Toxic Free Kids Act Interim Report to the Legislature

Minnesota Department of Health

Minnesota Pollution Control Agency

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Executive Summary

The Minnesota Toxic Free Kids Act (Minn. Stat. 116.9401 – 116.9407) became law in May 2009. It establishes a framework by which the Minnesota Department of Health (MDH), in consultation with the Minnesota Pollution Control Agency (MPCA), will compile a list of chemicals of high concern. It also requires the MDH to designate and publish a list of priority chemicals in children's products by February 1, 2011. The statutes require three reports to the Legislature: an interim report from each agency that is due in January 2010 and a final report from the MPCA due in December 2010. In its December report, the MPCA is required to make recommendations about mechanisms to reduce and phase out the use of priority chemicals in children's products and to promote consumer product design that uses green chemistry principles and that considers a product's impact over its life cycle. Finally, the new statutes permit donations, grants and other funds to be accepted for the purposes of completing this work and allow for participation by Minnesota in the Interstate Chemicals Clearinghouse (IC2).

This legislation was passed following substantial debate on the subject of unregulated and potentially toxic chemicals in consumer products and especially children's products during the 2009 and preceding sessions. Similar debates have occurred in several other states that have already passed or are considering enacting legislation that seeks to regulate the presence of toxic chemicals in consumer products. The driving force behind state-led efforts to establish chemicals policy and/or regulations is the nearly universal conclusion that the federal Toxic Substance Control Act (TSCA) has failed in its charge to regulate toxic chemicals in the U.S. marketplace. Consumers and an array of advocacy groups (including environmental, public health, and children's health organizations) are voicing their concerns about the presence of toxic chemicals in everyday products.

The MPCA and the MDH are working together on the reporting requirements of this bill and will submit one joint interim report on January 15, 2010 and a final report on December 15, 2010. This report fulfills the requirements for interim reports due January 15, 2010 from the MPCA and MDH. It includes information on:

- Progress by the federal government, states and international organizations in prioritizing, evaluating and regulating the use of chemicals of high concern and priority chemicals in children's products
- Progress of states, federal and international efforts in determining the availability of safer alternatives for specific applications and promoting the use of those safer alternatives
- MDH progress and approach to creating the list of chemicals of high concern and the list of priority chemicals
- MPCA progress toward preparation of the December 15, 2010 final report and plans for MPCA stakeholder efforts

Progress of Federal Efforts to Prioritize, Evaluate and Regulate Toxic Chemicals

Toxic Substances Control Act (TSCA) reform

Chemicals used in commerce in the United States are regulated by the federal government under the 1976 TSCA. The framework established in this law for regulating chemicals in consumer products and commercial processes is widely viewed as inadequate and in need of reform. At time of passage of the act, existing chemicals were "grandfathered in" and presumed to be safe. Since TSCA became law in 1976, the United States Environmental Protection Agency (EPA) has issued regulations to control very few existing chemicals, and basic toxicity information is only available for a small percentage of the chemicals used in commerce.

In September 2009 EPA Administrator Lisa Jackson announced the following set of six principles designed to guide Congress in fixing the flaws of TSCA:

- 1. Chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment.
- 2. Manufacturers should provide EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment.
- 3. Risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations.
- 4. Manufacturers and EPA should assess and act on priority chemicals, both new and existing, in a timely manner.
- 5. Green chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened.
- 6. EPA should be given a sustained source of funding for implementation.

More information on these principles is available at: http://www.epa.gov/oppt/existingchemicals/pubs/principles.html.

Several other organizations have also developed TSCA reform principles including the National Conference of State Legislatures, the national Safer Chemicals/Healthy Families campaign and the American Chemistry Council. A group of 13 states working together on TSCA reform released the States' Principles on Reform of the Toxic Substances Control Act on December 2, 2009. Three key recommendations are that manufacturers must demonstrate the chemicals they use and the products they make are safe for the public and the environment; safe products and chemicals should be promoted; and chemical and safety information should be widely available to regulators, businesses and the public. Interest is growing at the federal level for Congressional action, and hearings on this issue are expected in the coming months.

Consumer Product Safety Improvement Act (CPSIA)

In addition to broad TSCA reform efforts, new federal legislation regulating lead, cadmium and certain phthalates in children's products became law in August 2008. One goal of the Consumer Product Safety Improvement Act (CPSIA) was to have one statute for the entire country replacing a patchwork of differing state laws. This federal statute preempts state standards for lead, cadmium and phthalates in children's products.

The CPSIA requires manufacturers to certify that their products meet all applicable standards. This certification can be based on individual tests or a testing program with conformity assessed through accredited third parties. The certificates accompany the products and must be provided to distributors or retailers and are also to be provided to the Consumer Products Safety Commission upon request. Additional information on the CPSIA is available at http://www.cpsc.gov/cpsia.pdf

Progress of States in Regulating, Evaluating and Prioritizing Toxic Chemicals

In addition to federal efforts, several states have enacted legislation or begun initiatives that address toxic chemicals in products. This legislation will be discussed in the following categories: toxics in children's products, green chemistry approaches, other chemical prioritization approaches and single chemical bans.

Toxics in children's products state legislation

In addition to Minnesota, three states—Maine, Washington and Connecticut—have enacted legislation that focuses on chemicals in children's products.

Maine—Maine enacted legislation regulating toxic chemicals in children's products in May 2008. The statute requires publication of a list of chemicals of high concern that was posted in July 2009 and contains approximately 1700 chemicals. Designation of at least two priority chemicals is required by January 2011. Maine Department of Environmental Protection (DEP) may require disclosure of information including a safer alternatives assessment from any manufacturer and/or distributor of children's products containing a designated priority chemical. Sales bans may be proposed to the Board of Environmental Protection on children's products containing designated priority chemicals when distribution directly or indirectly exposes children and vulnerable populations to the priority chemical and one or more safer alternatives are available. Maine has initiated a first round of rulemaking to further clarify designation of priority chemicals and disclosure and set fees for manufacturers and distributors related to disclosure. The public hearing was held on December 17, 2009. For additional information see the Maine DEP Safer Chemicals website at http://www.maine.gov/dep/oc/safechem/

Washington—The 2008 Children's Safe Product Act required the Washington Department of Ecology along with the Washington Department of Health to identify and prioritize a list of high priority chemicals that children are likely to be exposed to, especially if present in children's products. Washington has named this list Chemicals of High Concern for Children (CHCCs). Washington's law requires companies to notify the state's Department of Ecology if CHCCs are present in children's products six months after rulemaking to implement the act is complete. Unlike Maine's law, Washington's legislation does not include a regulatory structure for banning the sale of products.

To date, the Washington Department of Ecology has identified substances that meet the definition of high priority chemicals and identified those high priority chemicals that are of high concern for children (CHCCs) by considering children's potential for exposure to these chemicals. State agencies are working with the University of Washington to develop a mechanism to prioritize the list of CHCCs and identify the 50 chemicals they will focus on initially. Priority will primarily be based on exposure and toxicity. Washington plans to publish its lists and proposed prioritization process in late December or early January. Washington will also begin a pilot rule in January. Additional information can be found at:

http://www.ecy.wa.gov/programs/swfa/cspa/index.html http://www.ecy.wa.gov/pubs/0907014.pdf

Connecticut—Amendments to the Connecticut Child Protection Safety Act in 2008 established limits for lead in children's products and banned children's products that fail to comply with the standards. It also prohibits the sale of toys or other articles marketed for children under age 16 that contain asbestos. The lead limits in the Act have been superseded by the federal CPSIA (see above), which took effect on February 10, 2009. The Connecticut law requires retailers and other businesses selling a product containing a banned substance to complete a certification of disposition to account for its disposal.

State green chemistry initiatives

Both California and Michigan have state initiatives that focus on green chemistry. Green chemistry is defined as the use of a set of principles to reduce or eliminate use or generation of hazardous substances in the design, manufacture and application of chemicals products. California's initiative was launched in April 2007 and two recommendations supporting the initiative were enacted by the Legislature in September 2008. The first (Assembly 1879) authorized California's Department of Toxic Substances Control to identify and prioritize chemicals of concern, evaluate alternatives and specify regulatory responses. It also established a Green Ribbon Science Panel to provide implementation advice. A second bill (Senate Bill 509) requires an online Toxics Information Clearinghouse to be established to provide public access to information on the toxicity of chemicals.

Currently, California is moving away from a prioritization approach based on lists of chemicals to an approach based on hazard traits of products, which has not yet been made public. They have also begun work on the clearinghouse.

The Michigan Green Chemistry program was created in 2006 by an executive directive. Its goal was to promote green chemistry for sustainable economic development and protection of public health. The Green Chemistry program has responsibility for promoting and coordinating green chemistry activities such as research, development, demonstration, education and technology transfer. The directive also established a Green Chemistry Roundtable, which meets quarterly. Recent progress in Michigan included a state Green Chemistry Conference and Green Chemistry Awards in September 2009.

Additional state chemical prioritization approaches

In 2007 the state of Oregon passed legislation (SB 737) mandating a priority list of toxic, persistent and bioaccumulative pollutants that have a documented effect on human health, wildlife and aquatic life. The final list was published in October 2009. It contains two types of toxic pollutants: substances that either persist in water environments or accumulate in the tissues of people, wildlife or plants; and chemicals that have been banned or restricted for years but remain in sediment and tissue samples at detectable levels. The list will be used to help the state identify sources of pollutants and develop ways to reduce their amounts in Oregon waters. The final list, which contains 118 chemicals, is available at: http://www.deq.state.or.us/wq/SB737 Next steps include development of pollutant "trigger levels" at which pollutant reductions would be recommended. Oregon's 52 largest municipal treatment plants will develop toxic reduction and targeted pollution plans by July 2011 to reduce persistent pollutants occurring in their effluent at levels above the trigger levels.

Single chemical bans

Many states have also put into place bans or phase-outs of single chemicals or use of chemicals in children's or consumer products. Examples include mercury, bisphenol A, phthalates, lead and flame retardants. The 2008 federal CPSIA supersedes state legislation for lead, cadmium and certain phthalates.

Multi-state efforts—Interstate Chemicals Clearinghouse

As allowed by the Toxic Free Kids Act, both the MPCA and MDH are participating in the Interstate Chemicals Clearinghouse (IC2). The IC2 is a partnership of state agencies formed in 2009 that is focused on sharing information on the development and use of safer chemicals and products. States in the IC2 are also sharing data on chemicals prioritization approaches and information on the use, hazard and exposure of chemicals and products.

Progress of International Efforts to Prioritize, Evaluate and Regulate Chemicals

This section summarizes the work to prioritize, evaluate and regulate chemicals of concern in Europe and Canada. It includes work on specific categories of hazardous chemicals as well as broader hazard-based approaches in Canada and Europe, including the European Union's (EU) Regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), which requires registration and hazard information for all chemicals produced or imported into the EU in quantities of one metric ton or more.

European Commission Endocrine Disruptor Program

In the late 1990s, the European Commission (EC) initiated a "Community Strategy for Endocrine Disruptors" to address potential environmental and health impacts of endocrine disruptors. This initiative led to publication of a list of possible endocrine disruptors. This list at http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list provides detailed information about possible endocrine disruptors. Three categories of disruptors were created, including:

- Category 1 evidence of endocrine disrupting activity in at least one species using intact animals;
- Category 2 at least some in vitro evidence of biological activity related to endocrine disruption;
- Category 3 no evidence of endocrine disrupting activity or no data available (European Commission, 2007).

This information, initially made available in 2007, was most recently updated in 2008. The EC has medium-term and long-term plans to continue testing and regulation of possible endocrine disruptors. In addition, Denmark noted concern about endocrine disruptor exposure to children at the October 2009 meeting of the Council of the European Union and asked that the topic be put on the agenda of the December 2009 meeting (Europa Press Release, 2009).

European Commission Persistent, Bioaccumulative, and Toxic chemicals (PBT)

A strategy to address persistent, bioaccumulative, and toxic (PBT) and very persistent and very bioaccumulative (vPvB) chemicals was initiated by the European Commission (EC) in June 2001. This "interim strategy for management of PBT and vPvB substances" involved use of screening data and screening estimation to evaluate chemicals, as well as exposure evaluation. The results are available on the EC Web site at

http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt

Directive on Dangerous Substances - 67/548/EEC

This regulation, which concerned classification, labeling, and packaging of substances and mixtures in the European Union, was replaced by EC Regulation 1272/2008 on January 20, 2009. Under this regulation,

the EC has classified certain substances into categories, such as "carcinogen" and "reproductive toxicant." The new list of chemicals under the new regulation is similar, but not identical, to the previous list. Reconciliation of the lists appears to be forthcoming. More information is available at http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=cla.

Directive concerning placing of biocidal products on the market

In February 1998, the European Parliament and Council passed a directive to restrict biocides, such as disinfectants, preservatives, and pest control products, on the EU market. The EC continues to review biocides and prohibits some biocidal products from being placed on the market, with the most recent addition of the list of chemicals of "non-inclusion" made in April 2009. A comprehensive list is available at http://ec.europa.eu/environment/biocides/pdf/list_dates_product_phasing_out.pdf.

REACH

In June 2007, the European Union enacted legislation called REACH, which replaces about 40 pieces of previous European legislation on chemicals. It is designed to streamline and improve the chemical legislative framework (European Chemicals Agency, 2009).

Essentially, REACH will require all manufacturers and importers of chemicals in quantities of one metric ton (about 2,200 lbs) or more per year to register the chemical, provide information about the chemical, and to show that hazards related to the chemical are being effectively managed. The European Chemical Agency (ECHA), created under REACH, will review the information and ensure that chemicals are adequately controlled. When chemicals of very high concern are identified, ECHA will ensure progressive use of a safer substitute or that the chemical is used only when it clearly benefits society. Restrictions on use might be implemented when necessary. More information about REACH is available at http://guidance.echa.europa.eu/about_reach_en.htm. Currently, REACH has identified 17 chemicals of very high concern. More information is available at http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

OSPAR

In 1972, the Oslo-Paris Commission (OSPAR) was created to control dumping in the North Sea. The work of OSPAR has expanded to include identification of chemicals that could threaten the North Sea, especially persistent, bioaccumulative, or toxic chemicals. OSPAR has published a list of chemicals of possible concern, in addition to a list of chemicals requiring priority action. The most recent list of priority action chemicals is from 2007 and the list of chemicals of possible concern is from 2008. Another update of chemicals of possible concern is scheduled for 2009. The MDH and MPCA will continue to watch this site, at http://www.ospar.org/content/content.asp?menu=00940304440050_000000_000000, for further updates. As of November 18, 2009, there were no published changes to the list.

Canada

In 2006, Canadian government published information concerning an evaluation of the hazards of existing chemicals, under the Canadian Environmental Protection Act, 1999. Several lists of chemicals posing possible human health hazards and threats to the environment were created. There is also a repository of information used in these evaluations located at http://www.chemicalsubstanceschimiques.gc.ca/assess-eval/CAES-ECSE_e.html, which continues to be updated. MDH will monitor this site for updates as well.

Progress in Determining the Availability of Safer Alternatives

The availability of safer alternatives goes hand in hand with the regulation and phase out of chemicals of high concern. Typically, legislation that seeks to eliminate or phase out chemicals of high concern in consumer products requires manufacturers and others to find a substitute or alternative chemical that can replace the chemical of high concern that can be shown to be *safer than* the chemical being phased out. A key problem is that often very little hazard or toxicological information is available to assess the safety of the proposed alternative compared to the chemical it would replace.

Widespread legislative activity at the state level directed at phasing out the use of polybrominated diphenyl ethers (PBDEs) has driven much of the recent activity around the identification of safer alternatives. PBDEs are a class of brominated flame retardants that have been used extensively since the 1960s in a variety of consumer and commercial products, including plastic enclosures for televisions and computers, textiles, and a multitude of other lower volume applications. Many studies have documented the presence and increasing concentration of PBDEs in the environment, in wildlife, and in people, leading to widespread concern about the continuing use of these chemicals in everyday consumer and commercial products.

Legislators in several states have discussed and/or enacted legislation to phase out the use of PBDEs, even though these chemicals have had an important role in reducing the incidence and severity of fires. Where legislation has passed, it has typically emphasized that the phase-out of PBDEs be preceded by a determination that an alternative exists that can achieve fire safety standards and is also safer, from a chemical hazard standpoint, than the PBDEs they replace. The states of Maine, Washington, Illinois and Minnesota all prepared legislative reports that evaluated chemical alternatives with the potential to provide the performance characteristics required by manufacturers and are potentially safer than PBDEs. On December 17, 2009, the principal manufacturers of decaBDE, Albemarle Corporation and Chemtura Corporation, and the principal importer, ICL Industrial Products, Inc., announced their commitment to a three-year phase-out of decaBDE. More information is available at: http://www.epa.gov/oppt/pbde/

The Toxic Use Reduction Institute (TURI) in Massachusetts organized a two-day State Alternatives Assessment Forum in September 2008 entitled, "Identifying Safer Alternatives to Chemicals of High Concern," which was designed to bring states and affiliated organizations together to share information and strategies, and develop plans for creating a document that will support state agencies in performing alternatives assessments. TURI, together with the Lowell Center for Sustainable Production (part of the University of Massachusetts-Lowell) and Clean Production Action, another Massachusetts-based affiliate, has been a leader in facilitating this conversation.

One outcome of the September 2008 forum was development of a States Alternatives Assessment "wiki" that is based on the protocol outline developed by participants. The wiki is an online tool that enables member states to work collaboratively to outline basic steps and provide a set of resources to draw from when an alternatives assessment is performed. The wiki is under development and is available at: http://turigreen.wetpaint.com/.

Green chemistry

Many companies and organizations are also developing alternatives in product design and production using frameworks that are based on the 12 Principles of Green Chemistry shown on the next page (American Chemical Society, 2009). First introduced in 1998, the principles have been adopted by the U.S. EPA and the American Chemical Society (relating to chemical products and processes).

Principles of Green Chemistry

- 1. Prevention better to prevent waste than to treat or clean up waste after it has been created
- 2. Atom economy incorporate all materials used in the process into the final product
- 3. Less hazardous chemical syntheses use and generate substances with little or no toxicity
- 4. Designing safer chemicals effect a desired function while minimizing chemical product toxicity
- 5. Safer solvents and auxiliary substances should be made unnecessary or innocuous when used
- 6. Design for energy efficiency minimize energy use (e.g. use of heat and pressure in synthesis)
- 7. Use of renewable feedstocks wherever practicable, raw material should be renewable
- 8. Reduce derivatives should be minimized; extra steps require reagents and can generate waste
- 9. Catalysis catalytic reagents (as selective as possible) are superior to stoichiometric reagents
- 10. Design for degradation should break down into innocuous, non-persistent degradation products
- 11. Real-time and in-process monitoring and control prior to the formation of hazardous substances
- 12. Inherently safer chemistry for accident prevention minimize potential for releases, explosions, fires

These principles were followed in 2003 by 12 Principles for Green Engineering, which mirror those above for chemistry. Both sets of principles support Minnesota's existing Toxic Pollution Prevention Act (Minn. Stat. 1990, Ch. 115D) by focusing prevention efforts at their highest-leverage point: the beginning of product and process design.

While federal and state policy for chemical use has not yet taken a precautionary approach similar to Europe's, companies and organizations are adopting many voluntary or collaborative frameworks for selecting materials in product and production design. Examples include The Green Screen for Safer Chemicals, the Environmental Defense Fund/DuPont Nanomaterials Risk Framework, EPA's Design for the Environment program, and design decision-making frameworks internal to companies such as 3M. Frameworks such as these can be reactive by approving or excluding use of chemicals already listed and assessed for risk, or they can be proactive by guiding designers away from higher-risk potential classes of chemicals being considered for future development (Clean Production Action, 2009) (Nano Risk Framework, 2009) (U.S. EPA, 2009c).

The positive outcomes of using the green chemistry and engineering principles are illustrated in:

- Consumer electronics, where companies like Apple, Seagate, Sony Ericsson and others have reduced or eliminated bromine and chlorine from the production of printed circuit boards, cell phones, personal computers, music devices, disk drives, and semiconductor chips. Bromine and chlorine use in resins or as flame retardants in electronic devices and components has been documented to produce dioxin when these products are smelted or burned at the end of their life (Clean Production Action, 2009).
- Pharmaceuticals, with the case study of ibuprofen, which was redesigned after patent expiration and over-the-counter approval in 1984. The original production process was reagent-based, used six steps and had an overall atom economy (inputs incorporated into the final product) of about 40%. The new process used catalysts, took three steps, eliminated 44 million pounds of waste per year, reduces use of the non-renewable aluminum trichloride and has an atom economy of 77%.

Some Minnesota companies have had similar successes in green chemistry, as shown by their own initiatives or their involvement in or recognition by EPA's Design for the Environment or Presidential Green Chemistry Challenge Awards (U.S. EPA, 2009d).

MDH Progress and Approach to Developing a List of Chemicals of High Concern

In 2009, the Minnesota legislature passed a law directing the Minnesota Department of Health (MDH), in cooperation with the Minnesota Pollution Control Agency (MPCA), to create a list of chemicals of high concern, which must be published by July 1, 2010, followed by a list of priority chemicals, which must be published by February 1, 2011. The chemicals of high concern, per Minn. Stat. 2009 116.9401 subd. e, are those that have been identified on the basis of credible scientific evidence by a state, federal, or international agency as being known or suspected with a high degree of probability to:

- (1) harm the normal development of a fetus or child or cause other developmental toxicity;
- (2) cause cancer, genetic damage, or reproductive harm;
- (3) disrupt the endocrine or hormone system;
- (4) damage the nervous system, immune system, or organs, or cause other systemic toxicity;
- (5) be persistent, bioaccumulative, and toxic; or
- (6) be very persistent and very bioaccumulative.

From the list of chemicals of high concern, the priority chemicals will be selected according to the following criteria, per Minn. Stat. 2009 116.9403. The chemical:

- (1) has been identified as a high-production volume chemical by the United States Environmental Protection Agency; and
- (2) meets any of the following criteria:
 - (i) the chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine, or other bodily tissues or fluids;
 - (ii) the chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment; or
 - (iii) the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment.

Under Minn. Stat. 2009 116.9403, by February 1, 2011, MDH must "publish a list of priority chemicals in the State Register and on the department's Internet Web site and shall update the published list whenever a new priority chemical is designated."

In working toward the creation of the initial list of chemicals of high concern, MDH has conferred with other states, especially Maine and Washington, and monitored the progress of related initiatives on the federal level. Further, MDH has been reviewing similar actions in other countries. The following summarizes progress toward developing the chemicals of high concern list:

Planning and coordination meetings

In early August 2009, MDH met with MPCA to discuss the requirements of the statute. The background of the statute, the status of similar legislation in other states, and a basic approach for beginning the task in Minnesota were discussed during this meeting.

In addition, MDH and MPCA have been participating in both general IC2 meetings, as well as the Chemical Data Workgroup, a subset of the IC2 participants.

Upon request, MDH and MPCA met with members from citizen groups with interest in the priority chemicals issues to provide updates on plans for evaluation of chemicals for the lists. These meetings took place in August and November 2009.

Evaluation of chemicals

Because the states of Maine and Washington were among the first to promulgate legislation related to prioritizing chemicals by hazard characteristics, these two states have already collected substantial information on chemicals. The Maine list was retrieved by MDH in August 2009 and put into a database for evaluation.

To better understand how Maine's list was created, the staff person in Maine responsible for coordinating the creation and review of the list was contacted by MDH in September 2009. Overall, Maine's initial list of chemicals was created by compiling lists of potentially hazardous chemicals created by other state, federal, and international agencies and selecting chemicals that would be most appropriate for the list (see http://www.maine.gov/dep/oc/safechem/highconcern/DEH.CDC. Web.Document Background 6.26.09.doc). This selection of chemicals was reviewed by a Maine toxicologist and examined by the state's Department of Environmental Protection. After the list was published, there was opportunity for stakeholders to comment on the list. Stakeholder comments are available from Maine's Web site at http://www.maine.gov/dep/oc/safechem/meetings.htm

Likewise, the Washington Department of Ecology (Ecology) has been working on a creating a list of Chemicals of High Concern for Children (CHCC) under a similar law that was passed in 2008. A staff person from Ecology was contacted in October 2009 for further information about the state's progress on this list. Washington, working closely with Maine, developed a list of high priority chemicals by collecting information on chemicals from several different sources, including the sources used for Maine's list of chemicals of high concern. Washington Ecology also reviewed additional chemicals from sources that Maine did not use, such as chemicals named in EPA's Voluntary Children's Chemical Evaluation Program.

Washington's legislation requires that exposure data be included in the determination of the final CHCC list, but staff found little U.S. information existed in a form that fit the need described in the legislation. Washington Ecology therefore reviewed available U.S. exposure studies and literature from other governments, such as the Danish EPA and the Dutch government.

Using this background information, MDH is examining the existing chemicals of high concern lists and other states' laws to determine how closely these lists meet the criteria for the chemicals of high concern in Minnesota. The lists from Maine and Washington include many of the chemicals appropriate for Minnesota chemicals of high concern list, but a substantial difference among the state priority chemical laws will require MDH to collect additional information from other sources. Specifically, Minn. Stat. 2009 116.9403 requires a priority chemical to be a high production volume (HPV) chemical identified by the EPA. EPA high production volume (HPV) chemicals are those that are produced or imported to the U.S. in quantities greater than or equal to 1 million pounds per year (Environmental Protection Agency (EPA), 2009e). If the chemical is an HPV, the chemical must also meet other health-related criteria specified in Minnesota statutes. Maine Stat. 38§1694, in contrast, lists the EPA HPV criterion as one of many factors for consideration when identifying a priority chemical. Washington's law does not make any reference to HPVs, though HPV might be used as a criterion for selecting substances for the final Chemical of High Concern for Children's list. Therefore, MDH needs to ensure that all relevant chemicals identified by EPA as HPV be included on Minnesota's initial chemicals of high concern list.

Background on EPA's high production volume chemicals

Chemicals manufactured or imported into the U.S. in quantities of 1 million pounds or more per year are designated HPVs by EPA. To determine which chemicals meet this definition, EPA uses data from Inventory Update Reporting (IUR), which is required every four years under the Toxic Substances Control Act (TSCA). For the IUR, businesses must report all chemicals produced or imported to the United States in a quantity of 25,000 pounds or more per year to EPA. From data received from the IUR, EPA calculates which chemicals are being produced or imported at quantities of 1 million pounds or more. For example, if 40 businesses each reported producing or importing 25,000 pounds of a certain chemical for the 2002 IUR, that chemical is considered an HPV for the 2002 IUR. The most recent inventory available is from 2006, with the next IUR scheduled for 2010. MDH has obtained 2006 IUR data, as well as IUR data from years 1990, 1994, 1998, and 2002.

In 1998, the EPA began the HPV Challenge Program. Based on data from the 1990 IUR, this program "challenged" manufacturers to "sponsor" a chemical by furnishing health and environmental data about the chemical to EPA and to the public. The current sponsored chemical list on EPA's Web site reflects the 1990 IUR HPV chemicals sponsored under this Challenge Program. The EPA notes on its Web site that about 2,250 chemicals were sponsored, with about 1,400 sponsored directly through the EPA HPV Challenge program and about 860 sponsored through international efforts (EPA, 2009a). For chemicals that were not sponsored, called "unsponsored chemicals," the EPA plans to use authority under TSCA Section 4 test rules and TSCA Section 8(a)/8(d) rules to require companies to submit data. The most recent unsponsored chemical list from November 2006 contains 267 chemicals and is on the EPA Web site at http://www.epa.gov/chemrtk/pubs/general/hpvunspn.pdf

After collecting the submitted data, EPA began reviewing the HPV chemical data to summarize human and environmental hazards related to the chemicals. The initial task of developing screening-level hazard characterizations (HC) was done by the EPA Office of Pollution Prevention and Toxics. The screeninglevel HCs contain data on internationally agreed-upon endpoints that are indicators of potential hazards for humans and the environment (EPA, 2009b). EPA does not develop a screening-level HC for a chemical that already has a Screening Information Data Set (SIDS) developed by the Organisation of Economic Co-operation and Development (OECD) HPV Programme. The OECD HPV Programme, an international organization consisting of 30 members countries, including the U.S, is based in Paris, France and governed by a Council consisting of representatives of the member countries (Organisation for Economic Co-operation and Development, 2008). OECD collects information on HPV chemicals from 30 OECD member countries in addition to countries in the European Union. A SIDS contains robust information about a chemical, such as "physical characteristics, sources and levels of exposure, environmental fate and pathways, and ecotoxicological and toxicological data" (EPA, 2009f). EPA uses both screening-level HCs and SIDS documents for screening hazards of HPVs. At this point, EPA HCs are available for about 150 HPV chemicals. There are about 380 SIDS documents available for chemicals on the EPA HPV sponsored chemical list. (Some of the final OECD SIDS are temporarily available on OECD's Web site at http://cs3-hq.oecd.org/scripts/hpv/. These documents are gradually being moved to United Nations Environment Programme Chemicals Web site at http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html, where all final SIDS will be available to the public.)

From 2008 to 2009, additional risk-based chemicals prioritizations were done for HPVs through EPA's Chemical Assessment and Management Program (ChAMP). There are about 200 chemicals with risk-based prioritizations (RBP) available on the EPA Web site at http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report?doctype=1. Information from the

available RBPs will be reviewed by MDH for possible consideration in selecting chemicals for the

required lists. With the change in White House administration, however, the ChAMP program has been discontinued and no additional RBPs will be available.

With this information on HPVs, MDH will need to determine which HPV chemicals to use for creation of the lists. At this point, MDH is evaluating chemicals that have been named an HPV for any of the IUR inventories from 1990 to 2006. However, because toxicity and environmental data are not available for all of these chemicals, some of these chemicals will be excluded from the lists unless more data from a credible source becomes available.

Other issues

When interpreting the language of the statute, MDH has found some ambiguities that will require resolution before creation of Minnesota lists.

First, Minn. Stat. 2009 116.9402 defines chemicals that should be considered for the chemicals of high concern list. However, Minn. Stat. 2009 116.9405 makes exclusions:

The requirements of sections 116.9401 to 116.9407 do not apply to:

- (1) chemicals in used children's products;
- (2) priority chemicals used in the manufacturing process, but that are not present in the final product;
- (3) priority chemicals used in agricultural production;
- (4) motor vehicles as defined in chapter 168 or watercraft as defined in chapter 86B or their component parts, except that the use of priority chemicals in detachable car seats is not exempt;
- (5) priority chemicals generated solely as combustion by-products or that are present in combustible fuels:
- (6) retailers;
- (7) pharmaceutical products or biologics;
- (8) a medical device as defined in the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 321(h);
- (9) food and food or beverage packaging, except a container containing baby food or infant formula;
- (10) consumer electronics products and electronic components, including but not limited to personal computers; audio and video equipment; calculators; digital displays; wireless phones; cameras; game consoles; printers; and handheld electronic and electrical devices used to access interactive software or their associated peripherals; or products that comply with the provisions of directive 2002/95/EC of the European Union, adopted by the European Parliament and Council of the European Union now or hereafter in effect; or
- (11) outdoor sport equipment, including snowmobiles as defined in section <u>84.81</u>, subdivision 3; all-terrain vehicles as defined in section <u>84.92</u>, <u>subdivision 8</u>; personal watercraft as defined in section <u>86B.005</u>, <u>subdivision 14a</u>; watercraft as defined in section <u>86B.005</u>, <u>subdivision 18</u>; and off-highway motorcycles, as defined in section <u>84.787</u>, subdivision 7, and all attachments and repair parts for all of this equipment.

While exclusions in subdivisions 2, 3, 4 and 5 above specifically reference priority chemicals, it is unclear whether other exclusions are also intended only for the priority chemical list or whether they reference both the chemicals of high concern list and the priority chemicals list. In addition, the types of items to be

excluded are not specifically defined, leaving ability for broad interpretation of the applicability of exclusions. For example, "pharmaceutical products or biologics" as described under subdivision 7 are not sufficiently defined to determine if a household soap containing an additive such as an antimicrobial agent would be under this exclusion. More generally, if a chemical is used in a product that is not excluded, and also in a product that is excluded, it is unclear if the chemicals should be included in the Minnesota lists.

These issues will need to be addressed as MDH proceeds in creating the two lists. Our current intention is to construct a broad-based list of chemicals of high concern consisting of the Maine and Washington lists and HPVs. Chemicals will be considered for the priority chemicals list if they appear in a non-excluded product even if they also appear in an excluded product.

In addition, it is currently not clear how the Minnesota lists will be sustained after February 2011. Current funding provides resources for work on the lists, but there are currently no resources for continued revision and updating of the lists, as is required by the statute.

Minnesota's review of HPVs and development of lists

With the information gathered, MDH has begun reviewing the screening-level HC and SIDS for HPV chemicals that could qualify for Minnesota's lists of chemicals of high concern and priority chemicals. The available basic toxicity and environmental data are being reviewed and added to a database. When all of the screening-level HCs and SIDS have been reviewed, information about the remaining HPV chemicals will be likely sought from other credible sources, such the National Toxicology Program, EPA IRIS, and others.

When all appropriate available data have been added to the database, the list of chemicals of high concern will be compiled using the information gathered. If other states in addition to Maine and Washington publish a list during the development of Minnesota's list, these chemicals will also be reviewed to ensure completeness of Minnesota's list. The draft Minnesota chemicals of high concern list will be reviewed internally at MDH during March and April 2010. After the review, any remaining issues will be addressed and the MPCA will be consulted for additional comments.

During this time, a web page will be prepared for the MDH Web site. The web page will describe the statute and the process by which the chemical lists are being developed. The chemicals of high concern list will be added to the web page no later than July 1, 2010. If resources permit, this list will be reviewed and updated at least every three years.

After the list of chemicals of high concern has been published, the priority chemicals list will be developed by selecting chemicals from the chemicals of high concern list. According to statute, the priority chemicals must be chemicals named by EPA as high production volume, in addition to requirements specified in Minn. Stat. 2009 116.9403 – 166.9405. Chemicals that meet these criteria will be identified as potential candidates for the priority chemicals list. Potential exposure conditions outlined in Minn. Stat. 2009 116.9403 will also be considered during this phase of the narrowing the list.

When the chemicals for the priority chemical list have been selected, and consultation with MPCA is complete, the list will be published on the MDH Web site. This will occur no later than February 1, 2011. If resources permit, the list will be reviewed and updated when new information about a chemical or group of chemicals becomes available.

MPCA Progress Toward Preparation of the December 15, 2010 Report and Plans for Stakeholder Efforts

Benchmarking efforts

To date, the MPCA has focused its efforts on benchmarking the work of other states, the federal government and other countries to reduce and phase out priority chemicals in children's products. This has included literature and Internet search on efforts of other states and telephone discussion with staff from other states on existing children's products legislation and green chemistry programs. The agency has also completed benchmarking of states and national reports focusing on green chemistry.

Participation in IC2

As mentioned earlier, the IC2 is a group of states working together on issues surrounding toxics in products. The MPCA has participated in the IC2 since the original organizing meeting in Lowell, Massachusetts in October 2008, and in April 2009, Minnesota was one of 10 states that signed a formal memorandum of agreement supporting the formation of the clearinghouse. The IC2's goals are to avoid duplication, to build state agency capacity to identify and promote safer chemicals and products and ensure that state agencies, businesses and the public have access to high-quality chemicals data and information.

In addition to participating in regular IC2 conference calls, the MPCA hosted a day-long IC2 videoconference on June 19, 2009. At this meeting, participants shared information about their state's laws and chemicals policy and discussed approaches for chemical prioritization and structure of the clearinghouse. The MPCA and MDH also participated in a webinar for states on alternatives assessments in November 2009. MPCA and MDH are also participating in the data work group, which is identifying information that states would like to share about chemicals and products and developing a database to store this information.

Stakeholder efforts

The MPCA currently has begun one stakeholder effort focusing on green chemistry. In 2009, the MPCA was awarded a pollution prevention grant from U.S. EPA, including funds for a research project focused on green chemistry and design. As part of this project, the MPCA will host four focus group meetings consisting of small manufacturers, large manufacturers and retailers as well as individual interviews with other green chemistry and design experts and stakeholders. The purpose of these focus groups and interviews is to learn more about what experiences Minnesota manufacturers have with implementing green chemistry and design techniques and what tools or resources could MPCA offer to encourage more widespread adoption. These meetings and interviews will take place in December 2009 and January 2010 and results of this stakeholder input will be included in the December 15, 2010 Report to the Legislature.

The MPCA is also aware that other interested parties are planning independent stakeholder efforts that address regulation of toxic chemicals and green chemistry. We will plan to include description of results from these efforts for the December final report to the extent they are available in advance of our deadline. We are also considering sharing our final report for comment by interested stakeholders in advance of the December 15, 2010 deadline. We would append any comments we receive from stakeholders to our report as additional input for the Legislature.

Final report outline

The MPCA's outline of expected content for the December 15, 2010 report is shown below.

Toxic Free Kids Act Final Report Outline

- A. Benchmarking of efforts by other states, federal government, and international efforts to address chemicals of high concern and priority chemicals in children's products
- B. Analysis of options for chemicals policy framework of incentives and/or regulation
- C. Analysis of potential funding mechanisms to implement reduction and phase out of priority chemicals in children's products
- D. Analysis of incentives for product design that use green chemistry principles and life-cycle analysis.
 - Benchmarking other states' efforts on green chemistry
 - Benchmarking on life cycle analysis and product stewardship
 - Description and findings to date on Minnesota's Green Chemistry P2 grant
 - Description and results of ongoing stakeholder efforts in Minnesota that address toxics in children's products, green chemistry or life cycle analysis.
 - MPCA Green Chemistry focus groups and interviews
 - Summary of other stakeholder efforts conducted through October 2010
- E. Recommendations

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