State of Minnesota

Minnesota Department of Health

In the Matter of Proposed Rules
of the Minnesota Department of Health
Relating to Health Risk Limits,
Minnesota Rules, Parts 4717.7100 to 4717.7800

Statement of Need
and Reasonableness

Date:
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I. STATUTORY AUTHORITY AND NEED FOR RULES

The 1989 Groundwater Protection Act provides statutory authority for the proposed health risk limits rules. Minnesota Statutes, section 103H.201, subdivision 1, paragraph (a) states:

> If groundwater quality monitoring results show that there is a degradation of groundwater, the commissioner of health may promulgate health risk limits under subdivision 2 for substances degrading the groundwater.

Minnesota Statutes, section 103H.005, subdivision 6 defines "degradation:"

> "Degradation" means changing groundwater from its natural condition by human activities.

To determine if there are substances degrading the groundwater, staff of the Minnesota Department of Health's Environmental Health Division, Section of Health Risk Assessment, consulted groundwater monitoring programs of the Minnesota Pollution Control Agency (MPCA). Staff of the MPCA provided the department with a list of chemicals and substances identified in groundwater at various sites, including landfills, industrial sites, monitoring wells, private wells, and municipal wells (MDH/HRA, 1990a, MPCA memo, 10/4/90).

This list from the MPCA provides evidence that substances have reached groundwater through human activities. The list includes synthetic chemicals and substances not naturally found in the environment, and chemicals and substances detected at concentrations above natural background levels. According to a summary of the Minnesota Groundwater Protection Act of 1989, prepared by the Minnesota State Planning Agency, agricultural practices, leakage from petroleum storage tanks, improper disposal of chemicals and leakage from landfills all contribute substances to the groundwater (MSPA, 1989, p. 2). Therefore, human activities have changed Minnesota groundwater from its natural condition, meeting the statutory definition of "degradation" (Minnesota Statutes, section 103H.005, subdivision 6). As stated in Minnesota Statutes, section 103H.201, subdivision 1, paragraph (a), the commissioner may promulgate health risk limits for substances degrading the groundwater.

Minnesota Statutes, section 103H.005, subdivision 3, defines health risk limits as follows:

> "Health risk limits" means a concentration of a substance or chemical adopted by rule of the commissioner of health that is a potential drinking water contaminant because of a systemic or carcinogenic toxicological result from consumption.

Minnesota Statutes, section 103H.201, subdivision 1 specifies the methods for determining health risk limits. Paragraphs (c) and (d) of this section list the parameters for the development of specific health risk limits:

> (c) For systemic toxicants that are not carcinogens, the adopted health risk limits shall be derived using United States Environmental Protection Agency risk assessment methods using a reference dose, a drinking water equivalent, an uncertainty factor, and a factor for relative source contamination, which in general will measure an estimate of daily exposure to the human population, including sensitive subgroups, that is unlikely to result in deleterious effects during long-term exposure.
>
> (d) For toxicants that are known or probable carcinogens, the adopted health risk limits shall be derived from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency's carcinogen assessment group.

The Minnesota Department of Health interprets "relative source contamination" [Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c)] to refer to the "relative source contribution" factor used by the United States Environmental Protection Agency to calculate drinking water standards and guidelines so as to give effect to the statute. Otherwise this statutory phrase has no known meaning. The use of relative source "contamination" in the Groundwater Protection Act is most likely an error.

Minnesota Statutes, section 103H.201 HEALTH RISK LIMITS lists only factors related to the protection of human health. This section does not specify that the health risk limits incorporate economic or technological factors, the protection of the environment, or the health of non-human species. Other sections of the Groundwater Protection Act do consider such issues. For example, Minnesota Statutes, section 103H.275 MANAGEMENT OF POLLUTANTS WHERE GROUNDWATER IS POLLUTED refers to "best management practices" defined in Minnesota Statutes, section 103H.005, subdivision 4:

> "Best management practices" means practicable voluntary practices that are capable of preventing and minimizing degradation of groundwater, considering economic factors, availability, technical feasibility, implementability, effectiveness, and environmental effects.

Thus, the Groundwater Protection Act appears to make a distinction between risk assessment, which gives information on health risk, and risk management, which describes the action to be taken based on this information. The proposed health risk limits are an

example of risk assessment, where the sole intent is to determine a level of exposure that should not cause a health hazard. By contrast, best management practices are an example of risk management, where many types of factors are taken into consideration to determine the most practical means of reducing exposure.

Accordingly, the parameters for systemic toxicants that are not carcinogens, stated in paragraph (c) above, indicate the elements that the United States Environmental Protection Agency uses to set Maximum Contaminant Level Goals (MCLGs) for noncarcinogens in drinking water. MCLGs are health-based drinking water guidelines, as opposed to the Maximum Contaminant Levels (MCLs), which are drinking water standards that factor in economics and technological feasibility. The National Primary Drinking Water Regulations published in the Federal Register state (Federal Register, 1991a, p. 3531):

> MCLGs are set at concentration levels at which no known or anticipated adverse health effects would occur, allowing for an adequate margin of safety.

Although the statute does not describe the method for calculating the health risk limits for carcinogens in as much detail as it does for systemic toxicants, the Minnesota Department of Health interprets the intent of the statute to be that the development of health risk limits for carcinogens follow the same human health-based premise as specified for systemic toxicants.

A health risk limit estimates the long-term exposure level of a substance or chemical, found to degrade groundwater, that is unlikely to result in deleterious effects to humans. A health risk limit is expressed as a concentration, or calculated as a "hazard index."

II. NOTICE OF SOLICITATION FOR COMMENT

In accordance with Minnesota Statutes, section 14.10 the Minnesota Department of Health published Notices of Solicitation of Outside Information or Opinions in the State Register on August 7, 1989 at 14 S.R. 292 and on January 22, 1990, at 14 S.R. 1879 (State Register, 1989).

Following publication of the Notice of Solicitation of Outside Information or Opinions about the proposed rules in the *State Register*, the department received letters from four parties commenting about the rules to be proposed (MDH2, 1991). Two were from Commissioners of the Minnesota Pollution Control Agency, one was from the Commissioner of the Minnesota Department of Agriculture, and one was from a citizen representing an interested organization.

III. DEVELOPMENT OF THE PROPOSED HEALTH RISK LIMIT RULES, TECHNICAL ADVISORY WORK GROUP AND EDUCATIONAL OUTREACH

The Minnesota Department of Health developed the proposed health risk limits rules in consultation with a technical advisory work group convened specifically for this purpose. The 14 member technical advisory work group consisted of persons from industry, environmental consulting firms, environmental organizations, academia, University extension, agribusiness, and other state agencies (MDH/HRA, 1990b). The technical advisory work group met six times between August 1990 and March 1991 to discuss technical and policy questions concerning the proposed rules (MDH/HRA, 1991a). Staff of the department's Section of Health Risk Assessment prepared briefing papers on various risk assessment and policy issues (MDH/HRA, 1990c-g; MDH/HRA, 1991c-f). These papers were presented to the work group for information and to stimulate discussion. The Technical Advisory Work Group members were asked to review three initial drafts of the proposed health risk limits rules. Several members sent in comments on the drafts (MDH3, 1991). The minutes and positions of the work group meetings are summarized in a report prepared by the department, and distributed to members for review before its completion (MDH/HRA, 1991b).

The technical advisory work group minutes, the report of the proceedings of the technical advisory work group, the briefing papers, and fact sheets record the evolution of the proposed rules. Some of the positions discussed in these documents are not identical with the positions put forth in the proposed rules or this statement of need and reasonableness. It should be emphasized that the work group was an advisory group. The Minnesota Department of Health considered the work group discussions, positions, and comments in formulating positions on various issues for the proposed rules. Some of the department positions were modified or decided after the conclusion of the work group meetings. Hence, the technical advisory work group minutes, the report on the proceedings of the technical advisory work group, and the briefing papers reflect the historical development of the proposed rules; the statement of need and reasonableness represents the Minnesota Department of Health's current position on the proposed rules. In the case of discrepancies between any historical or educational outreach documents and the statement of need and reasonableness or the proposed rules, the statement of need and reasonableness and the proposed rules are the governing documents.

In addition to publication of the Notices of Solicitation of Outside Information or Opinions regarding the proposed rules and the formation of the technical advisory work group in August 1990, the department's Section of Health Risk Assessment initiated educational outreach about the development of health risk limits rules (MDH/HRA, 1990h). Interested parties were identified, and included persons representing interested local health departments

in Minnesota and organizations and agencies that provide education or services related to groundwater or environmental health protection.

A mass mailing was sent in December 1990 to 651 persons in agencies or organizations concerned about environmental health or groundwater, requesting their cooperation as a communication link with communities they represent (MDH/HRL: Mailing A). Included were chairpersons of local boards of health, community health service administrators, county water planning coordinators, local environmental health staff, University Extension agents, and organizations representing environmental educational, research, citizen, civic and industry and professional interests. Organizations represented in the technical advisory work group were included in this network. The 375 persons who responded to this initial mailing comprise the basis of a newly-formed "Groundwater Outreach Network."

Of the 375 people who responded to the December 1990 mailing, 29 wrote comments or questions to the department under "questions or concerns I want you to know about" on the mailing reply forms (MDH1, 1990). Other people who subsequently contacted the department and requested information about the proposed health risk limits rules were also added to this network. As of July 31, 1992, 443 persons were listed in the department's Groundwater Outreach Network database.

Two fact sheets on health risk limits were produced during the development of the proposed health risk limits rules, and distributed in a mailing in February 1991 (MDH/HRL: Mailing B). Approximately 7,000 each of two fact sheets, "What are the health-based groundwater standards--health risk limits?," and "How a health risk limit is calculated" (MDH/HRA, 1991g), were distributed for educational purposes. The fact sheets, briefing papers, minutes and report of the Health Risk Limits Technical Advisory Work Group were provided to Network members who requested them. Educational activities on the proposed health risk limits rules also included presentations in various regions of the state, augmented by visual aids such as slides and displays.

Much of the education on the health risk limits rules was channeled through interested organizations to their members. Articles or notices describing health risk limits were placed in newsletters of network constituents, including the department's community health services publications *This Week's Mailing* and *Commentary* (MDH/HRL: Articles).

After completion of the work group's meetings, members were surveyed about their satisfaction with the work group's proceedings. Out of the 15 surveyed, nine responded (60%). Most members who responded indicated satisfaction with the meeting minutes, briefing papers that proposed the group's positions, and

felt that the purpose and activity of the group was clear (MDH/HRA, 1991h).

The department also evaluated the perceived usefulness of the health risk limits educational outreach program by surveying members of Groundwater Outreach Network in December 1991 (MDH/HRA, 1992). Included in this evaluation were comments relating to the proposed health risk limits rules, as well as other department environmental health programs.

IV. PUBLICATION OF PROPOSED RULES AND NOTICE TO ADOPT

In addition to publication of the proposed rules and notice to adopt in the State Register and mailing of the notice and proposed rules to parties on the department's certified mailing list, the notice to adopt and proposed rules were also sent to a discretionary mailing list compiled for this purpose. The discretionary list includes people in the Groundwater Outreach Network, plus Minnesota county commissioner chairs, county water planners not in the groundwater outreach network, and other organizations interested in environmental affairs listed in the Minnesota State Planning Agency's 1991-92 *Environmental Directory* or the Alliance for Sustainable Agriculture's 1991 *Green Pages* (MDH4, 1992).

V. FISCAL IMPACT: COST OF IMPLEMENTATION TO STATE AND LOCAL GOVERNMENT

Pursuant to Minnesota Statutes, sections 3.982, 14.11 and 15.065, the Department is compelled to assess the net cost of the proposed rules on state and local public bodies. The proposed rules do not require the expenditure of public monies by state or local public bodies. The health risk limits proposed are not being directly applied by the Minnesota Department of Health to any public programs, services or public party in these proceedings. If the Minnesota Department of Health or other agencies apply the proposed health risk limits in the future, the impact of this would have to be determined by those agencies.

VI. SMALL BUSINESS CONSIDERATIONS

Minnesota Statutes, section 14.115, requires that an agency consider five factors for reducing the impact of proposed rules on small business. The proposed rules will have no impact on small business because the limits as proposed in these proceedings are not being directly applied by the department to any program, service or party.

VII. IMPACT ON AGRICULTURAL LAND

Minnesota Statutes, section 14.11, subdivision 2 states that:

> If the agency proposing the adoption of the rule determines that the rule may have a direct and substantial adverse impact on agricultural land in the state, the agency shall comply with the requirements of sections 17.80 to 17.84.

Minnesota Statutes, sections 17.80 to 17.84 is the state Agricultural Land Preservation and Conservation Policy. The aim of this policy is to prevent the conversion of agricultural land to other uses. While planned development and soil and water conservation are pinpointed, the policy also states that policy will be best met by a) "providing relief from escalating property taxes and special assessments...," [Minnesota Statutes, section 17.80, subdivision 2 (c)] and b) promoting the use of management procedures that maintain or enhance the productivity of lands well suited to the production of food and agricultural products [M.S. section 17.83, subdivision 2 (f)]."

The proposed rules will have no direct or substantial adverse impact on agricultural land because the health risk limits are not being directly applied by the Minnesota Department of Health in these proceedings to any program, service or party. The proposed health risk limits may become a standard or be considered as a criteria or factor for future remediation or clean up programs or advisory activity by other agencies or by the Minnesota Department of Health in future proceedings. At this time, the Minnesota Department of Health cannot estimate the specific cost or impact of any future application. If such future application is proposed, the impact at that time will be assessed by those agencies determining the application.

VIII. INTRODUCTION TO RISK ASSESSMENT METHODS

Health risk limits are health-based standards. Their calculation is based on United States Environmental Protection Agency (USEPA) risk assessment methods and USEPA toxicologic data.

Methods

The derivation of health risk limits is consistent with the United States Environmental Protection Agency (USEPA) risk assessment methods, described generally in the USEPA's The Risk Assessment Guidelines of 1986 (USEPA, 1987), and more specifically in the USEPA's Risk Assessment, Management and Communication of Drinking Water Contamination (USEPA, 1990a) and in the National Primary Drinking Water Regulations; Final Rule, published in the Federal Register (Federal Register, 1991a). These methods were summarized in a briefing paper, Summary of Risk Assessment Methods

for Developing Exposure Guidelines for Groundwater Contaminants (MDH/HRA, 1990c), presented to the rule's technical advisory work group. The credibility of the USEPA methods lies in their extensive review by USEPA scientists as well as by experts outside of the USEPA (USEPA, 1987; USEPA, 1990a; Federal Register, 1991a). These methods have also been subject to public comment (USEPA, 1987; Federal Register, 1991a). Furthermore, a recent survey, conducted in part by the Federal-State Toxicology and Regulatory Alliance Committee, shows that most states use USEPA risk assessment methods, demonstrating the general acceptance of these procedures (Paull et al., 1991).

The Minnesota Department of Health has used USEPA risk assessment methods to develop recommended allowable limits (RALs), which have served as exposure guidelines for private water supplies since 1986 (MDH/HRA, 1986; MDH/HRA, 1988; MDH/HRA, 1991i). The derivation and use of recommended allowable limits are described in the Minnesota Department of Health's Recommended Allowable Limits for Drinking Water Contaminants. Release No. 3 (MDH/HRA, 1991i) and in a briefing paper presented to the rule's technical advisory work group, The Relationship and Application of MCLs, RALs, and HRLs (MDH/HRA, 1991f). The methods used to calculate health risk limits are consistent with the methods used to calculate the recommended allowable limits.

The following summarizes the methods used to determine the proposed health risk limits. The USEPA uses different methods to calculate safe levels of exposure to substances or chemicals that are carcinogens (cause cancer) and substances or chemicals that are systemic toxicants (do not cause cancer) (USEPA, 1990a, p. 3-6). Consistent with USEPA methods, different equations are used to calculate health risk limits for carcinogens and systemic toxicants. The use of different equations arises from the USEPA's assumption that systemic toxicants have a threshold dose below which they do not cause adverse effects. By contrast, the USEPA assumes that carcinogens are non-threshold agents. Therefore, any dose of a carcinogen above zero presents some risk of causing cancer. Classification of substances or chemicals as either carcinogens or systemic toxicants is done according to the USEPA classification system called the "categorization of overall weight of evidence for human carcinogenicity" described in detail in Section IX (USEPA, 1987, p. 1-11, 1-12, Statement of Need and Reasonableness, Section IX, rule-by-rule justification for part 4717.7150, subpart 2).

Reference Doses and Slope Factors

The critical variable in the calculation of a health risk limit is the potency of the substance or chemical. The measure of potency for systemic toxicants is called the "reference dose" and the measure of potency for carcinogens is called the "slope factor." The toxicologic data used to calculate reference doses

and slope factors usually come from laboratory studies on animals. Human data from epidemiologic studies are used when available.

The statute indicates that the Minnesota Department of Health use reference doses and slope factors published by the USEPA [Minnesota Statutes, section 103H.201, subdivision 1, paragraphs (c) and (d)]. According to Minnesota Statutes, section 103H.201, subdivision 1, paragraph (d):

> (d) For toxicants that are known or probable carcinogens, the adopted health risk limits shall be derived from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency's carcinogen assessment group.

This paragraph clearly specifies that the data used to calculate the health risk limits for carcinogens, the "quantitative estimate of the chemical's carcinogenic potency" (slope factor), come from the USEPA. The department believes the direction to use USEPA data also extends to the calculation of health risk limits for systemic toxicants. Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c) specifies, "...health risk limits [for systemic toxicants] shall be derived using United States Environmental Protection Agency risk assessment methods...." In light of this phrase, as well as paragraph (d) above, the department believes it is reasonable to interpret the intent of the statute to be that the use of USEPA risk assessment methods includes the use of USEPA data.

The department obtained the reference doses and slope factors used to calculate the proposed health risk limits from the USEPA's Integrated Risk Information System (IRIS). IRIS is an electronic database containing health risk and regulatory information on over 500 chemicals. The USEPA is composed of many offices and consequently publishes various sources of toxicologic data. According to the background documents on IRIS (USEPA, 1988a), "IRIS was developed for EPA staff in response to a growing demand for consistent risk information on chemical substances for use in decision-making and regulatory activities." The USEPA acknowledges IRIS as the USEPA source for reference doses and slope factors that have undergone the most thorough and standardized scientific review. Background documents for IRIS describe the review process for the data published on this network (USEPA, 1988a; USEPA, 1988b; USEPA, 1988c). Essentially, the data published on IRIS are reviewed either by the USEPA's Reference Dose Work Group, which reviews the toxicologic data for reference doses, or by the Carcinogen Risk Assessment Verification Work Group, which reviews the data for slope factors. These work groups are made up of scientists from the USEPA program offices and the USEPA Office of Research and Development. The appropriate work group must reach consensus before the USEPA will publish a reference dose or slope factor on IRIS (USEPA, 1988a; USEPA, 1988b; USEPA, 1988c).

The department believes that the use of IRIS is consistent with the intent of the statute. Minnesota Statutes, section 103H.201, subdivision 1, paragraph (d) specifies that the slope factors for carcinogens come from, "...the United States Environmental Protection Agency's carcinogen assessment group." The USEPA has been reorganized since adoption of the Groundwater Protection Act. Consequently there is no longer a group called the "carcinogen assessment group." The Carcinogen Risk Assessment Verification Work Group is the current equivalent of the carcinogen assessment group (personal communication[1]). The carcinogen assessment group was formed in the 1970's. In the early 1980's the carcinogen assessment group consisted of an expert professional staff who reviewed data on carcinogens, developed slope factors, and were the final authority on carcinogen risk assessment for the USEPA. In the late 1980's the carcinogen assessment group was absorbed into the Carcinogen Risk Assessment Verification Work Group. Since the carcinogen assessment group no longer exists and the Carcinogen Risk Assessment Verification Work Group is it's current functional equivalent, and since the Carcinogen Risk Assessment Verification Work Group publishes it's slope factors on IRIS, the department believes it is reasonable to interpret the statute to indicate the use of IRIS for obtaining the slope factors for carcinogens. The department also believes that if the statute indicates the use of IRIS to obtain slope factors, it is reasonable to interpret the statutory intent to extend to the selection of reference doses. IRIS lists only data that have undergone the highest level of USEPA review; the USEPA itself uses IRIS for federal rulemaking. This further supports the department's use of IRIS for calculating the proposed health risk limits. Therefore the department believes it is reasonable to obtain the reference doses and slope factors for the calculation of the health risk limits from IRIS.

Multiple Routes of Exposure

Calculation of a health risk limit is based on a standard adult ingestion rate of two liters of water per day (USEPA, 1989a, p. 2-1, 2-2; MDH/HRA, 1990c; Statement of Need and Reasonableness, Section IX, rule-by-rule justification for part 4717.7200, subpart 2, item F). Yet exposure to water contaminants can occur through pathways other than ingestion. For example, bathing results in dermal contact with water. Showering, cooking, running a humidifier, and other activities where water evaporates (volatilizes) result in exposure through inhalation. Therefore the department raised the question of whether the equations for the health risk limits should be modified to account for multiple routes of exposure to the rule's technical advisory work group.

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[1]Telephone conversation with Robert Cantilli of the USEPA Office of Drinking Water, Washington, D.C., May 22, 1991.

The department concluded, after consultation with the rule's technical advisory work group, that the equations should not be modified to account for multiple routes of exposure to groundwater contaminants (MDH/HRA, 1991a, 11/1/90, p.8). Although dermal absorption and inhalation are potentially important means of contact with groundwater contaminants, adequate models for assessing exposure through these pathways have not been developed.

A briefing paper, Multiple Routes of Exposure and Relative Source Contribution, presented to the technical advisory work group, discusses the assumptions and uncertainties built into existing models (MDH/HRA, 1990g). According to environmental scientists Andelman (Andelman, 1985) and McKone (McKone, 1987), the magnitude of inhalation exposure depends on factors such as volume of the dwelling, ventilation and temperature, which vary considerably from site to site (MDH/HRA, 1990g). In addition, the USEPA does not currently incorporate models for dermal and inhalation exposure into the calculation of their drinking water advisories or standards (Federal Register, 1991a, p. 3535). Instead the USEPA,

> ...maintains the position that exposure to drinking water contaminants from volatilization and dermal absorption is generally limited and adequately accounted for in the selection of relative source contribution factors (Federal Register, 1991a, p. 3535).

The relative source contribution factor is incorporated into the calculation of the health risk limits for systemic toxicants to account for exposure to the substance or chemical that might occur from sources other than water such as food or air. (A detailed explanation of the relative source contribution factor follows in Section IX, under the rule-by-rule justification for part 4717.7150, subpart 8). In general, the USEPA sets drinking water levels at one-fifth of the total allowable exposure from all sources. According to the National Primary Drinking Water Regulations, published in the Federal Register (Federal Register, 1991a, p. 3535), the USEPA believes this assumption is sufficient to account for multiple routes of exposure until they develop more accurate and applicable models for dermal and inhalation exposure to drinking water contaminants. This position was supported by the technical advisory work group (MDH/HRA, 1991a, 11/1/90, p.8).

Mixtures

Groundwater monitoring data may reveal the presence of more than one contaminant. Therefore the proposed health risk limits rules include a provision in parts 4717.7600 - 4717.7750 for determining the health risk limit for a mixture. The department believes that the statutory language "substance or chemical" (Minnesota Statutes, section 103H.005, subdivision 3) is broad enough to include mixtures. For example, The American Heritage

Dictionary, Second College Edition (American Heritage, 1985, p. 263) defines "chemical" as, "A substance that is produced by or used in a chemical process." This dictionary (American Heritage, 1985, p. 1213) defines "substance" as, "1. a. That which has mass and occupies space; matter. b. A material of a particular kind or constitution." Webster's Third New International Dictionary of the English Language (Merriam-Webster, 1986, p.2279) defines "substance" as, "...c: matter of definite or known chemical composition : an identifiable chemical element, compound, or mixture..." Given these definitions, the department believes that it is reasonable to interpret the meaning of "substance" to include both individual chemicals and mixtures of chemicals for the purposes of the proposed rules.

Reference doses and slope factors listed on IRIS are usually calculated from studies of exposures to single chemicals. A mixture of chemicals, even if each chemical is present at a concentration below it's health risk limit, may produce effects that would be not be predicted based on exposure to each component of the mixture alone. E.J. Calabrese, a professor of toxicology at the University of Massachusetts and a former member of the U.S. National Academy of Sciences and NATO Countries Safe Drinking Water committees, documented many types of chemical interactions (Calabrese, 1991). Sometimes a substance or chemical will increase the potency of another as in the case of asbestos and tobacco. Other times the opposite may be true, or there is no interaction. Finally, mixtures of substances or chemicals may act as though they are one material of a dose equal to the sum of their individual doses. The health risk limits calculated for individual chemicals or substances do not account for these possibilities.

Data are not available on every conceivable mixture and most of the existing data on mixtures come from experiments done at doses higher than those normally associated with environmental exposure. Nevertheless, concern about environmental exposure to mixtures prompted the USEPA to include a section on the risk assessment of mixtures in their risk assessment guidelines and the National Research Council to devote the major part of a volume of Drinking Water and Health to this issue (USEPA, 1987; NRC, 1989). Likewise, the department believes that the possible increase of adverse effects due to the presence of multiple chemicals warrants consideration of mixtures in the proposed health risk limits rules. Although the technical advisory work group did not reach a consensus on this issue, the majority of work group members present at the February technical advisory work group meeting (half of the members) did support the inclusion of a mixtures provision in the proposed rules (MDH/HRA, 1991a, 2/7/91).

The mixtures provision, (described in detail in Section IX, under the rule-by-rule justification for parts 4717.7600 - 4717.7750) follows the USEPA Guidelines for the Health Risk Assessment of Mixtures, which recommend applying an additivity

model when data are not available for a specific mixture or a similar mixture (USEPA, 1987). This additivity model has been adopted by the Minnesota Pollution Control Agency in rules applying to solid waste[2] [Minnesota Rules 7035.2815, subpart 4., item J., subitem (2)] and surface waters (Minnesota Rules 7050.0220, subpart 3, items E and G).

Detection Limits

The fact that some of the proposed health risk limits are below a level that can be detected using current and readily available analytical methods was also discussed with the rule's technical advisory work group. The department does not believe that the health-based calculation of a health risk limit should be compromised to meet a current analytical detection limit. The rule's technical advisory work group supported this position (MDH/HRA, 1991a, 1/3/91, p.8). As analytical methods improve, detection limits may be lowered. For example, if a health risk limit is set at the current detection limit, and in the future analytical methods improve, the result would be a health risk limit that is neither health based nor technologically based. In essence, the department believes that the protection of public health, not technology, should drive the health risk limits.

Selection of Substances or Chemicals

The selection of a substance or chemical for the proposed health risk limits rules was based on two criteria: 1) detection in Minnesota groundwater; and 2) publication of a reference dose or slope factor on IRIS.

According to the Groundwater Protection Act [Minnesota Statutes, section 103H.201 subdivision 1, paragraph (a)],

> If groundwater quality monitoring results show that there is a degradation of groundwater, the commissioner of health may promulgate health risk limits under subdivision 2 for substances degrading the groundwater.

Staff of the Minnesota Department of Health's Environmental Health Division, Section of Health Risk Assessment consulted the groundwater monitoring programs of the Minnesota Pollution Control Agency, the Minnesota Department of Agriculture, and the Minnesota Department of Health. Staff of the Minnesota Pollution Control Agency provided the department with a list of chemicals and

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[2]Minnesota Rules 7035.2815, subpart 4., item J., subitem (2) specifically cite "Guidelines for the Health Risk Assessment of Chemical Mixtures," published by the USEPA in the Federal Register on September 24, 1986, volume 51, pages 34014-34025 (USEPA, 1987).

substances identified in groundwater (MDH/HRA, 1990a, MPCA memo, 10/4/90). The department verified this list with the Department of Agriculture and the Department of Health's section of Water Supply and Well Management.

Staff of the Minnesota Department of Health's Section of Health Risk Assessment cross referenced the list of substances or chemicals against the USEPA's IRIS data base (See MDH/HRA 1990a for a description of this process). As discussed above, under **Reference Doses and Slope Factors**, the department interprets the statute to indicate the use of IRIS for obtaining reference doses and slope factors. Health risk limits were not developed for complex mixtures, like gasoline, for which there is no reference dose or slope factor listed on IRIS. Instead, health risk limits were developed for the components of complex mixtures, for which there is a reference dose or slope factor published on IRIS. This is a reasonable approach since monitoring data usually report both the detection of a complex mixture, such as gasoline, and detection of the components of the mixture, such as benzene, 1,2-dichloroethane, etc.

IX. RULE-BY-RULE JUSTIFICATION

4717.7100 PURPOSE.

This part is necessary to indicate the content of the proposed rules. The proposed rules specify the methods and factors for calculating the health risk limits; the proposed rules do not specify the application of the health risk limits. The Groundwater Protection Act specifies one application for the health risk limits. Section 103H.275 MANAGEMENT OF POLLUTANTS WHERE GROUNDWATER IS POLLUTED states that the pollution control agency or the commissioner of agriculture may adopt water [re]source protection requirements if implementation of best management practices has proven to be ineffective [Minnesota Statutes, section 103H.275, subdivision 1, item (b)]. If water resource protection requirements are adopted, then the health risk limits must be used in their development. Minnesota Statutes, section 103H.275, subdivision 1, item (c) states:

> (c) The water resources protection requirements must be: (1) designed to prevent and minimize the pollution to the extent practicable; (2) designed to prevent the pollution from exceeding the health risk limits; and (3) submitted to the legislative water commission.

Although the Groundwater Protection Act only specifies one application for the health risk limits, the Minnesota Department of Health anticipates other state groundwater protection programs may also use the health risk limits. The Minnesota Department of Health may consider health risk limits when reviewing plans for the construction of new wells or the continued use of wells in areas

with contaminated groundwater. Other state agencies may also reference health risk limits in new rules or in rules undergoing revision.

4717.7150 DEFINITIONS.

Subpart 1. **Scope.** Subpart 1 is necessary to establish that the definitions in this part have a meaning specific to the proposed rules. These definitions are necessary for the consistent and intended interpretation of the proposed rules.

Subpart 2. **Carcinogen.** This definition is needed because Minnesota Statutes, section 103H.201, subdivision 1, paragraph (b) states:

> Health risk limits shall be determined by two methods depending on their toxicological end point.

Paragraph (c) of section 103H.201 outlines the method for determining the health risk limits for "systemic toxicants that are not carcinogens." "Carcinogen" is thus used throughout the proposed rules to refer to those substances or chemicals that have a common toxicological endpoint, cancer, and to which the method for determining a health risk limit specified in Minnesota Statutes, section 103H.201, subdivision 1, paragraph (d) is applied. Paragraph (d) outlines the method for developing health risk limits for toxicants that are "known or probable carcinogens." The department considers the statutory language "known" and "probable" to be equivalent to the language "human" and "probable human" used by the United States Environmental Protection Agency in the section on the "categorization of overall weight of evidence for human carcinogenicity" in the United States Environmental Protection Agency's The Risk Assessment Guidelines of 1986 (USEPA, 1987, p. 1-12). The proposed definition of "carcinogen" is reasonable since the United States Environmental Protection Agency's National Primary Drinking Water Regulations, published in the Federal Register (Federal Register, 1991a, p. 3533) state:

> Category I contaminants [human and probable human carcinogens] are those contaminants [for] which [the] EPA has determined that there is strong evidence of carcinogenicity from drinking water ingestion.

The proposed definition of "carcinogen" does not include substances or chemicals classified by the USEPA as "possible human carcinogens." "Possible human carcinogens" are classified as such because there is limited or equivocal evidence that they cause cancer in humans (USEPA, 1987; Federal Register, 1991a; USEPA, 1990a). The USEPA generally sets drinking water Maximum Contaminant Level Goals (MCLGs) for "possible human carcinogens" using the same approach that is used for systemic toxicants with the addition of an extra uncertainty factor. The National Primary

Drinking Water Regulations, published in the Federal Register (Federal Register, 1991a, p. 3533) state:

> For Category II contaminants [possible human carcinogens] two approaches are used to set the MCLGs--either (I) setting the goal based upon noncarcinogenic endpoints (the RfD) then applying an additional uncertainty (safety) factor of up to 10 or (2) setting the goal based upon a nominal lifetime cancer risk calculation in the range of 10^{-5} to 10^{-6} using a conservative calculation model. The first approach is generally used; however, the second is used when valid noncarcinogenicity data are not available and adequate experimental data are available to quantify the cancer risk.

"Possible human carcinogens" are therefore not included in the definition of "carcinogens" because of the limited evidence of carcinogenicity and because the health risk limit for a "possible human carcinogen" is not calculated by the same method used for a carcinogen.

Subpart 3. **Chemical abstracts service registry number or CAS RN.** This definition is needed because "CAS RN" is used throughout the proposed rules to identify substances or chemicals that may be known by various synonyms. The Chemical Abstracts Service, a division of the American Chemical Society, has assigned a unique Chemical Abstracts Service Registry Number ("CAS RN") to over 600,000 substances or chemicals (CAS, 1991). The scientific community uses CAS RNs as a universal means to identify substances or chemicals. The Chemical Abstracts Service maintains these numbers in a computer data base as well as publishing them in many documents including The Registry Handbook-Common Names, which is updated annually (CAS, 1991).

Subpart 4. **Health risk limit or HRL.** "Health risk limit" or "HRL" is defined in Minnesota Statutes, section 103H.005, subdivision 3. The definition is included because "health risk limit" or "HRL" is referred to throughout the rule. Reference to the statute ensures consistency between the proposed rules and the meaning given in statute.

Subpart 5. **Integrated Risk Information System or IRIS.** This definition is needed because IRIS is referred to throughout the proposed rules as the source for reference doses and slope factors.

As discussed in section VIII **Introduction to Risk Assessment Methods, Reference Doses and Slope Factors**, IRIS is an USEPA electronic database containing health risk, toxicologic and regulatory information on over 500 chemicals. The USEPA acknowledges IRIS as the USEPA source for reference doses and slope

factors that have undergone the most thorough and standardized scientific review.

Section VIII **Introduction to Risk Assessment Methods, Reference Doses and Slope Factors**, explains why the department believes it is reasonable to use IRIS as the source for reference doses and slope factors.

Subpart 6. **Possible human carcinogen.** This definition is needed because "possible human carcinogen" is used to describe a subclass of systemic toxicants in part 4717.7200, subpart 4 of the proposed rules.

The definition for "possible human carcinogen" comes from The Risk Assessment Guidelines of 1986 published by the USEPA (USEPA, 1987). These guidelines define "possible human carcinogens" as follows:

> This group ["possible human carcinogens"] is used for agents with limited evidence of carcinogenicity in animals in the absence of human data.

"Possible human carcinogens" are not included in the definition of carcinogens: 1) because of the limited evidence of carcinogenicity; and 2) because the USEPA generally sets drinking water standards for "possible human carcinogens" using the same approach that is used for systemic toxicants with the addition of an extra uncertainty factor (Federal Register, 1991a, p. 3533). In accordance with USEPA risk assessment methods, the health risk limit for a "possible human carcinogen" will be calculated using the same method used for calculating a health risk limit for a systemic toxicant, and incorporate an additional safety factor.

Subpart 7. **Reference Dose or RfD.** This definition is needed because Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c) requires the use of a reference dose (RfD) for the calculation of a health risk limit for a systemic toxicant.

The USEPA publication Risk Assessment, Management and Communication of Drinking Water Contamination defines a RfD as follows (USEPA, 1990a, p. 3):

> The RfD is an estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse systemic health effects over the person's lifetime. The RfD is usually given in milligrams of chemical per kilogram of body weight per day (mg/kg/day), has an overall built-in uncertainty spanning perhaps an order of magnitude, and takes into consideration sensitive human subgroups.

The RfD is not an absolute benchmark of safety. Rather, the necessity of extrapolating from animal data to human health effects, coupled with the range of sensitivities within the human population, makes the RfD a best estimate, with a reasonable margin of safety, of the dose below which no adverse effects should occur.

Derivation of the RfD is explained in many USEPA documents, including the National Primary Drinking Water Regulations published in the Federal Register (Federal Register, 1991a, p.3531-3532) and in Risk Assessment, Management and Communication of Drinking Water Contamination (USEPA, 1990a, p. 4), as well as in a briefing paper prepared for the rule's technical advisory work group, Summary of Risk Assessment Methods for Developing Exposure Guidelines for Groundwater Contaminants (MDH/HRA, 1990c). Basically, the RfD is calculated by dividing the no-observed-adverse-effect-level (NOAEL) or lowest-observed-adverse-effect-level (LOAEL) by an uncertainty factor:

$$\frac{\text{(NOAEL or LOAEL)}}{\text{Uncertainty Factor}}$$

The NOAEL is usually derived from experimental animal data and reflects the highest estimated dose at which no adverse effects of the agent should occur. The LOAEL is the lowest dose at which adverse effects have been observed. The use of a NOAEL or LOAEL depends on the available data. Because NOAELs and LOAELs are expressed in terms of milligram of the substance or chemical per kilogram of body weight per day, and the uncertainty factor is unitless, the RfD is also expressed in terms of milligram of the substance or chemical per kilogram of body weight per day.

The uncertainty factor results from multiplying numbers that represent various sources of uncertainty in the data. For example, a factor of 10 is included when animal data are used to derive values that are applied to human health. Another factor of 10 is incorporated to consider that some members of the population may be more sensitive to a substance or chemical than others. [This factor represents the inclusion of "sensitive subgroups" into the derivation of the health risk limit as required by Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c)]. These two common sources of uncertainty would result in an uncertainty factor of 100 (10 x 10). Numbers reflecting other sources of uncertainty, such as the quality of the data and the use of the LOAEL instead of the NOAEL, can also contribute to the uncertainty factor. The department believes the uncertainty factor used to calculate an RfD satisfies the statutory requirement for an uncertainty factor stated in Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c).

The department believes the statute indicates the use of IRIS to obtain reference doses, as discussed in section VIII

Introduction to Risk Assessment Methods, 'Reference Doses and Slope Factors.' Therefore the department believes it is reasonable to limit the definition of reference dose or RfD to those listed on IRIS.

Subpart 8. **Relative Source Contribution or RSC.** This definition is needed because these terms are used in parts 4717.7200 and 4717.7800.

The department interprets the phrase "relative source contamination" in Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c) to mean the "relative source contribution" (RSC) factor used by the USEPA to calculate drinking water standards. The use of "relative source contamination" in statute is most likely an error since the USEPA widely refers to relative source **contribution** but does not, to the department's knowledge, use any factor called relative source **contamination.**

The RSC is incorporated into the equation to estimate the percent of total exposure to a substance or chemical, including air and food, that comes from ingesting water. For example, if the USEPA estimates that 20 percent of exposure to a substance comes from drinking water, they use an RSC factor of 0.2. The USEPA summarized their approach to assigning RSC factors in the National Drinking Water Regulations published in the 1991 Federal Register (Federal Register, 1991a, p. 3535). When adequate data are available to estimate the percent of total exposure to a substance or chemical from drinking water, and that value is between 20 percent and 80 percent, the USEPA uses that data for the RSC factor. If exposure from drinking water is less than 20 percent, the USEPA uses an RSC factor of 20 percent (0.2). If exposure from drinking water is above 80 percent, the USEPA generally uses an RSC factor of 80 percent (0.8). As stated in the Federal Register (Federal Register, 1991a, p. 3535):

> EPA believes that the 20 percent floor is very protective and represents a level below which additional incremental protection is negligible. In addition, below 20 percent RSC from water is a clear indication that control of other more contaminated media will have a significantly greater reduction in exposure. EPA believes the 80 percent ceiling is required because, even if nearly all exposure is currently via drinking water, some portion, albeit small, of the adjusted daily intake (ADI) should be reserved to protect populations with unusual exposures and future changes in the distribution of the contaminant in the environment.

When adequate exposure data are not available, the USEPA generally assumes that 20 percent of total exposure to a substance or chemical comes from drinking water and therefore uses an RSC factor of 0.2. This is a conservative, protective assumption since it

means that only one fifth of the allowable exposure to a substance or chemical from all sources will come from drinking water.

The statute indicates the use of USEPA methods to calculate the proposed health risk limits (Minnesota Statutes, section 103H.201, subdivision 1, paragraph c; section VIII **Introduction to Risk Assessment Methods**, 'Reference Doses and Slope Factors'). Therefore, the department believes it is reasonable to limit the definition of RSC to those values listed by the USEPA. The USEPA lists RSCs in either the Health Advisories, published by the USEPA, Office of Drinking Water, the Federal Register, or on IRIS.

Subpart 9. **Slope factor.** This definition is needed because this term is used throughout the proposed rules.

The slope factor is the quantitative estimate of potency required in Minnesota Statutes, section 103H.201, subdivision 1, paragraph (d). The risk of cancer from the low levels of carcinogens usually found in groundwater cannot be directly measured using either animal models or epidemiologic studies (USEPA, 1988c). Instead the USEPA uses mathematical models to extrapolate from high study doses to low environmental exposure levels. These models, which generate the slope factors, are described in the USEPA's Guidelines for Carcinogen Risk Assessment and in the background documents to IRIS (USEPA, 1987, p. 1-8 - 1-9; USEPA, 1988c). The slope factor is expressed in terms of the inverse of milligrams of the substance or chemical per kilogram of body weight per day ($[mg/kg/day]^{-1}$).

As discussed in section VIII **Introduction to Risk Assessment Methods**, **Reference Doses and Slope Factors**, the department believes the statute indicates the use of IRIS to obtain slope factors. Therefore the department believes it is reasonable to limit the definition of slope factor to those listed on IRIS.

Subpart 10. **Systemic toxicant.** This term is used throughout the rule for a class of substances or chemicals that, according to the "categorization of overall weight of evidence for human carcinogenicity" in The Risk Assessment Guidelines of 1986, published by the USEPA, have inadequate human and animal evidence of carcinogenicity or for which no data on carcinogenicity are available (USEPA, 1987). The health risk limit for a "systemic toxicant" is based on a toxicologic endpoint other than cancer, such as liver damage, kidney damage or damage to other organs or organ systems. The definition is based in Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c) which refers to "systemic toxicants which are not carcinogens." As discussed under subpart 6 of this part, possible human carcinogens are a subclass of systemic toxicants.

Subpart 11. **Uncertainty factor or UF.** This definition is needed because the terms appear in parts 4717.7200 and 4717.7800.

The calculation of a health risk limit for a possible human carcinogen incorporates a specific uncertainty factor to account for the possible carcinogenicity of a substance of chemical. The use of this specific uncertainty factor complies with the USEPA method for determining the Maximum Contaminant Levels Goals for possible human carcinogens as stated in the Federal Register (Federal Register, 1991a, p. 3533):

> For Category II contaminants [possible human carcinogens] two approaches are used to set the MCLGs--either (I) setting the goal based upon noncarcinogenic endpoints (the RfD) then applying an additional uncertainty (safety) factor of up to 10 or (2) setting the goal based upon a nominal lifetime cancer risk calculation in the range of 10^{-5} to 10^{-6} using a conservative calculation model. The first approach is generally used; however, the second is used when valid noncarcinogenicity data are not available and adequate experimental data are available to quantify the cancer risk.

The statute indicates the use of USEPA methods to calculate the proposed health risk limits (Minnesota Statutes, section 103H.201, subdivision 1, paragraph c; section VIII **Introduction to Risk Assessment Methods**, 'Reference Doses and Slope Factors'). Therefore, the department believes it is reasonable to limit the definition of UF to those values listed by the USEPA. The USEPA lists UFs (also called safety factors) in either the Health Advisories, published by the USEPA, Office of Drinking Water, the Federal Register, or on IRIS.

4717.7200 HEALTH RISK LIMITS FOR SYSTEMIC TOXICANTS.

Subpart 1. **Scope.** This part describes the proposed methods for the calculation of health risk limits for systemic toxicants, which includes the proposed method for possible human carcinogens. The proposed methods are the same methods used by the USEPA to calculate maximum contaminant level goals for systemic toxicants and possible human carcinogens, as described in the National Primary Drinking Water Regulations published in the Federal Register, January 30, 1991, p. 3531-3535 (Federal Register, 1991a). The proposed methods comply with the procedure for deriving health risk limits for "systemic toxicants that are not carcinogens" as stated in Minnesota Statutes, section 103H.201, subdivision 1, paragraph (c):

> (c) For systemic toxicants that are not carcinogens, the adopted health risk limits shall be derived using United States Environmental Protection Agency risk assessment

methods using a reference dose, a drinking water equivalent, an uncertainty factor, and a factor for relative source contamination, which in general will measure an estimate of daily exposure to the human population, including sensitive subgroups, that is unlikely to result in deleterious effects during long-term exposure.

Subpart 2. **Equation for systemic toxicants other than nitrate (as nitrogen) or possible human carcinogens.** The equation proposed in subpart 2 is consistent with the equation used by the USEPA in the national primary drinking water regulations to calculate maximum contaminant level goals (MCLGs) for systemic toxicants (Federal Register, 1991a p. 3532). This equation incorporates all of the parameters listed in Minnesota Statutes, section 103H.201, paragraph (c). Three parameters listed in the statute are not explicitly listed in this subpart, "relative source contamination", discussed in the rule-by-rule justification for items C and D of this subpart, "uncertainty factor", discussed in the rule-by-rule justification for part 4717.7150, subpart 7, and "drinking water equivalent."

The USEPA calculates a drinking water equivalent (DWEL) as follows (Federal Register, 1991a, p. 3532; USEPA, 1990a, p. 4):

$$DWEL = \frac{(RfD)(70)}{2}$$

where RfD represents the reference dose, 70 represents 70 kilograms, the standard weight of an adult, (see USEPA, 1989a, p. 5-7 and justification for item B of this subpart), and 2 represents 2 liters of water per day, the standard volume of water consumed by an adult, (see USEPA, 1989a, p. 2-1, 2-2 and justification for item F of this subpart). All three of these factors are incorporated into the proposed equation:

$$HRL = \frac{\mathbf{(RfD)\,(70)}\,(RSC)\,(1,000)}{\mathbf{(2)}}$$

In other words the drinking water equivalent appears in the equation in the form of its three components, where the RfD and 70 are in the numerator and 2 is in the denominator. Therefore calculation of a health risk limit for a systemic toxicant includes a drinking water equivalent.

A. Item A states the units of concentration "microgram or micrograms per liter" for expressing a health risk limit. Micrograms per liter are convenient and widely used units of concentration.

B. The USEPA's Exposure Factors Handbook recommends using 70 kilograms as the standard weight for an adult (USEPA, 1989a, p. 5-

7). Accordingly, the USEPA uses 70 kilograms for adult body weight in the calculation of drinking water standards for public water supplies (Federal Register 1991, p. 3532; USEPA, 1990a, p. 4).

C. As discussed under the definition of RSC (see rule-by-rule justification for part 4717.7150, subpart 8), the USEPA generally assumes a RSC value of 0.2 when total exposure data are not available for a substance or chemical (Federal Register, 1991a, p. 3535). This is a protective assumption since it means that only 20 percent (one fifth) of the allowable exposure to a substance or chemical from all sources will come from drinking water. Therefore the department believes it is reasonable to use a RSC of 0.2 for systemic toxicants unless otherwise indicated by the USEPA.

D. This item lists the substances or chemicals included in part 4717.7500 for which the USEPA has estimated an RSC factor other than 0.2.

(1) The USEPA used an RSC of 0.4 to calculate the maximum contaminant level goal (MCLG) for antimony (CAS RN 7440-36-0), according to the National Primary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals; Final Rule, published in the Federal Register (Federal Register, 1992, p. 31784). The USEPA arrived at a RSC of value of 0.4 after reviewing data on dietary intake of antimony and intake due to drinking water.

(2) The USEPA drinking water advisory for barium (CAS RN 7400-39-3) lists a relative source contribution from water of 83 percent (RSC = 0.83) (ODW, 1987, p.8). To be consistent with the USEPA's general policy of applying an RSC factor of 0.8 where drinking water exposure is estimated to constitute 80 percent or greater of the total exposure, the proposed health risk limit for barium was calculated using an RSC factor of 0.8.

(3) The USEPA assigned a drinking water contribution of 25 percent (RSC = 0.25) to cadmium (CAS RN 7440-43-9) in the National Primary and Secondary Drinking Water Regulations proposed in the Federal Register (Federal Register, 1989, p. 22075). The proposed MCLG was adopted in 1991 (Federal Register, 1991a, p. 3536). In the 1989 Federal Register, the USEPA states:

> Regarding the 25 percent drinking water contribution for cadmium, EPA believes that this value is appropriate, since evidence indicates that absorption of cadmium is greater from water than from food.

(4) The USEPA discusses the RSC for chromium (CAS RN 18540-29-9) in the proposed National Primary and Secondary Drinking Water Regulations published in the 1989 Federal Register, (Federal Register, 1989 p. 22075):

> EPA agrees that food normally contributes over 50 percent of the total dietary intake of chromium. However, in cases where chromium drinking water concentrations are at the MCLG of .1 mg/l, available data indicate that drinking water provides about 70 percent of the total daily chromium intake.

The proposed health risk limit for chromium VI, 100 micrograms per liter (0.1 mg/l), is the same as the MCLG adopted in 1991 (Federal Register, 1991a, p. 3536-7.) The department believes it is reasonable to be consistent with the USEPA and use 0.7 as the RSC for chromium VI.

(5) The department believes it is reasonable to specify a RSC for manganese (CAS RN 7439-96-5) of 0.8 as a protective measure.

The reference dose for manganese was calculated from an epidemiologic study in which the source of manganese was well water (USEPA, 1993m). Since the study population ingested manganese through well water and food, this RfD should account for manganese exposure that comes from both sources.

Nevertheless, the department believes it is reasonable to specify a RSC for manganese of 0.8 in accordance with the USEPA methods discussed in the definition of RSC (see 4717.7200, subpart 8 above). Essentially, even if the RfD accounts for over 80% of total exposure, the USEPA generally uses an RSC factor of 80 percent (0.8). As stated in the Federal Register (Federal Register, 1991a, p. 3535):

> EPA believes the 80 percent ceiling is required because, even if nearly all exposure is currently via drinking water, some portion, albeit small, of the adjusted daily intake (ADI) should be reserved to protect populations with unusual exposures and future changes in the distribution of the contaminant in the environment.

An RSC of 0.8 allows a margin of protection to account for variability in manganese exposure due to diet, lifestyle and occupation.

E. There are 1,000 micrograms in every milligram. Therefore the incorporation of a factor of 1,000 into the equation is necessary and reasonable to convert the units of concentration from milligrams per liter to micrograms per liter. The latter is a more convenient expression of concentration for a health risk limit.

F. According to the Exposure Factors Handbook published by the USEPA's Exposure Assessment Group, Office of Health and Environmental Assessment (USEPA, 1989a, p. 2-1, 2-2), the USEPA currently uses 2 liters per day as the long-term average consumption rate of water by an adult. This value includes the

consumption of food and beverages made with tap water such as juice, soup or coffee. This document also states that USEPA officials believe that a water consumption rate of 2 liters per day is an overestimate for most people. Therefore 2 liters per day is a protective value. Since the health risk limits are calculated for long-term exposure and the USEPA uses 2 liters per day as the average daily water consumption to calculate the MCLGs, the department believes that 2 liters per day is a reasonable standard for adult water consumption (Federal Register, 1991a, p. 3532).

Subpart 3. **Equation for nitrate (as nitrogen).** The proposed equation for calculating the health risk limit for nitrate (as nitrogen) comes from the IRIS file for nitrate and is based on water consumption by infants up to 3 months of age (USEPA, 1992n2). (The concentration of nitrate in water is reported as "nitrate as nitrogen"). According to the United States Environmental Protection Agency, infants up to 3 months of age are the subpopulation most susceptible to nitrate toxicity (Federal Register, 1985, P. 46973):

> The toxicity of nitrate in humans is due to the body's reduction of nitrate to nitrite. This reaction takes place in saliva of humans at all ages and in the gastrointestinal tract of infants during the first three months of life. The toxicity of nitrite is demonstrated by vasodilatory/cardiovascular effects at high dose levels and methemoglobinemia at lower dose levels. Methemoglobinemia is an effect in which hemoglobin is oxidized to methemoglobin, resulting in asphyxia.
>
> Infants up to 3 months of age are the most susceptible subpopulation with regard to nitrate. This is due to the fact that in the adult and child, about 10 percent of ingested nitrate is transformed to nitrite, while 100 percent of ingested nitrate can be transformed to nitrite in the infant.

Because infants up to 3 months of age are the most susceptible subpopulation to nitrate and because the United States Environmental Protection Agency bases the calculation of the Maximum Contaminant Level Goal for nitrate (as nitrogen) on ingestion of water by infants up to 3 months of age (Federal Register, 1985, P. 46973), it is reasonable to calculate the health risk limit for nitrate (as nitrogen) based on ingestion of water by infants up to 3 months of age. Furthermore, the health risk limit for nitrate (as nitrogen) calculated by this method, 10,000 micrograms per liter, is the same value as the Maximum Contaminant Level Goal for nitrate (as nitrogen).

A. The justification for the meanings of "HRL" and "1,000" are the same as for subpart 2 of this part.

B. The United States Environmental Protection Agency uses 4 kilograms as the standard weight of an infant up to 3 months of age (USEPA, 1992n2).

C. The United States Environmental Protection Agency uses 0.64 liters per day as the standard amount of water used to prepare formula for an infant up to 3 months of age (USEPA, 1992n2).

Subpart 4. **Equation for possible human carcinogens.** The proposed equation for calculating the health risk limit for a possible human carcinogen is the same as the equation for the other systemic toxicants except for the incorporation of an additional uncertainty factor. This method complies with the USEPA method for determining the Maximum Contaminant Levels Goals for possible human carcinogens as stated in the Federal Register (Federal Register, 1991a, p. 3533):

> For Category II contaminants [possible human carcinogens] two approaches are used to set the MCLGs--either (I) setting the goal based upon noncarcinogenic endpoints (the RfD) then applying an additional uncertainty (safety) factor of up to 10 or (2) setting the goal based upon a nominal lifetime cancer risk calculation in the range of 10^{-5} to 10^{-6} using a conservative calculation model. The first approach is generally used; however, the second is used when valid noncarcinogenicity data are not available and adequate experimental data are available to quantify the cancer risk.

A. The justification for the meanings of "HRL," "70," "RSC," "2," and "1,000" are the same as for subpart 2 of this part.

B. As discussed in the rule-by-rule justification for part 4717.7150, subpart 11, the USEPA uses an uncertainty factor ranging from 1 to 10 is to calculate a drinking water limit for a possible human carcinogen. Where the USEPA has not published a specific uncertainty factor as specified in item C, the uncertainty factor for possible human carcinogens is 10. The department believes this is a reasonable approach since 10 is the most protective uncertainty factor used by the USEPA.

C. The Integrated Risk Information System (IRIS) file for 1,1,1,2-tetrachloroethane (CAS RN 630-20-6) assigns an uncertainty factor of 3 to this possible human carcinogen to account for possible cancer risk (USEPA, 1992t1).

4717.7300 HEALTH RISK LIMITS FOR CARCINOGENS.

Subpart 1. **Scope.** This subpart is necessary to state the purpose of the rule part.

Subpart 2. **Equation for carcinogens.** Subpart 2 specifies the method for calculating a health risk limit for a carcinogen. The proposed method follows USEPA risk assessment methods for carcinogens described in the Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) (USEPA, 1989b, p. 7-10 - 7-13), Risk Assessment Management and Communication of Drinking Water Contamination (USEPA, 1990a, p.5) and the background documents for the USEPA's Integrated Risk Information System (IRIS) (USEPA, 1988c). These methods are summarized in Summary of Risk Assessment Methods for Developing Exposure Guidelines for Groundwater Contaminants (MDH/HRA, 1990c), a paper prepared for the technical advisory work group. Minnesota Statutes, section 103H.201, subdivision 1, paragraph (d) states the general procedure for deriving the health risk limit for toxicants that are known or probable carcinogens:

> (d) For toxicants that are known or probable carcinogens, the adopted health risk limits shall be derived from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency's carcinogen assessment group.

The department believes that the "slope factor" in this equation, discussed in the rule-by-rule justification for part 4717.7150, subpart 9, satisfies the requirement for a quantitative estimate of the chemical's carcinogenic potency.

As discussed above, in section VIII **Introduction to Risk Assessment Methods, Reference Doses and Slope Factors**, the department also believes that the intent of Minnesota Statutes, section 103H.201, subdivision 1, paragraph (d) is that the department use the most reliable USEPA source available for obtaining the slope factor. To reiterate, at the time the statute was written the USEPA's carcinogen assessment group provided the most highly reviewed data on carcinogens. The carcinogen assessment group was formed in the 1970's. In the early 1980's the carcinogen assessment group consisted of an expert professional staff who reviewed data on carcinogens, developed slope factors, and was the final authority on carcinogen risk assessment for the USEPA. Since the Groundwater Protection Act was adopted, the USEPA has been reorganized. Consequently there is no longer a group called the "carcinogen assessment group." In the late 1980's the carcinogen assessment group was absorbed into the Carcinogen Risk Assessment Verification Work Group. The Carcinogen Risk Assessment Verification Work Group is the current equivalent of the carcinogen assessment group (personal communication[3]). Since the carcinogen assessment group no longer exists and the Carcinogen Risk Assessment Verification Work Group is it's current functional

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[3]Telephone conversation with Robert Cantilli of the USEPA Office of Drinking Water, Washington, D.C., May 22, 1991.

equivalent, and since the Carcinogen Risk Assessment Verification Work Group publishes it's slope factors on the USEPA electronic data base IRIS, the department believes it is reasonable to interpret the statute to indicate the use of IRIS for obtaining the slope factors for carcinogens.

A. The justification for item A is the same as for part 4717.7200, subpart 2, item A.

B. The lifetime risk level in item B represents the probability that exposure to the carcinogen for a lifetime will cause cancer. Thus, a person exposed to a concentration of a carcinogen corresponding to the proposed lifetime risk level of 10^{-5} for a lifetime would have a 1 in 100,000 chance of developing cancer from this exposure. In other words, if 100,000 people were exposed to a carcinogen at a level corresponding to the proposed lifetime risk level of 10^{-5}, no more than 1 out of those 100,000 people would be expected to develop cancer over their lifetime.

The use of a lifetime risk level factor to calculate exposure limits for carcinogens stems from the USEPA assumption that carcinogens are non-threshold agents, such that exposure to any level of a carcinogen above zero presents some risk of causing cancer. The department recognizes that setting the health risk limits for carcinogens at zero ignores the possible benefits of some chemicals or the processes that produce them. These benefits can be economic, technological and also health related. For example, from the view of public health, the benefit of chlorinating water--preventing the spread of infectious disease--outweighs the small risk of developing cancer from the resulting chlorinated compounds. The department justifies setting a cancer risk level above zero by weighing large benefits against small risks, and by recognizing that the presence of a low level of risk does not preclude safety.

The department has set exposure limits for carcinogens at a lifetime risk level of 10^{-5} since 1981 (MDH/HRA, 1985, p. 3) and proposes to use the same lifetime risk level to calculate the health risk limits for carcinogens. At least three lines of evidence support the reasonableness of 10^{-5}. First, 10^{-5} is well within the range of lifetime risk levels (10^{-4} - 10^{-6}) recommended by the USEPA (FSTRAC, 1990; USEPA, 1990a). Second, 10^{-5} has already been adopted into two Minnesota rules, the Minnesota Pollution Control Agency's Solid Waste Rules [Minnesota Rules, part 7035.2815, subpart 4, item H, subitem (5), subsubitem (b)] and their Surface Water Rules (Minnesota Rules, part 7050.0218, subpart 6, item C). Finally, the proposed lifetime risk level of 10^{-5} was unanimously supported by the rule's technical advisory work group (MDH/HRA, 1991a, 1/3/91).

The USEPA does not provide specific guidelines on how to choose a lifetime risk level. Instead, the USEPA health advisories for carcinogens in drinking water, as well as the IRIS files for carcinogens, give doses corresponding to three lifetime risk levels, 10^{-4} (1 in 10,000), 10^{-5} (1 in 100,000) and 10^{-6} (1 in a million). According to the Summary of State and Federal Drinking Water Standards and Guidelines compiled by the Federal-State Toxicology and Regulatory Alliance Committee (FSTRAC, 1990, p. 38):

> For EPA guidelines (Health Advisories), the drinking water concentrations associated with 10^{-4}, 10^{-5} and 10^{-6} cancer risk levels are reported so the risk manager can make a health decision based on the specific contamination situation.

While the USEPA recommends using a lifetime risk level between 10^{-4} and 10^{-6}, they leave the choice of a specific lifetime risk level up to the discretion of the regulatory agency.

A position paper written by staff of the department's section of health risk assessment, Tolerable Risk (MDH/HRA, 1985), presents the rationale for the choice of 10^{-5}. A supplementary paper, Carcinogen Lifetime Risk Level, (MDH/HRA, 1991c) was prepared for the technical advisory work group. A paragraph from Tolerable Risk summarizes the original paper:

> In 1977 the Minnesota Department of Health formalized environmental health risk assessment activities with the creation of the Section of Health Risk Assessment (HRA) in the Division of Environmental Health. In 1980-81 HRA conducted a critical review of the risk assessment/risk management literature (Gray, 1981). Included in this review was an examination of the tolerable risk issue. This report concluded that the "benefit-risk analysis" methods proposed by Starr (1969, 1972) was the best alternative for the selection of a lifetime tolerable risk. Using this method HRA derived a lifetime tolerable risk level of 10^{-5}.

C. The justification for this item is the same as for part 4717.7200, subpart 2, item B.

D. The justification for this item is the same as for part 4717.7200, subpart 2, item E.

E. The justification for this item is the same as for part 4717.7200, subpart 2, item F.

4717.7400 HEALTH RISK LIMITS.

This part lists the variables listed in the table of health risk limits in part 4717.7500. For each substance or chemical the variables listed are the chemical name, CAS RN, reference dose for systemic toxicants or slope factor for carcinogens, and the health risk limit. Since these variables are critical to the identification of a chemical or substance and calculation of a health risk limit, it is reasonable to list them.

Item A. To identify the substance or chemical for which a health risk limit is listed, it is necessary to list the common name of the substance or chemical.

Item B. The CAS RN is necessary as a universal means to identify substances or chemicals known by various synonyms.

Item C. It is reasonable to include the reference dose (RfD) for systemic toxicants since this is the critical variable for the calculation of a health risk limit for a systemic toxicant. Likewise it is reasonable to include the slope factor for carcinogens since this is the critical variable for the calculation of a health risk limit for a carcinogen.

Item D. It is necessary to list the health risk limit for each substance or chemical expressed in micrograms per liter.

4717.7500 TABLE OF HEALTH RISK LIMITS.

Subpart 1. **Generally.** This subpart is necessary to specify the health risk limits and the numerical factors used to derive the health risk limits. A health risk limit is calculated by putting into the equations specified in parts 4717.7200 and 4717.7300 the variables listed, and where appropriate the RSC factors specified in part 4717.7200, subpart 2, items C and D, and for possible human carcinogens the uncertainty factors specified in part 4717.7200, subpart 4, items B and C.

Since the variables used to calculate the health risk limits are generally only accurate to one significant digit, the resulting health risk limits are rounded down to one significant digit. For example, the RfD for acenapthene is 0.06 mg/kg/day. When this value is put into the equation for systemic toxicants, specified in part 4717.7200, subpart 2, the result is 420 micrograms per liter. This number is rounded down to 400, so that the health risk limit for acenapthene is 400 micrograms per liter. The RfD for 1,1-biphenyl is 0.05 mg/kg/day. When this value is put into equation for systemic toxicants, specified in part 4717.7200, subpart 2, the result is 350 micrograms per liter. This number is rounded down to 300, so that the health risk limit for 1,1-biphenyl is 300 micrograms per liter. Note, all digits 5 and under are rounded down. All digits 6 and over are rounded up. For example, the RfD

for fluoranthene is 0.04 mg/kg/day. When this value is put into equation for systemic toxicants, specified in part 4717.7200, subpart 2, the result is 280 micrograms per liter. This number is rounded up so that the health risk limit is 300 micrograms per liter.

Subpart 2. **Acenaphthene.** The CAS RN assigned to acenaphthene by the Chemical Abstracts Service is 83-32-9. Acenapthene is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for acenaphthene. The oral RfD for acenaphthene listed on IRIS is 0.06 milligram/kilogram/day (USEPA, 1992a1). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.06 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 400 micrograms per liter.

Subpart 3. **Acetone.** The CAS RN assigned to acetone by the Chemical Abstracts Service is 67-64-1. Acetone is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for acetone. The oral RfD for acetone listed on IRIS is 0.1 milligram/kilogram/day (USEPA, 1992a2). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.1 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 700 micrograms per liter.

Subpart 4. **Aldicarb.** The CAS RN assigned to aldicarb by the Chemical Abstracts Service is 116-06-3. Aldicarb is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for aldicarb. The oral RfD for aldicarb listed on IRIS is 0.0002 milligram/kilogram/day (USEPA, 1992a3). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.0002 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 1 microgram per liter.

Subpart 5. **Anthracene.** The CAS RN assigned to anthracene by the Chemical Abstracts Service is 120-12-7. Anthracene is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for anthracene. The oral RfD for anthracene listed on IRIS is 0.3 milligram/kilogram/day (USEPA, 1992a4). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When

the RfD of 0.3 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 2,000 micrograms per liter.

Subpart 6. **Antimony.** The CAS RN assigned to antimony by the Chemical Abstracts Service is 7440-36-0. Antimony is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for antimony. The oral RfD for antimony listed on IRIS is 0.0004 milligram/kilogram/day (USEPA, 1992a5). As stated in part 4717.7200, subpart 2, item D, subitem 1, the RSC is 0.4. When the RfD of 0.0004 milligram/kilogram/day and the RSC of 0.4 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 6 micrograms per liter.

Subpart 7. **Barium.** The CAS RN assigned to barium by the Chemical Abstracts Service is 7440-39-3. Barium is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for barium. The oral RfD for barium listed on IRIS is 0.07 milligram/kilogram/day (USEPA, 1992b1). As stated in part 4717.7200, subpart 2, item D, subitem 2, the RSC is 0.8. When the RfD of 0.07 milligram/kilogram/day and the RSC of 0.8 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 2,000 micrograms per liter.

Subpart 8. **Benzene.** The CAS RN assigned to benzene by the Chemical Abstracts Service is 71-43-2. The USEPA classifies benzene as a known human carcinogen (USEPA 1992b2). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for benzene. The oral slope factor for benzene listed on IRIS is 0.029 $[mg/kg/day]^{-1}$ (USEPA, 1992b2). When the slope factor of 0.029 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 10 micrograms per liter.

Subpart 9. **Benzoic acid.** The CAS RN assigned to benzoic acid by the Chemical Abstracts Service is 65-85-0. Benzoic acid is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for benzoic acid. The oral RfD for benzoic acid listed on IRIS is 4 milligrams/kilogram/day (USEPA, 1992b3). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 4 milligrams/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part

4717.7200, subpart 2, the resulting health risk limit is 30,000 micrograms per liter.

Subpart 10. **Beryllium.** The CAS RN assigned to beryllium by the Chemical Abstracts Service is 7440-41-7. The USEPA classifies beryllium as a probable human carcinogen (USEPA, 1992b4). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for beryllium. The oral slope factor for beryllium listed on IRIS is 4.3 $[mg/kg/day]^{-1}$ (USEPA, 1992b4). When the slope factor of 4.3 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.08 microgram per liter.

Subpart 11. **1,1-Biphenyl (Diphenyl).** The CAS RN assigned to 1,1-biphenyl (diphenyl) by the Chemical Abstracts Service is 92-52-4. 1,1-Biphenyl (diphenyl) is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 1,1 biphenyl (diphenyl). The oral RfD for 1,1-biphenyl (diphenyl) listed on IRIS is 0.05 milligram/kilogram/day (USEPA, 1992b5). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.05 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 300 micrograms per liter.

Subpart 12. **Bis(chloroethyl)ether (BCEE).** The CAS RN assigned to bis(chloroethyl)ether (BCEE) by the Chemical Abstracts Service is 111-44-4. The USEPA classifies bis(chloroethyl)ether (BCEE) as a probable human carcinogen (USEPA, 1992b6). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for bis(chloroethyl)ether (BCEE). The oral slope factor for bis(chloroethyl)ether (BCEE) listed on IRIS is 1.1 $[mg/kg/day]^{-1}$ (USEPA, 1992b6). When the slope factor of 1.1 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.3 microgram per liter.

Subpart 13. **Bis(chloromethyl)ether (BCME).** The CAS RN assigned to bis(chloromethyl)ether (BCME) by the Chemical Abstracts Service is 542-88-1. The USEPA classifies bis(chloromethyl)ether (BCME) as a known human carcinogen (USEPA 1992b7). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for bis(chloromethyl)ether (BCME). The oral slope factor for bis(chloromethyl)ether (BCME) listed on IRIS is 220 $[mg/kg/day]^{-1}$ (USEPA, 1992b7). When the slope factor of 220 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.002 micrograms per liter.

Subpart 14. **Boron.** The CAS RN assigned to boron by the Chemical Abstracts Service is 7440-42-8. Boron is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for boron. The oral RfD for boron listed on IRIS is 0.09 milligram/kilogram/day (USEPA, 1992b8). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.09 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 600 micrograms per liter.

Subpart 15. **Bromodichloromethane.** The CAS RN assigned to bromodichloromethane by the Chemical Abstracts Service is 75-27-4. The USEPA classifies bromodichloromethane as a probable human carcinogen (USEPA, 1993b). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for bromodichloromethane. The oral slope factor for bromodichloromethane listed on IRIS is 0.062 $[mg/kg/day]^{-1}$ (USEPA, 1993b). When the slope factor of 0.062 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 6 micrograms per liter.

Subpart 16. **Bromoform.** The CAS RN assigned to bromoform by the Chemical Abstracts Service is 75-25-2. The USEPA classifies bromoform as a probable human carcinogen (USEPA, 1992b9). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for bromoform. The oral slope factor for bromoform listed on IRIS is 0.0079 $[mg/kg/day]^{-1}$ (USEPA, 1992b9). When the slope factor of 0.0079 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 40 micrograms per liter.

Subpart 17. **Bromomethane (Methyl bromide).** The CAS RN assigned to bromomethane (methyl bromide) by the Chemical Abstracts Service is 74-83-9. Bromomethane (methyl bromide) is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for bromomethane (methyl bromide). The oral RfD for bromomethane (methyl bromide) listed on IRIS is 0.0014 milligram/kilogram/day (USEPA, 1992b10). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.0014 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 10 micrograms per liter.

Subpart 18. **n-Butanol.** The CAS RN assigned to n-butanol by the Chemical Abstracts Service is 71-36-3. n-Butanol is not

classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for n-butanol. The oral RfD for n-butanol listed on IRIS is 0.1 milligram/kilogram/day (USEPA, 1992b11). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.1 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 700 micrograms per liter.

Subpart 19. **Butyl benzyl phthalate.** The CAS RN assigned to butyl benzyl phthalate by the Chemical Abstracts Service is 85-68-7. The USEPA classifies butyl benzyl phthalate as a possible human carcinogen (USEPA, 1992b12). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for butyl benzyl phthalate. The oral RfD for butyl benzyl phthalate listed on IRIS is 0.2 milligram/kilogram/day (USEPA, 1992b12). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.2 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 100 micrograms per liter.

Subpart 20. **Butylphthalyl butylglycolate (BPBG).** The CAS RN assigned to butylphthalyl butylglycolate (BPBG) by the Chemical Abstracts Service is 85-70-1. Butylphthalyl butylglycolate (BPBG) is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for butylphthalyl butylglycolate (BPBG). The oral RfD for butylphthalyl butylglycolate (BPBG) listed on IRIS is 1 milligram/kilogram/day (USEPA, 1989c). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 1 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 7,000 micrograms per liter.

Subpart 21. **Cadmium.** The CAS RN assigned to cadmium by the Chemical Abstracts Service is 7440-43-9. Cadmium is not classified by the USEPA as either a human, probable or possible human carcinogen by oral exposure. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for cadmium. The oral RfD for cadmium listed on IRIS is 0.0005 milligram/kilogram/day (USEPA, 1992c1). As stated in part 4717.7200, subpart 2, item D, subitem 3, the RSC is 0.25. When the RfD of 0.0005 milligram/kilogram/day and the RSC of 0.25 are put into the equation for systemic

toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 4 micrograms per liter.

Subpart 22. **Carbon disulfide.** The CAS RN assigned to carbon disulfide by the Chemical Abstracts Service is 75-15-0. Carbon disulfide is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for carbon disulfide. The oral RfD for carbon disulfide listed on IRIS is 0.1 milligram/kilogram/day (USEPA, 1992c2). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.1 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 700 micrograms per liter.

Subpart 23. **Carbon tetrachloride.** The CAS RN assigned to carbon tetrachloride by the Chemical Abstracts Service is 56-23-5. The USEPA classifies carbon tetrachloride as a probable human carcinogen (USEPA, 1992c3). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for carbon tetrachloride. The oral slope factor for carbon tetrachloride listed on IRIS is 0.13 $[mg/kg/day]^{-1}$ (USEPA, 1992c3). When the slope factor of 0.13 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 3 micrograms per liter.

Subpart 24. **Chlorobenzene.** The CAS RN assigned to chlorobenzene by the Chemical Abstracts Service is 108-90-7. Chlorobenzene is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for chlorobenzene. The oral RfD for chlorobenzene listed on IRIS is 0.02 milligram/kilogram/day (USEPA, 1992c4). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.02 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 25. **Chloroform.** The CAS RN assigned to chloroform by the Chemical Abstracts Service is 67-66-3. The USEPA classifies chloroform as a probable human carcinogen (USEPA, 1992c5). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for chloroform. The oral slope factor for chloroform listed on IRIS is 0.0061 $[mg/kg/day]^{-1}$ (USEPA, 1992c5). When the slope factor of 0.0061 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 60 micrograms per liter.

Subpart 26. **2-Chlorophenol.** The CAS RN assigned to 2-chlorophenol by the Chemical Abstracts Service is 95-57-8. 2-Chlorophenol is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2-chlorophenol. The oral RfD for 2-chlorophenol listed on IRIS is 0.005 milligram/kilogram/day (USEPA, 1992c6). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.005 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 30 micrograms per liter.

Subpart 27. **Chromium VI.** The CAS RN assigned to chromium VI by the Chemical Abstracts Service is 18540-29-9. Chromium VI is not classified by the USEPA as either a human, probable or possible human carcinogen by oral exposure. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for chromium VI. The oral RfD for chromium VI listed on IRIS is 0.005 milligram/kilogram/day (USEPA, 1992c7). As stated in part 4717.7200, subpart 2, item D, subitem 4, the RSC is 0.7. When the RfD of 0.005 milligram/kilogram/day and the RSC of 0.7 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 28. **Cumene (Isopropyl benzene).** The CAS RN assigned to cumene (isopropyl benzene) by the Chemical Abstracts Service is 98-82-8. Cumene (isopropyl benzene) is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for cumene (isopropyl benzene). The oral RfD for cumene (isopropyl benzene) listed on IRIS is 0.04 milligram/kilogram/day (USEPA, 1992c8). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.04 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 300 micrograms per liter.

Subpart 29. **Cyanide, free.** The CAS RN assigned to cyanide, free by the Chemical Abstracts Service is 57-12-5. Cyanide, free is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for cyanide, free. The oral RfD for cyanide, free listed on IRIS is 0.02 milligram/kilogram/day (USEPA, 1992c9). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.02 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants

specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 30. **Dibromochloromethane.** The CAS RN assigned to dibromochloromethane by the Chemical Abstracts Service is 124-48-1. The USEPA classifies dibromochloromethane as a possible human carcinogen (USEPA, 1992d1). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for dibromochloromethane. The oral RfD for dibromochloromethane listed on IRIS is 0.02 milligram/kilogram/day (USEPA, 1992d1). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.02 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 10 micrograms per liter.

Subpart 31. **1,2-Dibromoethane (Ethylene dibromide, EDB).** The CAS RN assigned to 1,2-dibromoethane (ethylene dibromide, EDB) by the Chemical Abstracts Service is 106-93-4. The USEPA classifies 1,2-dibromoethane (ethylene dibromide, EDB) as a probable human carcinogen (USEPA, 1992d2). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for 1,2-dibromoethane (ethylene dibromide, EDB). The oral slope factor for 1,2-dibromoethane (ethylene dibromide, EDB) listed on IRIS is 85 $[mg/kg/day]^{-1}$ (USEPA, 1992d2). When the slope factor of 85 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.004 microgram per liter.

Subpart 32. **Dibutyl phthalate.** The CAS RN assigned to dibutyl phthalate by the Chemical Abstracts Service is 84-74-2. Dibutyl phthalate is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for dibutyl phthalate. The oral RfD for dibutyl phthalate listed on IRIS is 0.1 milligram/kilogram/day (USEPA, 1992d3). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.1 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 700 micrograms per liter.

Subpart 33. **Dicamba.** The CAS RN assigned to dicamba by the Chemical Abstracts Service is 1918-00-9. Dicamba is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for dicamba. The oral RfD for dicamba listed on IRIS is 0.03 milligram/kilogram/day (USEPA, 1992d4). As stated in part

4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.03 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 200 micrograms per liter.

Subpart 34. **1,2-Dichlorobenzene.** The CAS RN assigned to 1,2-dichlorobenzene by the Chemical Abstracts Service is 95-50-1. 1,2-Dichlorobenzene is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 1,2-dichlorobenzene. The oral RfD for 1,2-dichlorobenzene listed on IRIS is 0.09 milligram/kilogram/day (USEPA, 1992d5). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.09 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 600 micrograms per liter.

Subpart 35. **3,3'-Dichlorobenzidine.** The CAS RN assigned to 3,3'-dichlorobenzidine by the Chemical Abstracts Service is 91-94-1. The USEPA classifies 3,3'-dichlorobenzidine as a probable human carcinogen (USEPA, 1992d6). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for 3,3'-dichlorobenzidine. The oral slope factor for 3,3'-dichlorobenzidine listed on IRIS is 0.45 $[mg/kg/day]^{-1}$ (USEPA, 1992d6). When the slope factor of 0.45 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.8 microgram per liter.

Subpart 36. **Dichlorodifluoromethane.** The CAS RN assigned to dichlorodifluoromethane by the Chemical Abstracts Service is 75-71-8. Dichlorodifluoromethane is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for dichlorodifluoromethane. The oral RfD for dichlorodifluoromethane listed on IRIS is 0.2 milligram/kilogram/day is (USEPA, 1992d7). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.2 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 1,000 micrograms per liter.

Subpart 37. **p,p'-Dichlorodiphenyl dichloroethane (DDD).** The CAS RN assigned to p,p'-dichlorodiphenyl dichloroethane (DDD) by the Chemical Abstracts Service is 72-54-8. The USEPA classifies p,p'-dichlorodiphenyl dichloroethane (DDD) as a probable human carcinogen (USEPA, 1992d8). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for p,p'-dichlorodiphenyl dichloroethane (DDD). The oral slope factor for p,p'-dichlorodiphenyl dichloroethane (DDD) listed

on IRIS is 0.24 $[mg/kg/day]^{-1}$ (USEPA, 1992d8). When the slope factor of 0.24 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 1 microgram per liter.

Subpart 38. **p,p'-Dichlorodiphenyldichloroethylene (DDE).** The CAS RN assigned to p,p'-dichlorodiphenyldichloroethylene (DDE) by the Chemical Abstracts Service is 72-55-9. The USEPA classifies p,p'-dichlorodiphenyldichloroethylene (DDE) as a probable human carcinogen (USEPA, 1992d9). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for p,p'-dichlorodiphenyldichloroethylene (DDE). The oral slope factor for p,p'-dichlorodiphenyldichloroethylene (DDE) listed on IRIS is 0.34 $[mg/kg/day]^{-1}$ (USEPA, 1992d9). When the slope factor of 0.34 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 1 microgram per liter.

Subpart 39. **p,p'-Dichlorodiphenyltrichloroethane (DDT).** The CAS RN assigned to p,p'-dichlorodiphenyltrichloroethane (DDT) by the Chemical Abstracts Service is 50-29-3. The USEPA classifies p,p'-dichlorodiphenyltrichloroethane (DDT) as a probable human carcinogen (USEPA, 1992d10.). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for p,p'-dichlorodiphenyltrichloroethane (DDT). The oral slope factor for p,p'-dichlorodiphenyltrichloroethane (DDT) listed on IRIS is 0.34 $[mg/kg/day]^{-1}$ (USEPA, 1992d10). When the slope factor of 0.34 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 1 microgram per liter.

Subpart 40. **1,2-Dichloroethane.** The CAS RN assigned to 1,2-dichloroethane by the Chemical Abstracts Service is 107-06-2. The USEPA classifies 1,2-dichloroethane as a probable human carcinogen (USEPA, 1992d11). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for 1,2-dichloroethane. The oral slope factor for 1,2-dichloroethane listed on IRIS is 0.091 $[mg/kg/day]^{-1}$ (USEPA, 1992d11). When the slope factor of 0.091 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 4 micrograms per liter.

Subpart 41. **1,1-Dichloroethylene (Vinylidene chloride).** The CAS RN assigned to 1,1-dichloroethylene (vinylidene chloride) by the Chemical Abstracts Service is 75-35-4. The USEPA classifies 1,1-dichloroethylene (vinylidene chloride) as a possible human carcinogen (USEPA, 1992d12). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for 1,1-dichloroethylene (vinylidene chloride). The oral RfD for 1,1-dichloroethylene (vinylidene chloride) listed on IRIS is 0.009

milligram/kilogram/day (USEPA, 1992d12). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.009 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 6 micrograms per liter.

Subpart 42. **1,2-Dichloroethylene, trans-.** The CAS RN assigned to 1,2-dichloroethylene, trans by the Chemical Abstracts Service is 156-60-5. 1,2-Dichloroethylene, trans- is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 1,2-dichloroethylene, trans. The oral RfD for 1,2-dichloroethylene, trans listed on IRIS is 0.02 milligram/kilogram/day (USEPA, 1992d13). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.02 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 43. **Dichloromethane (Methylene chloride).** The CAS RN assigned to dichloromethane (methylene chloride) by the Chemical Abstracts Service is 75-09-2. The USEPA classifies dichloromethane (methylene chloride) as a probable human carcinogen (USEPA, 1992d14). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for dichloromethane (methylene chloride). The oral slope factor for dichloromethane (methylene chloride) listed on IRIS is 0.0075 $[mg/kg/day]^{-1}$ (USEPA, 1992d14). When the slope factor of 0.0075 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 50 micrograms per liter.

Subpart 44. **2,4-Dichlorophenol.** The CAS RN assigned to 2,4-dichlorophenol by the Chemical Abstracts Service is 120-83-2. 2,4-Dichlorophenol is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2,4-dichlorophenol. The oral RfD for 2,4-dichlorophenol listed on IRIS is 0.003 milligram/kilogram/day (USEPA, 1992d15). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.003 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 20 micrograms per liter.

Subpart 45. **2,4-Dichlorophenoxyacetic acid (2,4-D).** The CAS RN assigned to 2,4-dichlorophenoxyacetic acid (2,4-D) by the

Chemical Abstracts Service is 94-75-7. 2,4-Dichlorophenoxyacetic acid (2,4-D) is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2,4-dichlorophenoxyacetic acid (2,4-D). The oral RfD for 2,4-dichlorophenoxyacetic acid (2,4-D) listed on IRIS is 0.01 milligram/kilogram/day (USEPA, 1992d16). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.01 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 70 micrograms per liter.

Subpart 46. **Di(2-ethylhexyl)phthalate (DEHP).** The CAS RN assigned to di(2-ethylhexyl)phthalate (DEHP) by the Chemical Abstracts Service is 117-81-7. The USEPA classifies di(2-ethylhexyl)phthalate (DEHP) as a probable human carcinogen (USEPA, 1992d17). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for di(2-ethylhexyl)phthalate (DEHP). The oral slope factor for di(2-ethylhexyl)phthalate (DEHP) listed on IRIS is 0.014 $[mg/kg/day]^{-1}$ (USEPA, 1992d17). When the slope factor of 0.014 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 20 micrograms per liter.

Subpart 47. **Diethyl phthalate.** The CAS RN assigned to diethyl phthalate by the Chemical Abstracts Service is 84-66-2. Diethyl phthalate is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for diethyl phthalate. The oral RfD for diethyl phthalate listed on IRIS is 0.8 milligram/kilogram/day (USEPA, 1992d18). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.8 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 6,000 micrograms per liter.

Subpart 48. **2,4-Dimethylphenol.** The CAS RN assigned to 2,4-dimethylphenol by the Chemical Abstracts Service is 105-67-9. 2,4-Dimethylphenol is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2,4-dimethylphenol. The oral RfD for 2,4-dimethylphenol listed on IRIS is 0.02 milligram/kilogram/day (USEPA, 1992d19). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.02 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 49. **2,4-Dinitrophenol.** The CAS RN assigned to 2,4-dinitrophenol by the Chemical Abstracts Service is 51-28-5. 2,4-dinitrophenol is not classified by the USEPA as either a human, probable or possible human carcinogen. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2,4-dinitrophenol. The oral RfD for 2,4-dinitrophenol listed on IRIS is 0.002 milligram/kilogram/day (USEPA, 1992d20). As stated in part 4717.7200, subpart 2, item C, the RSC is 0.2. When the RfD of 0.002 milligram/kilogram/day and the RSC of 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 10 micrograms per liter.

Subpart 50. **Ethylbenzene.** The CAS RN assigned to ethylbenzene by the Chemical Abstracts Service is 100-41-4. Ethylbenzene is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for ethylbenzene. The oral RfD for ethylbenzene listed on IRIS is 0.1 milligram/kilogram/day (USEPA, 1992e1). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.1 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 700 micrograms per liter.

Subpart 51. **S-Ethyl dipropylthiocarbamate (EPTC).** The CAS RN assigned to S-ethyl dipropylthiocarbamate (EPTC) by the Chemical Abstracts Service is 759-94-4. S-Ethyl dipropylthiocarbamate (EPTC) is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for S-ethyl dipropylthiocarbamate (EPTC). The oral RfD for S-ethyl dipropylthiocarbamate (EPTC) listed on IRIS is 0.025 milligram/kilogram/day (USEPA, 1990b). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.025 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 200 micrograms per liter.

Subpart 52. **Ethyl ether.** The CAS RN assigned to ethyl ether by the Chemical Abstracts Service is 60-29-7. Ethyl ether is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for ethyl ether. The oral RfD for ethyl ether listed on IRIS is 0.2 milligram/kilogram/day (USEPA, 1991). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.2

milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 1,000 micrograms per liter.

Subpart 53. **Fluoranthene.** The CAS RN assigned to fluoranthene by the Chemical Abstracts Service is 206-44-0. Fluoranthene is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for fluoranthene. The oral RfD for fluoranthene listed on IRIS is 0.04 milligram/kilogram/day (USEPA, 1992f1). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.04 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 300 micrograms per liter.

Subpart 54. **Fluorene (9H-Fluorene).** The CAS RN assigned to fluorene (9H-fluorene) by the Chemical Abstracts Service is 86-73-7. Fluorene (9H-fluorene) is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for fluorene (9H-fluorene). The oral RfD for fluorene (9H-fluorene) listed on IRIS is 0.04 milligram/kilogram/day (USEPA, 1992f2). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.04 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 300 micrograms per liter.

Subpart 55. **Heptachlor.** The CAS RN assigned to heptachlor by the Chemical Abstracts Service is 76-44-8. The USEPA classifies heptachlor as a probable human carcinogen (USEPA, 1992h1). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for heptachlor. The oral slope factor for heptachlor listed on IRIS is 4.5 $[mg/kg/day]^{-1}$ (USEPA, 1992h1). When the slope factor of 4.5 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.08 microgram per liter.

Subpart 56. **Heptachlor epoxide.** The CAS RN assigned to heptachlor epoxide by the Chemical Abstracts Service is 1024-57-3. The USEPA classifies heptachlor epoxide as a probable human carcinogen (USEPA, 1992h2). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for heptachlor epoxide. The oral slope factor for heptachlor epoxide listed on IRIS is 9.1 $[mg/kg/day]^{-1}$ (USEPA, 1992h2). When the slope factor of 9.1 $[mg/kg/day]^{-1}$ is put into the equation for

carcinogens specified in part 4717.7300 the resulting health risk limit is 0.04 microgram per liter.

Subpart 57. **Hexachlorobenzene.** The CAS RN assigned to hexachlorobenzene by the Chemical Abstracts Service is 118-74-1. The USEPA classifies hexachlorobenzene as a probable human carcinogen (USEPA, 1992h3). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for hexachlorobenzene. The oral slope factor for hexachlorobenzene listed on IRIS is 1.6 $[mg/kg/day]^{-1}$ (USEPA, 1992h3). When the slope factor of 1.6 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.2 microgram per liter.

Subpart 58. **Hexachlorobutadiene.** The CAS RN assigned to hexachlorobutadiene by the Chemical Abstracts Service is 87-68-3. The USEPA classifies hexachlorobutadiene as a possible human carcinogen (USEPA, 1992h4). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for hexachlorobutadiene. The oral RfD for hexachlorobutadiene listed on IRIS is 0.002 milligram/kilogram/day (USEPA, 1992h4). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.002 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 1 microgram per liter.

Subpart 59. **Isophorone.** The CAS RN assigned to isophorone by the Chemical Abstracts Service is 78-59-1. The USEPA classifies isophorone as a possible human carcinogen (USEPA, 1992i). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for isophorone. The oral RfD for isophorone listed on IRIS is 0.2 milligram/kilogram/day (USEPA, 1992i). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.2 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 100 micrograms per liter.

Subpart 60. **Linuron.** The CAS RN assigned to linuron by the Chemical Abstracts Service is 330-55-2. The USEPA classifies linuron as a possible human carcinogen (USEPA, 1992l). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for linuron. The oral RfD for linuron listed on IRIS is 0.002 milligram/kilogram/day (USEPA, 1992l). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part

4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.002 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 1 microgram per liter.

Subpart 61. **Manganese.** The CAS RN assigned to manganese by the Chemical Abstracts Service is 7439-96-5. Manganese is not classified by the USEPA as either a human, probable or possible human carcinogen by oral exposure. Therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for manganese. The oral, drinking water RfD for manganese listed on IRIS is 0.005 milligram/kilogram/day (USEPA, 1993m). As stated in part 4717.7200, subpart 2, item D, subitem 5, the RSC is 0.8. When the RfD of 0.005 milligram/kilogram/day and the RSC of 0.8 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 62. **2-Methyl-4-chlorophenoxyacetic acid (MCPA).** The CAS RN assigned to 2-methyl-4-chlorophenoxyacetic acid (MCPA) by the Chemical Abstracts Service is 94-74-6. 2-Methyl-4-chlorophenoxyacetic acid (MCPA) is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2-methyl-4-chlorophenoxyacetic acid (MCPA). The oral RfD for 2-methyl-4-chlorophenoxyacetic acid (MCPA) listed on IRIS is 0.0005 milligram/kilogram/day (USEPA, 1992m1). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.0005 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 3 micrograms per liter.

Subpart 63. **2-Methylphenol (o-Cresol).** The CAS RN assigned to 2-methylphenol (o-cresol) by the Chemical Abstracts Service is 95-48-7. The USEPA classifies 2-methylphenol (o-cresol) as a possible human carcinogen (USEPA, 1992m2). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for 2-methylphenol (o-cresol). The oral RfD for 2-methylphenol (o-cresol) listed on IRIS is 0.05 milligram/kilogram/day (USEPA, 1992m2). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.05 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 30 micrograms per liter.

Subpart 64. **3-Methylphenol (m-Cresol).** The CAS RN assigned to 3-methylphenol (m-cresol) by the Chemical Abstracts Service is 108-39-4. The USEPA classifies 3-methylphenol (m-cresol) as a possible human carcinogen (USEPA, 1992m3). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for 3-methylphenol (m-cresol). The oral RfD for 3-methylphenol (m-cresol) listed on IRIS is 0.05 milligram/kilogram/day (USEPA, 1992m3). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.05 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 30 micrograms per liter.

Subpart 65. **Metolachlor.** The CAS RN assigned to metolachlor by the Chemical Abstracts Service is 51218-45-2. The USEPA classifies metolachlor as a possible human carcinogen (USEPA, 1992m4). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for metolachlor. The oral RfD for metolachlor listed on IRIS is 0.15 milligram/kilogram/day (USEPA, 1992m4). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.15 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 100 micrograms per liter.

Subpart 66. **Metribuzin.** The CAS RN assigned to metribuzin by the Chemical Abstracts Service is 21087-64-9. Metribuzin is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for metribuzin. The oral RfD for metribuzin listed on IRIS is 0.025 milligram/kilogram/day (USEPA, 1992m5). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.025 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 200 micrograms per liter.

Subpart 67. **Nickel, soluble salts.** The CAS RN assigned to nickel, soluble salts by the Chemical Abstracts Service is 7440-02-0. Nickel, soluble salts is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for nickel, soluble salts. The oral RfD for nickel, soluble salts listed on IRIS is 0.02 milligram/kilogram/day (USEPA, 1992n1). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.02 milligram/kilogram/day

and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 68. **Nitrate (as nitrogen).** The CAS RN assigned to nitrate by the Chemical Abstracts Service is 14797-55-8. Nitrate is not classified by the USEPA as either a human, probable or possible human carcinogen. The method for nitrate (as nitrogen) specified in part 4717.7200, subpart 3 was used to calculate the health risk limit for nitrate (as nitrogen). The oral RfD for nitrate (as nitrogen) listed on IRIS is 1.6 milligrams/kilogram/day (USEPA, 1992n2). When the RfD of 1.6 milligrams/kilogram/day is put into the equation for nitrate (as nitrogen) specified in part 4717.7200, subpart 3, the resulting health risk limit is 10,000 micrograms per liter.

Subpart 69. **N-Nitrosodiphenylamine.** The CAS RN assigned to N-nitrosodiphenylamine by the Chemical Abstracts Service is 86-30-6. The USEPA classifies N-nitrosodiphenylamine as a probable human carcinogen (USEPA, 1992n3). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for N-nitrosodiphenylamine. The oral slope factor for N-nitrosodiphenylamine listed on IRIS is 0.0049 $[mg/kg/day]^{-1}$ (USEPA, 1992n3). When the slope factor of 0.0049 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 70 micrograms per liter.

Subpart 70. **Pentachlorophenol.** The CAS RN assigned to pentachlorophenol by the Chemical Abstracts Service is 87-86-5. The USEPA classifies pentachlorophenol as a probable human carcinogen (USEPA, 1992p1). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for pentachlorophenol. The oral slope factor for pentachlorophenol listed on IRIS is 0.12 $[mg/kg/day]^{-1}$ (USEPA, 1992p1). When the slope factor of 0.12 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 3 micrograms per liter.

Subpart 71. **Phenol.** The CAS RN assigned to phenol by the Chemical Abstracts Service is 108-95-2. Phenol is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for phenol. The oral RfD for phenol listed on IRIS is 0.6 milligram/kilogram/day (USEPA, 1992p2). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.6 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 4,000 micrograms per liter.

Subpart 72. **Picloram.** The CAS RN assigned to picloram by the Chemical Abstracts Service is 1918-02-1. Picloram is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for picloram. The oral RfD for picloram listed on IRIS is 0.07 milligram/kilogram/day (USEPA, 1992p3). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.07 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 500 micrograms per liter.

Subpart 73. **Prometon.** The CAS RN assigned to prometon by the Chemical Abstracts Service is 1610-18-0. Prometon is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for prometon. The oral RfD for prometon listed on IRIS is 0.015 milligram/kilogram/day (USEPA, 1992p4). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.015 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 100 micrograms per liter.

Subpart 74. **Propachlor.** The CAS RN assigned to propachlor by the Chemical Abstracts Service is 1918-16-7. Propachlor is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for propachlor. The oral RfD for propachlor listed on IRIS is 0.013 milligram/kilogram/day (USEPA, 1992p5). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.013 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 90 micrograms per liter.

Subpart 75. **Pyrene.** The CAS RN assigned to pyrene by the Chemical Abstracts Service is 129-00-0. Pyrene is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for pyrene. The oral RfD for pyrene listed on IRIS is 0.03 milligram/kilogram/day (USEPA, 1992p6). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.03 milligrams/kilograms/per day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 200 micrograms per liter.

Subpart 76. **Selenium.** The CAS RN assigned to selenium by the Chemical Abstracts Service is 7782-49-2. Selenium is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for selenium. The oral RfD for selenium listed on IRIS is 0.005 milligram/kilogram/day (USEPA, 1992s1). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.005 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 30 micrograms per liter.

Subpart 77. **Silver.** The CAS RN assigned to silver by the Chemical Abstracts Service is 7440-22-4. Silver is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for silver. The oral RfD for silver listed on IRIS is 0.005 milligram/kilogram/day (USEPA, 1992s2). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.005 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 30 micrograms per liter.

Subpart 78. **1,1,1,2-Tetrachloroethane.** The CAS RN assigned to 1,1,1,2-tetrachloroethane by the Chemical Abstracts Service is 630-20-6. The USEPA classifies 1,1,1,2-tetrachloroethane as a possible human carcinogen (USEPA, 1992t1). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for 1,1,1,2-tetrachloroethane. The oral RfD for 1,1,1,2-tetrachloroethane listed on IRIS is 0.03 milligram/kilogram/day (USEPA, 1992t1). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item C, the uncertainty factor is 3. When the RfD of 0.03 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 3 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 70 micrograms per liter.

Subpart 79. **Toluene.** The CAS RN assigned to toluene by the Chemical Abstracts Service is 108-88-3. Toluene is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for toluene. The oral RfD for toluene listed on IRIS is 0.2 milligram/kilogram/day (USEPA, 1992t2). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.2 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants

specified in part 4717.7200, subpart 2, the resulting health risk limit is 1,000 micrograms per liter.

Subpart 80. **Toxaphene.** The CAS RN assigned to toxaphene by the Chemical Abstracts Service is 8001-35-2. The USEPA classifies toxaphene as a probable human carcinogen (USEPA, 1992t3). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for toxaphene. The oral slope factor for toxaphene listed on IRIS is 1.1 $[mg/kg/day]^{-1}$ (USEPA, 1992t3). When the slope factor of 1.1 $[mg/kg/day]^{-1}$ is put into the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 0.3 microgram per liter.

Subpart 81. **1,1,2-Trichloroethane.** The CAS RN assigned to 1,1,2-trichloroethane by the Chemical Abstracts Service is 79-00-5. The USEPA classifies 1,1,2-trichloroethane as a possible human carcinogen (USEPA, 1992t4). Therefore the method for possible human carcinogens specified in part 4717.7200, subpart 4 was used to calculate the health risk limit for 1,1,2-trichloroethane. The oral RfD for 1,1,2-trichloroethane listed on IRIS is 0.004 milligram/kilogram/day (USEPA, 1992t4). As specified in part 4717.7200, subpart 4, item A, the RSC is 0.2. As specified in part 4717.7200, subpart 4, item B, the uncertainty factor is 10. When the RfD of 0.004 milligram/kilogram/day, the RSC of 0.2 and the uncertainty factor of 10 are put into the equation for possible human carcinogens specified in part 4717.7200, subpart 4, the resulting health risk limit is 3 micrograms per liter.

Subpart 82. **Trichlorofluoromethane.** The CAS RN assigned to trichlorofluoromethane by the Chemical Abstracts Service is 75-69-4. Trichlorofluoromethane is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for trichlorofluoromethane. The oral RfD for trichlorofluoromethane listed on IRIS is 0.3 milligram/kilogram/day (USEPA, 1992t5). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.3 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 2,000 micrograms per liter.

Subpart 83. **2,4,6-Trichlorophenol.** The CAS RN assigned to 2,4,6-trichlorophenol by the Chemical Abstracts Service is 88-06-2. The USEPA classifies 2,4,6-trichlorophenol as a probable human carcinogen (USEPA, 1992t6). Therefore the method for carcinogens specified in part 4717.7300 was used to calculate the health risk limit for 2,4,6-trichlorophenol. The oral slope factor for 2,4,6-trichlorophenol listed on IRIS is 0.011 $[mg/kg/day]^{-1}$ (USEPA, 1992t6). When the slope factor of 0.011 $[mg/kg/day]^{-1}$ is put into

the equation for carcinogens specified in part 4717.7300 the resulting health risk limit is 30 micrograms per liter.

Subpart 84. **2,4,5-Trichlorophenoxyacetic acid (2,4,5-T).** The CAS RN assigned to 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) by the Chemical Abstracts Service is 93-76-5. 2,4,5-Trichlorophenoxyacetic acid (2,4,5-T) is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2,4,5-trichlorophenoxyacetic acid (2,4,5-T). The oral RfD for 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) listed on IRIS is 0.01 milligram/kilogram/day (USEPA, 1992t7). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.01 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 70 micrograms per liter.

Subpart 85. **2 (2,4,5-Trichlorophenoxy) propionic acid.** The CAS RN assigned to 2 (2,4,5-trichlorophenoxy) propionic acid by the Chemical Abstracts Service is 93-72-1. 2 (2,4,5-Trichlorophenoxy) propionic acid is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 2 (2,4,5-trichlorophenoxy) propionic acid. The oral RfD for 2 (2,4,5-trichlorophenoxy) propionic acid listed on IRIS is 0.008 milligram/kilogram/day (USEPA, 1992t8). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.008 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 60 micrograms per liter.

Subpart 86. **1,2,3-Trichloropropane.** The CAS RN assigned to 1,2,3-trichloropropane by the Chemical Abstracts Service is 96-18-4. 1,2,3-Trichloropropane is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 1,2,3-trichloropropane. The oral RfD for 1,2,3-trichloropropane listed on IRIS is 0.006 milligram/kilogram/day (USEPA, 1992t9). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.006 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 40 micrograms per liter.

Subpart 87. **1,1,2-Trichloro-1,2,2-trifluoroethane.** The CAS RN assigned to 1,1,2-trichloro-1,2,2-trifluoroethane by the Chemical Abstracts Service is 76-13-1. 1,1,2-Trichloro-1,2,2-

trifluoroethane is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 1,1,2-trichloro-1,2,2-trifluoroethane. The oral RfD for 1,1,2-trichloro-1,2,2-trifluoroethane listed on IRIS is 30 milligrams/kilogram/day (USEPA, 1992t10). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 30 milligram/kilogram/per day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 200,000 micrograms per liter.

Subpart 88. **1,3,5-Trinitrobenzene.** The CAS RN assigned to 1,3,5-trinitrobenzene by the Chemical Abstracts Service is 99-35-4. 1,3,5-Trinitrobenzene is not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for 1,3,5-trinitrobenzene. The oral RfD for 1,3,5-trinitrobenzene listed on IRIS is 0.00005 milligram/kilogram/day (USEPA, 1992t11). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 0.00005 milligram/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 0.3 microgram per liter.

Subpart 89. **Xylenes (mixture of isomers o, m, p).** The CAS RN assigned to xylenes (mixture of isomers o, m, p) by the Chemical Abstracts Service is 1330-20-7. Xylenes (mixture of isomers o, m, p) are not classified by the USEPA as either a human, probable or possible human carcinogen, therefore the method for systemic toxicants specified in part 4717.7200, subpart 2 was used to calculate the health risk limit for xylenes (mixture of isomers o, m, p). The oral RfD for xylenes (mixture of isomers o, m, p) listed on IRIS is 2 milligrams/kilogram/day (USEPA, 1992x). As stated in part 4717.7200, subpart 2, item C, the relative source contribution factor (RSC) is 0.2. When the RfD of 2 milligrams/kilogram/day and the RSC 0.2 are put into the equation for systemic toxicants specified in part 4717.7200, subpart 2, the resulting health risk limit is 10,000 micrograms per liter.

Subpart 90. **Reference doses and slope factors.** *RfD refers to the reference dose (RfD) of a substance or chemical classified by the USEPA as a possible human carcinogen. The RfDs for possible human carcinogens are annotated with a "(C)" to distinguish them from the other systemic toxicants. This annotation is reasonable since a health risk limit for a possible human carcinogen is calculated by a different equation than a health risk limit for a systemic toxicant that is not classified as a possible human carcinogen.

The data used for the reference doses (RfDs) and slope factors, indicated by the double crosses (++), were the most current data available through the United States Environmental Protection Agency's Integrated Risk Information System (IRIS) up until a reasonable time prior to proposal of these rules. February 1993 was the latest reasonable date to obtain data for calculating the health risk limits for the proposed rules.

4717.7600 HEALTH RISK LIMITS FOR MIXTURES

Groundwater monitoring data may reveal the presence of multiple contaminants where the concentration of each does not exceed its health risk limit. As discussed above, in section VIII **Introduction to Risk Assessment Methods**, **Mixtures**, the department believes that the statutory language "substance or chemical" (Minnesota Statutes, section 103H.005, subdivision 3) is broad enough to include mixtures. For example, The American Heritage Dictionary, Second College Edition (American Heritage, 1985, p. 263) defines "chemical" as, "A substance that is produced by or used in a chemical process." This dictionary (American Heritage, 1985, p. 1213) defines "substance" as, "1. a. That which has mass and occupies space; matter. b. A material of a particular kind or constitution." Webster's Third New International Dictionary of the English Language (Merriam-Webster, 1986, p.2279) defines "substance" as, "...**c:** matter of definite or known chemical composition **:** an identifiable chemical element, compound, or mixture..." Given these definitions, the department believes that it is reasonable to interpret the meaning of "substance" to include both individual chemicals and mixtures of chemicals for the purposes of the proposed rules.

The health risk limits specified in part 4717.7500 are calculated from data that is generally based on exposure to a single substance or chemical. Consequently the health risk limits specified in part 4717.7500 may not account for the possible interaction of multiple substances or chemicals. For example a mixture of substances or chemicals may cause an adverse effect that would not be predicted for exposure to each substance or chemical alone, even if each component of the mixture is present at a concentration below its health risk limit specified in part 4717.7500. The proposed rules account for this possibility by including a provision for calculating the health risk limit for a mixture.

The proposed mixtures provision applies an additive model from the Guidelines for the Health Risk Assessment of Mixtures published by the USEPA as part of the Risk Assessment Guidelines of 1986 (USEPA, 1987). The proposed method for calculating the health risk limit for a mixture was described in a briefing paper prepared for discussion by the technical advisory work group, Mixtures or Exposures to Multiple Contaminants (MDH/HRA, 1990f). The additive model is a reasonable approach to evaluating the risk from

mixtures. As stated in the USEPA risk assessment guidelines (USEPA, 1987 p. 3-10):

> Based on current information, additivity assumptions are expected to yield generally neutral risk estimates (i.e., neither conservative nor lenient) and are plausible for component compounds that induce similar types of effects at the same sites of action.

Furthermore, the additive model for mixtures is already incorporated into some federal guidelines and state standards. The American Conference of Governmental Industrial Hygienists includes the additive model in their guidelines for occupational exposures to mixtures of airborne substances (ACGIH, 1988). Two Minnesota rules also include this additive model for mixtures (Minnesota Rules part 7035.2815, subpart 4, item J, subitem (2)[4] and Minnesota Rules 7050.0220, subpart 3, items E and G).

In Multiple Chemical Interactions, E.J. Calabrese, a professor of toxicology at the University of Massachusetts School of Public Health, and former member of the U.S. National Academy of Sciences and NATO Countries Safe Drinking Water committees, describes many cases where combinations of substances or chemicals cause effects that differ from those caused by each component alone (Calabrese, 1991). For example, one substance or chemical may change the production of enzymes that in turn alter the rate of detoxification, activation or the composition of metabolic products of another substance or chemical. In other cases the absorption, distribution to target organs, or excretion of substances or chemicals from the body may be altered. Such interactions can influence the magnitude of a biological response. In some cases the different substances or chemicals act as though they are one material of a dose equal to the sum of the individual doses. This results in an additive response. Other substances or chemicals act synergistically, inducing a greater than additive response. The actions of different compounds may also be antagonistic such that the response is less than additive. Finally, the components of a mixture may act independently resulting in no detectable change in response. From a public health perspective, underestimating the risk from additive or synergistic effects is a greater concern than overestimating the risk from antagonistic or independent action.

Unfortunately little quantitative data are available for most mixtures. What data are available often describe the interaction of only two substances or chemicals at a limited number of doses.

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[4]Minnesota Rules 7035.2815, subpart 4., item J., subitem (2) specifically cite "Guidelines for the Health Risk Assessment of Chemical Mixtures," published by the USEPA in the Federal Register on September 24, 1986, volume 51, pages 34014-34025 (USEPA, 1987).

The biological response to two substances or chemicals could be altered by the presence of a third as well as by a change in the concentrations of the components. The problem grows more complex as the number of substances or chemicals increases. Finally most of the toxicologic data on mixtures come from experiments that use doses that are much higher than the concentrations usually found in groundwater. Despite the uncertainty, concern about environmental exposure to mixtures prompted the USEPA to include a section on the risk assessment of mixtures in their risk assessment guidelines and the National Research Council to devote the major part of a volume of Drinking Water and Health to the issue of mixtures (USEPA, 1987; NRC, 1989).

The USEPA guidelines for the health risk assessment of chemical mixtures includes a "decision tree" (USEPA, 1987, p.3-5). The first steps involve evaluating the health effects and toxicology data on the mixture or a similar mixture (USEPA, 1987). Due to the paucity of data on mixtures, usually little or no information is available on the toxicology of a specific mixture. If data exist only for the components of the mixture, the USEPA guidelines recommend using an additive model for predicting risk (USEPA, 1987, p. 3-7):

> If data are not available on an identical or reasonably similar mixture, the risk assessment may be based on the toxic or carcinogenic properties of the components in the mixture. When little or no quantitative information is available on the potential interaction among the components, additive models (defined in the next section) are recommended for systemic toxicants. Several studies have demonstrated that dose additive models often predict reasonably well the toxicities of mixtures composed of a substantial variety of both similar and dissimilar compounds (Pozzani et al., 1959; Smythe et al., 1969, 1970; Murphy, 1980). The problem of multiple toxicant exposure has been addressed by the American Conference of Governmental Industrial Hygienists (ACGIH, 1983), the Occupational Safety and Health Administration (OSHA, 1983), the World Health Organization (WHO, 1981), and the National Research Council (NRC, 1980a,b). Although the focus and purpose of each group was somewhat different, all groups that recommended an approach elected to adopt some type of dose additive model. Nonetheless, as discussed in section IV, dose additive models are not the most biologically plausible approach if the compounds do not have the same mode of toxicologic action. Consequently, depending on the nature of the risk assessment and the available information on modes of action and patterns of joint action, the most reasonable additive model should be used.

The additive model generates a hazard index (HI) for the mixture by adding the ratios of the concentration of each substance or chemical detected in the groundwater (E_x) to its maximum tolerated level, which in the case of the proposed rules is the health risk limit (HRL_x):

$$HI = \frac{E_1}{HRL_1} + \frac{E_2}{HRL_2} + \ldots + \frac{E_x}{HRL_x}$$

For example, E_1 represents the concentration of one substance or chemical detected in the groundwater and HRL_1 represents the health risk limit for that substance or chemical. E_2 represents the concentration of a second substance or chemical detected in the same groundwater and HRL_2 represents the health risk limit of the second substance or chemical. The ratios for all of the substances or chemicals are included in the equation such that E_x and HRL_x represent the values for the last (third, fourth, fifth, etc.) substance or chemical where "X" equals the total number of substances or chemicals in the mixture.

Like the health risk limits for individual substances or chemicals, the hazard index is not an absolute quantitation of risk, but rather an indicator of acceptable exposure limits. As the hazard index approaches 1, the level of concern about the mixture increases. A hazard index equal to 1 for a mixture is analogous to the health risk limit for an individual substance or chemical. A hazard index greater than one indicates that the mixture exceeds the health risk limit.

The application of the additive model is most appropriate when the components of the mixture cause the same toxicological result, such as damaging the same organ or organ system. To refine the additive model, the USEPA Risk Assessment Guidelines recommend generating a separate hazard index for each group of chemicals defined by a common "endpoint of concern" (USEPA, 1987 p. 3-7). (For the purposes of the proposed rules, the phrase "toxic endpoint" is used instead of either the USEPA language "endpoint of concern" or the statutory language "toxicological result" simply because "toxic endpoint" is the less cumbersome phrase. The department believes it is reasonable to consider these three phrases to be synonymous). This refinement of the additive model is supported by the National Research Council in Drinking Water and Health, vol. 9 (NRC, 1989, p.105):

> 2. Systemic contaminants that have similar toxic end points, such as those resulting in specific organ toxicity or peripheral nerve damage, can be grouped and treated as having additive effects under most conditions.

In accordance with the recommendations of both the USEPA and the National Research Council all carcinogens fall under one toxic

endpoint: cancer (USEPA, 1987, p. 3-8; NRC, 1989, p. 97, 104). In the proposed rules the additive model is only applied to those systemic toxicants that affect a common organ or organ system such as the cardiovascular system, developmental effects, endocrine system, eyes, hematologic system, immune system, kidney, liver, male reproductive system, nervous system and stomach.

The same studies used by the USEPA to calculate the reference doses were used to identify the toxic endpoints for the systemic toxicants. Substances or chemicals can cause different effects at different doses. For example, a low dose may cause liver damage, a moderate dose more severe liver damage plus kidney damage, and finally a high dose will cause death. The USEPA generally bases the reference dose on the lowest dose at which an adverse effect is observed. These effects are listed in the IRIS files under "Principal and Supporting Studies" or "Critical Effect." Since the individual health risk limits for systemic toxicants are calculated using USEPA reference doses, it is reasonable to specify the toxic endpoint or endpoints to be the physiological effect or effects on which calculation of the reference dose is based.

A hazard index should not be calculated for substances or chemicals in a mixture that do not have a toxic endpoint listed in part 4717.7650. For those substances or chemicals, only the individual health risk limit specified in part 4717.7500 will apply.

Likewise, substances or chemicals in a mixture that do not share a common endpoint with any other substance or chemical in that mixture should not be included in the calculation of a hazard index. Instead the individual health risk limit specified in part 4717.7500 will apply. For example:

> A mixture contains chemicals A, B, C, and D. The toxic endpoint for chemical A is liver. The toxic endpoint for chemicals B, C, and D is kidney. A hazard index would be calculated for chemicals B, C, and D. The individual health risk limit would be applied to chemical A.

The additive model is a reasonable approach to evaluating the health risk of mixtures. If a mixtures provision was not included in proposed rules, the health risk limits would not provide a margin of safety for either additive or synergistic effects that might result from combinations of substances or chemicals. In Drinking Water and Health, vol. 9, the National Research Council suggests that synergism could be accounted for by multiplying the hazard index by an uncertainty factor (NRC, 1989). The value of the uncertainty factor would vary, depending on the weight of evidence regarding synergism. This is more protective than the proposed approach, but could lead to an overestimation of risk in the case of either an additive response, antagonism or independent action. The department believes that the hazard index alone is

reasonably protective since synergistic effects probably do not occur at low environmental exposures. According to the National Research Council publication Drinking Water and Health (NRC, 1989, p.98):

> On a practical level, ambient exposures to mixtures usually involve low concentrations of the constituents. At concentrations that yield small increases in relative risks, additive and multiplicative responses are essentially indistinguishable, and additivity is a satisfactory first approximation.

The proposed additive model is reasonable because it provides a margin of safety for public health, yet is less likely to overestimate risk than the model that incorporates an additional uncertainty factor to account for synergism. Calculating a separate hazard index for each group of substances or chemicals sharing a toxic endpoint further reduces the potential for overestimating risk. To reiterate the USEPA risk assessment guidelines (USEPA, 1987 p. 3-10):

> Based on current information, additivity assumptions are expected to yield generally neutral risk estimates (i.e., neither conservative nor lenient) and are plausible for component compounds that induce similar types of effects at the same sites of action.

Subpart 1. **Definitions.** The definitions in this part are necessary for the consistent and intended interpretation of parts 4717.7600 to 4717.7750.

Subpart 2. **Groundwater.** "Groundwater" is defined in Minnesota Statutes, section 115.01, subdivision 21. This definition is necessary for the definition of "mixture" in subpart 3. Reference to the statute ensures consistency between the proposed rules and the meaning given in statute.

Subpart 3. **Mixture.** The definition is necessary to identify the cases to which the procedures specified in this part apply. This definition is reasonable since it limits mixture to mean a combination of only those substances or chemicals that have a health risk limit specified in part 4717.7500.

Subpart 4. **Toxic Endpoint.** According the USEPA's Guidelines for the Health Risk Assessment of Chemical Mixtures (USEPA, 1987, p.3-7) the additivity model specified in parts 4717.7700 and 4717.7750 is reasonable when a hazard index is calculated for substances or chemicals that have the same mode of toxicological action:

> Since the assumption of dose addition is most properly applied to compounds that induce the same effect by

similar modes of action, a separate hazard index should be generated for each end point of concern.

The assumption of dose addition is most clearly justified when the mechanisms of action of the compounds under consideration are known to be the same. Since the mechanisms of action for most compounds are not well understood, the justification of the assumption of dose addition will often be limited to similarities in pharmacokinetic and toxicologic characteristics.

The definition of "toxic endpoint" is necessary for determining the substances and chemicals specified in part 4717.7500 that have similarities in pharmacokinetic and toxicologic characteristics.

A. This item is necessary to limit the definition of "toxic endpoint" for a systemic toxicant specified in part 4717.7500. Substances or chemicals can cause different effects at different doses. A USEPA reference dose is generally calculated using the physiological effect or effects that occur at the lowest dose. Therefore it is reasonable to limit the definition of "toxic endpoint" to the physiological effect that is (or effects that are) listed in the study or studies used by the USEPA to calculate the reference dose.

B. Both the USEPA in Guidelines for the Health Risk Assessment of Chemical Mixtures (USEPA, 1987,p.3-8) and the National Research Council in Drinking Water and Health, volume 9 (NRC, 1989, p. 97) recommend considering cancer a separate toxic endpoint. It is reasonable that only those substances or chemicals specified in part 4717.7500 for which a health risk limit has been calculated using the method for carcinogens will have cancer as a toxic endpoint.

4717.7650 TOXIC ENDPOINTS.

Subpart 1. **Scope.** This part is necessary to specify the toxic endpoint or endpoints for the substances or chemicals to which the procedures in part 4717.7700 or part 4717.7750 will be applied. Both the chemical name and CAS RN are listed for positive identification of a substance or chemical.

Subpart 2. **Acenaphthene.** The CAS RN assigned to acenaphthene by the Chemical Abstracts Service is 83-32-9. The USEPA does not list acenaphthene as either a human or probable human carcinogen. The IRIS file for acenaphthene lists "hepatotoxicity" as the "critical effect" (USEPA, 1992a1). According to the American Heritage Dictionary, Second College Edition (American Heritage, 1985, p. 606), "hepato-" is a prefix meaning liver. Therefore "hepatotoxicity" means toxicity to the liver and liver is the toxic endpoint for acenaphthene.

Subpart 3. **Acetone.** The CAS RN assigned to acetone by the Chemical Abstracts Service is 67-64-1. The USEPA does not list acetone as either a human or probable human carcinogen. The IRIS for acetone lists "nephrotoxicity" under "critical effect" (USEPA, 1992a2). According to the American Heritage Dictionary, Second College Edition (American Heritage, 1985, p. 837) "nephro-" is a prefix meaning kidney. Therefore "nephrotoxicity" means kidney toxicity and the toxic endpoint for acetone is kidney.

Subpart 4. **Aldicarb.** The CAS RN assigned to aldicarb by the Chemical Abstracts Service is 116-06-3. The USEPA does not classify aldicarb as either a human or probable human carcinogen. The IRIS file for aldicarb lists plasma cholinesterase inhibition under "critical effect" (USEPA, 1992a3). According to Casarett and Doull's Toxicology. The Basic Science of Poisons (Doull, et al., 1980, p. 375-377), cholinesterase inhibitors are toxic to the nervous system and plasma cholinesterase inhibition is used as an indicator of nervous system damage. Therefore the toxic endpoint for aldicarb is nervous system.

Subpart 5. **Barium.** The CAS RN assigned to barium by the Chemical Abstracts Service is 7440-39-3. The USEPA does not classify barium as either a human or probable human carcinogen. The IRIS file for barium lists increased blood pressure under "critical effect" (USEPA, 1992b1). Therefore the toxic endpoint for barium is cardiovascular system.

Subpart 6. **Benzene.** The CAS RN assigned to benzene by the Chemical Abstracts Service is 71-43-2. The USEPA classifies benzene as a human carcinogen (USEPA, 1992b2). Therefore the toxic endpoint for benzene is cancer.

Subpart 7. **Beryllium.** The CAS RN assigned to beryllium by the Chemical Abstracts Service is 7440-41-7. The USEPA classifies beryllium as a probable human carcinogen (USEPA, 1992b4). Therefore the toxic endpoint for beryllium is cancer.

Subpart 8. **1,1-Biphenyl (Diphenyl).** The CAS RN assigned to 1,1-biphenyl (diphenyl) by the Chemical Abstracts Service is 92-52-4. The USEPA does not classify 1,1-biphenyl (diphenyl) as either a human or probable human carcinogen. The IRIS file for 1,1-biphenyl (diphenyl) lists "kidney damage" as the "critical effect" (USEPA, 1992b5). Therefore the toxic endpoint for 1,1-biphenyl (diphenyl) is kidney.

Subpart 9. **Bis(chloroethyl)ether (BCEE).** The CAS RN assigned to bis(chloroethyl)ether (BCEE) by the Chemical Abstracts Service is 111-44-4. The USEPA classifies bis(chloroethyl)ether (BCEE) as a probable human carcinogen (USEPA, 1992b6). Therefore the toxic endpoint for bis(chloroethyl)ether (BCEE) is cancer.

Subpart 10. **Bis(chloromethyl)ether (BCME).** The CAS RN assigned to bis(chloromethyl)ether (BCME) by the Chemical Abstracts Service is 542-88-1. The USEPA classifies bis(chloromethyl)ether (BCME) as a human carcinogen (USEPA, 1992b7). Therefore the toxic endpoint for bis(chloromethyl)ether (BCME) is cancer.

Subpart 11. **Boron.** The CAS RN assigned to boron by the Chemical Abstracts Service is 7440-42-8. The USEPA does not classify boron as either a human or probable human carcinogen. The IRIS file for boron lists the "testicular atrophy" and "spermatogenic arrest" under "critical effect" (USEPA, 1992b8). Therefore the toxic endpoint for boron is male reproductive system.

Subpart 12. **Bromodichloromethane.** The CAS RN assigned to bromodichloromethane by the Chemical Abstracts Service is 75-27-4. The USEPA classifies bromodichloromethane as a probable human carcinogen (USEPA, 1993b). Therefore the toxic endpoint for bromodichloromethane is cancer.

Subpart 13. **Bromoform.** The CAS RN assigned to bromoform by the Chemical Abstracts Service is 75-25-2. The USEPA classifies bromoform as a probable human carcinogen (USEPA, 1992b9). Therefore the toxic endpoint for bromoform is cancer.

Subpart 14. **Bromomethane (Methyl bromide).** The CAS RN assigned to bromomethane (methyl bromide) by the Chemical Abstracts Service is 74-83-9. The USEPA does not classify bromomethane (methyl bromide) as either a human or probable human carcinogen. The IRIS file for bromomethane (methyl bromide) lists "epithelial hyperplasia of the forestomach" under "critical effect" (USEPA, 1992b10). Human stomachs do not have a segment called a "forestomach." Nevertheless, the department believes it is reasonable to assume that if bromomethane (methyl bromide) effects the forestomach in rats, it might effect a similar tissue in humans. Therefore the toxic endpoint for bromomethane (methyl bromide) is stomach.

Subpart 15. **n-Butanol.** The CAS RN assigned to n-butanol by the Chemical Abstracts Service is 71-36-3. The USEPA does not classify n-butanol as either a human or probable human carcinogen. The IRIS file for n-butanol lists "central nervous system effects" in the summary of principal and supporting studies used for calculation of the reference dose (USEPA, 1992b11). Therefore the toxic endpoint for n-butanol is nervous system.

Subpart 16. **Cadmium.** The CAS RN assigned to cadmium by the Chemical Abstracts Service is 7440-43-9. The USEPA does not list cadmium as either a human or probable human carcinogen by oral exposure. The IRIS file for cadmium lists "significant proteinuria" as the "critical effect" (USEPA, 1992c1). According to Organ Function Tests in Toxicity Evaluation, "Increased total proteinuria is observed in renal failure" (Tyson and Sawhney, 1985,

p. 116). According to the American Heritage Dictionary, Second College Edition (American Heritage, 1985, p. 1046) "renal" means "Of, pertaining to, or in the region of the kidneys." Casarett and Doull's Toxicology. The Basic Science of Poisons also states, "The current view is that the kidney is the most cadmium-sensitive organ" (Doull, et al., 1980, p.433). Therefore the toxic endpoint for cadmium is kidney.

Subpart 17. **Carbon disulfide.** The CAS RN assigned to carbon disulfide by the Chemical Abstracts Service is 75-15-0. The USEPA does not list carbon disulfide as either a human or probable human carcinogen. The IRIS file for carbon disulfide lists "fetotoxicity/malformations" under "critical effect" (USEPA, 1992c2). According to the USEPA's Guidelines for Developmental Toxicity Risk Assessment (Federal Register, 1991b, p. 63801, 63802), fetotoxicity and malformations are indicators of developmental toxicity. Therefore the toxic endpoint for carbon disulfide is developmental effects.

Subpart 18. **Carbon Tetrachloride.** The CAS RN assigned to carbon tetrachloride by the Chemical Abstracts Service is 56-23-5. The USEPA classifies carbon tetrachloride as a probable human carcinogen (USEPA, 1992c3). Therefore the toxic endpoint for carbon tetrachloride is cancer.

Subpart 19. **Chlorobenzene.** The CAS RN assigned to chlorobenzene by the Chemical Abstracts Service is 108-90-7. The USEPA does not list chlorobenzene as either a human or probable human carcinogen. The IRIS file for chlorobenzene lists "histopathologic changes in liver" as the "critical effect" (USEPA, 1992c4). Therefore the toxic endpoint for chlorobenzene is liver.

Subpart 20. **Chloroform.** The CAS RN assigned to chloroform by the Chemical Abstracts Service is 67-66-3. The USEPA classifies chloroform as a probable human carcinogen (USEPA, 1992c5). Therefore the toxic endpoint for chloroform is cancer.

Subpart 21. **2-Chlorophenol.** The CAS RN assigned to 2-chlorophenol by the Chemical Abstracts Service is 95-57-8. The USEPA does not list 2-chlorophenol as either a human or probable human carcinogen. The IRIS file for 2-chlorophenol lists "reproductive effects" as the "critical effect" (USEPA, 1992c6). The summary of principal and supporting studies used to calculate the reference dose lists an increase in the number of stillborns and a decrease in litter size as reproductive effects. According to the USEPA's Guidelines for Developmental Toxicity Risk Assessment (Federal Register, 1991b, p. 63802, 63804), an increase in the number of stillborns is an indicator of developmental toxicity. Therefore the toxic endpoint for 2-chlorophenol is developmental effects.

Subpart 22. **Cyanide, free.** The CAS RN assigned to cyanide, free by the Chemical Abstracts Service is 57-12-5. The USEPA does not list cyanide, free as either a human or probable human carcinogen. The IRIS file for cyanide, free lists "thyroid effects and myelin degeneration" under "critical effect" (USEPA, 1992c9). The thyroid gland produces the hormone thyroxin. Organs that produce hormones are part of the endocrine system (VanNostrand, 1976, p. 951). Myelin is a fatty material that encases nerve fibers and therefore myelin degeneration indicates neurotoxicity. Therefore the toxic endpoints for cyanide, free are endocrine system and nervous system.

Subpart 23. **Dibromochloromethane.** The CAS RN assigned to dibromochloromethane by the Chemical Abstracts Service is 124-48-1. The USEPA does not list dibromochloromethane as either a human or probable human carcinogen. The IRIS file for dibromochloromethane lists "hepatic lesions" as the "critical effect" (USEPA, 1992d1). Therefore the toxic endpoint for dibromochloromethane is liver.

Subpart 24. **1,2-Dibromoethane (Ethylene dibromide, EDB).** The CAS RN assigned to 1,2-dibromoethane (ethylene dibromide, EDB) by the Chemical Abstracts Service is 106-93-4. The USEPA classifies 1,2-dibromoethane (ethylene dibromide, EDB) as a probable human carcinogen (USEPA, 1992d2). Therefore the toxic endpoint for 1,2-dibromoethane (ethylene dibromide, EDB) is cancer.

Subpart 25. **Dicamba.** The CAS RN assigned to dicamba by the Chemical Abstracts Service is 1918-00-9. The USEPA does not list dicamba as either a human or probable human carcinogen (USEPA, 1992d4). The IRIS file for dicamba lists "fetal toxicity" under "critical effect" (USEPA, 1992d4). According to the USEPA's Guidelines for Developmental Toxicity Risk Assessment (Federal Register, 1991b, p. 63801, 63802), fetal toxicity is an indicator of developmental toxicity. Therefore the toxic endpoint for dicamba is developmental effects.

Subpart 26. **1,2-Dichlorobenzene.** The CAS RN assigned to 1,2-dichlorobenzene by the Chemical Abstracts Service is 95-50-1. The USEPA does not list 1,2-dichlorobenzene as either a human or probable human carcinogen (USEPA, 1992d5). The IRIS file for 1,2-dichlorobenzene lists "liver necrosis" in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992d5). Therefore the toxic endpoint for 1,2-dichlorobenzene is liver.

Subpart 27. **3,3'-Dichlorobenzidine.** The CAS RN assigned to 3,3'-dichlorobenzidine by the Chemical Abstracts Service is 91-94-1. The USEPA classifies 3,3'-dichlorobenzidine as a probable human carcinogen (USEPA, 1992d6). Therefore the toxic endpoint for 3,3'-dichlorobenzidine is cancer.

Subpart 28. **p,p'-Dichlorodiphenyl dichloroethane (DDD).** The CAS RN assigned to p,p'-dichlorodiphenyl dichloroethane (DDD) by the Chemical Abstracts Service is 72-54-8. The USEPA classifies p,p'-dichlorodiphenyl dichloroethane (DDD) as a probable human carcinogen (USEPA, 1992d8). Therefore the toxic endpoint for p,p'-dichlorodiphenyl dichloroethane (DDD) is cancer.

Subpart 29. **p,p'-Dichlorodiphenyldichloroethylene (DDE).** The CAS RN assigned to p,p'-dichlorodiphenyldichloroethylene (DDE) by the Chemical Abstracts Service is 72-55-9. The USEPA classifies p,p'-dichlorodiphenyldichloroethylene (DDE) as a probable human carcinogen (USEPA, 1992d9). Therefore the toxic endpoint for p,p'-dichlorodiphenyldichloroethylene (DDE) is cancer.

Subpart 30. **p,p'-Dichlorodiphenyltrichloroethane (DDT).** The CAS RN assigned to p,p'-dichlorodiphenyltrichloroethane (DDT) by the Chemical Abstracts Service is 50-29-3. The USEPA classifies p,p'-dichlorodiphenyltrichloroethane (DDT) as a probable human carcinogen (USEPA, 1992d10). Therefore the toxic endpoint for p,p'-dichlorodiphenyltrichloroethane (DDT) is cancer.

Subpart 31. **1,2-Dichloroethane.** The CAS RN assigned to 1,2-dichloroethane by the Chemical Abstracts Service is 107-06-2. The USEPA classifies 1,2-dichloroethane as a probable human carcinogen (USEPA, 1992d11). Therefore the toxic endpoint for 1,2-dichloroethane is cancer.

Subpart 32. **1,1-Dichloroethylene (Vinylidene chloride).** The CAS RN assigned to 1,1-dichloroethylene (vinylidene chloride) by the Chemical Abstracts Service is 75-35-4. The USEPA does not list 1,1-dichloroethylene (vinylidene chloride) as either a human or probable human carcinogen. The IRIS file for 1,1-dichloroethylene (vinylidene chloride) lists "hepatic lesions" as the "critical effect" (USEPA, 1992d12). Therefore the toxic endpoint for 1,1-dichloroethylene (vinylidene chloride) is liver.

Subpart 33. **Dichloromethane (Methylene chloride).** The CAS RN assigned to dichloromethane (methylene chloride) by the Chemical Abstracts Service is 75-09-2. The USEPA classifies dichloromethane (methylene chloride) as a probable human carcinogen (USEPA, 1992d14). Therefore the toxic endpoint for dichloromethane (methylene chloride) is cancer.

Subpart 34. **2,4-Dichlorophenol.** The CAS RN assigned to 2,4-dichlorophenol by the Chemical Abstracts Service is 120-83-2. The USEPA does not list 2,4-dichlorophenol as either a human or probable human carcinogen. The IRIS file for 2,4-dichlorophenol lists "decreased delayed hypersensitivity response" as the "critical effect" (USEPA, 1992d15). According to the chapter "Approaches and Methodology for Examining the Immunological Effects of Xenobiotics," in the text Immunotoxicology, delayed hypersensitivity response is an indicator of damage to the immune

system (Dean, et al., 1983, p. 205). Therefore the toxic endpoint for 2,4-dichlorophenol is immune system.

Subpart 35. **2,4-Dichlorophenoxyacetic acid (2,4-D).** The CAS RN assigned to 2,4-dichlorophenoxyacetic acid (2,4-D) by the Chemical Abstracts Service is 94-75-7. The USEPA does not list 2,4-dichlorophenoxyacetic acid (2,4-D) as either a human or probable human carcinogen. The IRIS file for 2,4-dichlorophenoxyacetic acid (2,4-D) lists "Hematologic, hepatic and renal toxicity" as the "critical effect" (USEPA, 1992d16). Therefore the toxic endpoints for 2,4-dichlorophenoxyacetic acid (2,4-D) are hematologic system, kidney and liver.

Subpart 36. **Di(2-ethylhexyl)phthalate (DEHP).** The CAS RN assigned to di(2-ethylhexyl)phthalate (DEHP) by the Chemical Abstracts Service is 117-81-7. The USEPA classifies di(2-ethylhexyl)phthalate (DEHP) as a probable human carcinogen (USEPA, 1992d17). Therefore the toxic endpoint for di(2-ethylhexyl)phthalate (DEHP) is cancer.

Subpart 37. **2,4-Dimethylphenol.** The CAS RN assigned to 2,4-dimethylphenol by the Chemical Abstracts Service is 105-67-9. The USEPA does not list 2,4-dimethylphenol as either a human or probable human carcinogen (USEPA, 1992d19). The IRIS file for 2,4-dimethylphenol lists "Clinical signs (lethargy, prostration, and ataxia and hematological changes" as the "critical effect" (USEPA, 1992d19). Ataxia, which is a loss of lack of muscular coordination, is an indicator of neurotoxicity (Haley and Berndt, 1987. The hematological changes included lower mean corpuscular volume and mean corpuscular hemoglobin concentration indicating that blood is also a target. Therefore the toxic endpoints for 2,4-dimethylphenol are hematologic system and nervous system.

Subpart 38. **2,4-Dinitrophenol.** The CAS RN assigned to 2,4-dinitrophenol by the Chemical Abstracts Service is 51-28-5. The USEPA does not list 2,4-dinitrophenol as either a human or probable human carcinogen. The IRIS file for 2,4-dinitrophenol lists "cataract formation" as the "critical effect" (USEPA, 1992d20). Therefore the toxic endpoint for 2,4-dinitrophenol is eyes.

Subpart 39. **Ethylbenzene.** The CAS RN assigned to ethylbenzene by the Chemical Abstracts Service is 100-41-4. The USEPA does not list ethylbenzene as either a human or probable human carcinogen. The IRIS file for ethylbenzene lists "liver and kidney toxicity" as the "critical effect" (USEPA, 1992e1). Therefore the toxic endpoints for ethylbenzene are kidney and liver.

Subpart 40. **S-Ethyl dipropylthiocarbamate (EPTC).** The CAS RN assigned to S-ethyl dipropylthiocarbamate (EPTC) by the Chemical Abstracts Service is 759-94-4. The USEPA does not list S-ethyl dipropylthiocarbamate (EPTC) as either a human or probable human

carcinogen. The IRIS file for S-ethyl dipropylthiocarbamate (EPTC) lists "degenerative cardiomyopathy" as the "critical effect" (USEPA, 1990b). The IRIS file for S-ethyl dipropylthiocarbamate (EPTC) also lists "neuropathy" under "Data Considered for Establishing the RfD" and "depressed brain cholinesterase activity" under "Other Data Reviewed" (USEPA, 1990b). According to Casarett and Doull's Toxicology. The Basic Science of Poisons the class of compounds called carbamates, of which S-ethyl dipropylthiocarbamate (EPTC) is a member, inhibit acetylcholinesterase and acetylcholinesterase inhibitors are toxic to the nervous system (Doull, et al., 1980, p. 375-377). Therefore the toxic endpoints for S-ethyl dipropylthiocarbamate (EPTC) are cardiovascular system and nervous system.

Subpart 41. **Fluoranthene.** The CAS RN assigned to fluoranthene by the Chemical Abstracts Service is 206-44-0. The USEPA does not list fluoranthene as either a human or probable human carcinogen. The IRIS file for fluoranthene lists "nephropathy" and "liver lesions" in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992f1). Therefore the toxic endpoints for fluoranthene are kidney and liver.

Subpart 42. **Fluorene (9H-Fluorene).** The CAS RN assigned to fluorene (9H-fluorene) by the Chemical Abstracts Service is 86-73-7. The USEPA does not list fluorene (9H-fluorene) as either a human or probable human carcinogen. The IRIS file for fluorene (9H-fluorene) lists "decreased in red blood cell count and packed cell volume" in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992f2). Therefore the toxic endpoint for fluorene (9H-fluorene) is hematologic system.

Subpart 43. **Heptachlor.** The CAS RN assigned to heptachlor by the Chemical Abstracts Service is 76-44-8. The USEPA classifies heptachlor as a probable human carcinogen (USEPA, 1992h1). Therefore the toxic endpoint for heptachlor is cancer.

Subpart 44. **Heptachlor epoxide.** The CAS RN assigned to heptachlor epoxide by the Chemical Abstracts Service is 1024-57-3. The USEPA classifies heptachlor epoxide as a probable human carcinogen (USEPA, 1992h2). Therefore the toxic endpoint for heptachlor epoxide is cancer.

Subpart 45. **Hexachlorobenzene.** The CAS RN assigned to hexachlorobenzene by the Chemical Abstracts Service is 118-74-1. The USEPA classifies hexachlorobenzene as a probable human carcinogen (USEPA, 1992h3). Therefore the toxic endpoint for hexachlorobenzene is cancer.

Subpart 46. **Hexachlorobutadiene.** The CAS RN assigned to hexachlorobutadiene by the Chemical Abstracts Service is 87-68-3.

The USEPA does not list hexachlorobutadiene as either a human or probable human carcinogen. The IRIS file for hexachlorobutadiene lists "kidney toxicity" as the "critical effect" (USEPA, 1992h4). Therefore the toxic endpoint for hexachlorobutadiene is kidney.

Subpart 47. **Isophorone.** The CAS RN assigned to isophorone by the Chemical Abstracts Service is 78-59-1. The USEPA does not list isophorone as either a human or probable human carcinogen. The IRIS file for isophorone lists "kidney pathology" under "critical effect" (USEPA, 1992i). Therefore the toxic endpoint for isophorone is kidney.

Subpart 48. **Linuron.** The CAS RN assigned to linuron by the Chemical Abstracts Service is 330-55-2. The USEPA does not list linuron as either a human or probable human carcinogen. The IRIS file for linuron lists decreased red blood cell count and "abnormal blood pigment" in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992l). Therefore the toxic endpoint for linuron is hematologic system.

Subpart 49. **Manganese.** The CAS RN assigned to manganese by the Chemical Abstracts Service is 7439-96-5. The USEPA does not list manganese as either a human or probable human carcinogen. The IRIS file for manganese lists "CNS effects" under "critical effect" (USEPA, 1993m). CNS stands for central nervous system. Therefore the toxic endpoint for manganese is nervous system.

Subpart 50. **2-Methyl-4-chlorophenoxyacetic acid (MCPA).** The CAS RN assigned to 2-methyl-4-chlorophenoxyacetic acid (MCPA) by the Chemical Abstracts Service is 94-74-6. The USEPA does not list 2-methyl-4-chlorophenoxyacetic acid (MCPA) as either a human or probable human carcinogen. The IRIS file for 2-methyl-4-chlorophenoxyacetic acid (MCPA) lists "kidney and liver toxicity" as the "critical effect" (USEPA, 1992m1). Therefore the toxic endpoints for 2-methyl-4-chlorophenoxyacetic acid (MCPA) are kidney and liver.

Subpart 51. **2-Methylphenol (o-Cresol).** The CAS RN assigned to 2-methylphenol (o-cresol) by the Chemical Abstracts Service is 95-48-7. The USEPA does not list 2-methylphenol (o-cresol) as either a human or probable human carcinogen. The IRIS file for 2-methylphenol (o-cresol) lists "neurotoxicity" under "critical effect" (USEPA, 1992m2). Therefore the toxic endpoint for 2-methylphenol (o-cresol) is nervous system.

Subpart 52. **3-Methylphenol (m-Cresol).** The CAS RN assigned to 3-methylphenol (m-cresol) by the Chemical Abstracts Service is 108-39-4. The USEPA does not list 3-methylphenol (m-cresol) as either a human or probable human carcinogen. The IRIS file for 3-methylphenol (m-cresol) lists "neurotoxicity" under "critical effect" (USEPA, 1992m3). Therefore the toxic endpoint for 3-methylphenol (m-cresol) is nervous system.

Subpart 53. **Metolachlor.** The CAS RN assigned to metolachlor by the Chemical Abstracts Service is 51218-45-2. The USEPA does not list metolachlor as either a human or probable human carcinogen. The IRIS file for metolachlor lists "reduced pup weights" under "critical effect" (USEPA, 1992m4). According to the USEPA's Guidelines for Developmental Toxicity Risk Assessment (Federal Register, 1991b, p. 63801, 63802), a change in offspring weight is an indicator of developmental toxicity. Therefore the toxic endpoint for metolachlor is developmental effects.

Subpart 54. **Metribuzin.** The CAS RN assigned to metribuzin by the Chemical Abstracts Service is 21087-64-9. The USEPA does not list metribuzin as either a human or probable human carcinogen. The IRIS file for metribuzin lists "liver and kidney effects" under "critical effect" (USEPA, 1992m5). Therefore the toxic endpoints for metribuzin are kidney and liver.

Subpart 55. **Nitrate (as nitrogen).** The CAS RN assigned to nitrate by the Chemical Abstracts Service is 14797-55-8. The USEPA does not list nitrate as either a human or probable human carcinogen. The IRIS file for nitrate lists methemoglobinemia under "critical effect" (USEPA, 1992n2). Methemoglobinemia reduces the oxygen-carrying capacity of the blood (USEPA, 1992n2). Therefore the toxic endpoint for nitrate (as nitrogen) is hematologic system.

Subpart 56. **N-Nitrosodiphenylamine.** The CAS RN assigned to N-nitrosodiphenylamine by the Chemical Abstracts Service is 86-30-6. The USEPA classifies N-nitrosodiphenylamine as a probable human carcinogen (USEPA, 1992n3). Therefore the toxic endpoint for N-nitrosodiphenylamine is cancer.

Subpart 57. **Pentachlorophenol.** The CAS RN assigned to pentachlorophenol by the Chemical Abstracts Service is 87-86-5. The USEPA classifies pentachlorophenol as a probable human carcinogen (USEPA, 1992p1). Therefore the toxic endpoint for pentachlorophenol is cancer.

Subpart 58. **Phenol.** The CAS RN assigned to phenol by the Chemical Abstracts Service is 108-95-2. The USEPA does not list phenol as either a human or probable human carcinogen. The IRIS file for phenol lists "reduced fetal body weight in rats" as the "critical effect" (USEPA, 1992p2). According to the USEPA's Guidelines for Developmental Toxicity Risk Assessment (Federal Register, 1991b, p. 63801, 63802), altered growth is an indicator of developmental toxicity. Therefore the toxic endpoint for phenol is developmental effects.

Subpart 59. **Picloram.** The CAS RN assigned to picloram by the Chemical Abstracts Service is 1918-02-1. The USEPA does not list picloram as either a human or probable human carcinogen. The IRIS file for picloram lists "increased liver weights" as the "critical

effect" (USEPA, 1992p3). This IRIS file for picloram also lists liver histopathology under "Additional Comments." Therefore the toxic endpoint for picloram is liver.

Subpart 60. **Pyrene.** The CAS RN assigned to pyrene by the Chemical Abstracts Service is 129-00-0. The USEPA does not list pyrene as either a human or probable human carcinogen. The IRIS file for pyrene lists "kidney effects" as the "critical effect" (USEPA, 1992p6). Therefore the toxic endpoint for pyrene is kidney.

Subpart 61. **1,1,1,2-Tetrachloroethane.** The CAS RN assigned to 1,1,1,2-tetrachloroethane by the Chemical Abstracts Service is 630-20-6. The USEPA does not list 1,1,1,2-tetrachloroethane as either a human or probable human carcinogen. The IRIS file for 1,1,1,2-tetrachloroethane lists "mineralization of the kidneys" and "hepatic clear cell change" under "critical effect" (USEPA, 1992t1). Therefore the toxic endpoints for 1,1,1,2-tetrachloroethane are kidney and liver.

Subpart 62. **Toluene.** The CAS RN assigned to toluene by the Chemical Abstracts Service is 108-88-3. The USEPA does not list toluene as either a human or probable human carcinogen. The IRIS file for toluene lists "histopathologic changes in both the liver and kidney" in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992t2). Therefore the toxic endpoints for toluene kidney and liver.

Subpart 63. **Toxaphene.** The CAS RN assigned to toxaphene by the Chemical Abstracts Service is 8001-35-2. The USEPA classifies toxaphene as a probable human carcinogen (USEPA, 1992t3). Therefore the toxic endpoint for toxaphene is cancer.

Subpart 64. **1,1,2-Trichloroethane.** The CAS RN assigned to 1,1,2-trichloroethane by the Chemical Abstracts Service is 79-00-5. The USEPA does not list 1,1,2-trichloroethane as either a human or probable human carcinogen. The IRIS file for 1,1,2-trichloroethane lists "depressed humoral immune status" in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992t4). Therefore the toxic endpoint for 1,1,2-trichloroethane is immune system.

Subpart 65. **2,4,6-Trichlorophenol.** The CAS RN assigned to 2,4,6-trichlorophenol by the Chemical Abstracts Service is 88-06-2. The USEPA classifies 2,4,6-trichlorophenol as a probable human carcinogen (USEPA, 1992t6). Therefore the toxic endpoint for 2,4,6-trichlorophenol is cancer.

Subpart 66. **2,4,5-Trichlorophenoxyacetic acid (2,4,5-T).** The CAS RN assigned to 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) by the Chemical Abstracts Service is 93-76-5. The USEPA does not list 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) as either a human or

probable human carcinogen. The IRIS file for 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) lists "increased urinary coproporphyrins" and "reduced neonatal survival" under "critical effect" (USEPA, 1992t7). Increased urinary coproporphyrins indicates a disruption in the heme biosynthesis (Haley and Berndt, 1987 p.403). Heme is necessary for the synthesis of hemoglobin. Because red blood cells contain hemoglobin to transport oxygen, disruption of heme biosynthesis could effect the hematopoietic system. According to the USEPA's Guidelines for Developmental Toxicity Risk Assessment (Federal Register, 1991b, p. 63801, 63802), reduced neonatal survival is and indicator of developmental toxicity. Therefore the toxic endpoints for 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) is developmental effects and hematologic system.

Subpart 67. **2 (2,4,5-Trichlorophenoxy) propionic acid.** The CAS RN assigned to 2 (2,4,5-trichlorophenoxy) propionic acid by the Chemical Abstracts Service is 93-72-1. The USEPA does not list 2 (2,4,5-trichlorophenoxy) propionic acid as either a human or probable human carcinogen. The IRIS file for 2 (2,4,5-trichlorophenoxy) propionic acid lists "histopathological changes in the liver" as the "critical effect" (USEPA, 1992t8). Therefore the toxic endpoint for 2 (2,4,5-trichlorophenoxy) propionic acid is liver.

Subpart 68. **1,2,3-Trichloropropane.** The CAS RN assigned to 1,2,3-trichloropropane by the Chemical Abstracts Service is 96-18-4. The USEPA does not list 1,2,3-trichloropropane as either a human or probable human carcinogen. The IRIS file for 1,2,3-trichloropropane lists decreased red blood cell mass and histopathological changes in liver and kidney in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992t9). Therefore the toxic endpoints for 1,2,3-trichloropropane are hematologic system, kidney and liver.

Subpart 69. **Xylenes (mixture of isomers o, m, p).** The CAS RN assigned to xylenes (mixture of isomers o, m, p) by the Chemical Abstracts Service is 1330-20-7. The USEPA does not list xylenes (mixture of isomers o, m, p) as either a human or probable human carcinogen. The IRIS file for xylenes (mixture of isomers o, m, p) lists central nervous system toxicity in the summary of principal and supporting studies used to calculate the reference dose (USEPA, 1992x). Therefore the toxic endpoint for xylenes (mixture of isomers o, m, p) is nervous system.

4717.7700 PROCEDURE FOR DETERMINING IF THE HEALTH RISK LIMIT FOR A MIXTURE OF CARCINOGENS IS EXCEEDED.

This part specifies the procedure for determining if a mixture of carcinogens exceeds the health risk limit.

A. Item A specifies the equation for determining a "hazard index" for carcinogens, those substances or chemicals where the toxic endpoint is specified as cancer in part 4717.7650. The "hazard index" indicates whether the mixture of carcinogens exceeds the health risk limit. This equation is consistent with the general equation published by the USEPA in the Guidelines for the Health Risk Assessment of Chemical Mixtures (USEPA, 1987, p.3-8):

$$HI = \frac{E_1}{DR_1} + \frac{E_2}{DR_2} + \ldots + \frac{E_n}{DR_n}$$

(1) E_{Cn}, which appears in the hazard index equation in this item, represents the concentration of a carcinogen detected in the groundwater. E_{Cn} in the proposed equation in Item A is equivalent to the "exposure level" "E_n" in the USEPA equation above.

(2) HRL_{Cn} represents the health risk limit for a carcinogen specified in part 4717.7500. This is equivalent to the "DR_n" in the USEPA equation, which is the dose of a carcinogen associated with a set level of risk. In this case the dose is a health risk limit set at a lifetime risk of 10^{-5}.

B. Each ratio E_{Cn}/HRL_{Cn} represents a fraction of the dose of a carcinogen set at a lifetime risk level of 10^{-5}. If the result of adding the ratios in the equation is 1, then the mixture of carcinogens presents a lifetime risk level of 10^{-5}.

C. Because the health risk limit for a carcinogen is set at a lifetime risk level of 10^{-5}, as specified in part 4717.7300, and a hazard index of one indicates a lifetime risk of 10^{-5}, a hazard index of one equals the health risk limit for a mixture of carcinogens.

D. Since a hazard index of 1 equals the health risk limit, then a hazard index greater than 1 exceeds the health risk limit.

4717.7750 PROCEDURE FOR DETERMINING IF THE HEALTH RISK LIMIT FOR A MIXTURE OF SYSTEMIC TOXICANTS IS EXCEEDED.

This part specifies the procedure for determining if a mixture of systemic toxicants exceeds the health risk limit. This procedure involves calculating a hazard index which indicates if the health risk limit has been exceeded.

A. Item A specifies the first step in the procedure for determining if a mixture of systemic toxicants exceeds the health risk limit. The first step is to group the substances or chemicals according to the common toxic endpoint specified in part 4717.7650. This step is reasonable because according to the USEPA's Guidelines for the Health Risk Assessment of Chemical Mixtures (USEPA, 1987, p.3-7) the additivity model specified in part 4717.7750 is

reasonable when a hazard index is calculated for substances or chemicals that have the same mode of toxicological action:

> Since the assumption of dose addition is most properly applied to compounds that induce the same effect by similar modes of action, a separate hazard index should be generated for each end point of concern.
>
> The assumption of dose addition is most clearly justified when the mechanisms of action of the compounds under consideration are known to be the same. Since the mechanisms of action for most compounds are not well understood, the justification of the assumption of dose addition will often be limited to similarities in pharmacokinetic and toxicologic characteristics.

In the absence of information to the contrary, it is reasonable to assume that systemic toxicants that have a similar toxic endpoint also have similar toxicologic characteristics. Therefore it is reasonable to group the systemic toxicants by toxic endpoint.

B. Item B specifies the second step in the procedure for determining if a mixture of systemic toxicants exceeds the health risk limit. This step is to calculate a hazard index for each group of substances or chemicals that share the same toxic endpoint as determined in item A. Item B specifies the equation for determining a "hazard index" for systemic toxicants. The proposed equation is consistent with the equation published by the USEPA in the Guidelines for the Health Risk Assessment of Chemical Mixtures (USEPA, 1987, p.3-7):

$$HI = \frac{E_1}{AL_1} + \frac{E_2}{AL_2} + \ldots + \frac{E_i}{AL_i}$$

(1) E_{STn} represents the concentration of a systemic toxicant detected in the groundwater. This is equivalent to the "exposure level" "E_i" in the USEPA equation.

(2) HRL_{STn} represents the health risk limit for a systemic toxicant specified in part 4717.7500. HRL_{STn} is equivalent to the maximum acceptable level "AL_i" in the USEPA equation.

C. Each ratio E_{STn}/HRL_{STn} represents a fraction of the health risk limit of a systemic toxicant detected in the groundwater. If the result of adding the ratios of all of the systemic toxicants in the mixture equals 1, then the health risk limit has been reached. Therefore a hazard index of 1 equals the health risk limit for a mixture of systemic toxicants.

D. Since a hazard index of 1 equals the health risk limit, as specified in item C above, then a hazard index greater than 1 exceeds the health risk limit.

4717.7800 REVISION OF PARTS 4717.7500 and 4717.7650

Subpart 1. **Scope.** This part is needed to state the conditions under which a health risk limit or toxic endpoint shall be removed, revised or added. As discussed above in section VIII **Introduction to Risk Assessment Methods, Reference Doses and Slope Factors**, the department believes the statute indicates the use of IRIS to obtain RfDs and slope factors. The data on IRIS changes infrequently, but when it does change it is necessary to remove, revise or add a health risk limit or toxic endpoint accordingly. The proposed method to revise parts 4717.7500 and 4717.7650 is reasonable because the conditions for revision are linked to the availability of a reference dose or slope factor on IRIS.

Subpart 2. **Removing a health risk limit or toxic endpoint.** This subpart is needed to specify the conditions under which a health risk limit or toxic endpoint shall be removed from parts 4717.7500 or 4717.7650 respectively. Essentially a health risk limit and toxic endpoint shall be removed if a RfD or slope factor for a substance or chemical is no longer available on IRIS.

A. As discussed in section VIII **Introduction to Risk Assessment Methods, Reference Doses and Slope Factors**, the department believes the statute indicates the use of IRIS to obtain RfDs and slope factors. Therefore if the USEPA no longer lists a RfD or slope factor for a substance or chemical on IRIS it is reasonable to remove the health risk limit for that substance or chemical from part 4717.7500 and remove the corresponding toxic endpoint from part 4717.7650.

B. The methods in part 4717.7200 specify the use of a RfD to calculate the health risk limit for a systemic toxicant; the methods in part 4717.7300 specify the use of a slope factor to calculate the health risk limit for a carcinogen. If the classification of a substance or chemical changes from carcinogen to systemic toxicant, the health risk limit calculated by the methods specified in part 4717.7300, using a slope factor, is no longer valid. Instead it is necessary to calculate a revised health risk limit by the methods specified in part 4717.7200, which use a RfD. The toxic endpoint also needs to be revised from "cancer" to the toxic endpoint indicated by the RfD. If a RfD is not listed on IRIS then a health risk limit cannot be calculated and a toxic endpoint cannot be determined. Therefore it is reasonable to remove the health risk limit and toxic endpoint from parts 4717.7500 and 4717.650 respectively.

C. The justification for this item is essentially the same as the justification for item B of this subpart. If the

classification of a substance or chemical changes from systemic toxicant to carcinogen, a health risk limit calculated with a RfD is no longer valid. If a slope factor for the substance or chemical is not listed on IRIS, a revised health risk limit cannot be calculated using the methods specified in part 4717.7300. Therefore it is reasonable to remove the health risk limit and toxic endpoint from parts 4717.7500 and 4717.650 respectively.

Subpart 3. **Revising a health risk limit or toxic endpoint.** This subpart is needed to specify the conditions under which a health risk limit or toxic endpoint shall be revised in parts 4717.7500 or 4717.7650 respectively. Essentially, a health risk limit or toxic endpoint shall be revised if the USEPA lists a revised RfD or slope factor on IRIS, if the USEPA publishes a revised RSC or UF, or if the USEPA changes the classification of a substance or chemical. The department believes it is reasonable to revise a health risk limit or toxic endpoint to reflect revisions in RfDs, slope factors or classification that appear on IRIS, or revisions in RSCs or UFs that are published by the USEPA.

A. If the USEPA revises a RfD or slope factor for a substance or chemical specified in part 4717.7500 and lists the revised value on IRIS, it is reasonable to revise the health risk limit and toxic endpoint for that substance or chemical. This item is needed to keep the proposed health risk limits current with the data on IRIS.

B. As discussed in the rule-by-rule justification for part 4717.7150, subpart 8, and part 4717.7200, subpart 2, items C and D, the USEPA uses a default RSC of 0.2 unless data indicate the use of another value. If data do become available and the USEPA calculates a specific RSC for a substance or chemical, it is reasonable that the health risk limit for the substance or chemical be revised to incorporate the more accurate RSC value. Because the definition of RSC is limited to those listed by the USEPA, it is reasonable to limit the conditions in this subpart to the case where a revised RSC is listed by the USEPA. The USEPA lists RSCs in either the Health Advisories, published by the USEPA, Office of Drinking Water, the Federal Register, or on IRIS.

C. As discussed in the rule-by-rule justification for part 4717.7150, subpart 11 and part 4717.7200, subpart 4, items B and C, the USEPA uses a default UF of 10 unless data indicate the use of another value. If data do become available and the USEPA calculates a specific UF for a substance or chemical, it is reasonable that the health risk limit for the substance or chemical be revised to incorporate the more accurate UF value. Because the definition of UF is limited to those listed by the USEPA, it is reasonable to limit the conditions in this subpart to the case where a revised UF is listed by the USEPA. The USEPA lists UFs (also called safety factors) in either the Health Advisories, published by the USEPA, Office of Drinking Water, the Federal Register, or on IRIS.

D. The justification for this item is essentially the same as the justification for subpart 2, item B. If the USEPA changes the classification of a substance or chemical from carcinogen to systemic toxicant, it is necessary to revise the health risk limit according to the methods specified in part 4717.7200, which require a RfD. If the RfD for the substance or chemical is listed on IRIS, it is reasonable to calculate a revised health risk limit and specify a revised toxic endpoint accordingly.

E. The justification for this item is essentially the same as the justification for item D of this subpart. If the classification of a substance or chemical changes from systemic toxicant to carcinogen, it is necessary to revise the health risk limit by calculating it according to the methods specified in part 4717.7300, which require a slope factor. If the slope factor for the substance or chemical is listed on IRIS, it is reasonable to calculate a revised health risk limit and specify a revised toxic endpoint accordingly.

F. If the USEPA reclassifies a systemic toxicant to be a possible human carcinogen, it is reasonable to revise the health risk limit to reflect the new classification, using the methods specified in part 4717.7200, subpart 4.

G. If the USEPA reclassifies a substance or chemical so that it is no longer a possible human carcinogen, it is reasonable to revise the health risk limit to reflect the new classification, using the methods specified in part 4717.7200, subpart 2.

Subpart 4. **Methods.** This subpart is necessary to specify that all revised health risk limits shall be calculated and all revised toxic endpoints specified according to same methods used for the proposed health risk limits and toxic endpoints. This is reasonable, since it ensures consistency in the calculation of present and future health risk limits and the specification of present and future toxic endpoints.

Subpart 5. **Adding a health risk limit or toxic endpoint.** This subpart is needed to specify the mechanism by which a health risk limit and corresponding toxic endpoint can be added to the proposed rules. As discussed in section VIII **Introduction to Risk Assessment Methods, Selection of Substances or Chemicals**, the selection of a substance or chemical for the proposed health risk limits rules was based on two criteria: 1) detection in Minnesota groundwater; and 2) publication of a reference dose or slope factor on IRIS. If these two criteria are met, the department believes it is reasonable to add the following to the proposed rules: a substance or chemical, its health risk limit, and its toxic endpoint where appropriate. It is also reasonable that the new health risk limit be calculated and corresponding toxic endpoint specified according to the same methods as the proposed health risk limits and toxic endpoints.

Subpart 6. **Frequency of revisions.** This subpart is necessary to state the frequency with which the proposed rules will be updated. Although the USEPA updates IRIS every month, the RfDs and slope factors for individual substances or chemicals listed on IRIS do not change nearly that frequently. The USEPA's Reference Dose Work Group and the Carcinogen Risk Assessment Verification Work Group, which review the data that are listed on IRIS, meet monthly. Each month they review 5-15 substances or chemicals.[5] The work groups review both data for substances or chemicals that already have a RfD or slope factor on IRIS and data for substances and chemicals that don't yet have a RfD or slope factor on IRIS. According to the IRIS data base manager, only 1 - 2 % of the RfDs or slope factors change per year. Between April 1, 1992 and December 15, 1992 only eight substances or chemicals were added to IRIS.[6]

The department believes it is reasonable to revise the proposed rules at least annually. This revision schedule allows for the regular update of the proposed health risk limits. The department must balance keeping the proposed rules absolutely current against the time, effort and cost required to frequently publish changes. The proposal of at least annually is reasonable because the department predicts that less than 10% of the health risk limits will change each year due to IRIS revisions. The proposal would allow for more frequent revision should a change in a RfD or slope factor of a particular substance or chemical warrant a more frequent update.

Publication of the revisions in the State Register is reasonable to provide a mechanism for public review. The proposal to allow the revisions to go into effect within 30 days, unless 25 requests are received, is consistent with current Administrative Procedures Act comment period and petition provisions. This subpart is also reasonable in that it provides a mechanism for public review and comment when a revision is challenged, in accordance with Minnesota Statutes, sections 14.001 to 14.560.

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[5]Personal communication. Karen Grissom, IRIS user support, 513-569-7254, December 14, 1992.

[6]Personal Communication, Pat Daunt, IRIS data base manager, 513-569-7254, December 15, 1992.

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USEPA, 1992t5. IRIS file for trichlorofluoromethane.

USEPA, 1992t6. IRIS file for 2,4,6-trichlorophenol.

USEPA, 1992t7. IRIS file for 2,4,5-trichlorophenoxyacetic acid (2,4,5-T).

USEPA, 1992t8. IRIS file for 2 (2,4,5-trichlorophenoxy) propionic acid.

USEPA, 1992t9. IRIS file for 1,2,3-trichloropropane.

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