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

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