



Maine Department of Environmental Protection

Department Rule Chapter 884

*Designation of Cadmium as a Priority Chemical and
Regulation of Cadmium in Children's Products*

Basis Statement

May 2014

TABLE OF CONTENTS

INTRODUCTION.....	3
I. CADMIUM BACKGROUND INFORMATION	4
A. Health Concerns.....	4
II. STATUTORY PREREQUISITES FOR PRIORITY DESIGNATION.....	6
A. Priority Designation Biomonitoring Criteria.....	6
B. Priority Designation Presence in the Home Environment Criteria.....	6
C. Priority Designation Presence in Consumer Products Used or Present in the Home...	7
III. PURPOSE OF PRIORITY DESIGNATION.....	8
REFERENCES.....	9

INTRODUCTION

The objective of Maine Law *Toxic Chemicals in Children's Products*, Title 38 M.R.S.A. §§1691 - 1699-B, is to reduce exposure of children and other vulnerable populations to chemicals of high concern by substitution of safer alternatives when feasible, as set forth in the Legislature's Declaration of Policy under 38 M.R.S.A. §1692. To accomplish this, the law provides the Department of Environmental Protection ("Department") the regulatory authority to collect information on chemical use and, if applicable, prohibit the sale of children's products containing priority chemicals when safer alternatives are available.

The law requires that a substance meet certain criteria to be designated a priority chemical, and that the Department provide its findings in support of such a designation. This document sets forth such findings of fact supporting the designation of cadmium as a priority chemical, and is intended to serve as the Basis Statement for the designating rule, Chapter 884, *Designation of Cadmium as a Priority Chemical and Regulation of Cadmium in Children's Products*. Department rule Chapter 880, *Regulation of Chemical Use in Children's Products*, establishes routine technical rulemaking as the process by which the Department may designate priority chemicals.

Although cadmium is found widely in the environment, in foods, and in tobacco, the exposure of children to cadmium through the products they use has been of recent concern at both the state and federal levels. Reports of high levels of cadmium use in children's jewelry in 2010 led to a U.S. Consumer Product Safety Commission ("CPSC") investigation (Lui 2010), which resulted in specific recall notices for jewelry sold by Clair's and Wal-Mart stores (CPSC 2010). However, a substantial gap in information available in the public domain, regarding cadmium's specific use in children's products, limits the Department's ability to determine potential exposure risk to Maine's children.

Therefore, the Department proposed a reporting rule for certain categories of products in order to determine where cadmium may be present in children's products currently available for sale in the State of Maine. Through this rulemaking, the Department designates cadmium (registered Chemical Abstract Service number 7440-43-9 as noted on Maine's Chemical of High Concern list) as a priority chemical in accordance with 38 M.R.S.A. §1694 and establishes a reporting requirement for manufacturers offering certain children's products for sale in the State of Maine.

I. CADMIUM BACKGROUND INFORMATION

Cadmium is a naturally occurring metal, typically found as a mineral combined with other elements such as oxygen (cadmium oxide), chlorine (cadmium chloride), or sulfur (cadmium sulfate, cadmium sulfide). Most cadmium used in the United States is extracted during the production of other metals like zinc, lead, and copper. Due to its anticorrosive properties, cadmium is most commonly used for electroplating steel, metal alloys, silver solders, welding, paint pigments, as an electrode component in alkaline batteries, or to stabilize plastic. (HSDB 2010)

Cadmium is found widely in the environment from natural sources and industrial activities, as well as from the use of phosphate containing fertilizers and nonferrous metals production, and is found in foods and tobacco (Morrow 2010). Diet is the most significant source of cadmium exposure for most people.

Because of its similarities to lead, cadmium has been used as its replacement in numerous consumer products, particularly those with metal components, such as jewelry. A child's exposure to cadmium most likely results from the handling of cadmium containing products and then transferring material from hands to mouth, through direct mouthing of products, or from swallowing parts of products. (CPSC Report 2010)

A. Health Concerns

Strong, credible scientific evidence leading to exposure concerns includes cadmium's classification as a *known human carcinogen* by the U.S. Department of Health and Human Services, National Toxicology Program ("NTP") and the World Health Organization, International Agency for the Research of Cancer ("IARC").

The NTP Report on Carcinogens Listing Criteria describes this classification as, "*Known To Be Human Carcinogen: There is sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.*" (NTP 2011). This classification reported in the NTP's 12th Congressional Report on Carcinogens (2011), represents the strongest level of confidence in a carcinogenicity rating.

In addition, the International Agency for the Research of Cancer has placed cadmium into its highest cancer toxicity classification, *carcinogenic to humans* (Group 1) (IARC Monographs, Volumes 58 (1993) and 100C (2012)), described by the IARC Monographs Preamble as, "Group 1: The agent is *carcinogenic to humans*. This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity."

Humans exposed to cadmium may experience a number of varying effects. Inhalation of cadmium can result in irritation to the lungs, causing bronchial and pulmonary irritation, sore throat, and coughing. Ingestion of cadmium can irritate the stomach and respiratory tract. Chronic exposure to cadmium can lead to a build-up of the metal in the kidneys, resulting in kidney disease, and frequently the formation of kidney stones. Some studies indicate that younger animals absorb more cadmium than adults. Animal studies also indicate that the young are more susceptible than adults to a loss of bone and decreased bone strength from cadmium exposure. (ATSDR 2012)

Cadmium accumulates largely in the kidney and liver, and only a small portion of absorbed cadmium is excreted in urine or feces. Cadmium can accumulate in the body and may remain for several decades. (ATSDR 2008, OECD 2004). Because of cadmium's cumulative nature inside the human body, additional exposure beyond general environmental sources adds to the overall risk of adverse health effects (CPSC Report 2010).

Jewelry items are among the most commonly ingested products by young children. Data on ingested objects is found in a 1998 study that evaluated 100 children ages 9 months to 13 years. Ingested objects included such foreign bodies as coins, jewelry, toys, nails, screws, tacks, or bolts (CPSC 2006).

With this in mind, a child-specific standard for cadmium exposure was adopted in 1994 by the European Commission as the toy safety standard EN 71-3, which limited exposure to cadmium from toys for young children at 0.6 micrograms per day. This standard was re-evaluated using more recent data on the way cadmium affects human kidneys, and revised effective July 20, 2013, to a limit of 0.2 micrograms per day ("µg/day"). This limit is not expressed in terms of body weight, rather it is a daily limit for cadmium exposure that has been adjusted to account for the weight of a young child (approximately 16.5 pounds) (CPSC Report 2010).

In the United States, the Agency for Toxic Substances Disease Registry developed a minimal risk level ("MRL") for intermediate length exposure of 0.5 µg/kg/day (intermediate exposure defined as 15 through 364 days). However, due to inadequacies in data regarding acute oral exposure, the ATSDR did not derive an acute duration MRL for cadmium (acute exposure defined as 1 through 14 days). (ATSDR 2008, CPSC Report 2010)

These standards highlight the concern for the potential exposure of children to cadmium through the use of commonly available children's products. Due to the considerable lack of information on the use of cadmium in children's products in the present, the Department believes it is important to compel the reporting of this information.

II. STATUTORY PREREQUISITES FOR PRIORITY DESIGNATION

To be included on Maine’s list of Chemicals of High Concern (“CHC”), a chemical must have strong, credible scientific evidence classifying it as either a reproductive or developmental toxicant, endocrine disruptor, or human carcinogen. Cadmium meets this requirement after having received the highest possible rating of carcinogenicity by two of the world’s leading cancer research centers (IARC 2012 and NTP 2011) as a *known human carcinogen*.

Title 38 M.R.S.A. § 1694 states that the, “commissioner may designate a chemical of high concern as a priority chemical if the commissioner finds, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention:

- A. 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;
- B. The chemical has been found through sampling and analysis to be present in household dust, indoor air or drinking water, or elsewhere in the home environment; or
- C. The chemical is present in a consumer product used or present in the home.”

The statute authorizes the Commissioner to designate chemicals that meet one or more of these criteria as priority chemicals by the adoption of routine technical rules. Arsenic meets all three criteria.

A. Priority Designation Biomonitoring Criteria

As noted in supporting documents for Maine’s CHC list, eight different biomonitoring studies have found cadmium to be present in human urine, blood, including umbilical cord blood, or human breast milk (ME-CDC 2013). In addition, urine samples from a representative population of the United States, collected through the National Health and Nutrition Examination Survey (“NHANES”), from the year 1999 through 2010, found detectable levels of cadmium in urine for all age groups surveyed (ME-CDC 2013), further solidifying the meeting of this criterion.

B. Priority Designation Presence in the Home Environment Criteria

Cadmium has also been detected in household dust although limited research is available for U.S. consumer homes. A large study of households, representative of urban Canadian homes, measured cadmium in household dust at levels greater than the natural background level found in the soil (Rasmussen et al. 2013). The Siefert et al (2000) study evaluated metals present in German households and found that cadmium was present in dust samples in over 3000 adult households and 600 households with children ages 6-14 years. Sampling in homes within the United States found cadmium present in the indoor dust of homes located near mining sites in Oklahoma at levels greater than the soil concentrations which surround the homes (Zota et al 2011, ME-CDC 2013).

C. Priority Designation Presence in Consumer Products Used or Present in the Home

Cadmium is used to make pigments such as shades of yellow, orange, red, and maroon. Particularly used in paints, cadmium containing pigments may also be used in textiles, inks, specialty paints, print pigments, and rubber (Just Paint 1996). The European Union Risk Assessment Report Cadmium Oxide and Cadmium Metal (2007) lists cadmium consumption in the Western World in 1994 by application. The breakdown of cadmium's use included pigments at 16% of total consumption, PVC stabilizers at 12% of total consumption and protective coatings at 7% of total consumption (EU RAR 2007).

In June 2010, McDonald's Corporation voluntarily recalled more than 12 million promotional "Shrek Forever After 3D" Collectible Drinking Glasses due to concerns over the cadmium levels in paint pigments used on the glassware (Neuman 2010).

Cadmium has been measured in consumer products including children's school bags, children's clothing, jewelry, and pet supplies. The Danish Environmental Protection Ministry, Consumer Product Survey No. 94, "*Survey and health assessment of chemical substances in jewelleries,*" found that 24% of the 318 pieces of jewelry screened contained cadmium above 75 parts per million ("ppm"). Several jewelry pieces tested in the study confirmed the migration of cadmium to the skin in an amount with the potential to cause negative health effects. (DEPA 2008).

The European Union Restriction of Hazardous Substances ("RoHS") 2 Directive 2011/65/EU restricts the use of cadmium in homogenous materials to a maximum concentration of 0.01% or 100 ppm, a more restrictive limit than the other five chemicals RoHS regulates which have a maximum allowable concentration level of 0.1% or 1000 ppm. In September 2012, the European Union amended REACH (Regulation (EC) No 1907/2006 Annex XVII) to list specific plastic materials in which cadmium and cadmium compounds shall not be used or placed on the market if the concentration of cadmium is equal to, or greater than, 0.01% by weight of the plastic material (European Chemicals Agency, Helsinki, Finland).

The U.S. Federal Consumer Product Safety Improvement Act ("CPSIA") of 2008, set 75 ppm (75 mg/kg) as the maximum amount of soluble cadmium allowed in the surface coating of children's products subject to the law. Although federal law limits the amount of cadmium that may be present in certain products, available information indicates its use continues.

As of October 2013, some manufacturers reported to the Washington State Department of Ecology ("WDOE") cadmium is either present as a contaminant or had been intentionally added to 63 children's products, as defined by Washington rule Chapter 173-334 WAC. Reported information describes cadmium's use as a pigment, texture, stabilizer, and plasticizer. Some of the product categories reported include: child safety seats, shoes, occasion supplies, clothing, jewelry, bedding, personal accessories, toys and games, and craft supplies.

Sufficient information exists to support a finding that cadmium is present in consumer products in the home, in addition to naturally occurring cadmium.

III. PURPOSE OF PRIORITY DESIGNATION

The presence of cadmium has been confirmed in commonly used children's products through product testing and most recently through the limited manufacturer reporting requirement by Washington State Department of Ecology. The Department now seeks to gain insight into the current use of cadmium in children's products sold within the State of Maine to analyze whether additional regulatory management would be appropriate.

Due to its toxicity, Maine has already designated cadmium as a priority toxic chemical under Maine's Toxic Use Reduction law ("TUR") 38 M.R.S.A. §§ 2321 to 2330. In an effort to reduce cadmium's use in manufacturing processes, this law provides the Department the authority to require manufacturers within the State of Maine using more than 1,000 pounds of cadmium a year to report this use to the program. Technical assistance provided through the TUR program encourages industry to reduce cadmium's use by manufacturers and encourages the use of safer alternatives. This designation through TUR provides the Department with valuable information regarding the use of cadmium in manufacturing processes within the State of Maine, but does not encompass children's products within its scope.

Designating cadmium as a priority chemical within the Safer Chemicals Program will require disclosure on how and where cadmium is intentionally added to certain categories of consumer products. This information regarding the use of cadmium in manufacturing processes and products available to the Maine consumer will provide the Department with more details regarding its use than has been gleaned from any current public source, and will serve to shape a more complete analysis than can be accomplished in the absence of such a reporting requirement.

References

- “Claire’s Recalls Children’s Metal Charm Bracelets Due to High Levels of Cadmium,”
U.S. Consumer Product Safety Commission. Washington, D.C. May 10, 2010. Press Release #10-227.
- Danish Ministry of the Environment, Environmental Protection Agency (DEPA). 2008. *Survey and health assessment of chemical substances in jewellery, Survey of chemical substances in consumer products, No. 94*. Prepared by Strandesen, Maria, Pia Poulsen, and FORCE Technology, (2008).
- European Union Risk Assessment Report (EU RAR). 2007. European chemical Substances Information System, European Chemicals Bureau, *European Union Risk Assessment Report, Cadmium Oxide and Cadmium Metal, Risk Assessment*, Volume 72 and Volume 74. Publication EUR 22919 ENV and EUR 22767 EN.
- Lui, Marco. 2010. “U.S. to Develop Safety Standards for Toxic Metals,” *Business Week*. January 12, 2010.
- Maine Center for Disease Control (ME-CDC). 2013. *Rationale for Concurrence by Maine Center for Disease Control and Prevention on the Designation of Cadmium as a Priority Chemical*, (Augusta, Maine: December 2013).
- Morrow, H.. 2010. “Cadmium and Cadmium Alloys,” *Kirk-Othmer Encyclopedia of Chemical Technology*, (2010). John Wiley & Sons, 1-36. ISBN 978-0-471-23896-6.
- National Library of Medicine, TOXNET, Hazardous Substance Data Bank (HSDB). 2010. *Uses and Manufacturing: Cadmium for Cadmium*. (Accessed September 17, 2013 at website: <http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@rn+7440-43-9>)
- Neuman, William. 2010. “McDonald’s Recalls 12 Million ‘Shrek’ Glasses,” *The New York Times*. (June 4, 2010).
- Organization for Economic Cooperation and Development (OECD). 2004. *Initial Assessment Profile: Cadmium Oxide and Cadmium Metal*. Paris, France, (2004).
- Rasmussen et al.. 2013. *Canadian House Dust Study: population-based concentrations, loads and loading rates of arsenic, cadmium, chromium, copper, nickel, lead, and zinc inside urban homes*, *Science of the Total Environment*. (January 15, 2013). 443:520-9.
- Seifert et al.. 2000. *The German Environmental Survey 1990/1992 (GerES II): reference concentrations of selected environmental pollutants in blood, urine, hair, house dust, drinking water and indoor air*, *Journal of Exposure Analysis and Environmental Epidemiology*. (Nov-Dec 2000). 6 Pt 1: 552-65.
- U.S. Consumer Product Safety Commission (CPSC). 2006. Memorandum from Craig O’Brien to Kristina M. Hatlelid, “Analysis of Data on Child Ingestions,” dated November 30, 2006. Presented as part of: “Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry,” (Petition No. HP 06-01). December 4, 2006.

U.S. Consumer Product Safety Commission (CPSC). 2010. “McDonald’s Recalls Movie Themed Drinking Glasses Due to Potential Cadmium Risk.” Washington, D.C. June 4, 2010. Press Release #10-257.

U.S. Department of Health and Human Services, National Toxicology Program (NTP). 2011. *Congressional Report on Carcinogens (RoC), 12th Edition*, Research Triangle Park, North Carolina (2011).

U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR). *Toxicological Profile for Cadmium*, (2008).

U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR). *Toxicological Profile for Cadmium*, (2012).

U.S. Federal Hazardous Substances Act (FHSA). 15 U.S.C. §§ 1261-1278.

U.S. Consumer Product Safety Commission (CPSC). 2010. *Staff Report: Cadmium in Children’s Metal Jewelry*, (October 2010), 3. (Cited as (CPSC Report 2010).)

U.S. Department of Health and Human Services, National Toxicology Program (NTP). 2011. *Report on Carcinogens*, Listing Criteria. (Last Updated June 15, 2011; Accessed January 9, 2014 at website: <http://ntp.niehs.nih.gov>).

“Will Cadmium Always Be On The Palette? Alternative Pigments Are Becoming Available”. *Just Paint*. Issue 4. Golden Artist Colors, Inc., October 1996.

World Health Organization, International Agency for Research on Cancer (IARC). 2012. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans; Arsenic, Metals, Fibres, and Dusts. Volume 100C*, (2012).

World Health Organization, International Agency for Research on Cancer (IARC). 1993. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans; Beryllium, Cadmium, Mercury, and Exposures in the Glass Manufacturing Industry Volume 58*, (1993).

Zota et al.. 2011. *Metal sources and exposures in the homes of young children living near a mining-impacted Superfund site*, *Journal of Exposure Science & Environmental Epidemiology* (May 18, 2011). 21(5):495-505. ISSN 1559-0631.