

Minnesota Priority Chemicals List Methodology and Summaries

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Acronyms and Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
BBP	Butyl benzyl phthalate
BLL	Blood Lead Level
BPA	Bisphenol A
CA Prop 65	California Proposition 65
CAS	Chemical Abstract Service
CASRN	Chemical Abstract Service Registry Number
CDC	U.S. Centers for Disease Control and Prevention
CHC	Chemicals of High Concern
DBP	Dibutyl phthalate
decaBDE	decabromodiphenyl ether
DEHP	Di-ethylhexyl phthalate
EC	European Commission
ECHA	European Chemicals Agency
EPA	U.S. Environmental Protection Agency
ESIS	European Substances Information System
EU	European Union
FDA	U.S. Food and Drug Administration
HBCD	Hexabromocyclododecane
HBV	Health Based Value (Minnesota guidance)
HC	Hazard Characterization
HHS	U.S. Department of Health and Human Services
HPVIS	High Production Volume Information System
HRA	Health Risk Assessment
HRL	Health Risk Limit (Minnesota guidance)
HSDB	Hazardous Substances Data Bank (maintained by NLM)
IARC	International Agency for Research on Cancer
IRIS	Integrate Risk Information System (under EPA)
IUR	Inventory Update Reporting (conducted by EPA)
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
MCL	Maximum Concentration Limit (EPA)
MDH	Minnesota Department of Health
mg/kg bw	milligrams/kilogram of body weight
Minn. Stat.	Minnesota Statute
MPCA	Minnesota Pollution Control Agency
NHANES	National Health and Nutrition Examination Survey
NIH	U.S. National Institutes of Health
NLM	U.S. National Library of Medicine
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
NTP	U.S. National Toxicology Program
NTP 11 th ROC	U.S. National Toxicology Program 11 th Report on Carcinogens
octaBDE	octabromodiphenyl ether

OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
PBDE	Polybrominated Diphenyl Ethers
PBT	Persistent, Bioaccumulative and Toxic
PC	Priority Chemical
pentaBDE	pentabromodiphenyl ether
ppb	parts per billion
ppm	parts per million
RBP	Risk Based Prioritization
REACH	<u>R</u> egistration <u>E</u> valuation <u>A</u> uthorization and Restriction of <u>C</u> hemicals
RBP	Risk Based Prioritization
SIAR	SIDS Initial Assessment Report
SIDS	Screening Information Data Set
SVHC	Substance of Very High Concern
TRI	Toxic Release Inventory (maintained by EPA)
TSCA	Toxic Substance Control Act
U.S.	United States of America
vPvB	very Persistent and very Bioaccumulative
WHO	World Health Organization

I. Selection of Priority Chemicals

A. Introduction

In 2009, the Minnesota Legislature passed a bill related to concerns about chemicals used in consumer products, particularly products intended for children. This legislation requires the Minnesota Department of Health (MDH) to create two lists of chemicals: Chemicals of High Concern (CHC) and Priority Chemicals (PC). The legislation also requires the Minnesota Pollution Control Agency (MPCA) to report on options to phase out use of priority chemicals, encourage use of alternative chemicals, and provide recommendations on promoting principles of green chemistry and life cycle analysis. Further, MPCA is required to provide recommendations on potential funding mechanisms for these efforts.

The first list of chemicals that MDH is required to create, called “Chemicals of High Concern”, is defined in Minnesota Statute 2010 116.9401. Subd. e:

“Chemical of high concern” means a chemical 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.”

The CHC list was published on July 1, 2010 and contains 1,756 chemicals. The process used for selecting these chemicals can be found in a separate document called “Minnesota Chemicals of High Concern List Methodology.” This document is available from the MDH website at <http://www.health.state.mn.us/divs/eh/hazardous/topics/toxfreekids/highconcern.html>, by contacting MDH at 1-800-657-3908, option “4,” or by e-mail at health.hazard@state.mn.us.

The list of PCs was to be selected from the CHC list. The statutory criteria for a PC are as follows in Minn. Stat. 2010 116.9403, Subd. (a) and (b):

- (a) The department, after consultation with the agency, may designate a chemical of high concern as a priority chemical if the department finds that 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.

(b) By February 1, 2011, the department shall 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.

This document describes the selection of the PCs and provides brief summaries about the properties, uses, and toxicity information for each PC.

B. High Production Volume (HPV) Chemicals

According to Minn. Stat. 2010 116.9403, a PC must be a high production volume (HPV) chemical named by the U.S Environmental Protection Agency (EPA). HPV chemicals are those that are produced or imported into the United States at quantities of one million pounds or more per year. Information about the quantities produced or imported is obtained from the EPA Inventory Update Reporting (IUR) data, which has been conducted approximately every four years since 1986. Quantities submitted from all sources for a particular chemical are summed to determine total production and importation for the U.S. during the specified calendar year. If the number is one million pounds or more for that year, the chemical is deemed HPV (Environmental Protection Agency [EPA], 2010d).

EPA has changed the reporting requirements for the IUR over time. One change involved reporting of inorganic chemicals, which was not required until the 2006 IUR inventory. This change was not initially considered by MDH when determining a system for identifying HPV chemicals eligible for the Priority Chemical list as described in "Minnesota Chemicals of High Concern List Methodology." The result of this oversight was that only 414 chemicals on the CHC list were initially identified as HPV. After identifying inorganic chemicals required to be reported only in 2006, there were a total of 443 HPV chemicals. More information about this designation can be found in a document called "October 2010 Updates to the Chemicals of High Concern List" available at <http://www.health.state.mn.us/divs/eh/hazardous/topics/toxfreekids/chclist/update1010.pdf>.

In addition to being an HPV chemical, a PC must also meet additional criteria. Per the statute, a PC must be found a) in human tissues or body fluids, b) in household dust, indoor air, drinking water, or elsewhere in the home environment, or c) in fish, wildlife or the natural environment. Additionally, the PC candidates must not be specifically excluded by statute. There are 11 exclusions related to this statute, which are as follows:

“The requirements of sections Minn. Stat. 2010 116.9401 - 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 84.81, subdivision 3; all-terrain vehicles as defined in section 84.92, subdivision 8; personal watercraft as defined in section 86B.005, subdivision 14a; watercraft as defined in section 86B.005, subdivision 18; and off-highway motorcycles, as defined in section 84.787, subdivision 7, and all attachments and repair parts for all of this equipment.”

These requirements and exclusions were considered when screening the 443 HPV chemicals for PC eligibility. If a chemical was excluded under one use condition, but remained eligible under another, the chemical remained eligible as a PC candidate. For example, if a chemical could be found in a used children's toy and would be excluded under 116.9405 Subd. 1, but could also be found in a new children's toy, the chemical was still considered eligible to be a PC.

C. Evaluation of Chemicals

The 443 HPV chemicals were screened and evaluated as candidate PCs. Information used to evaluate the chemicals was primarily from toxicity and exposure-related reports created by U.S. federal agencies or international sources. These sources, listed below, provide reports that are accessible via the Internet without charge. The sources are described in Section II "Toxicity, Exposure and Environmental Disposition Data Sources":

United States Sources

- Centers for Disease Control and Prevention (CDC)
 - Agency for Toxic Substances and Disease Registry (ATSDR)
 - National Health and Nutrition Examination Survey (NHANES)
- Environmental Protection Agency (EPA)
 - Chemical Action Plans (Existing Chemicals)
 - High Production Volume Information System (HPVIS)
 - Integrated Risk Information System (IRIS)
 - Inventory Update Reporting (IUR)
 - Office of Pollution Prevention and Toxics (OTTP)
 - Toxic Release Inventory (TRI)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
 - National Library of Medicine (NLM)
 - Hazardous Substances Data Bank (HSDB)
 - Household Products Database
 - National Toxicology Program (NTP)

International Sources

- Government of Canada
 - Environment Canada
 - Health Canada
- European Commission
 - Joint Research Centre of the European Commission
- European Chemicals Agency
- Organisation for Economic Co-operation and Development (OECD)
- World Health Organization
 - International Agency for Research on Cancer (IARC)

With the time allotted by statute to name PCs, a complete literature search for each eligible chemical could not be conducted. Rather, MDH relied on summaries produced by the agencies or organizations named above. Most of these summaries drew upon published, peer-reviewed toxicity studies or exposure evaluations. Occasionally, MDH used published materials from journals, as cited in the reference section of each Priority Chemical summary below. Opinions from MDH toxicologists and staff at MPCA were also solicited about the chemicals under consideration.

Another consideration in selecting the PCs was the amount of information available for each chemical. There were a few chemicals identified that met the statutory requirements for a PC and could be of public health interest. However, the amount of information readily available varied by chemical. Those without sufficient information available for an adequate timely assessment were removed from further consideration for the initial PC list.

The intent of the statute was considered when selecting chemicals for the PC list. The statute does not explicitly state that PCs must be found in consumer products, but the language of the statute suggests that this is so. Therefore, consumer products found in the home, particularly those intended for children but also those accessible to children and pregnant women, were considered when evaluating candidate PCs.

Studies related to effects on human health at all life stages, including in-utero, were considered during the evaluation. Actions taken by other agencies were also considered. After final review, the following chemicals were named to the first list of Minnesota PCs:

Name	Chemical Abstract Service (CAS) Registry Number
Bisphenol A (BPA)	80-05-7
Butyl benzyl phthalate (BBP)	85-68-7
Cadmium	7440-43-9
Decabromodiphenyl ether (decaBDE)	1163-19-5
Dibutyl phthalate (DBP)	84-74-2
Di (2-ethylhexyl) phthalate (DEHP)	117-81-7
Formaldehyde	50-00-0
Hexabromocyclododecane (HBCD)	3194-55-6
Lead	7439-92-1

Summaries for these chemicals are available in the following pages. Chemical uses or forms that were specifically excluded in Minn. Stat. 2010 116.9405, such as chemicals in foods, beverages or cigarette smoke, were not considered and generally not discussed within these summaries. Research continues on the chemicals named, and new findings will be considered during future revisions of the PC list.

II. Toxicity, Exposure and Environmental Disposition Data Sources

The following sources were used for information about toxicity, exposure and environmental disposition for the chemicals evaluated as candidate Priority Chemicals (PCs). A summary was not necessarily available from each source for each chemical. Sources used in evaluating a particular chemical are referenced within the MDH summary for that chemical.

A. United States

1. Centers for Disease Control and Prevention (CDC)

a. Agency for Toxic Substances and Disease Registry (ATSDR)

ATSDR creates Toxicological Profiles for some chemicals, with a total of 310 profiles currently available (Agency for Toxic Substances and Disease Registry [ATSDR]. 2010). A Toxicological Profile is a peer-reviewed document that describes potential toxicity and related adverse health effects for a chemical (ATSDR, 2007). For most chemicals, an abbreviated Public Health Statement, which discusses key points from the Toxicological Profile, is also available. Examples of topics covered are physical and chemical properties, toxicity, exposure pathways, environmental disposition, use, and effects on children. For the PC screening, Toxicological Profiles were useful for information about toxicity, health endpoints, and possible consumer exposures to the chemical.

b. National Health and Nutrition Examination Survey (NHANES)

Since 1999, the Centers for Disease Control and Prevention's National Center for Health Statistics has been conducting a survey of human exposure to chemicals as part NHANES. Volunteers provide samples of blood, serum, and urine for analysis (Centers for Disease Control and Prevention [CDC], 2010). The samples are tested for presence of certain environmental chemicals or metabolites and reported in the National Report on Human Exposure to Environmental Chemicals. Some chemicals have been studied since NHANES began in 1999, while other chemicals have been surveyed only in recent years (CDC, 2010). Because one possible criterion for a PC under Minn. Stat. 2010 116.9403 is for the chemical to be found in human tissue or body fluid, data from this survey were useful.

2. Environmental Protection Agency (EPA)

a. Chemical Action Plans – Existing chemicals

Through a comprehensive approach to chemical management being implemented by EPA, chemicals of concern to the public are being identified and evaluated (Environmental Protection Agency [EPA], 2010c). Summaries of plans to manage these chemicals have been created by EPA. These documents outline the chemicals' toxicity to humans and the environment, uses of the chemicals, and EPA plans for managing these chemicals. Currently, there are a total of nine chemicals action plans available. These documents and further information are available at <http://www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html>.

b. High Production Volume Information System (HPVIS)

HPVIS is a collection of information maintained by EPA that was obtained during the High Production Volume Chemical Challenge program that began in the late 1990s. Through this program, industries that produced or imported more than one million pounds per year of a chemical were "challenged" to "sponsor" a chemical. For sponsored chemicals, health and

environmental effects data were provided to EPA. EPA used this screening level information to create chemical summaries called “Hazard Characterizations” (HC) and later to produce documents called “Risk Based Prioritizations” (RBP). The HCs were similar to the Screening Information Data Set (SIDS) Initial Assessment Reports (SIAR) produced by the international Organisation for Economic Co-operation and Development (OECD), which include information on toxicity, use, and exposure pathways (EPA, 2010b). The RBPs provided a general ranking for the potential risk associated with a chemical (EPA, 2010a).

c. Inventory Update Reporting (IUR)

Under the Toxic Substances Control Act (TSCA), the EPA has been collecting data on quantities of chemicals manufactured or imported into the U.S. through Inventory Update Reporting (IUR). Manufacturers or importers of certain chemicals must submit this information to the EPA during a reporting year for the previous calendar year. In the past 20 years, there have been five IUR inventories completed (1990, 1994, 1998, 2002 and 2006). The next reporting year is 2011, which will require information from calendar year 2010 (EPA, 2010e).

For the 2006 inventory, importers and manufacturers of quantities of more than 300,000 pounds of an organic chemical were required to report use information for that chemical. This information included general use categories, such as “rubber and plastics,” ranges of the percentage of the chemical in the product, and whether the chemical is used in products intended for children up to age 14. Many records from the 2006 IUR inventory show “Not Readily Obtainable” (NRO), however. When available, these data are somewhat useful in ascertaining to which chemicals children might be exposed.

For future inventories, EPA has proposed several changes, such as returning the reporting schedule to every four years, increasing the number of years for which data are collected and broadening requirements for usage reporting. For more information on the IUR proposed changes, see <http://www.epa.gov/iur> (EPA, 2010d).

d. Integrated Risk Information System (IRIS)

The IRIS program evaluates risk information about exposure to environmental contaminants and effects on human health (EPA, 2010f). For non-cancer health effects, IRIS develops estimates of safe levels of lifetime exposure called Reference Doses (RfDs) (oral exposures) and Reference Concentrations (RfCs) (inhalation exposures). IRIS also assesses the carcinogenic potential of chemicals. More information about IRIS is available at <http://www.epa.gov/iris/>.

e. National Center for Environmental Assessment (NCEA)

The NCEA provides guidance and risk assessments aimed at protecting human health and the environment (EPA, 2010g). More information is available at <http://www.epa.gov/ncea/>.

f. Office of Pollution Prevention and Toxics (OPPT)

Under TSCA and the Pollution Prevention Act, OPPT evaluates new and existing chemicals and their risks, in addition to finding ways to prevent or reduce pollution (EPA, 2010h). This program also has information on hazards of certain chemicals, such as lead and cadmium. For more information about this program, see <http://www.epa.gov/oppt/>.

g. Toxic Release Inventory (TRI) data

Manufacturers that release chemicals into the environment (land, air or water) through production or disposal processes are required to submit a yearly report to the EPA about the releases. The Toxic Release Inventory (TRI) data are intended to help residents of communities understand the types of chemicals being used and released in the area (EPA, 2010i). These data also help illustrate how a chemical is handled, the amount being used, and the way usage changes over time. These data show only chemicals released by manufacturing facilities, and do not reflect the disposition of chemicals used in consumer products. See <http://www.epa.gov/tri/> for more information about the TRI.

3. Food and Drug Administration (FDA)

The FDA regulates food, human and veterinary medications, biological products, cosmetics, and sources that emit radiation (FDA, 2010). The FDA has published summary information for certain chemicals. This information was accessed when screening the PC candidate chemicals.

4. National Institutes of Health (NIH)

a. National Library of Medicine (NLM)

(1) Hazardous Substances Data Bank (HSDB)

The HSDB is maintained by the NLM Toxicology Data Network. Information it contains is derived from current books, technical reports and government documents. This database contains toxicity information, but it also contains information about human exposure, uses of the chemical, environmental fate, emergency response, and several other topics. This peer-reviewed database can be found at <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB> (National Library of Medicine [NLM], 2010a).

(2) Household Products Database

Maintained by the NLM, this database contains information about consumer products and the chemicals they contain, which assists in determining general exposure potential. The database can be queried by a chemical's name or Chemical Abstract Service Registry Number (CAS number), as well as a product's brand name. Data are derived from product labels or material safety data sheets (MSDS) (NLM, 2010b). Because information about chemicals in products can be claimed as a trade secret by manufacturers and can change rapidly, the database is not a comprehensive source of information. However, it provides general information useful for screening the Priority Chemicals candidates. This database can be found at <http://householdproducts.nlm.nih.gov/index.htm>.

b. National Toxicology Program (NTP)

The NTP evaluates environmental toxicants in laboratory studies (National Toxicology Program [NTP], 2010). It creates the Report on Carcinogens and houses the NTP Center for the Evaluation of Risks to Human Reproduction. Results of studies on substances of concern to public health are also available from its website. When available, NTP findings for candidate PCs were reviewed. More information about the NTP is available at <http://ntp.niehs.nih.gov/index.cfm>.

B. International Sources

U.S. agency sources were used when available. Materials from sources outside the U.S. were also reviewed as supplements, particularly when there was limited information from U.S. sources or newer information from an international source. Information used is referenced in each Minnesota Priority Chemical summary. Sources include the following:

1. Canadian Government

a. Environment Canada

Environment Canada is responsible for protecting the environment, conserving Canada's natural heritage, and providing weather and environmental predictions (Environment Canada, 2010). Environment Canada is working with Health Canada on evaluating hazards of chemicals in commerce. Part of this effort is called the "Challenge." The results of the Challenge are used to determine if regulatory actions to restrict chemical uses are necessary (Government of Canada, 2009). For more information, please see [http://www.chemicalsubstanceschimiques.gc.ca/about-
apropos/index-eng.php](http://www.chemicalsubstanceschimiques.gc.ca/about-
apropos/index-eng.php).

b. Health Canada

Health Canada is responsible for maintaining and improving the health of Canadians (Health Canada, 2009). Health Canada is working jointly with Environmental Canada to assess and manage chemicals in the environment. Many substances have been tested and evaluated through the "Challenge" program, where characteristics of chemicals currently in commerce have been screened and characterized. Regulatory action for specific chemicals is implemented when a need is determined (Government of Canada, 2009). Further information can be found at [http://www.chemicalsubstanceschimiques.gc.ca/about-
apropos/index-eng.php](http://www.chemicalsubstanceschimiques.gc.ca/about-
apropos/index-eng.php).

2. Europe

a. Joint Research Centre of the European Commission

The European Commission, the executive body for the European Union, conducts risk assessments on some chemicals. These assessments are conducted under the Institute for Health and Consumer Protection within the Joint Research Centre of the European Commission. They are available from the European Commission website through the European Chemical Substances Information System (ESIS), at <http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ein>. (Some of the information in this system is now being transferred to the European Chemicals Agency (ECHA) (European Commission, 2010).

b. European Chemicals Agency (ECHA)

ECHA was created to ensure safe use of chemicals and to foster innovation (European Chemicals Agency [ECHA], 2010). ECHA is responsible for administering the Registration, Evaluation, Authorization, and restriction of Chemicals (REACH) program in the European Union. This agency provides summary information about chemicals that were named to the REACH Substances of Very High Concern (SVHC) list. This information was used, when available, in evaluating the candidate PCs. More information about ECHA is available at http://echa.europa.eu/about_en.asp.

3. Organisation for Economic Co-operation and Development (OECD)

The OECD is an international organization with 34 member countries, including the United States. The OECD goals are to support sustainable economic growth, boost employment, raise living standards, maintain financial stability, assist other countries' economic development, and contribute to growth in world trade (Organisation for Economic Co-operation and Development [OECD], 2010a). The OECD has a high production volume chemicals program that evaluates hazards related to chemicals produced in member countries in quantities of more than 1000 tons per year (OECD, 2010b). For evaluated chemicals, Screening Information Data Sets (SIDS) Initial Assessment Reports (SIAR) are available. These summaries were used to evaluate toxicity, possible exposure pathways, and uses of some chemicals. More information is available at

http://www.oecd.org/document/21/0,3746,en_2649_34379_1939669_1_1_1_1,00.html.

4. World Health Organization (WHO)

International Agency for Cancer Research (IARC)

IARC promotes international collaboration on cancer research. It uses an interdisciplinary approach to identify the causes of cancer (IARC, 2010). Among IARC publications are chemical monographs that discuss the carcinogenic potential of a chemical. Based on its findings, IARC assigns a chemical one of four categories of carcinogenicity potential. This information was used by MDH in creating the chemical summaries. Information about IARC can be accessed at

<http://www.iarc.fr/>.

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III. Priority Chemical Summaries

A. Bisphenol A

CAS Number 80-05-7

NOTE: THE FOLLOWING BISPHENOL A (BPA) SUMMARY WAS CREATED IN 2011 TO SUPPORT DEVELOPMENT OF THE “PRIORITY CHEMICALS” LIST AND IMPLEMENTATION OF THE MN TOXIC FREE KIDS ACT (Minn.Stat.2010 116.9401-116.9407). THE FOLLOWING INFORMATION REFLECTS THE BPA INFORMATION AVAILABLE IN EARLY 2011. FOR CURRENT MDH INFORMATION ON TOXICITY, EXPOSURE, AND MINNESOTA/FEDERAL LEGISLATIVE ACTIVITIES FOR BPA, SEE

**[[Bisphenol A http://www.health.state.mn.us/divs/eh/risk/chemhazards/bisphenola.html](http://www.health.state.mn.us/divs/eh/risk/chemhazards/bisphenola.html)]
[[Regulations Regarding BPA... http://www.health.state.mn.us/div/eh/risk/chemhazards/bpalaw.html](http://www.health.state.mn.us/div/eh/risk/chemhazards/bpalaw.html)].**

(Note added October 2014).

1. Overview

Bisphenol A (BPA) is used to manufacture polycarbonate plastics and epoxy resins, which are in products like baby bottles, high impact plastics, thermal paper, and some toys (Centers for Disease Control and Prevention [CDC], 2010; Environmental Protection Agency [EPA], 2010a). This substance has been used in manufacturing for many years, but recently there has been concern about possible latent health effects from exposure to this chemical, especially as it relates to exposures to fetuses, infants and young children.

Currently, there is little information on the effect of BPA specifically on human health. However, laboratory studies indicate that this chemical could cause developmental damage, and the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) has stated, “The NTP has *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A.” (National Toxicology Program [NTP] (original emphasis), 2008; EPA, 2010a). The category of “some concern” is the mid-point of the NTP CERHR rating system (NTP, 2008). There is still much uncertainty and much research is still in progress or proposed for BPA (CDC, 2010). Governmental agencies continue to evaluate the outcomes of the research (FAO/WHO, 2010).

As described below, while the toxicity of BPA to humans is still being studied and debated, some of the concern related to BPA is based on the ubiquity of this man-made chemical and its presence in humans. In the National Health and Nutrition Examination Survey (NHANES), 93% of the participants sampled in 2003-2004 showed BPA present in the urine (NTP, 2010). Because the chemical is eliminated quickly from the body, these results signal that the exposure was recent and could be occurring frequently (CDC, 2010; NTP, 2008).

In an effort to reduce human exposure to this chemical, a statute passed by the Minnesota Legislature in 2009 (Minn. Stat. 2010 325F.723) prohibits BPA in children’s food or beverage containers sold in retail stores in Minnesota as of January 1, 2011.

The information below provides an overview of potential human exposure to BPA, the toxicity of BPA, and current state and federal actions related to BPA:

2. Exposure and Environmental Disposition

(Note: This section includes examples of exposure and environmental information retrieved from several sources. This summary is not intended to be comprehensive.)

There is substantial evidence that humans are exposed to BPA at all life stages, including during the time before birth. BPA has been found in serum, breast milk, urine, amniotic fluid, fetal blood, and umbilical cord blood, as well as other human tissues and body fluids (EPA, 2010a; NTP, 2008). Diet is one of the main sources of human exposure to BPA (CDC, 2010; NTP, 2008). BPA can leach into food and beverages that are held in containers, such as baby bottles, made with BPA. According to the NTP, the extent of migration of BPA to a liquid appears to be temperature dependent: warmer temperatures result in greater migration (NTP, 2008). Very young children may have additional exposure to BPA through breast milk and as a result of crawling and mouthing behavior, whereby BPA in household dust, toys, or other products may be transferred to the skin and mouth (CDC, 2010; EPA, 2010a; NTP, 2008).

a. Centers for Disease Control and Prevention (CDC)

National Health and Nutrition Examination Survey (NHANES)

In the National Report on Human Exposure to Environmental Chemicals produced under NHANES, the CDC reports that in the 2003-2004 survey, children, women, and people at lower income levels were more likely to have higher levels of BPA in their urine. This level reflects recent and possibly frequent exposure to BPA, because BPA does not accumulate in the body (CDC, 2010; NTP, 2008).

b. Environmental Protection Agency (EPA)

(1) EPA Inventory Update Reporting (IUR)

According to the EPA IUR from 2006, this chemical is used in rubber and plastic products where it can be 61-90% of the product mass. The IUR data indicate that some of these products are intended for children (EPA, 2010b). Because these data are several years old, it is unknown how well current use is reflected.

2006 EPA Inventory Update Reporting data		
Chemical	Maximum concentration in product category	Used in a product intended for children up to age 14
Adhesives and sealants	1-30%	NRO
Electrical and electronic products	1-30%	Yes
Paints and Coatings	1-30%	No
Rubber and Plastic Products	61-90%	Yes
NRO = "not readily obtainable" (EPA, 2010b)		

(2) EPA Toxic Release Inventory (TRI)

In 2009, the EPA reports a total of 1.2 million pounds of BPA released in the U.S. from on-site or off-site disposal or through other activities. For Minnesota, there was a total of 190 lbs reported released from one site in 2009. This release was reportedly to an off-site landfill. For the

past 20 years, the peak releases in Minnesota occurred in 2001 (21,007 lbs) and 2002 (9,404 lbs). These releases were primarily to off-site landfills or disposal impoundments (EPA, 2010c). The amount of BPA released in Minnesota by manufacturers appears to have been declining over the past 10 years.

c. National Institutes of Health

National Library of Medicine (NLM)

(1) Household Products Database

The NLM Household Products Database currently lists only three products found in the home that contain BPA (National Library of Medicine [NLM], 2010). All of the products are epoxy products, and one is flagged as an “old product” that is probably not produced any longer. This database would not likely include products for which a material data safety sheet (MSDS) is not produced, such as food containers.

(2) Hazardous Substance Data Bank

In addition to the consumer products noted above, BPA has been found in drinking water, surface water, ground water, wastewater, effluents, outdoor air, and in purchased milk (Hazardous Substances Data Bank [HSDB], 2010). There may be additional media where BPA is found that are not reported here.

3. Toxicity

(Note: This section provides examples of toxicity information from several sources. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention (CDC)

National Health and Nutrition Examination Survey (NHANES)

NHANES reports that reproductive and developmental changes have been found at high BPA dose levels in laboratory studies (CDC, 2010). Some developmental effects have also been reported from low BPA doses in recent studies, but research is ongoing (CDC, 2010).

b. Environmental Protection Agency (EPA)

EPA Integrated Risk Information System (IRIS)

Oral Reference Dose for BPA: 5×10^{-2} mg/kg/day

Uncertainty factor: 1000 (EPA, 1993)

c. Food and Drug Administration (FDA)

In January 2010, the FDA reported that it, along with the National Toxicology Program (NTP), has some concerns about “the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children.” (Food and Drug Administration [FDA], 2010a). FDA plans to work with NTP to clarify the risks of BPA.

d. National Institutes of Health (NIH)

National Toxicology Program (NTP)

NTP has five categories for classifying concern about a chemical. For BPA, NTP has indicated that it has “some concern,” or the middle category, for developmental toxicity for fetuses, infants and children related to the brain, behavior, and prostate gland. For developmental toxicity for

fetuses, infants and children related to effects on the mammary gland, early puberty, and reproductive toxicity of workers, NTP has “minimal concern” or the second to lowest category of concern. For reproductive toxicity in adult men and women, NTP states there is “negligible concern,” or the lowest concern category. A summary of this information can be found at <http://www.niehs.nih.gov/health/docs/bpa-factsheet.pdf> (NTP, 2008; NTP, 2010).

4. Statutory Requirements

The following table shows how BPA meets the statutory requirements of Minn. Stat. 2010 116.9401–116.9407, and lists some of the BPA toxicity findings from laboratory tests or human surveys and environmental disposition characteristics.

Statute	Information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity	Brain, behavior and prostate effects in fetuses, infants, children	NTP 2008
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	Delayed sexual maturity	CDC 2010
	Prostate gland	NTP 2008
Subd. (e)(3) disrupt the endocrine or hormone system	Weakly estrogenic, endocrine disruption	CDC 2010 EPA 2010a
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	Brain, behavior	NTP 2008
	Body weight	EPA 1993
	Eye irritation, skin sensitization	CDC 2010 HSDB 2010
Subd. (e)(5) be persistent, bioaccumulative, and toxic		
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	1 billion pounds or more	EPA 2010b
Subd (2) Meets any of the following criteria:		

Statute	Information	References
Subd. (a)(2)(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	Blood, breast milk, umbilical cord blood, serum, urine and other body fluids and tissues	CDC 2010 NTP 2008
Subd. (a)(2)(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	Household dust, indoor air, drinking water	HSDB 2010 NTP 2008
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Surface water, groundwater	HSDB 2010

5. Current Regulations

a. Federal

There are currently no U.S. federal-level restrictions on BPA in consumer products, though several bills have been introduced in Congress (Library of Congress, 2010).

b. States and Cities

As of November 2010, there are seven states (Connecticut, Maryland, Minnesota, New York, Vermont, Washington, and Wisconsin), four New York counties (Albany, Rock Island, Schenectady, Suffolk) and two cities (San Francisco, CA and Chicago, IL) that have implemented restrictions on BPA, such as prohibitions on manufacture, sale, or distribution of a children's product containing BPA (Lowell Center for Sustainable Production, 2010). The states of Maine and Washington have proposed to designate BPA as a Priority Chemical or a Chemical of High Concern for Children (CHCC), respectively (Maine Department of Environmental Protection [Maine DEP], 2010; Washington Department of Ecology [Washington Ecology], 2010). Reporting requirements and other restrictions may follow this designation in these states.

The Minnesota statute is as follows:

“BISPHENOL-A IN CHILDREN'S PRODUCTS

325F.172 DEFINITIONS.

Subdivision 1.Scope.

For the purposes of sections 325F.172 to 325F.173, the following terms have the meanings given them.

Subd. 2.Child."Child" means a person under three years of age.

Subd. 3.Children's product. "Children's product" means an empty bottle or cup to be filled with food or liquid that is designed or intended by a manufacturer to be used by a child.

325F.173 BISPHENOL-A IN CERTAIN CHILDREN'S PRODUCTS.

- (a) By January 1, 2010, no manufacturer or wholesaler may sell or offer for sale in this state a children's product that contains bisphenol-A.
- (b) This section does not apply to sale of a used children's product.
- (c) By January 1, 2011, no retailer may sell or offer for sale in this state a children's product that contains bisphenol-A.”

(Minn. Stat. 2010 325F.172 - 325F.173)”

Specific State and Local Government Regulations

Within U.S. states, several pieces of legislation have been introduced. The following legislation involves enacted law on the state and local levels that contains prohibitions on BPA. The summaries are from the Lowell Center for Sustainable Production U.S. State Chemical Policy Database, available at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>:

Minnesota

Year: 2009

S.F. 247, 86th Leg., Reg. Sess. (Minn. 2009).

As noted above, the state of Minnesota has passed a ban on BPA in children’s food containers, effective January 1, 2010 for manufacturers and wholesalers and January 1, 2011 for retailers.

San Francisco, California

Year: 2006

San Francisco Board of Supervisors, Ordinance No. 120-06 (June 15, 2006).

Prohibits the manufacture, sale, or distribution in commerce of any toy or child care article that is intended for use by a child under three years of age if it contains bisphenol-A or phthalates.

Requires manufacturers to use the least toxic alternative to those substances.

Connecticut

Year: 2009

H.B. 6572, 2009 Gen. Assemb., Jan. Sess. (Conn. 2009).

Prohibits the manufacture, sale, or distribution of any reusable food or beverage container containing bisphenol A. Prohibits the manufacture, sale, or distribution of any instant formula or baby food that is stored in a plastic container, jar, or can that contains bisphenol A.

Chicago, Illinois

Year: 2009

Chicago City Council, Ordinance No. 7-28-637 (2009).

Prohibits the sale of any container that is composed of bisphenol A that is sold or distributed without containing any liquid, food, or beverage. Requires containers to be affixed with a label indicating that the product is not composed with bisphenol A.

Maryland

Year: 2010

H.B. 33, 427th Gen. Assemb., Reg. Sess. (Md. 2010); S.B. 213, 427th Gen. Assemb., Reg. Sess. (Md. 2010).

Prohibits the manufacture, sale, or distribution of any children's toy or child care article containing bisphenol A. Requires the replacement of bisphenol A with the least toxic alternative.

Prohibits the replacement of bisphenol A with a carcinogen, reproductive toxicant, developmental toxicant, or a chemical that causes birth defects.

New York

Year: 2010

A. 6919, 232nd Leg., Reg. Sess. (N.Y. 2009); S. 3296, 232nd Leg., Reg. Sess. (N.Y. 2009). Prohibits the sale of any child care product intended for use by a child three years of age or younger containing bisphenol A. Permits the Commissioner to authorize product labeling of products that do not contain bisphenol A.

Albany County, New York

Year: 2009

Albany County Legislature, Local Law No. 5, (Apr. 13, 2009).

Prohibits the sale of children's beverage containers that contain bisphenol A within the County of Albany.

Rockland County, New York

Year: 2010

Rockland County Legislature, Local Law No. 5 (April 20, 2010).

Prohibits the sale of any children's beverage container or sucking/teething product that contains bisphenol A.

Schenectady County, New York

Year: 2009

Schenectady County Legislature, Local Law No. 02-2009 (Aug. 11, 2009).

Prohibits the sale of children's beverage containers that contain bisphenol A.

Suffolk County, New York

Year: 2009

Suffolk County Legislature, Res. 1017-2009 (Apr. 2, 2009).

Bans the sale or use of children's beverage containers containing bisphenol A.

Vermont

Year: 2010

2010 Vt. Acts & Resolves 112.

Prohibits the manufacture, sale, or distribution of any reusable food or beverage container containing bisphenol A. Prohibits the manufacture, sale, or distribution of any infant formula or baby food stored in a plastic container, jar, or can that contains bisphenol A. Requires manufacturers to use the least toxic alternative when replacing bisphenol A and are prohibited from replacing bisphenol A with known or likely human carcinogens, reproductive toxicants, or developmental toxicants.

Washington

Year: 2010

S.B. 6248, 61st Leg., Reg. Sess. (Wash. 2010).

Prohibits the manufacture, sale, or distribution of any empty bottle, cup, or other container, except a metal can, that contains bisphenol A if that container is designed or intended to be filled with any liquid, food, or beverage primarily for use by children three years of age or younger.

Wisconsin

Year: 2010

S.B. 271, 2009-2010 Leg., Reg. Sess. (Wis. 2009).

Prohibits manufacturing or selling an empty baby bottle or spill-proof cup primarily intended for use by a child five years of age or younger if the child's container contains bisphenol A. Requires manufacturers and wholesalers to ensure that a child's container sold or offered for sale is conspicuously labeled as not containing bisphenol A.

6. Planned Actions

a. Federal

While there are currently no federal regulations for BPA in consumer products, the U.S. FDA, NTP and EPA are currently reviewing information about the chemical.

(1) Environmental Protection Agency

The EPA has created a Chemical Action Plan that describes the use of BPA, associated health and environmental concerns, physical characteristics, risk management, and planned actions. As EPA notes, the FDA has authority to evaluate risks related to food containers, cosmetics and medical devices, where BPA is commonly used. EPA plans to address the environmental risks related to BPA, particularly related to aquatic species. According to the EPA, the FDA is working with the CDC and the National Institute of Environmental Health Sciences to assess information about BPA and to evaluate the risks to human health. EPA plans to work with FDA and other agencies in attempt to find alternatives to BPA. Some of the actions that EPA plans in 2010-2012 include:

- Consider initiating rulemaking under TSCA 5(b)(4) to add BPA to the Concern List for long-term risks for aquatic species.
- Consider initiating rulemaking under TSCA 4(a) to develop data to help determine actual risks of BPA to the environment. This could include testing or monitoring data in the vicinity of landfills, manufacturing facilities, or other locations in order to assess how much BPA could enter surface water, groundwater, or drinking water.
- Conduct alternative assessments under the EPA's Design for the Environment program to ultimately enable reduction of BPA use. Assessment of thermal and carbonless paper coatings is one of the planned assessments (EPA, 2010a).

(2) Food and Drug Administration

The FDA lists on its website the following actions related to BPA as it studies the possible related health effects. Some of FDA actions include:

- Supporting the end of BPA usage in food containers, particularly those for infants.

- Considering a more “robust regulatory framework” for oversight of BPA. FDA believes it could react more quickly to hazards under a modernized framework similar to that of the current food contact substances framework.
- Seeking public and technical comment on BPA.
- In concert with Health Canada, FDA is encouraging industry to develop manufacturing methods that reduce the migration of BPA in infant formula can linings to the formula. Further, FDA participated in a World Health Organization and United Nations Food and Agriculture Organization discussion about BPA (FDA, 2010b).

b. States

Maine:

Year: 2010

The state of Maine has proposed BPA as one of the two Priority Chemicals it will designate in 2011 under the Toxic Chemicals in Children’s Products law. Under Maine law, manufacturers with products containing intentionally-added BPA will be required to report information about the product produced, sold or distributed in Maine to the state government. Some uses of BPA in children’s food or beverage containers could be banned from sale or distribution in Maine as of January 1, 2012 (Maine DEP, 2010).

Washington

Year: 2010

Under the Children’s Safe Products Act, Washington has named BPA a Chemical of High Concern for Children (CHCC). Washington intends to require manufacturers to report to the state which products contain CHCC chemicals (Washington Ecology, 2010).

7. Conclusion

Because of the widespread presence of BPA in humans and the uncertainty about effects on human health, together with laboratory evidence of BPA’s toxicity and the likelihood of children’s exposure to the substance, MDH is naming BPA a Priority Chemical. Per Minn. Stat. 2010 116.9405 (9), food and food or beverage packaging, except a container containing baby food or infant formula, are excluded from this Priority Chemical designation. MDH will continue to monitor ongoing studies of BPA to determine if the status as a Priority Chemical remains appropriate.

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B. Cadmium

CAS Number 7440-43-9

1. Overview

Cadmium, a natural metal found in the earth's crust, is extracted during the refining of other metals, including zinc, lead and copper (Centers for Disease Control and Prevention [CDC], 2010). According to the U.S. Agency for Toxic Substances and Disease Registry (ATSDR), 83% of extracted cadmium is used in batteries, 8% in pigments, 7% in plating and coatings, and the remainder in plastics and other applications (Agency for Toxic Substances and Disease Registry [ATSDR], 2008).

Cadmium enters the body through ingestion or inhalation. Cadmium levels in blood reflect recent exposures, while levels of cadmium in urine reflect body burden from longer term exposures (Organisation for Economic Co-operation and Development [OECD], 2004). With repeated exposure, cadmium can accumulate in the body, especially in the kidney and liver, with potential of remaining in the body for several decades (ATSDR, 2008; OECD, 2004). The kidney can be damaged after over-exposure to cadmium (ATSDR, 2008; CDC, 2010). Cadmium can also cause malformation of bone, bone loss or decrease in bone strength. Further, there is some limited evidence that cadmium is a neurotoxin and an endocrine disruptor (ATSDR, 2008). In animal laboratory studies, cadmium has been found to be absorbed more readily by younger animals (ATSDR, 2008). Children have more years to accumulate cadmium and to manifest related health effects, making cadmium in children's products a concern.

Cadmium has been found to cause lung cancer in some workers who have been exposed to it occupationally. It has been named a known carcinogen by the Department of Health and Human Services' National Toxicology Program (NTP) (National Toxicology Program [NTP], 2005), as well as being named a Group 1 carcinogen by the International Agency for Research on Cancer (IARC) (International Agency for Research on Cancer [IARC], 1997), and a probable carcinogen by the Environmental Protection Agency (EPA) (Environmental Protection Agency [EPA], 1992).

Because cadmium has some properties that are similar to lead, cadmium could be used as a substitute for lead in products. After the Consumer Product Safety Improvement Act (CPSIA) of 2008 lowered the limit of lead allowable in children's products, there was concern that cadmium would be used as an alternative. In the early part of 2010, the Consumer Product Safety Commission (CPSC) issued six recalls related to cadmium in children's products. A survey of children's products by the Associated Press, and later by the Canadian government, reported finding some children's products with high cadmium content, sometimes topping 90% (Health Canada, 2010; Pesce, 2010). While currently no federal standard related to cadmium in children products exists, an industry standard is under development. In the interim, four state governments, including Minnesota, have attempted to limit children's exposure to cadmium through state law. Federal and state policies related to cadmium will be discussed further below in Section 5 "Regulations" and Section 6 "Action Plans".

Cadmium is being named a Priority Chemical by Minnesota Department of Health (MDH) because of its potential health effects, including kidney and bone damage, its ability to accumulate and remain in the body, and its use in products intended for children.

Further information about toxicity, potential exposure pathways, and current state and federal actions is provided below.

2. Exposure and Environmental Disposition

(Note: This section includes examples of exposure and environmental information for cadmium. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention (CDC)

(1) Agency for Toxic Substances and Disease Registry (ATSDR)

Cadmium that enters the body tends to accumulate in the kidney and liver. Cadmium in the kidneys can have a half-life of several decades. Cadmium in the blood indicates recent exposures, while cadmium in the urine is related to the concentration of cadmium in the kidneys (ATSDR, 2008).

(2) National Health and Nutrition Examination Survey (NHANES)

NHANES data show levels of cadmium detected in humans have been declining since 2001. People of age 20 years and older had higher blood cadmium levels than people of younger ages. Females had slightly higher levels than males (CDC, 2010).

b. Consumer Product Safety Commission (CPSC)

A report by the CPSC determined that a test method for chemicals such as cadmium migrating from small swallowed items should be based on solubility in an acidic solution for 24 hours. CPSC has requested that an industry trade group make recommendations about voluntary cadmium standards (Consumer Product Safety Commission [CPSC], 2010a).

c. Environmental Protection Agency (EPA)

(1) Inventory Update Reporting (IUR)

Data from the 2006 IUR indicate that cadmium was produced or imported into the U.S. in a range of 1 million to 10 million pounds. EPA rules in place during the 2006 inventory did not require use information to be reported for inorganic chemicals like cadmium. Cadmium usage information will be required in the 2011 reporting period under current EPA rules (EPA, 2010a).

(2) Office of Pollution Prevention and Toxics (OPPT)

Products containing cadmium, such as jewelry, can be put in a child's mouth and result in oral exposure (EPA, 2010c).

(3) Toxic Release Inventory (TRI)

There were no cadmium or cadmium compound releases reported for Minnesota in 2009 (EPA, 2010d). Cadmium was reported released in Minnesota from 1988-1994, with the highest release in 1990 of 1,612 pounds. This release was a transfer to a landfill (EPA, 2010e). For cadmium compounds, there were releases reported in 1988-1995 and 2005. The greatest release was 4,693 pounds reported in 1991. This release was primarily to landfills (EPA, 2010e).

d. National Institutes of Health (NIH)

National Library of Medicine (NLM)

(a) Hazardous Substances Data Bank (HSDB)

Cadmium has been found in fish (Hazardous Substance Data Bank [HSDB], 2010).

(b) Household Product Database

This database shows only two products, a glaze with less than 1% cadmium and a concrete material with an unspecified amount of cadmium. However, as noted in the Household Product Database background information, products for which a material safety data sheet (MSDS) is not created are not included. Therefore, jewelry and novelty glassware would not likely be listed (NLM, 2010a; NLM, 2010b).

3. Toxicity

(Note: This section provides examples of toxicity information from several sources. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention (CDC)

(1) Agency for Toxic Substances and Disease Registry (ATSDR)

Cadmium can cause tissue damage leading to decreased function of the kidney. The effects of low level cadmium exposure over time on the kidney are not entirely understood. However, it is possible that adults exposed to cadmium as children might be at higher risk for the renal toxicity of cadmium than people exposed only as adults. Exposure to cadmium can also cause bones to weaken (ATSDR, 2008).

(2) National Health and Nutrition Examination Survey (NHANES)

NHANES reports that the kidney is the critical target of cadmium exposure. At high exposures, such as those encountered occupationally, irreversible proteinuria signals renal damage. Indicators of renal damage from environmental exposure levels are not as well understood. Effects on bone density have been reported from exposure to cadmium in areas with soil contamination (CDC, 2010).

b. Environmental Protection Agency (EPA)

Integrated Risk Information System (IRIS)

EPA Reference Dose:

5×10^{-4} mg/kg/day (water) (proteinuria)

1×10^{-3} mg/kg/day (food) (proteinuria) (EPA, 1994)

Cadmium is a probable human carcinogen (EPA, 1992).

c. National Institutes of Health (NIH)

National Toxicology Program (NTP)

NTP has determined that cadmium is a known human carcinogen via inhalation.

d. World Health Organization (WHO)

International Agency for Cancer Research (IARC)

Cadmium is classified as a Group I carcinogen: carcinogenic to humans (IARC, 1997).

4. Statutory Requirements

In relation to Minn. Stat. 2010 116.9401-116.907, cadmium met the following criteria:

Statute	Information	References
Minn. Stat.2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity	Development: Nervous system and skeletal system	ATSDR 2008
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	Cancer: EPA B1: Probable carcinogen	EPA 1992
	Cancer: NTP: Known human carcinogen (inhalation)	NTP 2005
	Cancer: IARC: Group 1: Carcinogenic to humans (inhalation)	IARC 1997
Subd. (e)(3) disrupt the endocrine or hormone system		
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	Neurobehavioral	ATSDR 2008
	Bones, kidney	ATSDR 2008 CDC 2010
Subd. (e)(5) be persistent, bioaccumulative, and toxic	(Designated as a Persistent Bioaccumulative and Toxic (PBT) Priority Chemical in the EPA National Waste Minimization Program)	EPA 2009
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	1 to 10 million pounds	EPA 2010b
Subd (2) Meets any of the following criteria:		
Subd. (a)(2)(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	Blood, kidney, liver, umbilical cord blood	CDC 2010 HSDB 2010
Subd. (a)(2)(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		
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Fish (Also a naturally occurring element)	HSDB 2010

5. Current Regulations

a. Federal

There are currently no mandatory federal regulations for cadmium in children's products, though the CPSIA requires a standard, which is currently under development. Progress is described below in Section V "Planned Actions".

b. States

Minnesota

During the 2010 Minnesota Legislative Session, a law (Minn. Stat. 2010 325E.3891) limiting the amount of cadmium permitted in jewelry intended for children age 6 or younger was passed. The law states:

Cadmium in any surface coating or accessible substrate material of metal or plastic components of children's jewelry shall not exceed 75 parts per million, as determined through solubility testing for heavy metals defined in the ASTM International Safety Specification on Toy Safety, ASTM standard F-963 and subsequent versions of this standard, if the product is sold in this state unless this requirement is superseded by a federal standard regulating cadmium in children's jewelry. (Minn. Stat. 2010 325E.3891, Sub.2)

This Minnesota law takes effect on January 1, 2011.

Many states have laws prohibiting certain metals, including cadmium, in packaging. The following states have legislation related to cadmium in other products to which children might be exposed. (Most information below was obtained from the Lowell Center for Sustainable Production's US State Chemicals Policy database, available from <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.)

California

Year: 2010

S.B. 929, 2009-10 Leg., Reg. Sess. (Cal. 2010)

In fall 2010, the governor of the State of California signed a bill that will limit cadmium levels in jewelry intended for children 6 years of age or younger. Under the new law, cadmium can comprise no more than 0.03% of total composition. This law will go into effect in January 2012 (California Department of Toxic Substances Control, 2011).

Because California has a large market share in the United States, standards passed in California are usually also applied to products sold outside of California. The effect is to apply the standard throughout the United States.

Year: 2010 (Amendment)

Cal. Health & Safety Code §§ 108550-108585 (2008)

Prohibits the manufacture or sale of any toy contaminated with any toxic substance, coated with paints and lacquers containing compounds of lead, or coated with soluble compounds of antimony, arsenic, cadmium, mercury, selenium or barium.

Connecticut

Year: 2010

H.B. 5314, 2010 Gen. Assemb., Feb. Sess. (Conn. 2010)

Prohibits the manufacture, sale, or distribution of any children's jewelry that contains cadmium at more than .004 percent by weight.

Illinois

Year: 2010

H.B. 5040, 96th Gen. Assemb., Reg. Sess. (Ill. 2010)

Prohibits the manufacture, sale, or distribution of children's jewelry containing cadmium.

Authorizes the Illinois Environmental Protection Agency to participate in an interstate clearinghouse to promote safer chemicals in consumer products.

Washington

Year: 2008

2008 Wash. Sess. Laws 288.

Contains limits on lead, cadmium, or phthalates in children's products. (Largely preempted by the Federal Consumer Product Safety Improvement Act of 2008.)

(Lowell Institute for Sustainable Production, 2010)

6. Planned Actions

a. Federal

The CPSIA referred to industry standards under ASTM F963-08 to limit cadmium in coatings or accessible substrates of children's products. However, in August 2010 there was a petition from the Empire State Consumer Project, Sierra Club, and others, requesting the CPSC issue a ban of cadmium in toy metal jewelry containing more than trace amounts of the substance (Federal Register, 2010). Petitioners also requested that the CPSC ban cadmium at levels applicable to lead if there is currently insufficient information available to determine appropriate levels of cadmium in products. This petition was open for comment until October 18, 2010.

In October 2010, the CPSC announced that it would defer regulation of cadmium in children's products and allow a voluntary industry standard to be developed and implemented. The CPSC also announced an acceptable daily intake (ADI) for cadmium of 0.1 ug/kg/day (CPSC, 2010a).

The Environmental Protection Agency also received a petition from this group requesting that EPA use its authority under the Toxic Substances Control Act (TSCA) to require submission of health and safety studies. EPA has granted the petition and plans to collect information and to work with CPSC. If CPSC does not act, EPA announced that it intends to publish a rule under TSCA section 6 (EPA, 2010c).

The CPSC made six recalls of consumer products, including five jewelry items for children and one type of glassware in 2010 (CPSC, 2010b). Many of the recalled items were manufactured outside of the U.S.

b. Retailers

Some retailers have begun requiring manufacturers to meet standards for cadmium set by the European Union (Pritchard, 2010; Walmart Stores, 2010). The standard passed by California in 2010 (see above) will take effect in 2012. This standard is stricter than the European Union standard because it limits total cadmium; not only cadmium in the coating or accessible substrate. Because California standards sometimes are applied nationally, this might affect retailer policy on cadmium.

7. Conclusion

Cadmium is being named a Minnesota Priority Chemical because of its potential health effects, including kidney and bone damage, its ability to accumulate and remain in the body, and its use in products intended for children. After Minnesota's statute related to cadmium in children's jewelry takes effect January 1, 2011 and national standards are developed, cadmium will be limited in children's products, but assurance of compliance will be needed. It will also be important to ensure that cadmium in products not covered by the regulations or guidance do not pose a threat to children.

New findings on cadmium toxicity and exposure routes will be monitored, as will developments in federal and state policy.

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C. Decabromodiphenyl ether

CAS Number 1163-19-5

1. Overview

Decabromodiphenyl ether (decaBDE) is used as a flame retardant in a variety of products, including thermoset resin plastics, textiles, and adhesives. While decaBDE itself is not known to be highly toxic, it is capable of debrominating into other polybrominated diphenyl ether (PBDE) congeners such as pentabromodiphenyl ether (pentaBDE) or octabromodiphenyl ether (octaBDE) (Centers for Disease Control and Prevention [CDC], 2010, Environment Canada, 2010; Minnesota Pollution Control Agency [MPCA], 2008). These congeners can be more persistent, bioaccumulative, and toxic (PBT) than decaBDE (CDC, 2010; Environmental Protection Agency [EPA], 2009). Neither pentaBDE nor octaBDE have been produced in the United States since 2004, when the Great Lakes Chemical Corporation stopped production during a voluntary phase-out of the chemical (EPA, 2009).

Although pentaBDE and octaBDE are no longer produced in the U.S, they continue to be found in the environment and in humans (Environment Canada, 2010; EPA, 2009; MPCA, 2008). EPA reports that levels of these chemicals in the environment could be increasing (EPA, 2009). Various congeners of PBDEs have been found in human adipose (fat) tissue, urine, breast milk, and blood (Agency for Toxic Substances and Disease Registry [ATSDR], 2004; CDC, 2010). They are also known to bioaccumulate in fish at low levels (ATSDR, 2004; CDC, 2010). Possible sources of pentaBDE and octaBDE are imported items, decaBDE as it breaks down in the environment (EPA, 2009; MPCA, 2008) or when it is metabolized by animals or humans (EPA, 2009).

The most recent Inventory Update Reporting (IUR) data from the EPA show that decaBDE was manufactured or imported into the U.S. in a quantity of 50 to 100 million pounds in 2005 (EPA, 2010a).

A significant source of children's exposure to PBDEs might be household dust (CDC, 2010; MPCA, 2008). Crawling and mouthing behaviors could make a child's exposure to household dust relatively greater than an adult's exposure. EPA reports the PBDE found most frequently in household dust is decaBDE (EPA, 2009).

The health effects of PBDEs on humans at levels found in the environment and reported in biomonitoring studies are not known (CDC, 2010), though research is being done. In animal laboratory studies, ingested decaBDE has been found to affect behavior, the liver and other organs (CDC, 2010; EPA, 2008; EPA, 2009). While decaBDE is believed to be only moderately bioaccumulative, it can degrade to PBDE congeners which are known to be bioaccumulative (Environment Canada, 2010; Hazardous Substances Data Bank [HSDB], 2010; MPCA, 2008). There is concern that some congeners of PBDEs might affect human development and reproduction, in addition to producing neurobehavioral effects (ATSDR, 2004; CDC, 2010; EPA, 2009).

DecaBDE is being named a Minnesota Priority Chemical for its toxicity, persistence, and potential to degrade into congeners which are persistent, bioaccumulative and toxic. DecaBDE is

used on some electronic products that are specifically excluded in Minn. Stat. 2010 116.9405, (i.e., consumer electronic products and electronic components). Therefore, the Priority Chemical designation is focused on the use of the chemical in textiles, polystyrene, polybutylene terephthalate, and other non-exempted consumer products.

Further information about toxicity, potential exposure pathways, and current state and federal actions is provided below.

2. Exposure and Environmental Disposition

(Note: This section includes examples of exposure and environmental information. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention

(1) Agency for Toxic Substances and Disease Registry (ATSDR)

Sediments in bodies of water often are reservoirs of decaBDEs. PBDEs do not dissolve easily in water, but lower PBDE congeners have been found to bioaccumulate in fish (ATSDR, 2004).

(2) National Health and Nutrition Examination Survey (NHANES)

Surveys for several PBDE congeners in humans have been conducted by NHANES, though there has been no testing for decaBDE. The surveys show that several congeners continue to be found in human serum. Congener BDE-47 (with four bromine atoms) was found in nearly all of the participants. Four other congeners, BDE-28 (three bromine atoms), BDE-99 (five bromine atoms), BDE-100 (five bromine atoms), and BDE-153 (six bromine atoms) were found in more than 60% of the participants. Levels of BDE-47 appear to have been increasing in human samples in recent years. In several small studies, levels in the U.S. have been found to be greater than levels in residents of other countries, including Japan, Europe, Sweden and Norway (CDC, 2010). The source of these exposures is not entirely clear, but could include food, consumer products, environmental exposures, and the breakdown of more highly brominated chemicals, such as decaBDE (ATSDR, 2004; CDC, 2010).

b. Environmental Protection Agency

(1) Inventory Update Reporting (IUR)

Data from 2006 EPA Inventory Update Reporting (IUR) indicate that decaBDE is used in the following product categories at the indicated rates:

Chemical	Maximum concentration in product category	Used in a product intended for children up to age 14
Adhesives and sealants	1-30%	No
Electrical and Electronic products	1-30%	No
Fabrics, textiles and apparel	1-30%	No
Rubber and Plastic Products	1-30%	No
(EPA, 2010a)		

None of the data indicate that decaBDE was used in products specifically intended for children. However, children use consumer products in these categories, particularly the “fabrics, textiles and apparel” category. Because these data are from 2006, it is not clear how well they reflect current use of the chemical.

(2) Toxic Release Inventory (TRI)

The EPA TRI data show that in 2009 there were 509,839 pounds of decaBDE released in the U.S. In Minnesota in 2009, there were 4,100 pounds of decaBDE released from four companies. These releases were primarily related to on-site land disposal or transfer to a waste broker (i.e., a waste broker took the waste for disposal). This is down from a peak of 20,775 pounds reported released in Minnesota from five companies in 2006. The amount of decaBDE released appears variable since 1998, with an average reported release per year of 7,603 pounds (EPA, 2010c).

An agreement made among the main manufacturers and importers of decaBDE will result in the phase-out of manufacturing and importation of this chemical into the U.S. by 2013. Articles made with decaBDE and recycling of materials containing decaBDE are not affected by this agreement (EPA, 2009).

(3) National Center for Environmental Assessment

Primary sources of human exposure to PBDEs appear to be house dust. Ingestion and dermal contact both contribute to exposure. Infants have the highest exposure to PBDEs through breast milk (EPA, 2010b).

3. Toxicity

(Note: The section below contains information pertaining to toxicity. It is not intended to provide a comprehensive summary.)

a. Centers for Disease Control and Prevention

(1) Agency for Toxic Substances and Disease Registry (ATSDR)

ATSDR reports that nothing definite is known about the toxicity of PBDEs in humans. In laboratory studies, animals that ate small amounts of less brominated congeners of PBDEs over several weeks showed effects in the liver and thyroid, as well as some behavioral effects in the animals exposed as infants (ATSDR, 2004).

(2) National Health and Nutrition Examination Survey (NHANES)

NHANES remarks that decaBDE is less toxic than pentaBDE. The most sensitive endpoints of pentaBDE are neurobehavioral and reproductive toxicity, as shown in animal studies (CDC, 2010).

b. Environmental Protection Agency

Integrated Risk Information System (IRIS)

The IRIS program has listed information for decaBDE as follows, based on animal laboratory studies:

Oral Reference Dose:
 7×10^{-3} mg/kg/day (neurobehavioral effects)
 Uncertainty Factor: 300 (EPA, 2008)

Cancer:
 Suggestive evidence of carcinogenic potential (EPA, 2008)

c. National Institutes of Health

(1) National Toxicology Program (NTP)

NTP tested decaBDE in 1986 and reported some evidence of carcinogenicity in rats, equivocal evidence of carcinogenicity in male mice, and no evidence of carcinogenicity in female mice (National Toxicology Program [NTP], 1986).

(2) National Library of Medicine

Hazardous Substance Data Bank (HSDB)

Animal laboratory studies reported in the HSDB indicate liver effects. Neurobehavioral effects were also found in some studies (HSDB, 2010).

d. World Health Organization

International Agency for Research on Cancer (IARC)

IARC has placed decaBDE in a Group 3 classification: “Not classifiable as to its carcinogenicity to humans.” (International Agency for Research on Cancer [IARC], 1999)

4. Statutory Requirements

The table and information summary below provide current information about decaBDE and how it meets the criteria of Minn. Stat. 2010 116.9401 – 116.9407.

Statute	Information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity		
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm		
Subd. (e)(3) disrupt the endocrine or hormone system		
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	Neurobehavioral effects	EPA 2008 CDC 2010
Subd. (e)(5) be persistent, bioaccumulative, and toxic;	Remains in sediments. Accumulates in some species. Some breakdown congeners have been found to be persistent and bioaccumulative.	ATSDR 2004 Env. Canada 2010 EPA 2009
Subd. (e)(6) be very persistent and very bioaccumulative		

Statute	Information	References
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	50 to 100 million pounds	EPA 2010a
Subd (2) Meets any of the following criteria:		
Subd. (a)(2)(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	Human adipose tissue, blood, breast milk, serum	ATSDR 2004 EPA 2009 HSDB 2010
Subd. (a)(2)(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	Indoor air, household dust	ATSDR 2004 EPA 2009 HSDB 2010
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Ambient air, birds, fish, mussels, water sediments	HSDB 2010 NHANES 2010

5. Current Regulations

a. Federal

There are currently no federal regulations related to decaBDE, though several bills were introduced in Congress in recent years (Library of Congress, 2010).

There is a voluntary phase-out agreement related to the production and importation of this chemical that will be fully in place by December 2013. This phase out does not include articles made with decaBDE or recycling processes (EPA, 2009).

b. States

Within U.S. states, several pieces of legislation have been introduced. The following legislation is related to decaBDE or PBDEs. The summaries are from the Lowell Center for Sustainable Production US State Chemical Policy Database, available at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.

Minnesota

Year: 2008

Minnesota legislation which restricted sale of articles with decaBDE (SF 657) was passed by the Legislature but vetoed by the governor in 2008.

Year: 2007

Minn. Stat. 2010 325E.385-325E.388 (2008)

Prohibits the manufacturing, processing, or distribution of a product or flame-retardant part of a product containing certain concentrations of pentabromodiphenyl ether or octabromodiphenyl

ether. Requires the Commissioner of the Pollution Control Agency to review uses of decabromodiphenyl ether, availability of technically feasible and safer alternatives, fire safety, and any evidence regarding the potential harm to public health and the environment posed by commercial decabromodiphenyl ether and the alternatives. Requires that equipment, supplies, and other products that do not contain polybrominated diphenyl ethers be made available to all state agencies.

Hawaii

Year: 2010

S.R. 107, 25th Leg., Reg. Sess. (Haw. 2010); H.R. 165, 25th Leg. Reg. Sess. (Haw. 2010);

H.C.R. 235, 25th Leg., Reg. Sess. (Haw. 2010)

Statement of support for the phase-out of decaBDE production.

Illinois

Year: 2005

H.B. 2572, 94th Gen. Assemb., Reg. Sess. (Ill. 2005)

Prohibits the manufacture, processing, or distribution of products or flame retardant parts of a product containing more than one tenth of 1% penta-BDE or octa-BDE. Directs the Illinois Environmental Protection Agency to review current literature on the health impacts of and alternatives available to decaBDE by 2006 and submit this report to the Governor. (The Illinois EPA was also instructed to do a follow up study on the environmental impacts of decaBDE in a letter from the governor in 2006.)

Maine

Year: 2010

L.D. 1568, 124th Leg., 2nd Reg. Sess. (Me. 2009)

Prohibits the manufacture and sale of shipping pallets or any product manufactured from recycled shipping pallets containing decaBDE. Permits the Department of Environmental Protection to restrict the use of other flame retardants in plastic shipping pallets if the flame retardant is harmful to the public health and the environment and a safer alternative to the flame retardant is available. Requires that decaBDE be replaced with safer alternatives. Prohibits the replacement of decaBDE with a chemical alternative that is a persistent, bioaccumulative, and toxic chemical or another brominated or chlorinated flame retardant. Permits the Department to supervise an alternatives assessment study to determine the availability of safer alternatives to the use of decaBDE in shipping pallets.

Year: 2009 (Amended)

Me. Rev. Stat. Ann. tit. 38, § 1609 (2008)

Prohibits the sale or distribution of a product containing more than 0.1% of the "penta" or "octa" mixtures of polybrominated diphenyl ethers. Restricts the manufacturing and sale of any mattress, mattress pad, upholstered furniture for indoor use, television or computer that has a plastic housing or contains plastic fibers with the "deca" mixture of polybrominated diphenyl ethers. Permits the Commissioner of Environmental Protection to adopt rules to prohibit the manufacture, sale or distribution of certain products with a flame retardant deemed harmful to human health and the environment and an alternative exists.

Year: 2009

L.D. 1568, 124th Leg., 2nd Reg. Sess. (Me. 2009).

A prohibition on the manufacturing and sale of shipping pallets or materials made with shipping pallets containing decaBDE. The law also requires that decaBDE be replaced with an alternative that is not persistent, bioaccumulative or toxic.

Maryland

Year: 2010

S.B. 556, 427th Gen. Assemb., Reg. Sess. (Md. 2010).

Phases out the use of decaBDE in products. Prohibits the manufacture, lease, sale, or distribution for sale or lease of mattresses, upholstered furniture designed for residential use, and electrical or electronic equipment containing decaBDE by 2010. Prohibits of manufacture, lease, sale, or distribution for sale or lease any product that contains decaBDE by 2012. Prohibits the manufacture, lease, sale, or distribution for sale or lease of transportation equipment, military equipment, or components of transportation or military equipment by 2013.

Year: 2005

Md. Code Ann., Envir. §§ 1201-1205 (2008).

Prohibits the manufacture, processing, sale, or distribution of a new product or flame-retardant part of a new product that contains more than a specified amount of penta- or octa-brominated diphenyl ether. Requires the Department of the Environment, in conjunction with interested parties, to report to the Legislature on the use of decabrominated diphenyl ether (decaBDE) in products sold in the state, any data available on the human body burden or environmental occurrence of decaBDE, recommendations regarding the use, sale, and disposal of products containing decaBDE, and any other recommendations to further protection of public health and the environment from decaBDE.

New York

Year: 2004

N.Y. Envtl. Conserv. Law § 37-0111 (2008).

Prohibits the use of pentabrominated diphenyl ether or octabrominated diphenyl ether in any product or as use as a flame retardant. Creates the state task force on flame retardant safety to, at a minimum, review and report on relevant studies, risk assessments, findings, or rulings in connection with the flame retardant decabrominated diphenyl ether and evaluate the availability of safer alternatives to decabrominated diphenyl ether.

Oregon

Year: 2009

S.B. 596, 75th Leg. Assemb., Reg. Sess. (Or. 2009).

Prohibits introduction or delivery for introduction into commerce any product containing more than one-tenth of one percent by mass of decaBDE.

Year: 2005

S.B. 962, 73rd Leg. Assemb., Reg. Sess. (Or. 2005).

Restricts the introduction into commerce of any product containing pentabrominated diphenyl ether or octabrominated diphenyl ether.

Rhode Island

Year: 2006

R.I. Gen. Laws §§ 23-13.4-1-23-13.4-6 (2008).

Restricts the manufacturing or distribution of flame retardants containing pentaBDE or octaBDE. Requires study on decaBDE.

Vermont

Year: 2009

H. 444, 2009-2010 Leg., Reg. Sess. (Vt. 2009)

Prohibits the sale or distribution of a product containing octaBDE or pentaBDE. Prohibits the manufacture, sale, or distribution of a mattress or mattress pad, upholstered furniture intended for indoor use in a home or other residential occupancy, or a television or computer with plastic housing containing decaBDE. Prohibits a manufacturer from replacing decaBDE with a chemical that is classified as "known to be a human carcinogen" or "reasonably anticipated to be a human carcinogen" or is identified by the U.S. EPA as causing birth defects, hormone disruption, or harm to reproduction or development.

Washington

Year: 2007

Wash. Rev. Code Ann. §§ 70.76.005-70.76.110 (2008)

Restricts the sale of noncombustible products containing PBDEs and mattresses containing commercial decaBDE. Requires the Department of Ecology and the Department of Health to study alternatives to PBDEs and decaBDEs. Restricts the sale of televisions, computers, and residential upholstered furniture containing decaBDE as a result of the Departments' finding that safer and technically feasible alternatives that meet fire safety standards are available.

(Lowell Center for Sustainable Production, 2010)

6. Planned Actions

a. Federal

Environmental Protection Agency

The EPA has created a Chemical Action Plan for PBDEs. Within the plan, risks to children's health are discussed, as well approaches to control these risks through both regulatory and voluntary actions (EPA, 2009). Some of the planned actions include:

- Support voluntary phase out of manufacture or importation of decaBDE. A voluntary phase out is already underway, with an ultimate cessation of manufacturing and importation of decaBDE by December 31, 2013. EPA states it will encourage other importers that are not participating in this agreement to also cease importation. However, articles made with decaBDE are not currently part of this agreement (EPA, 2009) and importation of articles already treated with decaBDE could continue.
- Initiate significant new use rule (SNUR) rulemaking under the Toxic Substances Control Act (TSCA) that would prohibit manufacturer or importation of decaBDE (excluding articles containing decaBDE). A SNUR would require a 90-day notice be filed with EPA

before beginning manufacture or importation of a chemical. Under TSCA, EPA could evaluate the use and impose restrictions or prohibitions on the new activity.

- EPA proposes simultaneously creating a SNUR designating manufacture and importation of decaBDE and articles made with decaBDE a significant new use, and a test rule under section 4 of TSCA. The test rule would require information about effects of manufacturing, use or other activities related to decaBDE. It would implement this test rule, rather than the SNUR, if decaBDE continues to be manufactured or imported into the U.S.
- Initiate rulemaking under TSCA section 5(b)(4) to add commercial PBDE mixtures and congeners to a list of chemicals which could present unreasonable risk to health or the environment.
- Conduct an alternatives analysis for commercial decaBDE mixtures. This analysis would be intended to assist users of decaBDE in finding suitable alternatives.

Activities not related to decaBDE that EPA intends to initiate:

- Initiate significant new use rule (SNUR) rulemaking under the Toxic Substances Control Act (TSCA) that would prohibit manufacturer or importation of articles with added pentaBDE or octaBDE.

b. States

Washington

Under the Children's Safe Products Act, Washington has named decaBDE a Chemical of High Concern for Children. Washington plans to implement reporting requirements for manufacturers related to this designation (Washington, 2010).

7. Conclusion

The toxicity, persistence, pervasiveness and potential to degrade into lower congeners are characteristics for which decaBDE is being named a Minnesota Priority Chemical. The planned phase-out of this chemical may help to reduce the presence of decaBDE and its breakdown products in the environment. However, decaBDE may continue to be used in articles and will continue to be present during recycling activities. New information about the chemical that becomes available will be monitored.

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D. Formaldehyde

CAS number: 50-00-0

1. Overview

Formaldehyde is used in a wide number of applications. It can be used as a solvent, a fixative, and to make binders or adhesives such as phenol, urea, or melamine resins. Examples of products made using formaldehyde are insulation, composite wood, paints, laboratory solutions, cosmetics, personal care products and preservatives (Agency for Toxic Substances and Disease Register [ATSDR], 1999; National Toxicology Program [NTP], 2010). The Environmental Protection Agency (EPA) Inventory Update Reporting (IUR) data show that for each of the five inventories since 1990, one billion pounds or more of formaldehyde was produced or imported into the U.S. (Environmental Protection Agency [EPA], 2010a). Living systems also produce formaldehyde in small amounts. It does not persist in the environment nor does it bioaccumulate.

Formaldehyde volatilizes easily and is pervasive in the air. Outdoor ambient air sample concentrations of formaldehyde have been reported at 0.2 ppb in rural areas and 10-20 ppb urban and industrial areas (ATSDR, 1999). Often, formaldehyde concentration is higher in indoor air, though the levels depend on the type of building materials used in the structure's construction and the type of materials inside the structure (e.g., furniture, paints). Levels up to 800 ppb have been reported in residences, but the overall median was 2.5 ppb (ATSDR, 1999).

Formaldehyde can cause respiratory and eye irritation, and may contribute to symptoms of asthma (EPA, 2010b; International Agency for Research on Cancer [IARC], 2006). EPA has created a draft document with candidate Reference Concentrations for formaldehyde in the range of 2.8 ppb to 11 ppb based on respiratory endpoints. Dermal contact with formaldehyde can be irritating to skin, with evidence that formaldehyde can cause skin sensitization (ATSDR, 1999; EPA, 2010b; IARC, 2006). Formaldehyde will also irritate the gastrointestinal tract when ingested (ATSDR, 1999).

Formaldehyde has been associated with nasal cancers in workers exposed to formaldehyde in occupational settings (ATSDR, 1999; EPA, 2010b; NTP, 2010). It has been named a Group 1 carcinogen by the International Agency for Research on Cancer (IARC), meaning "there is sufficient evidence in humans for the carcinogenicity of formaldehyde" (IARC, 2006). The National Toxicology Program (NTP) classified formaldehyde as "reasonably anticipated to be a human carcinogen," though there is currently a proposal to reclassify formaldehyde as "known to be a human carcinogen" (NTP, 2010). The EPA Integrated Risk Information System (IRIS) currently lists formaldehyde as Class B1: probable human carcinogen, though the draft IRIS document states "Formaldehyde is Carcinogenic to Humans by the Inhalation Route of Exposure" (EPA, 2010b).

In summary, formaldehyde is pervasive, causes eye and respiratory effects, is carcinogenic and can be found at relatively high levels in indoor air concentrations (EPA, 2010b). As described below, recent federal legislation related to formaldehyde emissions from wood composites will help to reduce human exposure to formaldehyde in indoor environments. Consumer awareness also will be a factor that can help reduce risks to children from formaldehyde in certain consumer products.

2. Exposure and Environmental Disposition

(Note: The section includes examples of exposure and environmental information. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention (CDC)

Agency for Toxic Substances and Disease Registry (ATSDR)

The Toxicological Profile for formaldehyde notes that formaldehyde is produced naturally and through human activity. Examples of formaldehyde concentrations typically in indoor air (median 2.5 ppb) and outdoor air (1 ppb – 68 ppb) are provided. Indoor air is one of the primary routes of exposure to formaldehyde for the general public, though reduction in use of urea-formaldehyde insulation foam has reduced the amount of formaldehyde in residences.

Manufactured wood products have been another source of formaldehyde in indoor air (ATSDR, 1999).

b. Environmental Protection Agency

(1) Inventory Update Report (IUR)

Data from the 2006 EPA IUR indicate that formaldehyde is used in the following product categories at the indicated rates:

Chemical	Maximum concentration in product category	Used in a product intended for children up to age 14
Adhesives and sealants	31-60%	NRO
Fabrics, textiles and apparel	31-60%	No
Glass and ceramic products	31-60%	No
Lawn and garden products (non-pesticide)	31-60%	No
Other	31-60%	No
Paper Products	1-30%	No
Rubber and Plastic Products	NRO	NRO
Transportation Products	31-60%	No
Wood and Furniture	31-60%	No
NRO = "not readily obtainable"		
(EPA, 2010a)		

None of the products listed indicate specific intent for children. However, children use or contact consumer products in these categories, such as Rubber and Plastic products and Wood and Furniture.

(2) EPA Toxic Release Inventory (TRI)

The EPA Toxic Release Inventory (TRI) data show that in 2009 there were about 14.6 million pounds of formaldehyde released in the United States (EPA, 2010d). In Minnesota in 2009, there were 47,692 pounds of formaldehyde released from 15 companies (EPA, 2010c). Most of these releases were point source air emissions (e.g., stack discharge). This is down from a peak of 758,994 pounds reported released in Minnesota from 18 companies in 1988. In the past ten years, the highest quantity of formaldehyde released was 353,553 pounds in 2003 from stack or point source air emissions or fugitive air emissions (EPA, 2010e).

c. National Institute of Health (NIH)

(1) Household Products database

As of November 2010, the Household Products Database lists 45 products that contain formaldehyde. Examples of product use categories are arts and crafts, home maintenance, personal care products, and pet care. Most of the products list formaldehyde at levels of 2.5% of the product composition or lower, though a fish pond treatment product is listed at 10% - 25% formaldehyde (National Library of Medicine [NLM], 2010). This list represents products for which material safety data sheets (MSDSs) are available. Products like furniture and cabinets do not appear to be included in this database.

(2) Hazardous Substances Data Bank (HSDB)

HSDB indicates formaldehyde is used in pesticides, disinfectants, resins, plastics, fertilizers, foam insulation, textile finish, preservatives, stabilizers, food additives, embalming fluids, brightening agent, chemical production, and for several other purposes (Hazardous Substance Data Bank [HSDB], 2010).

3. Toxicity

(Note: This section includes examples of toxicity information. This summary is not intended to be comprehensive.)

a. Environmental Protection Agency

Integrated Risk Information System (IRIS)

In June 2010, IRIS published draft candidate Reference Concentrations (RfC) and a carcinogenicity characterization for formaldehyde. The draft document containing this information is under review. Reference Dose (RfD) and carcinogenicity information were available in IRIS from prior work.

Oral Reference Dose:

2×10^{-1} mg/kg/day (reduced weight gain – histopathology)

Uncertainty Factor: 100 (EPA, 1990)

Cancer: B1 Probable human carcinogen (EPA, 1991)

Candidate Reference Concentrations (range: draft only)

2.8 – 11 ppb

Uncertainty Factor: to be determined (EPA, 2010b)

b. National Institutes of Health

National Toxicology Program (NTP)

The NTP listed formaldehyde as “reasonably anticipated to be a human carcinogen” in 1981 (NTP, 2005), and is currently evaluating a possible change in classification to “known to be a human carcinogen” (NTP, 2010). NTP has assembled a background document on formaldehyde as part of this process, available at

http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/November/Formaldehyde_BD_Final.pdf.

Formaldehyde is also noted as an eye, respiratory, and skin irritant, and a skin sensitizer.

c. World Health Organization

International Agency for Research on Cancer (IARC)

In 2006, IARC published “IARC Monographs of the Evaluation of Carcinogenic Risks to Humans. Formaldehyde, 2-Butoxyethanol, and 1-tert-Butoxypropan-2-ol” (IARC, 2006). This document contains an overview of the toxicity of formaldehyde, including carcinogenic effects, and classifies formaldehyde as a Group 1 carcinogen.

4. Statutory Requirements

The table and information summary below provide some of the current information about formaldehyde and indicates how it meets the criteria of Minn. Stat. 116.9401 – 116.9407.

Statute	Information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity		
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	EPA IRIS: B1: Probable human carcinogen IARC: Group I: Sufficient evidence in humans for the carcinogenicity of formaldehyde. NTP: Reasonably anticipated to be a human carcinogen <i>Note: There is a proposal for NTP to change its rating of formaldehyde to: “Known to be a human carcinogen.”</i> Reproductive effects	EPA 1991 IARC 2006 NTP 2005 NTP 2010 EPA 2010b
Subd. (e)(3) disrupt the endocrine or hormone system		
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	Nervous system effects Eye irritation Respiratory effects Skin irritation, skin sensitization Immune system effects	ATSDR 1999 EPA 2010b ATSDR 1999 EPA 2010b ATSDR 1999 EPA 2010b NTP 2010 ATSDR 1999 NTP 2010 IARC 2006 EPA 2010b NTP 2010
Subd. (e)(5) be persistent, bioaccumulative, and toxic;		

Statute	Information	References
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	1 billion pounds or more	EPA 2010b
Subd (2) Meets any of the following criteria:		
Subd. (a)(2)(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		
Subd. (a)(2)(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	Indoor air	ATSDR 1999 EPA 2010b HSDB 2010
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Found in ambient air	ATSDR 1999 EPA 2010b HSDB 2010

5. Current Regulations and Planned Actions

a. Federal

(1) Consumer Product Safety Commission (CPSC)

Because urea-formaldehyde insulation can off-gas formaldehyde in the first months after being installed, in 1982 the CPSC voted to ban this type of insulation in the U.S. The ban was repealed by the courts in 1983 (CPSC, 1997). The CSPC continues to provide information to consumers about safe levels of formaldehyde.

(2) Environmental Protection Agency

Pressed or composite woods can off-gas formaldehyde into the indoor environment. Manufacturers have reduced the amount of formaldehyde released from pressed wood products when compared to products from several decades ago.

The amount of formaldehyde released from many of these products should decline even further after the implementation of the Formaldehyde Standards for Composite Wood Products Act, which was signed into law in 2010 and will be implemented in stages during the next few years. Under the new regulation, both domestically manufactured and imported composite wood will need to comply with formaldehyde emissions standards. The emission limits vary based on the type of wood used in the product. The Act contains requirements similar to the State of

California Air Resources Board standards. Because most U.S. manufacturers were already in compliance with the California requirements, many welcomed the new legislation as a way to equalize the requirements for domestic and imported composite wood products (Composite Panel Association, 2009).

This new law will require EPA to create rules under the Toxic Substances Control Act (TSCA) to test and certify standards in manufacturing facilities and products.

b. States

Examples of state-level regulations: Information for states was obtained from the Lowell Center for Sustainable Production's U.S. State Chemicals Policy database, available from <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>. (The information below is not intended to be comprehensive.)

Minnesota

Year: 1994

Health Risk Limit for Formaldehyde: 1000 µg/L (in groundwater) (MDH, 2010b)

Year: 2002

Acute Health Risk Value for Formaldehyde: 94 µg/m³ (in air) (MDH, 2010a)

Year: 2006

Chronic Risk Assessment Advice: 2 µg/m³ (in air) (MDH, 2006)

California

Year: 2007

Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products - 2007

This law establishes limits on the amount of formaldehyde that can be emitted from composite wood products.

California Inhalation Reference Exposure Level for formaldehyde: 2 ppb

Massachusetts

Year: 1960

A law requires urea-formaldehyde foamed in place insulation to be banned from commerce.

New Hampshire:

Year: 1965

A law bans urea-formaldehyde foam insulation and requires that particle board manufactured with urea-formaldehyde or homes manufactured with urea-formaldehyde not be sold without a cautionary warning.

Washington

Year: 2010

Under the Children's Safe Product Act, formaldehyde was named a Chemical of High Concern for Children. Washington plans to implement reporting requirements for manufacturers related to this designation (Washington, 2010).

6. Conclusion

Because formaldehyde causes respiratory effects, is a carcinogen, and there is potential that children will be exposed to it in the home, MDH is naming formaldehyde a Priority Chemical.

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E. 1,2,5,6,9,10-Hexabromocyclododecane (HBCD)

CAS Number 3194-55-6

1. Overview

1,2,5,6,9,10-Hexabromocyclododecane (HBCD) is a flame retardant primarily used for expanded polystyrene foam and extruded foam, which are used in building insulation. HBCD can also be used as a fire retardant for textiles in furniture. This chemical is added to products – it is not chemically bound. Therefore it is more likely to dislodge from the product over time during use or after disposal (Environmental Protection Agency [EPA], 2010b; Government of Canada, 2010b).

According to the U.S. Environmental Protection Agency (EPA), HBCD is persistent by some measures, mobile in the environment and very bioaccumulative. EPA has noted that HBCD has low persistence according to half-life criteria set forth in the EPA Toxic Substances Control Act (TSCA) pre-manufacture notice program and the international Persistent Organic Pollutant protocol (EPA, 2010b). However, like other brominated flame retardants, this manmade chemical has been found in unexpected places in the natural environment, including the Arctic (European Commission [EC], 2008; European Chemicals Agency [ECHA], 2008; EPA, 2010b). A European risk assessment indicated HBCD has high potential for long range transport. Further, the concentration of HBCD has been found to be increasing in some wildlife, such as in guillemot eggs in the Baltic Sea (EC, 2008). Therefore, EPA suggests that HBCD is persistent in the environment with capability of long-range transport, as well as being very bioaccumulative (EPA, 2010b).

Concern has prompted some U.S. federal programs, such the EPA's Integrated Risk Information System (IRIS), the EPA Toxic Release Inventory (TRI) program and the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES), to propose further assessment or monitoring. In addition, the European Union has named HBCD a Substance of Very High Concern, prompting additional requirements to be followed by producers and importers in the European Union (ECHA, 2008).

The health effects on children from low dose exposures have not been determined, but this chemical is pervasive in the environment. In laboratory studies on mammals, HBCD has been found to affect the thyroid (EPA, 2010b). The European Commission has also noted concerns about possible reproductive toxicity (EC, 2008). Because HBCD can be used as a substitute for decabromodiphenyl ether (decaBDE) in some applications (Minnesota Pollution Control Agency [MPCA], 2008), use might increase in coming years as decaBDE is phased out. For these reasons, this chemical is being named as a Minnesota Priority Chemical.

Information about the toxicity, exposure routes, and proposals related to HBCD can be found below.

2. Exposure and Environmental Disposition

(Note: This section includes examples of exposure and environmental information. This summary is not intended to be comprehensive.)

a. Environmental Protection Agency (EPA)

(1) Inventory Update Report (IUR)

The 2006 IUR data show that 10 to 50 million pounds of HBCD were produced or imported into the United States during 2005 (EPA, 2010a). The two categories for this substance listed are:

Chemical	Maximum concentration in product category	Use in children's products
Fabrics, textiles, and apparel	1%-30%	No
Rubber and plastics	1%-30%	No
(EPA, 2010a)		

Neither of the product categories listed indicates specific intent for children. However, children use, contact, or are in proximity to textiles, like furniture and curtains, which could contain this substance.

(2) Toxic Release Inventory (TRI)

Reporting on HBCD releases is currently not required in the TRI. EPA plans to initiate rulemaking to require reporting of HBCD releases (EPA, 2010b).

b. National Institutes of Health (NIH)

(1) Hazardous Substances Data Bank (HSDB)

HBCD has been found in minnows (Hazardous Substances Data Bank [HSDB], 2010).

(2) Household Substances Database

The Household Substances Database lists eight insulation products that contain HBCD in the range of 0.5% to 1.5%. One of these products is listed as an “old product” (National Library of Medicine [NLM], 2010b). Because this database only contains information for which there is a material safety data sheet (MSDS), it is unlikely that products such as furniture upholstery would be listed in this particular source (NLM, 2010a).

3. Toxicity

(Note: The section below contains excerpts pertaining to the toxicity of the substance. It is not intended to provide a comprehensive summary.)

a. Canadian Government

The Canadian Government has conducted a preliminary assessment of HBCD. In the draft assessment results, Canada found that “HBCD has the potential to remain in the environment for a long time, accumulate in organisms and cause harm to organisms.” The Canadian government did not consider HBCD a threat to human health at the levels of current exposure. However, the government is considering methods to reduce releases to the environment (Government of Canada, 2010a).

b. Environmental Protection Agency

(1) Action Plan

The EPA Hexabromocyclododecane Action plan, which contains summaries of study results, notes that disturbances in the thyroid hormone system were observed in both male and female rats in laboratory studies after repeated exposure to HBCD. Further, transient changes in learning and memory were observed in males, and delayed eye opening was observed in second generation offspring. There was high, dose-dependent pup mortality during lactation (EPA, 2010b).

(2) Integrated Risk Information System (IRIS)

IRIS currently contains no information related to HBCD. However, HBCD was nominated for review and it is presently on the IRIS agenda, though a date for completion has not been determined (EPA, 2010c).

4. Statutory Requirements

The following table shows how HBCD meets the statutory requirements of Minn. Stat. 2010 116.9401 – 116.9407.

Statute	Relative information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity	Developmental effects	EC 2008 EPA 2010b
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm		
Subd. (e)(3) disrupt the endocrine or hormone system	Thyroid effects	EC 2008 ECHA 2008 EPA 2010b
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity		
Subd. (e)(5) be persistent, bioaccumulative, and toxic	Persistent, Bioaccumulative and Toxic	EC 2008 ECHA 2008 EPA 2010b
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	10 million to 50 million	EPA 2010b
Subd (2) Meets any of the following criteria:		
Subd. (a)(2)(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	Adipose tissues, blood, breast milk, serum,	EPA 2010b

Statute	Relative information	References
Subd. (a)(2)(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	Household dust, indoor air	EPA 2010b Government of Canada, 2010a and 2010b
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Wildlife	EC 2008 HSDB 2010

5. Current Regulations

a. Federal

There do not appear to be current federal laws regulating manufacture or use of HBCD.

b. States

There do not appear to be current state laws related to HBCD.

6. Planned Actions

a. Federal

Environmental Protection Agency

The EPA has indicated that it plans to consider the following actions related to HBCD in order to protect human health and the environment:

- Initiating rulemaking under TSCA 5(b)(4) to add HBCD to the list of chemicals that may present risk to human health or the environment. This is planned for the end of 2011.
- Initiating rulemaking under TSCA 5(a)(2) to develop a significant new use rule (SNUR) related to domestic manufacturing or processing of HBCD for use as a flame retardant on consumer textiles. The SNUR would also apply to importing textiles containing HBCD. This would require manufacturers to notify EPA before any use of this sort is initiated. EPA would have the opportunity to review the use and prohibit it.
- Initiating rulemaking under TSCA section 6(a) to regulate HBCD. This could allow prohibition of the manufacturing, processing, or distribution of the substance. EPA notes that the rule could be targeted as appropriate.
- Adding HBCD to the EPA Toxic Release Inventory, requiring manufacturers or importers to report releases to the environment.
- Conducting an alternatives assessment under the EPA's Design for the Environment and Green Chemistry program.

b. States

Washington

Year: 2010

HBDCD (under CAS # 25637-99-4), has been placed on the Washington Chemicals of High Concern for Children list under the Children's Safe Products Act. Washington plans to implement reporting requirements for manufacturers related to this designation (Washington, 2010).

7. Conclusion

HBDCD is being named a Minnesota Priority Chemical because it is persistent, bioaccumulative, and toxic and it has been found in the home environment. It is likely that children are exposed to the chemical through house dust and breast milk. Further, in laboratory studies on mammals, this chemical has been found to affect the thyroid and show possible toxicity to the reproductive system. Concern about this chemical has prompted the U.S. EPA to create an action plan. An additional review has been proposed by the EPA IRIS program and inclusion in NHANES is being considered. Research related to this chemical continues, and MDH will monitor results.

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F. Lead

CAS Number 7439-92-1

1. Overview

Lead is a soft metal that is found naturally in the earth's crust. Before 1978, lead was frequently used in paints. Lead paint can still be found in many older residential structures. Other examples of uses of lead are in gasoline (formerly), piping, solder, coatings, glazes, leaded crystal, jewelry and toys.

Lead, a neurotoxin, is a danger for young children when it is ingested. Lead in household dust, paint chips, toys or jewelry may be ingested by young children when they chew, mouth, or swallow items or crawl on the floor and mouth their hands.

There are standards in the U.S. for the amount of lead that can be used in children's toys, but in some cases products are not in compliance and children are exposed to lead. An example of this occurred in 2006 when a young boy in Minnesota died from acute lead poisoning after ingesting a charm that did not comply with lead standards. In 2010, the Consumer Product Safety Commission (CPSC), which is responsible for monitoring compliance with federal consumer safety product standards, made 24 recalls of infant and children's products that contained more than permitted levels of lead. Often the recalls involved imported items, though some products were manufactured in the U.S. (Consumer Product Safety Commission [CPSC], 2010b).

Because of its toxicity, pervasiveness, and continued effect on children despite regulatory action, lead is being named a Minnesota Priority Chemical.

Further information about exposure, toxicity, and regulation are described below.

2. Exposure and Environmental Disposition

(Note: This section includes examples of exposure and environmental information. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention

(1) Agency for Toxic Substances and Disease Registry (ATSDR)

People can be exposed to lead from contaminated soil, dust, drinking water that has been transported in lead pipes, and lead paint chips. Jewelry can also contain lead that can be transferred to the skin, but the skin does not absorb lead readily (Agency for Toxic Substances and Disease Registry [ATSDR], 2007). Other potential sources of exposure, particularly for infants and children, are breast milk, toys, hair dyes, cosmetics and some home remedies.

(2) National Health and Nutrition Examination Survey (NHANES)

Sources of exposure to lead can include lead paint chips, water transported in lead pipes, ceramics coated with lead-based glaze, stained glass window framing, toys and trinkets, lead on the clothing of workers in certain occupations, lead-containing cosmetics and home remedies (Centers for Disease Control and Prevention [CDC], 2010a).

For adults, NHANES reports that blood lead levels (BLLs) have been declining over the past decade, with the U.S. adult BLLs similar or slightly lower than in other developed countries. In the 2005-2006 data, the geometric mean of the adult BLL was 1.41 µg/dL (CDC, 2010b).

For children, lead levels have also been decreasing over time. In the 2005-2006 data, the geometric mean for children age less than 5, the geometric mean was 1.46 µg/dL (CDC, 2010b). However, children with certain risk factors, such as non-white minority race, urban residence, or low family income tend to have higher BLLs (CDC, 2010a).

b. Consumer Product Safety Commission (CPSC)

In 2010, there were 24 recalls of children's or infant products listed on the CPSC website. Some of the recalled items were children's jewelry (CPSC, 2010b). Most, but not all, of these recalls involved materials produced outside of the U.S. At least one of the recalled products involved the need to treat a child for high lead levels (CPSC, 2010c).

c. Environmental Protection Agency (EPA)

(1) Inventory Update Reporting (IUR)

Lead was produced or imported into the U.S. at quantities of 1 billion pounds or more in the 2006 EPA Inventory Update Reporting (IUR) data (Environmental Protection Agency [EPA], 2010a). No use information was available for inorganic chemicals in this inventory, but usage information for inorganic chemicals will be required in the 2011 inventory.

(2) Toxic Release Inventory (TRI)

In 2009, there were about 14.3 million pounds of lead reportedly released to the environment in the U.S. (EPA, 2010d). In Minnesota in 2009, there were 12,973 pounds of lead released from 109 sites throughout the state (EPA, 2010c). The primary release method was disposal to off-site storage for an indefinite time and to landfills. This is an increase from the amounts reported released annually in Minnesota from 2002 - 2008, but a decrease from the peak in 1998, when 293,303 pounds of lead were released (EPA, 2010e).

d. Minnesota Department of Health (MDH)

In 2009, there were 778 children with high BLLs reported in Minnesota (Minnesota Department of Health [MDH], 2010a). While the BLLs in children have been decreasing, the goal is to eliminate this preventable condition. Lead poisoning in children often is related to ingestion of paint chips in older homes, though exposure to toys and other products containing lead can also result in lead exposure.

e. National Institutes of Health

(1) Hazardous Substances Data Bank (HSDB)

Lead has been found in wildlife (Hazardous Substances Data Bank [HSDB], 2010) and may appear in food.

Maternal milk might be a source of lead for offspring, particularly when the mother has elevated BLLs (HSDB, 2010).

(2) Household Products Database

In the Household Products Database, there are currently eight products containing lead. Six of these products are solder, one is ceramic glaze, and one is a colorant for landscaping concrete. The lead content listed for these items ranges from 0 to 100%, with some at 30-60% (National Library of Medicine [NLM], 2010). Because the Household Product Database provides information found in material safety data sheets (MSDS), if an MSDS is not required for the product, it is unlikely the product will appear this database.

3. Toxicity

(Note: This section provides examples of toxicity information from several sources. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention

(1) Agency for Toxic Substances and Disease Registry (ATSDR)

Lead targets the nervous system in humans. It can result in weakness, increased blood pressure, anemia, and brain and kidney damage. High exposure levels can result in miscarriage or affect sperm production. Exposures to lead can affect development and behavior in children (ATSDR, 2007).

(2) National Health and Nutrition Exposure Survey (NHANES)

Lead can interfere with actions of nutrients, enzymes, regulatory proteins, and other physiological mechanisms in the body, as well as gene expression. Lead poisoning can result in anemia, kidney damage, seizures, abdominal pain, and neurocognitive effects (CDC, 2010a).

b. Environmental Protection Agency

(1) Integrated Risk Information System (IRIS)

Cancer: B2 (Probable human carcinogen) (EPA, 1990)

(2) Office of Pollution Prevention and Toxics (OPPT)

Lead is known to be toxic to the neurological system, with manifestations of conditions such as lowered intelligence, decreased coordination, behavioral and learning problems, slowed growth, and hearing problems (EPA, 2010b).

c. National Institutes of Health

National Toxicology Program (NTP)

For carcinogenic potential, lead has been classified as: Reasonably anticipated to be a human carcinogen (National Toxicology Program [NTP], 2004).

d. World Health Organization

International Agency for Research on Cancer (IARC)

Lead is classified as a Group 2A carcinogen: Probably carcinogenic to humans (International Agency for Research on Cancer [IARC], 2006).

4. Statutory Requirements

In relation to Minn. Stat. 2010 116.9401-116.907, lead meets the following criteria:

Statute	Information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity	Developmental effects	ATSDR 2007
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	Reproductive effects Cancer: EPA IRIS: B2 probable human carcinogen Cancer: IARC: Probably carcinogenic to humans (Group 2A). Cancer: NTP: Reasonably anticipated to be a human carcinogen	ATSDR 2007 EPA 1990 IARC 2006 NTP 2004
Subd. (e)(3) disrupt the endocrine or hormone system	Disruption at high blood lead levels	ATSDR 2007
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	Neurotoxicity Kidney damage	ATSDR 2007 ATSDR 2007 CDC 2010a
Subd. (e)(5) be persistent, bioaccumulative, and toxic;	(The EPA has designated lead as a PBT for the Toxic Release Inventory program.)	EPA 2001
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	1 billion pounds or greater	EPA 2010a
Subd (2) Meets any of the following criteria:		
Subd. (a)(2)(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	Blood, tissue, breast milk	ATSDR 2007 CDC 2010a HSDB 2010
Subd. (a)(2)(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	Household dust, indoor air, drinking water	ATSDR 2007 CDC 2010a EPA 2010b
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Fish, wildlife (also a naturally occurring element)	HSDB 2010

5. Current Regulations

a. Federal

(1) Consumer Product Safety Commission (CPSC)

Standards related to lead in children's toys have been in place for many years. In 2008, the Consumer Product Safety Improvement Act (CPSIA) lowered the limits allowable in children's toys. During a phase-in period, the allowable levels of total lead by weight for any part of a children's toy dropped from 600 ppm in February 2009 to 300 ppm in August 2009. In August 2011, the limit is scheduled to drop to 100 ppm. However, the CPSC is yet determining if the 100 ppm level is feasible. After August 2009, a limit of 90 ppm on the surface coatings on consumer products went into effect (CPSC, 2010a). There have been several recent recalls related to children's products for unacceptably high lead content.

(2) Environmental Protection Agency

In 2010, EPA enacted a rule intended to minimize potential hazards related to lead during renovation. This rule has requirements for contractors performing renovation to ensure that homeowners and tenants are informed about lead in the home. Contractors are also required to complete certification concerning knowledge of safe lead practices (MDH, 2010b). For more information, please see <http://www.health.state.mn.us/divs/eh/lead/prof/pre/index.html> or <http://www.epa.gov/lead/pubs/lscp-press-materials.htm>.

b. States

Several states have enacted regulations to reduce lead use and/or exposure. Many states have laws prohibiting certain metals from packaging and restricting lead components in automobiles and recreational equipment. Because most of these products are excluded from the requirements of Minn. Stat. 2010 116.9401-116.9407, these items are not included here.

Aside from packaging, automobile and recreational equipment-related legislation, the following information, taken from The Lowell Center for Sustainable Production, US State Chemicals Policy database at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>, describes state-level legislation related to lead for uses that could pertain to children.

Minnesota

Year: 2007

Minn. Stat. 325E.389 (2008)

Restricts the sale or manufacturing of any jewelry that is offered for sale in Minnesota unless the jewelry is made entirely from a Class 1, Class 2, or Class 3 material. Prohibits the sale of any jewelry as children's jewelry or body piercing jewelry represented to contain safe levels of lead, unless the jewelry meets certain requirements. (Became effective August 30 and 31, 2009)

California

Year: 2010 (Amendment)

Cal. Health & Safety Code §§ 108550-108585

Prohibits the manufacture or sale of any toy contaminated with any toxic substance, coated with paints and lacquers containing compounds of lead, or coated with soluble compounds of antimony, arsenic, cadmium, mercury, selenium or barium.

Year: 2006

Cal. Health & Safety Code §§ 25214.1-25214.4.2

Prohibits a person, on and after March 1, 2008, from manufacturing, shipping, selling, or offering for sale jewelry, body piercing jewelry and children's jewelry for retail sale in the state, unless it contains less than 200 or 600 parts per million of lead by weight (standard varies by material). Includes civil and criminal penalties for a person who violates the prohibitions. Specifies the testing methods and protocols for determining compliance with the prohibitions.

Year: 1997

Cal. Health & Safety Code §§116875-116880

Concerns prohibitions on the use of lead in water pipes

Prohibits the use of any pipe, pipe or plumbing fitting or fixture, solder, or flux that is not lead free (not more than 0.2% lead with respect to solder and flux and not more than 8% lead with respect to pipes and pipe fittings) in the installation or repair of any public water system or any plumbing in a facility providing water for human consumption. Prohibits the introduction into commerce of any pipe, pipe or plumbing fitting, or fixture that is not lead free. Prohibits people engaged in the business of selling plumbing supplies, except manufacturers, from selling solder or flux that is not lead free. Requires labeling of solder and flux that is not lead free.

Connecticut

Year: 2008

H.B. 5650, 2008 Gen. Assemb., Feb. Sess

Requires the Commissioners of Public Health and Environmental Protection to compile a list of toxic substances and the recommended maximum amount of such toxic substances that may exist in children's products. Requires the Commissioner of Consumer Protection to compile a list of safer alternatives to using said toxic substances. Requires certain consumer products determined by the Commissioner of Consumer Protection that bear lead-containing paint or that have lead in any part of the product and that a child may reasonably or foreseeably come into contact with, to carry a warning label. Permits the Commissioner of Consumer Protection to adopt a stricter standard than one hundred parts per million total lead content by weight for any part of a children's product if the Administrator determines that a stricter standard is feasible. Permits the Commissioner of Environmental Protection to participate in an interstate clearinghouse to (1) prioritize chemicals existing in commercial goods; (2) organize and manage available data on chemicals; (3) produce and inventory information on safer alternatives for specific uses of chemicals and model policies and programs related to such alternatives; and (4) provide technical assistance to businesses and consumers relating to safer chemicals.

Delaware

Year: 2008

H.B. 362, 144th Gen. Assemb., Reg. Sess. (Del. 2008).

Prohibits the sale of a toy that contains a toxic substance (defined as lead or a coating on an item that contains lead or a substance that has been deemed toxic or harmful to the health of children by the U.S. Consumer Product Safety Commission).

Illinois

Year: 2007 (Amendment)

410 Ill. Comp. Stat. Ann. 45/1-45/17 (2008).

Amends existing legislation to strengthen protection from lead poisoning in children. Prohibits the addition of lead to surfaces children occupy, or which children could put in their mouths, including toys, jewelry, furniture.

Louisiana

Year: 1998 (Amendment)

La. Rev. Stat. Ann. §§ 40:1299.26 (2008)

Prohibits the sale or application of lead-based paint or similar surface coating material on toys or articles intended for use by children, residential furniture and fixtures that can be readily chewed by children, and cooking, eating, and drinking utensils. Prohibits the sale of any toy or other article intended for use by children, residential furniture, cooking, drinking or eating utensils to which any lead-based paint or similar surface coating material has been applied

Maine

Year: 2008

Me. Rev. Stat. Ann. tit. 22, § 1316-A (2008)

Restricts the sale, manufacture or distribution of lead-containing children's products.

Year: 2006

Exec. Order Promoting Safer Chemicals in Consumer Products and Services (February 22, 2006)
Requires the Department of Environmental Protection to incorporate readily available information on source reduction and safer alternatives to hazardous chemicals in consumer products into their public education efforts. Requires the Department to continue to virtually eliminate mercury from human caused sources, assess lead-free alternatives to the current use of lead in consumer products, and review emerging information related to the availability of alternatives to brominated flame retardants. Requires executive branch agencies to avoid products and services that contain, use, or release chemicals that are PBTs or carcinogens whenever safer alternatives are available, effective, and affordable. Creates the Governor's Task Force to Promote Safer Chemicals. Requires the Task Force to identify and promote the use and development of safer alternatives to hazardous chemicals in consumer goods and services made, provided, or sold in Maine.

Maryland

Year: 2010

H.B. 372, 427th Gen. Assemb., Reg. Sess. (Md. 2010)

Requires the use of lead-free pipes, pipe fittings, plumbing fittings, fixtures, solder, or flux in the installation or repair of plumbing intended to dispense water for human consumption. Prohibits the sale of pipes, pipe fittings, plumbing fittings, or fixtures that will be used in the installation or repair of any plumbing that dispenses water for human consumption unless they are lead-free. Prohibits the sale of solder or flux that is not lead-free unless the solder or flux bears a label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing that dispenses water for human consumption.

Year: 2009

H.B. 119, 426th Gen. Assemb., Reg. Sess. (Md. 2009)

Amends existing legislation prohibiting lead-containing children's products (See H.B. 62). Clarifies the manufacturers and importers that are required to perform certain testing and the children's products to be tested to determine whether they are lead-containing products.

Year: 2008

H.B. 62, 425th Gen. Assemb., Reg. Sess. (Md. 2008)

Prohibits the manufacture, sale, offer for sale, importation, or distribution of specified lead-containing children's products by any means, including through a sales outlet or the Internet.

Massachusetts

Year: 2009

Exec. Order No. 515 (Oct. 27, 2009)

Requires the Executive Department of the Commonwealth of Massachusetts and its agencies to reduce their impact on the environment and enhance public health by procuring environmentally preferable products and services whenever such products and services are readily available, perform to satisfactory standards, and represent best value. Environmentally preferable products include, but are not limited to, products and services that are less toxic and hazardous.

Establishes a Toxic Reduction Task Force to provide guidance on and assist agencies with identifying and eliminating purchases of products that contain toxic chemicals. Requires the EPP Program and agencies to, wherever feasible, eliminate products procured by the Commonwealth that contain toxic chemicals in concentrations that pose a significant threat to the environment and/or public health.

Year: 2008 (Amendment)

Mass. Gen. Laws, ch. 111, § 196 (2008)

Prohibits the sale, delivery, or possession with intent to sell, deliver or give away any toy, furniture, cooking, drinking or eating utensil to which any lead-based paint, glaze or other substance has been applied.

Year: 2008 (Amendment)

Mass. Gen. Laws, ch. 94B, §§ 1-10 (2008)

Prohibits any person from selling, delivering, giving away, or introducing into commerce any misbranded hazardous substance or banned hazardous substance. Permits the Commissioner of Public Health to declare any substance or mixture of substances, which meet certain requirements, to be a hazardous substance. Under this authority, the Commissioner has declared formaldehyde, urea-formaldehyde foamed in-place insulation, and children's leaded jewelry to be hazardous substances. The Commissioner has declared urea-formaldehyde foamed in-place insulation and children's leaded jewelry to be banned hazardous substances. Requires urea-formaldehyde foamed in-place insulation and children's leaded jewelry to be removed from commerce. (105 CMR 650)

Michigan

Year: 2007

H.B. 4132, 94th Leg., Reg. Sess. (Mich. 2007)

Prohibits a lead-bearing substance from being used in or on any children's jewelry. Prohibits the sale of children's jewelry containing a lead-bearing substance. Makes information about the hazards of lead-bearing substances and any programs offered to educate individuals about those hazards available via the internet.

Year: 2007

H.B. 4399, 94th Leg., Reg. Sess. (Mich. 2007).

Prohibits the sale of lunch boxes that contain a lead-bearing substance.

Year: 2007

S.B. 174, 94th Leg., Reg. Sess. (Mich. 2007)

Prohibits use or application of a toxic substance (i.e. substance that contains lead, or a coating on an item that contains lead) in or on any toy or child care article. Prohibits the sale, or transfer of a toy or child care article in this state that contains a toxic substance.

Vermont

Year: 2008

2008 Vt. Acts & Resolves 193.

Prohibits the sale of any children's product that contains lead. Prohibits the sale of any jewelry that contains lead. Requires phase out of wheel weights containing lead. Requires labels on all plumbing equipment for sale that contains lead. Prohibits the sale of solder or flux for plumbing that contains lead. Requires a warning on all nonresidential paints and primers containing lead. Requires warning labels on salvaged building materials for sale stating that these products may contain lead.

Washington

2008

2008 Wash. Sess. Laws 288.

Contains limits on lead, cadmium, or phthalates in children's products (preempted by the Federal Consumer Product Safety Improvement Act).

(Lowell Center for Sustainable Production, 2010)

6. Conclusion

Lead continues to pose a threat to children, despite attempts to control it. However, there is evidence that human BLLs are decreasing. Because of its toxicity and pervasiveness, lead is being named a Minnesota Priority Chemical. Information on any changes in federal or state policy, as well new information as health impacts and exposure routes, especially in children, will be monitored.

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G. Phthalates

The following phthalates are discussed in this document:

Chemical Name	Chemical Abstract Service (CAS) number
Butyl benzyl phthalate (BBP)	85-68-7
Dibutyl phthalate (DBP)	84-74-2
Di (2 – ethylhexyl) phthalate (DEHP)	117-81-7

1. Overview

Phthalates are manufactured chemicals added to polyvinyl chloride (PVC), plastics, paints, cosmetics, wood varnish, and medical supplies to increase flexibility or improve other characteristics, such as durability. In addition to being in consumer products, phthalates are pervasive in the environment and have been found in food, drinking water, household dust, and indoor air (Agency for Toxic Substances and Disease Registry [ATSDR], 2002; Centers for Disease Control and Prevention [CDC], 2010d; Consumer Products Safety Commission [CPSC], 2010a). It is likely that children’s mouthing, chewing and crawling behaviors result in greater relative exposure to phthalates when compared to adults. Phthalate exposure can occur through ingestion, inhalation, and direct contact (ATSDR, 2002; Environmental Protection Agency [EPA], 2009).

Laboratory tests have shown that phthalates can cause developmental and reproductive effects, kidney and liver damage, as well as mortality (ATSDR, 2002; CPSC 2010a; EPA, 2009). Some studies have also reported adverse effects of phthalate exposure on human reproductive and developmental outcomes (EPA, 2009; Swan et. al, 2005). Surveys of human populations are currently being completed in effort to further investigate this possibility.

Recently, interest in the possible health effects from exposure to several phthalates in combination has risen. An evaluation of phthalates and children’s health has been proposed and is scheduled to be conducted by the CPSC Chronic Hazard Advisory Panel (CHAP) (EPA, 2009; National Academy of Sciences, 2008). Information about this work is available at <http://www.cpsc.gov/about/cpsia/chapmain.html>

Di (2–ethylhexyl) phthalate (DEHP) has been named a probable human carcinogen by EPA in the Integrated Risk Information System (IRIS). The classification of DEHP as a carcinogen varies by agency, however. The National Toxicology Program has categorized DEHP as “reasonably anticipated to be a human carcinogen,” while the International Agency for Research on Cancer (IARC) has categorized DEHP as “Group 3: not classifiable as to human carcinogenicity” (ATSDR, 2002; EPA, 1991; International Agency for Research on Cancer [IARC], 2000). The other two phthalates, butyl benzyl phthalate (BBP), and dibutyl phthalate (DBP), are not considered to be carcinogens by these agencies.

As described below, there are already regulations in place that attempt to limit a child’s exposure to phthalates. However, compliance with regulations may vary. In addition, phthalates are still in many consumer products. While these products may not be specifically designed for children, many of the products are in the home environment where there are pathways of exposure for

children. In addition, women who are pregnant could have exposure to items containing phthalates, possibly resulting in fetal exposure.

2. Brief chemical profiles

a. Butyl benzyl phthalate (BBP)

CAS Number 85-68-7

2006 U.S. production volume (manufacturer or imported): 50-100 million pounds (EPA, 2010a)

Use: BBP is used in polyvinyl chloride (PVC) as a stain-resistant plasticizer, specifically in vinyl tiles. The Household Products Database lists BBP in several products used in home maintenance, such as tile mastic, caulk, and sealants, as well as some paints and adhesives (National Library of Medicine [NLM], 2010a).

EPA Toxic Release Inventory (TRI): Reporting releases of this chemical is not currently required by EPA under TRI. Reporting was required from 1993-1998, where TRI data show BBP was reported released in Minnesota in quantities ranging from 875 pounds (1993) to 4,591 pounds (1992). The largest release amount in 1992 was reported by a cabinet maker conducting on-site disposal of the chemical (EPA, 2010b). Because of recent interest in this chemical, EPA is considering proposing rules that would once again require reporting of BBP releases to the TRI (EPA, 2009).

NHANES: Biomonitoring data from NHANES show that metabolites of this chemical are found in urine samples from all population groups (children 6-11 years and 12-19 years, adults, males, females and in people of the sampled ethnicities) (CDC, 2010a).

Other biomonitoring data:

BBP was reported in human adipose tissue in the U.S. (Hazardous Substances Data Bank [HSDB], 2010a).

Environmental disposition of the chemical: (Note: this information is not intended to be comprehensive.) BBP has been found in indoor air, fish, drinking water, surface water, groundwater, plants, animals, runoff water (HSDB, 2010a).

EPA Integrated Risk Management System Oral Reference Dose:

2×10^{-1} mg/kg/day (Liver-to-body weight and liver-to-brain weight ratios in rats)
Uncertainty factor: 1000 (EPA, 1993)

EPA Integrated Risk Management System Inhalation Reference Concentration:

None

Action in U.S. states:

(Information taken from the Lowell Center for Sustainable Production States US Chemical Policy database at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.)

California: Prohibits BBP and other phthalates in products intended for young children at quantities greater than 0.1% (California Health & Safety Code §§ 108935-108939).

Vermont: Restricts sale of a toy or childcare article that contains BBP and other phthalates (18 V.S.A. § 1511).

Washington: Limits the amount of BBP and other phthalates in children's products (RCW 70.240.020). This law was pre-empted by the Federal Consumer Product Safety Improvement Act.

(Lowell Center for Sustainable Production, 2010).

b. Dibutyl phthalate (DBP)

CAS Number: 84-74-2

2006 U.S. production volume (manufactured or imported): 10-50 million pounds (EPA, 2010c)

Uses: DBP is used for manufacture of plastics, paints, wood varnishes, and lacquers. It has also been used in textiles, propellants, paper, printing inks, and cosmetics such as nail polish (ATSDR, 2001; CDC, 2010c; U.S. Food and Drug Administration [FDA], 2010). The Household Products Database shows that DBP is found in home maintenance products like joint compound and crack filler, as well as floor finishers and cosmetics (NLM, 2010b). It appears that DBP was used in food packaging in the past. In recent years, industry representatives from the American Plastics Council and the American Chemistry Council have stated that food packaging in the U.S. no longer contains phthalates (Enneking, 2006). It is unclear if phthalates are no longer in *any* food packaging, including food packaging manufactured outside of the U.S. (Note: Minn. Stat. 2010 116.9405 exempts food packaging from consideration for Priority Chemicals, except for packaging used for baby food or infant formula.)

EPA Toxic Release Inventory (TRI) data: According to the TRI, the amount of DBP that has been reported released to air, water or land in Minnesota from 1991-2009 has been zero for most years, except 1991, 1992, 1993, and 2001. In 2001, there were 400 pounds reported released, with no further releases reported since that time (EPA, 2010c).

NHANES: Biomonitoring information from NHANES shows that metabolites of this phthalate are found in all population groups tested. There were reportedly age-related differences in levels among the children tested, with toddlers showing the highest median levels of urinary metabolites from the 1999-2004 data (CDC, 2010c). From the 1999-2000 data, children age 6-11 years showed higher median level concentrations than adults and adolescents (CDC, 2010c).

Other biomonitoring data:

DBP has been found in human adipose tissue, tissue, blood, breast milk, and serum (HSDB, 2010b).

Environmental disposition: (Note: This list is not intended to be comprehensive.)

This chemical has been reported in drinking water, groundwater, surface water, seawater, precipitation, wastewater treatment plant leachate, landfill leachate, soil, sediment, indoor air, rural area air, urban area air, fish, seafood, birds, and household dust (HSDB, 2010b).

EPA Integrated Risk Management System Oral Reference Dose:

1×10^{-1} mg/kg/day (Increased mortality in rat studies)

Uncertainty factor: 1000 (EPA, 1990).

EPA Integrated Risk Management System Reference Concentration:

None

Action in U.S. states:

(Information taken from the Lowell Center for Sustainable Production States US Chemical Policy database at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.)

California: Prohibits DBP and other phthalates in products intended for young children at quantities greater than 0.1% (California Health & Safety Code §§ 108935-108939).

Vermont: Restricts sale of a toy or childcare article that contains DBP and other phthalates (18 V.S.A. § 1511).

Washington: Limits the amount of DBP and other phthalates in children's products (RCW 70.240.020). This law was pre-empted by the Federal Consumer Product Safety Improvement Act.

(Lowell Center for Sustainable Production, 2010).

c. Di (2-ethyl hexyl) phthalate (DEHP)

CAS Number 117-81-7

2006 U.S. production volume (manufactured or imported): 100-500 million pounds (EPA, 2010a).

Uses: DEHP is used as a plasticizer to soften plastic and polyvinyl chloride (PVC) products (CDC, 2010b; HSDB, 2010c). It is widely used in medical devices (intravenous tubing and blood bags), as well as in a variety of consumer products and industrial products. Example of products containing DEHP from ATSDR are “wall coverings, tablecloths, floor tiles, furniture upholstery, shower curtains, garden hoses, swimming pool liners, rainwear, baby pants, dolls, some toys, shoes, automobile upholstery and tops, packaging film and sheets, sheathing for wire and cable, medical tubing, and blood storage bags” (ATSDR, 2002). CDC notes that DEHP has been removed from most toys and packaging in the U.S. (CDC, 2010b). DEHP was used in baby teethingers and rattles in the past, but it is no longer used in these products produced domestically (ATSDR, 2002; CPSC, 2010d).

EPA Toxic Release Inventory (TRI): During the past 10 years, the amount of DEHP reported released in Minnesota in the TRI has decreased to nearly zero. Since 2006, no releases to land, air or water have been reported. In 2009, one company reported 250 pounds of DEHP shipped off-site for treatment. The peak amount of DEHP released was in 1995, when over 42,000 pounds were reported released, mostly by a rubber roller manufacturer. Thereafter, the reported releases of DEHP from the manufacturing processes appear to have decreased in the state (EPA, 2010d).

NHANES: The four metabolites of DEHP surveyed through NHANES were Mono-2-ethylhexyl phthalate (MEHP), Mono-(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP), Mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP) and Mono-(2-ethyl-5-carboxypentyl) phthalate (MECPP). All of the metabolites were detected in all population groups. NHANES reports relatively higher levels in children when compared to adults, and higher levels in females when compared to males (CDC, 2010b).

Other biomonitoring data: DEHP has been found in human adipose tissue, serum, breast milk, and cord blood (HSDB, 2010c).

Environmental disposition: (Note: This information is not intended to be comprehensive.) This chemical has been detected in drinking water, groundwater, surface water, seawater, precipitation, soil, sediment, indoor air, rural area air, urban area air, fish, animals, dairy milk, and house dust (HSDB, 2010c).

EPA Integrated Risk Management System Oral Reference Dose:
 2×10^{-2} mg/kg/day (Increase in relative weight in guinea pig study)
Uncertainty factor: 1000 (EPA, 1991)

Actions in U.S. states:

(Information taken from the Lowell Center for Sustainable Production States US Chemical Policy database at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.)

California: Prohibits DEHP and other phthalates in products intended for young children at quantities greater than 0.1% (California Health & Safety Code §§ 108935-108939).

Vermont: Restricts sale of a toy or childcare article that contains DEHP and other phthalates (18 V.S.A. § 1511).

Washington: Limits the amount of DEHP and other phthalates in children's products (RCW 70.240.020). This law was pre-empted by the Federal Consumer Product Safety Improvement Act.

(Lowell Center for Sustainable Production, 2010).

3. Statutory Requirements

The table and information summary below provide information about how the three phthalates meet the criteria of Minn. Stat. 2009 116.9401 – 116.9407.

Statute	Information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity	<p>BBP: “Phthalate syndrome”: birth defects at high doses, male reproductive organ development</p> <p>DBP: Birth defects, reproductive organ development</p> <p>DEHP: Birth defects, fetal death</p>	<p>CPSC 2010b NTP 1989</p> <p>CPSC 2010c EPA 2009 HSDB 2010b</p> <p>ATSDR 2002 CPSC 2010d NTP 1983</p>
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	<p>BBP: Decrease in sperm production in parent: effects extended to offspring</p> <p>DBP: Reproductive effects: decreased pregnancies, reduced fertility</p> <p>DEHP: Reproductive effects: changes to reproductive organ morphology</p> <p>DEHP: Cancer: B2 – probable human carcinogen</p> <p>DEHP: Cancer: Group 3: Not classifiable as to human carcinogenicity</p> <p>DEHP: Cancer: Reasonably anticipated to be a human carcinogen</p>	<p>CPSC 2010b HSDB 2010a</p> <p>CPSC 2010c</p> <p>ATSDR 2002 CPSC 2010d EPA 2009</p> <p>EPA 1991</p> <p>IARC 2000</p> <p>NTP 2005</p>
Subd. (e)(3) disrupt the endocrine or hormone system	<p>BBP: increases peroxisome proliferating activated receptor and pituitary-gonadal hormones, decreases thyroid hormones</p> <p>DBP: Possible hormonal effects</p> <p>DEHP: Estradiol metabolism and estrogen receptor function altered</p>	<p>CPSC 2010b</p> <p>CPSC 2010c</p> <p>CPSC 2010d</p>
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	<p>BBP: Decreased body weight, increased organ weights</p> <p>DBP: Increased mortality, toxic effects on liver and kidney</p> <p>DEHP: Toxic effects on kidney, liver, reproductive organs, thyroid</p>	<p>CPSC 2010b EPA 1993 HSDB 2010a</p> <p>CPSC 2010c EPA 1990</p> <p>ATSDR 2002 CPSC 2010d HSDB 2010c</p>

Statute	Information	References
Subd. (e)(5) be persistent, bioaccumulative, and toxic;	DEHP: Persistent in environment, can be bioaccumulative in some species, but often metabolized	ATSDR 2002 HSDB 2010c
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	BBP: 50 to 100 million pounds DBP: 10 to 50 million pounds DEHP: 100 to 500 million pounds	EPA 2010a
Subd (2) Meets any of the following criteria:		
Subd. (a)(2)(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	BBP: Found in human adipose tissue, amniotic fluid, blood, breast milk, cord blood, urine DBP: Found in human adipose tissue, breast milk, serum, urine DEHP (or metabolites): Found in blood, human breast milk, lungs of newborns, urine, other tissues and fluids	CDC 2010b CPSC 2010b HSDB 2010a CPSC 2010c HSDB 2010b ATSDR 2002 CPSC 2010d HSDB 2010c
Subd. (a)(2)(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	BBP: Indoor air in residences, household dust, drinking water DBP: Found in indoor air, household dust , drinking water, other products in the home environment DEHP: Found in indoor air, drinking water, household dust	CPSC 2010b HSDB 2010a ATSDR 2002 CPSC 2010c HSDB 2010b NLM 2010b ATSDR 2002 HSDB 2010c
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	BBP: found in fish, animals, soil DBP: Found in fish, shellfish, groundwater DEHP: Found in fish, wildlife, surface waters, rainwater, groundwater	CPSC 2010b HSDB 2010a HSDB 2010b ATSDR 2002 HSDB 2010c

4. Current Regulations

Concern about phthalates has prompted international, federal, and state level actions. BBP, DBP, and DEHP were prohibited by the European Commission in 1999 in soft toys intended for children age 3 or younger that were meant to be put into a child's mouth. The ban was expanded and made permanent in 2005 by European Commission Directive 2005/84/EC, which prohibited use of BBP, DBP and DEHP in all toys and childcare articles. The phthalates diisodecyl phthalate (DIDP), di-iso nonyl phthalate (DINP) and di-n-octyl phthalate (DNOP) were restricted from use in toys that could be put into a child's mouth (Europa, 2008).

The Australian government is currently studying phthalates DEHP, DIDP, BBP, DBP, and others. In a report on DEHP, the Australian government's Department of Health and Ageing stated that the reproductive risk to children and the general population from this chemical was unacceptable and called for restriction on this chemical in toys, childcare articles, and cosmetics (Australian Department of Health and Ageing, 2010).

In the U.S., the CPSC implemented a permanent ban on three phthalates, DEHP, BBP, and DBP, in children's products under the Consumer Product Safety Improvement Act of 2008. Children's product can contain no more than 0.1% of these phthalates individually (CPSC, 2008). An additional three chemicals, DINP, DIDP and DnOP were temporarily banned from children's products meant to be placed in a child's mouth. These three chemicals are being assessed by the CPSC CHAP. The CHAP will make recommendations about whether the temporary ban on the three chemicals should be extended (CPSC, 2010).

5. Planned Actions

a. Federal

(1) Consumer Product Safety Commission (CPSC)

As described above, the three phthalates, DINP, DIDP and DnOP, that are under a temporary ban in children's products will be evaluated by the CPSC CHAP. Decisions from the CHAP will guide future regulation of phthalates in consumer products. The work of the CHAP is expected to be completed in 2012.

(2) Environmental Protection Agency

The EPA has created a Chemical Action Plan for phthalates that describes the use of phthalates, associated health and environmental concerns, physical characteristics, risk management, and planned actions. Some of the planned actions for 2010-2012 include:

- Initiate rulemaking to add six of the eight phthalates addressed in EPA's Action Plan to the TRI: Diisobutyl phthalate (DIBP), BBP, Di-n-pentyl phthalate (DnPP), DnOP, DINP and DIDP.
- Consider implementing a significant new use provision for di-n-pentyl phthalate (DnPP) to require manufacturers or importers to notify EPA before using this chemical in any significant new use processes.
- Lay groundwork to consider initiating rulemaking under TSCA to regulate eight phthalates, after cooperating with CPSC and FDA to assess the use, exposure and substitutes available.
- Study the cumulative effect of exposure to several of the phthalates. Also, the EPA plans to look at the impacts of phthalates on children.
- Conduct a Design for the Environment and Green Chemistry alternatives assessment by 2012 (EPA, 2009).

b. States

As noted above, some states, specifically California, Vermont, and Washington, have implemented bans similar to the CPSC on children's toys or child care products containing phthalates in quantities of 0.1% or more. In the past four years, there has been other legislation introduced related to phthalates in an additional 17 states, including Minnesota. Many of the bills were not passed through the states' legislative body or were vetoed (Lowell Center for Sustainable Production, 2010). It is unknown if future actions are planned on the state level, though the trend in recent years has been for state action on chemicals of concern.

6. Conclusion

The ubiquity of phthalates and the current incomplete understanding of associated health effects in humans, especially from chronic and/or combined low dose exposures, raise concern. Currently, MDH has selected BBP, DBP, DEHP for the Priority Chemical list. All of these chemicals were high production volume chemicals in 2006 and in three or more of the remaining EPA IUR inventories since 1990. In addition, these chemicals meet relevant criteria of Minn. Stat. 2010 116.9401 – 116.9407, including exhibiting toxicity and being detected in human body fluids, the home environment, or the natural environment. There is a relatively new national ban on these three chemicals in children's toys and child care articles, but exposure will likely continue because of use in other consumer products that children and pregnant women contact.

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