

# **Minnesota Chemicals of High Concern List Methodology**

**July 1, 2010**



Minnesota Department of Health ♦ Division of Environmental Health ♦ Environmental Surveillance and Assessment

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## Acronyms and Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CA Prop 65	California Proposition 65
CAS	Chemical Abstract Service
ChAMP	Chemicals Assessment and Management Program (under EPA)
CHC	Chemicals of High Concern
ECHA	European Chemicals Agency
EPA	U.S. Environmental Protection Agency
EU	European Union
HBV	Health Based Value (Minnesota guidance)
HC	Hazard Characterization
HHS	U.S. Department of Health and Human Services
HSDB	Hazardous Substances Data Bank (maintained by NLM)
HPV	High Production Volume
HRA	Health Risk Assessment
HRL	Health Risk Limit (Minnesota guidance)
HRV	Health Risk Value (Minnesota guidance)
IARC	International Agency for Research of Cancer
IRIS	Integrated Risk Information System (maintained by EPA)
IUR	Inventory Update Reporting (EPA)
LOAEL	Lowest Observed Adverse Effect Level
MCL	Maximum Concentration Limit (EPA)
MDH	Minnesota Department of Health
mfg	manufacturing
mg/kg bw	milligrams/kilogram of body weight
NIH	U.S. National Institutes of Health
NLM	U.S. National Library of Medicine
NOAEL	No Observed Adverse Effect Level
NTP	U.S. National Toxicology Program
NTP 11th ROC	U.S. National Toxicology Program 11 <sup>th</sup> Report on Carcinogens
NWM	National Waste Minimization Program (EPA)
OECD	Organisation for Economic Co-operation and Development (international agency)
Oregon P <sup>3</sup> List	Oregon Priority Persistent Pollutant List
OSPAR	Oslo and Paris Commission
PAH	Polycyclic aromatic hydrocarbon
PBT	Persistent, Bioaccumulative and Toxic
PBiT	Persistent, Bioaccumulative and inherently Toxic
PC	Priority Chemical
PCB	Polychlorinated biphenyl
PCN	Polychlorinated naphthalene
PFC	Perfluorochemical
ppm	parts per million
RAA	Risk Assessment Advice (Minnesota guidance)

RBP	Risk Based Prioritization
REACH	<u>R</u> egistration, <u>E</u> valuation, <u>A</u> uthorization and Restriction of <u>C</u> hemicals (Europe)
reg.	registered (i.e., EPA reg. pesticide)
SIAR	SIDS Initial Assessment Report
SIDS	Screening Information Data Set
TRI	Toxic Release Inventory (collected by EPA)
vPvB	very Persistent and very Bioaccumulative
WA Appen1	State of Washington Appendix1 – used in developing Washington Chemicals of High Concern for Children list
WA Appen2	State of Washington Appendix2 – used in developing Washington Chemicals of High Concern for Children list
WA CHCC	Washington Chemicals of High Concern for Children list
WA PBT	State of Washington Persistent Bioaccumulative and Toxic list

## Minnesota Chemicals of High Concern List Methodology July 2010

### Background

Legislation related to concerns about chemicals in consumer products, especially those designed for children, passed in 2009. This legislation requires the Minnesota Department of Health (MDH), in consultation with the Minnesota Pollution Control Agency, to create two lists of chemicals. The initial list, called the Chemicals of High Concern, is defined in Minn. Stat. 116.9401 (2009):

- (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 Chemicals of High Concern list must be published by July 1, 2010. In addition, the statute notes in Minn. Stat. 116.9402 (2009):

- (b) The department must periodically review and revise the list of chemicals of high concern at least every three years. The department may add chemicals to the list if the chemical meets one or more of the criteria in Minn. Stat. 116.9401 (2009).
- (c) The department shall consider chemicals listed as a suspected carcinogen, reproductive or developmental toxicant, or as being persistent, bioaccumulative, and toxic, or very persistent and very bioaccumulative by a state, federal, or international agency. These agencies may include, but are not limited to, the California Environmental Protection Agency, the Washington Department of Ecology, the United States Department of Health, the United States Environmental Protection Agency, the United Nation's World Health Organization, and European Parliament Annex XIV concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals.
- (d) The department may consider chemicals listed by another state as harmful to human health or the environment for possible inclusion in the list of chemicals of high concern.

From the Chemicals of High Concern, a second, smaller list of chemicals must be selected. This list, called the Priority Chemicals list, must meet additional criteria, defined in Minn. Stat. 116.9403 (2009):

- (a) The department, after consultation with the [Minnesota Pollution Control] 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.

This list must be published on the MDH website by February 1, 2010. According to the statute, the Priority Chemicals list must be updated whenever a new priority chemical is named. MDH will be developing a process to select Priority Chemicals from the Chemicals of High Concern list according to the statutory requirements. Information about this selection process will be published on the MDH website when the Priority Chemical list is released.

This document describes the process of selecting the chemicals for the Chemicals of High Concern list.

### **Maine and Washington Lists**

Two U.S. states, Maine and Washington, currently have legislation that is very similar to the Minnesota statute (Maine Department of Environmental Protection [DEP], 2009; Washington Department of Ecology [Ecology], 2010a). Like Minnesota, Maine must publish two lists of chemicals: Chemicals of High Concern (CHC) and Priority Chemicals (PC). Washington must publish one list called the Chemicals of High Concern for Children (CHCC).

The Maine CHC list was published in July 2009 (Maine DEP, 2009). This list contained 1739 items. Most of the chemicals were listed individually by Chemical Abstracts Service Registry Number (CAS number), while other chemicals were listed without a CAS number in a category such as “Diesel engine exhaust.”

Washington needed to publish only one list of chemicals, unlike Maine and Minnesota, which were required to publish a Chemicals of High Concern list and a Priority Chemicals list. The Washington CHCC was published in January 2010. This draft list,

which will be reduced to 50 chemicals, contained 66 chemicals listed by CAS number (Washington Ecology, 2010a).

Washington Ecology also published lists of chemicals that were initially selected as candidates for the CHCC list. These lists, in appendices 1-4, are available from the Washington Ecology website. Appendix 1 and Appendix 2 include chemicals with unique CAS numbers and chemicals without CAS numbers, respectively, named on chemical lists created by other agencies. Chemicals in these appendices match many of the chemicals on the Maine CHC list and were considered for the Minnesota CHC list. From the Washington list documentation, the remaining appendices did not appear to be created with criteria that matched the Minnesota CHC criteria and these appendices were not used in the review for the Minnesota CHC list.

To create the CHC list in Minnesota, work done by Maine, Washington and other sources was reviewed, as described below.

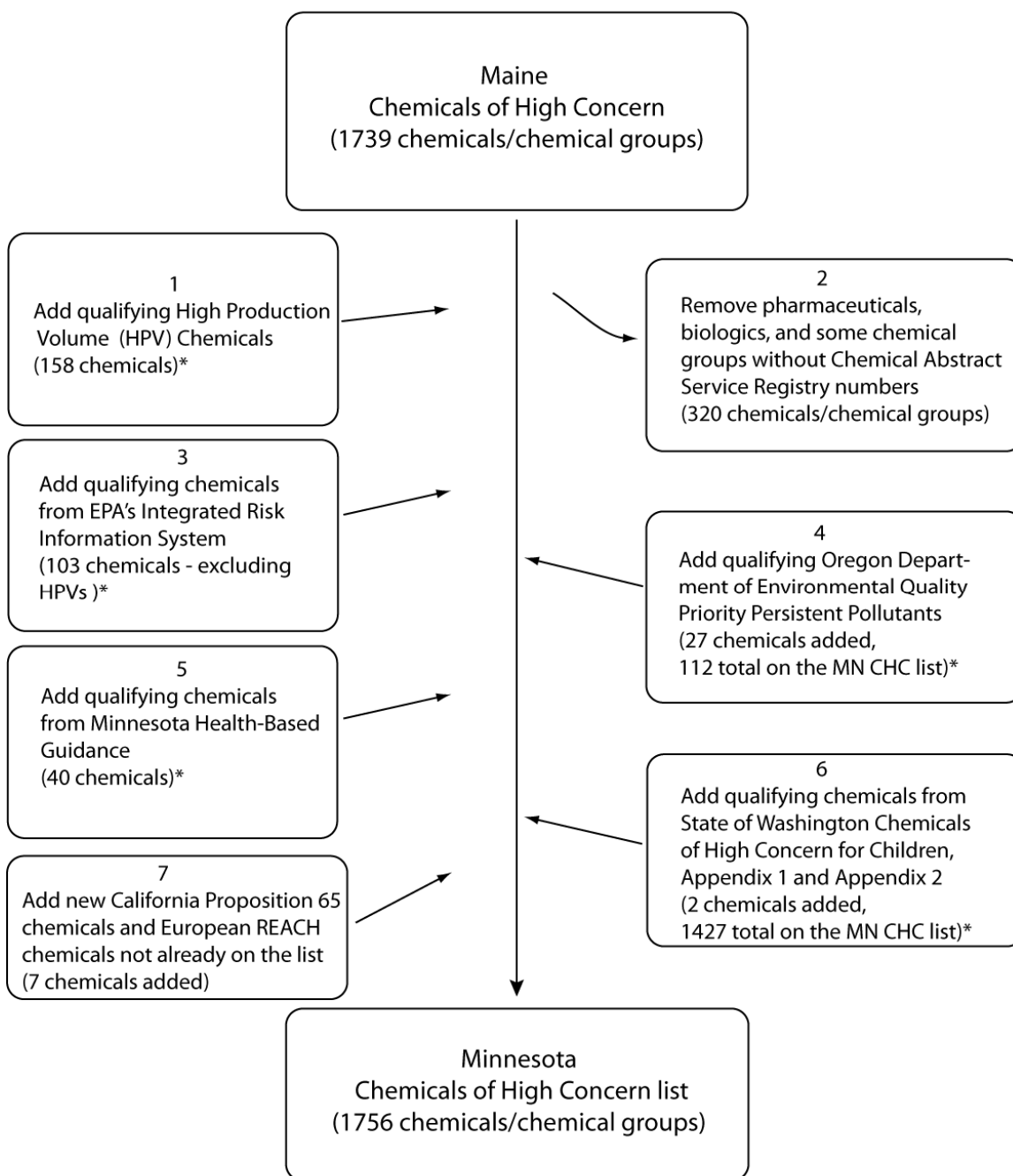
### **Chemical Selection Process**

The process of creating the initial Minnesota CHC list began in August 2009. MDH retrieved the Maine CHC list and began review of the substances on this list. Because this list was available and the Maine statute mirrors Minnesota's statute on several points, the Maine CHC list was used as a starting point for the Minnesota CHC list. As described in the documentation for the Maine CHC (Maine DEP, 2009), chemicals on this list were selected from lists of other agencies. A brief listing of these sources is available in Appendix 1.

Next, pharmaceutical products and biologics were removed from the list according to the exclusion under Minn. Stat. 116.9407, subdivision 7 (2009). Each chemical on the Maine CHC list that appeared to be used only as a medication (human or veterinary) or appeared to be a biologic as defined by the U.S. Food and Drug Administration (U.S. Food and Drug Administration [FDA], 2009) was identified and removed from the Minnesota CHC list (Figure 1).

Because of the high number of chemicals on Maine's CHC list (1739), in-depth review of all of the chemicals on this list was not possible, and most chemicals were retained for the Minnesota CHC list. This lack of review could have resulted in retention of some chemicals from the Maine CHC list that may not meet the toxicity or persistence and bioaccumulative criteria for a CHC chemical established by MDH (described below). A more thorough review will be needed for future revisions of the CHC list (see Limitations).

**Figure 1.  
Process Diagram**



\* Chemicals could be eligible for the Minnesota CHC list based on information from multiple sources (i.e., there is "overlap" of sources on the CHC list)

Note: The chart provides a simplified depiction of the process: review of several chemicals was ongoing.

MDH reviewed additional chemicals not on the Maine list to determine if they met the criteria of the statute and should be included on the Minnesota CHC list. These chemicals included high production volume chemicals (HPV) named by EPA; Priority Persistent



Pollutants named by the Oregon Department of Environmental Quality; chemicals with non-cancer endpoints in the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS); Minnesota Health-Based Guidance for drinking water and air; and sources named in Minn. Stat. 116.9402 (2009).

For all of these chemicals, statutory criteria were used during evaluation of suitability for the Minnesota CHC list. The statute indicates that CHC chemicals need to be “known or suspected with a high degree of probability” to cause health effects or be a chemical that is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). Because “high degree of probability” was not defined, MDH needed to establish a guideline for this determination when reviewing chemicals. Ideally, a full process for chemical evaluation would have been developed, but this was not possible with the time and resources available. MDH therefore relied on work done by other agencies for determining likelihood of a chemical to cause harm. After reviewing process documentation from other agencies, it was determined that Minnesota would initially use guidelines established by the EPA Chemical Assessment and Management Program (ChAMP) to determine which chemicals posed the highest probability of risk. While ChAMP is no longer active at EPA, the program’s methodology provided a basis by which to prioritize chemical hazards. As described further in later sections, these ChAMP guidelines were used to assess high production volume chemicals, chemicals with non-cancer endpoints in IRIS, and the Minnesota Health-Based Guidance values, but they were not applied to chemicals that were already listed on the Maine CHC list.

The ChAMP program developed guidelines based on the lowest-observed-adverse-effect-level (LOAEL) from mammalian toxicity testing to classify chemicals into priority categories of “High,” “Moderate” or “Low” (Environmental Protection Agency [EPA], 2010a). If the LOAEL from repeated dose or reproductive mammalian toxicological studies reviewed by MDH was within the hazard category of “High” or “Moderate” conferred by ChAMP, the chemical was considered eligible for the Minnesota CHC list. A chemical with a LOAEL in the “Low” category conferred by ChAMP (for all applicable studies) was excluded from further consideration for the CHC list unless it qualified otherwise. Because the ChAMP guidelines do not address chronic studies (more than 90 days), if the LOAEL listed for the chemical was based on a chronic study, the study design, results, and LOEAL were further evaluated and professional judgment was applied in the decision to include or exclude the chemical.

Guideline values for PBT and vPvB were also selected from ChAMP and the European Chemicals Agency (ECHA), respectively, but not all of the chemicals had readily available information on persistence and bioaccumulation and there was limited time to research these characteristics. All chemicals that were named PBT or vPvB on the Maine list were retained for the Minnesota CHC list, unless they were statutorily excluded (e.g., pharmaceutical) or duplicates listed without a CAS number. The PBT and vPvB guidelines are listed in Appendix 2.

Another statutory criterion for the CHC list is genotoxicity. Because many types of genotoxicity tests exist, MDH toxicologists were consulted for guidance. It was

determined that only positive *in vivo* genotoxicity tests would be used as a determinant for inclusion on the CHC list.

Further, MDH assessed some of the HPV chemicals for severe irritation of skin, eyes, and respiratory system. These health effects are often not measured in terms of LOAEL values, but are often noted. If a chemical is a sensitizer or causes severe irritation, burns or corrosion, the chemical was included on the draft CHC list.

## **Chemical Review**

### **High Production Volume Chemicals**

Minnesota's definition of a PC requires that the chemical be an HPV chemical named by EPA. An HPV chemical is one that is manufactured or imported into the U.S. in quantities of one million pounds or more per year. Because the PC list must be derived from the CHC list, HPV chemicals needed to be reviewed and added to the CHC list in order to be considered for the PC list. To accomplish this review, MDH obtained information from EPA about HPV chemicals.

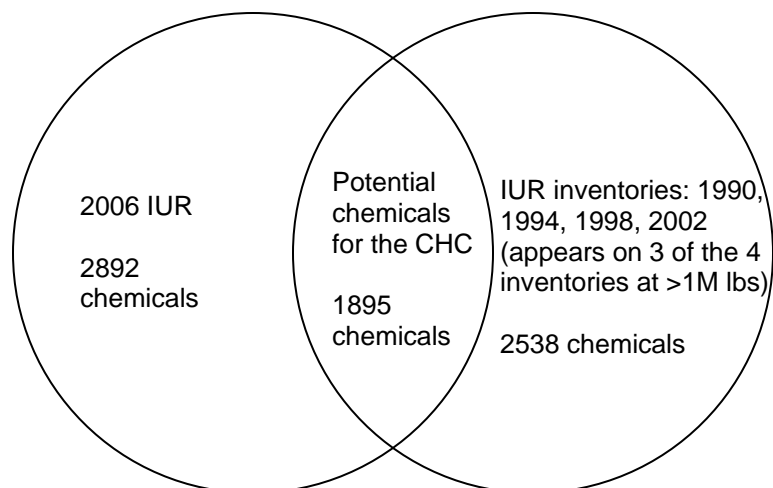
Under the U.S. Toxic Substances Control Act, manufacturers or importers of a chemical in a quantity of 25,000 pounds or more per year must report this to EPA during the Inventory Update Reporting (IUR) cycle, which occurs every four years. EPA publishes the total amount of the chemical reported from all sources in downloadable lists from its website. MDH retrieved the IUR lists available for approximately the past 20 years, which includes inventories for 1990, 1994, 1998, 2002 and 2006, and identified the HPV chemicals (those reported in quantities of 1 million pounds or more).<sup>\*</sup> Through this process, 4755 chemicals with unique CAS numbers were identified.

Because the HPV chemicals vary somewhat over time and reviewing all of the HPV chemicals from the past 20 years was impractical, MDH focused on the chemicals that appeared on *both* on the most recent available inventory, 2006, and on three of the four remaining inventories from 1990-2002. Under this plan, for example, an HPV chemical that appeared on the 1994, 1998, 2002 and 2006 IUR inventories was reviewed and an HPV chemical that was on the 1994, 2002 and 2006 IUR inventories or the 2006 inventory only was not reviewed. This grouping of HPV data resulted in a total of 1895 chemicals to review (Figure 2).

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<sup>\*</sup> Using the field notation from the IUR, chemicals in the categories of >1M – 10M or greater were selected from 1990, 1994, 1998, and 2002 inventories, and the categories of 1 million - <10 million or greater were selected for 2006.

Figure 2. High Production Volume Chemical selection for Chemicals of High Concern List



For the selected HPV chemicals, information about the health endpoint and hazard was needed. For HPVs that were already identified with a health endpoint on the Maine CHC list (about 250 chemicals), no additional information was sought. For other HPV chemicals, reliable information was needed to assess the chemical's appropriateness for the Minnesota CHC list.

For this part of the process, MDH used online government sources, which included:

- ◆ U.S. Environmental Protection Agency
  - Chemical Assessment and Management Program (ChAMP) (for categorization)
  - High Production Volume Challenge Program
    - Hazard Characterizations
    - Risk-Based Prioritizations
  - Integrated Risk Information System (IRIS)
- ◆ U.S. Department of Health and Human Services (HHS)
  - National Institutes of Health (NIH)
    - National Library of Medicine (NLM)
      - Hazardous Substances Data Bank (HSDB)
    - National Toxicology Program (NTP)
  - Agency for Toxic Substances and Disease Registry
- ◆ Organisation for Economic Co-operation and Development (OECD)
  - High Production Volume Chemical Program

Both EPA and the international Organisation for Economic Co-operation and Development (OECD) have developed summary documents describing the potential human and environmental hazards of HPVs, as well exposure potential, production, and uses. Most of the EPA summaries are called Hazard Characterizations (HC), with a few additional documents called Risk-Based Prioritizations (RBP). The RBP assign priorities of “High,” “Medium,” or “Low” to an HPV chemical based on screening level hazard, exposure and risk characterizations. These priorities from the RBPs are based on the guidelines described in ChAMP (EPA, 2010a) (see Chemical Selection Process). In addition, the OECD provides documents called Screening Information Data Sets (SIDS), summarized in SIDS Initial Assessment Reports (SIARs). The SIARs provide the same type of information contained in the HCs developed by EPA. EPA notes that it regards the SIDS/SIAR documents as equivalent to the HCs, and it does not develop an HC for a chemical for which a SIDS/SIAR has already been developed (EPA, 2009).

The EPA and OECD libraries of HC, RBP and SIDS/SIAR documents were checked for information on each of the HPV chemicals identified as candidates for the CHC list. There was an HC, RBP, or SIDS/SIAR for about 560 of these chemicals. For chemicals that were not already on the Maine CHC list, these documents were reviewed to assess whether the chemical qualified for the Minnesota CHC list using the ChAMP criteria described above (see Chemical Selection Process). For the HPV chemicals without an HC, RBP, or SIDS/SIAR available, information about the chemical’s hazards and health endpoints was collected from other programs within EPA and HHS named above, such as the IRIS, HSDB or NTP. When Minnesota Health-Based Guidance, described below, was available for these HPV chemicals, it was also considered. If information could not be obtained from any of these sources, the HPV chemical was no longer considered for the CHC list. This resulted in elimination of about 900 HPV chemicals and addition of 158 chemicals to the draft CHC list.

#### **Additional Chemicals Considered for CHC**

In addition to the HPV chemicals, chemicals from the state of Oregon’s Priority Persistent Pollutant List (P<sup>3</sup> List), chemicals in EPA IRIS with non-cancer health endpoints, MDH Health-Based Guidance, and chemicals listed by agencies or programs named in Minn. Stat. 116.9402 (2009) were considered for the CHC list.

#### Oregon Priority Persistent Pollutant List (P<sup>3</sup> List)

In 2007, Oregon legislation required the Oregon Department of Environmental Quality (DEQ) to consult with “all interested parties” to develop a list of priority persistent pollutants. The pollutants were to be persistent and/or bioaccumulative and have a documented effect on humans, wildlife or aquatic life (Oregon Department of Environmental Quality [DEQ], 2010). A scientific panel was assembled to create the list, which was published in late 2009. As of May 4, 2010, the list had 118 substances. More information about the Oregon P<sup>3</sup> List can be found at <http://www.deq.state.or.us/wq/sb737/>

Because the Minnesota CHC list also requires consideration of chemicals that are persistent, bioaccumulative and toxic, the Oregon P<sup>3</sup> List was reviewed for potential CHC list candidates. One hundred twelve chemicals from the Oregon P<sup>3</sup> List are on the Minnesota CHC list; all but 26 were also named by another source.

#### EPA Integrated Risk Information System

The EPA Integrated Risk Information System (IRIS) contains information about assessment of risks of exposure to chemicals found in the environment, including information about cancer endpoints and non-cancer endpoints. Several chemicals with cancer endpoints were already included in Maine's initial list (Appendix 1). For chemicals with evaluations for non-cancer endpoints, such as damage to liver, developmental toxicity, or nervous system toxicity, EPA has developed an "oral reference dose" (Oral RfD) for ingestion of a chemical and an "inhalation reference concentration" (Inhalation RfC) for inhalation exposures. These are estimates of the amount of daily exposure to a chemical that a human can have over a lifetime without an adverse effect from the exposure (EPA, 2010b). In deriving these numbers, EPA often uses mammalian toxicity test information called no-observed-adverse-effect-level (NOAEL) and lowest-observed-adverse-effect-level (LOAEL). The NOAEL is a dose that produces no known effect, and the LOAEL is the lowest tested exposure level that shows an effect. The NOAEL and LOAEL are useful in evaluating how likely exposure to a chemical will produce a recognized adverse health effect. More information on IRIS can be found at <http://www.epa.gov/ncea/iris/>

There were 438 substances for which a non-cancer Oral RfD or Inhalation RfC were available online. In reviewing these chemicals, if a LOAEL published in IRIS fell into the range of "High" or "Moderate" hazard developed by EPA ChAMP (see Chemical Selection Process), the chemical was included on the draft CHC list. There are 117 chemicals from IRIS on the Minnesota CHC list that were not listed by Maine. Fourteen of these were high production volume chemicals.

#### MDH Health-Based Guidance: Health Risk Limits, Health Risk Values, Health-Based Values, and Risk Assessment Advice numbers

The Minnesota Department of Health (MDH) develops guidance on contaminants found in ambient air and groundwater to safeguard and protect public health. The guidance specifies the health-protective limit for the concentration of a contaminant that is likely to pose little or no risk to human health, based on current scientific knowledge.

MDH guidance values for ambient air and groundwater are called Health Risk Values (HRVs) and Health Risk Limits (HRLs), respectively. Both HRVs and HRLs are formally adopted through rulemaking. MDH also develops two additional types of guidance for air and groundwater contaminants—Health Based Values (HBVs) and Risk Assessment Advice (RAA). These are not promulgated into rule, but are derived using the same methodology as the HRVs and HRLs.

The type of guidance developed depends on the availability of scientific data (animal/human toxicity studies, exposure pathways and duration/time-period exposure

data) and the priorities and needs expressed by MDH's partner state agencies. For more information on MDH guidance, please see <http://www.health.state.mn.us/divs/eh/risk/guidance/index.html>

Because the MDH HRA unit develops guidance values for chemicals detected in Minnesota groundwater or air, these chemicals were appropriate for consideration for the Minnesota CHC list. The ChAMP criteria, described earlier, were used in assessing chemicals with MDH guidance for the CHC list, resulting in addition of 74 chemicals to the CHC list. Some chemicals with MDH guidance had already been included on the CHC list after evaluation of other sources. There are a total of 157 chemicals on the CHC list that have Minnesota guidance.

#### Agencies or programs named in Minn. Stat. 116.9402 (2009)

Within Minn. Stat. 116.9402 (2009), specific state, federal, and international agencies are identified as possible sources of chemicals of concern to consider for the Minnesota CHC list. Below is a brief description of a review of the agencies named, and the chemicals included from the corresponding source (see Appendix 1).

#### California Environmental Protection Agency, Proposition 65

The California Environmental Protection Agency (CA EPA), through the Office of Environmental Health Hazard Assessment, creates a list of chemical carcinogens, developmental toxicants, and reproductive toxicants under California Proposition 65. Most of the California Proposition 65 chemicals were already listed in the Maine CHC list and were therefore included in the first Minnesota CHC list, but there were a few additional chemicals named to California Proposition 65 after the Maine CHC was published. Ten chemicals named to California Proposition 65 were not on the Maine list, though three were HPVs and an additional two were named on the Washington Appendix 1 list. All ten were added to the draft Minnesota CHC list. Chemicals named to the California Proposition 65 list after April 30, 2010 were not included on the Minnesota CHC list.

#### European Parliament Annex XIV concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals

The Minnesota statute also names the European Parliament Annex XIV concerning Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) as an international program with chemicals to consider for the Minnesota CHC list. Chemicals named to the REACH Substances of Very High Concern list through April 30, 2010 were reviewed. Most of these chemicals were already on the CHC list after being named to the Maine CHC list. Two chemicals categories, Aluminosilicate Refractory Ceramic Fibers and Zirconium and Aluminosilicate Refractory Ceramic Fibers, were added to the Minnesota CHC list. These chemicals are listed as carcinogens by REACH.

#### United Nations World Health Organization

The International Agency for Research on Cancer (IARC) publishes a List of Classifications of chemicals as they relate to cancer. On Maine's list, the Group 1 and Group 2A (known and probable) carcinogens were included. MDH used Maine's list as a basis for the Minnesota CHC and retained all 80 of the chemicals from the IARC list. No additional chemicals named specifically by IARC were included on the Minnesota CHC at this time.

#### United States Department of Health and Human Services

The U.S. Department of Health and Human Services (HHS) houses many agencies. For the Minnesota CHC, HHS sources for information were the Agency for Toxic Substances and Disease Registry, the National Library of Medicine, and the National Toxicology Program. There are 53 chemicals on the Minnesota CHC list with at least one of these sources used for information in the review process.

#### United States Environmental Protection Agency

Several sources from the U.S. Environmental Protection Agency were used in compilation of the Minnesota CHC list. The Maine CHC list, used as a starting point for the Minnesota CHC list, included chemicals listed as EPA National Waste Minimization Program Priority Chemicals, Priority PBT Chemicals, Emergency Preparedness Community Right to Know Act/Toxic Release Inventory (TRI) Reporting PBT chemicals, as well as some carcinogens named in the Integrated Risk Information System (IRIS). These chemicals from the Maine list were retained on the Minnesota CHC list. In addition, IRIS, High Production Volume Chemicals Hazard Characterizations and High Production Volume Chemicals Risk-Based Prioritizations were sources for an additional 141 chemicals added to the Minnesota CHC list.

#### Washington Department of Ecology

As described previously, the Washington Department of Ecology (Ecology) published a draft list of Chemicals of High Concern for Children (CHCC) in January 2010. In addition, Ecology published lists of chemicals that were considered for the draft CHCC in appendices. The chemicals listed in Appendix 1 and Appendix 2 were selected from many of the same sources used for the Maine CHC, with a few differences (Washington Ecology, 2010b). The CHCC list, along with Appendix 1 and Appendix 2, was considered for the Minnesota CHC list. Sixty of the 66 chemicals on Washington's CHCC draft list and 210 chemicals from Appendix 1 and Appendix 2 were included on the Minnesota CHC list. However, all but two of these selected chemicals were either already listed on Maine's list or found to qualify for the Minnesota CHC through review of other sources, particularly IRIS.

### **Limitations**

There were limitations in creating the initial Minnesota CHC list. Primarily, the limitations were related to lack of readily available information for some chemicals and insufficient time and resources to review the high number of chemicals that could qualify

for the Minnesota CHC list. These limitations and resulting effect on the CHC list are described below.

#### High Production Volume (HPV) Chemicals

The statute requires that only HPV chemicals be named to the PC list. Because the PC list must be derived from the CHC list, HPVs must be included on the initial CHC list. A query of the IUR from EPA resulted in 4755 HPV chemicals from the past twenty years. Because there was very limited time to create the CHC list, an in-depth review of all HPVs identified was not possible. Many HPVs were excluded from the CHC list because of lack of readily available information. It is not known to what extent the chemicals excluded would have met the criteria for the CHC list and the degree of hazard they could pose to humans or the natural environment. Further, for HPV chemicals that were listed on the CHC list, only examples of health endpoints or persistent and bioaccumulation information that were readily available are shown. The chemicals may have additional health endpoints or persistence and bioaccumulation that are not noted on this initial list.

Data from the EPA IUR indicate that reporting of high production volume chemicals is variable across reporting cycles. According to EPA, prior to 2003 amendments to the reporting rule, only organic chemicals manufactured in quantities of 10,000 lbs or more were required to be reported (EPA, 2010c), though some data exists for inorganic chemicals for earlier years. For example, lead (CAS 7439-92-1) was reported at >100M - 500M lbs in the 1998 IUR records and at 1 billion pounds and greater for 2006, but there are no reports (no data) for the 1990, 1994, and 2002 IUR inventories. Even for some chemicals that would seem to have required reporting for all years, such as 1, 2, 3, - trichloropropane (CAS 96-18-4), no data are available from the 1994 or 2006 inventories. This inconsistency of data is problematic when evaluating the status of some high production volume chemicals in relation to both the Minnesota CHC list and the Minnesota PC list.

#### Review of Maine's List

The statute requiring Maine to develop a CHC list is similar to Minnesota's statute. Many of the sources referenced in Maine's initial CHC list are also referenced in the Minnesota statute. To build on work already completed, MDH used Maine's CHC list as a starting point for developing the Minnesota CHC list. Initially, MDH planned to review the chemicals on Maine's list for appropriateness to Minnesota. However, with the necessity to include HPV chemicals on the Minnesota CHC list and the volume of chemicals to review, a complete review of the Maine list was not possible in the time available. MDH decided to retain chemicals appearing on Maine's initial CHC list until further review can occur.

#### Persistent, Bioaccumulative and Toxic Chemicals

The Minnesota statute states that a chemical that is persistent, bioaccumulative and toxic or a chemical that is very persistent and very bioaccumulative qualifies for the CHC list. These characteristics are not defined in the statute, and definitions of persistence and bioaccumulation vary among agencies. The ChAMP methodology from EPA does provide some guidelines for these characteristics which are within the range of many of



the definitions. Under ChAMP, a moderately to highly persistent chemical has a half life of 60 days or more in water, soil or sediment. A chemical is considered to have a moderate to high bioaccumulation potential if it has a BCF of 1000 or more. The ChAMP methodology does not provide guidelines for very persistent and very bioaccumulative (vPvB) characteristics, so the European REACH guidelines were used for this category. In general, a substance with a half life of more than 60 days in water and 180 days or more in soil or sediment is considered very persistent. A substance with a bioaccumulation factor of 5000 or more is considered very bioaccumulative.

Because of time limitations, the persistent and bioaccumulation characteristics of all of chemicals considered for the Minnesota CHC list could not be researched. All of the PBT chemicals on the Maine list, except those excluded by statute, were retained for the Minnesota CHC at this time. Further review of these chemicals will be needed, however, because not all of the chemicals called PBT on the Maine list meet the ChAMP or REACH criteria for PBT and vPvB. Specifically, the PBT chemicals named by the Oslo-Paris (OSPAR) Commission use more inclusive criteria than most agencies, with persistence defined as a half life of 50 days or more in freshwater or marine water and bioaccumulative defined as a BFC of more than 500. Additionally, more information about several of Canada's PBT chemicals was recently published under "The Challenge" program. Many of these chemicals will need to be more closely reviewed for the next iteration of the Minnesota CHC list to ensure that they meet the persistent and bioaccumulation criteria for the list.

#### List notation

The information provided in the CHC list columns is explained in Appendix 3. As noted, the list does not provide complete information about the chemical. Rather, it notes only examples of the chemical's names, health endpoint(s), other agencies that have noted concern about the chemical, and use or classification. In addition, the persistence and bioaccumulation column is not complete for all chemicals.

#### **Future Plan**

Going forward, the CHC list will be used as a base for evaluation and selecting chemicals for the PC chemicals list. As information is obtained during the process of reviewing chemicals for the PC list, the information will be retained for use in future reviews of the CHC list. MDH will also review the process for selecting HPVs for future lists.

## References:

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- OSPAR Convention for the Protection of the Maine Environment of the North-East Atlantic. 2005. Cut-Off Values for the Selection Criteria of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances. p.1 Retrieved May 4, 2010 from [http://www.ospar.org/content/content.asp?menu=00200304000000\\_000000\\_0000](http://www.ospar.org/content/content.asp?menu=00200304000000_000000_0000)
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- U.S. Food and Drug Administration. 2009. What are “Biologics” Questions and Answers. Retrieved June 9, 2010 from <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm133077.htm>.

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Washington Department of Ecology. 2010b. Phase 1. Retrieved January 28, 2009 from <http://www.ecy.wa.gov/programs/swfa/rules/pdf/p1text.pdf>

## Appendix 1 Sources

The following agencies have developed list of chemicals that are of concern to human health or the environment. These chemicals were considered for the Minnesota Chemicals of High Concern list. Not all of the chemicals from any one source were necessarily incorporated into the list, and some chemicals appear in more than one source. This is documented in the "Source" column of the Chemicals of High Concern list.

### I. Environmental Protection Agency (EPA)

#### A. High Production Volume Chemicals

*Screened with information from:*

Agency for Toxic Substances and Disease Registry

EPA Health Characterizations

National Library of Medicine

Hazardous Substance Data Bank

National Toxicology Program

Organization for Economic Organization and Development

Screening Information Data Sets (SIDS)

/SIDS Initial Assessment Reports (SIAR)

#### B. Integrated Risk Information System (IRIS)

Substances with primarily non-cancer effects

### II State of Maine

#### Chemicals of High Concern list

(See Maine's "CHC Background Information" at

<http://www.maine.gov/dep/oc/safechem/highconcern/> for complete information.)

#### A. California Proposition 65 (469 chemicals)

Carcinogens

Developmental Toxicants

Reproductive Toxicants

#### B. Canada Domestic Substance List (387 chemicals)

Persistent, Bioaccumulative, and inherently Toxic chemicals\*

#### C. Environmental Protection Agency

Integrated Risk Information system (81 chemicals)

Carcinogens

Group A, B1 and B2 (1986 Guidelines)

Known/likely human carcinogen (1996 Guidelines)

Carcinogenic to humans, likely to be carcinogenic to humans (1999 Guidelines)

Persistent, Bioaccumulative, and Toxic Lists (64 chemicals)

National Waste Minimization Program Priority Chemicals

Priority PBT Chemicals  
Emergency Planning Community Right to Know Act/  
Toxic Release Inventory PBT Chemicals

D. European Union

- Directive on Dangerous Substances (Category I carcinogens and Category I reproductive toxicants)\*
- Endocrine Disruptors (Category I) (174 chemicals)
- Persistent, Bioaccumulative, and Toxic list (22 chemicals)
- Registration, Evaluation, Authorization, and Restriction of Chemicals - Substances of Very High Concern (29 chemicals)

E. International Agency for Research of Cancer (80 chemicals)  
Carcinogens (Group I and Group 2A)

F. National Toxicology Program (196 chemicals)  
Center for the Evaluation of Risks to Human Reproduction  
11<sup>th</sup> Report on Carcinogens

G. Oslo-Paris Convention (263 chemicals)  
Substances of Possible Concern\*  
Chemicals for Priority Action\*

H. State of Washington (74 chemicals)  
Persistent, Bioaccumulative, and Toxic list

**III. State of Minnesota**

**Minnesota Department of Health (157 chemicals)**  
Health Based Values  
Health Risk Limits  
Health Risk Values  
Risk Assessment Advice

**IV. State of Oregon (112 chemicals)**  
**Priority Persistent Pollutant List**

**V. State of Washington**

- A. Appendix 1 and Appendix 2  
(from development of the Chemicals of High Concern for Children list)
- B. Chemicals of High Concern for Children

\* Will require review for future versions of the CHC list

## Number of Chemicals on the Minnesota Chemicals of High Concern (CHC) List, by source

Source	Number of Chemicals
California Proposition 65 (added)*	10
California Proposition 65 (total)**	479
European Union Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Substances of Very High Concern (added)*	2
Substances of Very High Concern (total)**	31
Maine Chemicals of High Concern list (see above in Appendix 1 for a list of Maine's sources)	1419
Minnesota Department of Health - Health-Based Guidance (added)*	74
Minnesota Department of Health - Health-Based Guidance (total)**	157
Oregon Persistent Pollutant Priority (P <sup>3</sup> ) List (added)*	27
Oregon Persistent Pollutant Priority (P <sup>3</sup> ) List (total)**	112
(CAS 50-29-3 (4,4-DDT) is listed generally under chemical group "DDT, DDE, DDD" on the MN CHC list)	
Organisation for Economic Co-operation Development Screening Information Data Sets (SIDS) / SIDS Initial Assessment Report (SIAR) for High Production Volume Chemicals (added)*	50
U.S. Department of Health and Human Service Agency for Toxic Substances and Disease Registry (added)*	5
Hazardous Substances Data Bank (added)*	52
National Toxicology Program (added)*	7
U.S. Environmental Protection Agency High Production Volume Chemical Hazard Characterization (added)*	17
High Production Volume Chemical Risk-Based Prioritization (added)*	7
Integrated Risk Information System (added, including HPV chemicals)*	117
Washington Department of Ecology Appendix 1 (added)*	209
Appendix 1 (total)**	1403
Appendix 2 (added)*	1
Appendix 2 (total)**	24
Chemicals of High Concern for Children list (added)*	6
Chemicals of High Concern for Children list (total)**	60

\* chemicals not on the Maine Chemicals of High Concern list

\*\* total on Minnesota CHC list, including those from Maine's CHC list

*Note: Because more than one source might list a chemical, the numbers provided will not total the number of chemicals on the Minnesota Chemicals of High Concern list – see also Figure 1 in the text of the methodology*

## Appendix 2 Toxicity Guidelines

The values for the lowest-observed-adverse-effect-level (LOAEL) shown below were used for assessing high production value chemicals and chemicals with non-cancer endpoints from the Environmental Protection Agency (EPA) Integrated Risk Information System and the Minnesota Health-Based Guidance for the Minnesota Chemicals of High Concern (CHC) list. These values were taken from the Environmental Protection Agency's Chemicals Assessment and Management Program (ChAMP) methodology.\* If a LOAEL from a study for the chemical reviewed was within the range of values listed, the chemical was further considered for the CHC list. If the LOAEL was not in the range, it was no longer considered for the CHC list, unless it qualified as a CHC for another reason.

Minn. Stat. 116.9401-116.9407 relates to consumer products designed for children, and exposure to these products would likely result in longer term, lower-level repeated exposures versus brief concentrated high exposure. For this reason, repeated-dose toxicity and reproductive/developmental studies guidelines were used for the chemicals evaluation rather than the acute toxicity studies guidelines. The ChAMP and European Chemical Agency (ECHA) guidelines for persistence and bioaccumulation are also noted below for reference. *However, because of time limitations, persistence and bioaccumulation estimates for most chemicals were not researched for the first Minnesota CHC list and will need to be evaluated for future revisions of the list.*

<b>Type of Study</b>	<b>LOAEL guidelines</b>
<b>Repeated Dose Toxicity</b>	
Oral	mg/kg-bw/day
90 days	<=100
40-50 days	<=200
28 days	<=300
 Dermal	
90 days	<=200
40-50 days	<=400
28 days	<=600
 Inhalation (vapor)	mg/L/6hrs/day
90 days	<=1.0
40-50 days	<=2.0
28 days	<=3.0
 Inhalation (dust/ mist/ fume)	mg/L/6hrs/day
90 days	<=0.2
40-50 days	<=0.4
28 days	<=0.6
 Inhalation (gas)	ppm/6hrs/day
90 day	<=250
40-50 days	<=500
28 days	<=750

<b>Reproductive/Developmental</b>	<b>LOAEL guidelines</b>
Oral	<=250 mg/kg-bw/day
Dermal	<=500 mg/kg-bw/day
<b>Reproductive/Developmental</b>	<b>LOAEL guidelines</b>
<b>Type of Study</b>	
Inhalation (vapor)	<=2.5 mg/L/day
Inhalation (dust/mist/fume)	<=0.5 mg/L/day
Inhalation (gas)	<=250 ppm/day
<b>Persistence</b>	
Water, Soil, Sediment	>=60 days half life
<b>Bioaccumulation</b>	
Bioconcentration factor (BCF)	>=1000

Very Persistent and very Bioaccumulative  
(Definition from the European Union Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program)<sup>†</sup>.

Very persistent	Half life
water	> 60 days
sediment	> 180 days
soil	> 180 days

Very bioaccumulative	
BCF	> 5000

\* U.S. Environmental Protection Agency. 2009. Methodology for Risk-Based Prioritization Under ChAMP. Retrieved February 10, 2010 from

[http://www.epa.gov/CHAMP/pubs/rbp/RBPMethodology\\_Web\\_April202009.pdf](http://www.epa.gov/CHAMP/pubs/rbp/RBPMethodology_Web_April202009.pdf)

<sup>†</sup> European Chemicals Agency. 2007. Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern. pp53-54. Retrieved May 4, 2010 from [http://guidance.echa.europa.eu/docs/guidance\\_document/svhc\\_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/svhc_en.pdf)



## Appendix 3 List Notation

The following provides a description of the content the seven columns of the Minnesota Chemicals of High Concern list:

### Chemical Abstracts Service (CAS) Registry Number

The first column contains the chemical's CAS number, which is assigned by the American Chemical Society. This number is unique for a particular chemical and widely used in scientific literature.

### Chemical Name

The second column provides a name for the chemical is listed. Many chemicals have many synonyms. For some of the chemicals, a scientific name is followed by a more common name in parenthesis. A useful website for obtaining a list of synonyms for a chemical is the Hazardous Substances Data Bank (HSDB) at <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>. (Type the chemical's CAS number in the box. If the chemical is available in the HSDB, a link with CAS number and a chemical name will be displayed. Clicking on the link will open the records and a heading called "Synonyms" on the left side can be selected for a list of names used for the chemical.)

### Health endpoint(s)

In the third column, health endpoints, or health effects, are listed. For the CHC list, Minn. Stat. 116.9401 names health endpoints that would qualify a chemical for the CHC list, such as damage to the nervous system, immune system, reproduction, or other organs. Health endpoints identified during the chemical review were recorded in this column. However, the health endpoints listed in this column might not be the only health endpoints or even the most common health endpoints for this chemical. **This column provides only examples of health endpoints that qualify the chemical for the CHC list.**

### Persistent, Bioaccumulative and Toxic or very Persistent and very Bioaccumulative

Likewise, the statute states that a chemical that is persistent, bioaccumulative and toxic (PBT) or a chemical that is very persistent and very bioaccumulative (vPvB) qualifies for the CHC list. For some chemicals added to the CHC, such as some of the high production volume chemicals, chemicals in the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS), and Minnesota Health-Based Guidance, persistence and bioaccumulation characteristics were not researched and information was not included on the Minnesota CHC list. If the chemical was known to be considered a PBT or vPvB, an "x" was added to this column.

### Source(s)

The fifth column shows the source of the information used for naming the chemical to the CHC list. The chemical might be listed by additional sources or in other lists made by other agencies. The sources listed here are only those used for developing the CHC list.

Use example(s) or class

The sixth column provides one or more example of use or the class of the chemical. The use information was obtained primarily from the EPA, the U.S. National Library of Medicine or Environment Canada. In some cases, the chemical is a by-product from combustion or cooking and there is no known use of the chemical. In other cases, a class was listed for the chemical, such as "PCB," which indicates the chemical is a polychlorinated biphenyl. Many PCB chemicals, for example, are known to be carcinogenic, persistent in the environment and have been found accumulating in fish.