

PRELIMINARY DRAFT: March 13, 2009

The preliminary draft rules/Strawman language below has been developed by the DEP to inform stakeholder meeting discussion. Rule language will not be finalized until completion of formal Board of Environmental Protection rulemaking later this year. At that time, the board will be asked to begin formal rule adoption proceedings in accordance with the requirements of the Maine Administrative Procedures Act, 5 MRSA §§ 8052 through 8057-A. The rule adoption process will include a public hearing, with additional opportunity to comment on the proposed rule, during those proceedings.

**Chapter 880: REGULATION OF CHEMICAL USE IN CHILDREN’S PRODUCTS**

**SUMMARY:** This rule sets forth the process by which the Board 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.

- 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. Available.** “Available” or “available at comparable cost” as used in section 4 of this rule means 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” or “available at comparable cost” means capable of being produced and sold at a price that is not likely to pose a financial hardship to users of the product.
  - C. Board.** “Board” means the Board of Environmental Protection.
  - D. CFR.** “CFR” means the Code of Federal Regulations.
  - E. 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.
  - F. Chemical of high concern.** “Chemical of high concern” means a chemical identified by the department pursuant to 38 MRSA §1693.
  - G. Children’s product.** “Children’s product” means a consumer product intended for use by children, 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’s or a fetus’s being exposed to that chemical.
  - H. Commissioner.** “Commissioner” means the Commissioner of the Department of Environmental Protection.
  - I. Consumer product.** “Consumer product” means any item sold for residential or commercial use, including any component parts and packaging. “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 federal Environmental

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Protection Agency. “Consumer product” also does not include a drug or biologic regulated by the federal Food and Drug Administration or the packaging of a drug or biologic regulated by the federal Food and Drug Administration if the packaging is regulated by the federal Food and Drug Administration.

**I. Department.** “Department” means the Department of Environmental Protection, which includes both the Board and the Commissioner.

**J. Distributor.** “Distributor” means a person who sells consumer products to retail establishments on a wholesale basis.

**K. Good laboratory practice.** “Good laboratory practice” means the conduct of research and generation of data in accordance with the Good Laboratory Practice regulations of the federal U.S. Food and Drug Administration or the Principles of Good Laboratory Practice outlined by the Organisation for Economic Cooperation and Development.

**L. Green screen.** “Green screen” means the chemical screening method called Green Screen for Safer Chemicals, Version 1.0, published by Clean Production Action in March 2007.

**M. Maine CDC.** “Maine CDC” means the Maine Center for Disease Control & Prevention within the Department of Health and Human Services.

**N. 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.

**O. MRSA.** “MRSA” means the Maine Revised Statutes Annotated.

**P. 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.

**Q. Priority chemical.** “Priority chemical” means a chemical identified as such by the board pursuant to section 2 of this rule.

**2. Designation of priority chemicals.**

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**A. Prerequisites for designation.** The board may designate a priority chemical if the board finds, in concurrence with the Maine CDC, that:

- (1) The chemical is listed as a chemical of high concern on the list published by the department pursuant to 38 MRSA §1693; and

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NOTE: The list of chemicals of high concern can be viewed at  
<http://www.maine.gov/dep/oc/safechem/index.htm>

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- (2) One of the following criteria is 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, drinking water or elsewhere in the home environment;
- (c) The chemical has been found through monitoring to be present in fish, wildlife or the natural environment;
- (d) The chemical is present in a consumer product used or present in the home;
- (e) The chemical has been identified as a high production volume chemical by the federal Environmental Protection Agency; or
- (f) The sale or use of the chemical or a product containing the chemical has been banned in another state within the United States.

**B. Additional factors that may be considered by the board.** When determining whether to designate a chemical of high concern as a priority chemical, the board may consider:

- (1) The financial and human resources available to the department;
- (2) Actions being undertaken with respect to chemicals of high concern in other states and jurisdictions;
- (3) The volume of the chemical in commerce in Maine; and
- (4) The need for information on the extent to which the chemical is used in products sold in Maine;

**C. Designation by rule required.** The board must designate a chemical of high concern as a priority chemical by routine technical rule in accordance with the rulemaking

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requirements of the Maine Administrative Procedures Act, 5 MRSA §§8001 through 8064. The rule, or the basis statement to the rule if appropriate, must:

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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).

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- (1) Identify the priority chemical;
- (2) Specify which of the criteria under section 2(A)(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 board’s decision to designate the chemical as a priority chemical;
- (4) Specify the information, if any, that must be submitted by manufacturers and distributors of children’s product that contain the chemical; and
- (5) Specify the deadline for submission of the required information.

In specifying the information that must be submitted by product manufacturers and distributors, the board may waive the information requirements of 38 MRSA §1695(1) if substantially equivalent information already is publicly available, the specified use is small in volume or if the information otherwise is not needed. The board also may require information of the type listed under section 3(B)(1), (2) and (3) of this chapter.

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NOTE: 38 MRSA §1695(1) requires manufacturers and distributors of children’s products containing a priority chemical to disclose the following information unless waived by the commissioner: a description of the product, the number of units sold or distributed for sale in the State or nationally, the amount of priority chemical in each unit of children’s product and the purpose of the chemical.

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- 3. 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 must submit the information specified by the board pursuant to section 2(D)(4) to the department not later than 180 days after effective date of the rule that designates the chemical as a priority chemical. The information may be submitted by regular or electronic mail.

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NOTE: Address regular mail submissions to: DEP-BRWM, Chemical Safety Program, 17 SHS, Augusta ME 04330. If submitting by electronic mail, call (207) 287-2651 for the appropriate email address.

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- A. Commissioner authority to extend submittal deadline.** Upon request by a manufacturer or distributor, the commissioner may extend the deadline established by the board for submittal of information on products that contain a priority chemical.
- B. Commissioner authority to request supplemental information.** Upon review of information submitted pursuant to a board rule designating a priority chemical, the commissioner may request the manufacturer or distributor of a children's product to clarify the submittal, to supplement incomplete information or provide the following additional information:
- (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 and pathways (e.g. inhalation, ingestion) by which exposure could occur;
  - (2) Information on the extent to which the chemical is present in the environment and humans; and
  - (3) 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. An acceptable assessment must:
    - (a) Describe the specific children's product or product in which the priority chemical is used;
    - (b) Provide U.S. sales data for the product, including, at a minimum, the number of units sold during the previous calendar year and the amount of the priority chemical used in the manufacture of those products;
    - (c) Describe the function of the priority chemical in the product and list the specific characteristics of the chemical that led to its selection to fulfill that function;
    - (d) Identify functionally equivalent products (e.g., other TVs if the product is a TV) offered for sale in the U.S. but made without the priority chemical. For each such product, provide the following information:
      - (i) The product manufacturer;
      - (ii) The number of product units sold in the U.S. during the previous calendar year;
      - (iii) The specific chemical or non-chemical alternative used in lieu of the priority chemical;

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- (iv) If the alternative identified under division (iii) is another chemical, a comparison of the properties of that chemical to the properties of the priority chemical for each of the specific characteristics listed pursuant to subparagraph (c) above; and.
- (v) The basis for choosing to use the priority chemical in the manufacture of the product in lieu of the available alternatives;
- (e) Identify and describe emerging chemical and non-chemical alternatives to use of the priority chemical in the product. For each such alternative, provide 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;
- (f) List the key, distinguishing human health and environmental hazards (or “endpoints”) associated with the priority chemical, as identified in consultation with the department and the Maine CDC;
- (g) List and provide copies of all peer-reviewed studies or government-generated studies identified through a search of publicly accessible databases using search terms agreed on by the department in consultation with the Maine CDC. Also list industry or advocacy group studies conducted in accordance with good laboratory practice. The search must be conducted for the priority chemical and for each chemical alternative identified pursuant to subparagraph (d) and (e) and must, at a minimum, include as search terms the hazard endpoints identified pursuant to subparagraph (f); and
- (h) An evaluation of the human health and environmental hazard posed by priority chemical and each identified chemical alternative using the Green Screen or other evaluation methodology approved by the Maine CDC.

**C. Disclosure by trade associations.** Information required under this section may be submitted by a trade association representing manufacturers or distributors of products

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containing the priority product provided the information is presented in a form acceptable to the commissioner.

#### **4. 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 product containing a priority chemical 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.

If there are several available safer alternatives to a priority chemical, 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, the board shall consider all relevant evidence to that effect including but not limited to:
- (a) The affordability of the alternatives as demonstrated by their availability in the marketplace and sales volumes;
  - (b) The purchase price differential between the product containing the priority chemical and alternatives that are free of the chemical; and

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- (c) Information bearing on the ease with which the alternative could be substituted for the use of the priority chemical.

The board is not obligated to consider information related to the redesign, retooling or other costs incurred by the product manufacturer to discontinue the use of the priority chemical. The essential inquiry for the board is whether the cost of the alternative will pose a financial hardship to users of the product.

- (2) **Safety.** An alternative is safer if, when compared to a priority chemical that it could replace, the alternative would reduce the potential for harm to human health or the environment. In determining if an alternative chemical is safer, the department, in consultation with the Maine CDC, 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 persistence of the chemical and its tendency to bio-accumulate;
- (c) The potential human health effects from exposure to the chemical; and
- (d) The eco-toxicity of the chemical.

If the department identifies several available safer alternatives to a priority chemical, the Maine CDC 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 high concern;
- (b) Presume that an alternative is available if the alternative is sold and in wide use 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; 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 priority

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chemical subject to a prohibition adopted under section 4 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 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.