STATE OF MAINE
DEPARTMENT OF ENVIRONMENTAL PROTECTION

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MEMO

To: **Chairman Foley and members of the Board of Environmental Protection and Commissioner Aho**

From: **George M. MacDonald, Director, Sustainability Division**

Date: **January 3, 2013**

Subject: **Department Recommendations on the Citizen's Petition Concerning Bisphenol A in Packaging of Infant Formula, Baby Food and Toddler Food, and the Definitions for Intentionally Added and Toddler Food**

On June 21, 2012, a Citizen's Petition to initiate rulemaking concerning 06-096 C.M.R. ch. 882, *Designation of Bisphenol A as a Priority Chemical and Regulation of Bisphenol A in Children's Products,* was submitted to both the Board of Environmental Protection (Board) and the Department of Environmental Protection (Department). The petition is seeking to extend the existing prohibition on the sale of reusable food and beverage containers containing bisphenol-A (BPA) to packaging used for infant formula, baby food, and toddler food. In addition the petition seeks the adoption of a modified definition for "intentionally added", and the adoption of the term "toddler food."

The decision concerning the sales prohibition on packaging of infant formula, baby food, and toddler food containing BPA is considered major substantive, and therefore, under the jurisdiction of the Board. The decision of whether or not to adopt the proposed definitions for "intentionally added" and "toddler food," is routine technical, which is decided by the Department's Commissioner.

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The regulatory framework that is available to guide the Board in its decision regarding the sales prohibition of infant formula, baby food and toddler food in packaging containing BPA can be found at 38 MRS § 1696. If the Board finds, after the consideration of information filed under 38 MRS § 1695, as well as other relevant information that a children's product containing BPA in an amount greater than the de minimis level for sale in the State exposes children to BPA, and one or more safer alternatives to BPA are available at a comparable cost, then the Board may adopt rules prohibiting the manufacture, distribution or sale of those children's products. The statutory framework gives the Board a great deal of discretion in that even if there is a positive finding regarding exposure and alternatives, the Board is not required to adopt rules to enact a sales prohibition.

Further guidance is provided in 06-096 C.M.R. ch. 880, *Regulation of Chemical Use in Children's Products*. Of particular usefulness to the analysis is 06-096 C.M.R. ch. 880 § 6, which provides a more detailed scope for assessing alternatives, especially in determining if an alternative is available at a comparable cost.

Since this rulemaking is a joint, but separate function of both the Board and the Commissioner, the Department is combining its recommendations on the citizen's petition, which is seeking the adoption of a rule to prohibit the sale of infant formula, baby food, and toddler food packaged in containers manufactured with BPA, as well as the content for the proposed definitions for intentionally-added and toddler food for convenience and ease of analysis. Also included for reference in the appendices are 06-096 C.M.R. ch. 880, 06-096 C.M.R. ch. 882, and 38 MRS §§ 1691 -1699-B.

Board's Jurisdiction - Sales Prohibition: Infant Formula, Baby Food and Toddler Food

During an October 2010 work session to discuss the then proposed language for Rule Chapter 882, members of the board questioned why the Department would not propose a sales prohibition on packaging with intentionally added BPA and instead request manufacturers submit information beyond the reporting requirements. In response, the Department expressed concern that a lack of information regarding available alternatives for packaging these sensitive food categories could lead to regrettable substitutions. The resulting rule, which became effective on January 9, 2011, gave notice to the regulated community that Maine would be performing an analysis of infant formula and baby food packaging in an effort to gather information on BPA packaging and its alternatives.

The Department has proceeded with fully implementing Maine's Toxic Chemicals in Children's Products law and has collected valuable information from manufacturers regulated by Rule Chapter 882. Of the manufacturers reporting the use of BPA in their products four reported infant formula, three reported baby food, and one manufacturer reported use within both categories.

Infant Formula Packaging Category

Exposure

Through 38 MRS § 1696(1)(A) the Board has authority to consider a sales prohibition if, among other things, there is confirmation that distribution of the product directly or indirectly exposes children to the priority chemical.

There is agreement among numerous federal and international government agencies, including the U.S. Public Health Service Food and Drug Administration (FDA) that the

consumption of food packaged in metal which is lined with epoxy containing BPA, exposes the consumer to BPA via consumption of the food product. In its March 30, 2012, response to a petition submitted by the Natural Resources Defense Council, the FDA, a division of the U.S. Department of Health & Human Services (U.S. DHHS), states, *"FDA has reviewed these materials and concurs that BPA migrates from certain food contact articles, becomes a component of food, and is therefore consumed."*[1]

After taking notice of legislation regulating canned food packaging and consumer's expressions of concern, manufacturers of the infant formula product category have responded by removing BPA from their respective product lines. In fact, of the infant formula manufacturers that have submitted reports to the Department, those representing nearly 97% of the national infant formula market modified their manufacturing process to eliminate the use of BPA packaging in 2011. Manufacturers in this sector affirmatively responded to consumer demand, resulting in a product that, as marketed today, has nearly eliminated BPA in its packaging. However, there are still products available that contain BPA in its packaging within this food category; therefore, there is still the potential for exposure to children under three years of age.

Alternatives

Additionally, within 38 MRS § 1696(1)(B) the Board may adopt a rule prohibiting the sale of a product if, among other criteria, one or more safer alternatives to the priority chemical are available at comparable cost.

Reports from manufacturers of infant formula state that the use of BPA in their product packaging functions as a protective coating, a barrier between the metal substrate and the food held within it, preventing the growth of dangerous bacteria that when consumed results in serious illness, particularly to the susceptible population category

[1] FDA Letter in Response to Petition Docket No. FDA-2008-P-0577-0001/CP, March 30, 2012, pages 4-5.

of infants. The recently submitted alternatives assessment, prepared by TechLaw confirms previous reports that there is currently no known chemical replacement for BPA which provides the same function and standards of performance while maintaining an equivalent safety record for use within the packaging of this sensitive food category.

While the alternatives analysis presented to the Board includes several options for alternative packaging to metal cans, including polypropylene and polyethylene, and the local market currently provides some of these packaging options, there remains an absence of detailed information regarding cost to the consumer when a change in packaging material is implemented by this manufacturing sector. Although there is a lack of specific data concerning comparable cost, infant formula in alternative packaging is known to be available and for sale in the State. This availability could lead one to presume that the cost differential for alternative packaging in this food category, if any, is not unreasonable for the consumer.

Based on this information, the criteria set forth in law have been met and supports the request of the petitioners to modify Chapter 882 to include a sales prohibition on infant formula packaging which contains BPA above de minimis levels. The Department recommends that the language proposed by the petitioners concerning a sales prohibition on packaging for this product category is reviewed to ensure that it is both correct and clear.

Baby Food Packaging Category

Exposure

The board is provided the same authorities noted in the previous sections with regard to the baby food category.

The Department has also received reports on the use of BPA in the packaging of baby

food, specifically used as an adhesive on the metal lids of glass jars. Reporting manufacturers in this food category that have modified their packaging process to eliminate the use of BPA represent 92% of the national baby food market share. The one reporting manufacturer that has not yet changed packaging represents approximately one percent of the national market share for this product.

While there is agreement among numerous federal and international government agencies that the consumption of food packaged in metal cans which are lined with BPA containing epoxy exposes the consumer to BPA, there exists limited information which speaks to the use of BPA as an adhesive on the surface or within a layer of the metal lids used to cap glass jars of baby food.

One of the few studies specific to this food category analyzed 122 baby food products of seven brands in glass jars with metal lids. The presence of BPA could not be confirmed for 23 of the products. For the 99 products remaining, 15% showed BPA levels less than the average method detection limit, 70% showed BPA levels of less than 1 ng/g (1 ppb), and the remaining measured concentration levels were between 1 ng/g and the highest concentration for all samples of 7.2 ng/g. The average BPA level for all 99 products was 1.1 **ng/g (1.1 ppb)** (Cao et al, *Bisphenol A in Baby Food Products in Glass Jars with Metal Lids from Canadian Markets*, Journal of Agricultural and Food Chemistry (2009)).

The Certificate of Analysis provided by the petitioners within their Exhibit 16 highlights the uncertainty of exposure to the consumer when consuming the contents of a glass jar sealed with a metal lid. Of the 12 samples tested by the petitioner-retained laboratory, only four samples resulted in any detection within the food product and each of these four samples showed results well below the estimated detection limit for content of 5 ppb.

Based upon the evidence in the record, it is unclear whether BPA used in metal lids comes in contact with the food product and further, whether BPA used in this manner causes any exposure to the consumer. Exposure information within this product category remains limited at this time.

The petitioners, within their submitted assessment of available alternatives, themselves categorize the use of glass jars with metal lids as a "Safer Alternative" to metal cans. Exhibit 15 of the petition includes a document written by Michael Belliveau and referred to by the petitioners as *Safer Alternatives to Bisphenol A Are Available for Food and Beverage Packaging for Young Children: An Assessment of BPA-Free Alternatives for Infant Formula, Baby Food and Toddler Food* (June 2012), which provides a detailed table outlining safer alternatives to the use of metal cans lined with BPA containing epoxy (Table 9). Within Table 9 petitioners point to the use of glass jars with metal lids by Eden Foods, Inc., going so far as to highlight this manufacturer's choice of packaging material as a "Safer Alternative" because of "reduced BPA exposure," and concludes that the company's use of glass jars with metal lids makes this product "BPA-Free Since: Starting in 2011."

The petitioner submits that there are suitable alternatives for packaging of baby foods and uses Eden Foods' use of glass jars with metal lids as an example of a currently available safer alternative.

The Eden Foods, Inc. website describes their use of glass jars with metal lids as nearly identical to the Department's understanding of how metal lids are used on jars of baby food that are the subject of the petition. Eden Foods, Inc. goes on to describe their process, which includes, *"...the lining is epoxy based and does contain a minute amount of BPA...The cap's inner surface is separated from the food by an area of air...The surface area exposed to the food is substantially less for a twist cap than canned goods."*[2]

[2] Eden Foods, Inc. website, *Eden Foods Bisphenol-A (BPA) Free Pioneer,* www.edenfoods.com/articles/view.php?articles_id=178

Alternatives

Some manufacturers of baby food have expanded the products available in the market to include foods packaged in laminated pouches, which according to the Department's recently submitted alternatives assessment report contain benign components. While the alternatives analysis presented to the Board for this food category offers several possible packaging options, including polypropylene, aseptic containers, and polyethylene, there remains limited information regarding cost to the consumer when a change in packaging material is implemented. Any consideration of cost to consumer must incorporate a change in volume when packaging is modified, consumer storage requirements and shelf, as well as retail outlet purchasing leverage.

An additional consideration is the available option of alternative packaging which must maintain safety for all food types (i.e. acidic, aqueous, and fatty) and accommodate the various food processing requirements. At this time glass jars are accepted for all food types and have been scrutinized over a period of decades for use as a safe and reliable food container.

It is for these reasons that the Department recommends against the baby food packaging sales prohibition as proposed by the citizen initiated petition.

Toddler Food Packaging Category

38 MRS § 1697(8) states that food and beverage packaging is exempt from the requirements of these regulations unless the product is intentionally marketed or intended for the use of children under three years of age. Many of the products that would be captured under the definition of toddler food as proposed by the petitioners are not clearly identifiable as intentionally marketed to or intended for use by children under three years of age. These products are often products that are marketed to and intended for use by older children or adults. The difficulty in enforcing a ban on toddler

food is not only one of how the Department is to make determinations on who is regulated, but is one that does not provide the regulated community with a sufficiently clear, fair notice of whether or not they are subject to the regulation.

Through 38 MRS § 1696(1), the Board may only adopt rules supporting a sales prohibition on a children's product containing a priority chemical, after they consider information filed under 38 MRS § 1695 and other relevant information submitted to or obtained by the Board. A review of this information would assist the Board in determining whether there is exposure, either directly or indirectly, and if there are one or more safer alternatives available at a comparable cost. Since toddler food is a category newly introduced by this petition, information under 38 MRS § 1695 has not been filed at this time. Without this reporting, it is not possible to determine if the requirements of 38 MRS § 1696(1)(A) & (B) have been met.

To determine exposure, the Board would need to know what products are captured by this toddler food category, how such products are packaged, and whether the packaging contains BPA. The petitioners do not provide much information on the "intended for the use of children under three years old" part of their definition, which differs considerably from "marketed to children under three years old." When the petitioners reference products that are intended for the use of children under three years of age, in most instances, it is for products already captured by the baby food category, since this product category overlaps greatly with toddler food. A prohibition on the manufacturing, distribution and sale of toddler food packaging containing BPA would essentially result in a ban on most, if not all canned food, which is contrary to the law. That is because food packaging is specifically exempt from these regulations except under a limited set of circumstances, which is when the product is intended for the use of and intentionally marketed to children under three years of age. (See 38 MRS § 1697(8)). Infant formula and baby food readily fit into this definition; however, toddler food as defined by the petitioners becomes less clearly identifiable, and would create a

regulatory scheme that guesses at whether, for example, a "can of peas" is intended for use by children under three years of age. Simply because children under three can consume canned peas, does not mean the peas are intended for use by children under three years old. The word 'intended' connotes that it is deliberate or specifically aimed at something, not simply something that may be utilized by that age group.

The petitioners do however go into great detail on the "intentionally marketed" portion of the proposed definition, relying heavily on the use of animated characters in the marketing of products. The Department's concerned that while an animated character may be suitable for children under three; many are also designed for an audience that extends beyond three years old. In order to implement such a prohibition, the Department would have to answer the question "Was the placement of an animated character, such as Cinderella, on a label deliberately marketing that product to a child under three years old?" This question cannot be easily answered. This clearly illustrates the guesswork that would be associated with implementing such a ban, and guesswork is not a defensible way to regulate. Regulations should clearly define what is regulated, so those subject to the regulation can reasonably understand what is expected. Adopting a prohibition on packaging containing BPA for this product category, at this time, inevitably would lead to uneven enforcement because toddler food, as defined by the petitioners, is not a bright line enforceable food category.

In addition to determining whether there is exposure, before adopting rules to enact a ban on the sale of a product, the Board must also determine whether there are one or more safer alternatives available at a comparable cost. Again, because toddler food is a new category to consider, reporting under 38 MRS § 1695 has not been considered. The petitioners even acknowledge that the Board should extend the existing BPA alternatives assessment requirement to the toddler food category before the effective date of a sales prohibition due to a lack of verifiable information regarding the safety of alternative metal coatings. If there is a need for a proper alternatives assessment before

enacting a ban, based on the information in the record before the Department and the Board, it appears the requirements of 38 MRS § 1696(1)(A) & (B) have not been met.

The alternatives assessment recently submitted by the Department to the Board on infant formula and baby food packaging, has limited to no value in answering the question of safer alternative to toddler food packaging, because the food captured by the petitioners in their definition of toddler food is of a differing consistency and content than infant formula and baby food. These foods could potentially be more acidic and fatty, which may require differing packaging alternatives than infant formula and baby food to ensure food preservation and safety, and at this time it is unknown if there are suitable alternatives for packaging available at a comparable cost.

The law does provide that in the absence of persuasive evidence to the contrary, the Board may utilize certain presumptions to determine whether a safer alternative is available (See 38 MRS § 1696(2) and 06-096 C.M.R. ch. 880 § 6(B)(3)). However, because the breadth of products is so large for toddler food, as defined by the petitioners, it would be difficult to make these presumptions. Simply because there are alternatives to cans on the market for infant formula, does not mean these same alternatives would be effective for toddler foods; therefore, a presumption cannot necessarily be made that an alternative is available if it is sold in the United States because it is for products with differing packaging requirement. No other state has banned packaging containing BPA for toddler food; therefore, one could not presume that a safer alternative is available because the product has been banned by another state based on the availability of alternatives.

While the FDA Memorandum dated October 22, 2009, which was received during the comment period, references BPA concentrations for toddler food, this document never specifically defines toddler food. However, when referencing toddler food, the FDA Memorandum describes the packaging as being primarily "glass containers with

polymer-coated metal closures and small plastic containers," which is consistent with the way baby food packaging is defined by Maine law, and the report uses both terms interchangeably throughout the document. Furthermore, the Department believes that in looking at the description of the products reviewed in this study, as found in Attachment V of the memorandum, that most if not all products listed would meet the definition of baby food as found at 06-096 C.M.R. ch. 882 § 2(A). This further illustrates that toddler food, as defined by the petitioners, has not been clearly studied. It would not only be difficult for the Board to determine exposure and whether there are alternatives, but if rules were adopted by the Board to enact a prohibition on packaging containing BPA for this category, it would be difficult for the Department to regulate in a consistent, fair manner.

Department staff is recommending that at this time the Board not adopt rules prohibiting the manufacture, sale or distribution of toddler food packaging containing BPA, as defined by the petitioners. Even if a modified definition for toddler food is adopted by the Commissioner, Department staff would contend that a prohibition on the manufacture, distribution or sale on packaging for this product category is inappropriate because the requirements of the statute and rule have not been met.

Commissioner's Jurisdiction – Definitional Determinations: Intentionally Added and Toddler Food

Intentionally Added

The current definition of "intentionally added" has been provided by the Legislature with the passage of what is now codified as PL 2011, Ch 319. The Department has established rules reflective of the legislative mandate provided in law.

The current definition of intentionally added is sufficient to maintain its effectiveness, and allows for flexibility should changes occur within the regulated product or product packaging. Chapter 882 encompasses what the petitioners are asking for: a consistent structure with the maximum enforcement authority possible under the existing framework. The definition of intentionally added, as currently written, is appropriately comprehensive and provides for case-by-case evaluation of regulated products.

The proposed amendment to this definition is limiting and unnecessary. Petitioners contend this amendment is necessary to bring more manufacturers into compliance with the rule. A definitional change is unlikely to cause a greater number of manufacturers to become captured by the rule. If the petitioners are aware of manufacturers regulated by the rule that are not in compliance due to a failure to report, the most effective means of bringing such entities into compliance is to make the Department aware so that the enforcement authority provided may be pursued – as exemplified by the Department's implementation of Chapter 882 to date. This would be the most effective and efficient manner of bringing manufacturers into compliance. Modification of this definition will not achieve the same effect.

The Department's program is currently applying the definition of intentionally added in a way that is consistent with the language agreed upon by the legislature and upholds the

intent of the law. In fact, the Department has applied the current definition in much the same way that the petitioners have interpreted its meaning. An amendment to the definition would have no efficacy in the way the Department pursues implementation of this law.

Therefore, the Department does not recommend changes to the language used to define intentionally-added as currently written in Maine law.

Toddler Food

The petitioners are seeking a sales prohibition on toddler food that utilizes packaging containing BPA. In order to regulate this product category, the petitioners have included a definition of toddler food, which is as follows:

> "Toddler food" means any food or beverage, other than baby food or infant formula, that is intentionally marketed or intended for use of children under 3 years of age. 'Toddler food' includes but is not limited to canned foods with labels or related marketing materials that prominently display animated characters from television shows or films that include preschool children among their target audience.

This proposed definition is flawed in numerous ways and would make administration and enforcement of the regulations concerning this food category difficult and unpredictable.

The statute at 38 MRS § 1697(8), exempts food and beverage packaging from the requirements of these regulations unless the product is intentionally marketed or intended for the use of children under three years of age. The use of the words "intentionally" and "intended" make the scope of food products where packaging can be regulated very narrow. The use of those words generally implies that the regulation of food and beverage packaging would be the exception and not the rule. However, as

defined in the petition, the toddler food product category would likely result in regulating food and beverage packaging beyond the scope of what the regulation intended.

In looking at the terminology used in statute and included in the definition provided by the petitioners for toddler food, the terms "intentionally" and "intended" infer that something is done deliberately, or has been specifically planned or contemplated. Therefore, in order to regulate something as toddler food, as defined by the petitioners, the product would have to be deliberately aimed to be used by or consumed by children under three years of age, in order to be considered intentionally marketed to. To be considered intended for use of children under three years of age, that product would have to be specifically contemplated for use by children under three years of age. The issue with making these determinations is that toddlers consume a wide array of food that may encompass products that are deliberately aimed or specifically contemplated for use by people over three years of age, such as canned vegetables, fruits and soups. This is simply not a discrete product category, such as baby food or infant formula.

To determine if something is intentionally marketed to children under three years of age, the petition itself speaks to marketing that uses animated characters on food product packaging. While many characters are suitable for audiences that range from two years of age and up, to then make the leap to say that inclusion of the character on the label means that the product is specifically meant for use by a child under three, would be an unsubstantiated assumption. The use of that character could have been to deliberately aim that product at children older than three years of age. This not only illustrates that utilizing the definition proposed by the petitioners would create a vague regulation that would make it difficult for the Department to determine who is subject to the regulation, but would make it challenging for the regulated community to know if they were subject to the rule. Regulating by the Department of Environmental Protection based on a marketing scheme is not appropriate for the Department and would create insurmountable challenges to enforcement, because marketing is fickle and subject to

quick changes. This would likely negate any attempt at regulation because one week a product may feature an animated character, and the next week the character is no longer appearing on the label. The way the petitioners suggest how to determine if something is intentionally marketed to children under three years of age is not an effective way to regulate.

The problem with making determinations on whether a product is intended for the use of children under three years of age is the same for deciding if something is intentionally marketed to children under three years of age. Simply because a product can be used by children under three, does not mean that it was specifically contemplated to be for use by children under three years of age. In order for Department staff to enforce such a regulation, they would need to guess if a product was manufactured, distributed or sold to be used specifically by children under three years of age. The only way to effectively do that in a fair manner would be if the product was specifically labeled as being for children under three years of age.

Furthermore, where the Department has sought to regulate food and beverage packaging, the food or beverage itself has been specifically described in the definition found in rule. Department rule at 06-096 C.M.R. ch. 882 § 2(A) & (F), defines baby food and infant formula by describing the consistency of the food. The petitioners simply suggest a definition that utilizes the language from statute that allows for food and beverage packaging to be regulated as the basis for their definition. The proposed definition would be inconsistent with the Department's current regulatory scheme for identifying products where food and beverage packaging is subject to regulation.

Creating a definition for toddler food that includes a description of the food would result in one of two potential challenges to implementation. First, due to the fact that baby food, as defined in rule, does encompass foods that are meant for toddler aged children, at least a portion of the definition of toddler food would be the same or similar

to the baby food definition, and therefore, would create unnecessary duplicity within the law. The other challenge to implementation would be that toddler food can potentially be most any food. Describing the food in definition would mean describing all foods, which illustrates that this category would go beyond what the statute intended, when it provided the narrowly defined exemption for the regulation of food and beverage packaging.

It is for these reasons that the Department is recommending that the Commissioner not adopt a definition for toddler food. It is simply a product category that is both already captured by baby food as defined in rule, and is one that extends beyond what is contemplated by statute for the regulation of food and beverage packaging. The addition of this definition would create too many unknowns. However, if the Commissioner decides to adopt a definition of toddler food, the Department would suggest the following, modified definition:

> "Toddler food means any food or beverage, other than baby food or infant formula, that is solely intended for use by children under three years of age, and is specifically labeled as being for children under three years of age."

While this definition is still inconsistent with how food products are currently defined in rule, there is no effective way to define toddler food by describing the food itself, because of the variation in development stages, which directly correlates to what foods are consumed by children in this age group. Department review of regulations throughout the country has not provided any guidance on the toddler food category. In fact no other state is regulating toddler food as a category that is distinct from baby food, as currently defined in rule. At a minimum, the definition above eliminates the guesswork that would be needed by both the Department and the regulated community. With this modified definition, if the Board decides to adopt a rule that prohibits the

manufacture, distribution and sale of toddler food that utilizes packaging containing BPA, the Department would be able to better administer and enforce such regulations.

Considerations for Both the Board and the Commissioner

5 MRSA §§ 8052(5-A) and 8063, require that any agency rule consider the fiscal impacts to municipalities, counties and small businesses. The Department is concerned with the potential fiscal impact from the adoption of any rule that would result in a sales prohibition of products containing BPA in its packaging. The impacts could include: the need to alter procurement, manufacturing, and distribution processes to accommodate the alternative packaging/materials; potential changes in the handling and shipping of the products; the altering of marketing initiatives; and the possible modifications to displays at the retail level. To better identify and quantify these potential impacts, the Department has sought assistance from the State Economist, but due to staffing and time constraints it is unknown if this information will be available in a timely manner.

Fiscal impact concerns are especially relevant to the proposed toddler food category. The definition for toddler food, as proposed by the petitioner, can be construed to be so broad that there is concern with the potential impacts a prohibition on packaging would have on Maine businesses.

Such a sales prohibition on the broadly defined toddler food category would undoubtedly also cause impacts to food pantries and how they manage and receive donations. Specifically, cans are known to withstand dramatic changes in temperature and withstand rough handling without compromising the safety of its contents. Some of the currently available alternatives are more sensitive to temperature change, handling process, and particularly susceptible to puncture. Shelf life of new packaging also has the potential to become limiting for those relying on donations of unsold or overstocked product.

An additional consideration is storage capability, for instance if a food item is not compatible with one of the available alternative packages the manufacturer may choose to use a freezing process and provide consumers with a frozen food. The question is whether this change in what petitioners categorize as toddler food would impact a food pantry relying on canned goods. The capacity to store and present frozen goods as an option to their clientele may be so limiting that food pantries without freezer storage, and the resources to maintain them, may be forced to reduce the food categories available to those in need.

Would a sales prohibition result in an alternative method of packaging that would become limiting or potentially burdensome for food pantries? These are clearly questions that have not been addressed, but should be considered as part of the deliberations on the citizen's petition to initiate rulemaking.

Appendix A: 38 MRS §§ 1691-1699-B

Maine Revised Statute Title 38, Chapter 16-D:
TOXIC CHEMICALS IN CHILDREN'S PRODUCTS

Table of Contents

38 §1691. DEFINITIONS

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings. [2007, c. 643, §2 (NEW).]

1. Alternative. "Alternative" means a substitute process, product, material, chemical, strategy or combination of these that serves a functionally equivalent purpose to a chemical in a children's product.

[2007, c. 643, §2 (NEW) .]

2. Chemical. "Chemical" means a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or substances that form through decomposition, degradation or metabolism.

[2007, c. 643, §2 (NEW) .]

2-A. Chemical of concern. "Chemical of concern" means a chemical identified by the department pursuant to section 1693.

[2011, c. 319, §2 (NEW) .]

3. Chemical of high concern. "Chemical of high concern" means a chemical identified by the department pursuant to section 1693-A.

[2011, c. 319, §2 (AMD) .]

4. Chemical of low concern. "Chemical of low concern" means a chemical for which adequate toxicity and environmental data are available to determine that it is not a chemical of high concern, a chemical of concern, a chemical of potential concern or a chemical of unknown concern.

[2011, c. 319, §2 (AMD) .]

5. Chemical of potential concern. "Chemical of potential concern" means a chemical identified by an authoritative governmental entity on the basis of credible scientific evidence as being suspected of causing an adverse health or environmental effect listed in section 1693, subsection 1.

[2011, c. 319, §2 (AMD) .]

6. Chemical of unknown concern. "Chemical of unknown concern" means a chemical for which insufficient data are available to classify it as a chemical of high concern, a chemical of concern, a chemical of potential concern or a chemical of low concern.

[2011, c. 319, §2 (AMD) .]

7. Children's product. "Children's product" means a consumer product intended for, made for or marketed for use by children under 12 years of age, such as baby products, toys, car seats, personal care products and clothing, and any consumer product containing a chemical of high concern that when used or disposed of will likely result in a child under 12 years of age or a fetus's being exposed to that chemical.

[2011, c. 319, §2 (AMD) .]

8. Consumer product. "Consumer product" means any item sold for residential or commercial use, including any component parts and packaging, that is sold for:

A. An indoor use in a residence, child care facility or school; or [2011, c. 319, §2 (NEW).]

B. An outdoor residential use if a child under 12 years of age may have direct contact with the item. [2011, c. 319, §2 (NEW).]

"Consumer product" does not include a food or beverage or an additive to a food or beverage, a tobacco product or paper or forest products or a pesticide regulated by the United States Environmental Protection Agency. "Consumer product" also does not include a drug or biologic regulated by the United States Department of Health and Human Services, Food and Drug Administration or the packaging of a drug or biologic regulated by the Food and Drug Administration if the packaging is regulated by the Food and Drug Administration. "Consumer product" also does not include an item sold for outdoor residential use that consists of a composite material made from polyester resins.

[2011, c. 319, §2 (AMD) .]

8-A. Credible scientific evidence. "Credible scientific evidence" means the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency, including but not limited to the United States Department of Health and Human Services, National Toxicology Program, Food and Drug Administration and Centers for Disease Control and Prevention; the United States Environmental Protection Agency; the World Health Organization; and the European Union, European Chemicals Agency.

[2011, c. 319, §2 (NEW) .]

8-B. De minimis level. "De minimis level" means:

A. For a chemical of high concern or priority chemical that is an intentionally added chemical in a component of a children's product, the practical quantification limit; or [2011, c. 319, §2 (NEW).]

B. For a chemical of high concern or priority chemical that is a contaminant present in a component of a children's product, a concentration of 100 parts per million. [2011, c. 319, §2 (NEW).]

[2011, c. 319, §2 (NEW) .]

9. Distributor. "Distributor" means a person who sells consumer products to retail establishments on a wholesale basis.

[2007, c. 643, §2 (NEW) .]

9-A. Intentionally added chemical. "Intentionally added chemical" means a chemical that was added during the manufacture of a product or product component to provide a specific characteristic, appearance or quality or to perform a specific function.

[2011, c. 319, §2 (NEW) .]

10. Manufacturer. "Manufacturer" means any person who manufactured a final consumer product or whose brand name is affixed to the consumer product. In the case of a consumer product that was imported into the United States, "manufacturer" includes the importer or first domestic distributor of the consumer product if the person who manufactured or assembled the consumer product or whose brand name is affixed to the consumer product does not have a presence in the United States.

[2007, c. 643, §2 (NEW) .]

10-A. Practical quantification limit. "Practical quantification limit" means the lowest concentration of a chemical that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness and comparability during routine laboratory operating conditions. The practical quantification limit is based on scientifically defensible, standard analytical methods. The practical quantification limit for a given chemical may be different depending on the matrix and the analytical method used.

[2011, c. 319, §2 (NEW) .]

11. Priority chemical. "Priority chemical" means a chemical identified as such by the commissioner pursuant to section 1694, subsection 1.

[2007, c. 643, §2 (NEW) .]

12. Safer alternative. "Safer alternative" means an alternative that, when compared to a priority chemical that it could replace, would reduce the potential for harm to human health or the environment or that has not been shown to pose the same or greater potential for harm to human health or the environment as that priority chemical.

[2007, c. 643, §2 (NEW) .]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §2 (AMD).

38 §1692. DECLARATION OF POLICY

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE UNTIL 7/1/12)

It is the policy of the State, consistent with its duty to protect the health, safety and welfare of its citizens, to reduce exposure of children and other vulnerable populations to chemicals of high concern by substituting safer alternatives when feasible. By enactment of this chapter, the Legislature confers upon the department the regulatory power to collect information on chemical use and prohibit the sale of children's products containing priority chemicals when safer alternatives are available. The policy represented in this chapter is in furtherance of the toxics use reduction policies under chapter 26. [2007, c. 643, §2 (NEW).]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2009, c. 579, Pt. B, §12 (AMD). 2009, c. 579, Pt. B, §13 (AFF).

38 §1692. DECLARATION OF POLICY

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SECTION HISTORY
2007, c. 643, §2 (NEW). 2009, c. 579, Pt. B, §12 (AMD). 2009, c. 579, Pt. B, §13 (AFF).

38 §1693. IDENTIFICATION OF CHEMICALS OF CONCERN

1. Criteria. By January 1, 2010, the department, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, shall publish a list of chemicals of high concern, referred to after September 1, 2011 as "the list of chemicals of concern." A chemical may be included on the list only if it has been identified by an authoritative governmental entity on the basis of credible scientific evidence as being:

A. A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor; [2011, c. 319, §3 (RPR).]

B. Persistent, bioaccumulative and toxic; or [2011, c. 319, §3 (RPR).]

C. Very persistent and very bioaccumulative. [2011, c. 319, §3 (RPR).]

[2011, c. 319, §3 (RPR) .]

2. Revisions. By January 1, 2012, the department, with input from interested persons and with the concurrence of the Department of Health and Human Services, Maine Center for Disease Control and Prevention, shall remove any chemical from the list published pursuant to subsection 1 that it finds is:

A. Used solely in an item that is not a consumer product, including, but not limited to, a food or beverage, drug or biologic, paper or forest product or pesticide; or [2011, c. 319, §3 (NEW).]

B. Used solely in a consumer product that is exempt from the requirements of this chapter pursuant to section 1697. [2011, c. 319, §3 (NEW).]

The department may periodically review and revise the list published pursuant to subsection 1. The department may add chemicals to the list if, in the judgment of the Department of Health and Human Services, Maine Center for Disease Control and Prevention, the chemical meets one or more of the criteria in subsection 1.

[2011, c. 319, §3 (RPR) .]

3. Removal by petition. A person may petition the department to remove a chemical from the list published pursuant to subsection 1. The department, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, may grant a petition if the person demonstrates to the satisfaction of the department that the chemical:

A. Does not meet the criteria for listing pursuant to subsection 1; or [2011, c. 319, §3 (NEW).]

B. Meets the criteria for removal from the list pursuant to subsection 2. [2011, c. 319, §3 (NEW).]

Upon receipt of a petition under this subsection, the department shall notify interested persons and provide an opportunity for review and comment on the evidence submitted by the petitioner. The department shall make a determination within 180 days of receipt of the petition and notify interested persons of the basis for its decision. If the petition is granted, the department shall immediately remove the chemical from the list published pursuant to subsection 1.

[2011, c. 319, §3 (NEW) .]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §3 (RPR).

38 §1693-A. IDENTIFICATION OF CHEMICALS OF HIGH CONCERN

1. List. By July 1, 2012, the department shall publish a list of no more than 70 chemicals of high concern. The Department of Health and Human Services, Maine Center for Disease Control and Prevention, in consultation with the department, shall develop the list. To be listed as a chemical of high concern, a chemical must be on the list of chemicals of concern pursuant to section 1693 and meet the eligibility criteria of subsection 2.

[2011, c. 319, §4 (NEW) .]

2. Criteria. A chemical of concern on the list of chemicals of concern pursuant to section 1693 may be included in the list published pursuant to subsection 1 if the department, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, determines that there is strong credible scientific evidence that the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen, and there is strong credible scientific evidence that the chemical meets one or more of the following criteria:

A. The chemical has been found through biomonitoring studies to be present in human blood, human breast milk, human urine or other bodily tissues or fluids; [2011, c. 319, §4 (NEW).]

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 [2011, c. 319, §4 (NEW).]

C. The chemical has been added to or is present in a consumer product used or present in the home. [2011, c. 319, §4 (NEW).]

[2011, c. 319, §4 (NEW) .]

3. Updates. The commissioner shall review the list published pursuant to subsection 1 at least every 3 years. The commissioner shall remove any chemical from the list of chemicals of high concern that has been designated as a priority chemical pursuant to section 1694 or that no longer meets any of the criteria of subsection 2. The commissioner may identify additional chemicals of high concern according to the criteria and requirements of this section. The list of chemicals of high concern may not consist of more than 70 or fewer than 10 chemicals of high concern, unless fewer than 10 chemicals of high concern meet any of the criteria under subsection 2.

[2011, c. 319, §4 (NEW) .]

4. Rules. The department shall adopt rules to implement the provisions of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

[2011, c. 319, §4 (NEW) .]

SECTION HISTORY
2011, c. 319, §4 (NEW).

38 §1694. IDENTIFICATION OF PRIORITY CHEMICALS

Effective July 1, 2012, a chemical is eligible for designation as a priority chemical only if that chemical has been identified and listed as a chemical of high concern pursuant to section 1693-A. [2011, c. 319, §5 (NEW).]

1. Criteria. 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; [2007, c. 643, §2 (NEW).]

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 [2011, c. 319, §5 (AMD).]

[PL 2011, c. 319, § 5 (RP).]

C. [2011, c. 319, §5 (RP).]

D. The chemical is present in a consumer product used or present in the home. [2011, c. 319, §5 (AMD).]

[PL 2011, c. 319, § 5 (RP).]

E. [2011, c. 319, §5 (RP).]

[PL 2011, c. 319, § 5 (RP).]

F. [2011, c. 319, §5 (RP).]

[2011, c. 319, §5 (AMD) .]

2. Designation. The commissioner shall designate at least 2 priority chemicals by January 1, 2011. The commissioner may designate additional priority chemicals if the commissioner finds that the chemicals meet one of the criteria listed in subsection 1.

[2011, c. 319, §5 (AMD) .]

The commissioner shall adopt rules to implement the provisions of this section. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. [2007, c. 643, §2 (NEW).]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §5 (AMD).

38 §1695. DISCLOSURE OF INFORMATION ON PRIORITY CHEMICALS

1. Reporting of chemical use. Not later than 180 days after a priority chemical is identified pursuant to section 1694, a person who is a manufacturer or distributor of a children's product for sale in the State that contains a priority chemical in an amount greater than a de minimis level shall notify the department in writing unless waived by the commissioner pursuant to this section or exempt from this chapter pursuant to section 1697. This written notice must identify the children's product, the number of units sold or distributed for sale in the State or nationally, the priority chemical or chemicals contained in the children's product, the amount of such chemicals in each unit of children's product and the intended purpose of the chemicals in the children's product.

[2011, c. 319, §6 (AMD) .]

2. Supplemental information. The manufacturer or distributor of a children's product that contains a priority chemical shall provide the following additional information if requested by the department:

A. Information on the likelihood that the chemical will be released from the children's product to the environment during the children's product's life cycle and the extent to which users of the children's product are likely to be exposed to the chemical; [2007, c. 643, §2 (NEW).]

B. Information on the extent to which the chemical is present in the environment or human body; and [2007, c. 643, §2 (NEW).]

C. An assessment of the availability, cost, feasibility and performance, including potential for harm to human health and the environment, of alternatives to the priority chemical and the reason the priority chemical is used in the manufacture of the children's product in lieu of identified alternatives. If an assessment acceptable to the department is not timely submitted, the department may assess a fee on the manufacturer or distributor to cover the costs to prepare an independent report on the availability of safer alternatives by a contractor of the department's choice. [2007, c. 643, §2 (NEW).]

The manufacturer or distributor of a children's product that contains a priority chemical may provide additional information to the department regarding the potential for harm to human health and the environment from specific uses of the priority chemical.

[2007, c. 643, §2 (NEW) .]

3. Waiver of reporting; fee; extension of deadline. The commissioner may waive all or part of the notification requirement under subsection 1 for one or more specified uses of a priority chemical if the commissioner determines that substantially equivalent information is already publicly available, that the information is not needed for the purposes of this chapter or that the specified use or uses are minor in volume. The department may assess a fee payable by the manufacturer or distributor upon submission of the notification to cover the department's reasonable costs in managing the information collected. The department may extend the deadline for submission of the information required under subsection 1 for one or more specified uses of a priority chemical in a children's product if it determines that more time is needed by the manufacturer or distributor to comply with the submission requirement or if the information is not needed at that time.

[2007, c. 643, §2 (NEW) .]

4. Rulemaking to determine fees. If the department assesses a fee pursuant to subsection 2, paragraph C or subsection 3, the department shall determine the appropriate fee through major substantive rulemaking, as defined in Title 5, chapter 375, subchapter 2-A.

[2007, c. 643, §2 (NEW) .]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §6 (AMD).

38 §1696. SALES PROHIBITION; RULES; SAFER ALTERNATIVES TO PRIORITY CHEMICALS

1. Authority. The board may adopt rules prohibiting the manufacture, sale or distribution in the State of a children's product containing a priority chemical in an amount greater than a de minimis level if the board finds, after consideration of information filed under section 1695 and other relevant information submitted to or obtained by the board, that:

A. Distribution of the children's product directly or indirectly exposes children and vulnerable populations to the priority chemical; and [2007, c. 643, §2 (NEW).]

B. One or more safer alternatives to the priority chemical are available at a comparable cost. [2007, c. 643, §2 (NEW).]

If there are several available safer alternatives to a priority chemical, the board may prohibit the sale of children's products that do not contain the safer alternative that is least toxic to human health or least harmful to the environment.

A rule established pursuant to this subsection must specify the effective date of the prohibition, which may not be sooner than 12 months after notice of the proposed rule is published as required under Title 5, section 8053, subsection 5. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

[2011, c. 319, §7 (AMD) .]

2. Alternatives assessment; presumptions. For the purpose of determining whether a safer alternative is available under subsection 1, paragraph B, the board may, in the absence of persuasive evidence to the contrary:

A. Presume that an alternative is a safer alternative if the alternative is not a chemical of concern; [2011, c. 319, §8 (AMD).]

B. Presume that a safer alternative is available if the sale of the children's product containing the priority chemical has been banned by another state within the United States based on the availability of a safer alternative; [2011, c. 319, §8 (AMD).]

C. Presume that a safer alternative is available if the children's product containing the priority chemical is an item of apparel or a novelty; and [2007, c. 643, §2 (NEW).]

D. Presume that a safer alternative is available if the alternative is sold in the United States. [2007, c. 643, §2 (NEW).]

[2011, c. 319, §8 (AMD) .]

3. Implementation. No later than 180 days prior to the effective date of a prohibition adopted under subsection 1, the manufacturer or distributor of a children's product that contains the priority chemical and that is subject to the prohibition at the time of adoption shall file a compliance plan with the commissioner or seek a waiver under subsection 5. A compliance plan must:

A. Identify the children's product that contains the priority chemical; [2007, c. 643, §2 (NEW).]

B. Specify whether compliance will be achieved by discontinuing the sale of the children's product in the State or by substituting a safer alternative in the product; and [2007, c. 643, §2 (NEW).]

C. If compliance is achieved by substitution of a safer alternative in the product, identify the safer alternative and the timetable for substitution. [2007, c. 643, §2 (NEW).]

[2007, c. 643, §2 (NEW) .]

4. Responsibility. A manufacturer or distributor of a children's product containing a priority chemical shall notify persons that offer the product for sale or distribution in the State of the requirements of this chapter.

[2007, c. 643, §2 (NEW) .]

5. Waiver for specific uses. The manufacturer or distributor of a children's product that contains a priority chemical and that is subject to a prohibition adopted pursuant to subsection 1 may apply to the commissioner for a waiver for one or more specific uses of the priority chemical. The waiver application must, at a minimum:

A. Identify the specific children's product use or uses for which the waiver is sought; [2007, c. 643, §2 (NEW).]

B. Identify the alternatives considered for substitution of the priority chemical; [2007, c. 643, §2 (NEW).]

C. Explain the basis for concluding that the use of an alternative is not feasible; and [2007, c. 643, §2 (NEW).]

D. Identify the steps that have and will be taken to minimize the use of the priority chemical. [2007, c. 643, §2 (NEW).]

The commissioner may grant a waiver with or without conditions upon finding that there is a need for the children's product in which the priority chemical is used and there are no technically or economically feasible alternatives for the use of the priority chemical in the children's product. Waivers may be granted for a term not to exceed 5 years and may be renewed for one or more additional 5-year terms upon written application demonstrating that technically or economically feasible alternatives remain unavailable. The commissioner shall deny or grant waiver requests within 60 days after receipt of a completed waiver application.

[2007, c. 643, §2 (NEW) .]

6. Petitions. If rulemaking to prohibit the sale of a children's product containing a priority chemical is initiated by petition under Title 5, section 8055, the department shall consider the information submitted in support of the petition but is not obligated to conduct a search of other sources of information on the chemical or its uses. The petitioner bears the burden of demonstrating that the criteria under subsection 1 for adoption of rules are met.

[2007, c. 643, §2 (NEW) .]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §§7, 8 (AMD).

38 §1697. APPLICABILITY

1. Used products. This chapter does not apply to chemicals in used products.

[2007, c. 643, §2 (NEW) .]

2. Industry. The requirements of this chapter do not apply to priority chemicals used in or for industry or manufacturing, including chemicals processed or otherwise used in or for industrial or manufacturing processes.

[2007, c. 643, §2 (NEW) .]

3. Transportation. The requirements of this chapter do not apply to motor vehicles as defined in Title 29-A, section 101, subsection 42 or watercraft as defined in Title 12, section 13001, subsection 28 or their component parts, except that the use of priority chemicals in detachable car seats is not exempt.

[2007, c. 643, §2 (NEW) .]

4. Combustion. The requirements of this chapter do not apply to priority chemicals generated solely as combustion by-products or that are present in combustible fuels.

[2007, c. 643, §2 (NEW) .]

5. Retailers. A retailer is exempt from the requirements of this chapter unless that retailer knowingly sells a children's product containing a priority chemical after the effective date of its prohibition for which that retailer has received prior notification from a manufacturer, distributor or the State.

[2007, c. 643, §2 (NEW) .]

6. Mercury-added products. The commissioner may designate mercury or a mercury compound as a priority chemical for the purpose of adopting rules under section 1696 to prohibit the manufacture, sale or distribution of a mercury-added product that is not regulated under section 1661-C or 1667 prior to the effective date of this section. The disclosure requirements of section 1695 do not apply to the manufacturer or distributor of a children's product that contains the designated mercury or mercury compound if the manufacturer has complied with the notification requirement under section 1661-A.

[2007, c. 643, §2 (NEW) .]

7. Telecommunications. The disclosure requirements of section 1695 do not apply to a service provider whose name appears on a telecommunications device unless the service provider is the actual manufacturer of the device. As used in this subsection, "service provider" has the meaning set out in Title 35-A, section 7107, subsection 1, paragraph C.

[2007, c. 643, §2 (NEW) .]

8. Food and beverage packaging. A container or packaging for a food or beverage product is exempt from the requirements of this chapter, unless that product is intentionally marketed or intended for the use of children under 3 years of age.

[2007, c. 643, §2 (NEW) .]

9. Regulatory efficiency. The department may, in exercising its discretionary authority under this chapter, consider the extent to which a chemical of high concern in a children's product is adequately regulated by the Federal Government or an agency of this State to reduce or prevent the same public health threats that would be the basis for addressing the chemical under this chapter.

[2011, c. 319, §9 (NEW) .]

10. Inaccessible components. The requirements of sections 1695 and 1696 do not apply to a priority chemical contained in a component of a children's product that during reasonably foreseeable use and abuse would not come into direct contact with a child's skin or mouth, such as inaccessible components of children's products. The department may adopt a rule, based on a case-by-case evaluation, to subject such components to the requirements of sections 1695 and 1696. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

[2011, c. 319, §9 (NEW) .]

11. Contaminants. The requirements of sections 1695 and 1696 do not apply to a priority chemical that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.

[2011, c. 319, §9 (NEW) .]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §9 (AMD).

38 §1698. INTERSTATE CLEARINGHOUSE TO PROMOTE SAFER CHEMICALS

The department is authorized to participate in an interstate clearinghouse to promote safer chemicals in consumer products in cooperation with other states and governmental entities. The department may cooperate with the interstate clearinghouse to classify existing chemicals in commerce into one of 5 categories: chemicals of high concern, chemicals of concern, chemicals of potential concern, chemicals of unknown concern and chemicals of low concern. [2011, c. 319, §10 (AMD).]

The department may also cooperate with the interstate clearinghouse in order to organize and manage available data on chemicals, including information on uses, hazards and environmental concerns; to produce and inventory information on safer alternatives to specific uses of chemicals of concern and on model policies and programs; to provide technical assistance to businesses and consumers related to safer chemicals; and to undertake other activities in support of state programs to promote safer chemicals. [2007, c. 643, §2 (NEW).]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §10 (AMD).

38 §1699. EDUCATION AND ASSISTANCE

As resources allow, the department shall develop a program to educate and assist consumers and retailers in identifying children's products that may contain priority chemicals. [2007, c. 643, §2 (NEW).]

SECTION HISTORY
2007, c. 643, §2 (NEW).

38 §1699-A. ENFORCEMENT AND IMPLEMENTATION

1. Failure to provide notice. A children's product containing a priority chemical may not be sold, offered for sale or distributed for sale in this State if the manufacturer or distributor has failed to provide information required under section 1695 by the date required in that section. The commissioner shall exempt a children's product from this prohibition if, in the commissioner's judgment, the lack of availability of the children's product could pose an unreasonable risk to public health, safety or welfare.

[2007, c. 643, §2 (NEW) .]

2. Certificate of compliance. If there are grounds to suspect that a children's product is being offered for sale in violation of this chapter, the department may request the manufacturer or distributor of the product to provide a certificate of compliance with the provisions of this chapter. Within 30 days of receipt of a request under this subsection, the manufacturer or distributor shall:

A. Provide the department with the certificate attesting that the children's product does not contain the priority chemical; or [2007, c. 643, §2 (NEW).]

B. Notify persons who sell the product in this State that the sale of the children's product is prohibited and provide the department with a list of the names and addresses of those notified. [2007, c. 643, §2 (NEW).]

[2011, c. 319, §11 (AMD) .]

SECTION HISTORY
2007, c. 643, §2 (NEW). 2011, c. 319, §11 (AMD).

38 §1699-B. DONATIONS TO THE STATE

The department, through the Governor, may accept donations, grants and other funds to carry out the purposes of this chapter. [2007, c. 643, §2 (NEW).]

SECTION HISTORY
2007, c. 643, §2 (NEW).

Appendix B: 06-096 C.M.R. ch. 880

Chapter 880: REGULATION OF CHEMICAL USE IN CHILDREN'S PRODUCTS

SUMMARY: This rule sets forth the process by which the Commissioner of the Department of Environmental Protection may designate a chemical for regulatory scrutiny as authorized under Title 38, chapter 16-D, §§ 1691-1699-B of the Maine Revised Statutes Annotated, and reflects changes to the underlying statute enacted by PL 2011, c. 319 [*An Act to Provide the DEP with Regulatory Flexibility Regarding the Listing of Priority Chemicals,* LD 1129, 125th Legislature].

1. **Definitions.** The following terms, as used in this rule, have the following meanings:

   A. **Alternative.** "Alternative" means a substitute process, product, material, chemical, strategy or combination of these that serves a functionally equivalent purpose to a chemical in a children's product.

   B. **Board.** "Board" means the Board of Environmental Protection.

   C. **CFR.** "CFR" means the Code of Federal Regulations.

   D. **Chemical.** "Chemical" means a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or substances that form through decomposition, degradation or metabolism.

   E. **Chemical of concern.** "Chemical of concern" means a chemical identified by the department pursuant to 38 MRSA §1693.

   F. **Chemical of high concern.** "Chemical of high concern" means a chemical on the list of chemicals published by the department as required under 38 MRSA §1693-A.

   G. **Children's product.** "Children's product" means a consumer product intended for, made for or marketed for use by children under 12 years of age, such as baby products, toys, car seats, personal care products and clothing, and any consumer product containing a chemical of high concern that when used or disposed of will likely result in a child under 12 years of age or a fetus being exposed to that chemical.

   H. **CMR.** "CMR" means the Code of Maine Rules.

   I. **Commissioner.** "Commissioner" means the Commissioner of the Department of Environmental Protection.

   J. **Consumer product.** "Consumer product" means any item sold for residential or commercial use, including any component parts and packaging, that is sold for:

      (1) An indoor use in a residence, child care facility or school; or

      (2) An outdoor residential use if a child under 12 years of age may have direct contact with the item.

"Consumer product" does not include a food or beverage or an additive to a food or beverage, a tobacco product or paper or forest products or a pesticide regulated by the United States Environmental Protection Agency. "Consumer product" also does not include a drug or biologic regulated by the United States Department of Health and Human Services, Food and Drug Administration or the packaging of a drug or biologic regulated by the Food and Drug Administration if the packaging is regulated by the Food and Drug Administration. "Consumer product" also does not include an item sold for outdoor residential use that consists of a composite material made from polyester resins.

K. Credible scientific evidence. "Credible scientific evidence" means the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency, including but not limited to the United States Department of Health and Human Services, National Toxicology Program, Food and Drug Administration and Centers for Disease Control and Prevention, the United States Environmental Protection Agency, the World Health Organization, and the European Union, European Chemicals Agency.

L. De minimis level. "De minimis level" means:

A. For a chemical of high concern or priority chemical that is an intentionally added chemical to a children's product or component of a children's product, the practical quantification limit; or

B. For a chemical of high concern or priority chemical that is a contaminant present in a children's product or component of a children's product, a concentration of 100 parts per million.

M. Department. "Department" means the Department of Environmental Protection.

N. Distributor. "Distributor" means a person who sells consumer products to retail establishments on a wholesale basis.

O. GreenScreen™. "GreenScreen™" means the chemical screening method called GreenScreen™ for Safer Chemicals, published online by Clean Production Action.

P. Inaccessible component. "Inaccessible component" means a component of a children's product that during reasonably foreseeable use and abuse would not come into direct contact with a child's skin or mouth.

Q. Intentionally-added. "Intentionally-added" means a chemical that was added during the manufacture of a product or product component to provide a specific characteristic, appearance or quality, or to perform a specific function.

R. Maine CDC. "Maine CDC" means the Maine Center for Disease Control and Prevention within the Department of Health and Human Services.

S. **Manufacturer.** "Manufacturer" means any person who manufactured a final consumer product or whose brand name is affixed to the consumer product. In the case of a consumer product that was imported into the United States, "manufacturer" includes the importer or first domestic distributor of the product if the person who manufactured or assembled the consumer product or whose brand name is affixed to the consumer product does not have a presence in the United States.

T. **MRSA.** "MRSA" means the Maine Revised Statutes Annotated.

U. **Novelty.** "Novelty" means a product intended mainly for personal or household enjoyment or adornment. Novelties include, but are not limited to, items intended for use as practical jokes, figurines, knickknacks, toys, games, cards, ornaments, yard statues and figures, candles, jewelry and holiday decorations.

V. **Practical quantification limit.** "Practical quantification limit" means the lowest concentration of a chemical that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness and comparability during routine laboratory operating conditions. The practical quantification limit is based on scientifically defensible, standard analytical methods. The practical quantification limit for a given chemical may be different depending on the matrix and the analytical method used.

W. **Priority chemical.** "Priority chemical" means a chemical identified as such by the Commissioner pursuant to section 4 of this rule.

2. List of chemicals of concern

A. **Revision.** The department may periodically review and revise the list of chemicals of concern and may add chemicals if, in the judgment of the Maine CDC, the chemical has been identified by an authoritative governmental entity on the basis of credible scientific evidence as being:

(1) A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;

(2) Persistent, bioaccumulative and toxic; or

(3) Very persistent and very bioaccumulative.

B. **Removal by petition.** A person may petition the department to remove a chemical from the list. The department, in concurrence with the Maine CDC, may grant a petition if the person demonstrates to the satisfaction of the department that the chemical meets one or more of the following:

(1) Does not meet the criteria for listing under paragraph A;

(2) Is used solely in an item that is not a consumer product; or

(3) Is used solely in a consumer product that is exempt under 38 MRSA §1697 of statute.

Upon receipt of a petition under this subsection, the department shall notify interested persons and provide an opportunity for review and comment on the evidence submitted by the petitioner. The department shall make a determination within 180 days of receipt of the petition and notify interested persons of the basis for its decision. If the petition is granted, the department shall immediately remove the chemical from the list.

3. **Identification of chemicals of high concern.** This section requires the department to develop, in consultation with the Maine CDC, and publish a list of no more than 70 chemicals of high concern. A chemical may be listed as a chemical of high concern if:

   A. The chemical is on the list of chemicals of concern published pursuant to 38 MRSA §1693 (see section 2 of this chapter);

   B. The department, in concurrence with the Maine CDC, determines that there is strong credible scientific evidence that the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen; and

   C. There is strong credible scientific evidence that the chemical meets one or more of the following criteria:

      (1) The chemical has been found through biomonitoring studies to be present in human blood, human breast milk, human urine or other bodily tissues or fluids;

      (2) 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

      (3) The chemical has been added to or is present in a consumer product used or present in the home.

   The commissioner shall review the list at least every 3 years and remove any chemical that no longer meets the criteria for listing under this section or that has been designated as a priority chemical pursuant to section 4 of this chapter. The commissioner may identify additional chemicals of high concern according to the criteria and requirements of this section. The list may not consist of more than 70 or fewer than 10 chemicals, unless fewer than 10 meet the criteria for listing under this subsection.

4. **Designation of priority chemicals**

   A. **Purpose of designation.** This section authorizes the commissioner to designate one or more chemicals of high concern as a priority chemical. The designation of a priority chemical serves one or more of the following purposes:

(1) To facilitate the gathering of information on the use of the chemical in children's products and the extent to which children may be exposed to the chemical as a result of that usage;

(2) To facilitate the gathering of information on the safety and availability of alternatives to use of the chemical in children's products; and

(3) To facilitate the consideration of a ban on the sale of children's products to which the priority chemical has been intentionally added when safer alternatives are available.

The designation of a priority chemical does not constitute a determination that the designated chemical poses a greater risk to children than other chemicals on the list of chemicals of high concern. The commissioner may designate any chemical on the list of chemicals of high concern as a priority if at least one of the criteria under paragraph B(2) is met.

B. Prerequisites for designation. The commissioner may designate a priority chemical if the commissioner finds there is credible scientific evidence, in concurrence with the Maine CDC, that:

(1) The chemical appears on the list of chemicals of high concern published by the department pursuant to 38 MRSA §1693 (see section 2 of this chapter); and

(2) One or more of the following criteria are met:

(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.

C. Scope of review. The department recognizes that all chemicals on the list of chemicals of high concern are likely to meet the prerequisites for designation as priority chemicals. The department further recognizes that the resources available to the department to investigate priority chemicals are limited. When determining whether to designate a priority chemical, the commissioner shall consider all available and relevant evidence related to the need for and appropriateness of regulatory action by the State including but not limited to:

(1) The need for additional information on the use of the chemical in children's product;

(2) The extent to which the chemical is used in children's products and the likelihood that children will be exposed to the chemical as a result of its presence in children's products;

(3) The need for information on the availability and safety of alternatives to the chemical;

(4) Whether regulatory action is necessary and appropriate in light of actions taken or underway with respect to the chemical in other states and jurisdictions; and

(5) Whether the department and Maine CDC have adequate financial and human resources to accomplish the tasks associated with designation of the priority chemical.

D. Designation by rule required. When designating a priority chemical, the commissioner shall do so by adoption of a routine technical rule in accordance with the rulemaking requirements of the Maine Administrative Procedures Act, 5 MRSA §§ 8001 through 8064. The rule, or the basis statement to the rule, must:

NOTE: The term "basis statement" as used in this subsection refers to the written statement explaining the factual and policy basis for the rule. The Maine Administrative Procedures Act requires state agencies to adopt such a statement at the time of adoption of any rule. See 5 MRSA §8052(5).

(1) Identify the chemical and confirm its presence on the list of chemicals of high concern published by the department;

(2) Specify which of the criteria under subsection B(2) are met;

(3) Include findings of fact sufficient to apprise the chemical manufacturer, the chemical user and any interested member of the public of the basis for the commissioner's decision to designate the chemical as a priority chemical;

(4) Specify the information that must be submitted by manufacturers and distributors of children's product that contain the chemical, the basis for requesting the information and the deadline for submission. The commissioner may not specify a deadline that is sooner than 180 calendar days after the effective date of the rule.

NOTE: This rule seeks to minimize the burden of disclosure on product manufacturers and distributors by: i) requiring the department, in the text of the rule designating a priority chemical, to state with specificity the information it seeks from manufacturers and distributors; and ii) authorizing the department, when adopting such a rule, to waive the submission of chemical use information that otherwise would be required under the law [see 38 MRSA §1695(1)] if it determines the information already is available or otherwise is not needed. The department recognizes that it is unlikely to need the same type and range of information for each priority chemical and therefore intends, by this rule, to enable the scope of the required disclosure to be determined on a chemical by chemical basis, including, if appropriate, a threshold concentration below which reporting will not be required.

5. **Disclosure of information on priority chemicals.** The manufacturer or distributor of a children's product for sale in the State that contains a priority chemical in an amount greater than the de minimis level shall submit the information specified in the rule designating the priority chemical and any additional information requested by the commissioner pursuant to subsection D below. The information must be submitted to the department by the deadline specified in the rule. Submissions may be made by regular or electronic mail. The requirements of this section do not apply to a priority chemical that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component, as outlined in 38 MRSA §1697(11).

   A. **Information on chemical use.** The information to be disclosed shall include the following information on chemical use unless waived by the department in the rule designating the priority chemical:

      (1) A description of the children's product or products containing the priority chemical;

      (2) The number of product units sold or distributed for sale in the State or nationally during the most recent full year (fiscal or calendar year is dependent on filer accounting system) prior to the specified reporting date of the chemical reporting requirement;

      (3) The amount of the priority chemical in each unit of the children's product; and

      (4) The function of the chemical in the children's product.

      The department may waive submission of all or part of the information required under paragraphs (1) through (4) if it determines that substantially equivalent information already is publicly available, the specified use is minor in volume or the information otherwise is not needed.

   B. **Supplemental information.** The information to be disclosed shall also include the following supplemental information if specified in the rule designating the priority chemical or by the commissioner as authorized under subsection D below:

      (1) Information on the propensity for the chemical to be released from the product during use, the likelihood of child exposure to the chemical as a result of its use, the pathways (e.g. inhalation, ingestion) by which exposure could occur and the predicted magnitude of the exposure;

      (2) Information on the extent to which the chemical is present in the environment or humans; and

      (3) If information provided to or obtained by the department indicates that children or other vulnerable populations are exposed to a priority chemical in a product as a result of its distribution, an assessment of the availability, cost, feasibility and performance, including potential for harm to human health and the environment, of alternatives to the priority chemical and the reason the priority chemical is used in the manufacture of the children's product in lieu of identified alternatives. If an assessment acceptable to the department is not timely submitted, the department may assess fees as provided under 06-096 CMR 881 to cover the cost of preparing an independent assessment. An acceptable assessment is one that:

(a) Describes the function of the priority chemical in the product and list the specific characteristics of the chemical (e.g., physical or chemical properties, price, availability) that led to its selection to fulfill that function;

(b) Identifies the specific chemical and non-chemical alternatives considered in lieu of the priority chemical, and describes why the priority chemical was selected over each identified alternative;

(c) Identifies and describes any known emerging chemical and non-chemical alternatives to use of the priority chemical in the product and, for each such alternative, provides the following information:

(i) The status of research and development;

(ii) The current barriers to introduction of the alternative into the marketplace;

(iii) The projected timeframe for introduction of the alternative into the marketplace; and

(iv) The advantages and disadvantages of using the alternative in lieu of the priority chemical, assuming the alternative is successfully introduced into the marketplace;

(d) Identifies the key, distinguishing human health and environmental hazards (or "endpoints") associated with the priority chemical;

(e) Evaluates the human health and environmental hazard posed by the priority chemical and each identified chemical alternative using the GreenScreen™ or other evaluation methodology approved by the department; and

(f) Provides copies of all peer-reviewed studies or government-generated studies identified through a search of publicly accessible databases and lists the search terms used. The search must be conducted for the priority chemical and for each chemical alternative identified pursuant to subparagraph (b) and (c) and must, at a minimum, include as search terms the endpoints identified pursuant to subparagraph (d).

C. Extension of submission deadline; waiver of disclosure by the commissioner. The commissioner may extend the deadline established by rule for submission of information on children's products that contain a priority chemical if the commissioner determines that more time is needed to comply with the request or the information is not needed by the original deadline. The commissioner also may waive submission of all or part of the information required in the rule designating the priority chemical if the commissioner subsequently determines that substantially equivalent information already is publicly available, the specified use is minor in volume as demonstrated by the total number of products units sold in Maine during the 3 most recent calendar years or the information otherwise is not needed.

D. Commissioner authority to request additional information. Upon review of information submitted pursuant to a rule designating a priority chemical, the commissioner may request the manufacturer or distributor of a children's product provide additional information not specified in the rule, if the commissioner determines that the information is needed for the department to complete its evaluation of the priority chemical. The commissioner shall set a deadline for receipt of such information that is no sooner than 30 days after making the request.

Within 30 days after making a request for additional information under this subsection, the commissioner shall:

(1) Arrange for notice of the request to be published using the most widely available and accessible media for interested parties; including but not limited to, electronic news publications and the department sponsored website; and

(2) Mail notice electronically or via postal carrier to any trade group, professional association, interest group, or other person who either has notified the commissioner of their interest in the matter or, in the opinion of the commissioner, is likely to be interested.

The notice must identify the products covered by the request and must include directions on how manufacturers and distributors of children's products that contain the priority chemical or other interested persons may submit information related to the request for consideration by the department. The deadline for receipt of information may be no sooner than 30 days after the notice is published.

E. Compliance options; minimizing duplicative submissions. A manufacturer or distributor fulfills its obligation under this section when it:

(1) Submits the required information;

(2) Relies on information submitted on behalf of the manufacturer or distributor by a trade association, chemical manufacturer or other third party provided the information is presented in a form acceptable to the commissioner; or

(3) Obtains approval from the commissioner to rely on information submitted by another person.

To the extent practical and appropriate, the commissioner shall establish procedures to minimize the submission of duplicative information and shall develop, as appropriate, procedures for the equitable sharing of the costs of compiling the information and conducting assessments of alternatives.

F. **Data protection.** Records containing chemical use information of the type listed in subsection A above are presumptively public records under Maine's Freedom of Access Act ("FOAA"), 1 MRSA §401 *et seq*. Any records submitted to the department pursuant to this chapter that the submitting party believes are not subject to disclosure under FOAA must be clearly marked as "claimed confidential." Any request to the department under FOAA seeking records submitted under this chapter and marked as "claimed confidential" will be processed in accordance with 38 MRSA §1310-B, subsection 2.

This subsection does not authorize a manufacturer or distributor to refuse to disclose to the department information required under this chapter.

NOTE: The requirement to disclose information on the use of and exposure to priority chemicals in children's products is fundamental to the effective study and control of those chemicals, and is a key feature of the law on Toxic Chemicals in Children's Products. The public release of chemical use information submitted to the department pursuant to this requirement furthers the purpose of the law by providing consumers with more complete information on the products available to them and encourages the development of safer alternatives. However, records submitted to the department under this chapter that are either confidential by statute or otherwise exempt from the definition of "public records" set forth in 1 MRSA §402 are not subject to public disclosure.

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6. Authority to ban the sale of products containing a priority chemical

A. **Prerequisites for a ban.** The board may adopt rules prohibiting the manufacture, sale or distribution of one or more children's products containing a priority chemical in an amount greater than the de minimis level if the board finds that:

(1) Distribution of the children's product directly or indirectly exposes children and vulnerable populations to the priority chemical; and

(2) One or more safer alternatives to the priority chemical are available at a comparable cost.

An alternative is "available at comparable cost" if it is offered for sale in the U.S. at a price that is affordable as demonstrated by the number of product units sold. In the case of an alternative that is technically feasible but not yet offered for sale in the U.S., "available at comparable cost" means capable of being produced and sold at a price that is not likely to be a barrier to purchase by users of the product. If several available and safer alternatives are identified, the rule may prohibit the sale of children's products that do not contain the safer alternative that is least toxic to human health or least harmful to the environment.

Rules adopted pursuant this section are major substantive rules as defined in 5 MRSA §8071(2)(B) and therefore may be finally adopted by the board only after approval by the Legislature as provided under 5 MRSA §8072. The final rule must specify the effective date of the sales prohibition, which may not be sooner than 12 months after notice of the proposed rule has been published by the Secretary of State as provided under 5 MRSA §8053(5).

B. Assessment of alternatives; scope of review. In determining if safer alternatives to one or more specific uses of a priority chemical are available at a comparable cost, the board shall consider all relevant evidence to that effect including, but not limited to, alternatives assessments submitted by product manufacturers, alternatives assessments conducted by or on behalf of the department or other government agencies, and alternatives assessments conducted by non-governmental organizations and educational institutions.

(1) Availability. For the purpose of determining whether an alternative is available at comparable cost, the board shall consider all relevant evidence to that effect including but not limited to:

(a) The extent to which the alternative currently is available in the marketplace;

(b) The affordability of the alternative as demonstrated by sales volumes;

(c) The purchase price differential between the product containing the priority chemical and the alternative; and

(d) In the case of an alternative that is not already offered for sale, information bearing on the ease with which the alternative could be substituted for the use of the priority chemical and introduced into the U.S. market.

The board is not obligated to consider information related to the redesign, retooling or other costs incurred by a product manufacturer to discontinue the use of the priority chemical. The essential inquiry for the board is the cost to consumers to substitute a technically-feasible alternative.

(2) Safety. An alternative is safer if, when compared to a priority chemical that it could replace, the alternative has not been shown to pose the same or greater potential for harm to human health or the environment as the priority chemical. In determining if an alternative chemical is safer, the board shall consider all relevant evidence to that effect including but not limited to:

(a) The propensity of the chemical to be released from the product during use;

(b) The likelihood that children will be exposed to the chemical as a result of its use in the product and the predicted magnitude of that exposure;

(c) The persistence of the chemical and its tendency to bioaccumulate;

(d) The potential human health effects from exposure to the chemical; and

(e) The ecotoxicity of the chemical.

If available safer alternatives are identified, the board may, as resources allow, evaluate the alternatives to identify the alternative or alternatives least toxic to human health or least harmful to the environment.

(3) Presumptions. The board may, in the absence of persuasive evidence to the contrary:

(a) Presume that an alternative is safer if the alternative does not contain a chemical of concern;

(b) Presume that an alternative is available if the alternative is sold in the United States;

(c) Presume that an alternative is both safer and available if:

(i) The product containing the priority chemical has been banned by another U.S. state based on the availability of a safer alternative; or

(ii) The product containing the priority chemical is an item of apparel or novelty.

C. Exemptions from sales prohibitions. The manufacturer or distributor of a children's product subject to a prohibition adopted under subsection A may apply for an exemption for one or more specific uses of the priority chemical by filing an application with the commissioner. The exemption application must, at a minimum:

(1) Identify the specific product or products for which the exemption is sought;

(2) Identify the alternatives considered for substitution of the priority chemical;

(3) Explain the basis for concluding that substitution of the alternatives is not technically or economically feasible; and

(4) Set forth the steps that have and will be taken to minimize the use of the priority chemical.

Department staff shall determine whether the application is complete for processing within 15 days after it is received by the department. If the application is determined to be incomplete, staff shall notify the applicant in writing and specify the additional information needed to make complete the application. The commissioner shall deny or grant an exemption request within 60 days after receipt of a complete application.

The commissioner may grant an exemption with or without conditions upon finding that there is a need for the product in which the priority chemical is used and there is no technically or economically feasible alternative to the use of the priority chemical in the product. An exemption may be granted for a term not to exceed 5 years and may be renewed for one or more additional 5-year terms upon written application demonstrating that a technically or economically feasible alternative remains unavailable.

STATUTORY AUTHORITY: 38 MRSA §341-D(1-B)

EFFECTIVE DATE: March 3, 2010 – filing 2010-62

EFFECTIVE DATE: July 21, 2012 – filing 2012-195

Appendix C: 06-096 C.M.R. ch. 882

Chapter 882: DESIGNATION OF BISPHENOL A AS A PRIORITY CHEMICAL AND REGULATION OF BISPHENOL A IN CHILDREN'S PRODUCTS

SUMMARY: This chapter designates bisphenol A as a priority chemical, requires reporting for certain product categories that contain bisphenol A and prohibits sales of certain products containing bisphenol A.

1. Applicability

A. This chapter applies to manufacturers of children's products containing intentionally-added bisphenol A that are manufactured, sold, offered for sale or distributed for sale in Maine.

B. Exemptions

(1) **Used products.** This chapter does not apply to the chemical in used products.

(2) **Food and beverage packaging.** A container or packaging for a food or beverage product is exempt from the requirements of this chapter, unless that product is intentionally marketed or intended for the use of children under three years of age.

(3) **Transportation.** The requirements of this chapter do not apply to motor vehicles as defined in Title 29-A, section 101, subsection 42 or watercraft as defined in Title 12, section 13001, subsection 28 or their component parts, except that the use of bisphenol A in detachable car seats is not exempt.

2. Definitions.

For terms not defined in this chapter, the definitions found in 06-096 CMR Chapter 880, *Regulation of Chemical Use in Children's Products*, section 1 apply. The following terms, as used in this chapter, have the following meanings:

A. Baby food. "Baby food" means a prepared solid food consisting of a soft paste or an easily chewed food that is intended for consumption by children two years of age or younger and is commercially available.

B. Bisphenol A or BPA. "Bisphenol A" or "BPA" means a chemical compound having a CA (Chemical Abstract) Index Name of "Phenol, 4,4'-(1-methylethylidene)bis-" a chemical formula of $C_{15}H_{16}O_2$ and a CAS RN (Chemical Abstract Service Registry Number) of 80-05-7.

C. Child care article. "Child care article" means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

D. Exposure or exposed. "Exposure or exposed" in reference to a priority chemical means that a person is subjected in the course of daily life to a priority chemical from a product that enters the body in any quantity from any route of entry, including but not limited to inhalation, ingestion, skin contact or absorption.

E. Food and beverage packaging. "Food and beverage packaging" means containers, packaging, and packaging materials that contain and/or protect processed and raw foods and beverages at the point of sale. "Food and beverage packaging" does not include containers intended for storage or preparation of food that do not contain food or beverage when sold or purchased.

F. Infant formula. "Infant formula" means a liquid that purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

G. Reusable food or beverage container. "Reusable food or beverage container" means a container with a lid, cover, cap or nipple that is manufactured or intended for storing, carrying or transporting food or beverages, including, but not limited to, baby bottles, spill-proof cups, sports bottles and thermoses. "Reusable food or beverage container" does not include a receptacle that contains food or beverage when sold or purchased.

H. Tableware. "Tableware" means reusable or disposable dishes, utensils and other articles used in setting a table and/or serving a meal. "Tableware" includes but is not limited to: plates, bowls, cups/glasses, spoons, knives and forks.

I. Toy. "Toy" means a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays. "Toy" does not include helmets, masks, goggles or other personal protective equipment designed to protect the wearer's body from injury during sports and recreation activities.

3. Designation of bisphenol A as a priority chemical

A. Presence on chemicals of high concern list. Bisphenol A is present on the list of chemicals of high concern published by the department under 38 M.R.S.A. §1693.

NOTE: To view the full list, go to: www.maine.gov/dep/oc/safechem/highconcern/

B. Criteria for designation. The following criteria for designation of bisphenol A as a priority chemical, as set forth under 38 M.R.S.A. §1694, have been met as documented in the basis statement accompanying this chapter:

(1) Bisphenol A has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;

(2) Bisphenol A has been found through sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment;

(3) Bisphenol A has been found through monitoring to be present in fish, wildlife or the natural environment;

(4) Bisphenol A is present in a consumer product used or present in the home;

(5) Bisphenol A has been identified as a high production volume chemical by the federal Environmental Protection Agency; and

(6) The sale or use of bisphenol A or a product containing bisphenol A has been banned in another state within the United States.

4. Information submission required

A. Infant formula and baby food

(1) No later than 180 days after the effective date of this chapter, the manufacturer of infant formula or baby food that is sold in a plastic container, jar or can that contains intentionally-added bisphenol A, shall report to the department the following information:

(a) The name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer;

(b) A description of the product or products containing bisphenol A;

(c) The number of product units sold or distributed in Maine or nationally;

(d) The amount of bisphenol A in each unit of the product;

(e) The function of bisphenol A in the product; and

(f) Other information the manufacturer deems relevant to the reporting of the chemical.

(2) No later than January 1, 2012, the manufacturer of infant formula or baby food that is sold in a plastic container, jar or can that contains intentionally-added bisphenol A, shall submit to the department an assessment of the availability, cost, feasibility and performance, including potential for harm to human health and the environment, of alternatives to bisphenol A, polycarbonate plastic or epoxy resin, and the reason bisphenol A, polycarbonate plastic or epoxy resin is used in the manufacture of the infant formula or baby food container, jar or can in lieu of identified alternatives. This assessment must, at a minimum, include all of the elements of an acceptable assessment listed in 06-096 CMR Chapter 880 Regulation of Chemical Use in Children's Products.

(3) The commissioner may extend the deadline for submission of the alternatives assessment required under this paragraph. Request for a time extension must be made in writing on or before December 1, 2011. If an assessment acceptable to the department is not timely submitted, the department may assess fees as provided under 06-096 CMR 881 to cover the cost of preparing an independent assessment.

(4) Upon receipt and review of acceptable alternatives assessment(s) submitted to, or prepared for, the department, and no later than January 1, 2013, the department shall report the findings of the alternatives assessment(s) to the Board of Environmental Protection and, if appropriate, propose an amendment to this chapter reflecting those findings.

NOTE: In accordance with 06-096 CMR Chapter 880 section 3(A), a manufacturer may comply with the requirements of this section by relying on information submitted on behalf of the manufacturer by a trade association, chemical manufacturer or other third party, provided the information is presented in a form acceptable to the commissioner. Alternatively, manufacturers may comply by agreeing to fund an alternatives assessment contracted by the department to an independent party.

The department encourages manufacturers to prepare and submit a workplan for the alternatives assessment. The work plan should include a schedule for completion of the alternatives assessment and details concerning the submittal and content of interim deliverables to facilitate department approval of the alternatives assessment.

B. Toys, child care articles and tableware. No later than 180 days after the effective date of this chapter, the manufacturer of a toy, child care article, or tableware that contains intentionally-added bisphenol A, shall report to the department the following information:

(1) The name and address of the manufacturer;

(2) The name, address, and phone number of a contact person for the manufacturer;

(3) A description of the product or products containing bisphenol A, including the overall size of the product and/or the component of the product that contains BPA and whether the product or BPA-containing component of the product, can be placed in the mouth. A toy can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept

in the mouth by a child so that it can be sucked and chewed. If the children's product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.;

(4) The number of product units sold or distributed in Maine or nationally;

(5) The amount of bisphenol A in each unit of the product, or the amount of polycarbonate plastic or epoxy resin (percent by weight) in each unit of the product;

(6) The function of bisphenol A (or polycarbonate plastic/epoxy resin) in the product; and

(7) Other information the manufacturer deems relevant to the reporting of the chemical.

NOTE: Upon review of information submitted pursuant to section 4 of this chapter, the commissioner may request that a manufacturer clarify the submittal, supplement incomplete information or provide additional information not specified in this chapter if the commissioner determines that the information is needed for the department to complete its evaluation of the priority chemical. See department rules, 06-096 CMR 880(3)(D); see also 38 M.R.S.A. §1695(2).

5. Sales prohibition of children's products containing bisphenol A
(This section is effective August 1, 2011.)

A. Sales prohibition. Except as provided in section 1(B) of this chapter, no person shall sell, offer for sale or distribute for sale in Maine any reusable food or beverage container containing intentionally-added bisphenol A after January 1, 2012.

B. Compliance plan required. The manufacturer of a reusable food or beverage container subject to the sales prohibition of subsection A shall file, or cause all of its distributors to file, a compliance plan with the department no later than 180 days prior to the effective date of a sales prohibition under this section, unless the manufacturer receives a time extension in writing from the department. The compliance plan must:

(1) Identify the manufacturer's products subject to the sales prohibition;

(2) Specify whether compliance will be achieved by discontinuing the sale of the children's product in Maine or by substituting a safer alternative in the product;

(3) If compliance is achieved by substitution of a safer alternative in the product, identify the safer alternative and the timetable for substitution; and

(4) Confirm that the manufacturer has notified all persons that offer the product for sale or distribution in Maine of the sales prohibition, as required by 38 M.R.S.A. §1696(4).

(a) Confirmation shall include a copy of the notice and a list of the persons to whom it was sent.

(b) A retailer is exempt from the sales prohibition requirements of this section if the manufacturer failed to notify the wholesaler and retailer in accordance with this subsection, and the department did not notify the retailer of the sales prohibition.

C. Waiver for specific uses. The manufacturer or distributor of a children's product that is subject to a sales prohibition under subsection 5(A) may apply to the commissioner for a waiver for one or more specific uses of bisphenol A. The waiver application must be submitted at least 180 days

prior to the effective date of a sales prohibition, or prior to a new product being sold in Maine and must, at a minimum:

(1) Identify the specific children's product use or uses for which the waiver is sought;

(2) Identify the alternatives considered for substitution of the priority chemical;

(3) Explain the basis for concluding that the use of an alternative is not feasible; and

(4) Identify the steps that have and will be taken to minimize the use of the priority chemical.

D. The commissioner may grant a waiver with or without conditions upon finding that there is a need for the children's product in which the priority chemical is used and there are no technically or economically feasible alternatives for the use of the priority chemical in the children's product. Waivers may be granted for a term not to exceed 5 years and may be renewed for one or more additional 5-year terms upon written application demonstrating that technically or economically feasible alternatives remain unavailable. The commissioner shall deny or grant waiver requests within 60 days after receipt of a completed waiver application.

6. Department Address. Information submissions may be made by regular or electronic mail. The department may provide electronic or paper reporting forms. Use the following address to send all correspondence to the department:

Maine Department of Environmental Protection
Bureau of Remediation and Waste Management, Safer Chemicals Program
17 State House Station
Augusta, ME 04333

NOTE: Electronic reporting forms and/or email addresses for reporting will be provided at: www.maine.gov/dep/oc/safechem/index.htm

STATUTORY AUTHORITY: 38 M.R.S.A. §§ 1691 through 1699-B

EFFECTIVE DATE:

January 9, 2011 – filing 2011-3 (except Section 5)
August 1, 2011 – filing 2011-205 (Section 5), major substantive final adoption

Appendix D: Unit Conversions

No Observed Adverse Effect Level 5000 ug/kg-bw/day is equal to 5000ppb

1 ppb = 1 ng/g or 1 ug/kg (solid) or 1 ug/L (liquid)
1 ppm = 1 ug/g or 1 mg/kg (solid) or 1 mg/L (liquid)

1 mg (milligram) = 1,000 ug (micrograms) = 1,000,000 ng (nanograms)
1 kilogram = 1,000 grams

1 milligram (mg) = 0.00000220462262 pounds (lb) = 0.0000352739619 ounces (oz) = 0.001 grams (g) = 0.000001 kilogram (kg)