the food establishment. If food is being delivered during the inspection, inspectors should:

- Verify internal product temperatures
- Examine package integrity upon delivery
- Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
- Examine delivery truck and products for potential for cross-contamination
- Observe the food establishment's behaviors and practices as they relate to the establishment's control of contamination and holding and cooling temperatures of received products
- Review receiving logs and other documents, product labels, and food products to ensure that foods are received from regulated food processing plants (no foods prepared at home) and at the proper temperature.

When evaluating approved sources for shellfish, such as clams, oysters, and mussels, inspectors should ask whether shellfish are served at any time during the year. If so, inspectors should review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified Shellfish Shippers List found at (<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm>). Inspectors should note whether all required information is provided on the tags or label (harvester's certification number, harvest waters and date, type and quantity of shellfish and similar information for each dealer that handles the shellfish after the harvester). Shellstock tags should also be retained for 90 days in chronological order.

With regard to fish, inspectors should verify that fish are commercially caught and harvested and received from reputable vendors. If fish are being delivered during the inspection or if they were received just before inspectors' arrival, temperatures should be taken, especially if there are finfish such as tuna, mahi-mahi, bluefish, mackerel, and snapper. These fish are subject to scombrototoxin formation if time/temperature abused.

Inspectors should verify freshness by conducting an organoleptic inspection of the gills, eyes, and bodies of the fish.

Inspector should verify that fish, except for certain species of tuna, intended for raw or undercooked consumption have been frozen for the required time and temperature parameters to destroy parasites by either reviewing freezing records or verifying that a letter of guarantee from the purveyor is kept on file. If freezing is conducted on-site, inspectors should verify that the freezing records are maintained for at least 90 days beyond the date of sale or service.

With regard to the service of game or wild mushrooms, inspectors should ask if these products are served at any time during the year. If so, inspectors should verify that they are from an approved source by reviewing invoices.

With regard to juice and milk products, inspectors should verify that fluid milk and milk products are pasteurized and received at the proper temperature. For packaged juice, inspectors should verify that the juice was pasteurized or otherwise treated to achieve a 5-log reduction of the most resistant microorganism.

During the inspection, inspectors should inquire as to the source of foods that have been removed from their original containers. If at any time during the inspection there is any doubt as to the source of certain products, inspectors should ask for invoices or receipts to demonstrate their source. Certain products, such as flat breads, waffles, pies, and cakes may require special cooking equipment to prepare. If suitable equipment is not on-site to prepare such products and the products are not stored in original containers, then inspectors should inquire as to the source of these products.

Food from unapproved, unsafe, or otherwise unverifiable sources should be discarded or put on hold or under embargo until appropriate documentation is provided. In addition, inspectors should ensure that management and employees are aware of the risk of serving or selling food from unapproved sources. Fish that are intended to be consumed raw or undercooked and for which no freezing certification or equipment is found on-site, can be used in menu items that will be fully cooked. If cooking is not an option due to the menu items served, the fish should be discarded.

(3) Assessing Contaminated Equipment and Potential for Cross-Contamination

This risk factor involves the proper storage and use of food products and equipment to prevent cross-contamination. The cleaning, sanitization, and storage of food-contact surfaces of equipment and utensils in a manner to prevent transmission of foodborne pathogens or contamination is also included in this risk factor.

As inspectors walk through the food establishment, they should examine food storage areas for proper storage, separation, segregation, and protection from contamination. Inspectors should look to see that raw animal foods and ready-to-eat foods are

separated during receiving, storage, and preparation. For example, cooked shrimp should not be returned to the same container that previously held uncooked product. Cutting boards should be washed, rinsed, and sanitized between trimming uncooked chicken and cooked steak.

In addition, raw animal foods should be separated by cooking temperatures such that foods requiring a higher cooking temperature, like chicken, should be stored below or away from foods requiring a lower temperature, like pork and beef. If TCS foods are not being cooled, they should be covered or packaged while in cold storage.

Following the flow of food as it is prepared in the food establishment may alert inspectors to opportunities for cross-contamination. When contamination has occurred between raw and ready-to-eat food, inspectors should assess whether the food can be reconditioned. In some cases, depending on the affected food, it may be possible to reheat the food to eliminate any hazards. If the food cannot be reconditioned, then the food should be discarded.

Inspectors should verify that exposed food such as chips, bread, and dipping sauces are not re-served to the consumer. Consumer self-service operations are addressed in the Code with regard to the types of food offered for consumer self-service, the protection of food on display, and the required monitoring by employees of such operations.

A visual check of the food-contact surfaces of equipment and utensils should be made to verify that the utensils are maintained clean and sanitized using the approved manner and frequency. Utensils that are observed to have debris, grease, or other visible contamination should be rewashed and resanitized.

Observations should be made to determine whether practices are in place to eliminate the potential for contamination of utensils, equipment, and single-service items by environmental contaminants, employees, and consumers. When clean equipment and utensils are stored where they are subject to environmental contamination such as near handwashing sinks or prep sinks, inspectors should have the operator rearrange the equipment in a manner to prevent cross-contamination. Depending on the circumstances, the operator may need to rewash and resanitize the equipment.

Inspectors should observe handwashing operations. If handwashing sinks and fixtures are located where splash may contaminate food contact surfaces or food, then splash guards should be installed or food-contact surfaces should be relocated to prevent cross-contamination.

Inspectors should pay particular attention to prep sinks, especially those that are currently in use at the time of the inspection. Built-up grime is a visible sign that the sink is not being washed, rinsed, and sanitized appropriately before use. If there are designated vegetable or meat sinks, inspectors should verify that the placement of sinks

and food preparation areas do not facilitate opportunities for cross-contamination from one to the other.

With regard to the cleaning and sanitization of food-contact surfaces, inspectors should verify the compliance of any warewashing operations by ensuring that cleaning and sanitizing procedures for all food-contact surfaces conform to the requirements in the Food Code. Questions should be asked to assess how utensils and cookware are washed, rinsed, and sanitized in the food establishment. When assessing the warewashing procedure and equipment, inspectors should pay particular attention to cooking and baking equipment that is too large to fit in the dishmachine or sinks. It is a good idea to have the person responsible for dishwashing demonstrate the procedure that is followed in the food establishment by setting up the sinks and watching the dishwashing procedure.

(4) Assessing Cooking Temperatures

Food cooking temperatures and times should be verified by inspectors during each inspection. Every effort should be made to assess the cooking temperatures of a variety of products served in the food establishment.

To assess cooking, inspections must occur at times when food is being cooked. It is also important to conduct inspections during busy times, such as lunch and dinner, as there may be a tendency for the operator to rush the cooking of foods during these times.

Critical limits for cooking TCS foods in the Food Code include specifications that all parts of the food be heated to a certain temperature. For large roasts, temperature measurement should take into account post-cooking heat rise which allows the temperature to reach equilibrium throughout the food. The critical limit of time at the terminal temperature must also be measured during inspections. For example, a roast beef cooked at 54°C (130°F) is required to be held at this temperature for 112 minutes to ensure destruction of pathogens. Cooking times and temperatures should be noted on the inspection report.

The correct temperature measuring device and technique are essential in accurately determining the temperatures of TCS foods. The geometric center or thickest part of a product are the points of measurement of product temperature particularly when measuring critical limits for cooking.

Inspectors should take internal temperatures of products using a thermocouple or thermistor with a probe suitable for the product thickness. A thin diameter probe should be used for temperature measurements of hamburger patties and fish filets. Alternately, although less desirable, an inspector may use a suitable, calibrated bimetal stem thermometer for checking cooking temperatures of thick foods. Infrared thermometers are inappropriate for measuring internal cooking temperatures.

In order to better assess cooking during all phases of the inspection, inspectors could enlist the help of cooperative food employees to notify them of foods that have finished cooking. This allows inspectors to continue with the inspection in other areas of the operation yet continue to verify that proper cooking temperatures are being met.

Food establishments should routinely monitor cooking temperatures. Inspections should verify that monitoring is occurring by involving the person in charge in these activities during the regulatory inspection. The presence of required thermometers and their proper use should be assessed.

Comparisons should be made between inspectors' calibrated temperature measuring device and those used by the food establishment. Notation of deviations should be made on the inspection report. Inspectors should ask food establishment personnel to demonstrate proper calibration of their temperature measuring devices.

If required cooking temperatures are not met, inspectors should have the operator continue cooking the food until the proper temperature is reached. Additionally, inspectors should explain the public health significance of inadequate cooking to management and food employees.

(5) Assessing Holding Time and Temperatures and Date Marking

Hot and cold holding temperatures, as well as cooling time and temperatures, of TCS foods should be thoroughly checked with a thermocouple, thermistor, or other appropriate temperature measuring device during each inspection. This includes the temperature of TCS food during transport, e.g., hot holding carts being used to transport food to patient rooms in a hospital, satellite kitchens, or off-site catering events. As a rule, every effort should be made to assess every hot and cold holding unit in the food establishment during a risk-based inspection.

Use of an infrared thermometer for verifying holding temperatures is not consistent with Food Code requirements since verifying only the surface temperature of the food may not alert inspectors to problems that exist under the food's surface. Such problems could stem from improper cooling, in the case of cold-held foods, or improper reheating, in the case of hot-held foods. In addition, inspectors should not stir a food before taking its temperature since it is important to know the temperature of the food before it is agitated.

The geometric center of a product is usually the point of measurement of product temperature particularly when measuring the critical limit for cold holding.

The hot holding critical limit may need additional measurements taken at points farthest from the heat source, e.g., near the product surface for food held on a steam table. Temperatures monitored between packages of food, such as cartons of milk or packages of meat, may indicate the need for further examination. However, the temperature of a TCS food itself, rather than the temperature between packages, is

necessary for regulatory citations. In large holding units and on steam tables, it is necessary to take the temperatures of foods in various locations to ensure that the equipment is working properly. If deviations are noted in the product temperatures, it is important to take extra steps to find out whether the problem is the result of equipment failure or whether a breakdown in a process such as cooling or reheating is the reason for the problem.

Corrective actions for foods found in violation should be required based on the jurisdiction's regulatory food code. If foods are to be discarded, forms such as those used for stop sale or embargo may need to be completed and signed by the person in charge in accordance with the jurisdiction's regulatory food code. In order to properly evaluate the degree of time and temperature abuse and the proper disposition of the affected food, several issues must be considered. Answers to these questions, in combination with observations made during the inspection, should provide inspectors with enough information to make the appropriate recommendation for on-site correction:

- Are there any written procedures in place for using time alone as a public health control and, if so, are they being followed properly?
- What are the ingredients of the food and how was it made?
- Is it likely that the food contains *Clostridium perfringens*, *Clostridium botulinum*, or *Bacillus cereus* as hazards?
- Has there been an opportunity for post-cook contamination with raw animal foods or contaminated equipment?
- If there has been an opportunity for post-cook contamination, can the hazards of concern be eliminated by reheating?
- Are the food employees practicing good personal hygiene including frequent and effective handwashing?
- Was the food reheated or cooked to the proper temperature before being allowed out of temperature control?
- What is the current temperature of the food when taken with a probe thermometer?
- How long has the food been out of temperature control (ask both the manager and food employees)? Are the answers of the food employees and the manager consistent with one another?
- Is it likely that food has cooled to its current temperature after being out of temperature control for the alleged time?
- Will the food be saved as leftovers?
- How long before the food will be served?
- Given what is known about the food, the food's temperature, the handling of the food, and the alleged time out of temperature, is it reasonably likely that the food already contains hazards that cannot be destroyed by reheating?

Even if food can be reconditioned by reheating, steps should be taken by the person in charge to ensure compliance in the future. Examples include repairing malfunctioning or inoperative equipment or implementing a risk control plan (RCP) to modify

preparation procedures or to institute a procedure for monitoring holding temperatures of food.

If using time only or time-temperature combinations in lieu of temperature for controlling the growth and toxin-formation of pathogenic bacteria, strict controls must be in place and followed. Inspectors should verify that the written procedures are on-site and followed in accordance with the Food Code.

Date marking is the mechanism by which active managerial control of time-temperature combinations can prevent the growth of *Listeria monocytogenes* in TCS, ready-to-eat foods during cold storage. With exceptions, all ready-to-eat, TCS foods prepared on-site and held for more than 24 hours should be date marked to indicate the day or date by which the foods need to be served or discarded. Inspectors should ask questions to ascertain whether the system in place to control for *L. monocytogenes* meets the intent of the Food Code. Food that should be date marked and is not should be discarded.

(6) Assessing Reheating for Hot Holding

In order to assess a food establishment's control of reheating for hot holding, the time of day that the inspection occurs is a key factor. Every effort should be made to schedule an inspection during pre-opening preparation. If inspections are conducted during pre-opening preparation or other preparation periods, inspectors should ask questions regarding the history of hot-held foods. Foods in compliance for minimum hot holding temperatures may have in fact been improperly reheated before being placed into hot holding units or steam tables.

If items are found "reheating" on the steam table, further inquiry is needed to assess whether the equipment in question is capable of reheating the food to the proper temperature within the maximum time limit. Corrective action for foods found out of compliance for reheating for hot holding would depend on how long the food had been out of temperature and other factors. In most cases, however, the food may be rapidly reheated and hot held.

(7) Assessing Cooling

Improper cooling remains a major contributor to bacterial foodborne illness. Cooling temperatures and times need to be closely evaluated during every inspection. In order to assess whether a food establishment has control over cooling, the time of day that the inspection occurs is critical. Early morning inspections allow an opportunity to verify that leftovers from the night before were cooled properly or cooled using a proper cooling method. Alternatively, afternoon inspections may allow an inspector to verify cooling of products that may have been prepared that morning.

Because many food establishments prepare bulk products only on certain days of the week, it is essential that inspectors become as familiar as possible with each operation and schedule their inspections accordingly.

Due to the time parameters involved in cooling, inspectors should always inquire at the beginning of the inspection whether there are any products currently being cooled. This allows inspectors an opportunity to take initial temperatures of the products and still have time to re-check temperatures later in the inspection in order to verify that critical limits are being met.

Problems with cooling can often be discovered through inquiry alone. Even when no cooling is taking place, inspectors should ask the food employees and managers questions about the cooling procedures in place.

When examining cold holding units, bulk containers and buckets, tightly packed pans, shrouded rolling racks, or closed rolling cabinets should warrant further temperature and time investigation. Bulk containers and buckets should be opened since they are commonly reused for food storage and cooling.

The geometric center of a product is often chosen as the point of measurement of product temperature particularly when measuring the critical limits for cooling. For foods that are being cooled, temperature profiles throughout the product may show proper temperatures at outer edges and hot spots at the core of the product. Inspectors can verify cooling by first taking a temperature measurement in the geometric center of the product, then at various points around the perimeter of the product. Warmer temperatures in the center of the product, in combination with cooler temperatures around the perimeter, indicate that a product is cooling. Additional questions should be asked to ascertain the cooling time parameters of the food in question. Information gained from food employees and management, in combination with temperature measurements taken, should form the basis for assessing compliance of cooling during an inspection.

The following guidance may be used for determining the appropriate corrective action for improper cooling. Cooked hot food may be reheated to 165 °F for 15 seconds and the cooling process started again using a different cooling method if the food is:

- Above 70 °F and two hours or less into the cooling process; and
- Above 41 °F and six hours or less into the cooling process.

Cooked hot food should be discarded immediately if the food is:

- Above 70 °F and more than two hours into the cooling process; or
- Above 41 °F and more than six hours into the cooling process.

A different, more accelerated, cooling method may be used for prepared ready-to-eat foods if the food is above 41 °F and less than four hours into the cooling process; however, such foods should be discarded if the food is above 41 °F and more than four hours into the cooling process.

(8) Assessing Personal Hygiene, Hands As a Vehicle of Contamination, and Proper Implementation of Employee Health Policies

Special attention should be given to the potential for hands as a vehicle of contamination. An effective management system for prevention of hand contamination involves three elements:

- Employee health policy
- Proper handwashing
- No bare hand contact with ready-to-eat foods.

There are a wide range of communicable diseases and infections that can be transmitted by an infected food employee. Proper management of the risks associated with ill food employees begins with employing healthy people and implementing a policy that excludes or restricts ill employees as specified in Chapter 2 of the Food Code. Employees must be aware of the symptoms, illnesses, or conditions that must be reported to the person in charge. In addition, the person in charge must be knowledgeable regarding the appropriate action to take should certain symptoms, illnesses, or conditions be reported.

With regard to the employee health policy, inspectors should ask a series of open-ended questions to ascertain whether the employee health policy in place complies with the Food Code. The following are example questions that may be asked:

- What kind of policy do you have in place for handling sick employees?
- Is there a written policy? (Note: a written policy is not required in the Food Code, but having a written policy may give an indication of the formality of the policy being discussed.)
- Describe how managers and food employees are made knowledgeable about their duties and responsibilities under the employee health policy.
- Are food employees asked if they are experiencing certain symptoms or illnesses upon conditional offer of employment? If so, what symptoms or illnesses are food employees asked about? Is there a written record of this inquiry?
- What are food employees instructed to do when they are sick?
- What conditions or symptoms are reported?
- What may some indicators be of someone who is working while ill?
- When are employees restricted from working with exposed food or food-contact surfaces? When are they excluded from working in the food establishment?
- For employees that are sick and cannot come to work, what policy is in place for allowing them to return and for notifying the regulatory authority?

Special attention should be given to the potential for hands as a vehicle of contamination. Ensuring that hands are washed using the proper procedure and at the

appropriate times must be a top priority during every inspection. Data show that viruses can be tenacious even in the presence of good handwashing. Inspectors should observe employee use of utensils and gloves during the preparation and service of ready-to-eat foods and ingredients, such as salads and sandwiches.

If ready-to-eat food is touched with bare hands, inspectors will need to address several questions in order to make the appropriate on-site correction recommendation. The answers to the following questions should provide enough information to determine the likelihood of occurrence of hazards transmitted by bare hands and should be the basis for making a recommendation for on-site correction:

- Does the facility have an employee health policy to identify, restrict, and exclude ill employees?
- Did the employees working with the food in question effectively wash their hands and are handwashing facilities adequate?
- Is there an approved, alternate procedure to no bare hand contact in place and was it followed before the bare hand contact?
- Has there been an opportunity for the employee's hands to become contaminated?

Inspectors should examine the location of handwashing sinks in relation to where food is being prepared. Many jurisdictions use a basic distance measurement as a guideline when considering the location and number of handwashing sinks required in a food establishment during the plan review process. While this information can be used to assist with the review process, it should not be used as the sole basis for determining whether there are an adequate number of handwashing sinks or whether the handwashing sinks are conveniently located.

Special emphasis should be placed on spacing in and around fixed equipment, the expected staffing, and the flow of food throughout a food establishment. For instance, a kitchen may be 30 feet in length and 12 feet wide. Although the size of the kitchen may dictate only one handwashing sink using a basic distance measurement, if a prep table the length of the line is placed between the line and the handwashing sink, the handwashing sink may not be conveniently located. Likewise, one handwashing sink located at the end of cook line is useless to employees working at the other end if there is limited space for employees to go around one another during busy periods.

(9) Assessing Compliance with Approved Procedures

When conducting certain specialized processes, variances and HACCP plans are required by the Code. This is because such processes carry a considerable risk if not conducted under strict controls. For food establishments conducting specialized processes, each inspection should involve a review of the written variance, if applicable,

and the implementation of the HACCP plan to ensure that food safety hazards are being consistently controlled.

(10) Assessing Special Requirements Related to Highly Susceptible Populations (HSP)

Food establishments that serve highly susceptible populations (HSP) must adhere to additional requirements as specified under Part 3-8 of the Code. Every effort should be made to inspect such facilities during preparation, service, or other applicable times to assess these additional requirements as well as those in other sections of the Food Code.

Because those persons who are very young, elderly, or who live in a facility that provides custodial care are extremely vulnerable to foodborne illness because of age or health status, it is important that risk factors be controlled on-site in a timely manner. Inspections of HSP facilities should be conducted by inspectors knowledgeable in the control of foodborne illness risk factors who take extra care to assure that the most vulnerable segment of the population are not at risk.

(11) Assessing Labeling, Storage, and Use of Poisonous and Toxic Chemicals

During each inspection, the proper labeling, storage, and use of poisonous and toxic chemicals should be verified. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label. Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies should be clearly and individually identified with the common name of the material. Only chemicals that are necessary to the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, should be in the food establishment. Medicines necessary for the health of employees may be allowed in a food establishment, but they should be labeled and stored to prevent contamination of food and food-contact surfaces.

Inspectors should verify that solutions containing poisonous and toxic chemicals, like mop water, are discarded in an appropriate service sink to prevent contamination of food and food-contact surfaces. In addition, inspectors should check delivery trucks to verify that food is protected from chemical contamination during shipment. Any food that has been cross-contaminated with poisonous or toxic chemicals should be discarded or rejected immediately.

(12) Assessing Compliance with Consumer Advisory

Inspectors should ascertain whether animal foods such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish are served or sold raw, undercooked, or without otherwise

being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food. Inspectors should review the menu or food list to verify that a consumer advisory with a disclosure and reminder is present as specified under § 3-603.11 of the Food Code.

In addition to reviewing the menu or food list, inspectors should ask whether raw or undercooked foods are served or sold routinely or seasonally. It is useful to know foods that are often served in this manner such as oysters-on-the half shell, hollandaise sauce, béarnaise sauce, eggnog, salad dressings, hamburgers to order, or sunny-side-up eggs.

H. Evaluating Basic Sanitation and Facilities (Good Retail Practices)

An important part of a risk-based, routine inspection is to review how the food establishment actively monitors the active managerial control of foodborne illness risk factors and interventions; however, overall sanitation should not be overlooked. Systems to control basic operational and sanitation conditions within a food establishment, referred to as Good Retail Practices (GRPs), are the foundation of a successful food safety management system. GRPs found to be out-of-compliance may give rise to conditions that may lead to foodborne illness, e.g., sewage backing up in the kitchen. Just as monitoring is required by the food establishment to ensure that foodborne illness risk factors are controlled and interventions are in place, monitoring of basic sanitation conditions in the food establishment allows the operator an excellent opportunity to detect weaknesses and initiate actions for improvement. Basic operational and sanitation programs must be in place to:

- Protect products from contamination by biological, chemical, and physical food safety hazards
- Control bacterial growth that can result from temperature abuse during storage
- Maintain equipment, especially equipment used to maintain product temperatures.

Examples of concerns addressed by the basic operation and sanitation programs mentioned above include the following:

- Pest control
- Food protection (CORE ITEM)
- Equipment maintenance
- Water
- Plumbing
- Toilet facilities
- Sewage
- Garbage and refuse disposal
- Physical facilities.

5. ACHIEVING ON-SITE AND LONG-TERM COMPLIANCE

A. Developing an Effective Compliance and Enforcement Protocol

Compliance and enforcement are essential elements of a regulatory program and encompass all voluntary and regulatory enforcement actions taken to achieve compliance with regulations. Standards 3 and 6 of the Program Standards explain the need of regulatory jurisdictions to establish a compliance and enforcement protocol that results in credible follow-up for each violation noted during an inspection, especially violations related to foodborne illness risk factors and Food Code interventions. Lack of follow-up on the part of the regulatory agency signals to the operator that the priority item and priority foundation item violations noted were not important.

The resolution of out-of-compliance foodborne illness risk factors and Food Code interventions must be documented in each food establishment record. The desired outcome of Standard 6 is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Compliance and enforcement options may vary depending on state and local law. It is essential that regulatory jurisdictions develop a written compliance and enforcement protocol that details the order in which both voluntary corrections may be taken on the part of the operator and involuntary enforcement actions are to be taken on the part of the regulatory authority. Involuntary enforcement actions include, but are not limited to, such activities as warning letters, re-inspections, citations, administrative fines, permit suspensions, and hearings.

Food establishment with a history of noncompliance at a level predetermined by the jurisdiction or with the number of foodborne illness risk factors and interventions violated warranting a regulatory action, signals the need either a strong regulatory response or an alternate approach to compliance to protect public health, e.g., active managerial control, behavioral change.

Voluntary corrections taken on the part of the operator include, but are not limited to, such activities as on-site corrections at the time of inspection, voluntary destruction, risk control plans, and remedial training. Obtaining voluntary corrections by the operator can be very effective in achieving long-term compliance. Voluntary corrections by the operator are referred to in FDA's Regulator's Manual as "intervention strategies." Intervention strategies can be divided into two groups:

- Those designed to achieve immediate on-site correction
- Those designed to achieve long-term compliance.

Successful intervention strategies for out-of-control foodborne illness risk factors can be tailored to each operation's resources and needs. This will require inspectors to work

with the operator to identify weaknesses in the existing food safety management system and consulting with the operator to strengthen any weak areas noted.

B. On-site Correction

On-site corrections are intended to achieve immediate corrective action of out-of-control foodborne illness risk factors posing an immediate, serious danger to the consumer during the inspection. Usually these violations are "operational" rather than structural and can be addressed by management at the time of the inspection.

It is essential to consumer protection and to regulatory credibility for on-site correction to be obtained for any out-of-control foodborne illness risk factors before completing the inspection and leaving the food establishment. Obtaining on-site correction conveys the seriousness of the violation to management. Failure to require on-site correction when an out-of-control risk factor has been identified implies that the risk factor has little importance to food safety.

When recommending on-site correction, effective communication regarding out-of-control foodborne illness risk factors is essential and can be accomplished best by:

- Discussing food safety concerns in words that can be easily understood by the person in charge and employees
- Conveying the seriousness of the out-of-control foodborne illness risk factors in terms of increased risk of illness or injury.

During the discussion of inspection findings with the person in charge, inspectors should keep the discussion focused on correction of violations that present an immediate danger to the consumer. Discussion of less serious code violations should be deferred until out-of-control foodborne illness risk factors are discussed and on-site correction is obtained.

In most cases, selecting the most appropriate on-site correction when out-of-control foodborne illness risk factors are observed will be straightforward; however, in instances such as improper cooling, the appropriate corrective action may be more complicated. Since determining on-site correction depends on a number of factors, an inspector may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take.

C. Intervention Strategies for Achieving Long-term Compliance

While on-site correction of out-of-control foodborne illness risk factors is essential to consumer protection, achieving long-term compliance and behavior change is equally important. Overcoming several misconceptions about long-term compliance will help in achieving a desirable change of behavior. For example, in jurisdictions using a 44-item inspection report in which only observed violations are marked, it is often taken for

granted that if there are no violations marked, the foodborne illness risk factors are being controlled. This is not necessarily true since the observation of code violations is subject to many variables such as the time of day, day of the week, or duration of the inspection. An inspection system that records only observed violations rather than the actual status of all foodborne illness risk factors, such as whether the risk factor was in compliance, not observed, or not applicable to the operation, may be unable to detect some foodborne illness risk factors that are continually or cyclically out of control.

Another misconception is that training alone will result in foodborne illness risk factors being controlled. While training may help, there is no guarantee that knowledge acquired will equate to knowledge applied in the workplace. In order for knowledge to translate into changed behavior, it must be reinforced and the behavior must be repeated for a period of time sufficient for the behavior to become an ingrained pattern. Another assumption is that regulatory enforcement actions such as citations or administrative hearings or on-site corrections alone will automatically result in future management control. Unfortunately, there is no assurance that any of these actions will result in the long-term control of foodborne illness risk factors.

Long-term compliance may best be achieved through voluntary actions by the operator. If an operator supports the concept that a food safety management system is needed, there is a better chance that long-term compliance will be achieved. The following are ways operators can better ensure long-term active managerial control of foodborne illness risk factors.

(1) Change Equipment and Layout

Critical limits are difficult to achieve when equipment does not work properly. Proper calibration of equipment is vital to achieving food safety. When calibration is unsuccessful or is not feasible, equipment should be replaced. In addition to equipment malfunctioning, poor equipment layout can present opportunities for cross contamination and must be considered. For example:

- Hamburgers with uniform thickness and weight are not all reaching a safe cooking temperature in a given time. Upon examination, it is determined that the grill is distributing heat unevenly. A new element is installed to correct the problem.
- Splash from a nearby handwashing sink is seen on a prep table. A splash guard is installed to prevent cross contamination from the handwashing sink to the prep table.

(2) Establish Buyer Specifications

Written specifications for the goods and services purchased by a food establishment prevent many problems. For example:

- Fish posing a parasite hazard and intended for raw consumption have not been frozen for the specified time and temperature and no freezing equipment is on-site at the food establishment. Buyer specifications are established to place the responsibility for freezing the fish on the supplier.
- Lobster tails, hamburgers, or other products cooked with a set time parameter on a conveyor are not reaching the proper temperature in the specified time because they are larger than the size for which the conveyor is calibrated. Buyer specifications are established to restrict the size of products received from the supplier.

(3) Develop and Implement Recipe/Process Instructions

Simple control measures integrated into recipes and processes can improve management control over foodborne illness risk factors. For example:

- Process instructions that specify using color-coded cutting boards for separating raw animal foods from ready-to-eat products are developed to control the potential for cross contamination.
- Pasteurized eggs are substituted in recipes that call for raw or undercooked eggs to reduce the risk of foodborne illness.
- Commercially precooked chicken is used in recipes calling for cooked chicken such as chicken salad to reduce the risk of contaminating food-contact surfaces and ready-to-eat food with raw chicken.
- Pasta is chilled in an ice bath immediately after cooking and before apportioning into single servings. This is specified in the procedures for cooking spaghetti.

(4) Establish First-In-First-Out (FIFO) Procedures

Product rotation is important for both quality and safety reasons. “First-In-First-Out” (FIFO) means that the first batch of product prepared and placed in storage should be the first one sold or used. Date marking foods as required by the Food Code facilitates the use of a FIFO procedure in refrigerated, ready-to-eat, TCS foods. The FIFO concept limits the potential for pathogen growth, encourages product rotation, and documents compliance with time/temperature requirements.

(5) Develop and Implement Standard Operating Procedures (SOPs)

Following standardized, written procedures for performing various tasks ensures that quality, efficiency, and safety criteria are met each time the task is performed. Although every operation is unique, the following list contains some common management areas that can be controlled with SOPs:

- Personnel (disease control, cleanliness, training)
- Facility maintenance
- Sanitary conditions (general cleaning schedule, chemical storage, pest control, sanitization of food-contact surfaces)
- Sanitary facilities (approved water supply and testing, if applicable, scheduled in-house inspection of plumbing, sewage disposal, handwashing and toilet facilities, trash removal)
- Equipment and utensil maintenance.

SOPs can also be developed to detail procedures for controlling foodborne illness risk factors:

- Procedures are implemented for measuring temperatures at a given frequency and for taking appropriate corrective actions to prevent hazards associated inadequate cooking.
- Adequate handwashing is achieved by following written procedures that dictate frequency, proper technique, and monitoring.

(6) Develop and Implement Risk Control Plans (RCPs)

An RCP is a concisely written management plan developed by the retail or food service operator with input from inspectors that describes a management system for controlling specific out-of-control foodborne illness risk factors. An RCP is intended to be a voluntary strategy that inspectors and the person in charge jointly develop to promote long-term compliance for *specific* out-of-control foodborne illness risk factors. For example, if food is improperly cooled in the establishment, a system of monitoring and record keeping outlined in an RCP can ensure that new procedures are established to adequately cool the food in the future. An RCP should require that the basic control systems in the plan be implemented for a designated period of time (e.g., 60 – 90 days) and allow inspector oversight. The longer the plan is implemented, the more likely it is that the new controls will become "habits" that continue to be used in the food establishment after inspector oversight ends.

An RCP should stress simple control measures that can be integrated into the daily routine. It should be brief, no more than one page for each risk factor, and address the following points in very specific terms:

- What is the risk factor to be controlled?
- How is the risk factor controlled?
- Who is responsible for the control?
- What monitoring and record keeping is required?
- Who is responsible for monitoring and completing records?
- What corrective actions should be taken when deviations are noted?

- How long is the plan to continue?
- How are the results of the RCP communicated to inspectors?

By implementing an RCP, the retail or food service operator will have the opportunity to determine the appropriate corrective action for the identified problem and design an implementation strategy to best suit the establishment and operation. Since the RCP is tailored to meet the needs of the food establishment, the operator takes complete ownership of the plan and is ultimately responsible for its development and implementation. The role of inspectors are to consult with the operator by suggesting ways that the risk factor(s) might be controlled.

By creating an RCP, the operator realizes that a problem exists in the established food safety management system and commits to a specific correction plan rather than merely acknowledging a single violation. Follow up by telephone or in person indicates to the operator that inspectors are interested in seeing the plan succeed. This also gives inspectors an opportunity to answer any questions and offer feedback to the operator to make the RCP more useful. An example of an RCP, along with a blank template that can be used by regulatory jurisdictions, is found in FDA's Regulator's Manual: <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm>

(7) Develop and Implement Comprehensive Voluntary Food Safety Management Systems based on HACCP Principles

The *Food Code* only requires HACCP plans for a few specialized processes; however, the development of voluntary HACCP plans is always encouraged. FDA Operator's Manual, "*Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments*" is written to aid food establishment managers in the development of food safety management systems based on HACCP principles. A retail or food service operator, in consultation with an appropriate regulatory authority or other food safety professional, can use this document to establish an effective food safety management system to control for all foodborne illness risk factors. This document is available from FDA through the following website:

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm>

6. INSPECTION FORM AND SCORING

A. The Inspection Form

The inspection form is the official document utilized by a regulatory agency for documentation of compliance of the food establishment with regulatory requirements. The goal of the inspection form is to clearly, concisely, and fairly present the compliance status of the food establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection.

The inspection report should be kept in the food establishment's files for subsequent compliance actions and review before the next inspection. Individual inspection reports are to be made available for public review in accordance with Freedom of Information criteria.

Annex 7 of the Food Code provides an inspection form that may be completed for routine, follow-up, and compliance inspections. This inspection form meets requirements established in Standards 3 and 6 of the Program Standards.

B. Debiting Methodology

If a violation exists during an inspection, it should always be marked on the inspection report, even if corrected on site. Violations existing at the time of the inspection probably would have persisted if it were not for the inspection. Slight violations, such as one dirty utensil among hundreds of clean utensils, does not indicate that the food establishment is significantly deviating from the Code requirements; therefore, discretion in marking is required.

It is very important to investigate the root causes of violations and mark them appropriately. Without taking this extra step, inspectors will merely point out violations and will not identify weaknesses in the management system in place. If long-term control of the behaviors or practices leading to the violations is expected, inspectors must identify the causes.

C. Scoring

Regulatory agencies may use scoring methods to rate food establishments. Depending on the system used, establishment scoring may provide an indication of how well a food establishment is complying with the food safety rules of the regulatory agency.

Some agencies use a system of compliance tools as provided in Chapter 8 and Annex 1 of the Food Code to protect public health. The inspection score may serve as the basis for triggering follow-up inspections or other forms of regulatory sanctions when they fall too far from the accepted levels. In addition, scoring may provide a mechanism for consumers to make informed choices regarding where they want to eat.

Use of scoring systems also has negative consequences. For example, it is possible for a food establishment to receive a high numerical or letter score while exhibiting some very serious deficiencies. In recognition of this drawback, some jurisdictions forego scoring systems in favor of demerits or debit systems without assigning a final score. This focuses attention on the items needing correction. Compliance and enforcement decisions can still be based on the increasing levels of identified deficiencies. Whatever method or system of establishment rating is used, policies regarding follow-up and enforcement actions should be established in writing, linked to the rating system, and administered consistently.

7. CLOSING CONFERENCE

The closing conference should include a detailed discussion of the food establishment's plans for correcting violations found during the inspection. The evidence collected or observed during the inspection and the alternatives available for compliance should be emphasized. On-site corrections made during the inspection should be acknowledged on the inspection report and in the closing conference.

The compliance plan should address changes in procedures that will prevent the recurrence of noted violations. The food establishment's compliance plans should be formally documented on the inspection report form. Follow-up letters may be necessary to elicit fulfillment of these agreements. It is important to stress to the operator that long-term correction of violations related to foodborne illness risk factors and Food Code interventions is far more important than corrections of core items.

8. SUMMARY

Although a retail and food service operator has the responsibility for establishing a food safety management system for controlling foodborne illness risk factors, inspectors have a vital, multi-faceted role in consumer protection. It is essential that inspectors are provided with the proper training, equipment, time, and resources to adequately perform their jobs.

The primary role of inspectors is to ensure that the operator has effective control of foodborne illness risk factors. Once inspectors have established a dialogue with the person in charge and employees, conducted a menu/food list review, and established a dialogue with the person in charge, inspectors will have enough information to mentally place menu items into one of the three process flows. The inspection can then focus on assessing the operator's active managerial control of foodborne illness risk factors associated with each process.

Once out-of-control foodborne illness risk factors are identified, the role of inspectors shifts to assisting the operator with strengthening the existing food safety management system through intervention strategies designed to achieve immediate and long-term compliance. With inspector's assistance, a retail and food service operator can achieve long-term behavioral change resulting in a reduction in risk factor occurrence and an increase in public health protection.

6

Food Processing Criteria

1. INTRODUCTION
2. REDUCED OXYGEN PACKAGING
3. SMOKING AND CURING

1. INTRODUCTION

From its inception, the retail segment of the food industry has prepared foods in consumer-sized portions, using commercially available equipment for cutting, grinding, slicing, cooking, and refrigeration, and applying herbs and spices readily available to consumers at their local grocery.

Over the past score of years, retail segment operators have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment that are sometimes microprocessor-controlled. Many now desire to alter the atmospheres within food packages, or apply federally regulated chemical food additives as a method of food preservation. Food processing operations now being conducted or proposed include cook-chill; vacuum packaging; sous vide; smoking and curing; brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water; and custom processing of animals.

The Food Code specifies that a HACCP plan acceptable to the regulatory authority be the basis for approving food manufacturing/processing operations at retail. The HACCP plans are to be provided and accepted in two ways as follows.

(A) Reduced Oxygen Packaging

Section 3-502.12 of the Food Code provides the criteria that are to be met in the HACCP plans of those operators who are conducting reduced oxygen packaging (ROP) operations. Unless prior approval of the HACCP plan is required by the regulatory authority, the HACCP plan covering this operation along with the related records documenting monitoring and corrective actions need only be available and acceptable to the regulatory authority at the time of inspection.

(B) Other Food Manufacturing/Processing Operations

Except for ROP as discussed in (A) above, the Food Code specifies under §§ 3-502.11, 8-103.10, 8-103.11, and 8-201.13 that the food establishment operator must obtain a variance from the regulatory authority for all food manufacturing/processing operations based on the prior approval of a HACCP plan.

The purpose of this Annex is to provide processing criteria for different types of food manufacturing/processing operations for use by those preparing and reviewing HACCP plans and proposals. Criteria for additional processes will be provided as they are developed, reviewed, and accepted.

2. REDUCED OXYGEN PACKAGING

(A) Introduction

ROP which provides an environment that contains little or no oxygen, offers unique advantages and opportunities for the food industry but also raises many microbiological concerns. Products packaged using ROP may be produced safely if proper controls are in effect. Producing and distributing these products with a HACCP approach offer an effective, rational, and systematic method for the assurance of food safety. Non-time/temperature control for safety food, defined in Chapter 1, does not require a variance or HACCP Plan for ROP. This Annex will provide guidelines for effective food safety controls for retail food establishments covering the receipt, processing, packaging, holding, displaying, and labeling of food in reduced oxygen packages.

(B) Definitions

The term ROP can be used to describe any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include packaging options such as:

(1) *Cook-chill* packaging, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(2) *Controlled Atmosphere Packaging (CAP)* in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(3) *Modified Atmosphere Packaging (MAP)* in which the atmosphere of a package of food is modified so that its composition is different from air but the

atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.

(4) *Sous Vide*, in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(5) *Vacuum Packaging* in which air is removed from the package of food and the package is hermetically sealed so that a vacuum remains inside the package.

(C) Benefits of ROP

ROP can create a significantly anaerobic environment that prevents the growth of aerobic spoilage organisms, which generally are Gram-negative bacteria such as pseudomonads or aerobic yeast and molds. These organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage.

ROP can be used to prevent degradation or oxidative processes in food products. Reducing the oxygen in and around a food retards the amount of oxidative rancidity in fats and oils. ROP also prevents color deterioration in raw meats caused by oxygen. An additional effect of sealing food in ROP is the reduction of product shrinkage by preventing water loss.

These benefits of ROP allow an extended shelf life for vacuum packaged (VP), modified atmosphere packaged (MAP) and controlled atmosphere packaged (CAP) foods displayed for retail sale. Cook chill (CC) and sous vide (SV) processed food cannot be sold directly to consumers or other businesses but the extended shelf life and quality benefits internal service and use of the products. Providing an extended shelf life for ready-to-eat convenience foods and advertising foods as "Fresh – Never Frozen" are examples of economic and quality advantages.

(D) Safety Concerns

Use of ROP with some foods can markedly increase safety concerns. Unless time/temperature control for safety foods are protected inherently, simply placing them in ROP without regard to microbial growth will increase the risk of foodborne illnesses. ROP processors and regulators must assure that during distribution of foods or while foods are held by retailers or consumers, refrigerated temperatures must be consistently maintained. In fact, a serious concern is that the increased use of vacuum packaging at retail supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer. Consequently, at least one barrier or multiple hurdles resulting in a barrier needs to be incorporated into the production process for products packaged using ROP. The incorporation of several sub-inhibitory barriers, none of which could individually inhibit microbial growth but which in combination provide a full barrier to growth (the hurdle concept), is necessary to ensure food safety.

Some products in ROP contain no preservatives and frequently do not possess any intrinsic inhibitory barriers (such as, pH, a_w , or salt concentrations) that either alone or in combination will inhibit microbial growth. Thus, product safety is not provided by natural or formulated characteristics.

A reduced oxygen atmosphere provides the potential for growth of several important foodborne pathogens. Some of these pathogens such as *Listeria monocytogenes* are psychrotrophic and grow slowly at temperatures near the freezing point of foods. Additionally, the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur.

The use of one form of ROP, vacuum packaging, is not new. Many food products have a long and safe history of being vacuum packaged in ROP. However, the early use of vacuum packaging for smoked fish had disastrous results, causing a long-standing moratorium on certain uses of this technology at the retail level.

(1) Refrigerated Holding Requirements for Foods in ROP

Safe use of ROP technology demands that adequate refrigeration be maintained during the entire shelf-life of time/temperature control for safety foods to ensure product safety.

Bacteria, with the exception of those that can form spores, are eliminated by pasteurization. However, pathogens may survive in the final product if pasteurization is inadequate, poor quality raw materials or poor handling practices are used, or post-processing contamination occurs. Even if foods that are in ROP receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens.

If products in ROP are subjected to mild temperature abuse, i.e., 5°-12°C (41°-53°F), at any stage during storage or distribution, foodborne pathogens, including **Bacillus cereus**, **Salmonella** spp., **Staphylococcus aureus**, and **Vibrio parahaemolyticus**, can grow slowly. Marginal refrigeration that does not facilitate growth may still allow **Salmonella** spp., **Campylobacter** spp., and **Brucella** spp. to survive for long periods of time.

Published surveys indicate that refrigeration practices at retail need improvement. Some refrigerated products offered in convenience stores were found at or above 7.2°C (45°F) 50% of the time; in several cases temperatures as high as 10°C (50°F) were observed. Delicatessen display cases have been shown to demonstrate poor temperature control. Foods have been observed above 10°C (50°F) and above 12.8°C (55°F) in several instances. Supermarket fresh meat cases appear to have a relatively good record of temperature control. However, even these foods can occasionally be found above 10°C (50°F).

Temperature abuse is common throughout distribution and retail markets. Strict adherence to temperature control and shelf-life must be observed and documented by the establishment using ROP. Buyer specifications for refrigerated distribution systems as well as internal time/temperature controls should be implemented by the establishment. Information on temperature control should also be provided to the consumer. Currently these controls are not extensively used.

(2) *Control of **Clostridium botulinum** and **Listeria monocytogenes** in Reduced Oxygen Packaged Foods*

There has been an increased interest in ROP at retail using conventional refrigeration units for holding. Refrigerated foods packaged at retail may be chilled either after they are physically prepared and repackaged, or packaged after a cooking step. In either case **Clostridium botulinum** and **Listeria monocytogenes** are the pathogens of concern for ROP products.

Clostridium botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. The organism is an anaerobic spore-forming bacteria that produces a potent neurotoxin. The spores are ubiquitous in nature, relatively heat-resistant, and can survive most minimal heat treatments that destroy vegetative cells. Certain strains of **C. botulinum** (type E and non-proteolytic types B and F), which have been primarily associated with fish, are psychrotrophic and can grow and produce toxin at temperatures as low as 3.3°C (38°F). Other strains of **C. botulinum** (type A and proteolytic types B and F) can grow and produce toxin at temperatures slightly above 10°C (50°F). If present, **C. botulinum** could potentially grow and render a food PACKAGED and held in ROP toxigenic because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable.

This is particularly true of psychrotrophic strains of **C. botulinum** that do not produce tell-tale proteolytic enzymes which result in a distinct bad odor. Because botulism is

potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.

The potential for ***Clostridium botulinum*** toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide processing of foods which will not destroy the spores of ***C. botulinum***. Mild heat treatments (heat shocks) in combination with ROP may actually select for ***C. botulinum*** by killing off competitors. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration below 3.3°C (38°F) to prevent spore germination and toxin formation and ensure product safety. For this reason, sous vide products are frequently frozen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill ***L. monocytogenes*** can be re-contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place. Hard and semi-soft cheeses that meet the Standards of Identity for those cheeses in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese and 21 CFR 133.187 Semi-soft cheeses may be packaged using ROP without a variance. Refer to Annex 3 Public Health Reasons, Sections 3-501.17 and 3-501.18 for a partial list of hard and semi-soft cheeses.

Processors of products using ROP should build in extra safeguards if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls of products and refrigeration equipment. If extended shelf life is sought, a temperature of 3.3°C (38°F) or lower must be maintained at all times to prevent outgrowth of ***C. botulinum*** and the subsequent production of toxin. ***Listeria monocytogenes*** can grow at even lower temperatures; consequently, appropriate use-by dates must be established. Growth barriers are provided by hurdles such as low pH, a_w , or short shelf life, and constant monitoring of the product temperature. Any one hurdle, or a combination of several, may be used with refrigeration to control pathogenic outgrowth.

(3) *Design of Heat Processes for Foods in Reduced Oxygen Packages*

Heat processes for sous vide or cook-chill operations must be designed so that, at a minimum, all vegetative pathogens are destroyed by a pasteurization process and temperature control is verified. When temperature is the only barrier and no other intrinsic or extrinsic factors add protection against the growth of foodborne pathogens and formation of toxin, the product may not be sold to other business entities or to the consumer in the ROP package because of the inability to verify temperature control.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), chartered by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), commented on the microbial safety of refrigerated foods

containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and are ready-to-eat or prepared with little or no additional heat treatment. NACMCF recommended guidelines for evaluating the ability of thermal processes to inactivate ***L. monocytogenes*** in extended shelf life refrigerated foods. Specifically, it recommended a proposed requirement for demonstrating that an ROP process provides a heat treatment sufficient to achieve a 4 decimal log reduction (4D) of ***L. monocytogenes***.

Other scientific reports recommend more extensive thermal processing. Thermal processes for sous vide practiced in Europe are designed to achieve a 12-13 log reduction (12-13D) of the target organism ***Streptococcus faecalis***. It is reasoned that thermal inactivation of this organism would ensure destruction of all other vegetative pathogens.

Food manufacturers with adequate in-house research and development programs may have the ability to design their own thermal processes. However, small retailers and supermarkets may not be able to perform the microbiological challenge studies necessary to provide the same level of food safety. If a retail establishment wishes to use an ROP process with different time-temperature parameters from those provided in Section 3-502.12 of the Food Code, microbiological inoculation studies should be performed by, or in conjunction with, an appropriate process authority or person knowledgeable in food microbiology who is acceptable to the regulatory authority.

Finally, if foods are held long enough, even under proper refrigeration, extended shelf life may be a problem. A study on fresh vegetables inoculated with ***L. monocytogenes***, conducted to determine the effect of MAP on shelf life, found that MAP lengthened the time that all vegetables were considered acceptable, but that populations of ***L. monocytogenes*** increased during that extended storage.

(4) *Consumer Handling Practices and In-Home Refrigerator Temperatures*

Extended shelf life provided by ROP is cause for concern because of the potential for abuse by the consumer. Consumers often cannot, or do not, maintain adequate refrigeration of time/temperature control for safety foods at home. Under the best of circumstances, home refrigerators can be expected to range between 5° and 10°C (41°-50°F). One study reported that home refrigerator temperatures in 21% of the households surveyed were 10°C (50°F). Another study reported more than 1 of 4 home refrigerators are above 7.2°C (45°F) and almost 1 of 10 are above 10°C (50°F). Thus, refrigeration alone cannot be relied on for ensuring microbiological safety after foods in ROP leave the establishment.

Consumers have come to expect that certain packages of foods would be safe without refrigeration. Low-acid canned foods have been thermally processed, which renders the food shelf-stable. Retort heating ensures the destruction of *C. botulinum* spores as well as all other foodborne pathogens. Yet consumers may not understand that most products that are packaged in ROP are not commercially sterile or shelf-stable and must be refrigerated. A clear label statement to keep the product refrigerated must be provided to consumers.

The use of ROP has been extensively studied by regulators and the food industry over the past several years. Recommendations have been adapted from the Association of Food and Drug Officials "Retail Guidelines - Refrigerated Foods in Reduced Oxygen Packages" and New York State Department of Agriculture and Markets "Proposed Reduced Oxygen Packaging Regulations." As provided in the Food Code, some ROP operations may be conducted under provision 3-502.12 Reduced Oxygen Packaging, Criteria. Food that is packaged by an ROP method under these provisions is considered safe while it is under the control of the establishment and, if the labeling instructions are followed, while under the control of the consumer.

(E) Safety Barrier Verification

The safety barriers for all ROP processed foods under a variance at retail must be verified in writing. Independent laboratory analysis using methodology approved by the regulatory authority such as official methods of the AOAC International (AOAC) can also be used to verify incoming product. ROP processed foods which comply with one of the methods in Section 3-502.12 do not require written verification.

Any changes in product formulation or processing procedures should be reflected in the HACCP plan and may require further product testing for validation. A record of all safety barrier verifications should be updated every 12 months. This record must be available to the regulatory authority for review at the time of inspection.

(F) USDA Process Exemption

Meat and poultry products cured at a food processing plant regulated by the U.S. Department of Agriculture using substances specified in 9 CFR 424, Preparation and Processing Operations, are exempt from the safety barrier verification requirements. Other ROP operations may be developed that do not meet the provisions of Section 3-502.12 of the Code and that will require a variance and prior approval by the regulatory authority under Section 3-502.11.

(G) Recommendations for ROP Without Multiple Barriers

(1) Employee Training

If ROP is used in a food establishment, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines in this Annex and the potential hazards associated with these foods. A description of the training and course content provided to the employees must either be available for review or have prior approval by the regulatory authority.

(2) Refrigeration Requirements

Refrigeration times and temperatures to inhibit **C. botulinum** and **L. monocytogenes** must be based on laboratory inoculation study data or follow one of the ROP methods in Section 3-502.12 which specifies the time and temperature combinations. The ROP package must be marked with a use-by date within either the manufacturer's labeled use-by date or as determined by the laboratory data, whichever comes first. Alternatively, foods packaged by ROP may be kept frozen if freezing is used as the declared primary safety barrier.

(3) Labeling - Refrigeration Statements

All foods offered for sale in ROP which rely on refrigeration at 5°C (41°F) or less as a barrier to microbial growth must bear the statement "Important - Must be kept refrigerated at 5°C (41°F)" or "Important - Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier. The statement must appear on the principal display panel in bold type on a contrasting background. Foods packaged using cook chill or sous vide processing methods which have lower refrigeration requirements below 5°C (41°F) as a condition of safe shelf life must be monitored for temperature history and must not be offered for retail sale in the package or sold to a different business entity. The labeling statement regarding cold holding temperatures is not required for food packaged using cook chill or sous vide processing.

(4) Labeling - "Use-by date"

The shelf life of ROP foods is based on storage temperature for a certain time and other intrinsic factors of the food (pH, a_w , cured with salt and nitrite, high levels of competing organisms, organic acids, natural antibiotics or bacteriocins, salt, preservatives, etc.). Each package of food in ROP must bear a "use-by" date. In some cases such as cook chill or sous vide processing when none of these intrinsic factors are present, a temperature lower than 3°C (38°F) must be the controlling factor for **C. botulinum** and **L. monocytogenes** growth and/or toxin formation. This "use by" date cannot exceed the number of days specified in one of the ROP methods in Section 3-502.12 or must be based on laboratory inoculation studies. The date assigned by a retail repacker cannot extend beyond the manufacturer's recommended expiration or "pull date" for the food. The "use-by" date must be listed on the principal display panel

in bold type on a contrasting background for any product sold to consumers. Any label on packages intended for consumer sale must contain a combination of a "sell-by" date and use-by instructions which makes it clear that the product must be consumed within the number of days determined to be safe as specified under Section 3-502.12 of the Food Code. Foods, especially fish, that are frozen before or immediately after packaging and remain frozen until use should bear a label statement, "Important, keep frozen until used, thaw under refrigeration immediately before use." Raw meat and poultry packaged using ROP methods must be labeled with safe handling instructions found in 9 CFR 317.2(l) and 9 CFR 381.125(b).

(H) Foods Which Require a Variance Under Code Section 3-502.11 if Packaged in Reduced Oxygen Atmosphere

(1) Unfrozen processed fish and smoked fish may not be packed by ROP unless retail food establishments have an approved variance application and HACCP plan to show **C. botulinum** spore germination and toxin production or **L. monocytogenes** growth will not occur and are inspected by the regulatory authority. Establishments packaging such fish products, and smoking and packing establishments, must be licensed in accordance with applicable law.

(2) Soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese with other ingredients such as vegetables, meat, or fish at retail must be approved for ROP through an approved variance application and HACCP plan and be inspected by the regulatory authority.

(3) Meat or poultry products which are smoked or cured at retail, except that raw food of animal origin which is cured in a USDA-regulated processing plant, or establishment approved by the regulatory authority to cure these foods, may be smoked in accordance with approved time/temperature requirements and packaged in ROP at retail if approved by the regulatory authority. Smoking which meets the time/temperature parameters in Section 3-401.11 does not require a variance. Cold smoking where the temperature achieved by the product is greater than 41°F requires a variance. Curing using nitrite or nitrate always requires a variance.

(I) Hazard Analysis and Critical Control Point (HACCP) Operation

All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations, the plan must include the requirements specified under ¶ 8-201.14(D). In addition, the HACCP plan may also include:

(1) A complete description of the processing, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring and verification schemes, and records required;

(2) A list of equipment and food-contact packaging supplies used, including compliance standards that may be required by the regulatory authority, i.e., a recognized third party equipment evaluation organization such as NSF International;

(3) A description of the lot identification system;

(4) A description of the employee training program;

(5) A listing and proportion of food-grade gasses used; and

(6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

(J) *Precautions Against Contamination at Retail*

Only unopened packages of commercially processed, ready-to-eat deli meats or cheeses obtained from sources that comply with the applicable laws relating to food safety should be used for ROP packaging at retail. If it is necessary to stop packaging for a period in excess of one-half hour, the remainder of that product should be diverted for another use in the retail establishment. Cook chill products that are cooked before packaging (ready-to-eat) should also be protected from cross-contamination before being packaged.

(K) *Disposition of Expired Product at Retail*

Processed reduced oxygen foods that exceed the "use-by" date or manufacturer's "pull date" cannot be sold in any form and must be disposed of in a proper manner.

(L) *Dedicated Area/Restricted Access*

All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose. There shall be an effective separation to prevent cross contamination between raw and cooked foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in food packaged by an ROP method. Some ROP procedures such as sous vide may require a "sanitary zone" or dedicated room with restricted access to prevent contamination.

(M) *References*

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3. SMOKING AND CURING

(A) Introduction

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat. The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled. A number of proprietary mixtures which are uniform in composition are available. The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 424. It is important to use curing methods which achieve uniform distribution of the curing mixture in the meat or poultry product.

(B) Definitions

Cured meat and poultry can be divided into three basic categories: (1) uncomminuted smoked products; (2) sausages; and (3) uncomminuted unsmoked processed meats.

(1) *Uncomminuted smoked products* - include bacon, beef jerky, hams, pork shoulders, turkey breasts, turkey drumsticks.

(2) *Sausages* - include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich spreads, and viennas. Coarse ground sausages include chorizos, kielbasa, pepperoni, salami, and summer sausages.

(3) *Cured sausages* - may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semidry, or fermented.

(4) *Uncomminuted, unsmoked processed products* - include corned beef, pastrami, pig's feet, corned tongues. This category of products may be sold as either raw ready-to-cook or ready-to-eat.

(C) Incorporation of Cure Ingredients

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminuting. Proper and thorough mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickle) solution. These methods depend on slow diffusion of the curing agents through the product. Products must be properly refrigerated during immersion curing.

Several methods may be used to shorten curing times. These include hot immersion curing greater than 49°C (>120°F), injection by arterial pumping (e.g., hams), and stitch pumping by a series of hollow needles. If the injection method is used, injection needles must be frequently monitored during processing to ensure that they are not fouled or plugged.

Tumbling or massaging may also be used as an aid to hasten curing. Proper sanitation must be observed to prevent contamination during this operation.

The dry curing method, a similar process, may also be used. In this case, curing ingredients are rubbed over cuts and surfaces of meat held under refrigeration. Precautions must include wearing sanitary gloves when meat is handled. Product temperature maintenance is critical.

(D) Smoking

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking. Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel. As with curing operations, a standard operating procedure must be established to prevent contamination during the smoking process.

(E) Fermentation and Dehydration

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below 4.6 and inhibit bacteria harmful to health as well as bacteria which can cause spoilage. Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step. Sanitary practices in the production of these products are extremely important because ***Staphylococcus aureus*** can be introduced. ***Staphylococcus aureus*** produces an enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Processed pork products require treatment to destroy *Trichinella spiralis*. At retail, products which contain raw pork and which are not subsequently cooked must be produced from certified trichina-free pork or treated to destroy trichinae. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichina in pork by heating, freezing, drying, or smoking.

Some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

(F) Recommendations for Safe Curing of Meat and Poultry

(1) *Posting of Acceptable Products*

A list of products approved by the regulatory authority, or by an approved knowledgeable authority on curing acceptable to the regulatory authority, must be posted in the processing area of the establishment.

(2) *Employee Training*

Employees assigned to cure meat or poultry must demonstrate familiarity with these guidelines and the potential hazards associated with curing foods. A description of the training and course content provided to the employees must be available for review by the regulatory authority.

(3) *HACCP*

A HACCP plan is needed for all curing operations. The following recommendations must be met to cure meat and poultry products in the establishment. References are available from local USDA extension offices, public libraries, and college or university food or meat science departments to develop HACCP plans for curing meat and poultry.

(a) *Critical Control Points*

The following are critical control points to be addressed:

- (i) Purchase of prepared cure mixes; or
- (ii) If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.

- (iii) Cure ingredients must be stored in a dry location. Cure must be discarded if the package is wet or appears to have been wetted.
- (b) *Raw Material Handling*
- (i) Thawing must be monitored and controlled to ensure thoroughness and to prevent temperature abuse. Improperly thawed meat could cause insufficient cure penetration. Temperature abuse can cause spoilage or growth of pathogens.
 - (ii) Meat must be fresh. Curing may not be used to salvage meat that has excessive bacterial growth or spoilage.
- (c) *Formulating, Preparation and Curing*
- (i) A formulation and preparation procedure must be documented.
 - (ii) All equipment and utensils must be cleaned and sanitized.
 - (iii) Pieces must be prepared to uniform sizes to ensure uniform cure penetration. This is extremely critical for dry and immersion curing.
 - (iv) Calibrated scales must be used to weigh ingredients.
 - (v) A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.
 - (vi) Methods and procedures must be strictly controlled to ensure uniform cure.
 - (vii) Mixing of curing formulation with comminuted ingredients must be controlled and monitored.
 - (viii) All surfaces of meat must be rotated and rubbed at intervals of sufficient frequency to ensure cure penetration when a dry curing method is used.
 - (ix) Immersion curing requires periodic mixing of the batch to facilitate uniform curing.

(x) The application of salt during dry curing of muscle cuts requires that the temperature of the product be strictly controlled between 1.7°C (35°F) and 7.2°C (45°F). The lower temperature is set to limit microbial growth and the upper temperature is set for the purpose of ensuring cure penetration. Refer to USDA regulations 9 CFR 318.10(c)(3)(iv) for specific details on dry curing.

(xi) Curing solutions must be discarded daily unless they remain with the same batch of product during its entire curing process.

(xii) Injection needles must be inspected for plugging when stitch pumping or artery pumping of muscle cuts is performed.

(xiii) Sanitary casings must be provided for sausage, chub or loaf forming.

(xiv) Casings may not be stripped for reuse in forming additional chubs or sausages from batch to batch.

(xv) Hot curing of bacon bellies, hams, or any other products must be performed at >49°C (120°F) as specified in 9 CFR 318.

(d) *Cooking and/or Smoking*

(i) When smokehouses are initially installed or structurally modified, calibration of product heating characteristics must be ascertained by competent food technologists. Tests should be run with full range of anticipated product loading. Verification of even airflow and moisture should be recorded in operational records of the smokehouse for these various loads.

(ii) Procedures for delivering the appropriate thermal treatment of cooked meats in conformance with the *Food Code* must be developed and used. (Also see 9 CFR 318.17 and 318.23 for USDA requirements for meat products.) A minimum of 73.9°C (165°F) should be used for cured poultry products.

(iii) Cooking equipment that provides even temperature control of the heating medium must be used.

(iv) Products must be adequately separated to prevent overlap in the cooking media whether immersed in hot water, sprayed with hot water, steamed, or oven heated.

(v) Calibrated temperature measuring devices must be used for

determining internal product temperatures.

(vi) Temperature measuring device probes must be sanitized to prevent contaminating products when internal temperatures are measured.

(vii) Calibrated temperature measuring devices must be used for measuring temperatures of the heating medium.

(viii) Raw products must be separated from cooked products.

(ix) Time/temperature parameters of the cooking process must be monitored and recorded. In some processes, the heating medium temperature should also be monitored.

(e) *Cooling*

(i) Cooling must be done in accordance with recommendations in the *Food Code* or under a variance. The USDA Cooling Guideline, FSIS Directive 7110.3 for special procedures for cured products, provides specific guidance.

(ii) Written cooling procedures must be established.

(iii) Chill water used in water sprays or immersion chilling which is in direct contact with products in casings or products cooked in an impervious package must be properly chlorinated.

(iv) Chill water temperature must be monitored and controlled.

(v) Chill water may not be reused until properly chlorinated. Reclaimed chill water must be discarded daily.

(vi) Product must be placed in a manner that allows chilled water or air to uniformly contact the product for assurance of uniform cooling.

(vii) Internal temperatures must be monitored during cooling by using calibrated temperature measuring devices.

(viii) Adequate cooling medium circulation must be maintained and monitored.

(ix) Temperatures of the cooling medium must be monitored and recorded in accordance with a written procedure.

(x) Handling of product must be minimized during cooling, peeling of

casing, and packaging. Sanitary gloves must be used in these procedures.

(f) *Fermentation and Drying*

(i) Temperature and time must be controlled and logs must be maintained that record the monitoring of this process.

(ii) Humidity must be controlled by use of a humidistat. Monitoring of the process must be recorded in a written log.

(iii) Product must be kept separated to allow adequate air circulation during the process.

(iv) Use of an active and pure culture must be ensured to effect a rapid pH drop of the product. Use of commercially produced culture is necessary and the culture must be used according to the manufacturer's instructions.

(v) Determination of the pH of fermented sausages at the end of the fermentation cycle must be recorded.

(vi) Handling of products must be minimized and only done with sanitary gloves or sanitized utensils.

(vii) Dry (unfermented) products may not be hot smoked until the curing and drying procedures are completed.

(viii) Semi-dry fermented sausage must be heated after fermentation to a time/temperature sufficient to control growth of pathogenic and spoilage organisms of concern.

(4) *Dedicated Area/Restricted Access*

All aspects of curing operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.

(5) *Equipment Cleaning and Sanitizing*

The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.

(G) References

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7

Model Forms, Guides, and Other Aids

- 1) Employee health information and Application form for bare hand contact Procedure
 - a) Form 1-A **CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE INTERVIEW**
 - b) Form 1-B **CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE REPORTING AGREEMENT**
 - c) Form 1-C **CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE MEDICAL REFERRAL**
 - d) Form 1-D **APPLICATION FOR BARE HAND CONTACT PROCEDURE**

- 2) Adoption information
 - a) Form 2-A **ADOPTION BY REFERENCE**
 - b) Form 2-B **ADOPTION BY SECTION-BY-SECTION REFERENCE**

- 3) Inspection information
 - a) Form 3-A **FOOD ESTABLISHMENT INSPECTION REPORT**
 - b) Guide 3-B **INSTRUCTIONS FOR MARKING THE FOOD ESTABLISHMENT INSPECTION REPORT, INCLUDING FOOD CODE REFERENCES FOR RISK FACTORS/INTERVENTIONS AND GOOD RETAIL PRACTICES**

- 4) Summary information
 - a) Chart 4-A **SUMMARY CHART FOR MINIMUM COOKING FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3**
 - b) Chart 4-B **SUMMARY CHART FOR MINIMUM FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3 FOR REHEATING FOODS FOR HOT HOLDING**
 - c) Chart 4-C **SUMMARY CHART – READY-TO-EAT, TIME/TEMPERATURE, CONTROL FOR SAFETY FOOD (TCS) DATE MARKING § 3-501.17(A) – (E) AND DISPOSITION § 3-501.18**
 - d) Chart 4-D **FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX**
 - e) Summary of Changes in the FDA Food Code

The documents provided in this Annex are intended to facilitate adoption of the Food Code and the application of its provisions as they relate to conditional employees' and food employees' health and to food establishment inspections.

Forms 1-A through 1-C are designed to assist those responsible for managing employees in order to prevent foodborne disease. The Food Code specifies that the **permit holder is responsible** for requiring conditional employees or food employees to report certain symptoms, diagnoses, and past illnesses, as they relate to diseases transmitted through food by infected workers. The **conditional employee or food employee is personally responsible** for reporting this information to the person in charge.

Form 1-D is a user-aid for a regulatory agency when considering a request to allow bare hand contact with ready-to-eat food.

Forms 2-A and 2-B can be used for the Code adoption process and Form 3-A is provided for use in recording HACCP information and inspectional observations and has been updated for consistency with changes made in the Supplement to the 2009 Food Code.

Guide 3-B, *Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices* has been updated to be consistent with changes made in the Supplement to the 2009 Food Code. The major headings from the Food Establishment Inspection Report form are condensed in Guide 3-B to key word phrases to assist the person conducting inspections in locating the Food Code citation that corresponds to a given violation and recording inspectional observations.

Guide 3-B is intended to be used during inspections to ensure that observations of the provisions of the Code are not overlooked during the inspection and accurately recorded on the Food Code Establishment Inspection Report form.

FORM 1-A	Conditional Employee and Food Employee Interview
Preventing Transmission of Diseases through Food by Infected Food Employees or Conditional Employees with Emphasis on Illness due to Norovirus, <i>Salmonella</i> Typhi (<i>S. Typhi</i>), <i>Shigella</i> spp., ShigaToxin-producing <i>Escherichia coli</i> (STEC), nontyphoidal <i>Salmonella</i> or Hepatitis A Virus	

The purpose of this interview is to inform conditional employees and food employees to advise the person in charge of past and current conditions described so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

Conditional Employee Name (print) _____
 Food Employee Name (print) _____
 Address _____
 Telephone Daytime: _____ Evening: _____
 Date _____

Are you suffering from any of the following symptoms? (Circle one)

	YES / NO	If YES, Date of Onset
Diarrhea?	YES / NO	_____
Vomiting?	YES / NO	_____
Jaundice?	YES / NO	_____
Sore throat with fever?	YES / NO	_____

Or

Infected cut or wound that is open and draining, or lesions containing pus on the hand, wrist, an exposed body part, or other body part and the cut, wound, or lesion not properly covered? YES / NO

(Examples: *boils and infected wounds, however small*)

In the Past:

Have you ever been diagnosed as being ill with typhoid fever (*S. Typhi*) YES / NO

If you have, what was the date of the diagnosis? _____

If within the past 3 months, did you take antibiotics for *S. Typhi*? YES / NO

If so, how many days did you take the antibiotics? _____

If you took antibiotics, did you finish the prescription? _____ YES / NO

History of Exposure:

1. Have you been suspected of causing, or have you been exposed to, a confirmed foodborne disease outbreak recently? YES / NO

If YES, date of outbreak: _____

a. If YES, what was the cause of the illness and did it meet the following criteria?

Cause: _____

i. Norovirus (last exposure within the past 48 hours)	Date of illness outbreak _____
ii. <i>E. coli</i> O157:H7 infection (last exposure within the past 3 days)	Date of illness outbreak _____
iii. Hepatitis A virus (last exposure within the past 30 days)	Date of illness outbreak _____
iv. Typhoid fever (last exposure within the past 14 days)	Date of illness outbreak _____
v. Shigellosis (last exposure within the past 3 days)	Date of illness outbreak _____

b. If YES, did you:

- i. Consume food implicated in the outbreak? _____
- ii. Work in a food establishment that was the source of the outbreak? _____
- iii. Consume food at an event that was prepared by person who is ill? _____

2. Did you attend an event or work in a setting, recently where there was a confirmed disease outbreak? YES / NO

If so, what was the cause of the confirmed disease outbreak? _____

If the cause was one of the following five pathogens, did exposure to the pathogen meet the following criteria?

- a. Norovirus (last exposure within the past 48 hours) YES / NO
- b. *E. coli* O157:H7 (or other STEC (last exposure within the past 3 days) YES / NO
- c. *Shigella* spp. (last exposure within the past 3 days) YES / NO
- d. *S. Typhi* (last exposure within the past 14 days) YES / NO
- e. Hepatitis A virus (last exposure within the past 30 days) YES / NO

Do you live in the same household as a person diagnosed with Norovirus, shigellosis, typhoid fever, hepatitis A, or illness due to *E. coli* O157:H7 or other STEC?
YES / NO Date of onset of illness _____

3. Do you have a household member attending or working in a setting where there is a confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, STEC infection, or hepatitis A?
YES / NO Date of onset of illness _____

Name, Address, and Telephone Number of your Health Practitioner or doctor:

Name _____

Address _____

Telephone – Daytime: _____ Evening: _____

Signature of Conditional Employee _____ Date _____

Signature of Food Employee _____ Date _____

Signature of Permit Holder or Representative _____ Date _____

FORM 1-B	Conditional Employee or Food Employee Reporting Agreement Preventing Transmission of Diseases through Food by Infected Conditional Employees or Food Employees with Emphasis on Illness due to Norovirus, <i>Salmonella</i> Typhi, <i>Shigella</i> spp., or Shiga toxin-producing <i>Escherichia coli</i> (STEC), nontyphoidal <i>Salmonella</i> or Hepatitis A Virus
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The purpose of this agreement is to inform conditional employees or food employees of their responsibility to notify the person in charge when they experience any of the conditions listed so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

I AGREE TO REPORT TO THE PERSON IN CHARGE:

Any Onset of the Following Symptoms, Either While at Work or Outside of Work, Including the Date of Onset:

1. Diarrhea
2. Vomiting
3. Jaundice
4. Sore throat with fever
5. Infected cuts or wounds, or lesions containing pus on the hand, wrist, an exposed body part, or other body part and the cuts, wounds, or lesions are not properly covered (*such as boils and infected wounds, however small*)

Future Medical Diagnosis:

Whenever diagnosed as being ill with Norovirus, typhoid fever (*Salmonella* Typhi), shigellosis (*Shigella* spp. infection), *Escherichia coli* O157:H7 or other STEC infection, nontyphoidal *Salmonella* or hepatitis A (hepatitis A virus infection)

Future Exposure to Foodborne Pathogens:

- 1. Exposure to or suspicion of causing any confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E. coli* O157:H7 or other STEC infection, or hepatitis A.**
- 2. A household member diagnosed with Norovirus, typhoid fever, shigellosis, illness due to STEC, or hepatitis A.**
- 3. A household member attending or working in a setting experiencing a confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E. coli* O157:H7 or other STEC infection, or hepatitis A.**

I have read (or had explained to me) and understand the requirements concerning my responsibilities under the **Food Code** and this agreement to comply with:

1. Reporting requirements specified above involving symptoms, diagnoses, and exposure specified;
2. Work restrictions or exclusions that are imposed upon me; and
3. Good hygienic practices.

I understand that failure to comply with the terms of this agreement could lead to action by the food establishment or the food regulatory authority that may jeopardize my employment and may involve legal action against me.

Conditional Employee Name (please print) _____

Signature of Conditional Employee _____ **Date** _____

Food Employee Name (please print) _____

Signature of Food Employee _____ **Date** _____

Signature of Permit Holder or Representative _____ **Date** _____

FORM

1-C

Conditional Employee or Food Employee Medical Referral

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on Illness due to Norovirus, Typhoid fever (*Salmonella Typhi*), Shigellosis (*Shigella* spp.), *Escherichia coli* O157:H7 or other Shiga Toxin-producing *Escherichia coli* (STEC), nontyphoidal *Salmonella* and Hepatitis A Virus

The **Food Code** specifies, under **Part 2-2 Employee Health Subpart 2-201 Disease or Medical Condition**, that Conditional Employees and Food Employees obtain medical clearance from a health practitioner licensed to practice medicine, unless the Food Employees have complied with the provisions specified as an alternative to providing medical documentation, whenever the individual:

1. Is chronically suffering from a symptom such as **diarrhea**; or
2. Has a **current illness** involving Norovirus, typhoid fever (***Salmonella Typhi***), shigellosis (***Shigella* spp.**) ***E. coli* O157:H7** infection (or other STEC), nontyphoidal *Salmonella* or hepatitis A virus (hepatitis A), or
3. Reports **past illness** involving typhoid fever (**S. Typhi**) within the past three months (while salmonellosis is fairly common in U.S., typhoid fever, caused by infection with **S. Typhi**, is rare).

Conditional Employee being referred: (Name, please print) _____

Food Employee being referred: (Name, please print) _____

4. Is the employee assigned to a food establishment that serves a population that meets the Food Code definition of a **highly susceptible population** such as a day care center with preschool-age children, a hospital kitchen with immunocompromised persons, or an assisted living facility or nursing home with older adults?

YES **NO**

Reason for Medical Referral: The reason for this referral is checked below:

- Is chronically suffering from vomiting or diarrhea; or (specify) _____
- Diagnosed or suspected Norovirus, typhoid fever, shigellosis, ***E. coli* O157:H7** (or other STEC) infection, nontyphoidal *Salmonella* or hepatitis A. (Specify) _____
- Reported past illness from typhoid fever within the past 3 months. (Date of illness) _____
- Other medical condition of concern per the following description: _____

Health Practitioner's Conclusion: (Circle the appropriate one; refer to reverse side of form)

- Food employee is free of **Norovirus** infection, typhoid fever (**S. Typhi** infection), ***Shigella* spp.** infection, ***E. coli* O157:H7** (or other **STEC** infection), nontyphoidal *Salmonella* infection or **hepatitis A** virus infection, and may work as a food employee without restrictions.
- Food employee is an asymptomatic shedder of ***E. coli* O157:H7** (or other **STEC**), ***Shigella* spp.**, or Norovirus, and is restricted from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles in food establishments that do not serve highly susceptible populations.
- Food employee is not ill but continues as an asymptomatic shedder of ***E. coli* O157:H7** (or other **STEC**), ***Shigella* spp.** and should be excluded from food establishments that serve highly susceptible populations such as those who are preschool-age, immunocompromised, or older adults and in a facility that provides preschool custodial care, health care, or assisted living.
- Food employee is an asymptomatic shedder of **hepatitis A** virus and should be excluded from working in a food establishment until medically cleared.
- Food employee is an asymptomatic shedder of **Norovirus** and should be excluded from working in a food establishment until medically cleared, or for at least 24 hours from the date of the diagnosis.
- Food employee is suffering from Norovirus, typhoid fever, shigellosis, ***E. coli* O157:H7** (or other **STEC** infection), or **hepatitis A** and should be excluded from working in a food establishment.
- Food employee is diagnosed with an infection from nontyphoidal *Salmonella* and is asymptomatic and

should be restricted from working in food establishments serving a highly susceptible population and food establishments not serving a highly susceptible population.

COMMENTS: (In accordance with Title I of the Americans with Disabilities Act (ADA) and to provide only the information necessary to assist the food establishment operator in preventing foodborne disease transmission, please confine comments to explaining your conclusion and estimating when the employee may be reinstated.)

Signature of Health Practitioner _____ **Date** _____

Paraphrased from the FDA Food Code for Health Practitioner's Reference

From Subparagraph 2-201.11(A)(2)

Organisms of Concern:

Any foodborne pathogen, with special emphasis on these 56 organisms:

1. **Norovirus**
2. **S. Typhi**
3. **Shigella** spp.
4. **E. coli** O157:H7 (or other STEC)
5. **Hepatitis A** virus
6. Nontyphoidal *Salmonella*

From Subparagraph 2-201.11(A)(1)

Symptoms:

Have any of the following symptoms:

Diarrhea

Vomiting

Jaundice

Sore throat with fever

From Subparagraph 2-201.11(A)(4)-(5)

Conditions of Exposure of Concern:

- (1) Suspected of causing a foodborne outbreak or being exposed to an outbreak caused by Norovirus, S. Typhi, *Shigella* spp., E. coli o157:H7 (or other STEC), Hepatitis A virus, at an event such as a family meal, church supper, or festival because the person:
 - Prepared or consumed an implicated food;
 - or consumed food prepared by a person who is infected or ill with the organism that caused the outbreak or who is suspected of being a carrier;
- (2) Lives with, and has knowledge about, a person who is diagnosed with illness caused by Norovirus, S. Typhi, *Shigella* spp., E. coli o157:H7 (or other STEC), Hepatitis A virus; or
- (3) Lives with, and has knowledge about, a person who works where there is an outbreak caused by Norovirus, S. Typhi, *Shigella* spp., E. coli o157:H7 (or other STEC), Hepatitis A virus -

From Subparagraph 2-201.12

Exclusion and Restriction:

Decisions to exclude or restrict a food employee are made considering the available evidence about the person's role in actual or potential foodborne illness transmission. Evidence includes:

Symptoms Diagnosis Past illnesses Stool/blood tests

In facilities serving highly susceptible populations such as day care centers and health care facilities, a person for whom there is evidence of foodborne illness is almost always excluded from the food establishment.

In other establishments such as restaurants and retail food stores, that offer food to typically healthy consumers, a person might only be restricted from certain duties, based on the evidence of foodborne illness.

Exclusion from any food establishment is required when the person is:

- Exhibiting or reporting diarrhea or vomiting;
- Diagnosed with illness caused by S. Typhi; or
- Jaundiced within the last 7 days.

For *Shigella* spp. or *Escherichia coli* O157:H7 or other STEC infections, the person's stools must be negative for 2 consecutive cultures taken no earlier than 48 hours after antibiotics are discontinued, and at least 24 hours apart or the infected individual must have resolution of symptoms for more than 7 days or at least 7 days have passed since the employee was diagnosed.

FORM
1-D

Application for Bare Hand Contact Procedure
(As specified in Food Code ¶ 3-301.11(E))

Please type or print legibly using black or blue ink

1. **Establishment Name:** _____

2. **Establishment Address:** _____

3. **Responsible Person:** _____ **Phone:** _____
Legal Representative Business

4. **List Procedure and Specific Ready-To-Eat-Foods** to be considered for use of bare hand contact with ready-to-eat foods:

5. **Handwashing Facilities:**

(a) There is a handwashing sink located immediately adjacent to the posted bare hand contact procedure and the hand sink is maintained in accordance with provisions of the Code. (§ 5-205.11, § 6-301.11, § 6-301.12, § 6-301.14) YES NO (Include diagram, photo or other information)

(b) All toilet rooms have one or more handwashing sinks in, or immediately adjacent to them, and the sinks are equipped and maintained in accordance with provisions of the Code. (§ 5-205.11, § 6-301.11, § 6-301.12, § 6-301.14) YES NO

6. **Employee Health Policy:** The written employee health policy must be attached to this form along with documentation that food employees and conditional employees acknowledge their responsibilities. (§ 2-201.11, § 2-201.12, § 2-201.13)

7. **Employee Training:** Provide documentation that food employees have received training in:

- The risks of contacting the specific ready-to-eat foods with bare hands
- Personal health and activities as they relate to diseases that are transmissible through food.
- Proper handwashing procedures to include how, when, where to wash, & fingernail maintenance. (§ 2-301.12, § 2-301.14, § 2-301.15, § 2-302.11)
- Prohibition of jewelry. (§ 2-303.11)
- Good hygienic practices. (§ 2-401.11, § 2-401.12)

8. **Documentation of Handwashing Practices:** Provide documentation that food employees are following proper handwashing procedures prior to food preparation and other procedures as necessary to prevent cross-contamination during all hours of operation when the specific ready-to-eat foods are prepared or touched with bare hands.

9. **Documentation of Additional Control Measures:** Provide documentation to demonstrate that food employees are utilizing two or more of the following control measures when contacting ready-to-eat foods with bare hands:

- Double handwashing;
- Use of nailbrushes;
- Use of hand antiseptic after handwashing;
- Incentive programs such as paid leave encouraging food employees not to work when they are ill; or
- Other control measures approved by the regulatory authority.

Statement of Compliance:

I certify all of the following: All food employees are individually trained in the risks of contacting ready-to-eat foods with bare hands, personal health and activities as they relate to diseases that are transmissible through food, proper handwashing procedures, prohibition of jewelry, and good hygienic practices. A record of this training is kept on site. I understand that bare hand contact with ready-to-eat food is prohibited except for those items listed in section four (4) above. A handwashing sink is located immediately adjacent to the posted bare hand contact procedure. All handwashing sinks are maintained with hot water, soap, and drying devices. I understand that documentation is needed for handwashing practices and additional control measures. I understand that records to document handwashing are kept current and kept on site.

SIGNATURE: _____

DATE _____

(Signature of legal representative of the facility listed above)

Regulatory Authority (RA) Use Only:

Permit Number: _____

File Review Conducted on History of Handwashing Compliance: Yes No

Site Visit Conducted Yes No Comments: _____

Approved: Effective Date: _____ RA name _____

Not Approved: Reason for Denial:

FORM
2-A

Adoption by Reference

This "short form" may be used by governmental bodies adopting the Food Code where authorized by law. Use of the adoption by reference form may substantially reduce the cost of publishing and printing.

The description of the Food Code, below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(statute/regulation/ordinance) Number

ADOPTING THE 2009 EDITION OF THE "FOOD CODE" REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING, AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The (governing body) of the (jurisdiction) does ordain as follows:

SECTION 1. ADOPTION OF FOOD CODE

That a certain document, three copies of which are on file in the office of the (jurisdiction's keeper of records) of the (type of jurisdiction) of (name of jurisdiction) being marked and designated as the *Food Code, 2009 Recommendations of the United States Public Health Service/Food and Drug Administration* as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration be, and is hereby adopted as, the Food Code of (type of jurisdiction) of (name of jurisdiction) in the State of (state name); for regulating the design, construction, management, and operation of food establishments, and providing for plans submission and approval and the issuance of permits and collection of fees therefore.

SECTION 2. INSERTIONS AND CHANGES

That the following provisions are hereby revised as follows:

Paragraph 8-911.10(B)(1) and (2) Insert **(Dollar Amount)**

Paragraph 8-913.10(B) Insert **(Dollar Amounts)**

Subparagraph 8-911.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That (statute/regulation/ordinance) number (present code number) of the (jurisdiction) titled, (complete title of the food code[s] in effect at the present time so they will be repealed by definite mention) and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the (jurisdiction's keeper of records) shall certify the adoption of this (statute/regulation/ordinance) and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect (time period) from and after the date of its final passage and approval.

PASSED AND APPROVED BY (name of adopting authority) on this (day) of (month, year) .

BY:

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Wholesale Food Violations:

Criminal fines and sentence for violations of up to **\$1,000** and up to **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **\$1,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars (\$25) or more than one thousand dollars (\$1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain misdemeanors of up to **\$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **\$25,000** and **three** years imprisonment; and

Civil penalties of up to **\$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **\$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **\$1,250** through **\$10,000**. Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Though rarely used with retail food establishments, **Federal** law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **\$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **\$250,000** for individuals and **\$500,000** for corporations.

FORM
2-B

Adoption by Section-by-Section Reference

This "long form" may be used by governmental bodies adopting the Food Code section-by-section.

The description of the "Food Code," below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(statute/regulation/ordinance) Number

ADOPTING A CODE REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The (governing body) of the (jurisdiction) does ordain as follows:

(REPRINT THE FOOD CODE, (date) RECOMMENDATIONS OF THE UNITED STATES PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION, SECTION-BY-SECTION)

SECTION 2. INSERTIONS AND CHANGES

That the following provisions may need to be completed as follows:

Paragraph 8-911.10(B)(1) and (2) Insert (**Dollar Amount**)

Paragraph 8-913.10(B) Insert (**Dollar Amounts**)

Subparagraph 8-911.10(B)(2) Insert (**Number of Year(s)**)

SECTION 3. INCONSISTENT CODES REPEALED

That (statute/regulation/ordinance) number (present code number) of the (jurisdiction) titled, (complete title of the food code[s] in effect at the present time so they will be repealed by definite mention) and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the (jurisdiction's keeper of records) shall certify the adoption of this (statute/regulation/ordinance) and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect (time period) from and after the date of its final passage and approval.

PASSED AND APPROVED BY (name of adopting authority) on this (day) of (month, year).

BY:

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Wholesale Food Violations:

Criminal fines and sentence for violations of up to **\$1,000** and up to **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **\$1,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars (\$25) or more than one thousand dollars (\$1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain misdemeanors of up to **\$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **\$25,000** and **three** years imprisonment; and

Civil penalties of up to **\$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **\$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **\$1,250** through **\$10,000**. Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Though rarely used with retail food establishments, **Federal** law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **\$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **\$250,000** for individuals and **\$500,000** for corporations.

FORM

3-A

Food Establishment Inspection Report

The food establishment inspection report is the official regulatory authority document regarding compliance of the establishment with agency requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection. The Food Establishment Inspection Report form is provided as a model for use during routine, follow-up, and investigative inspections.

Refer to Annex 5 for further information.

Food Establishment Inspection Report

As Governed by State Code Section XXX.XXX		No. of Risk Factor/Intervention Violations		Date	
Do Good County		No. of Repeat Risk Factor/Intervention Violations		Time In	
12344 Any Street, Our Town, State 11111		Score (optional)		Time Out	
Establishment	Address	City/State	Zip Code	Telephone	
License/Permit #	Permit Holder	Purpose of Inspection	Est. Type	Risk Category	

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Circle designated compliance status (IN, OUT, N/O, N/A) for each numbered item Mark "X" in appropriate box for COS and/or R

IN=in compliance OUT=not in compliance N/O=not observed N/A=not applicable COS=corrected on-site during inspection R=repeat violation

Compliance Status		Supervision		Compliance Status		Time/Temperature Control for Safety					
cos	R			cos	R						
		1	IN OUT	Person in charge present, demonstrates knowledge, and performs duties			17	IN OUT	Proper disposition of returned, previously served, reconditioned & unsafe food		
		2	IN OUT N/A	Certified Food Protection Manager			Time/Temperature Control for Safety				
Employee Health											
		3	IN OUT	Management, food employee and conditional employee; knowledge, responsibilities and reporting			18	IN OUT N/A N/O	Proper cooking time & temperatures		
		4	IN OUT	Proper use of restriction and exclusion			19	IN OUT N/A N/O	Proper reheating procedures for hot holding		
		5	IN OUT	Procedures for responding to vomiting and diarrheal events			20	IN OUT N/A N/O	Proper cooling time and temperature		
Good Hygienic Practices											
		6	IN OUT N/O	Proper eating, tasting, drinking, or tobacco use			21	IN OUT N/A N/O	Proper hot holding temperatures		
		7	IN OUT N/O	No discharge from eyes, nose, and mouth			22	IN OUT N/A N/O	Proper cold holding temperatures		
Preventing Contamination by Hands											
		8	IN OUT N/O	Hands clean & properly washed			23	IN OUT N/A N/O	Proper date marking and disposition		
		9	IN OUT N/A N/O	No bare hand contact with RTE food or a pre-approved alternative procedure properly allowed			24	IN OUT N/A N/O	Time as a Public Health Control; procedures & records		
		10	IN OUT	Adequate handwashing sinks properly supplied and accessible			Consumer Advisory				
Approved Source											
		11	IN OUT	Food obtained from approved source			Highly Susceptible Populations				
		12	IN OUT N/A N/O	Food received at proper temperature			25	IN OUT N/A	Consumer advisory provided for raw/undercooked food		
		13	IN OUT	Food in good condition, safe, & unadulterated			Food/Color Additives and Toxic Substances				
		14	IN OUT N/A N/O	Required records available: shellstock tags, parasite destruction			27	IN OUT N/A	Food additives: approved & properly used		
Protection from Contamination											
		15	IN OUT N/A N/O	Food separated and protected			28	IN OUT N/A	Toxic substances properly identified, stored, & used		
		16	IN OUT N/A	Food-contact surfaces; cleaned & sanitized			Conformance with Approved Procedures				
GOOD RETAIL PRACTICES											
Good Retail Practices are preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.											
Mark "X" in box if numbered item is not in compliance Mark "X" in appropriate box for COS and/or R COS=corrected on-site during inspection R=repeat violation											
Safe Food and Water		Proper Use of Utensils									
cos	R	cos	R								
		30		Pasteurized eggs used where required			43		In-use utensils: properly stored		
		31		Water & ice from approved source			44		Utensils, equipment & linens: properly stored, dried, & handled		
		32		Variance obtained for specialized processing methods			45		Single-use/single-service articles: properly stored & used		
Food Temperature Control				Utensils, Equipment and Vending							
		33		Proper cooling methods used; adequate equipment for temperature control			46		Gloves used properly		
		34		Plant food properly cooked for hot holding			47		Food & non-food contact surfaces cleanable, properly designed, constructed, & used		
		35		Approved thawing methods used			48		Warewashing facilities: installed, maintained, & used; test strips		
		36		Thermometers provided & accurate			49		Non-food contact surfaces clean		
Food Identification				Physical Facilities							
		37		Food properly labeled: original container			50		Hot & cold water available; adequate pressure		
Prevention of Food Contamination				Physical Facilities							
		38		Insects, rodents, & animals not present			51		Plumbing installed; proper backflow devices		
		39		Contamination prevented during food preparation, storage & display			52		Sewage & waste water properly disposed		
		40		Personal cleanliness			53		Toilet facilities: properly constructed, supplied, & cleaned		
		41		Wiping cloths: properly used & stored			54		Garbage & refuse properly disposed; facilities maintained		
		42		Washing fruits & vegetables			55		Physical facilities installed, maintained, & clean		
							56		Adequate ventilation & lighting; designated areas used		

Risk factors are important practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury. Public health interventions are control measures to prevent foodborne illness or injury.

Person in Charge (Signature)	Date:
Inspector (Signature)	Follow-up: YES NO (Circle one) Follow-up Date:

Guide**3-B Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices**

Guide 3-B is intended to be used during inspections to ensure that observations of the provisions of the Code are not overlooked during the inspection and accurately recorded on the Food Code Establishment Inspection Report form.

The major headings from the Food Establishment Inspection Report form are condensed in Guide 3-B into key word phrases to assist the person conducting inspections in locating the Food Code citation that corresponds to a given violation and recording inspectional observations. The risk designations (Priority^(P), Priority Foundation^(Pf) and Core^(C)) have been added to each applicable code section for reference when recording observations in the inspection report.

GUIDE

3-B

Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices

All references and code sections in these marking instructions are based on the 2009 Food Code and its Supplement.

A. GENERAL MARKING INSTRUCTIONS

HEADER Information

Establishment	Complete this section using the “usual/common name” or “Doing Business As” name of the business. This information should be the same as the license/permit application completed at the initiation of the business.
Address	Street address of the actual business location
Zip Code	Actual business location
Telephone	Contact phone number for the establishment
License/Permit #	License number or tracking identification
Permit Holder	Name of Owner or Operator as shown on application
Purpose	The reason for the inspection – routine, re-inspection, complaint, or follow-up, etc.
Est. Type	Description or code for describing the type of facility (e.g. restaurant, market, vehicle, temporary food facility)
Risk Category	Designation of risk/priority level for determining frequency of inspection
Number of Risk Factor/Intervention Violations	The number of boxes marked OUT in items 1-27 should be counted and the total number placed here
Number of Repeat Risk Factor/Intervention Violations	The number of boxes marked R (repeat) in items 1-27 should be counted and the total number placed here
Score (optional)	A score is optional for this form. If a jurisdiction has a scoring system, it should be incorporated into the inspection form and the score of an inspection placed here.
Date	The date of the inspection including month, day, and year
Time In	The actual time the inspection begins
Time Out	The actual time the inspection ends

B. RISK FACTORS AND INTERVENTIONS

Risk factors are food preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks. Risk factors include: Food from Unsafe Sources, Improper Holding Temperatures, Inadequate Cooking, Contaminated Equipment, and Poor Personal Hygiene. These items are prominent on the Food Establishment Inspection Report because maintaining these items in compliance is vital to preventing foodborne illness. Additionally, five key public health interventions were introduced in the 1993 Food Code that supplemented the other interventions long-established by the Food and Drug Administration (FDA) model codes and guidances to protect consumer health. The five key interventions are: Demonstration of Knowledge, Employee Health Controls, Controlling Hands as a Vehicle of Contamination, Time and

Temperature Parameters for Controlling Pathogens, and the Consumer Advisory.

For each item on the inspection report form in the Foodborne Illness Risk Factors and Public Health Interventions section, the inspector should indicate one of the following for **COMPLIANCE STATUS**: “**IN**” which means that the item is in compliance; “**OUT**” which means that the item is not in compliance; “**N.O.**” which means that the item was not observed during the inspection; or “**N.A.**” which means that the item is not applicable for the facility. If N.A. or N.O. is not listed as an option for a particular item, this means that this item must be evaluated during the inspection and a compliance status must be determined. **If the item is marked “OUT”, document details of each violation for the item number in the “Observations and Corrective Actions” section on the second page of the inspection report.** Compliance status should be determined as a result of observations that establish a pattern of non-compliance. Consideration should be given to the seriousness of the observation with regard to prevention of foodborne illness.

For items marked “**OUT**,” further indicate the status of the violation by marking an “**X**” in the corresponding box for Corrected On-Site (**COS**) during the inspection and/or Repeat violation (**R**). Marking **COS** indicates that all violations cited under that particular item number have been corrected and verified before completing the inspection. The actual corrective action taken for each violation should be documented in the “Observations and Corrective Actions” section of the inspection report. For example, Item #10 *Handwashing sink* is marked out of compliance because the establishment does not have soap and paper towels at the handwashing sink. The person in charge partially corrects the problem by putting soap at the sink, but does not replace the paper towels or provide any other effective means for drying hands. The corrective action taken for the soap is documented in the narrative on the form, but **COS** is not marked for Item #10 because all violations under that item were not corrected. Marking **R** indicates that the same violation under a particular item number was cited on the last inspection report. Using the same scenario, on the subsequent inspection if the provision of soap and paper towels is not in violation, but employees are not washing hands in the correct sink (which is also cited under Item #8 *Handwashing sink*), **R** would not be marked because this is a new violation which was not cited on the previous inspection report.

C. MARKING INSTRUCTIONS FOR EACH RISK FACTOR AND INTERVENTION ON THE INSPECTION REPORT

Supervision

1. PIC present, demonstrates knowledge, and performs duties

IN/OUT This item must be marked IN or OUT of compliance. The person in charge (PIC) has three assigned responsibilities – Presence; Demonstration of Knowledge; and Duties. This item is marked OUT of compliance if any one of the responsibilities is not met.

- A. Person in charge is present. This item is marked OUT of compliance if there is no PIC per 2-101.11(A) and (B).
- B. Demonstration of Knowledge. The PIC has three options for demonstrating knowledge. This item is marked IN compliance if the PIC meets at least one of the options. The three options for demonstration of knowledge allowed by the Food Code are:
 1. Certification by an ACCREDITED PROGRAM as specified in 2-102-20.
 2. Complying with this Code by having no violations of priority items during the current inspection; or

3. Correct responses to the inspector's questions regarding public health practices and principles applicable to the operation. The inspector should assess this item by asking open-ended questions that would evaluate the PIC's knowledge in each of the areas enumerated in ¶ 2-102.11(C)(1), (4)-(16). Questions can be asked during the initial interview, menu review, or throughout the inspection as appropriate. The Inspector should ask a sufficient number of questions to enable the inspector to make an informed decision concerning the PIC's knowledge of the Code requirements and public health principles as they apply to the operation. The dialogue should be extensive enough to reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.
- C. Duties of the PIC. This item must be marked IN or OUT of compliance based on the interaction and observation with the PIC and food employee. The inspector needs to determine the systems or controls the PIC has put into practice regarding oversight and/or routine monitoring of the Duties listed in § 2-103.11. This is accomplished by 1) discussion with the PIC, and 2) verified through observation that the systems or controls are actually being implemented. This concept is commonly referred to as Active Managerial Control. This item must be marked OUT of compliance when there is a pattern of non-compliance and obvious failure by the PIC to ensure employees are complying with the duties listed in § 2-103.11. Since marking this item out of compliance requires judgment, it is important that this item not be marked for an isolated incident, but rather for an overall evaluation of the PIC's ability to ensure compliance with the duties described in § 2-103.11.

N.A. Do Not Mark this item N.A.

N.O. Do Not Mark this item N.O.

Applicable Code Section:

2-101.11	Assignment ^(Pf)
2-102.11(A), B) and (C)(1), (4)-(16)	Demonstration ^(Pf)
2-103.11 (A)-(O)	Person-In-Charge-Duties ^(Pf)

2. Certified Food Protection Manager

IN/OUT This item must be marked IN or OUT of compliance. This item is marked IN compliance when it is observed that at least one employee that has supervisory and management responsibility and the authority to direct and control food preparation and service is a certified food protection manager. This item is marked OUT when it is observed that there is no employee with supervisory and management responsibility with the authority to direct and control food preparation that is deemed a certified food protection manager or the certified food protection manager certificate is deemed not to be from an accredited program.

N.A. This item may be marked N.A. if the establishment is deemed by the Regulatory Authority to not apply due to the minimal risk of causing, or contributing to foodborne illness based on the nature of the operation and extent of food operation.

N.O. Do **NOT MARK** this item N.O.

Applicable Code Section:

2-102.12(A) Certified Food Protection Manager ^(C)

Employee Health/Responding to Contamination Events

3. Management and food employee knowledge, and conditional employee; responsibilities and reporting.

IN/OUT This item must be marked IN or OUT of compliance. This item is marked IN compliance when the following criteria are met:

1. The PIC is aware of his or her responsibility to inform food employees and conditional employees of their responsibility to report certain symptoms or diagnosed diseases to the person in charge and for the PIC to report to the regulatory authority as specified under Food Code ¶ 2-103.11(M) and ¶¶ 2-201.11 (A),(B), (C), and (E); **and**
2. The PIC provides documentation or otherwise satisfactorily demonstrates during the inspection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as it relates to diseases that are transmissible through food, as specified under ¶ 2-201.11(A). Satisfactory compliance may be documented by completion of Form 1-B, Conditional Employees or Food Employees Reporting Agreement, in Annex 7 of the 2009 Food Code for each employee or other similar State or local form containing the same information; **or**
3. In lieu of Form 1-B, compliance may be demonstrated by:
 - a) Presenting evidence such as a curriculum and attendance rosters documenting that each employee has completed a training program which includes all the information required on Form 1-B regarding their reporting responsibilities; **or**
 - b) Implementation of an employee health policy which includes a system of employee notification using a combination of training, signs, pocket cards, or other means to convey all of the required information on Form 1-B to all food employees and conditional employees. A signed acknowledgement by the employee should be part of any employee health policy.

The regulatory authority is encouraged to establish a policy of selecting one employee at random during each inspection and requesting the PIC verify, by one of the previously listed methods, that the selected employee has been **informed** of his or her responsibility to report symptoms, exposures, and diagnosed illnesses to management. The PIC is not expected to quote symptoms and diseases from memory, but should be able to locate that information on Form 1-B or similar documents used to demonstrate compliance.

Additional information is provided in Annex 3 of the Public Health Reasons for Subpart 2-201, including a number of questions, which may be used as a reference to assist the regulatory authority in determining compliance with this item.

N.A. Do Not Mark this item N.A.

N.O. Do Not Mark this item N.O.

Applicable Code Sections:

2-102.11(C)(2),(3) and (17)

2-103.11(M)

2-201.11(A), (B), (C), & (E)

Demonstration ^(Pf)

Person in Charge-Duties ^(Pf)

Responsibility of Permit Holder, Person in Charge, and Conditional Employees ^(P,Pf)

4. Proper use of restriction and exclusion

IN/OUT This item must be marked IN or OUT of compliance. Compliance must be based on first hand observations or information and cannot be based solely on responses from the PIC to questions regarding hypothetical situations or knowledge of the Food Code. This item is marked IN when the following criteria are observed at the time of the inspection:

- There are no ill employees.
- There are no employees experiencing symptoms with or without a diagnosis that require reporting, or reason for the PIC to exclude or restrict an employee
- A food employee who works in a food establishment serving a HSP or non-HSP, is restricted due to diagnoses with an infection from nontyphoidal *Salmonella* and is asymptomatic

This item should be marked OUT of compliance when:

- The inspector observes a working employee with specific reportable symptoms (subparagraph 2-201.11 (A)(1)); or
- The inspector becomes aware that an employee has reported information about his or her health and activities as it relates to diseases that are transmissible through food and the PIC has not acted to restrict/exclude an employee as required by the Food Code (§2-201.12 & §2-201.13); or
- The inspector becomes aware that the PIC has not notified the Regulatory Authority that an employee is jaundiced or diagnosed with an illness due to a pathogen as specified under subparagraphs 2-201.11 (A)(2)(a)-(f) of the Food Code.
- There are food employees working in the food establishment that have been diagnosed with an illness as specified in paragraphs 2-201.11(A)(2-5); Additionally, in food establishments exclusively serving a highly susceptible population, there are to be no food employees with an active sore throat with a fever working in the food establishment.

N.A. Do Not Mark this item N.A.

N.O. Do Not Mark this item N.O.

Applicable Code Sections:

- 2-201.11 (D) and (F) Responsibility of Permit Holder, Person in Charge, and Conditional Employees- Responsibility of the PIC to Exclude or Restrict ^(P,)
- 2-201.12 Exclusions & Restrictions ^(P)
- 2-201.13 Removal, Adjustment, or Retention of Exclusions & Restrictions ^(P)

5, Clean-up of Vomiting and Diarrheal Events

IN/OUT This item should be marked IN or OUT of compliance. This items is marked IN compliance when it is demonstrated that the food establishment has procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. Refer to the Public Health Reasons (§2-501.11 Clean up of Vomiting and Diarrheal Events) for suggested recommendations as to what the food establishment can include within their plan (this is not an exhaustive list).

This item is marked OUT of compliance if the establishment does not demonstrate the ability to provide procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment.

N.A. Do Not Mark this item N.A.

N.O. Do Not Mark this item N.O.

Applicable Code Section:

- 2-501.11 Clean-up of Vomiting and Diarrheal Events ^(Pf)

Good Hygienic Practices

6. Proper eating, tasting, drinking, or tobacco use

IN/OUT This item should be marked IN or OUT of compliance based on direct observations or discussions of the appropriate hygienic practices of food employees. This item should be marked IN compliance when a food employee is observed drinking from a closed beverage container subsequently stored on a non-food-contact surface and separate from exposed food, clean equipment, and unwrapped single-service and single-use articles. This item should be marked OUT of compliance when food employees are observed improperly tasting food, eating, drinking, or smoking, or there is supporting evidence of these activities taking place in non-designated areas of the establishment. An open container of liquid in the kitchen preparation area does not necessarily constitute marking this item OUT. Further discussion with a food employee or the PIC may be needed to determine if the liquid, if labeled, is used as an ingredient in food, or may be an employee beverage that is consumed in another designated area. If the liquid is an open beverage that is consumed in a designated area, it must still be stored in a manner to prevent the contamination of food, equipment, utensils, linens and single-service/single-use articles.

N.A. **Do Not Mark** this item N.A.

N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection.

Applicable Code Sections:

2-401.11 Eating, Drinking, or Using Tobacco ^(C)
3-301.12 Preventing Contamination When Tasting ^(P)

7. No discharge from eyes, nose, and mouth

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food employees. This item should be marked IN compliance when no food employees are observed having persistent sneezing, coughing, or a runny nose that causes discharge from the eyes, nose or mouth. This item should be marked OUT of compliance when a food employee has persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose or mouth, subjecting food and food-contact surfaces to potential contamination.

N.A. **Do Not Mark** this item N.A.

N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection.

Applicable Code Sections:

2-401.12 Discharges from the Eyes, Nose, and Mouth ^(C)

Control of Hands as a Vehicle of Contamination

8. Hands clean and properly washed

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance only when employees are observed using proper handwashing techniques at appropriate times and places. Hands are not required to be washed between each change of gloves, if it is observed that there was no change in the task being performed and no activities which could potentially result in cross contamination.

N.A. **Do Not Mark** this item N.A.

N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection. (If there are no food workers present, but the PIC accompanies the inspector on the inspection and touches food, clean equipment, or utensils without washing his/her hands, this item is marked OUT.)

Applicable Code Sections:

2-301.11 Clean condition-Hands and Arms ^(P)
2-301.12 Cleaning Procedure ^(P)
2-301.14 When to Wash ^(P)
2-301.15 Where to Wash ^(Pf)
2-301.16 Hand Antiseptics ^(Pf)

9. No bare hand contact with RTE foods or a pre-approved alternate properly followed

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance only when food employees are observed using suitable utensils or gloves to prevent bare hand (or arm) contact with ready-to-eat foods or if the food employee contacts exposed RTE food with bare hands at the time the RTE food is being added as an ingredient to a food that:

- Contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to minimum temperatures specified in ¶3-401.11(A)-(B) or §3-401.12; or
- Does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 63°C (145°F).

This item is also marked IN compliance when food employees are observed properly following a pre-approved alternative procedure to no bare hand contact.

This item should be marked OUT of compliance if one food employee is observed ready-to-eat food with their bare hands in the absence of a prior approval and written procedures for bare hand contact. Refer to subparagraph 3-301.11 (E)(1)-(7) for a listing of conditions that must be met in order to receive prior approval by the Regulatory Authority. Bare hand contact by food employees serving a Highly Susceptible Population is prohibited and no alternative to bare hand contact is allowed. This item is also marked OUT when food employees contact exposed RTE food with bare hands that is to be added as ingredients to a food that is not properly heat treated as specified in Sub-¶3-301.11(D)(1)-(2).

N.A. This item may be marked N.A. for establishments that provide only packaged, or bulk food items that are not ready-to-eat.

N.O. This item may be marked N.O. for establishments that prepare ready-to-eat foods only, but no food preparation is performed at the time of inspection.

Applicable Code Sections:

3-301.11 Preventing Contamination from Hands ^(P, Pf, C)
3-801.11(D) Pasteurized Foods, Prohibited Re-Service, and Prohibited Foods ^(P)

10. Adequate handwashing sinks, properly supplied and accessible

IN/OUT This item must be marked IN or OUT of compliance based on observations in determining that handwashing sinks are properly equipped and conveniently located for employee use in food preparation, food dispensing and warewashing areas as well as in or immediately adjacent to toilet rooms. This item must be marked OUT of compliance when the facility is not stocked with soap, hand drying provisions or equipped with the required signage. In addition, if the handwashing sink is not located to be available to employees who are working in a food preparation area, food dispensing and warewashing areas and is blocked by portable equipment or stacked full of soiled utensils or other items, or the facility is unavailable for regular employee use, this item must be marked OUT of compliance.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

5-202.12 Handwashing Sinks, Installation ^{((Pf, C)}
5-203.11 Handwashing Sinks-Numbers and Capacities ^(Pf)

- 5-204.11 Handwashing Sinks-Location and Placement ^(Pf)
- 5-205.11 Using a Handwashing Sink-Operation and Maintenance ^(Pf)
- 6-301.11 Handwashing Cleanser, Availability ^(Pf)
- 6-301.12 Hand Drying Provision ^(Pf)
- 6-301.13 Handwashing Aids and Devices, Use Restrictions ^(C)
- 6-301.14 Handwashing Signage ^(C)

Approved Source

11. Food obtained from approved source

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food products, food labels and packaging, water analyses, and discussion with the PIC or other food employees. This item should be marked IN compliance when the regulatory authority is able to determine approved food sources. A review of supplier names, shipment invoices, buyer specification plans, molluscan shellfish tags, proof of regulatory permit/licensure of a food source, etc. can be used to document approved food sources. Wild harvested mushrooms if sold or served have been approved by the regulatory authority. Milk and milk products must comply with Grade A Standards. This item should be marked OUT of compliance when an approved food source cannot be determined and if the regulatory authority did not approve the sale or service of wild harvested mushrooms and it is observed in the food establishment for sale and service.

N.A. Do Not Mark this item N.A.

N.O. Do Not Mark this item N.O.

Applicable Code Sections:

- 3-201.11 Compliance with Food Law ^(P, Pf)
- 3-201.12 Food in a Hermetically Sealed Container ^(P)
- 3-201.13 Fluid Milk and Milk Products ^(P)
- 3-201.14 Fish ^(P)
- 3-201.15 Molluscan Shellfish ^(P)
- 3-201.16 Wild Mushrooms ^(P)
- 3-201.17 Game Animals ^(P, C)
- 3-202.13 Eggs ^(P)
- 3-202.14 Eggs and Milk Products, Pasteurized ^(P)
- 3-202.110 Juice Treated-Commercially Processed ^(P, Pf)
- 5-101.13 Bottled Drinking Water ^(P)

12. Food received at proper temperature

IN/OUT This item should be marked IN or OUT of compliance based on actual food temperature measurements of TCS foods being received. This item should be marked IN compliance when food is received and found at proper temperatures during the inspection (i.e. catered meal for child care center arrives during the inspection and the regulatory authority verifies receiving temperature). This item should be marked OUT of compliance if food is received and accepted, but an actual food temperature measurement of a TCS food by the regulatory authority at the time of delivery exceeds the temperature specifications for receiving as prescribed by the Code.

N.A. This item may be marked N.A. for retail operations when the establishment receives only foods that are not TCS food and that are not frozen.

N.O. This item may be marked N.O. if food is not received during the inspection.

Applicable Code Sections:

- 3-202.11 Temperature ^(P, Pf)

13. Food in good condition, safe and unadulterated

IN/OUT This item must be marked IN or OUT of compliance based on direct observations of the integrity of product packaging, wholesomeness, and signs of adulteration. This item must be marked IN compliance when a dent in a canned food has not compromised the hermetic seal; cuts made in outer cardboard packaging during opening of the case do not enter the inner product packaging; the true appearance, color, or quality of a food is not misrepresented; and food is honestly presented. This item must be marked OUT of compliance when the integrity of food packaging has been compromised or the true appearance, color, or quality of a food has been intentionally altered.

N.A. Do Not Mark this item N.A.

N.O. Do Not Mark this item N.O.

Applicable Code Sections:

3-101.11 Safe, Unadulterated and Honestly Presented ^(P)

3-202.15 Package Integrity ^(Pf)

14. Required records available: shellstock tags, parasite destruction

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of fish in storage, shellstock tags, and/or records of freezing of fish for parasite destruction. This item should be marked IN compliance if the permit holder provides a statement from supplier(s) identifying that fish sold as raw, raw-marinated or undercooked is frozen by supplier for parasite destruction; or there are freeze records maintained by the permit holder when fish are frozen for parasite destruction on the premises. This item should be marked OUT of compliance if there are no shellstock tags available, when the shellstock tags are incomplete, when there is evidence of commingling of shellstock, or when no records of freezing of fish for parasite destruction are available. Fish exempt from freezing requirements are found in paragraph 3-402.11(B).

N.A. This item may be marked N.A. when shellstock are not used in the establishment and the only fish sold as raw, raw-marinated or undercooked is the tuna species or aquacultured fish listed as exempted from freezing in the Food Code.

N.O. This item may be marked N.O. when shellstock or raw, raw-marinated and undercooked fish are sold periodically in the establishment, but are not being sold at the time of inspection and prior compliance through tags, invoices, or purchase records cannot be verified.

Applicable Code Sections:

3-202.18 Shellstock Identification ^(Pf, C)

3-203.12 Shellstock, Maintaining Identification ^(Pf)

3-402.11 Parasite Destruction ^(P, C)

3-402.12 Records, Creation, & Retention ^(Pf)

Protection from Contamination

15. Food separated and protected

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food storage and food handling practices. This item should be marked OUT of compliance when ready-to-eat foods are subject to potential contamination by raw animal foods; raw animal foods are observed not separated by type based on minimum cook temperatures by spacing or placing in separate containers; unpackaged comminuted or otherwise non intact meats are stored above unpackaged whole muscle intact cuts of meat; food is not packaged or covered during storage (unless in the process of cooling); or food is in contact with soiled equipment and utensils; or single-use gloves used for more than one task.

N.A. This item may be marked N.A. when there are no raw animal foods used in the facility and only prepackaged foods are sold.

N.O. This item is marked N.O. when raw animal foods are used or served seasonally and you are unable to determine compliance.

Applicable Code Sections:

- 3-302.11 Packaged and Unpackaged Food-Separation, Packaging, and Segregation ^(P, C)
- 3-304.11 Food Contact with Equipment, Utensils, and Linens ^(P)
- 3-304.15(A) Gloves, Use Limitation ^(P)
- 3-306.13(A) Consumer Self-Service Operations ^(P)

16. Food-contact surfaces: cleaned and sanitized

IN/OUT This item must be marked IN or OUT of compliance based on direct observations of food-contact surfaces of equipment and utensils; actual measurements/readings of chemical sanitizer concentration, hot water sanitizing temperature, pH, hardness, water pressure, etc. using test strips, heat-sensitive tapes, and equipment gauges; observations of cleaning and sanitizing procedures; and discussion of cleaning and sanitizing procedures and frequency with the PIC or other food employees. This item must be marked IN compliance when manual and/or mechanical methods of cleaning and sanitizing are effective, and performed at the prescribed frequency. There should be an overall assessment of the food-contact surfaces of equipment and utensils in clean storage and in use to determine compliance. For example, this item is not marked OUT of compliance based on one visibly soiled utensil, such as a plate or knife. This item must be marked OUT of compliance when manual and/or mechanical methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective, or if one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection. This item is also marked OUT if it is observed that equipment or utensils that have come into contact with a major food allergen such as fish was not cleaned and sanitized prior to use for other types of raw animal foods.

N.A. This item may be marked N.A. only when there is no requirement to clean equipment and utensils such as when only prepackaged foods are sold.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

- 4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures ^(P)
- 4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures ^(Pf)
- 4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure ^(C)
- 4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization-Temperature, pH, Concentration and Hardness ^(P, Pf)
- 4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers ^(C)
- 4-601.11(A) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils ^(Pf)
- 4-602.11 Equipment Food-Contact Surfaces and Utensils-Frequency ^(P, C)
- 4-602.12 Cooking and Baking Equipment ^(C)

- 4-702.11 Before Use After Cleaning ^(P)
4-703.11 Hot Water and Chemical-Methods ^(P)

17. Proper disposition of returned, previously served, reconditioned, and unsafe food

IN/OUT This item must be marked IN or OUT of compliance. This item is marked OUT of compliance if food is found unsafe, adulterated, not honestly presented, from an unapproved source, or if ready-to-eat food is contaminated by employees and is not discarded or reconditioned according to an approved procedure, or if previously served unwrapped, unprotected food is observed being re-served.

N.A. Do Not Mark this item N.A.

N.O. Do Not Mark this item N.O.

Applicable Code Sections:

- 3-306.14 Returned Food and Re-service of Food ^(P)
3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food ^(P)

Time Temperature Control for Safety Food (TCS Food)

18. Proper cooking time and temperatures

NOTE: *The cooking temperatures of foods must be measured to determine compliance or noncompliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or noncompliance. The temperature of raw animal foods in each species cooked during the inspection should be taken. For instance, if the facility fries chicken, scrambles eggs, bakes fish, grills hamburgers, and slow-roasts prime rib during the inspection – the cook temperatures of all of the products should be measured and recorded. Temperatures, both IN compliance and OUT of compliance, should be recorded in the “Temperature Observations” section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the “Observations and Corrective Actions” section on the second page of the inspection report. The time of inspections should be varied so that cooking can be observed.*

IN/OUT This item should be marked IN or OUT of compliance. This item should be marked OUT of compliance if the items checked do not meet the temperature requirements for cooking and the employee doing the cooking attempts to serve the product without returning the product to the cooking process. If a food is cooked below the required temperature but the facility has an approved Consumer Advisory or an approved variance with HACCP plan for that food item, mark the item IN compliance, record the temperature and document the reason it is IN compliance. Foods cooked with a non-continuous cooking process are marked OUT of compliance if the food item does not meet the time/temperature requirements for cooking as specified in 3-401.11(A)-(C) and if written procedures describing how the foods are prepared and stored after initial heating but prior to cooking for sale or service are not available for review.

N.A. This item may be marked N.A. when no raw animal foods are cooked in the establishment.

N.O. This item may be marked N.O. when you are unable to determine the cooking temperature of any food. The inspection should be arranged at an optimum time for measuring at least one cooked item.

Internal Cooking Temperature Specifications for Raw Animal Foods

Internal Cooking Temperature	Raw Animal Foods
145°F for 15 seconds	<ul style="list-style-type: none"> • Raw eggs cooked for immediate service • Fish, except as listed below • Meat, except as listed in the next 2 rows • Commercially raised game animals, rabbits
155°F for 15 seconds:	<ul style="list-style-type: none"> • Ratites (Ostrich, Rhea and Emu) • Injected meats • Mechanically tenderized meats • Raw eggs not for immediate service • Comminuted meat, fish, or commercially raised game animals
165°F for 15 seconds:	<ul style="list-style-type: none"> • Wild game animals • Poultry • Stuffed fish, meat, pork, pasta, ratites & poultry • Stuffing containing fish, meat, ratites & poultry

* **Whole Meat Roasts:** Refer to cooking charts in the *Food Code* ¶ 3-401.11(B)

Applicable Code Sections:

- 3-401.11 Raw Animal Foods-Cooking ^(P, Pf)
- 3-401.12 Microwave Cooking ^(C)
- 3-401.14 Non-Continuous Cooking of Raw Animal Foods ^(P, Pf)

19. Proper reheating procedures for hot holding

NOTE: The reheating temperatures of foods must be taken to determine compliance or noncompliance. Do not rely solely upon discussions with managers or cooks to determine compliance or noncompliance. Temperatures IN and OUT of compliance should be recorded in the “Temperature Observations” section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the “Observations and Corrective Actions” section of the inspection report.

IN/OUT This item should be marked IN or OUT of compliance based on actual temperature measurements of foods upon completion of the reheating process and prior to being placed in hot holding using a calibrated food temperature measuring device. This item should be marked OUT of compliance if the items checked are not reheated to the required temperatures or within 2 hours prior to hot holding.

N.A. This item may be marked N.A. when foods are not held over for a second service and/or reheating for hot holding is not performed in the establishment.

N.O. This item may be marked N.O. such as when foods are held over for a second service, but no foods are reheated during the time of inspection.

Applicable Code Sections:

- 3-403.11 Reheating for Hot Holding ^(P)

20. Proper cooling time and temperatures

NOTE: The requirement for cooling cooked TCS food, is that the food must be cooled from 135°F to 41°F or less in 6 hrs provided that the food is cooled from 135°F to 70°F within the first 2 hours. For example, if a facility cools chili from 135°F to 70°F in 1.5 hours; they then have 4.5 hours to get it from 70°F to 41°F or less. There are two critical limits that must be met with cooling. Discussions with the person in charge along with observations should be used to determine compliance. For instance, during discussion the person in charge says that a food product was cooled overnight in the walk-in cooler. The product is checked and the temperature is 50°F. Eight hours have elapsed from closing to opening. This item should be marked OUT because the product did not cool from 135°F to 70°F within two hours and from 135°F to 41°F or less within a total of 6 hours. Temperatures IN compliance and OUT of compliance should be recorded in the “Temperature Observations” section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the “Observations and Corrective Actions” section of the inspection report. Because the entire cooling process is difficult to observe during an inspection, at the onset of the inspection a determination of whether foods are currently being cooled should be made. If cooling is taking place, temperatures should be taken to make a determination of whether proper cooling is possible with procedures being used.

IN/OUT This item should be marked IN or OUT of compliance based on actual temperatures of TCS foods in the cooling process. The basis for determining IN or OUT of compliance can also be supported through discussion and/or record review which would provide the inspector reliable data of the “start time” for cooling from 135°F. See above NOTE for an example of using actual temperature and discussion with the PIC in determining OUT of compliance without actually being at the establishment during the entire cooling of TCS process, from start to finish.

N.A. This item may be marked N.A. when the establishment does **not** receive raw eggs, shellstock, or milk, prepares **no** TCS food from ambient temperature ingredients that require cooling, and does **not** cool cooked TCS food.

N.O. This item may be marked N.O. when the establishment does cool TCS food, but proper cooling per the prescribed temperature and time parameters cannot be determined during the length of the inspection.

Applicable Code Sections:

3-501.14 Cooling ^(P)

21. Proper hot holding temperatures

NOTE: Temperatures IN compliance and OUT of compliance should be recorded in the “Temperature Observations” section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the “Observations and Corrective Action” section of the inspection report.

IN/OUT This item should be marked IN or OUT of compliance based on actual food temperature measurements using a calibrated food temperature measuring device. This item should be marked IN compliance when the regulatory authority determines that, of the TCS food temperature measurements taken during the inspection, no hot holding temperatures are less than prescribed by the Code. This item is marked OUT of compliance if one TCS food is found out of temperature, unless Time as a Public Health Control (TPHC) is used for that TCS food.

N.A. This item may be marked N.A. when the establishment does **not** hot hold food.

N.O. This item may be marked N.O. when the establishment does hot hold foods, but no foods are being held hot during the time of inspection. Inspections should be conducted during a time when hot holding temperatures can be taken.

Applicable Code Sections:

3-501.16(A)(1) Time/Temperature Control for Safety Food, Hot and Cold Holding ^(P)

22. Proper cold holding temperatures

NOTE: Temperatures IN compliance and OUT of compliance should be recorded in the “Temperature Observations” section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the “Observations and Corrective Action” section of the inspection report.

IN/OUT This item should be marked IN or OUT of compliance based on actual food temperature measurements using a calibrated food temperature measuring device. Discussions should be made with the PIC to determine if a food is in the process of cooling, TPHC is used, or there is an approved method to render a food so that it is not TCS food. This item should be marked IN compliance when the regulatory authority determines that, of the temperature measurements taken during the inspection, no cold holding temperatures are greater than prescribed by the Code. This item should be marked OUT of compliance if one TCS food is found out of temperature, with supportive evidence, unless TPHC is used for that TCS food.

N.A. This item may be marked N.A. when the establishment does not cold hold food.

N.O. This item may be marked N.O. when the establishment does cold hold food, but no foods are being held cold during the time of inspection. Inspections should be conducted during a time when hot holding temperatures can be taken.

Applicable Code Sections:

3-501.16(A)(2) and (B) Time/Temperature Control for Safety Food, Hot and Cold Holding ^(P)

23. Proper date marking and disposition

IN/OUT This item should be marked IN or OUT of compliance. This item would be IN compliance when there is a system in place for date marking all foods that are required to be date marked and is verified through observation. If date marking applies to the establishment, the PIC should be asked to describe the methods used to identify product shelf-life or “consume-by” dating. The regulatory authority must be aware of food products that are listed as exempt from date marking. For disposition, mark IN when foods are all within date marked time limits or food is observed being discarded within date marked time limits or OUT of compliance, such as when date marked food exceeds the time limit or date-marking is not done.

N.A. This item may be marked N.A. when there is no ready-to-eat, TCS food prepared on-premise and held, or commercial containers of ready-to-eat, TCS food opened and held, over 24 hours in the establishment.

N.O. This item may be marked N.O. when the establishment does handle foods requiring date marking, but there are no foods requiring date marking in the facility at the time of inspection.

Applicable Code Sections:

3-501.17 Ready-To-Eat Time/Temperature Control for Safety Food, Date Marking ^(Pf)

3-501.18 Ready-To-Eat Time/Temperature Control for Safety Food, Disposition ^(P)

24. Time as a Public Health Control: procedures and records

IN/OUT This item should be marked IN or OUT of compliance based on direct observations, record review, a discussion with the PIC, and the review of any standard operating procedures to determine if the intent of the Code for use of TPHC is met. This provision only applies if it is the actual intention or conscious decision by the PIC to store TCS food out of temperature control using TPHC; otherwise, it may be a cold or hot holding issue. This item should be marked IN compliance if there is a written procedure at the food establishment that identifies the types of food products that will be held using time only, describes the procedure for how TPHC will be implemented, and if applicable delineates how food items, previously cooked and

cooled before time is used, are properly cooled; and food items (marked or identified) do not exceed the 4-hour limit at any temperature or 6-hour limit at 70°F or less. This item should be marked OUT of compliance when the PIC implies the use of TPHC but does not have an effective mechanism for indicating the point in time when the food is removed from temperature control to the 4 or 6-hour discard time, or a written procedure or an effective mechanism for using TPHC is not present at the facility.

N.A. This item may be marked N.A. when the establishment does not use time only as the public health control.

N.O. This item may be marked N.O. when the establishment uses time only as the public health control, but is not using this practice at the time of inspection.

Applicable Code Sections:

3-501.19 Time as a Public Health Control ^(P, Pf, C)

Consumer Advisory

25. Consumer advisory provided for raw or undercooked food

IN/OUT This item should be marked IN or OUT of compliance based on a thorough review with the PIC of the posted, written and special/daily menus, to determine if untreated shell eggs, meats, fish, or poultry are used as an ingredient or ordered as a raw, raw-marinated, partially cooked, or undercooked food. The advisory also applies to shellstock offered for sale from a retail service case. This item should be marked IN compliance if the establishment provides an advisory that meets the intent of the Food Code for both the disclosure and reminder components. This item should be marked OUT of compliance when raw or undercooked foods are served or sold and there is no consumer advisory, the food item is not **disclosed**, or there is no **reminder** statement. The consumer advisory does not exempt the requirement for freezing for parasite control, nor should it be used for foods that have only gone through the initial heating and cooling stages of a non-continuous cooking process.

N.A. This item may be marked N.A. when a food establishment does not serve a ready-to-eat food that necessitates an advisory, i.e., an animal food that is raw, undercooked, or not otherwise processed to eliminate pathogens.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens ^(Pf)

Highly Susceptible Population

26 Pasteurized foods used; prohibited foods not offered

NOTE: Discussions with the PIC and employees regarding whether or not certain foods are served or certain practices occur in the establishment, along with observations should be used to determine compliance.

IN/OUT This item should be marked IN or OUT of compliance based on direct observations and discussions with the PIC and food employees regarding whether or not certain foods are served or certain practices occur in an establishment serving a highly susceptible population. Violations of bare hand contact by food employees serving a highly susceptible population ¶ 3-801.11(D) is marked under Item #7. This item should be marked IN compliance if only treated/pasteurized juices/juice beverages are served; only pasteurized eggs are used in recipes if eggs are undercooked and if eggs are combined, unless there is a cook step or HACCP plan to control *Salmonella* enteritidis; no raw or partially cooked animal foods or raw

seed sprouts are served; and no unopened packaged food is re-served following service to patients in medical isolation or quarantine.

N.A. This item may be marked N.A. if a highly susceptible population is not served.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-801.11(A), (B), (C), (E) and (G) Pasteurized Foods, Prohibited Re-Service, and Prohibited Food ^(P, C)

Food/Color Additives and Toxic Substances

27. Food additives: approved and properly used

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food ingredients in storage and listed as product ingredients supplemented by discussion with the PIC. This item is marked IN compliance if approved food and color additives are on site and used properly or if sulfites are on the premises, and they are not applied to fresh fruits/vegetables for raw consumption. Approved food additives are listed and have threshold limits in accordance with the CFRs, and does not apply to food additives that are considered Generally Recognized as Safe (GRAS), such as salt, pepper, etc. This item is marked OUT of compliance if unapproved additives are found on the premises or approved additives are improperly used, such as sulfites being applied to fresh fruits or vegetables.

N.A. This item may be marked N.A. if the food establishment does **not** use any additives or sulfites on the premises.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-202.12 Additives ^(P)

3-302.14 Protection from Unapproved Additives ^(P)

28. Toxic substances properly identified, stored, and used; held for retail sale, properly Stored

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food labeling, storage, reconstitution, and application of bulk and working containers of cleaning agents and sanitizers, personal care items, first aid supplies, medicines, pesticides, and potential toxic and poisonous substances. This item should be marked IN compliance when bulk and working containers of cleaning agents and sanitizers are labeled; sanitizing solutions are not exceeding the maximum concentrations; personal care items, first aid supplies, medicines, and chemicals are stored separate from and not above food, equipment, utensils, linens, and single-service and single-use articles; and restricted use pesticides are applied only by or under the supervision of a certified applicator. This item should be marked OUT of compliance if a cleaning agent or sanitizer is not properly identified and stored; if a sanitizing solution has a higher concentration than prescribed and medicines and first aid kits are improperly labeled and stored. Violations of solutions exceeding the recommended concentration in chemical washes for fruits and vegetables (§7-204.12) would be marked under Item #42.

N.A. This item may be marked N.A. if the establishment does not hold poisonous or toxic materials for retail sale.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

7-101.11 Identifying Information, Prominence-Original Containers ^(Pf)

7-102.11 Common Name-Working Containers ^(Pf)

7-201.11 Separation-Storage ^(P)

7.202.11 Restriction-Presence and Use ^(Pf)

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7-202.12	Conditions of Use ^(P, Pf, C)
7-203.11	Poisonous or Toxic Material Containers-Container Prohibitions ^(P)
7-204.11	Sanitizers, Criteria-Chemicals ^(P)
7-204.12	Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria ^(P,)
7-204.13	Boiler Water Additives, Criteria ^(P)
7-204.14	Drying Agents, Criteria ^(P)
7-205.11	Incidental Food Contact, Criteria-Lubricants ^(P)
7-206.11	Restricted Use Pesticides, Criteria ^(P)
7-206.12	Rodent Bait Stations ^(P)
7-206.13	Tracking Powders, Pest Control and Monitoring ^(P, C)
7-207.11	Restriction and Storage-Medicines ^(P, Pf)
7-207.12	Refrigerated Medicines, Storage ^(P)
7-208.11	Storage-First Aid Supplies ^(P, Pf)
7-209.11	Storage-Other Personal Care Items ^(C)
7-301.11	Separation-Storage and Display, Stock and Retail Sale ^(P)

Conformance with Approved Procedures

29. Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan

NOTE Except for fish a HACCP plan is not required when a TCS food is packaged using a reduced oxygen packaging method and is labeled with production time and date, held at required cold holding temperature, and removed from ROP packaging within 48 hours after packaging at the food establishment.

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food preparation and storage, a discussion with the PIC to determine if there are specialized food processes [i.e. smoking food, curing food, reduced oxygen packaging, using food additives to render a food so that it is not TCS food, cook chill, sous vide, etc.] and the record review of standard operating procedures and HACCP documentation. This item should be marked IN compliance when observations of food operations and review of available records indicate compliance is being met with regards to specialized food processes and HACCP plans were submitted to the regulatory authority prior to conducting a ROP operation that conforms to procedures within §3-502.12. This item should be marked OUT of compliance if the inspection reveals specialized food processes that are not approved by the regulatory authority are performed or not conducted in accordance with the approved variance or a HACCP plan was not submitted to the regulatory authority prior to engaging in a ROP operation without a variance.

N.A. This item may be marked N.A. if the establishment is not required by the regulatory authority to have a variance or HACCP plan, juice is not packaged or reduced oxygen packaging is not done on the premises.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-404.11	Treating Juice ^(P, Pf)
3-502.11	Variance Requirement ^(Pf)
3-502.12	Reduced Oxygen Packaging, Criteria ^(P, Pf)
4-204.110(B)	Molluscan Shellfish Tanks ^(Pf)
8-103.12	Conformance with Approved Procedures ^(P, Pf)
8-201.13	When a HACCP Plan is Required ^(C)
8-201.14	Contents of a HACCP Plan ^(Pf)

Good Retail Practices (GRPs)

D. MARKING INSTRUCTIONS FOR EACH GOOD RETAIL PRACTICE (GRP) ON THE INSPECTION REPORT

Good Retail Practices (GRPs) are systems to control basic operational and sanitation conditions within a facility, and if not controlled, they could be contributing factors to foodborne illness by introducing hazards (biological, chemical and physical), into the end product, either directly or indirectly. For example, equipment in disrepair, such as a cutting board with deep grooves/cuts, makes effective cleaning difficult or impossible, and thereby could introduce a bacterial hazard onto food that comes into contact with the board. In addition, in assessing GRPs, it is important to make an overall assessment of the conditions by looking for trends versus an isolated incident; and the potential public health impact. For example, a few missing floor tiles in a dry area may not rise to the level of a “violation”; however, missing floor tiles in an area where equipment is subject to in-place manual cleaning without the use of an enclosed clean in place (CIP) system, i.e., using pressure hoses over band saws, slicers, or mixers, could create conditions whereby a bacterial hazard could be introduced on to the food equipment. These items usually require judgment, and if uncorrected, the regulatory authority must decide whether or not these conditions would lead to potential contamination.

GRPs are the methods used in, or the facilities or controls used for, the receiving, preparation, storage, serving, packaging or holding of food which are designed to assure unsanitary conditions do not lead to the introduction of hazards or unintentional substances into the end product. The intention of this inspection form is to focus the inspector’s attention on those factors that have been shown to be most often linked with causing foodborne illness. Since the major emphasis of an inspection should be on the Risk Factors that cause foodborne illness and the Public Health interventions that have the greatest impact on preventing foodborne illness, the GRPs have been given less importance on the inspection form and a differentiation between IN, OUT, N.A. and N.O. is not made in this area, with a few exceptions noted below. For marking the GRPs section, place an “X” in the box to the left of the numbered item if a code provision under that item is **OUT** of compliance. Document each violation of the code provision for the item number in the “Observations and Corrective Actions” section on the second page of the inspection report. For items marked **OUT** of compliance, further indicate the **VIOLATION STATUS** by marking an “X” in the corresponding box: **COS** = Corrected on site during inspection and **R** = Repeat violation per the same instructions as given in the Risk Factor section. References to the appropriate Food Code provisions that can be debited under each numbered GRP item are listed in Guide 3-B.

Note: Items 30, 32, and 33 will allow for either three or four marking options. Item 30 allows for IN OUT or N.A., and items 32 and 33 allow for IN, OUT, N.A. or N.O. For marking in the GRP Section place an “A” in the box to the left of the numbered item if the code provision under that item is **not applicable** or and “O” for **not observed**.

E. TEMPERATURE OBSERVATIONS

Item/location Record the common name of the food as well as the condition, process, and location of the food at the time of monitoring e.g. hot holding, refrigerator, prep-table. Temperatures in compliance and out of compliance should be documented. If there is insufficient space for the number of temperatures taken, record the additional temperatures in the “Observations and Corrective Actions” section of the inspection report.

Food

Temperature Record the temperature indicated on the inspector's thermometer. Specify the measurement in °F or °C. *(Note: Food temperature measuring devices that are scaled only in Fahrenheit should be accurate to ±2°F in the intended range of use. Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit should be accurate to ± 1°C in the intended range of use.)*

F. OBSERVATIONS AND CORRECTIVE ACTIONS

Include here specific descriptions of violations observed and recorded in the Risk Factors and Interventions section and Good Retail Practices check boxes. Also include corrective actions for the noted violations and temperatures if there is insufficient space in the allotted section for temperature recordings.

G. SIGNATURE BLOCK

Person in Charge The PIC is the individual present at a food establishment who is responsible for the operation at the time of the inspection.
Inspector The Inspector is the individual conducting the inspection.
Date The date the inspection is completed.
Follow-up The determination of whether to conduct a reinspection or other enforcement action.
Follow-up Date The date the follow-up inspection will be conducted.

Safe Food and Water

30. Pasteurized eggs used where required

Certain menu items use eggs as an ingredient in the preparation of RTE foods, such as Caesar salad, Hollandaise sauce, etc. This is verified by discussion with the PIC and food employees regarding the substitution of pasteurized egg products for raw eggs in uncooked foods, unless allowed under ¶ 3-401.11(D)(2).

Applicable Code Section:

3-302.13 Pasteurized Eggs Substituted for Raw Eggs for Certain Recipes ^(P)

31. Water and ice from approved source

There are two types of systems: Public Water System or Non-Public Water System. Regardless of its source, it must meet drinking water standards established by EPA and applicable state drinking water quality standards. If a non-public system is used as Drinking water, the water is sampled / tested at least yearly and records retained on file at the food establishment or per state regulations. Consideration must be given to the supply containers, piping, hoses, etc., connected to the APPROVED source when water is made available for mobile and/or temporary food establishment without a permanent supply.

Applicable Code Sections:

3-202.16 Ice ^(P)
5-101.11 Approved System-Source ^(P)
5-102.11 Standards-Quality ^(P)
5-102.12 Nondrinking Water ^(P)
5-102.13 Sampling ^(Pf)
5-102.14 Sample Report ^(C)
5-104.12 Alternative Water Supply ^(Pf)

32. Variance obtained for specialized processing methods

When a Food Establishment wants to deviate from a requirement in the code, utilizes Specialized Processing Methods as specified in § 3-502.11 such as Smoking Food for Preservation, curing food etc. a variance must first be obtained from the regulatory authority. A HACCP plan may also be required as listed in ¶ 8-201.13(A) as part of the variance request.

N.A. This item may be marked N.A. if the establishment is not engaged in a specialized processing method, other operation requiring a variance and a HACCP plan or a process or processing method determined by the regulatory authority to require a variance and a HACCP plan.

Applicable Code Section:

8-103.11 Documentation of Proposed Variance and Justification ^(Pf)

Food Temperature Control

33. Proper cooling methods used; adequate equipment for temperature control

A determination must first be made that cooling food is part of the processing step. To assess whether or not the methods used facilitate the cooling criteria specified under § 3-501.14, a discussion with the PIC should support actual observations used in cooling foods. There should be enough equipment with sufficient capacity used for the cooling, heating and hot/cold holding of foods requiring temperature control as specified in Chapter 3 to meet the demands of the operation. Observations must support the determination of compliance status. Frozen food is solid to the touch.

Applicable Code Sections:

3-501.11 Frozen Food ^(C)

3-501.15 Cooling Methods ^(Pf, C)

4-301.11 Cooling, Heating, and Holding Capacities-Equipment ^(Pf)

34. Plant food properly cooked for hot holding

In determining compliance, observation along with an actual cooking temperature must be obtained.

N.A. This item may be marked N.A. if vegetables and fruits are **not** cooked for hot holding in the establishment.

N.O. This item may be marked N.O. when plant foods are cooked for hot holding, but are not available for observation during the inspection.

Applicable Code Section:

3-401.13 Plant Food Cooking for Hot Holding ^(Pf)

35. Approved thawing methods used

Observing and then gaining an understanding of the establishment's thawing method(s) will help in determining whether a violation exists from the approved thawing methods found under § 3-501.13 as well as the level of risk imposed. Keep in mind that various food products especially those destined for deep-fat frying are often slacked (not thawed) prior to cooking.

Applicable Code Sections:

3-501.12 Time/Temperature Control for Safety Food, Slacking ^(C)

3-501.13 Thawing ^(C)

N.A. This item may be marked N.A. if TCS food are **not** thawed.

N.O. This item may be marked N.O. if this food is thawed, but thawing was not observed during the inspection.

36. Thermometers provided and accurate

Thermometers provide a means for assessing active managerial control of TCS food temperatures. Determine compliance by observing the in-use storage location and verifying the scaling of the temperature measuring devices in the range of use to measure food, water, or ambient air temperatures. Food thermometers must be calibrated at a frequency to ensure accuracy. Food thermometers should be accessible for use by employees and have a probe size appropriate to the food item.

Applicable Code Sections:

- 4-203.11 Temperature Measuring Devices, Food-Accuracy ^(Pf)
- 4-203.12 Temperature Measuring Devices, Ambient Air and Water-Accuracy ^(Pf)
- 4-204-112 Temperature Measuring Devices-Functionality ^(Pf, C)
- 4-302.12 Food Temperature Measuring Devices ^(Pf)
- 4-502.11(B) Good Repair and Calibration ^(Pf)

Food Identification

37. Food properly labeled; original container

Packaged foods are required to conform to specific labeling laws. Foods packaged within the food establishment must also conform to the appropriate labeling laws, with considerations given to accuracy as well as not being misleading. In addition, all major food allergens, if present, must be accurately declared on the package. Working containers and bulk foods removed from their original packaging require some level of assessment as to how recognizable the food is without labeling by its common name. Molluscan shellfish and vended TCS foods must specifically be assessed based on their specific packaging and labeling requirements.

Applicable Code Sections:

- 3-202.17 Shucked Shellfish, Packaging and Identification ^(Pf, C)
- 3-203.11 Molluscan Shellfish, Original Container ^(C)
- 3-302.12 Food Storage Containers Identified with Common Name of Food ^(C)
- 3-305.13 Vended Time/Temperature Control for Safety Food, Original Container ^(C)
- 3-601.11 Standards of Identity ^(C)
- 3-601.12 Honestly Presented ^(C)
- 3-602.11 Food Labels ^(Pf, C)
- 3-602.12 Other Forms of Information ^(C)

Prevention of Food Contamination

38. Insects, rodents and animals not Present

An assessment is made through observation and discussion with the PIC for measures taken to control the presence of pests in the food establishment, including elimination of entry points and harborage areas, and removal of pests and its evidence. Insect trapping devices must not be located over food preparation areas.

Applicable Code Sections:

- 2-403.11 Handling Prohibition-Animals ^(Pf)
- 6-202.13 Insect Control Devices, Design and Installation ^(C)
- 6-202.15 Outer Openings, Protected ^(C)
- 6-202.16 Exterior Walls and Roofs, Protective Barrier ^(C)
- 6-501.111 Controlling Pests ^(Pf, C)
- 6-501.112 Removing Dead or Trapped Birds, Insects, Rodents and other Pest ^(C)
- 6-501.115 Prohibiting Animals ^(Pf)

39. Contamination prevented during food preparation, storage and display

The observation and understanding of the flow of food items from the point of receipt to the point of sale, service or distribution is necessary to determine whether a violation exists. Food is subject to direct and indirect sources of contamination in the establishment. Sources may be related to the working environment, packaging, adequacy of storage facilities, and exposure of food on display to contamination (i.e. salad bars).

Applicable Code Sections:

3-202.19	Shellstock, Condition ^(C)
3-303.11	Ice Used as Exterior Coolant, Prohibited as Ingredient ^(P)
3-303.12	Storage or Display of Food in Contact with Water or Ice ^(C)
3-304.13	Linens and Napkins, Use Limitations ^(C)
3-305.11	Food Storage-Preventing Contamination from the Premises ^(C)
3-305.12	Food Storage, Prohibited Areas ^(C)
3-305.14	Food Preparation ^(C)
3-306.11	Food Display-Preventing Contamination by Consumers ^(P)
3-306.12	Condiments, Protection ^(C)
3-306.13(B) and (C)	Consumer Self-Service Operations ^(Pf)
3-307.11	Miscellaneous Sources of Contamination ^(C)
6-404.11	Segregation and Location-Distressed Merchandise ^(Pf)

40. Personal cleanliness

Observation of facility personnel for clean outer clothing, effective hair restraints, prohibited jewelry and the condition or protection of fingernails must be made.

Applicable Code Sections:

2-302.11	Maintenance-Fingernails ^(Pf)
2-303.11	Prohibition-Jewelry ^(C)
2-304.11	Clean Condition-Outer Clothing ^(C)
2-402.11	Effectiveness-Hair Restraints ^(C)

41. Wiping cloths; properly used and stored

Wiping cloths are to be used for a designated purpose and properly used. When stored in solution, the solutions should be reasonably clean and maintained at the proper sanitizer concentration (§4-501.114). Solutions exceeding the recommended sanitizer concentrations would be marked on the Inspection Form under item no.26, Toxic substances properly identified, stored, and used. Sponges, if present, are not to be used in contact with clean/sanitized food contact surfaces.

Applicable Code Sections:

3-304.14	Wiping Cloths, Use Limitation ^(C)
4-101.16	Sponges Use Limitation ^(C)
4-901.12	Wiping Cloths, Air Drying Location ^(C)

42. Washing fruits and vegetables

Raw fruits and vegetables are to be washed prior to their preparation or offered as RTE. Chemicals are allowed for washing fruits and vegetables, along with simply washing them in water. Chemicals that are used in the wash water for fruits and vegetables must be listed and approved with threshold limits in accordance with the CFR's. Refer to the label or labeling of the additive for adequate directions and to assure safe use. Discussion with the PIC and food employees will help determine the establishment's practice.

Applicable Code Sections:

3-302.15	Washing Fruits and Vegetables ^(Pf)
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7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria ^(P)

43. In-use utensils; properly stored

Based on the type of operation, there are a number of methods available for storage of in-use utensils during pauses in food preparation or dispensing, such as in the food, clean and protected, or under running water to prevent bacterial growth. If stored in a container of water, the water temperature must be at least 135°F. In-use utensils may not be stored in chemical sanitizer or ice between uses. Ice scoops may be stored handles up in an ice bin except for an ice machine.

Applicable Code Sections:

3-304.12 In-Use Utensils, Between-Use Storage ^(C)

44. Utensils, equipment and linens; properly stored, dried, handled

An assessment is made of the overall storage practices and handling of clean equipment and utensils, including tableware located in the various areas within an establishment, including the basement, wait station and dining room. Equipment must be air dried prior to storage, and linens must be properly cleaned and stored.

Applicable Code Sections:

4-801.11 Clean Linens ^(C)
4-802.11 Specifications-Laundering Frequency ^(C)
4-803.11 Storage of Soiled Linens ^(C)
4-803.12 Mechanical Washing ^(C)
4-901.11 Equipment and Utensils, Air-Drying Required ^(C)
4-903.11(A), (B) and (D) Equipment, Utensils, Linens and Single-Service and Single-Use Articles-Storing ^(C)
4-903.12 Prohibitions ^(C)
4-904.11 Kitchenware and Tableware-Preventing Contamination ^(C)
4-904.12 Soiled and Clean Tableware ^(C)
4-904.13 Preset Tableware ^(C)

45. Single-use/single-service articles; properly stored, used

These items are not designed to be cleaned and re-used; therefore, they must be properly stored and protected to prevent from possible contamination. Food establishments without facilities for cleaning and sanitizing kitchenware and tableware shall provide only single-use and single-service articles.

Applicable Code Sections:

4-502.12 Single-Service and Single-Use Articles, Required Use ^(P)
4-502.13 Single-Service and Single-Use Articles-Use Limitations ^(C)
4-502.14 Shells, Use Limitations ^(C)
4-903.11(A) and (C) Equipment, Utensils, Linens and Single-Service and Single-Use Articles-Storing ^(C)
4-903.12 Prohibitions ^(C)
4-904.11 Kitchenware and Tableware-Preventing Contamination ^(C)

46. Gloves used properly

The observation of food preparation activities and glove-use by food employees is necessary. There should be a discussion with the PIC on how gloves are used, if applicable, in food preparation activities. Gloves may serve as a source of cross-contamination if misused.

Applicable Code Sections:

3-304.15(B)-(D) Gloves, Use Limitations ^(C)

Utensils, Equipment and Vending

47. Food and non-food-contact surfaces cleanable, properly designed, constructed and used

Equipment and utensils must be properly designed and constructed, and in good repair. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (e.g., equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers.

Applicable Code Sections:

- 3-304.16 Using Clean Tableware for Second Portions and Refills ^(C)
- 3-304.17 Refilling Returnables ^(C)
- 4-101.11 Characteristics-Materials for Construction and Repair ^(P, C)
- 4-101.12 Cast Iron, Use Limitations ^(C)
- 4-101.13 Lead, Use Limitation ^(P, C)
- 4-101.14 Copper Use Limitation ^(P)
- 4-101.15 Galvanized Metal, Use Limitation ^(P)
- 4-101.17 Wood, Use Limitation ^(C)
- 4-101.18 Nonstick Coatings, Use Limitation ^(C)
- 4-101.19 Nonfood-Contact Surfaces ^(C)
- 4-102.11 Characteristics-Single-Service and Single-Use ^(P, C)
- 4-201.11 Equipment and Utensils-Durability and Strength ^(C)
- 4-201.12 Food Temperature Measuring Devices ^(P)
- 4-202.11 Food-Contact Surfaces-Cleanability ^(Pf)
- 4-202.12 CIP Equipment ^(Pf, C)
- 4-202.13 "V" Threads, Use Limitation ^(C)
- 4-202.14 Hot Oil Filtering Equipment ^(C)
- 4-202.15 Can Openers ^(C)
- 4-202.16 Nonfood-Contact Surfaces ^(C)
- 4-202.17 Kick Plates Removable ^(C)
- 4-204.12 Equipment Openings, Closures and Deflectors ^(C)
- 4-204.13 Dispensing Equipment, Protection of Equipment and Food ^(P, C)
- 4-204.14 Vending Machine Vending Stage Closure ^(C)
- 4-204.15 Bearings and Gear Boxes, Leakproof ^(C)
- 4-204.16 Beverage Tubing, Separation ^(C)
- 4-204.17 Ice Units, Separation of Drains ^(C)
- 4-204.18 Condenser Unit, Separation ^(C)
- 4-204.19 Can Openers on Vending Machines ^(C)
- 4-204.110(A) Molluscan Shellfish Tanks ^(P)
- 4-204.111 Vending Machines, Automatic Shutoff ^(P)
- 4-204.120 Equipment Compartments, Drainage ^(C)
- 4-204.121 Vending Machines, Liquid Waste Products ^(C)
- 4-204.122 Case Lot Handling Apparatuses, Movability ^(C)
- 4-204.123 Vending Machine Doors and Openings ^(C)
- 4-302.11 Utensils, Consumer Self-Service ^(Pf)
- 4-401.11 Equipment, Clothes Washers, Dryers and Storage Cabinets, Contamination Prevention-Location ^(C)
- 4-402.11 Fixed Equipment, Spacing or Sealing-Installation ^(C)
- 4-402.12 Fixed Equipment, Elevation or Sealing ^(C)

- 4-501.11 Good Repair and Proper Adjustment-Equipment ^(C)
- 4-501.12 Cutting Surfaces ^(C)
- 4-501.13 Microwave Ovens ^(C)
- 4-502.11(A) and (C) Good Repair and Calibration-Utensils and Temperature and Pressure Measuring Devices ^(C)
- 4-603.11 Dry Cleaning-Methods ^(C)
- 4-902.11 Food-Contact Surfaces-Lubricating and Reassembling ^(C)
- 4-902.12 Equipment-Lubricating and Reassembling ^(C)

48. Warewashing facilities, installed, maintained, used, test strips

Adequate warewashing facilities must be available and used for the cleaning and sanitization of food-contact surfaces, including the availability of means to monitor its use and the effectiveness of sanitization. For example, an irreversible registering temperature indicator is provided and readily accessible for measuring the utensil surface temperature for establishment that have a hot water mechanical warewashing operation. Observation of manual and mechanical warewashing methods are made to **assess** the procedure for cleaning and sanitizing equipment and utensils.

Applicable Code Sections:

- 4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment ^(C)
- 4-204.113 Warewashing Machine, Data Plate Operation Specifications ^(C)
- 4-204.114 Warewashing Machines, Internal Baffles ^(C)
- 4-204.115 Warewashing Machines, Temperature Measuring Devices ^(Pf)
- 4-204.116 Manual Warewashing Equipment, Heaters and Baskets ^(Pf)
- 4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers ^(Pf)
- 4-204.118 Warewashing Machines, Flow Pressure Device ^(C)
- 4-204.119 Warewashing Sinks and Drainboards, Self-Draining ^(C)
- 4-301.12 Manual Warewashing, Sink Compartment Requirements ^(Pf, C)
- 4-301.13 Drainboards ^(C)
- 4-302.13 Temperature Measuring Devices, Manual and Mechanical Warewashing ^(Pf)
- 4-302.14 Sanitizing Solutions, Testing Devices ^(Pf)
- 4-501.14 Warewashing Equipment, Cleaning Frequency ^(C)
- 4-501.15 Warewashing Machines, Manufacturers' Operating Instructions ^(C)
- 4-501.16 Warewashing Sinks, Use Limitation ^(C)
- 4-501.17 Warewashing Equipment, Cleaning Agents ^(Pf)
- 4-501.18 Warewashing Equipment, Clean Solutions ^(C)
- 4-501.19 Manual Warewashing Equipment, Wash Solution Temperature ^(Pf)
- 4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature ^(Pf)
- 4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration ^(Pf)
- 4-603.12 Precleaning ^(C)
- 4-603.13 Loading of Soiled Items, Warewashing Machines ^(C)
- 4-603.14 Wet Cleaning ^(C)
- 4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment ^(C)
- 4-603.16 Rinsing Procedures ^(C)

49. Non-food-contact surfaces clean

Observations should be made to determine if the frequency of cleaning is adequate to prevent soil accumulations on non-food-contact surfaces.

Applicable Code Sections:

- 4-601.11(B) and (C) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils ^(C)
- 4-602.13 Nonfood Contact Surfaces ^(C)

Physical Facilities

50. Hot and cold water available; adequate pressure

Regardless of the supply system, the distribution of water to the facility must be protected and operated according to law. Adequate pressure is to be maintained at all fixtures during peak demand including the capacity to provide hot water at peak hot water demand.

Applicable Code Sections:

- 5-103.11 Capacity-Quantity and Availability ^(Pf)
- 5-103.12 Pressure ^(Pf)
- 5-104.11 System-Distribution, Delivery, and Retention ^(Pf)

51. Plumbing installed; proper backflow devices

The observation of an approved plumbing system, installed and maintained, including the equipment and devices connected to the potable water supply, is necessary to determine whether a violation exists. An assessment of the layout of the establishment and the water distribution system is made to determine if there are any points at which the potable water supply is subject to contamination or is in disrepair.

Applicable Code Sections:

- 5-101.12 System Flushing and Disinfection ^(P)
- 5-201.11 Approved-Materials ^(P)
- 5-202.11 Approved System and Cleanable Fixtures ^(P, C)
- 5-202.13 Backflow Prevention, Air Gap ^(P)
- 5-202.14 Backflow Prevention Device, Design Standard ^(P)
- 5-202.15 Conditioning Device, Design ^(C)
- 5-203.13 Service Sink ^(C)
- 5-203.14 Backflow Prevention Device, When Required ^(P)
- 5-203.15 Backflow Prevention Device, Carbonator ^(C)
- 5-204.12 Backflow Prevention Device, Location ^(C)
- 5-204.13 Conditioning Device, Location ^(C)
- 5-205.12 Prohibiting a Cross Connection ^(P, Pf)
- 5-205.13 Scheduling Inspection and Service for a Water System Device ^(Pf)
- 5-205.14 Water Reservoir of Fogging Devices, Cleaning ^(P)
- 5-205.15 System Maintained in Good Repair ^(P, C)
- 5-301.11 Approved-Materials, Mobile Water Tank and Mobile Food Establishment Water Tank ^(P, C)
- 5-302.11 Enclosed System, Sloped to Drain ^(C)
- 5-302.12 Inspection and Cleaning Port, Protected and Secured ^(C)
- 5-302.13 "V" Type Threads, Use Limitation ^(C)
- 5-302.14 Tank Vent, Protected ^(C)
- 5-302.15 Inlet and Outlet, Sloped to Drain ^(C)
- 5-302.16 Hose, Construction and Identification ^(P, C)
- 5-303.11 Filter, Compressed Air ^(P)
- 5-303.12 Protective Cover or Device ^(C)
- 5-303.13 Mobile Food Establishment Tank Inlet ^(C)
- 5-304.11 System Flushing and Sanitization-Operation and Maintenance ^(P)
- 5-304.12 Using a Pump and Hoses, Backflow Prevention ^(C)
- 5-304.13 Protecting Inlet, Outlet and Hose Fitting ^(C)
- 5-304.14 Tank, Pump and Hoses, Dedication ^(P)

52. Sewage and waste water properly disposed

There are two types of systems: public sewage treatment plant and an individual sewage disposal system.

Observations of the facilities overall sewage and wastewater system is necessary to determine if a violation exists. Indications that a system is not functioning properly may include the presence of sewage

back-up into the establishment or outdoors on the ground. Condensate drippage and other non-sewage wastes must be drained to a system in accordance to LAW, and backflow prevention, if required, installed between the sewage system and drain of equipment holding food or utensils. Mobile wastewater holding tanks must also be assessed for capacity and maintenance.

Applicable Code Sections:

- 5-401.11 Capacity and Drainage ^(C)
- 5-402.11 Backflow Prevention ^(P)
- 5-402.12 Grease Trap ^(C)
- 5-402.13 Conveying Sewage ^(P)
- 5-402.14 Removing Mobile Food Establishment Wastes ^(Pf)
- 5-402.15 Flushing a Waste Retention Tank ^(C)
- 5-403.11 Approved Sewage Disposal System ^(P)
- 5-403.12 Other Liquid Wastes and Rainwater ^(C)

53. Toilet facilities: properly constructed, supplied, clean

A toilet facility should be assessed to determine if: it is not an attractant to insects; the number of fixtures are adequate; toilet tissue and a covered trash receptacle (ladies room only) are provided; fixtures are not being kept clean; and the door self-closes to prevent recontamination of hands.

Applicable Code Sections:

- 5-203.12 Toilets and Urinals ^(C)
- 5-501.17 Toilet Room Receptacle, Covered ^(C)
- 6-202.14 Toilet Rooms, Enclosed ^(C)
- 6-302.11 Toilet Tissue, Availability ^(Pf)
- 6-402.11 Conveniently Located ^(C)
- 6-501.18 Cleaning of Plumbing Fixtures ^(C)
- 6-501.19 Closing Toilet Room Doors ^(C)

54. Garbage/refuse properly disposed; facilities maintained

The assessment of the refuse collection and disposal areas for proper receptacles and maintenance is necessary to determine whether a violation exists. Since refuse areas may attract and harbor insects and pests, as well as create a public health nuisance, particular attention must be paid to the maintenance of the refuse facilities and area.

Applicable Code Sections:

- 5-501.11 Outdoor Storage Surface ^(C)
- 5-501.12 Outdoor Enclosure ^(C)
- 5-501.13 Receptacles ^(C)
- 5-501.14 Receptacles in Vending Machines ^(C)
- 5-501.15 Outside Receptacles ^(C)
- 5-501.16 Storage Areas, Rooms and Receptacles, Capacity and Availability ^(C)
- 5-501.18 Cleaning Implements and Supplies ^(C)
- 5-501.19 Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location ^(C)
- 5-501.110 Storage Refuse, Recyclables and Returnables ^(C)
- 5-501.111 Area, Enclosures and Receptacles, Good Repair ^(C)
- 5-501.112 Outside Storage Prohibitions ^(C)
- 5-501.113 Covering Receptacles ^(C)
- 5-501.114 Using Drain Plugs ^(C)
- 5-501.115 Maintaining Refuse Areas and Enclosures ^(C)
- 5-501.116 Cleaning Receptacles ^(C)
- 5-502.11 Frequency-Removal ^(C)

- 5-502.12 Receptacles or Vehicles ^(C)
- 5-503.11 Community or Individual Facility ^(C)
- 6-202.110 Outdoor refuse Areas, Curbed and Graded to Drain ^(C)

55. Physical facilities installed, maintained, and clean

Observations are made of the overall conditions or practices related to the physical facility (e.g., materials used, good repair, and maintained). It is important to make an overall assessment of the physical facility conditions to determine the level of compliance and the potential public health impact involved if compliance is not met. Storage of maintenance tools, use of laundry facilities, if applicable, disposal of mop water and separate living/sleeping quarters are included in this section.

Applicable Code Sections:

- 4-301.15 Clothes Washers and Dryers ^(C)
- 4-401.11(C) Equipment, Cloths Washers and Dryers, and Storage Cabinets, Contamination Prevention ^(C)
- 4-803.13 Use of Laundry Facilities ^(C)
- 6-101.11 Surface Characteristics-Indoor Areas ^(C)
- 6-102.11 Surface Characteristics-Outdoor Areas ^(C)
- 6-201.11 Floors, Walls and Ceilings-Cleanability ^(C)
- 6-201.12 Floors, Walls, and Ceilings, Utility Lines ^(C)
- 6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed ^(C)
- 6-201.14 Floor Carpeting, Restrictions and Installation ^(C)
- 6-201.15 Floor Covering, Mats and Duckboards ^(C)
- 6-201.16 Wall and Ceiling Coverings and Coatings ^(C)
- 6-201.17 Walls and Ceilings, Attachments ^(C)
- 6-201.18 Walls and Ceilings, Studs, Joists, and Rafters ^(C)
- 6-202.17 Outdoor Food Vending Areas. Overhead Protection ^(C)
- 6-202.18 Outdoor Servicing Areas, Overhead Protection ^(C)
- 6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain ^(C)
- 6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition ^(P)
- 6-202.112 Living or Sleeping Quarters, Separation ^(C)
- 6-501.11 Repairing-Premises, Structures, Attachments, and Fixtures-Methods ^(C)
- 6-501.12 Cleaning, Frequency and Restrictions ^(C)
- 6-501.13 Cleaning Floors, Dustless Methods ^(C)
- 6-501.15 Cleaning Maintenance Tools, Preventing Contamination ^(Pf)
- 6-501.16 Drying Mops ^(C)
- 6-501.17 Absorbent Materials on Floors, Use Limitation ^(C)
- 6-501.113 Storing Maintenance Tools ^(C)
- 6-501.114 Maintaining Premises, Unnecessary Items and Litter ^(C)

56. Adequate ventilation and lighting; designated areas used

Observations should be made to ensure that the ventilation is adequately preventing an accumulation of condensation, grease or other soil from potentially contaminating food and the surrounding environment and that lights are at an adequate light intensity, and personal belongings are properly stored to maintain clean and sanitary facility and protect food and equipment.

Applicable Code Sections:

- 4-202.18 Ventilation Hood Systems, Filters ^(C)
- 4-204.11 Ventilation Hood Systems, Drip Prevention ^(C)
- 4-301.14 Ventilation Hood Systems, Adequacy ^(C)
- 6-202.11 Light Bulbs, Protective Shielding ^(C)
- 6-202.12 Heating, Ventilation, Air Conditioning System Vents ^(C)
- 6-303.11 Intensity-Lighting ^(C)

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- 6-304.11 Mechanical-Ventilation ^(C)
- 6-305.11 Designation-Dressing Areas and Lockers ^(C)
- 6-403.11 Designated Areas-Employee Accommodations for eating / drinking/smoking ^(C)
- 6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition ^(C)
- 6-501.110 Using Dressing Rooms and Lockers ^(C)

Chart 4-A

Summary Chart for Minimum Cooking Food Temperatures and Holding Times Required by Chapter 3

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Raw Eggs prepared for immediate service Commercially Raised Game Animals and Exotic Species of Game Animals Fish, Pork, and Meat Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	<p align="center">63°C (145°F)</p>	<p align="center">15 seconds</p>
Raw Eggs not prepared for immediate service Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals Comminuted Fish and Meats Injected Meats Mechanically Tenderized Meats	<p align="center">70°C (158°F) 68°C (155°F) 66°C (150°F) 63°C (145°F)</p>	<p align="center">< 1 second 15 seconds 1 minute 3 minutes</p>
Poultry Baluts Stuffed Fish; Stuffed Meat; Stuffed Pasta; Stuffed Poultry; Stuffed Ratites Stuffing Containing Fish, Meat, Poultry, or Ratites Wild Game Animals	<p align="center">74°C (165°F)</p>	<p align="center">15 seconds</p>
Food Cooked in A Microwave Oven	<p align="center">74°C (165°F)</p>	<p align="center">and hold for 2 minutes after removing from microwave oven</p>

Chart 4-B

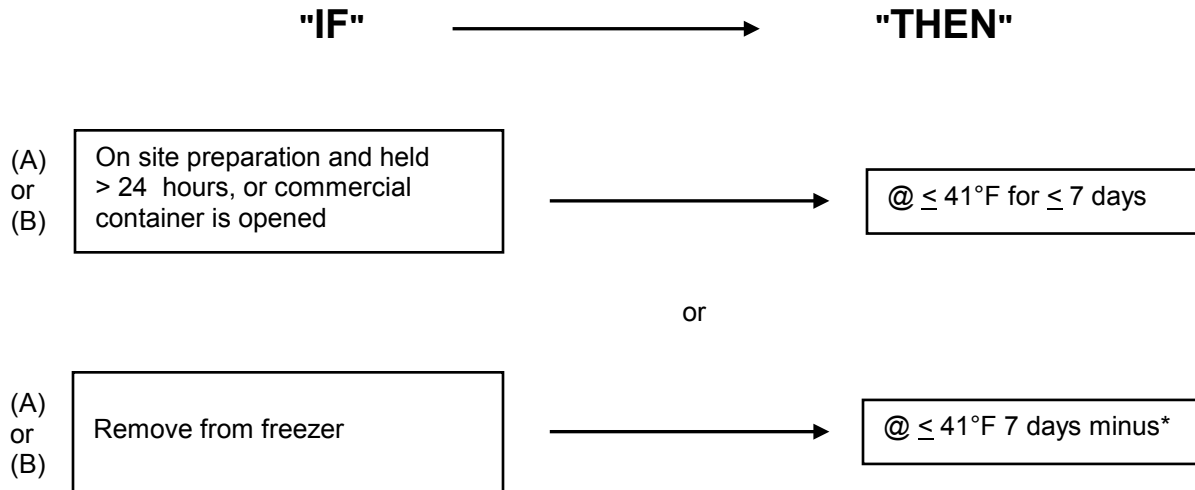
**Summary Chart for Minimum Food Temperatures and Holding Times
Required by Chapter 3 for Reheating Foods for Hot Holding**

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
¶ 3-403.11(A) and (D) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) and (D) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after reheating	2 hours
¶ 3-403.11(C) and (D) Food that is taken from a commercially processed, hermetically sealed container or intact package	57°C (135°F)	No time specified	2 hours
<u>Roasts: Option A</u> ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Not applicable
<u>Roasts: Option B</u> ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	74°C (165°F)	15 seconds	2 hours

Chart 4-C

Summary Chart

**Ready-to-Eat, Time/temperature Control for Safety Food)
Date Marking § 3-501.17(A) – (E) and Disposition § 3-501.18**



*Time from preparation, or opening commercial container, to freezing.

Example: The morning of October 1, a chicken was cooked, then cooled, refrigerated for 2 days at 41°F and then frozen. If the chicken is thawed October 10, the food must be consumed or discarded no later than midnight of October 14.

Date	Shelf Life Day	Action
Oct. 1	1	cook/cool
Oct. 2	2	cold hold at 41°F
Oct. 3		freeze
Oct. 10	3	thaw to 41°F
Oct. 11	4	cold hold
Oct. 12	5	cold hold
Oct. 13	6	cold hold
Oct. 14	7	consume or discard

Chart 4-D

FDA Food Code Mobile Food Establishment Matrix

This table is a plan review and inspectional guide for mobile food establishments based on the mobile unit's menu and operation. Mobile units range in type from push carts to food preparation catering vehicles.

To use the table, read down the columns based on the menu and operation in use. For example, if only prepackaged time/temperature control for safety food is served, then requirements listed in the **TCS Food Menu - *Prepackaged*** column apply. Likewise, if only food that is not time/temperature control for safety food is prepared on board, then requirements listed in the **Not TCS Menu - *Food Preparation*** column apply. Note that if a mobile food establishment has available for sale to the consumer both prepackaged time/temperature control for safety food and time/temperature control for safety food prepared on board, then the more stringent requirements of the **TCS Menu - *Food Preparation*** column apply.

It is important to remember that mobile units may also be subject to all Food Code provisions that apply to food establishments. Consult the local regulatory authority for specific local requirements.

The local regulatory authority's decision to require auxiliary support services such as a commissary or servicing area should be based on the menu, type of operation, and availability of on-board or on-site equipment.

NOTE: The Food Code definition of "Food Establishment" does not include an establishment that offers only prepackaged foods that are not time/temperature control for safety foods.

FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX

Food Code	Time/Temperature for Safety Food (TCS) Menu		Not TCS Food Menu
<i>Areas/Chapter</i>	<i>Food Preparation</i>	<i>Prepackaged</i>	<i>Food Preparation</i>
Personnel	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)
Food	3-101.11 3-201.11-.16 3-202.16; Applicable Sections of Part 3-3; 3-501.16 3-501.18(A)	3-101.11 3-201.11-.16 3-303.12(A) 3-501.16 3-305.11; 3-305.12 (Applicable to Service Area or Commissary)	3-101.11; 3-201.11 3-202.16; Applicable Sections of Part 3-3
Temperature Requirements	3-202.11; Applicable Sections of Parts 3-4 & 3-5	3-202.11 3-501.16	NONE
Equipment Requirements	Applicable Sections of Parts 4-1 - 4-9 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-6 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-5 - 4-6 and 5-5
Water & Sewage	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13-.15	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13 -.15	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13-.15
Physical Facility	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111	6-101.11 6-102.11(A) & (B) 6-202.15 6-501.111	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111
Toxic Materials	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7
Servicing	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code
Compliance and Enforcement	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1

Summary of Changes In the FDA Food Code

This Summary provides a synopsis of the textual changes from the 2009 FDA Food Code and the Supplement to the 2009 Food Code Chapters and Annexes to the 2013 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. ***This record should not be relied upon as an absolute comparison that identifies each and every change.***

General:

- Numerous editing changes were made throughout the document for internal consistency, to correct some errors in the 2009 Code and for clarification.
- Section and paragraph numbers listed refer to the 2009 Code and its Supplement unless otherwise noted. The numbering system was removed from Chapter 1 definitions in the 2005 version of this Code. An explanation regarding the rationale can be found in Annex 3, 1-201.10(B).
- Updated the web links throughout the Code and Annexes.
- Converted several Tables, charts, and images throughout the Code to meet web accessibility requirements under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). Section 508 mandates that all federal agencies eliminate the barriers in accessing electronic and information technology.

Preface

Amended Preface sections 1, 3, 5, 6, and 8 to add updated information and revise dates to make current.

Chapter 1 Purpose and Definitions

Deleted “**Enterohemorrhagic *Escherichia coli*” (EHEC)** as use of EHEC terminology is outdated.

Amended "**Packaged**" in (1) to delete the term "securely" to avoid undue emphasis on nature of the package; Amended "**Packaged**" in (2) to remove the phrase "or other nondurable container" to clarify when foods packaged at retail need to be labeled so that it reads: "**Packaged**" *does not include wrapped or placed in a carry-out container to protect the FOOD during service or delivery to the CONSUMER, by a FOOD EMPLOYEE, upon CONSUMER request.*

Deleted the term **Potentially Hazardous Food (Time/Temperature Control for Safety Food)** (PHF/TCS) and made a universal change throughout the Code to replace it with the term **"Time/Temperature Control for Safety Food" (TCS)**. The definition remains the same.

Revised "**Reduced Oxygen Packaging**" subparagraph (2)(e), to delete the phrase "placed in a hermetically sealed, impermeable bag" and replace it with "vacuum packaged in an impermeable bag" so it clearly defines the sous vide process as outlined in Annex 6(2)(B)(4)(b). It now reads: "Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens."

Revised "**Shiga toxin-producing *Escherichia coli***" (STEC) to reflect current nomenclature.

Chapter 2 Management and Personnel

2-201.11, 2-201.12, 2-201.13

Amended to add nontyphoidal *Salmonella* (NTS) as one of the reportable illnesses for action by the Person in Charge; Added Code language to address employee health controls for the exclusion and restriction of nontyphoidal *Salmonella*, and removal of exclusion and restriction from NTS.

2-301.14(H)

Amended to clarify that the requirement to wash hands before donning gloves is specific to the beginning of a task involving working with food and not during the task.

2-301.16(A)(2)

Amended to remove (A)(2)(b)(i-ii) and add new subparagraphs (A)(2)(b-e) to clarify and align the codified text with applicable CFR's and the FD&C Act with regard to the use of hand antiseptics as a food additive.

Chapter 3 Food

3-201.16(A)

Amended to remove existing 2009 ¶(A) language in reserve; Added new ¶(A) to recognize a regulatory authority's ability to approve the sale of wild mushrooms within a food establishment and regulate wild mushrooms according to their LAW.

3-301.11(D)

Amended to revise subparagraph (D)(2) to clarify that Paragraph (B) does not apply where a ready-to-eat food is added as an ingredient to another food that does not contain a raw animal food and the combined product will be heated to at least 63°C (145°F).

3-302.11

Amended to remove subparagraph (A)(3) and renumbered the remaining paragraphs as (4) – (8).

3-304.11

Amended to add a new ¶(C) to clarify that food may contact surfaces of linens and napkins as specified in §3-304.13 and added term "Linens" to the tag line.

3-304.13

Amended to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens.

3-304.17

Amended to relocate the requirement regarding the cleaning of returnables into this section from §4-603.17.

Amended ¶3-304.17(A) to clarify conditions under which the re-use of returnables are permitted.

Amended ¶3-304.17(B) to establish conditions under which refilling of returnable take-home containers is permitted.

Amended to relocate the exception for filling a food-specific container with a beverage from ¶4-603.17(B) to ¶3-304.17(C).

Amended to renumber ¶3-304.17(C) as a new ¶3-304.17(D).

Amended to relocate the exception for filling consumer-owned, personal take-out containers that are not food-specific from ¶4-603.17(C) to ¶3-304.17(E).

3-401.14

Amended to revise ¶(D) to clarify that prior to sale or service, raw animal foods cooked using a non-continuous cooking process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C).

3-402.11

Amended ¶3-402.11(B) to add a new ¶(2) to clarify that scallop products consisting solely of the shucked adductor muscle are excluded from the requirements for parasite destruction and re-designated existing ¶¶(2)-(4) to be new ¶¶ (3)-(5).

3-403.11

Amended ¶3-403.11(C) to clarify that this provision applies to all commercially processed TCS foods that are ready-to-eat. Previous text suggested that it applied only immediately upon removal of the food from a sealed container.

3-501.13

Amended to add new ¶(E) specifying frozen fish packaged using a ROP method be removed from the ROP environment either prior to initiating thawing procedures under refrigeration as specified in ¶ (A) or prior to, or immediately upon completion of, its thawing using procedures specified in ¶ (B) of this section.

3-501.17

Amended to add new ¶(F) that exempts raw, live in-shell molluscan shellfish from date marking and re-designated former ¶(F) as new ¶(G).

Amended existing subparagraph 3-501.17 (F)(6) to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing; Renumbered existing ¶(F)(6) as new ¶(G)(6) as a result of the addition of new ¶ (F).

3-502.11

Amended to revise ¶(D) to make clear that only TCS foods prepared under ROP methods that do not control for growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* require a variance.

3-502.12

Amended ¶¶3-502.12(B), (D), and (E) lead-in paragraphs to reference new ¶ (F) of this section.

Amended ¶3-502.12(B) lead in paragraph and subparagraphs (B)(6)(c), (D)(1), and (E)(2) to reference ¶8-201.14(B) along with existing reference to ¶ (D).

Amended subparagraphs 3-502.12(B)(3)(b) and (B)(4) to delete 14 days and add 30 days.

Amended ¶ 3-502.12(B) to add new subparagraph 7 specifying that a HACCP plan be provided to the regulatory authority prior to implementation.

Amended ¶3-502.12(D) lead in paragraph to delete the word “FOOD” and replace it with the term “Time/Temperature control for safety food” to clarify that this section applies to TCS food.

Amended subparagraph 3-502.12(D)(2)(b) to specify only the cooking parameters in ¶¶ 3-401.11(A), (B) and (C) apply.

Amended subparagraph 3-502.12(D)(2)(e)(ii) to allow for cold holding at 41°F for 7 days after cooling to 41°F.

Amended to delete existing subparagraph 3-502.12(D)(2)(e)(iii) and amended subparagraph 3-502.12(D)(2)(e)(iv) to renumber it as the new subparagraph (D)(2)(e)(iii).

Amended to add new ¶(F) to identify the conditions under which a HACCP Plan is not required for ROP TCS foods.

3-602.11

Amended ¶3-602.11(B)(2),(3),(5), and (7) to clarify the information that a label should include.

Amended subparagraph 3-602.11(B)(2) to clarify what information must be included in the statement of ingredients. The term “sub ingredients” was added to this subparagraph to clarify that individual component ingredients of a main ingredient must be disclosed in the statement of ingredients. This clarification helps to make clear that all individual ingredients in a packaged food will be disclosed in the statement of ingredients.

Amended subparagraph 3-602.11(C)(2) to remove cross reference to subparagraph (B)(5) to correctly refer to what a labeling device such as a card, sign, or other method of notification needs to declare. This change corrects an inadvertent error that was created in the 2005 Food Code when a new subparagraph (B)(5) for food allergens was added and the subparagraph for nutritional labeling was renumbered to (B)(6), but the accompanying cross reference in (C)(2) was not changed to correctly cross reference (B)(1), (2), and (6), nutritional labeling.

Chapter 4 Equipment, Utensils, and Linens

4-302.13

Amended the tag line to add “mechanical warewashing”

Amended to redesignate the existing section into ¶(A) and new ¶(B) to require the availability of irreversible registering temperature indicators.

4-602.11

Amended ¶ 4-602.11(B) to change the cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods. With this change, the exception to existing subparagraph (A)(1) found in ¶(B) now applies only to raw meat and poultry.

4-603.17

Amended to delete §4-603.17 and relocate its requirements into §3-304.17.

4-802.11

Amended ¶4-802.11(C) to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens as mentioned in ¶3-304.11(C) and §3-304.13.

Chapter 5 Water, Plumbing, and Waste

No Changes.

Chapter 6 Physical Facilities

No Changes.

Chapter 7 Poisonous or Toxic Materials

7-204.12

Amended ¶7-204.12(A) to redesignate ¶(A) into a lead-in paragraph with four new subparagraphs: Added 21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption as new subparagraph (A)(1); Added GRAS ingredients as new subparagraph (A)(2); Added effective food contact notifications as new subparagraph (A)(3); Added 40 CFR 156 Labeling Requirements for Pesticides and Devices as new subparagraph (A)(4) to allow the use of other antimicrobial agents allowed under the food contact notification program for washing fruits and vegetables as well as GRAS ingredients permitted as antimicrobials or for general food use.

Chapter 8 Compliance and Enforcement

8-201.13

Amended ¶8-201.13(B) to add new language to have the food establishment notify the Regulatory Authority through submission of a HACCP plan that they will be conducting ROP operations that conform with procedures in § 3-502.12.

8-304.11

Amended to add new ¶(K) to include a requirement for the permit holder to post a sign or placard notifying the public that inspectional information is available for review.

Annex 1 Compliance and Enforcement

No Changes.

Annex 2 References

Preface

Amended to redesignate numbers and alphabetize.

2-201.12 and 2-201.13

Amended to update three references and add twenty new references in support of including public health controls for the control of nontyphoidal *Salmonella* (NTS) in retail food establishments; references renumbered to keep alphabetical format.

3-401.11

Amended to redesignate numbers and alphabetize.

3-402.11

Amended to add one new reference (#6), the Fish and Fishery Products Hazards and Controls Guidance, 4th Edition, April 2011, and renumbered remaining references.

3-502.12

Amended to add two new references (#24, and #28) and renumbered the remaining references. The new references are regarding time to formation of *C. botulinum* toxin. These references provide support of the pH of 5 limit for the psychrotrophic strains of *C. botulinum* due to Code changes to allow a 7-day storage for ROP at 41°F and a 30-day hold for vacuum packaging and Cook-Chill/Sous Vide of foods with a pH of 5 or less.

4-603.17

Amended to move reference for deleted §4-603.17 to be under §3-304.17 since the two sections were merged into §3-304.17.

6-501.111

Amended to add new reference in support of this section on controlling pests.

7-204.12

Amended to add new reference to include 21 CFR 173.405, Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate.

3. Supporting Documents

Amended section **K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information**, to update with current USDA/FSIS information and documents. The update includes deleting existing paragraphs 5 and 6 and adding new paragraphs 5 and 6; Updated other existing paragraphs with editorial changes.

Amended to add new section, **S. CIFOR The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response**

Amended to add new section, **T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)**

Annex 3 Public Health Reasons/Administrative Guidelines

1-201.10

Packaged.

Amended to add a section on “Packaged” to clarify when foods packaged at retail need not be labeled and placed the text after the “Food Establishment and a food processing plant located within the same premises of a food establishment” section and before the “TCS” section.

2-2 Employee Health

Amended to add a description of nontyphoidal *Salmonella* between the descriptions of Norovirus and *Salmonella* Typhi.

Amended Part 2-2 and its related subparts and Tables/Decision Trees to be consistent with the changes in Chapter 2; Tables and Decision trees were revised to meet accessibility requirements for web posting.

Amended to update the list of *Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens* from CDC, effective November 30, 2012.

Amended the pathogen descriptions in subpart 2-201.11 to be consistent with the Bad Bug Book, 2nd Edition, 2012.

2-301.14

Amended to clarify that subparagraph ¶2-301.14(H) requires handwashing immediately before, during, and immediately after, the activities listed.

2-301.16

Amended the “As a Food Additive” Section to add a new paragraph 4 to elaborate on the prior sanction requirements under the food additive provision in the Federal Food, Drug and Cosmetic Act as it relates to the substances in a hand antiseptic reasonably expected to become a component of food based upon the product’s intended use; Renumbered the existing paragraph 4 as a new paragraph 5.

3-201.11

Amended to relocate information about safe food handling label instructions from Annex 3, §3-602.11 to Annex 3 §3-201.11.

3-201.16

Amended to delete last sentence in paragraph 2; revise paragraph 3; add new paragraphs 4-5; and delete existing paragraphs 4-8.

3-302.11

Amended to remove paragraph 3 to be consistent with change to delete subparagraph 3-302.11(A)(3).

3-304.17

Amended to describe the public health reasons for inclusion of an exception for reusing and refilling returned take-home containers with TCS- or non-TCS food; Relocated PHR text from §4-603.17 to §3-304.17.

3-401.14

Amended to revise paragraph 6 to clarify that during the final cooking step, raw animal FOODS cooked using a NON-CONTINUOUS COOKING process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C).

3-402.11

Amended to update paragraph 6 to be consistent with the Fish and Fisheries Products Hazards and Controls Guidance, Fourth edition.

Amended to add new paragraph 8 to explain why the requirements for parasite destruction do not apply to molluscan shellfish and scallop products consisting solely of the shucked adductor muscle.

3-403.11

Amended to add a new paragraph 4 to provide the public health reason for requiring a reheating temperature for commercially processed foods that is lower than that for foods prepared in the food establishment.

3-501.13

Amended to add three new paragraphs to address the removal of ROP frozen fish from its packaging before thawing to prevent *C. botulinum* toxin formation.

3-501.17

Amended to remove “PHF” from the Tagline so it references only TCS food.

Amended to add a new paragraph #13 under a new subheading “Shellstock” as public health rationale for exempting shellstock from date marking.

Amended paragraph 4 under subheading of USDA-regulated products to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing.

3-502.11

Amended with an editorial change to make a correction in the title of Chart 1 to accurately cross reference §3-502.11 rather than §3-501.11.

3-502.12

Amended the entire annex section to reorganize the information according to different concepts presented in the Annex, added sub-headings, and revised certain text within the existing paragraphs, such that changes are:

- In the introductory paragraphs,
 - amended paragraph 1 to add information about safety concerns when spoilage organisms are inhibited, and
 - amended paragraph 2 to delete information about oxygen transfer rate and add information about other ways oxygen is restricted not just by the packaging.
- Amended text under the new subheading, ROP with Two Barriers,
 - in paragraph 2, to provide examples of foods that have high levels of competing organisms and explained why the refrigerated shelf life time was increased from 14 calendar days to 30 calendar days for vacuum packaged ROP food, and
 - in paragraph 3, to address non-time/temperature control for safety food explaining why these foods do not require a variance or HACCP Plan for ROP.
- Amended the first sentence in paragraph 1 under the new subheading, ROP and Cheese, to remove “Naturally fermented” at the start of the sentence.
- Amended text under the new subheading, ROP with One Barrier (Cook-Chill and Sous Vide),
 - in paragraph 1 to change the four options to three options for inhibiting growth for cook/chill, sous vide processing, and

- in paragraph 2, to change the 38°F cold holding temperature noted to 41°F, to be consistent with the changes made in subparagraph 3-502.12(D)(2)(e).
- Amended text under the new subheading, The Relationship Between Time and ROP, to add new text that provides information regarding short-term ROP storage and exemption from a HACCP Plan.
- Amended text under the new subheading, HACCP Plans with ROP,
 - in paragraph 1 to add information on submitting a HACCP Plan to the regulatory authority, and
 - in paragraph 2 to clarify information for when an operator submits an application for a variance.
- Amended text under the new subheading, ROP with Fish, for internal consistency.

3-602.11

Amended to reorganize the entire public health reasons and include new subheading titles; removed outdated information from the food allergen labeling subsection; included information about astaxanthin, a color additive used in salmonid fish under its new subheading; New cross-reference created in §3-602.11 to direct the reader to §3-201.11 under the new safe handling instructions subheading.

Amended to clarify why food held under the direct control of the operator is exempt from the labeling requirements in 3-602.11, while food enclosed in a container or wrapping and placed on display for consumer self service is subject to the labeling requirements under §3-602.11.

Added public health rationale to explain the importance of having an accurate list of food ingredients on the label. Two examples were provided to illustrate the method that food establishments may use to list the ingredients on the label.

4-101.15

Amended paragraph 1 and added new paragraph 2 to add information about zinc and zinc poisoning

4-302.13

Amended to change the tag line and to add a new paragraph 2 with the public health rationale for the new ¶4-302.13(B).

4-602.11

Amended to add new paragraphs 5 and 6 to clarify that food contact surfaces of equipment and utensils that have contacted a raw animal food that is a major food allergen such as raw fish must be cleaned and sanitized prior to contacting different types of raw animal foods.

4-603.17

Removed Annex 3, §4-603.17 and relocated the public health reasons text from §4-603.17 to §3-304.17.

7-204.12

Amended to update web link in paragraph 1, revise paragraph 3 and add a new paragraph 4 that speaks to allowing food additives and food contact substances as well as substances generally recognized as safe (GRAS) that are permitted under FDA's regulations for washing fruits and vegetables.

8-304.11

Amended to add new public health reasons to explain the intent of adding in new ¶(K) a requirement to post a sign/placard notifying the public that inspectional information is available for review.

Annex 4 Management of Food Practices-Achieving Active Managerial Control of Foodborne Illness Risk Factors

Amended to convert Table 1 through Table 4 and the CCP Decision Tree 1 to meet web accessibility requirements.

Amended section **9. Resources and References (C) FDA Publications** to update the list of resources and references to also reference the Fourth Edition of the Fish & Fishery Products Hazards and Controls Guidance, April 2011.

Annex 5 Conducting Risk-Based Inspection

No Changes.

Annex 6 Food Processing Criteria

Amended Section 2, Reduced Oxygen Packaging, (B) Definitions, (1) through (5) to revise the ROP definitions to be consistent with the ROP definition in Chapter 1 (1-201.10).

Annex 7 Models Forms, Guides, and Other Aids

Amended the Tables and Charts throughout to be consistent with web accessibility requirements.

Amended Forms 1-A, 1-B, and 1-C to revise the forms to be consistent with the changes in Chapter 2 in regards to the use of the term STEC and not EHEC and NTS, as applicable.

Amended Forms 2-A and 2-B to change use of term “Potentially hazardous food (time/temperature control for safety food” to “time/temperature control for safety food”.

Amended Form 3-A, *Food Establishment Inspection Report* form, for consistency with changes made in the Supplement with the 2009 Food Code to add two new entries and renumber the subsequent items. This change added in a new item #2 Certified Food Protection Manager, renumbered existing #2-3 as new items #3-4; added in a new item #5 Procedures for responding to vomiting and diarrheal events, renumbered existing items #4-54 as new #6-56.

Amended Guide 3-B, *Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices* to add the risk designations (Priority ^(P), Priority Foundation ^(Pf) and Core ^(C)) to each applicable code section for reference when recording observations in the inspection report.

ADA = Americans with Disabilities Act

ASTM = American Society for Testing and Materials

CDC = Centers for Disease Control and Prevention

CFP = Conference for Food Protection

CFR = Code of Federal Regulations

HACCP = Hazard Analysis and Critical Control Point

IFT = Institute of Food Technologists

Lm = *Listeria monocytogenes*

NACMCF = National Advisory Committee on Microbiological Criteria for Foods

NSSP = National Shellfish Sanitation Program

OTC = Over The Counter

PMO = Pasteurized Milk Ordinance

PMP = Pathogen Modeling Program

ROP = Reduced Oxygen Packaging

USDA/FSIS = United States Department of Agriculture/Food Safety & Inspection Service

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Supplement to the 2013 Food Code

U.S. Public Health Service

FDA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

College Park, MD 20740

IMPORTANT - Save this Supplement. It is intended to keep the 2013 Food Code up-to-date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2013 Food Code effective upon issuance.

Supplement to the 2013 FDA Food Code

The Food Code (and its Supplement) is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents the Food and Drug Administration's (FDA) best advice for a uniform system of provisions that address safety and protection of food offered at retail and in food service.

This model is offered for adoption by local, state, territorial, tribal, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations.

This document is available via the internet in PDF at the following link:
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IMPORTANT. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2013 Food Code effective upon issuance via web posting or hard copy release.

Introduction

The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2013 Food Code (hereafter referred to as Supplement). This Supplement updates the 2013 Food Code to address several recommendations made at the 2014 Meeting of the Conference for Food Protection (CFP) with which the FDA, Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA) concur. The changes contained in this Supplement reflect current science and food safety practices to reduce the incidence of risk factors known to cause foodborne illness.

From 1993 through 2001, the complete Food Code was issued every two years. With the support of the CFP, FDA currently issues a new Food Code every 4 years. The next complete revision of the Food Code will be published in 2017. Until that time, this Supplement provides a means of incorporating into the Food Code several changes with which there is substantial concurrence among the federal agencies and the other stakeholders. The Supplement ensures that the most current food safety provisions are available to agencies planning to initiate rule-making activities prior to 2017. This Supplement provides other users of the Food Code, such as educators, trainers, and the food service, retail food, and vending industries, with up-to-date information of how to best mitigate risk factors that contribute to foodborne illness.

The Supplement has been organized to facilitate the adoption of its provisions by federal, state, local, territorial, and tribal authorities. The Supplement is divided into 3 Parts:

- Part 1 - Summary of Changes - a "quick view" of the modifications
- Part 2 - Amendments, Additions, Deletions to the Preface, Chapters 1-8 and the Annexes - actual language modifications
- Part 3 - New Terms added to the Index to the Food Code

For consistency, drafting conventions used in the Federal Register for announcing proposed changes to federal rules are used to announce changes found in the Supplement to the 2013 Food Code. The standard terms used to describe a change are:

Amend. "Amend" means that an existing Food Code provision has changed. Because it is an introductory term, it is always used with one of the following specific amendatory terms to precisely describe the change to the Food Code provision.

Amendatory Terms

Add - means a new provision has been inserted in the Food Code.

Redesignate - means to modify a Food Code provision by reformatting the text of the provision into a new structural nomenclature designation.

Remove - means an existing provision is being taken out of the Food Code.

Revise - means an existing Food Code provision is replaced in part, or in its entirety.

For example:

Amend Section 4-204.110 to **revise** subparagraph (B)(1) and to **add** subparagraph (B)(3) to read as follows: [text of changed subparagraph and newly added subparagraph]

Modifications are organized by Food Code chapter and are identified by Section (§) number and title, and the paragraph (¶), (e.g., ¶9-101.11(A)) or subparagraph (e.g., 9-101.00(A)(1)) to which the change is made. The full text of a Section is provided only if necessary to provide the proper context. Using Chapter 3 as an example, a change is introduced as follows:

Chapter 3 - Food

Amend § 3-202.11 to revise paragraph (D) to read as follows:

Specifications for Receiving **3-201.11 Temperature.***

[text of changed paragraph]

The Supplement also contains changes to the informational annexes of the Food Code. Using Annex 3 as an example, a change to the public health reasons for a Food Code provision in Chapter 4 is introduced as follows:

Annex 3- Public Health Reasons/ Administrative Guidelines

4-202.15 - Can Openers.

Amend Public Health Reason for §4-202.15 to revise to read as follows:

[text of changed paragraph]

We encourage all jurisdictions to examine the level of food safety protection their current rules and implementation strategies provide and take the steps necessary to increase that level in light of the 2013 Food Code and its Supplement. The adoption and implementation of the Food Code in all jurisdictions is an important strategy for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation's food safety system.

The Department of Health and Human Services (DHHS) and USDA, along with state, local, tribal and other federal government agencies and the food industry, share responsibility for ensuring that our food supply is safe. DHHS and USDA, in partnership with numerous others, will continue to take progressive steps to strengthen our nation's food safety system. We look forward to achieving uniform and effective standards of food safety for food service, retail stores, and other retail-level establishments nationwide.

Part 1. Summary of Changes

The amendments to the 2013 Food Code and its Annexes contained in the Supplement are summarized below. If an amendment relates directly to a recommendation of the Conference for Food Protection (CFP), the CFP issue number is provided in the parenthesis immediately after the summary entry.

Preface

No Change.

Chapter 1-Purpose and Definitions

No Change.

Chapter 2-Management and Personnel

Amended the Food Code and its Annexes, where applicable, to revise the descriptors of illness caused by *Salmonella* Typhi or nontyphoidal *Salmonella*. This change allows the use of plain language descriptors to simplify the restriction and exclusion criteria. (CFP Issue 2014-III-028)

2-103.11

Amended to add new paragraph (I) to address additional duty requirement for the Person in Charge to ensure employees are routinely monitoring food temperatures during hot and cold holding and redesignate paragraphs (I) - (O) as new paragraphs (J) - (P). (CFP Issue 2014-I-020)

2-201.11

Amended subparagraph **2-201.11(A)(2)(e)** to add the illness, Typhoid fever, to the descriptor for reportable diagnosis of illness diagnosed due to *Salmonella* Typhi so that it reads: "Typhoid fever (caused by *Salmonella* Typhi)". (CFP Issue 2014-III-028)

Amended subparagraph **2-201.11(A)(2)(f)** to add the word, *Salmonella*, to the descriptor for reportable diagnosis of illness diagnosed due to nontyphoidal *Salmonella* so that it reads: "*Salmonella* (nontyphoidal)". (CFP Issue 2014-III-028)

Amended subparagraph **2-201.11(A)(3)** to replace the phrase, "Had a previous illness" with the phrase "Had Typhoid fever" and to delete the phrase "due to *Salmonella* Typhi". (CFP Issue 2014-III-028)

Amended subparagraph **2-201.11(A)(4)(c)** to replace “*Salmonella Typhi*” with “Typhoid fever”. (CFP Issue 2014-III-028)

Amended subparagraph **2-201.11(A)(5)(c)** to add in descriptor text for the illness caused by *Salmonella Typhi* so that it reads: “. . . Typhoid fever (caused by *Salmonella Typhi*).” (CFP Issue 2014-III-028)

2-201.12

Amended subparagraph **2-201.12(A)(2)** to replace “nontyphoidal *Salmonella*” with “*Salmonella* (nontyphoidal)”. (CFP Issue 2014-III-028)

Amended the **margin tagline for subparagraph 2-201.12(C)** to replace “diagnosis or reported previous infection due to *S. Typhi*” with “diagnosis or reported previous illness with Typhoid fever”. (CFP Issue 2014-III-028)

Amended paragraph **2-201.12(C)** to replace “diagnosed with an infection from *Salmonella Typhi*” with “diagnosed with Typhoid fever or reports having had Typhoid fever”. (CFP Issue 2014-III-028)

Amended paragraph **2-201.12(G)** to replace “nontyphoidal *Salmonella*” with “*Salmonella* (nontyphoidal)”. (CFP Issue 2014-III-028)

2-201.13

Amended to:

- revise paragraph (A) to replace “*Salmonella Typhi*” with “Typhoid fever”
- revise subparagraph (A)(5) to replace “nontyphoidal *Salmonella*” with “*Salmonella* (nontyphoidal)”
- revise the margin tag line for paragraph (C) to replace “*S. Typhi* diagnosis – removing exclusions” with “Typhoid fever diagnosis – removing exclusions”
- revise subparagraph (C)(2) to replace “*S. Typhi* infection” with “Typhoid fever”
- revise subparagraph (G)(1) to replace “nontyphoidal *Salmonella* infection” with “*Salmonella* (nontyphoidal) infection”
- revise the margin tagline for subparagraph (J)(3) to replace “*S. Typhi*” with “Typhoid fever (*S. Typhi*)”
- revise subparagraph (J)(3) to replace “*S. Typhi*” with “Typhoid fever (caused by *Salmonella Typhi*)”

(CFP Issue 2014-III-028)

Chapter 3-Food

3-404.11

Amended paragraph **3-404.11(A)** to replace cross reference to paragraphs 8-201.14(B)-(E) with a cross reference to §8-201.14.

3-502.12

Amended Section 3-502.12 to revise paragraph (B) and subparagraphs (B)(6)(c), (D)(1), and (E)(2) to replace cross reference to paragraphs 8-201.14 (B) and (D) with a cross reference to paragraphs 8-201.14 (C) and (D).

3-801.11

Amended subparagraph **3-801.11(A)(3)** to replace cross reference to paragraphs 8-201.14 (B)-(E) with a cross reference to §8-201.14 (C)-(E).

Chapter 4-Equipment, Utensils, and Linens

Part 4-3-Numbers and Capacities

Amended to add **new Subpart 4-303**, Cleaning Agents and Sanitizers.
(CFP Issue 2014-I-030)

Amended to add **new Section 4-303.11** Cleaning Agents and Sanitizers, Availability, to require that equipment and utensil cleaning agents and sanitizers be provided and readily accessible for use. (CFP Issue 2014-I-030)

Chapter 5-Water, Plumbing, and Waste

No Change.

Chapter 6-Physical Facilities

No Change.

Chapter 7-Poisonous or Toxic Materials

No Change.

Chapter 8-Compliance and Enforcement

8-103.12

Amended paragraph (B) to replace existing cross reference to paragraphs 8-201.14 (D) and (E) with a cross reference to paragraph 8.201.14 (D) and subparagraph (E)(3).
(CFP Issue 2014-I-014)

8-201.14

Amended to:

- add new paragraph (A) to add a new specification for the permit holder or permit applicant to include general information with the HACCP plan submission;
- add a new paragraph (F) that is not a new requirement within §8-201.14, but rather clarifies what was already required under the previous paragraph (E). This new paragraph (F) requires the permit holder to include any other application or submission information required by the regulatory authority;
- delete paragraph (C) and move the food employee and supervisory training plan provision to new paragraph (E);
- redesignate existing paragraph (A) as new paragraph (B) where the intent of paragraph (B) remains the same, although the paragraph was revised to remove the list of examples;
- redesignate existing paragraph (B) (flow diagram) as new paragraph (C) which keeps its original intent, and includes a more descriptive list of what the flow diagram should include;
- Minor changes were made to subparagraph (D)(3) to clarify that a food employee or person in charge may monitor critical control points. The previous codified language implied that a food employee, rather than the person in charge, must monitor the critical control points. In some operations, it may be the responsibility of the person in charge to monitor some or all critical control points instead of a food employee;
- Minor changes were made to subparagraph (D)(5) to clarify that a person in charge, or a food employee, may be responsible for taking corrective action when a critical limit is not met. The previous codified language implied that the person in charge needed to take action when critical limits were not met. In some operations, a designated food employee may be responsible for taking correction action when critical limits are not met; and
- revise paragraph (E) to incorporate the food employee and supervisory training plan from deleted paragraph (C) and include a new requirement for the permit holder's or permit applicant's HACCP plan submission to incorporate copies of blank records forms necessary for implementation of the HACCP Plan.

(CFP Issue # 2014-I-014)

8-402.10

Amended to redesignate the existing paragraph into new paragraph (A); add a new paragraph (B) to address the requirement for the Regulatory Authority to ensure that authorized representatives who inspect food establishments or conduct plan reviews for compliance with this Code have access to training and continuing education as needed to properly identify violations and apply the Code. (CFP Issue # 2014-II-003)

Annex 1-Compliance and Enforcement

No Change.

Annex 2-References

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

Guidance on Responding to Food Emergencies:

Amended the References for 4. Food Defense Guidance From Farm To Table under the section on Guidance on Responding to Food Emergencies, to add one new reference (#4), **Conference for Food Protection (CFP) Emergency Action Plan for Retail Food Establishments, 2nd Edition**, and make an editorial correction and a web URL update to the existing bulleted list. (CFP Issue 2014-III-002)

Annex 3-Public Health Reasons

Chapter 2-Management and Personnel

Duties - 2-103.11 Person in Charge

Amended Public Health Reasons for §2-103.11 Person in Charge (Duties) to add a new paragraph 5 that describes why paragraphs (G),(H) and the new (I) are important to the safe operation of a food establishment and to update the paragraphs referencing (M) and (N) to reflect the updated designations for paragraphs that follow the new (I).

2-201.11

Title I of the Americans with Disabilities Act of 1990 (ADA)

Amended Public Health Reason for §2-201.11, Title I of the Americans with Disabilities Act of 1990 (ADA) in paragraph 3 to replace the term “*Salmonella* Typhi” with “Typhoid fever (caused by *Salmonella* Typhi)”. (CFP Issue 2014-III-028)

Amended Public Health Reason for §2-201.11, Title I of the Americans with Disabilities Act of 1990 (ADA), in paragraph 4 (Example 1) to replace the phrase “a disease caused by *Salmonella* Typhi” with the phrase “Typhoid fever (caused by *Salmonella* Typhi)”. (CFP Issue 2014-III-028)

4-303.11

Amended Public Health Reason for Chapter 4 Equipment, Utensils, & Linens, to add public health reasons for new §4-303.11 to address accessibility of cleaning agents and sanitizers for use. (CFP Issue 2014-I-030)

8-201.12/8-203.10

Amended Public Health Reason in paragraph 10 (the last paragraph) to update the cross reference to paragraph 2-103.11(L) to now cross reference the paragraph as renumbered, paragraph 2-103.11(N).

8-403.50

Amended Public Health Reason for Chapter 8 Compliance and Enforcement to add public health reasons for §8-403.50 Public Information to encourage the use of websites

to disseminate regulatory documents that describe the compliance status of a regulated food establishment. (CFP 2014-II-009)

Annex 4-Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors

No Change.

Annex 5-Conducting Risk-based Inspections

No Change.

Annex 6-Food Processing Criteria

2. Reduced Oxygen Packaging, Section (I), Hazard Analysis and Critical Control Point (HACCP) Operation

Amended Annex 6, Food Processing Criteria, 2. Reduced Oxygen Packaging, Section (I), Hazard Analysis and Critical Control Point (HACCP) Operation, to revise the introductory paragraph to replace the existing cross reference to paragraph 8-201.14(D) with a cross reference to §8-201.14.

Annex 7-Models Forms, Guides, and Other Aids

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices

Amended the Instructions for Marking the Food Establishment Report in Sections C (Risk Factors) and D (Good Retail Practices) to capture new or updated cross references based on changes made in this Supplement as follows:

Revised Section C, Supervision, Item #1, Applicable Code Section, to revise reference to paragraphs 2-103.11 (A)-(O) to be a reference to paragraphs 2-103.11 (A)-(P). (CFP Issue 2014-I-020)

Revised Section C, Employee Health/Responding to Contamination Events, Item #3, under #1, to update existing cross reference to paragraph 2-103.11(M) Person-in-Charge Duties (^{Pf}), and replace it with a cross reference to paragraph 2-103.11(O) and under Applicable Code Section, to replace reference to paragraph 2-103.11(M) with reference to paragraph 2-103.11(O). (CFP Issue 2014-I-020)

Revised Good Retail Practices (GRPs), Section D, Utensils, Equipment, and Vending, Item #48, to reflect compliance instructions for new §4-303.11 and add new §4-303.11 into the list of Applicable Code Sections. (CFP Issue 2014-I-030)

Part 2. Amendments, Additions, Deletions, to Chapters 1-8 and the Annexes

Preface

No Change.

Chapter 1- Purpose and Definitions

No Change.

Chapter 2- Management and Personnel

Amend §2-103.11 to add new paragraph (I), redesignate existing paragraphs (I)-(O) as new paragraphs (J)- (P) to read as follows:

Duties-2-103.11-Person in Charge

The PERSON IN CHARGE shall ensure that:

(A) - (H) -**No Change.**

(I) EMPLOYEES are properly maintaining the temperatures of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS during hot and cold holding through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures;^{Pf}

J) CONSUMERS who order raw or partially cooked READY-TO-EAT FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety;^{Pf}

K) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS before they are reused, through routine monitoring of solution temperature and exposure time for hot water SANITIZING, and chemical concentration, pH, temperature, and exposure time for chemical SANITIZING;^{Pf}

(L) CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets as specified under § 3-304.16;^{Pf}

(M) Except when APPROVAL is obtained from the REGULATORY AUTHORITY as specified in ¶ 3-301.11(E), EMPLOYEES are preventing cross-contamination of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT;^{Pf}

(N) EMPLOYEES are properly trained in FOOD safety, including FOOD allergy awareness, as it relates to their assigned duties; ^{Pf}

(O) FOOD EMPLOYEES and CONDITIONAL EMPLOYEES are informed in a verifiable manner of their responsibility to report in accordance with LAW, to the PERSON IN CHARGE, information about their health and activities as they relate to diseases that are transmissible through FOOD, as specified under ¶ 2-201.11(A); ^{Pf} and

(P) Written procedures and plans, where specified by this Code and as developed by the FOOD ESTABLISHMENT, are maintained and implemented as required. ^{Pf}

Amend §2-201.11 to revise subparagraphs (A)(2)(e) and (f), (A)(3), (A)(4)(c), and (A)(5)(c) to read as follows:

Responsibilities and Reporting Symptoms and Diagnosis

2-201.11-Responsibility of Permit Holder, Person in Charge, and Conditional Employees.

A) The PERMIT HOLDER shall require FOOD EMPLOYEES and CONDITIONAL EMPLOYEES to report to the PERSON IN CHARGE information about their health and activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report the information in a manner that allows the PERSON IN CHARGE to reduce the RISK of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE:

reportable symptoms

(1) Has any of the following symptoms:

(a) Vomiting, ^P

(b) Diarrhea, ^P

(c) Jaundice, ^P

(d) Sore throat with fever, ^P or

(e) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(i) On the hands or wrists, *unless an impermeable cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the impermeable cover,* ^P

(ii) On exposed portions of the arms, *unless the lesion is protected by an impermeable cover,*^P or

(iii) On other parts of the body, *unless the lesion is covered by a dry, durable, tight-fitting bandage,*^P

reportable diagnosis

(2) Has an illness diagnosed by a HEALTH PRACTITIONER due to:

(a) Norovirus,^P

(b) Hepatitis A virus,^P

(c) *Shigella* spp.,^P

(d) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*,^P

(e) Typhoid fever (caused by *Salmonella* Typhi)^P or

(f) *Salmonella* (nontyphoidal);^P

reportable past illness

(3) Had Typhoid fever, diagnosed by a HEALTH PRACTITIONER, within the past 3 months, without having received antibiotic therapy, as determined by a HEALTH PRACTITIONER;^P

reportable history of exposure

(4) Has been exposed to, or is the suspected source of, a CONFIRMED DISEASE OUTBREAK, because the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE consumed or prepared FOOD implicated in the outbreak, or consumed FOOD at an event prepared by a PERSON who is infected or ill with:

(a) Norovirus within the past 48 hours of the last exposure,^P

(b) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* or *Shigella* spp. within the past 3 days of the last exposure,^P

(c) Typhoid fever within the past 14 days of the last exposure,^P or

(d) Hepatitis A virus within the past 30 days of the last exposure;^P or

reportable history of exposure

(5) Has been exposed by attending or working in a setting where there is a CONFIRMED

DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual who works or attends a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

- (a) Norovirus within the past 48 hours of the last exposure,^P
- (b) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* or *Shigella* spp. within the past 3 days of the last exposure,^P
- (c) Typhoid fever (caused by *Salmonella* Typhi) within the past 14 days of the last exposure,^P or
- (d) Hepatitis A virus within the past 30 days of the last exposure.^P

Amend §2-201.12 to revise subparagraph (A)(2), and paragraphs (C) and (G), and the margin tagline to (G) to read as follows:

conditions of exclusion and restriction

2-201.12-Exclusions and Restrictions.

The PERSON IN CHARGE shall EXCLUDE or RESTRICT a FOOD EMPLOYEE from a FOOD ESTABLISHMENT in accordance with the following:

symptomatic with vomiting or diarrhea

(A) *Except when the symptom is from a noninfectious condition*, EXCLUDE a FOOD EMPLOYEE if the FOOD EMPLOYEE is:

- (1) Symptomatic with vomiting or diarrhea;^P or
- (2) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, *Shigella* spp., *Salmonella* (nontyphoidal), or SHIGA TOXIN-PRODUCING *E. COLI*.^P

(B) **No Change.**

diagnosed or reported previous illness with Typhoid fever

(C) EXCLUDE a FOOD EMPLOYEE who is diagnosed with Typhoid fever, or reports having had Typhoid fever within the past 3 months as specified under Subparagraph 2-201.11(A)(3).^P

(D) – (F)- **No Change.**

*diagnosed with **nontyphoidal Salmonella** and asymptomatic*

(G) If a FOOD EMPLOYEE is diagnosed with an infection from *Salmonella* (nontyphoidal) and is ASYMPTOMATIC, RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION or in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

(H) – (J)-**No Change.**

Amend §2-201.13 to revise paragraph (A), subparagraph (A)(5), paragraph (C), subparagraphs (C)(2), (G)(1), (J)(3) and the margin tagline to subparagraph (J)(3) to read as follows:

Managing Exclusions and Restrictions

2-201.13 – Removal, Adjustment, or Retention of Exclusions and Restrictions.

The PERSON IN CHARGE shall adhere to the following conditions when removing, adjusting, or retaining the EXCLUSION or RESTRICTION of a FOOD EMPLOYEE:

(A) *Except when a FOOD EMPLOYEE is diagnosed with Typhoid fever or an infection from hepatitis A virus:*

(1) - (4)-**No Change.**

Nontyphoidal Salmonella diagnosis

(5) If a FOOD EMPLOYEE was diagnosed with an infection from *Salmonella* (nontyphoidal) and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

(a) **No Change.**

(b) **No Change.**

(B) **No Change.**

Typhoid fever diagnosis – removing exclusions

(C) Reinstatement of a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(C) if:

(1) The PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY;^P and

(2) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the FOOD EMPLOYEE is free from Typhoid fever.^P

(D) – (F)-**No Change.**

nontyphoidal Salmonella- removing exclusion or restriction

(G) Reinstate a food employee who was EXCLUDED as specified under subparagraph 2-201.12(A)(2) or who was RESTRICTED as specified under ¶ 2-201.12(G) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY^P and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Salmonella* (nontyphoidal) infection based on test results showing 2 consecutive negative stool specimen cultures that are taken;

a) Not earlier than 48 hours after discontinuance of antibiotics,^P and

(b) At least 24 hours apart;^P

(2) **No Change.**

(3) **No Change.**

(H) – (I)-**No Change.**

exposure to foodborne pathogen and works in food establishment serving HSP – removing restriction

J) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(J) and was exposed to one of the following pathogens as specified under Subparagraph 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d):

(1)-(2)-**No Change.**

Typhoid fever (S. Typhi)

(3) Typhoid fever (caused by *Salmonella* Typhi) and one of the following conditions is met:

(a) More than 14 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;^P or

(b) More than 14 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.^P

(4) **No Change.**

Chapter 3-Food

Amend §3-404.11 to revise paragraph (A) to replace the cross reference to paragraphs 8-201.14 (B) - (E) with §8-201.14 to read as follows:

3-404.11 Treating Juice

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in §8-201.14 to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance;^P or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance:^{Pf}

(1) As specified under § 3-602.11,^{Pf} and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, JUICES that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."^{Pf}

Amend §3-502.12 to revise paragraph (B) and subparagraphs (B)(6)(c), (D)(1), and (E)(2) to read as follows:

Clostridium botulinum and Listeria monocytogenes Controls

3-502.12- Reduced Oxygen Packaging Without a Variance, Criteria

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of ***Clostridium botulinum*** and the growth of ***Listeria monocytogenes***.^P

(B) Except as specified under ¶(F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall implement a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (C) and (D) and that:^{Pf}

(1) – (5)- **No Change.**

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:^{Pf}

(a) Concepts required for a safe operation,^{Pf}

(b) EQUIPMENT and facilities,^{Pf} and

(c) Procedures specified under Subparagraph (B)(5) of this section and ¶¶ 8-201.14 (C) and (D).^{Pf}

(7) **No Change.**

(C) **No Change.**

(D) Except as specified under ¶(C) and ¶(F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a cook-chill or sous vide process shall:

(1) Provide to the REGULATORY AUTHORITY prior to implementation, a HACCP PLAN that contains the information as specified under ¶¶ 8-201.14 (C) and (D);^{Pf}

(2) – (4) **No Change.**

(E) Except as specified under ¶(F) of this section, a FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:

(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;^P

(2) Have a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (C) and (D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;^{Pf}

(3) Labels the PACKAGE on the principal display panel with a “use by” date that does not exceed 30 days from its packaging or the original manufacturer’s “sell by” or “use by” date, whichever occurs first;^{Pf} and

(4) Discards the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.^{Pf}

(F) **No Change.**

Amend §3-801.11 to revise subparagraph (A)(3) to read as follows:

Additional Safeguards

3-801.11- Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) The following criteria apply to JUICE:

(1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;

(2) PrePACKAGED JUICE or a prePACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale;^P and

(3) UnPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under §8-201.14 (C) - (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls.^P

(B) – (H) -No Change.

Chapter 4-Equipment, Utensils, and Linens

Amend Chapter 4 to add new Subpart, 4-303, Cleaning Agents and Sanitizers, and add a new Section 4-303.11 Cleaning Agents and Sanitizers, Availability, to read as follows:

4-3-NUMBERS AND CAPACITIES

Subparts

4-301-Equipment

4-302-Utensils, temperature Measuring Devices, and Testing Devices

4-303-Cleaning Agents and Sanitizers

4-303.11-Cleaning Agents and Sanitizers, Availability

(A) Cleaning agents that are used to clean EQUIPMENT and UTENSILS as specified under Part 4-6, shall be provided and available for use during all hours of operation.

(B) Except for those that are generated on-site at the time of use, chemical SANITIZERS that are used to sanitize EQUIPMENT and UTENSILS as specified under Part 4-7, shall be provided and available for use during all hours of operation.

Chapter 5-Water, Plumbing, and Waste

No Change.

Chapter 6-Physical Facilities

No Change.

Chapter 7-Poisonous or Toxic Materials

No Change.

Chapter 8-Compliance and Enforcement

Amend §8-103.12 to revise paragraph (B) to read as follows:

8-103.12-Conformance and Approved Procedures

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANS and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; ^P and

(B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under § 8-201.14 (D) and (E)(3) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring the CRITICAL CONTROL POINTS, ^{Pf}

(2) Monitoring of the CRITICAL CONTROL POINTS, ^{Pf}

(3) Verification of the effectiveness of the operation or process, ^{Pf} and

(4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT. ^{Pf}

Amend §8-201.14 to add new paragraphs (A) and (F); delete paragraph (C); redesignate existing paragraph (A) as new paragraph (B); redesignate existing paragraph (B) as new paragraph (C); make minor changes in subparagraphs (D)(3) and (D)(5); and revise paragraph (E) to incorporate information from deleted paragraph (C) to read as follows:

8-201.14-Contents of a HACCP Plan

For a food establishment that is required under § 8-201.13 to have a HACCP PLAN, the PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY a properly prepared HACCP PLAN that includes:

(A) General information such as the name of the PERMIT applicant or PERMIT HOLDER, the FOOD ESTABLISHMENT address, and contact information;

(B) A categorization of the types of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are to be controlled under the HACCP PLAN;^{Pf}

(C) A flow diagram or chart for each specific FOOD or category type that identifies:

(1) Each step in the process;^{Pf}

(2) The HAZARDS and controls for each step in the flow diagram or chart;^{Pf}

(3) The steps that are CRITICAL CONTROL POINTS;^{Pf}

(4) The ingredients, materials, and equipment used in the preparation of that FOOD;^{Pf}
and

(5) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved.^{Pf}

(D) A CRITICAL CONTROL POINTS summary for each specific FOOD or category type that clearly identifies:

(1) Each CRITICAL CONTROL POINT,^{Pf}

(2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,^{Pf}

(3) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the designated FOOD EMPLOYEE or the PERSON IN CHARGE,^{Pf}

(4) The method and frequency for the PERSON IN CHARGE to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS,^{Pf}

(5) Action to be taken by the designated FOOD EMPLOYEE or PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met, ^{Pf} and

(6) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed; ^{Pf}

(E) Supporting documents such as:

(1) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern; ^{Pf}

(2) Copies of blank records forms that are necessary to implement the HACCP PLAN; ^{Pf}

(3) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal. ^{Pf}

(F) Any other information required by the REGULATORY AUTHORITY.

Amend §8-402.10 to redesignate existing paragraph into new paragraph (A) and add a new paragraph (B) to read as follows:

Competency

8-402.10-Competency of Inspectors.

(A) An authorized representative of the REGULATORY AUTHORITY who inspects a FOOD ESTABLISHMENT or conducts plan review for compliance with this Code shall have knowledge, skills and ability to adequately perform the required duties.

(B) The REGULATORY AUTHORITY shall ensure that authorized representatives who inspect a FOOD ESTABLISHMENT or conduct plan review for compliance with this Code have access to training and continuing education as needed to properly identify violations and apply the Code.

Annex 1-Compliance and Enforcement

No Change.

Annex 2-References

Amend the References for 4. Food Defense Guidance From Farm To Table under the section on Guidance on Responding to Food Emergencies, to add one new reference (#4), Conference for Food Protection (CFP) Emergency Action Plan for

Retail Food Establishments, 2nd Edition, make an editorial correction and web URL update to the existing bulleted list to read as follows:

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to publications from federal regulatory agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest to regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed organization and those listed are up-to-date as of the printing of the 2005 Food Code.

FDA Publications: No Change.

USDA Publications: No Change.

Industry Publications: No Change.

Guidance on Responding to Food Emergencies:

- Centers for Disease Control and Prevention (CDC) Emergency Preparedness and Response information can be found at <http://www.bt.cdc.gov/>.
- USDA – Food and Nutrition Service food emergency publication, **Responding to a Food Recall** at http://www.fns.usda.gov/sites/default/files/Responding_Food_Recall_FNS_Final_May_30_2014.pdf
- FDA’s Office of Emergency Operations at 301-443-1240 for FDA regulated products and FSIS Technical Service Center at 1-800-233-3935 for USDA regulated products.
- **Conference for Food Protection (CFP) Emergency Action Plan for Retail Food Establishments, Second Edition** can be found at <http://www.foodprotect.org/>.

Annex 3- Public Health Reasons/Administrative Guidelines

Chapter 1 -Purpose and Definitions

No Change in Annex 3, Public Health Reasons, for Chapter 1.

Chapter 2- Management and Personnel

Amend Public Health Reasons for §2-103.11 to add a new paragraph 5 and revise paragraphs 7 and 8 to update the references to paragraphs 2-103.11(M) and (N) to

paragraphs (N) and (O) respectively, to reflect the redesignation in § 2-103.11 to read as follows:

Duties-2-103.11-Person in Charge

Paragraphs (1)-(4) - No Change.

New Paragraph 5: An important duty of the Person in Charge is to make sure that any required temperatures are achieved or maintained when foods are cooked, cooled or held in a food establishment. By making it a duty of the Person in Charge to ensure that employees are monitoring food temperatures to verify the critical temperature limits, the likelihood of temperature abuse is reduced. This includes oversight of temperature monitoring to ensure: 1) that animal foods are being cooked to the required minimum temperatures to prevent the survival of pathogens that may be present (2-103.11(G)); 2) that cooked foods are being cooled rapidly to ensure that the growth of bacterial pathogens and toxin production is prevented (2-103.11(H)); and 3) that foods that require temperature control for safety are being held at temperatures that adequately prevent pathogen growth and toxin production (new 2-103.11(I)).

Paragraph (N) “EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties” allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

Paragraph (O) emphasizes the important role the Person in Charge (PIC) has in making sure employees properly report certain information about their health status as it relates to diseases that are transmitted by food. In an effort to reinforce dialogue between food employees and the PIC, there must be a way to verify that food employees and conditional employees are informed of their responsibility to report such information. Examples of ways to verify that employees have been appropriately informed include:

[Continue bulleted List with No Changes.]

2-2- Employee Health

Responsibilities and Reporting Symptoms and Diagnosis

2-201.11-Responsibility of the Person in Charge, Food Employees, and Conditional Employees.

Paragraphs (1) – (4)-No Change.

Reporting Symptoms:-No Change.

Title I of the Americans with Disabilities Act of 1990 (ADA)

Amend Public Health Reason for §2-201.11, Title I of the Americans with Disabilities Act of 1990 (ADA) in paragraph 3 and paragraph 4 (Example 1) to read as follows:

Paragraphs (1) and (2) -No Change.

A food employer may exclude any employee under the Food Code upon initially learning that the employee has Typhoid fever (caused by *Salmonella Typhi*), or has a gastrointestinal symptom listed in the Food Code. The excluded employee may then ask for an ADA reasonable accommodation instead of the exclusion. In response, the employer's first step should be to ask the employee to establish that the employee is disabled by the disease or symptom (or that the symptom is caused by another ADA disability). If the employee successfully proves that the employee has an ADA disability, then the employer may continue to exclude the employee under the Food Code if:

- there is no reasonable accommodation at work that would eliminate the risk of transmitting the disease while also allowing the employee to work in a food handling position, or
- all reasonable accommodations would pose an undue hardship on the employer's business; and
- there is no vacant position **not involving food handling** for which the employee is qualified and to which the employee can be reassigned.

Example 1: A food employee working in the café of a department store informs the employer that the employee has been diagnosed with Typhoid fever (caused by *Salmonella Typhi*). The employer immediately excludes the employee under the requirements of the Food Code. The employee then establishes that the disease is an ADA disability because it is severe and long-term and the employee requests reasonable accommodation instead of an exclusion. The employer determines that no reasonable accommodation would eliminate the risk of transmitting Typhoid fever (caused by *Salmonella Typhi*) through food and refuses to remove the exclusion. However, there is a vacant clerical position in another part of the store for which the employee is qualified. Unless the employer can establish that reassigning the employee to this position would be an undue hardship, the employer's failure to make the reassignment instead of continuing the exclusion would be a violation of the ADA.¹

Paragraphs (5) – (11) -No Change.

Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens-No Change.

Chapter 3-Food

¹ Whether or not the employee in question is an individual with an ADA disability, in those jurisdictions where the Code is adopted, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

No Change in Annex 3, Public Health Reasons, for Chapter 3

Chapter 4-Equipment, Utensils, and Linens

Amend Public Health Reason for Chapter 4 Equipment, Utensils, & Linens, to add public health reasons for new §4-303.11 to read as follows:

4-303.11 Cleaning Agents and Sanitizers, Availability

If the appropriate cleaning agents and sanitizers are not on hand at all times they may not be available when needed to clean and sanitize equipment and utensils. It is also important that the cleaning agents and sanitizers be on hand, even at times where warewashing may not be in progress, so that their suitability can be verified by the regulatory authority and, if needed, by personnel who are responsible for servicing the equipment.

Chapter 5-Water, Plumbing, and Waste

No Change in Annex 3, Public Health Reasons, for Chapter 5.

Chapter 6-Physical Facilities

No Change in Annex 3, Public Health Reasons, for Chapter 6.

Chapter 7-Poisonous or Toxic Materials

No Change in Annex 3, Public Health Reasons, for Chapter 7.

Chapter 8-Compliance and Enforcement

Construction Inspection and Approval

8-201.12-Contents of the Plans and Specifications.

8-203.10-Preoperational Inspections.

Amend Public Health Reason in paragraph 10 to read as follows:

Paragraphs (1) – (9)- No Change.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with paragraph 2-103.11(N) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

8-403.50-Public Information

Amend Public Health Reason for Chapter 8 Compliance and Enforcement to add public health reasons for §8-403.50 Public Information to read as follows:

Regulatory documents that describe the compliance status of a regulated food establishment may be of particular interest to consumers, academia, industry, and other regulators. Certain laws may obligate government entities to make regulatory documents available to the public upon request. Proactively making these documents available to the public, by way of a website, may reduce the burden associated with requesting these documents, and therefore make it more likely that these documents will be accessible and reviewed by interested stakeholders.

Annex 4-Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors

No Change.

Annex 5-Conducting Risk-based Inspections

No Change.

Annex 6-Food Processing Criteria

Amend Annex 6, Food Processing Criteria, 2. Reduced Oxygen Packaging, Section (I), Hazard Analysis and Critical Control Point (HACCP) Operation, to revise the introductory paragraph to replace the existing cross reference to ¶8-201.14(D) with a cross reference to §8-201.14 to read as follows:

(I)-Hazard Analysis and Critical Control Point (HACCP) Operation

All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations, the plan must include the requirements specified under § 8-201.14. In addition, the HACCP plan may also include:

- (1) A complete description of the processing, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring and verification schemes, and records required;
- (2) A list of equipment and food-contact packaging supplies used, including compliance

standards that may be required by the regulatory authority, i.e., a recognized third party equipment evaluation organization such as NSF International;

(3) A description of the lot identification system;

(4) A description of the employee training program;

(5) A listing and proportion of food-grade gasses used; and

(6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

Annex 7-Model Forms, Guides, and Other Aids

Guide 3-B

Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices

Amend Section C, Supervision, Item #1, Applicable Code Section, to revise to read as follows:

C. MARKING INSTRUCTIONS FOR EACH RISK FACTOR AND INTERVENTION ON THE INSPECTION REPORT

Supervision

1. PIC present, demonstrates knowledge, and performs duties

Applicable Code Section:

2-101.11-Assignment ^(Pf)

2-102.11(A), B) and (C)(1), (4)-(16)-Demonstration ^(Pf)

2-103.11 (A)-(P)-Person-In-Charge-Duties ^(Pf)

Amend Section C, Employee Health/Responding to Contamination Events, Item #3, #1 to read as follows:

C. MARKING INSTRUCTIONS FOR EACH RISK FACTOR AND INTERVENTION ON THE INSPECTION REPORT

Employee Health/Responding to Contamination Events

3. Management and food employee knowledge, and conditional employee; responsibilities and reporting.

IN/OUT-This item must be marked IN or OUT of compliance. This item is marked IN compliance when the following criteria are met:

1. The PIC is aware of his or her responsibility to inform food employees and conditional employees of their responsibility to report certain symptoms or diagnosed diseases to the person in charge and for

the PIC to report to the regulatory authority as specified under Food Code ¶ 2-103.11 (O) and ¶¶ 2-201.11 (A),(B), (C), and (E); **and**

2. and 3. No Change.

Applicable Code Sections:

2-102.11(C)(2),(3) and (17) -Demonstration ^(Pf)

2-103.11 (O) -Person in Charge-Duties ^(Pf)

2-201.11(A), (B), (C), & (E)-Responsibility of Permit Holder, Person in Charge, and Conditional Employees ^(P,Pf)

Amend Good Retail Practices, Section D, Utensils, Equipment, and Vending, Item #48, to read as follows:

Good Retail Practices (GRPs)

D. MARKING INSTRUCTIONS FOR EACH GOOD RETAIL PRACTICE (GRP) ON THE INSPECTION REPORT

Utensils, Equipment and Vending

48. Warewashing facilities, installed, maintained, used, test strips

Adequate warewashing facilities must be available and used for the cleaning and sanitization of food-contact surfaces, including the availability of means to monitor its use and the effectiveness of sanitization. For example, an irreversible registering temperature indicator is provided and readily accessible for measuring the utensil surface temperature for establishments that have a hot water mechanical warewashing operation. Observation of manual and mechanical warewashing methods are made to **assess** the procedure for cleaning and sanitizing equipment and utensils. This item is marked OUT of compliance when cleaners and sanitizers are not available for use within the food establishment.

Applicable Code Sections:

4-203.13-Pressure Measuring Devices, Mechanical Warewashing Equipment ^(C)

4-204.113-Warewashing Machine, Data Plate Operation Specifications ^(C)

4-204.114-Warewashing Machines, Internal Baffles ^(C)

4-204.115-Warewashing Machines, Temperature Measuring Devices ^(Pf)

4-204.116-Manual Warewashing Equipment, Heaters and Baskets ^(Pf)

4-204.117-Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers ^(Pf)

4-204.118-Warewashing Machines, Flow Pressure Device ^(C)

4-204.119-Warewashing Sinks and Drainboards, Self-Draining ^(C)

4-301.12-Manual Warewashing, Sink Compartment Requirements ^(Pf, C)

4-301.13-Drainboards ^(C)

4-302.13-Temperature Measuring Devices, Manual and Mechanical Warewashing ^(Pf)

4-302.14-Sanitizing Solutions, Testing Devices ^(Pf)

4-303.11-Cleaning Agents and Sanitizers, Availability ^(Pf)

4-501.14 to end of the list at 4-603.16- No Change.

Part 3. New Terms added to the Index to the Food Code

Cleaning agents,
availability

nontyphoidal *Salmonella* (NTS). See *Salmonella* (nontyphoidal)

Sanitizer,
availability

NTS, *Salmonella* (nontyphoidal) or nontyphoidal *Salmonella*. See *Salmonella* (nontyphoidal)

Salmonella (nontyphoidal) See *nontyphoidal Salmonella (NTS) or NTS, Salmonella (nontyphoidal)*

Typhoid fever (caused by *Salmonella Typhi*)