BASIS STATEMENT

CHAPTER 880
REGULATION OF CHEMICAL USE IN CHILDREN'S PRODUCTS

In April 2008, the Legislature adopted Public Law Chapter 643, *An Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products* [38 MRSA §§1691 through 1699-B]. The goal of the law as set forth in the Legislature's Declaration of Policy under 38 MRSA §1692 is to reduce the exposure of children and other vulnerable populations to chemicals of high concern by substituting safer alternatives when feasible. To accomplish this goal, the law 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.

Chapter 880 implements and furthers the goal of the law by: 1) setting forth the process by which the department will identify priority chemicals for regulatory scrutiny; and 2) detailing the process by which the department will collect information from manufacturers on the use of priority chemicals in children's products.

The regulatory scheme generally follows a five-step process, as outlined below:

STEP ONE. Identification of Chemicals of High Concern

The Legislation directed the Department to, in Concurrence with the Maine Department of Health and Human Services, Center for Disease Control (Maine CDC), publish a list of chemicals of high concern (CHC List). Under the law and rule, the department may regulate the use of a chemical in children's products only if the chemical appears on that list. The department, with the assistance and concurrence of the Maine CDC published the initial list on its website in June 2009. Under 38 MRSA §1693, a chemical may be included on the list if it has been identified by an authoritative governmental entity on the basis of credible scientific evidence as being known as:

- A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;
- Persistent, bioaccumulative and toxic; or
- Very persistent and very bioaccumulative.

The Legislature gave further guidance on the development of this list in PL 2007 c. 643 Section 3. The CHC list and background information on how it was compiled, including the source lists from which the chemicals were drawn, are published on the department website at www.maine.gov/dep/oc/safechem.

STEP TWO. Identification of Priority Chemicals

The presence of a chemical on the CHC List does not, by itself, have regulatory consequences. In order to bring its regulatory authority to bear, the department must formally designate the chemical as a "priority chemical." The Legislation directed the Department to designate at least two priority chemicals by January 1, 2011 and to adopt rules to implement the priority chemical designation provisions of the statute. Section 2(D) of the rule requires the department to designate priority chemicals through the adoption of a routine technical rule in accordance with the Maine Administrative Procedures Act. Designating priority chemicals

by rule ensures that chemical manufacturers and other interested parties are notified of a department proposal to designate a priority chemical, and have the opportunity to provide comments that will assist the department in deciding whether to proceed with a designation. Through the rulemaking process the department provides a written explanation of the basis for its designation decision, including a written response to comments from the public and the regulated community.

STEP THREE. Collection and review of data on the use of priority chemicals in children's products

The adoption of a rule designing a priority chemical triggers a statutory obligation on the part of manufacturers and distributors to disclose information on their use of the chemical in children's products. This facilitates the gathering of information on the extent to which children may be exposed to the chemical as a result of its use in consumer products.

The exact information that must be disclosed will depend on the chemical. The department recognizes that information may already be publicly available, and that it therefore is not likely to need the same type and range of information for each priority chemical. Accordingly, the rule provides for the scope of the required disclosure to be determined on a chemical by chemical basis. This will be accomplished by having the board, in the rule designating a priority chemical, specify the exact information that must initially be submitted by manufacturers and distributors. Under section 3(D) of the rule, the commissioner may require additional information as needed for the department to complete its evaluation of the priority chemical.

STEP FOUR. Collection and review of data on the availability of safer alternatives

If the review of information on the use of a priority chemical in children's products suggests that safer alternatives should be substituted, the regulatory focus then shifts to an examination of the availability of effective, affordable and safer alternatives. Manufacturers and distributors of children's products that contain the chemical must submit an alternatives assessment *if requested by the department*. If the manufacturer or distributor fails to submit an acceptable assessment as defined in the rule, the department may assess a fee to cover the costs of arranging for an independent report on the availability of safer alternatives.

STEP FIVE. Substitution of safer alternatives

The statute at 38 MRSA §1696 authorizes the board to adopt a rule prohibiting the sale of a children's product that contains a priority chemical if the board finds that: 1) the distribution of the product directly or indirectly exposes children or vulnerable population to the chemical; and 2) a safer alternative is available at comparable cost. Under the law and rule, an alternative is safer if, when compared to the priority chemical that it could replace, the alternative has not been show to pose the same or greater potential for harm to human health or the environment. Chapter 880, at subsection 4(A), further provides that the board may find an alternative to be 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. The board also may presume that safer alternatives are available at comparable cost if another state has banned the sale of the product containing the priority product.

Rules prohibiting the sale of a children's product are designated "major substantive" under the statute and therefore must be approved by the Legislature in order for the sales ban to take effect.

The Legislature also directed the department to convene a stakeholder group to give recommendations to the Department on implementation of the Legislation (PL 2007, c. 643, §4). Four stakeholder meetings took place in the spring of 2009. The meeting agendas, highlights and a final report are available on the department website (www.maine.gov/dep/oc/safechems). A group convened to make recommendations on implementation of the law.

The Department shared a preliminary draft of the rule was with the stakeholders and revised the draft rule in response to stakeholder input. The Department presented this revised draft to the Board of Environmental Protection at its meeting of November 19, 2009. The board authorized department staff to begin rule adoption proceedings. Notice of the proposed rule was published in the *Bangor Daily News*, *Kennebec Journal*, *Lewiston Sun Journal*, *Portland Press Herald* and (*Waterville) Morning Sentinel* on November 25, 2009. Notice also was mailed to the members of the stakeholder group and to each person on the department's rulemaking subscription list.

The board held a public hearing on the rule on December 17, 2009. During the hearing and the public comment period followed, the Department received comments from 119 interested parties. The comments are summarized below, followed by the department's response.

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COMMENTS

GENERAL COMMENTS

General Support

1. Comment: The commenters support the regulation of chemicals in children's products and encourage the Board to adopt Chapter 880 as proposed. (5, 6, 8, 9, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-86; 88, 89, 91-97, 99-102, 106-114, 117, 118)

2. Comment: The commenter contends that the steps defined in the proposed rule—identifying chemicals, gathering pertinent data, assessing potential impacts and taking action—are the essential ingredients of a modern regulatory system. The commenter opines that the scope of the law and proposed rules is suitably modest. (20)

3. Comment: The commenter points out that, in addition to protecting the health of children exposed to consumer products, this rule will benefit workers in facilities where use of priority chemicals is reduced or eliminated, as well as people living in the communities around those facilities. (33)

4. Comment: The commenter suggests that the proposed rule is a reasonable first step. The commenter, acknowledging that it is not the intent of the rule, laments that the type of action the rule is taking is after the fact and suggests that more research needs to go into chemicals before they get into the environment. (99)

Response to comments # 1-4: The Department acknowledges the commenters' support. No change.

Other Jurisdictions

5. Comment: The commenter points out that Maine is part of a larger movement to reform chemicals policy and that other states, including Washington, California and Minnesota are moving forward with legislation similar to Maine's Safer Chemicals Program, that the European Union is implementing its comprehensive chemicals policy (REACH) and that the US government is reviewing the Federal Toxic Substances Control Act (ToSCA). (20)

6. Comment: The commenters urge the state to not wait for the Federal government to reauthorize the ToSCA; noting that the quickest way to move the Federal government to act is through state leadership. (13, 20, 40)

Response to comments # 5-6: The Department is aware of and monitoring developments in other states and at the Federal level. The Department is moving forward with rules to implement the program as required by the Legislature. No change.

Risk Analysis and Management

7. Comment: The commenter recommends that the BEP consider both the benefits of a product and the actual potential for harm from a priority chemical in a product. The commenter suggests that the proposed rule is biased against the manufacturers and distributors that will be affected by it and recommends that the rule be revised to incorporate a threshold of scientific analysis that leads to responsible decision-making and prioritization of chemicals, and to include consideration of the realities of the market from all reasonable perspectives. (1)

8. Comment: The commenter recommends that the proposed rule be amended to utilize the full range of risk management measures. The commenter contends that the proposed rule presents a "one size fits all" approach that ultimately results in banning children's products that contain priority chemical substances. The commenter recommends that as an alternative approach, the Department should focus on ways to assess potential risks and manage exposure so that chemicals can be used safely and effectively. The commenter asserts that even the most hazardous chemicals can be used safely when appropriate risk management measures are implemented and that such an approach can prevent widespread disruption in Maine's economy. (16)

9. Comment: The commenter recommends that this rulemaking process be allowed to move along without having perfect science, without having a clear, obvious connection between exposure A and outcome B in humans. The commenter supports the precautionary principle approach of relying on other data and a wealth of correlating data to make a reasonable judgment that this particular exposure is harmful or potentially harmful and worth our consideration. (22)

10. Comment: The commenter points out that the state needs to replace the piecemeal way that the Legislature has handled restricting chemicals in consumer products in the past with a system that is science-based and reasonable that identifies the worst chemical hazards, and phases them out of commerce. The commenter urges the Board to adopt the rule as proposed in order to implement such a system. (40)

11. Comment: The commenters suggest that current federal regulations seek to set safe exposures for harmful chemicals based on the idea that "the dose makes the poison." The commenters contend that this idea is outdated and no longer relevant, asserting that in fact, certain groups of chemicals are harmful even in very low doses, especially to developing fetuses. (30, 32, 99)

12. Comment: The commenter recommends that the Department's rules follow the "precautionary principle." (30)

13. Comment: The commenters contend that the proposed rule appropriately bases the designation of priority chemicals on their inherent hazard. (50-52, 61-71, 73-77, 79-82, 106-108)

14. Comment: The commenter recommends that the Department rewrite the rules to follow a risk-based approach. (87)

15. Comment: The commenters caution that tying rules to dose may miss regulating some of the most important environmental toxins and that with some toxins less is worse, as in the case of some endocrine disruptors. The commenter also cautions against requiring that an exact cause and effect relationship in humans be established before regulating any toxin. The commenter points out that because of the many variables, such as particular vulnerabilities, timing of exposure and synergistic factors this is a difficult task that could take years, if it is even possible and that because it is the DNA of an organism that is affected, adverse effects can be passed on to subsequent generations. (99,100)

16. Comment: The commenter recommends that any prioritization of chemicals take into account exposure. The commenter points out that under exposure-based chemical regulation, chemicals are prioritized for regulatory action based on defined characteristics with hazard assessment, dose-response, exposure assessment, and risk characterization as part of the process. The commenter recommends that when a substance meets hazard criteria, an exposure assessment be conducted followed by risk characterization to determine if risks are adequately controlled. (104)

17. Comment: The commenter recommends that the Department give more careful thought to hazard and exposure based criteria that include values for hazard characteristics and at a minimum some qualitative notion of exposure scenarios that might trigger a finding that a chemical is a high priority. (115)

18. Comment: The commenter suggests that there exist many useful data, assembled from a number of scientific disciplines, from animal toxicology to environmental epidemiology, that can guide prudent public health decisions to protect populations from exposures to environmental chemicals; and that we should err on the side of protecting public health. (118)

Response to comments # 7-18: The Governor's Task Force to Promote Safer Chemicals in Consumer Products recommended that the state develop a more comprehensive chemical policy framework, building on the previous successes with requiring safer alternatives to mercury, arsenic in pressure treated wood, and PBDE flame retardants. The Task Force Report, in discussing the need for chemical policy reform, observes that informed selection and sound use of chemicals requires a chemicals policy that is "hazard-based rather than exposure-based, meaning that it is driven primarily by the inherent properties of chemicals rather than by

estimations of exposure and risk," and that the aim should be to "transition chemical use from high hazard substances to low hazard substances."

The Maine Toxic Chemicals in Children's Products law (38 MRSA chapter 16-D), incorporates this chemicals policy model, rather than risk assessment, when it directs the Department to develop a list of Chemicals of High Concern (CHC list). Under the law and the proposed rule, the Department may regulate the use of a chemical only if the chemical appears on the CHC list. A chemical may be put on the list only if it has been identified by an authoritative governmental entity, on the basis of credible scientific evidence, as being known as:

- *A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;*
- *Persistent, bioaccumulative and toxic; or*
- *Very persistent and very bioaccumulative.*

Chemical hazard, rather than risk management or dose-response, is the touchstone of Maine's approach (likelihood of exposure is taken into account when designating a priority chemical. See response to comment #98). The law eliminates the need for debate on the matter of hazard by limiting the CHC list to chemicals that already are known in the scientific community as possessing one or more of the hazard traits listed above. The chemicals policy approach of the proposed rule is in keeping with the recommendations in the Final Task Force Report, and the purpose of the statute.

No change.

Chemicals of High Concern List

19. Comment: The commenter provided a list of objections to the Chemicals of High Concern List that the Department generated as required under PL 2007, c. 317 Section 3, and published on the Department website in June 2009. Specifically, the commenter: objects to the lack of public input to the development of the list; does not consider the source lists the department relied on in developing its list to be authoritative; does not believe the Department based its characterization of chemicals on a weight-of-evidence approach; objects to the use of the initial categorization of the Canadian Domestic Substances list rather than the final determined Canada priorities; and objects to the use of a European Union Endocrine Disruption priority listing that the commenter considers to be unreliable. (1)

20. Comment: The commenter objects to the Department and CDC's use of several source lists for the development of the Chemicals of High Concern List. Specifically, the commenter does not find the OSPAR PBT list, the Canadian PBT list and the EU endocrine disruptor lists to be credible sources from authoritative government entities and suggests that the Department eliminate chemicals that come from these sources from the Chemicals of High Concern list. The commenter recommends that the Board direct the Department to recreate the Chemicals of High Concern list using only authoritative entities as sources that use credible scientific evidence to determine where chemicals are known to present a hazard of concern and ensure the sources used are the most up-to-date. The commenter provides a list of recommended sources. (7)

21. Comment: The commenter objects to the use of the final categorized PBiT (persistent, bioaccumulative and inherently toxic) list from Canada and recommends that the Department use only Canada's top priority PBiTs. The commenter also objects to the use of the lists from

OSPAR because OSPAR appears to have the lowest criteria for Bioaccumulation and Persistence in the world. Additionally the commenter objects to the use of the EU Endocrine Disruption list, stating that the EU's science advisors did not find the source material, methodology and selection criteria to be scientifically adequate. Finally, the commenter believes one of the two columns in the table of EPA's TRI data to be incorrect and suggests that it be deleted. (10)

22. Comment: The commenter contends that the Department's process in developing the Chemicals of High Concern List is contrary to the language in the statute, which states that a substance "may be included on the list only if it has been identified by an authoritative governmental entity on the basis of credibly scientific evidence as being known as: A. a carcinogen, a reproductive or developmental toxicant or an endocrine disruptor; B. persistent, bioaccumulative and toxic; or C. very persistent and very bioaccumulative." The commenter recommends that the Department clearly define the universe of substances to which Chapter 880 may be applied. (16, 119)

23. Comment: The commenters recommend that the Department revise the Chemicals of High Concern list to focus on "known" hazards from scientifically credible and updated sources. (1, 2, 7, 10, 12, 104, 115)

24. Comment: The commenter recommends the Department undertake an immediate identification and robust monitoring of Chemicals of High Concern, those that have already been proven to be hazardous. (40)

25. Comment: The commenter asserts that it is entirely appropriate that nearly all of the research supporting the toxins identified on the Chemicals of High Concern list is animal. The commenter points out that while animal research cannot predict exact effects on humans, we do know from past experience that animal research showing adverse effects should raise great concern. The commenter contends that with 60,000+ chemicals in our environment, we cannot wait for human bodies to pile up to substantiate fully the risk, likening such a course of action with the experience with tobacco. (99)

Response to comments # 19-25: The Department, in consultation with a toxicologist from the Maine Department of Health and Human Services, Center for Disease Control and Prevention (CDC), developed and published a list of chemicals of high concern (CHC list), as directed by the Legislature in 38 MRSA§1693. This list, as well as a background document that describes the sources for the chemicals listed, is available on the Department's website at http://www.maine.gov/dep/oc/safechem/highconcern/.

Timing and Input

While the Legislature gave the Department a deadline of January 1, 2010 to publish such a list, it did not prevent the Department from publishing the list earlier than the deadline. Nor did the Legislature require any type of public process in developing the list. However, the Legislature gave the Department leave to periodically review and revise the CHC list, and add chemicals that in the judgment of the CDC meet one or more of the criteria laid out in statute, or remove a chemical based on evidence that it is not present in a children's product or is not subject to the requirements of the statute. The Department will consider the above comments when revising the list. However, revision to the list is not a prerequisite to proceeding with the subject rule-making effort.

Weight-of-Evidence

Many of the chemicals on the source lists consulted in developing Maine's CHC list appear on those source lists based on a weight-of-evidence analysis conducted by the listing body. The Maine law intentionally avoids the need to independently analyze the hazard traits of chemicals, through a weight-of-evidence approach or otherwise, by drawing on the analyses already undertaken by authoritative governmental entities.

Chemical Source Lists

The exclusion of the term "being known as" from the note in section 2(D) of the rule was an oversight on the part of the Department and has been corrected.

The Department does not ignore the Legislature's directive to confine the list to "known" sources of hazard. However, the Legislature further defines what it means by "known" in the legislation that established the Toxic Chemicals in Children's Products law, PL 2007 c. 643 Section 3. Under that section, the Legislature listed approximately ten examples of existing chemical lists that the Department "may consider" in developing Maine's Chemicals of High Concern List. Categories the Legislature recommends the Department use in developing its list include, for example, chemicals "reasonably anticipated to be a human carcinogen" as well as those "known to be a human carcinogen" by the US Department of Health and Human Services.

The majority of the source lists used in developing the CHC list came from those outlined in this section 3 of the enacting legislation. However, the Legislature did not limit the Department's options to just those suggested lists. Additional source lists were consulted where deemed appropriate in the judgment of the Maine CDC toxicologist who advised the Department. A discussion of the Department's and Maine CDC's basis for drawing on the specific lists referenced by the commenters follows:

> *The Canadian Priority Substance List (PSL) is designed to identify chemicals that need to be evaluated under the Canadian Environmental Protection Act. PSL1 came out in 1989, and consists of 44 chemicals. PSL2 came out in 1995 and consists of 25 chemicals. The Canadian government anticipates that chemicals will continue to be added. Canada's PBiT list was published in 2008 and is directly relevant to the criteria for inclusion on Maine's CHC list as specified in 38 MRSA §1693(1).*
>
> *The EU endocrine disruptor list is a categorization of the potential for chemicals to disrupt endocrine function, and consists of several categories. Only Category 1 chemicals were included. These are chemicals for which the EU considers that there is evidence of endocrine disruptive activities. The inclusion of this list meets the requirements of the Maine law for inclusion on the CHC list.*
>
> *The Maine CDC recommended the use of the OSPAR list, which includes mostly PBTs, along with some endocrine disruptors, in order to be as inclusive as possible in listing chemicals of potential interest to regulators. Many of the figures for bioaccumulation and persistence are estimated, and not based on actual data. Maine believes that inclusion of this list is justified because of the uncertainty in the calculations, and the recognition that chemicals can biomagnify to a considerable extent if released in substantial amounts over an extended period of time even with modest bioconcentration factors.*
>
> *The first column of TRI PBTs (Column L, "EPA Final PBT Rule for TRI") includes all of the approximately 64 persistent, bioaccumulative and toxic chemicals and chemical classes listed in Table 3 in the Federal Register Vol. 64, No. 209, Friday, October 29,*

1999 pages 58712-58714. The second column (Column M, "TRI PBT Chemical list") lists 16 PBT chemicals and 4 PBT chemical compound categories which are subject to reporting at lower thresholds under the EPCRA (Emergency Planning and Community Right to Know) section 313. The Department and Maine CDC consider both lists to be relevant to the statute, as they represent chemicals that EPA considers to be PBTs.

It is important to understand that any chemical that is a potential candidate for listing as a priority chemical will undergo further evaluation by the state. It should also be noted that the presence of a chemical on the CHC list does not, by itself, have regulatory consequences. In order to bring its regulatory authority to bear, the Department must formally designate the chemical as a "priority chemical." The proposed rule, in section 2(D), requires the Department to designate priority chemicals by rule. At the time that the Department designates a Priority Chemical, concerned parties can comment on the appropriateness of that chemical's presence on the CHC list.

Stakeholder Process and Rule Development Timeframe

26. Comment: The commenter suggests that the Department's stakeholder process and timeframe in developing the Chemicals of High Concern list and draft rule has moved too quickly to incorporate the views of the stakeholders, to consider the practical realities of the affected markets, and to truly gather all necessary information relating to the realities of the impacted markets. (1)

27. Comment: The commenter contends that requests for additional stakeholder input goes beyond the law; that the stakeholder process required in PL 2007, c. 643 § 4 took place over the summer. (17)

28. Comment: The commenter contends that the proposed rule is the result of a protracted Legislative debate, an arduous stakeholder process and a rational scientifically based analysis. (40)

29. Comment: The commenter suggests that the proposed rule does not offer sufficient notice and comment opportunities for interested stakeholders. (87)

Response to comments #26-29: The Department convened a stakeholder group as required under the legislation establishing the Toxic Chemicals in Children's Product's law [see PL 2007, c. 643]. The group met four times in the spring of 2009. No interested party was excluded. The meeting agendas, highlights and a final report are available on the Department's website (www.maine.gov/dep/oc/safechems).

Opportunity for stakeholder input continues with the public hearing and comment period in the process of adopting this rule. The proposed rule only lays out the framework for how the Safer Chemicals program will be operate. Each designation of a priority chemical (and subsequent ban, if called for) will be carried out through a future rulemaking process subject to the requirements of the Maine Administrative Procedures Act (5 MRSA § 8051 et seq.), which includes public notice of rulemaking proposal in all of the major newspapers in the state, a public hearing and comment period and adoption at a public meeting of the Board of Environmental Protection. Further, to ban a chemical, the Department must adopt a major substantive rule, which involves returning to the Legislature's Joint Standing Committee on Natural Resources Matters with a provisionally-adopted rule prior to final adoption.

No change to the rule.

Food Packaging Materials

30. Comment: The commenter suggests that because food packaging materials are regulated by the US Food and Drug Administration, further regulation of these materials by Maine under the proposed rule would be duplicative and conflict the with the Federal regulatory scheme and would violate the supremacy clause of the US Constitution. (3)

31. Comment: The commenter contends that the proposed rule would duplicate existing FDA regulations as they apply to food packaging and other food contact materials. (10)

32. Comment: The commenter expresses concern about the presence of toxic industrial chemicals in food and the implications for the health of Maine's children. The commenter points out that in addition to pesticides contaminating the food supply, other dangerous chemicals find their way into food through packaging, processing and cooking. The commenter cites some of the health effects linked to bisphenol A (BPA), which, the commenter points out, is used in a number of consumer products including almost all food and beverage cans. The commenter recommends that food packaging manufacturers be held to standards as strict as those that organic farmers must meet. (39)

Response to comments #30-32: The proposed rule does not conflict with federal regulations on its face, and as with any regulation, the Department will not apply it in practice in a manner that conflicts with federal regulations. Therefore the Department disagrees with the commenter's conclusion that the proposed rule is federally preempted. No change to the rule.

Medical Device Manufacturers

33. Comment: The commenter expresses concern that the proposed regulations could unintentionally hinder medical device manufacturers' ability to select the most appropriate materials to meet patients' health care needs. Since the safety and effectiveness of medical devices is regulated by the federal Food and Drug Administration, the commenter contends that such devices should be excluded from the regulations as was done with other health care products (drugs and biologics) regulated by the FDA. (116)

Response: The proposed rule establishes the process the department will follow in designating priority chemicals for regulatory attention. Under the proposed rule, each designation of a priority chemical will carried out through a future rulemaking proceeding. At that point, product manufacturers who use the chemical will have the opportunity to make their case to the board that the chemical either should not be designated or that their particular usage should not be regulated. At this point in the process the Department declines to exclude entire product categories from potential regulation. To do so would prematurely and unnecessarily limit the scope of the department's regulatory authority, and limit the information-gathering purpose of designating a priority chemical. No change.

Burdens on Business

34. Comment: The commenter points out that the burdens on businesses to compile data and recall products under the proposed rule are extensive and must be addressed on a case-by-case basis. (104)

Response: The Department agrees that data requests should be narrowly drawn to avoid unnecessary burdens on product manufacturers. The proposed rule is designed just for that purpose; priority chemicals will be designated individually by rule and the information required from users of the chemical will be determined on a case-by-case (or chemical-by-chemical) basis

after careful examination of what is already known. The board recognizes that it is unlikely to need the same range of information on each chemical. Section 3(E) of the proposed rule is intended to further minimize burdens and costs to manufacturers by allowing manufacturers to rely on information submitted by trade associations or other manufacturers in order to avoid duplicative submissions.

The Department acknowledges that a manufacturer whose product ultimately is banned from sale in Maine could face the need to recall unsold products from store shelves in the State. However, for that to happen, the several preliminary actions must occur:

1) *The board must designate a chemical in the product as a priority chemical;*
2) *The board must determine that one or more safer alternatives to the product are available at comparable cost;*
3) *The board must determine that distribution of the product exposes children or other vulnerable populations to the chemical;*
4) *The board must adopt a rule banning the sale of the product in Maine;*
5) *The Legislature must pass a bill authorizing adoption of the ban; and*
6) *The final rule cannot take effect until at least 12 months after the notice of the proposed ban.*

This multi-step, multi-layered process will ensure that manufacturers have ample advance notice of any ban, giving them time position themselves to minimize the need for a product recall.

No change.

Small Business and Retail Concerns

35. Comment: The commenter expresses concern that the rule will affect small manufacturers and retailers with high testing costs, unsalable merchandise and potentially put these companies out of business. The commenter cites the recently-adopted Federal Consumer Product Safety Improvement Act of 2008 (CPSIA), which requires manufacturers to test their materials for lead content, and suggested that this law put at least one small business in Maine (a manufacturer of fabric sun hats) out of business. The commenter also suggested that resellers, such as Goodwill, and surplus retailers like Marden's—a business that obtains its merchandise not through traditional distribution channels, but from closeouts, bankruptcies and overstocks—would also be harmed by the rule because they would not know what is in their goods and could not afford to test items for compliance. (12)

Response: The Department shares the commenter's desire to minimize regulatory burdens to Maine's manufacturers, retailers and other small businesses. To that end, there are some distinct differences between the CPSIA and the proposed rules. Mainly, while CPSIA requires third-party testing and certification for lead content of components of, and paint used on, children's products, the proposed Chapter 880 would require a manufacturer of a children's product that contains an intentionally-added designated priority chemical to provide the Department with chemical use information. If a product manufacturer (such as the commenter's example of a hat maker) does not use the priority chemical in the production of their product, and does not use a component to which the chemical has been added (a fabric chemically-treated with a priority compound, for example), the rule would not apply to that manufacturer. While manufacturers

will be required to know what chemicals went into the production of the components used in their products, they will not be required to submit certification of third-party testing for the chemical.

Unsalable Merchandise
In order to list a priority chemical and ban the sale of children's products containing that chemical, the Department must go through two additional rulemaking processes, at which time concerns regarding inventory and the possibility of a sell-through period will be taken into account. Additionally, the law and rule require a minimum 12-month lead time from when the rulemaking notice is published until the effective date of the ban, which in most cases should be sufficient notice and provide ample time for products to move off of retailers' shelves. (See response to comment #34 for a more detailed discussion of this process).

Used Items
In the case of resellers, such as Goodwill, 38 MRSA §1697(1) specifically exempts used products from the requirements of the law.

Surplus Retailers
The Department understands and sympathizes with the added complications for retailers such as the commenter's example of Marden's. The statute provides an exemption for retailers under 38 MRSA §1697(5), unless a retailer "knowingly sells a children's product containing a priority chemical after the effective date of its prohibition for which that retailer received prior notification from a manufacturer, distributor or the State." Sell-through periods established at the time of a sales prohibition should, in most cases, prevent the problem of unsalable stock. Additionally, the proposed rule is not unprecedented. The Department has existing rules prohibiting the sale of multiple consumer products, paints and coatings and gas cans that do not meet Maine-specified VOC (volatile organic compound) limits, as well as sales prohibitions on products that contain certain PBDE (poly-brominated diphenyl ether) fire retardants and mercury-containing products. In the interest of protecting the health of Maine's citizens, distributors and retailers should have a system in place for ensuring their merchandise is compliant with state environmental regulations. Additionally, in the case of some existing regulations, manufacturers have labeled their products, "not for sale in Maine."

No change to the rule.

SECTION 1. DEFINITIONS

Alternative
36. Comment: The commenter finds the definition of "alternative" combined with the concept of "available at comparable cost" in Section 4(B) of the proposed regulation problematic. (16)

Response: Please see response to comment # 118. No change to the rule.

Authoritative governmental entity or body
37. Comment: The commenter recommends that the Department include a definition of "authoritative governmental entity or body" and recommends the following language: "'<u>Authoritative governmental entity or body' means a government agency or formalized scientific organization that satisfies all of the following requirements:</u>
    (1) <u>It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.</u>

(2) It does not engage in advocacy.
(3) It bases its characterization of chemicals on a weight-of-evidence approach. To the extent available, it considers multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and gives full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.
(4) It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications." (2)

Response: The Legislature did not find it necessary to define "authoritative governmental entity" when directing the Department to derive its Chemicals of High Concern list from those sources. In Section 3 of the enacting bill (PL 2007, c. 317 Section 3), the Legislature listed a number of potential source lists for developing the list. Among those were lists developed by The World Health Organization, the United States Federal Government, the states of California and Washington and the European Union. That the Legislature considered these entities to be authoritative is neither surprising nor indicative of a need for clarification or elaboration.

The proposed definition does not lend clarity and is far too restrictive in ways that undermine statutory purpose. It would have the Department and CDC revisit and second guess every decision that any body has made, and sets the bar at risk assessment, which was not the intent of the Legislation; rather a chemical policy framework that focuses on reducing hazards rather than assessing risks was the basis of the law and the proposed rule.

No change.

Available

38. Comment: The commenter recommends that the Department include a definition of "available" and recommends the following language: "'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." (2)

Response: Essentially comparable language appears in section 4(A) of the proposed rule. The Department does not see a need to duplicate this language as a definition. No change.

1(E) Chemical of High Concern.

39. Comment: The commenter recommends making the following addition to the definition of "chemical of high concern": "'Chemical of high concern' means a chemical identified by the department pursuant to 38 MRSA §1693 and that has the following hazard characteristics:

1) 'Chemicals that cause cancer in humans' means chemicals that have been classified in (i) the International Agency for Research on Cancer ("IARC") category 1, 2a or (ii) an equivalent category in a similar classification system promulgated by another authoritative body such as US EPA's the National Toxicology Program Report on Carcinogens.

2) 'Chemicals that cause mutagenic effects in humans' means chemicals classified in (i) the European Union Category 1A or 1B under Annex VI, part 3 of Regulation (EC)

1272/2008 or (ii) an equivalent category in a similar classification system promulgate by another authoritative body.

3) 'Chemicals that are persistent in the environment, bioaccumulate and are toxic' means chemicals that meet all of the following standards.
   a) Persistent in the environment means the chemical has a half-life, as measured by reliable studies, equal to or greater than 180 days in water, or 180 days in soil, or 180 days in sediment, or 2 days in air.
   b) Bioaccumulate means the chemical has a bioaccumulation factor (BAF) or bioconcentration factor (BAF), as measured by reliable studies, greater than 5000.
   c) Toxic means a chemical has, as measured by repeat dose studies for mammalian toxicity or by acute or chronic studies for aquatic organisms, a subchronic oral value less than or equal to 10 mg/kg-bw/day for mammals; or, LC50 or EC50 less than or equal to 1.0 mg/L (for acute toxicity) or a No Observed Effect Concentration (NOEC) less than or equal to 0.1 mg/L (for chronic toxicity) for aquatic species.
   d) Identified as such by the State of Washington Department of Ecology in Washington Administrative Code, Chapter 173-333; or. The United States Environmental Protection Agency in 40 Code of Federal Regulations, Part 372.

4) 'Chemicals that cause reproductive harm' means chemicals that have been classified as reproductive or developmental toxicants by an authoritative body such as US EPA, California Proposition 65, the National Toxicology Program Center for Evaluation of Risks to Human Reproduction, or the European Union.

5) 'Endocrine Disruptors': identified through screening or testing conducted in accordance with protocols developed by the United States Environmental Protection Agency pursuant to the Federal Food, Drug and Cosmetic Act, 21 United States Code, 346a(p), as amended by the federal Food Quality Protection Act (Public Law 104-170) or the federal Safe Drinking Water Act, 42 United States Code, Section 300j-17. (2)

Response: The Department's proposed definition of "Chemical of High Concern" is essentially identical to the definition in the statute. The criteria for listing a Chemical of High concern are listed in the section of the statute referenced in the definition (38 MRSA §1693) and do not require further explanation as proposed by the commenter. Additionally, the Legislature gave further guidance as to potential source lists in Section 3 of the enacting bill [PL 2007, c. 317].

The commenter's suggested language is overly restrictive and problematic. The commenter's proposed definition of "toxic" is far too narrow; the proffered bioaccumulation factor criteria would have to be applied to each of the PBT chemicals on the list, when the authoritative government entities have already made the determination that the chemicals are bioaccumulative; and the suggested language on endocrine disruptors is tied to a US Environmental Protection Agency list that has no chemicals listed to date.

No change to the rule.

Child or Children

40. Comment: The commenters recommend that the Department include a definition of "children" in the rule and that such a definition should be narrow in scope. (1, 98)

41. Comment: The commenter contends that the definition of "child" or "children" was left intentionally nebulous by the Legislature because they wanted to assess what are the threats to children from whatever the vectors happen to be. (17)

42. Comment: The commenter recommends that the Department adopt the definition of "child" as defined in the state's Restrictions on Lead-Containing Children's Products (under 12 years of age). (103)

43. Comment: The commenter recommends that the Department define "children" as all persons 18 years and younger to ensure that teens are fully protected from chemicals that may disrupt them at puberty. (105)

44. Comment: The commenter points out that, while its IT electronics products (e.g., computers, printers and components) are not designed, intended or marketed for children, they are used by children in homes and schools. The commenter suggests that the Department narrow its definitions of children, children's product and consumer product, such as the definition in Maine's Lead Poisoning Control Act (up to 6 years in age); further restrictions on lead-containing children's products (under 12 years of age with clear definitions of child care article, children's jewelry and children's product); the Federal Consumer Product Safety Improvement Act of 2008 (designed or intended primarily for children under 12 years of age). (98)

Response to comments # 40-44: The board agrees that a definition of child will lend clarity to the rule. In the absence of a clear guidance on this point from the legislative record, the Department has incorporated the definition of child from the Maine rules of statutory construction, 1 MRSA §72, sub-§2-A:

> *"**Child or children.** 'Child' or 'children' means a person who has not attained the age of 18 years."*

The rules of statutory construction provide that this definition be used unless it is inconsistent with the plain meaning of the Toxic Chemicals in Children's Products statute or in the context in which the term is used in that statute. The Department concludes that this definition is consistent with legislative intent and the purposes of the proposed rule's enabling legislation.

1(F) Children's product and 1(I) consumer product

45. Comment: The commenter suggests that the definition of children's product is really broad and expands the definition of child beyond anything that's been done in terms of chemicals in children's products regulation. The commenter understands that the definition would capture almost any product anywhere and suggests that the Department insert some clarity as to what types of products will be looked at. (29)

46. Comment: The commenter suggests that while it is laudable to be considering first those chemicals most likely to affect children, it must be clear that children whose parents die of cancer or some other disease as a result of exposure to chemicals are not well served. The commenter points out that it is also likely that chemicals to which adults are primarily exposed very often make their way into the lives and bodies of children, citing the example that for years we thought that smoking only affected the smoker, but gradually it became clear that environmental tobacco smoke was also affecting those who never smoked. The commenter urges the Department, in considering these chemicals not to be too constrained by the concept of child exposure. (99)

47. Comment: The commenter suggests that the definition of "children's product" is overly broad, and recommends that the Department adopt the definition from state's Restrictions on Lead-Containing Children's Products, which is "a product that is marketed for use by a child or the use of which by a child is foreseeable." (103)

48. Comment: The commenter recommends that the Department narrow the definition of "consumer product" to true consumer products, by eliminating commercial, medical, industrial and other such equipment or products where there is essentially no risk to sensitive populations. (103)

49. Comment: the commenter agrees with the proposed definition of children's product. The commenter references biomonitoring studies that have identified hundreds of industrial chemicals, pollutants and pesticides in umbilical cord blood from American babies. The commenter cites tests that found levels of PBDEs to be roughly three times higher in toddlers than their mothers. The commenter points out that children's tendency to put their hands and objects in their mouths subjects them to greater exposure to toxic chemicals used in consumer products like paint, computers, stain-resistant fabrics and upholstered furniture. The commenter contends that these products are truly "children's products. (105)

Response to comments # 45-49: The Legislature defined both "children's product" and "consumer product" in 38 MRSA § 1691(7) and (8) respectively. The Department cannot redefine the terms to substantively expand or narrow the range of products that the Legislature has put into play with these definitions. The department can, however, take into account information on likelihood of children's exposure when determining what information to seek on the use of priority chemicals and when assessing whether safer alternatives should be substituted in a product that uses a priority chemical. (See also response to comments # 40-44). No change to the rule.

De minimis

50. Comment: The commenter recommends that the Department add a definition of "*de minimis*" and suggests the following language: "'*De minimis*' means the concentration of the chemical is less than 0.1% by weight in the children's product." (2)

51. Comment: The commenters recommend that the Department establish a *de minimis* threshold (of, for example, 0.1% by weight in a children's product) for evaluating any priority chemical. (1, 2, 3, 7, 10, 12, 87, 103, 104, 119)

Response to comments # 50-51: At this point, the Department does not see a compelling need to establish—and therefore is not proposing—an across-the-board de minimis *level for disclosure of information on the use of priority chemicals. In the case of some chemicals, even very low levels may pose a hazard. Moreover, the listing of priority chemicals is an exercise in information gathering; limiting applicability to chemicals present above a* de minimis *level could inhibit the ability of the Department to build an accurate usage profile for the chemical.*

However, the Department may wish to consider establishing de minimis *levels for individual chemicals, products or uses on a case-by-case basis at the time the chemical is proposed for designation by rule as a priority chemical. To that effect, the Department has incorporated the following language in the NOTE at the end of Section 2 of the proposed rule:*

"NOTE: This rule seeks to minimize the burden of disclosure on product manufacturers and distributors by: i) requiring the board to state with specificity the information it seeks from manufacturers and distributors; and ii) authorizing the board in section 3(C) below to waive the submission of chemical use information that otherwise would be required under the law [see 38 MRS §1695(1)] if the board determines that the information is not needed. The board 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.."

1(L) Green Screen

52. Comment: The commenter appreciates and in some case uses the Green Screen assessment tool, but feels the Department should not mandate or provide preference to specific alternative assessment/screening tools (103)

Response: The proposed rule references Green Screen merely as one example of a human health and environmental hazard evaluation methodology. The department welcomes suggestions of other methodologies that may serve the purpose as well or better than Green Screen. (See also response to comments # 104-106). No change to the rule.

1(M) Intentionally-added [also 2(A)(3); 3; and 4(A)]

53. Comment: The commenter appreciates the intent of using "intentionally-added" as a filter for minute quantities, but points out that the EU discovered when implementing the RoHS directive, "intent" is very difficult to determine and nearly impossible to enforce. The commenter contends that because of this reason, the EU eliminated "intentionally-added" as a factor in the Directive and set a numerical *de minimis* value. The commenter recommends that to maintain consistency with existing regulations that the Department should establish a *de minimis* threshold. The commenter suggests the OSHA Hazard Communication Standards (29 CFR 1910.1200(g)(2)(i)(C)(1) or a threshold of 0.1% by weight of the children's product, which is consistent with the substances in articles requirements in EU's REACH Regulation. (103)

54. Comment: The commenter objects to the use of "intentionally-added" as a criterion for listing a priority chemical. Instead, the commenter recommends that the proposed rule apply to any chemicals in products, since a chemical's ability to contaminate a child's body does not depend on whether or not the compound is intentionally-added to a product. (105)

Response to comments # 53-54: The Department interprets the statutory language to mean that the Legislature did not intend for the law to apply to products containing a chemical that is present as an impurity from the production process. Accordingly, in response to stakeholder concerns about the inadvertent capture of such products, the rule explicitly limits the reach of the law to products containing priority chemicals that were intentionally-added for a specific purpose during product formulation or manufacture.

The term "intentionally-added" is defined under section 1 of the proposed rule and used in the lead paragraph to section 3 (disclosure) and section 4(A) (product bans). This clarification is consistent with Legislative intent as evidenced by 38 MRSA §1692 (declaring the Legislature's intent to confer upon the department the regulatory power to collect information on "chemical use") and §1694 (requiring manufacturers to disclose, among other things, the "intended purpose of the chemical in the children's product.")

The Department understands the commenters' concerns with the concept of "intentionally-added." However, the Department believed that a manufacturer should be able to work backward through its supply chain to find out what chemicals have been added to its raw materials. (See also response to comments #50-51 for a discussion of de minimis)

No change to the rule.

1(O) Manufacturer

55. Comment: The commenter suggests that this definition potentially causes conflict with the definition of "consumer product" since "consumer product" is "any item…including component parts." The commenter points out that the term "final consumer product" is not defined in the document and is not clear who that entity is. The commenter suggests either clearly defining "final consumer product" or establishing clear responsibilities for specific members of a supply chain, since as the term is currently defined there may be multiple entities that meet the definition of "manufacturer" for a single "product" (as defined in the regulations). (103)

Response: The Department does not read the definitions to be in conflict. In reading the definition of "manufacturer" together with "consumer product" it is clear that a "final consumer product" refers to any item sold separately. For example, if the item sold has multiple components, it is the manufacturer who assembled the components into a single item, and not the component manufacturers, to whom the requirements of the rule apply. The component manufacturers would be subject to the disclosure requirement only if the component part is sold separately and contains the priority chemical.

At the time of designating a priority chemical the Department will clearly specify, in the rule, exactly what information must be reported and by whom in order to forestall any confusion on this point.

No change.

Reliable studies

56. The commenter recommends that the Department add a definition of "reliable studies" and offers the following language: "'Reliable studies' means studies or data generated according to valid accepted testing guidelines in which the test parameters documented are based on a specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship ('QSAR') approaches validated in keeping with OECD principles of validation for regulatory purposes, may be considered. Those studies or data which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable may also be considered reliable studies. The methodology used by the Organization for Economic Cooperation and Development (OECD) in their *Manual for Investigation of HPV Chemicals* (OECD Secretariat, July 2007) will be acceptable for the determination of reliable studies as well as methods used in the U.S. EPA's High Production Volume Challenge Program." (2)

Response: The suggested definition is relevant only to commenter-proposed definitions of "authoritative government entity" and "chemical of high concern," neither of which the Department accepted. (See also response to comments # 37 and 39). No change to the rule.

Structurally-related substances

57. Comment: The commenter recommends that the Department add a definition for "structurally-related substances and suggests the following language: "'Structurally-related substances' means substances for which experimental data are available for two or more members of a group of substances that allow for a trend analysis. This analysis can be used to interpolate or extrapolate to other members of the group for which comparable information is not available with a reasonable level of confidence for necessary endpoints. Necessary endpoints include: physicochemical properties, environmental fate attributes, and/or specific effects on human health or an environmental species." (2)

Response: The commenter's proposed definition substantially expands the definition of "structurally-related chemicals," with no reference to government publications that include such an expansion or how to interpret the proposed endpoints with respect to "similarity." Such an expansion is unwarranted, and would require substantial documentation to consider chemicals as being structurally similar. Reliance on chemical structure is adequate. No change to the rule.

Trade secret

58. Comment: The commenter recommends that the Department add a definition for "trade secret" and offers the following language: "'Trade secret' as defined in MRSA, Title 10, Ch. 302 §1542(4) means information, including, but not limited to, a formula, pattern, compilation, program, device, method, technique or process, that:
    A. Derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and
    B. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." (2)

Response: The commenter proposes the definition of "trade secret" in reference to the term's use in the commenter's proposed "Section 7. Confidential Business Information" which the department did not accept (see also response to comments # 107-112). No change to the rule.

Weight-of-evidence approach

59. Comment: The commenter recommends that the Department include a definition for "weight-of-evidence approach" and suggests the following language: "'Weight-of-evidence approach' means a transparent, criteria-based, methodological evaluation to review and interpret all available and relevant scientific research for a given issue." (2)

Response: The addition of this term is relevant to the commenter's proposed definition of "authoritative governmental entity or body," proposed replacement of Section 2, and proposed new Section 4, all of which were rejected after consideration (see response to comments #37, 70 and 83). Further, many of chemicals are on the source lists used in developing the CHC list because a weight-of-evidence analysis was done by the listing body. (See also response to comments #19-25.) No change to the rule.

SECTION 2. DESIGNATION OF PRIORITY CHEMICALS

2(B) Prerequisites of Designation

60. Comment: The commenter recommends several additional criteria for listing priority chemicals. Specifically, the commenter recommends that the Department: use information

from US EPA's Inventory Update Rule (IUR) to screen for chemicals actually made or imported into the US and used in consumer products in the US; consider a chemical's use pattern; establish a *de minimis* or threshold concentration in products; use a weight-of-evidence approach in designating priority chemicals; and set standards for the scientific stature of information sources used in listing priority chemicals (such as the OECD standards for testing protocol) and standards for judging the reliability, relevance and adequacy of studies. (7, 119)

61. Comment: The commenter recommends that the Department match up the Chemicals of High Concern list consumer/commercial use submitted pursuant to US EPA's Inventory Update Rule data focusing on those product uses intended for children to provide an initial screen and a more realistic starting point for candidate priority chemicals that are of greatest concern. (10)

62. Comment: The commenter recommends that the Board address and resolve the issue of whether actual exposure or harm should be demonstrated before a chemical is designated as a priority chemical. The commenter suggested that the DEP's interpretation that the statute requires no such demonstration would lead to unnecessary consumer fears and marketplace confusion if chemicals are listed as priorities without being shown to pose actual risks and could result in the substitution with a chemical that may not have lower exposure or less risk than the priority chemical. The commenter points out that if the statute does not require a demonstration of exposure, it does not prohibit the board from taking exposure and harm into consideration when designating a priority chemical. (16)

63. Comment: The commenter expresses concern with the criteria for designation of a priority chemical in Section 2(B) based on presence in human tissue or the environment, or volume of production, rather than levels of exposure. The commenter recommends that the Department consider hazard and exposure based criteria that include values for hazard characteristics and exposure scenarios and add these considerations in a new subsection 2(B)(3). (16)

64. Comment: The commenter suggests that the criteria in subsection 2(B) are so broad that almost every chemical listed as a Chemical of High Concern is likely to meet one or more of the criteria, specifically (c) and (d). The commenter points out that it is possible to find trace chemicals at the parts per trillion level, this meeting the "present" requirement in criterion (c). (103)

65. Comment: The commenter asserts that using "present" as a qualifier in criterion (d) is so vague as to capture a large number of chemicals that may only be present in trace amounts. The commenter suggests that the broad nature of subsection 2(B) renders subsection 2(C) Scope of Review useless as it will not serve to narrow down the list in any appreciable measure. (103)

66. Comment: The commenter strongly supports the proposal that chemicals found to be present in human blood or the indoor environment [section (2)(B)(2)(a) and (b) of the proposed rule] be eligible for listing as priority chemicals. The commenter points to studies that have detected nearly 500 chemicals in human tissues and contends that based on chemicals detected in umbilical cord blood, even before birth children are exposed to complex mixtures of dangerous substances that may have lifelong consequences, and that similar studies of household dusts suggest that young children have the potential for chronic exposure to these substances. (105)

67. Comment: The commenter suggests that the Department include a more detailed description of the hazard and exposure based criteria in Section 2(B) of the proposed rule, perhaps as a new subsection 2(B)(3). (115)

Response to comments # 60-67: The prerequisites for designation in subsection 2(B) are derived directly from the statute (38 MRSA §1694(1)). The Legislature gave the Department very clear guidance as to what criteria to use in designation of priority chemicals, and did not intend for the Department to undertake costly and complicated risk analysis of all 1700+ Chemicals of High Concern. The premise of the chemical policy framework, as laid out by the Governor's Task Force to Promote Safer Chemicals in Consumer Products and embodied in the statute and proposed rule, is that any amount of certain chemicals in the human body or the ecosystem poses a "level of concern." It is the intent of the chemical policy recommended by the task force to shift away from risk management and toward minimizing hazardous chemicals in consumer products and the environment.

The Department agrees with the observation that all 1700+ chemicals currently on the CHC list are potential candidates for designation as a priority chemical under the proposed rule; that is how the regulatory scheme is intended to work. All of the CHC chemicals are candidates for regulation and should remain so because all are known to have one or more of the hazards that the Maine Legislature decided warranted the attention of policy makers. However, in some cases some chemicals that appear on the CHC list that may not be considered for designation as a priority chemical or considered for a sales prohibition, for example usages of those chemicals that are already regulated by the US FDA as a drug or biologic or the US EPA under the Federal Insecticide Fungicide and Rodenticide Act.

The Department will, however, take exposure into account prior to requiring an alternatives assessment (see response to comment # 98).

See also response to comments # 50-51 for a discussion of de minimis *and the response to comments # 19-25 for a discussion of the CHC list.*

No change to the rule.

Consistency with Existing Regulations

68. Comment: The commenter recommends that the Department promote consistency and consensus with other states and the federal government on testing standards and reporting requirements and develop standards firmly rooted in existing assessments already undertaken by the U.S. Environmental Protection Agency (EPA) and the U.S. Consumer Product Safety Commission (CPSC) that are based on a human health risk assessment model for prioritizing the identification of chemicals of concern. The commenter urges the Department to use exposure and harm to characterize the nature and magnitude of health risks to humans from chemical the use of a chemical in a product and develop an "exposure and harm qualification protocol" that is in compliance with protocols as recommended by the U.S. National Academy of Sciences, to establish a clear threshold that warrants action by the Board to restrict the use of a chemical in a product. (1, 24)

69. Comment: The commenter urges the Department to establish and maintain consistency with similar regulations in other jurisdictions. The commenter provides the example that the electronics industry has been subject to the European Union's Restriction on the use of Hazardous Substances (RoHS) Directive since 2006. The Directive restricts the use of lead,

mercury, cadmium, hexavalent chromium and certain brominated flame retardants in the majority of electrical and electronic equipment sold in the European Union. The commenter contends that most global producers make RoHS compliant products available in all markets, including Maine. The commenter encourages the Department to focus on uses of priority chemicals in specific children's product applications where the exposure of risks to children are the highest and where existing regulatory controls or incentives do not exist. (103)

Response to comments # 68-69: The Department appreciates and agrees with the commenter's desire to avoid duplicate regulations. It is not the intent of this rule to regulate chemicals that are already being adequately addressed at the federal or international level. When selecting chemicals to designate as priority chemicals, the Department will consider existing regulations and voluntary efforts. No change to the rule.

Prioritizing Chemicals

70. Comment: The commenter recommends that the Department delete Section 2 as written and replace it with a new section entitled "Section 2. Prioritizing Chemicals and Designating Priority Chemicals." The commenter provides draft language for this proposed section, which lays out the process for prioritizing chemicals on the Chemicals of High Concern list, stipulating that chemicals that are established to be "highest" priority through this process may be designated as priority chemicals. (2)

71. Comment: The commenter recommends that the Department revise the list of Chemicals of High Concern into high, medium and low priority buckets with respect to the traits/characteristics they exhibit. (10)

72. Comment: The commenter contends that suggestions to set a very high standard for how to prioritize chemicals of the greatest concern, scrutinizing in minute detail what are the specific hazards, what are the exposures, what are the uses, what are the risks was not the intent of the Legislature. The comment suggests that the Legislature was very specific on where the bar was set and what the criteria for identification of priority chemicals are. (17)

73. Comment: The commenter suggests that calls to prioritize chemicals before taking action not only present the Department with a "Catch-22," but also are tactics intended to stall reform. (20)

74. Comment: The commenter recommends that the chemicals on the Chemicals of High Concern list be prioritized into high, medium and low priorities and that chemicals and products already regulated at the Federal level be exempted. (87)

Response to comments # 70-74: 38 MRSA §1694 gives the Department the authority to designate a chemical of high concern as a priority chemical if it meets one of the six stipulated criteria. The application of these criteria does not necessitate ranking the chemicals on the CHC list, nor does statute require the Department to rank chemicals, as suggested by the commenters. The criteria given in the statute for designation of priority chemicals very specifically require only that chemicals be present in human blood, in the natural environment, in a consumer product, etc. A risk analysis is not required.

As stated in subsection 2(A) of the proposed rule, one of the purposes of designating priority chemicals is to facilitate gathering of information on the use of chemicals in consumer products, the extent to which children may be exposed and the safety and availability of alternatives. The disclosure of this information by manufacturers will assist the Department in making an informed

decision regarding the need for and appropriateness of a ban. To require the Department to conduct a risk analysis of every chemical on the CHC list in order to rank them would stand this process on its head, such that the Department would need to have the very information it seeks in order to request it from manufacturers. The lack of complete information should not be a barrier to designation; on the contrary, it may be a compelling factor in favor of designation.

No change to the rule.

Notice and Comment

75. Comment: The commenters recommend that the Board provide an opportunity for stakeholder input or notice and comment prior to confirming a designated chemical as a priority chemical. (87, 119)

Response: The proposed rule already provides such an opportunity. Each designation of a priority chemical (and subsequent ban, if called for) will be carried out through a rulemaking process subject to the requirements of the Maine Administrative Procedures Act (5 MRSA § 8051 et seq). The MAPA requires the board to provide notice of the proposed rulemaking to the regulated community and other interested parties, provides those parties with the opportunity to submit comments, and commits the department to a written explanation of the basis for designation, including a written response to public comments with reasons for adopting or failing to adopt suggested changes. No change to the rule.

Number and Type of Chemicals Listed as Priority

76. Comment: The commenters recommend that the Department not limit its choices to only two Priority Chemicals pointing out that the new law directs that industry be assessed fees to cover costs of managing data, so the state would not incur additional costs for adding to the Priority Chemical list. The commenters suggest that the Department target all the phthalates, PBDEs, PFCs, and BPA, in addition to PVC, formaldehyde, PERC, styrene, toluene, and xylene and at least three toxic metals (arsenic, lead, and mercury). (37, 54)

Response: While the statute [38 MRSA §1694(1)] directs the Department to "designate at least 2 priority chemicals by January 1, 2011," there is nothing to limit the designation to just two compounds. However, in limiting the initial required designation to two, the Legislature recognized that the process of researching these chemicals and rulemaking will most likely be lengthy and time-consuming. While the fees assessed to manufacturers will offset costs of designation, the Department will still be limited in terms of staff numbers and time. However, the Department welcomes suggestions from stakeholders and the public regarding potential candidate chemicals for priority listing. No change to the rule.

77. Comment: The commenter recommends that the Department list mercury in dental amalgam as a priority chemical. (78)

Response: The Applicability Section of the Toxic Chemicals in Children's Products Law [38 MRSA §1697(6)] permits the Department to designate mercury or a mercury compound as a priority chemical for the purpose of adopting rules to prohibit the manufacture, sale or distribution of a mercury-added product that is not regulated under section 1161-C or 1667. Mercury in dental amalgam is regulated under 38 MRSA §1667 and therefore not subject to regulation under the proposed rule. No change.

78. Comment: The commenter recommends that the Department include a petition process to allow citizens to request the listing of new priority chemicals and/or to suggest alternatives to hazardous chemicals in products. (105)

Response: A mechanism for such a petition process already exists under Maine law. The Department's proposed Chapter 880 requires the board to designate priority chemicals by rule in accordance with the Maine Administrative Procedures Act (MAPA). The MAPA, at 5 MRSA §8055, authorizes any person to petition the department for the adoption of any rule. The MAPA further provides that, within 60 days after receipt of a petition, the board must either initiate rulemaking or explain in writing why it chooses not to do so. The department must begin rulemaking proceedings if a petition is signed by 150 or more registered voters. No change.

79. Comment: The commenter recommends that the Department allow listing of entire families of chemicals if evidence suggests that they share toxic properties, especially if these chemical groupings are employed by the US Environmental Protection Agency or other federal agencies. (105)

80. Comment: The commenter suggests that the Department should look at chemical classes when listing priority chemicals and recommends that the Department focus particularly on endocrine disruptors when selecting priority chemicals. (30)

Response to comments # 79-80: There is nothing in the law or rule that precludes the board from designating an entire family or class of chemicals as priority chemicals as long as each member of the family or class, or the class itself (e.g. lead compounds) appears on Maine's Chemicals of High Concern List. No change to the rule.

NOTE (after Section 2(D))

81. Comment: The commenter applauds the Department for adding within the NOTE after Section 2(D) the statement, "The board 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." (16)

Response: The Department acknowledges the commenter's support of this statement. No change to the rule.

SECTION 3. DISCLOSURE OF INFORMATION

82. Comment: The commenter recommends that the Department eliminate Section 3 as proposed and replace it with a new section entitled "Section 3. Identify uses of priority chemicals." The commenter provides suggested language for this alternate section that would require the Department to research available sources on chemical use data to identify uses of that chemical in children's product. The proposed language would allow the Department to request such information from manufacturers only after researching all of the sources of data listed. (2)

Response: The statute, at38 MRSA §1695, sub-§§1 and 2, very clearly requires the manufacturer or distributor of a children's product that contains a priority chemical to disclose certain basic information about the use of the chemical (e.g. the amount of chemical used in the product and why), unless waived by the Commissioner, as well as certain supplemental information if requested by the Commissioner. The Department, in the note at section 2(D) of the proposed

rule, explicitly recognizes that is not likely to need the same type and range of information for each priority chemical and, through the proposed rule, has committed to tailoring its information requests accordingly. The Department will not knowingly ask for information that already is publicly available. Product manufacturers can assist the Department in that regard by identifying sources of available information during rulemaking to designate priority chemicals.

If the Department does request information that is available from another source, a manufacturer is welcome to respond by directing the Department to that source. Section 3(C) allows the commissioner to waive submission of the chemical use information if substantially equivalent information is already publicly available.

No change to the rule.

Prioritizing Uses of Priority Chemicals

83. Comment: The commenter recommends that the Department add another section entitled, "Section 4. Prioritizing uses of priority chemicals." The commenter proposes language for this section which would require the Department to use a weight-of-evidence approach to determine which uses are of low-, medium-, or high-priority for action. (2)

84. Comments: The commenter recommends that product categories be narrowed significantly and be more focused, and that uses of concern should be identified and prioritized. (10)

85. Comment: The commenter recommends that the Department include a step in the proposed rule that would allow the state to prioritize the uses of priority chemicals for which it solicits the information outlined in 3(A) and (B). The commenter points out that while the onus of preparing the information is on the manufacturers, collecting and assessing this information will be a resource-intensive activity for the Department. Narrowing submissions to uses of the priority chemical where there are likely exposures to children and where existing regulations do not already address the substance will help to focus limited resources. The commenter recommends that the Department add criteria to narrow the field of required submissions, specifically, waiving the requirement if the use in the children's product is already sufficiently regulated or if the use in the children's product is in parts that are not accessible to a child or the child is not exposed during use (the commenter references similar exemptions in the Consumer Product Safety Improvement Act of 2008 as an example). (103)

Response to comments #83-85: The proposed rule invites consideration of information bearing on which products are likely to expose children to the priority chemical. Section 2(C) provides:

> "*When determining whether to designate a priority chemical, the board 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 …* ***[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.***" *(emphasis added)*

Manufacturers are welcome to provide information of this type during rulemaking to designate a priority chemical. The Department will consider it both for the purpose of deciding whether proceed with the proposed designation and to inform the manufacturer of the disclosure requirement so that only usages of concern are targeted. However, the Department declines to establish a framework for prioritizing chemical usage. The need for such a framework is not obvious and it could inhibit information gathering and deprive the board of the flexibility it needs

to realize its stated goal of tailoring the information it requests of product manufacturers on a chemical-by-chemical basis.

When designating individual chemicals as priority chemicals, or establishing sales prohibitions, the Department may take into consideration available use information to narrow the scope of any information requested as appropriate. However, listing of a priority chemical is an information-gathering process, and the Department may not have the information needed to narrow the scope until after it has gathered the information.

No change to the rule.

3(B) Supplemental Information and (C) Extension of submission deadline…

86. Comment: The commenter indicates that the information that the department is allowed to seek as supplemental information or additional information under Sections 3(B) &(C) respectively, is unduly burdensome and broad due to the costs of research and information compilation necessary to prepare adequate disclosures as well as the practicality and feasibility of being able to compile all of the information required by these sections. The commenter recommends that the rule be revised so that manufacturers and distributors would only be required to submit supplemental information to the extent that the information is in their possession, or may be easily obtained through public sources. (1)

Response: The supplemental information requirements under subsections 3(B) and (C) of the proposed rule are derived directly from statute at 38 MRSA §1694(2) and (3). The Department will seek supplemental information from product manufacturers only as necessary for one of the purposes listed in section 2(A) of the proposed rule and only if the information is not readily available form other sources. If the Board requests "supplemental information" in the rule designating a priority chemical and later finds that the information is not needed, the Commissioner can waive the requirement to submit it. No change.

87. Comment: The commenter suggests that manufacturers should not necessarily in all instances be required to provide information they don't have access to or cannot easily gain access to in the public domain. (14)

88. Comment: The commenter points out that many "final product" manufacturers will not have all of the supplemental information the Board may ask for in 3(B), particularly information on the extent to which a chemical is present in the environment. The commenter suggests that a particular product manufacturer will likely only have information on how a chemical is used in a given product. (103)

Response to comments #87-88: While a manufacturer may not have all of the information required in their possession at the time of a request, the manufacturer is more likely than the Department to have access to such information through its suppliers or other sources. Section 3(E) is intended to minimize burdens and costs to manufacturers and information overload at the Department by allowing manufacturers to rely on information submitted by trade associations or other manufacturers in order to avoid duplicative submissions. No change to the rule.

89. Comment: The commenter recommends that the Department revise Section 3(B) to incorporate the concepts of dose and exposure levels of concern. The commenter suggests that the Department add the phrase "at levels of concern" at the end of subsections 3(B)(1) and 3(B)(2). (16)

Response: The statute does not require that the exposure exceed a threshold of concern as a prerequisite for designating a priority chemical. If safer alternatives are available at comparable cost, the board can ban the sale of products containing a priority chemical if the use of those products may expose children or vulnerable populations to the chemical. The premise of the chemical policy framework, as laid out by the Governor's Task Force to Promote Safer Chemicals in Consumer Products and embodied in the statute and proposed rule, is that any amount of certain chemicals in the human body or the ecosystem poses a "level of concern." It is the intent of the chemical policy recommended by the task force to shift away from risk management and toward minimizing hazardous chemicals in consumer products and the environment. No change.

3(B)(3) Alternatives Assessment

90. Comment: The commenter suggests that the alternatives assessment follow appropriate methodologies and be adapted on a case-by-case basis for different product categories. (1, 2, 12, 104, 115)

91. Comment: The commenters recommend that the Department has an obligation to reach out directly to a range of consumer product manufacturers to learn more about realistic product development and analysis cycles. The commenter asserts that a one-size-fits-all approach that would apply equally to manufacturers of jet engine components and seasonal holiday decorations is neither reasonable nor workable, again placing the burden on manufacturers to defend their products again and again. (7)

Response to comments 90-91: The main purpose for designating a Priority Chemical is to gather information about that chemical's use, presence in the environment and existing alternatives. The Department believes that it is entirely appropriate under the statute and proposed rule to gather information about alternatives to all uses of a chemical that could result in exposure to children or vulnerable populations.

It should be pointed out that while a manufacturer who uses a priority chemical must submit an alternatives assessment if requested to so, the department's authority to request the assessment is discretionary. Alternatives assessments are not automatically required by operation of the law or rule upon designation of a priority chemical. The Department is unlikely to need or require manufacturer alternatives assessments for every, or even most, uses of a priority chemical.

In many cases, for example, credible alternatives assessments will be available in the public domain or the availability of safer alternatives may be obvious from their presence on store shelves. We also fully expect that trade association will step up and conduct alternative assessments on behalf of their members, making it unnecessary for the department to seek assessments from individual manufacturers. Finally, the rule, in the last paragraph of section 3(F), contemplates that department may, in some cases, be able to work with the regulated community to establish a mechanism for manufacturers to combine their resources to prepare a single assessment.

No change to the rule.

92. Comment: The commenter considers the proposed alternatives assessment process to be cumbersome, burdensome and overwhelming. The commenter contends that it is unrealistic to expect any single manufacturer to have knowledge of all possible global alternatives and

that the rule would open up to legal challenge any analysis that misses a single alternative. (10)

93. Comment: The commenter considers the term "acceptable assessment" to be problematic. The commenter contends that it is not likely that any manufacturer will know all of the "emerging alternatives" mandated under subparagraph (c). Additionally, the commenter points out that much of the information required in this subsection is confidential research and development information. (103)

Response to comments # 92-93: The Department agrees that it would be unrealistic to expect each manufacturer to have knowledge of all possible global alternatives. However, the Department believes that it is completely within reason to expect a manufacturer to know what alternatives that manufacturer considered when formulating a product, and why those alternatives were rejected. No change to the rule.

94. Comment: The commenter points out that a report recently released by The Stockholm Convention (to phase out PBTs), provides guidance on how to do a substitution alternatives assessment that almost is a mirror image of the approach proposed in the rule—collect data on target chemicals, how they are used what products they are in; identify alternatives; evaluate their technological and economic viability and safety. (15)

Response: The Department acknowledges the commenter's support. No change to the rule.

95. Comment: The commenter suggests that an effective and quick way to understand whether an alternative is technically and economically viable is to ask if it is on the marketplace in products doing the same function as the existing toxic chemical. (15)

Response: The Department concurs. No change to the rule.

96. Comment: The commenter objects to the proposed regulation requiring manufacturers to move directly to an alternatives assessment process once a priority chemical is identified. The commenter proposes that a more workable method would include an upfront evaluation step that evaluates the likelihood of harm from priority chemicals used as ingredients in consumer products to screen out low concerns and focus on real threats to health and the environment. (10)

Response: The rule does not require that the department invariably demand alternative assessments for all uses of each priority chemical or from all users. In some cases, there may be adequate information in the public domain on the availability of safer alternatives. In other cases, the Department may ascertain from its own data gathering that all or some of the uses of a priority chemical are not likely to expose children to the chemical. The Department may also choose to arrange for an independent alternatives assessment by contract, or agree to accept an assessment from a trade association on behalf of individual manufacturers.

If the board, in its rule designating a priority, requires manufacturers to submit an alternatives assessment for specified uses of the chemical and it is later determined that the assessment is not needed, the Department has the discretion under section 3(C) to waive the requirement.

No change to the rule.

97. Comment: The commenter recommends that any alternatives analysis include a life cycle analysis that can be used as the basis for comparison of environmental impacts between the alternative and the priority chemical. (10, 119)

Response: The Department submits that a life cycle analysis may, in some cases, be an appropriate tool for comparing the safety of alternatives to a chemical of high concern. The proposed rule does not preclude the consideration of life cycle analyses. Paragraph 4(B)(2) provides that the board, in determining if an alternative is safer, must consider "all relevant evidence to that effect…." Manufacturers or other interested parties are welcome to submit life cycle analyses as part of an alternatives assessment. However, the Department declines to require such an analysis in every case, as it may not be necessary and could prove overly burdensome to manufacturers. No change to the rule.

98. Comment: The commenter recommends that the Department conduct an exposure evaluation before the requirements for alternatives assessment data development and chemical ban. (1, 2, 10, 12, 104, 115, 119)

Comment: The Department agrees that a request for an alternatives assessment for products containing a priority chemical should take place only after first determining that the distribution of those products exposes children or other vulnerable populations to the chemical. The Department has amended section 3(B) as follows to make this prerequisite explicit:

> *"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, a~~A~~n 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."*

99. Comment: The commenter recommends that the Department include additional factors in the assessment of alternatives such as safety, functional performance, product efficacy and cost of alternatives, as laid out in the Intergovernmental Forum on Chemical Safety's discussion of informed substitution. (16)

Response: The statute at 38 MRSA §1695(2)(C) requires the manufacturer of a children's product that contains a priority chemical to provide an alternatives assessment if requesedt by the department. The statute further provides:

> *"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 (emphasis added).*

In section 3(B)(3) of the rule, the board has defined the minimum required elements of "an assessment acceptable to the department." These minimum elements were developed in consultation with Maine CDC and are intended to elicit the information the Department believes will be most useful in assessing the availability of safer alternatives. When providing alternatives assessments, manufacturers are welcome to include additional information, including data bearing on the factors (functional performance, product efficacy and cost of alternatives) mentioned in this comment. However, the Department declines to make these additional factors requirements of an acceptable assessment given the regulatory consequences. Doing so would

mean every manufacturer would have to submit that information, and thus be liable for the cost of an independent assessment if they failed to do so.

No change.

Alternatives Assessment—Timeframe

100. Comment: The commenters recommend that time frames be more flexible. (14, 119)

101. Comment: The commenter objects to the timeframe provided for producing an alternatives assessment and states that companies need years, not months, to complete such a process. (87)

102. Comment: The commenter expresses concern that there is no clear description of what would be considered "timely" for the sake of submitting an assessment. (103).

Response to comments # 100-102: The proposed rule in section 2(D)(4) establishes a minimum period of time the board must allow companies to provide information requested in the rule designating a priority chemical (i.e. no sooner than 180 days after the effective date of the rule). The department can allow more time if appropriate.

Alternatives assessments may not be required in all cases. Depending on the chemical or product indicated, sufficient information on alternatives may already be available, or the department may decide, based on information gathered, that substitution of safe alternatives is not warranted.

In cases where alternative assessments are deemed necessary, they are likely to be requested pursuant to the commissioner's authority to request additional information under section 3(D) of the proposed rule. The Department has amended that section as follows to clarify the commissioner's authority and intent to set a deadline at the time of making a request:

> ***"D. Commissioner authority to request additional 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 to 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."*

While the revised language gives the commissioner a minimum timeframe of 30 days, the commissioner has the authority to tailor the deadline on a chemical-by-chemical or product-by-product basis. Additionally, the proposed rule in section 3(C) recognizes the commissioner's authority to extend submission deadlines if necessary. (See also response to comments # 11-13 in the Basis Statement to Chapter 881).

103. The commenter contends that it is possible that the assessments called for may take several years and cost several thousand dollars, especially for more complex products. The commenter provides the example of EPA's Design for the Environment assessment of flame retardants in circuit boards, which started in 2006 and is projected to be complete in 2010, and was jointly funded by industry and EPA for approximately $75,000. (103)

Response: The Department emphasizes that the elements of an acceptable alternatives, as listed under section 3(B)(3) of the proposed rule do not require original research, but rather seek only information that that should be known to the manufacturer and existing information related to the priority chemical they are using. No change to the rule.

3(B)(3)(e)

104. Comment: The commenters objects to the reference to Green Screen methodology. (2, 7, 10)

105. Comment: The commenter recommends that the Department give further thought to how an alternatives assessment should be conducted, and recommends that the proposed Green Screen methodology be used as a model. (87)

106. Comment: The commenter appreciates and in some case uses the Green Screen assessment tool, but feels the Department should not mandate or provide preference to specific alternative assessment/screening tools and recommends that the Department remove the reference to Green Screen. (103)

Response to comments # 104-106: The proposed rule references Green Screen merely as one example of a human health and environmental hazard evaluation methodology. The department welcomes suggestions of other methodologies that may serve the purpose as well or better than Green Screen. (See also response to comment # 52). No change to the rule.

3(F) Data Protection

107. Comment: The commenter objects to the Department making the information disclosed under Section 3(A) of public record upon submission. The commenter points out that the identification of a chemical in a specific product, sales figures, the amount of a chemical in a product, and the function of a chemical in a product could all arguably be protected as a trade secret, as pending patentable research, or as confidential business information and suggests that without alternative bases on which to seek a waiver, or a mechanism to allow the disclosing party to protect the disclosure as confidential and outside the public record, companies may have to choose between non-compliance in order to protect valuable company information from the public eye, and potentially waiving protection of its intellectual property by disclosure to the public. The commenter concludes that without a process by which manufacturers and distributors can designate all types of information and disclosures required under the rule as confidential, the information gathering process will be impeded by appeals of the DEP's right to require disclosure of confidential information to the public record. Statutory provisions set forth at 38 M.R.S.A. §§ 343-F & 345(A)-4 require the DEP to recognize and respect legal protection afforded to information given to the DEP in accordance with required reports or disclosures. The commenter recommends that the Department establish a process of designation and protection of such information as a necessary part the rule. (1)

108. Comment: The commenter recommends that the Department eliminate this subsection and replace it with a new section entitled "Section 7. Confidential Business Information." The commenter provides suggested language for this new section, which lays out the process for designating and demonstrating that records constitute confidential business information and how the Department should handle these documents. (2)

109. Comment: The commenter expresses approval at the inclusion of Section 3(F) Data Protection in the proposed rule; however the commenter recommends that the information

required for submittal under 3(A), particularly amount and function of a priority chemical, should be protected as confidential business information. (16)

110. Comment: The commenters contend that the proposed rule provides appropriate protections for confidential information and preserves the collection and disclosure of information on the use of Priority Chemicals in consumer products. (50-52, 61-71, 73-77, 79-82, 106-108)

111. Comment: The commenter recommends that confidential business information be protected through a presumption of confidentiality for information submitted by companies. (1, 2, 10, 12, 104, 115)

112. Comment: The commenter recommends that the Department place strict limits on companies' ability to assert confidentiality claims in order to withhold information about the identity or potential health effects of listed chemicals. The commenter asserts that industry routinely uses claims of "Confidential Business Information" to place a cloak of secrecy over vital information about thousands of chemicals. (105)

Response to comments # 107-112: The proposed rule, under section 3(F), provides for the handling of information to be claimed confidential in accordance with 38 MRSA §1310-B. Under section 1310-B, any records clearly marked as 'claimed confidential' by the submitting party will be segregated. If the department receives a request for that information, the department will notify the submitter, who will then have 15 days to demonstrate that the information should not be disclosed because it is a trade secret or production, commercial or financial information, the disclosure of which would impair the competitive position of the submitter and would make available information not otherwise publicly available. This same law governs the handling of confidentiality claims by persons submitting information under the State's mercury-added products and electronic waste laws. No change to the rule.

SECTION 4. AUTHORITY TO BAN THE SALE OF PRODUCTS CONTAINING A PRIORITY CHEMICAL

113. Comment: The commenter recommends that the Department delete the language in Section 4(A) and (C) and replace it with a new section, entitled "Section 6. Authority to ban the sale of products containing an intentionally-added priority chemical." The commenter provides suggested language which defines the conditions that would need to be met for a ban to take place. (2)

Response: The Department derived the language in 4(A) directly from 38 MRSA §1696(1). The commenter's proposed language rests on an expanded alternatives assessment proposed by the commenter (see response to comment # 121) and expands the preconditions of a ban beyond what is prescribed by the Legislature. No change.

114. Comment: The commenter recommends that chemical use bans be evaluated for the potential for harm of a priority chemical ingredient and a potential alternative. (1, 2, 10, 12, 104, 115)

Response: Under the proposed rule, the board cannot adopt a rule banning the sale of products containing a priority chemical unless it first finds that one or more safer alternatives are available. Such "potential for harm" is evaluated under section 4(B)(2). No change.

115. Comment: The commenter contends that it was not the Legislature's intent to automatically ban all uses of a priority chemical. The commenter suggests that a range of actions, including no action, would be more appropriate in most cases. The commenter recommends that the Department calibrate its response actions with the level and likelihood of harm in a particular chemical use. (10)

Response: The Department concurs with the commenter and submits that it is also not the intent of the Department to ban all uses of a priority chemical. Through the gathering of information under Section 3, the Department may conclude that certain uses of the priority chemical do not fall within the parameters of the statute or are otherwise deemed to be not hazards. No change to the rule.

116. Comment: The commenter suggests that regulatory responses should be directed by Board decision, with opportunity for public comment and due process. (10)

Response: Each listing of a priority chemical (and subsequent ban, if called for) will be carried out through a rulemaking process subject to the requirements of the Maine Administrative Procedures Act (5 MRSA § 8051 et seq.), which includes public notice of rulemaking proposal in all of the major newspapers in the state, a public hearing and comment period, and adoption at a public meeting of the Board of Environmental Protection. Further, rules banning the sale of product are categorized as "major substantive," meaning the Legislature must enact a bill approving the rule prior to final adoption by the board [see 38 MRSA §1696(1) and 5 MRSA §8071]. No change to the rule.

4(A)(1)

117. Comment: The commenter recommends that the Department add the phrase "at levels of concern" at the end of this statement. (16)

Response: The premise of the chemical policy framework, as laid out by the Governor's Task Force to Promote Safer Chemicals in Consumer Products and embodied in the statute and proposed rule, is that any amount of certain chemicals in the human body or the ecosystem poses a "level of concern." It is the intent of the chemical policy recommended by the task force and embodied in the statute and proposed rule to shift away from risk management and toward minimizing hazardous chemicals in consumer products and the environment. No change.

4(A)(2)

118. Comment: The commenter suggests that the proposed definition of "alternative" combined with the concept of "available at comparable cost" in Section 4(A)(2) of the proposed regulation addresses only two concepts: technical feasibility and cost. The commenter points out that many more factors are involved if Maine hopes to achieve informed substitution that protects children's health. The commenter lists several factors companies examine when considering a substitution, including implications for safety, functional performance, product efficacy and cost of alternatives. The commenter recommends that the Department review the Intergovernmental Forum on Chemical Safety's discussion of informed substitution. (16)

Response: Cost is not the only consideration when evaluating alternatives under this rule. The Department also must consider the safety of the alternative under section 4(B)(2). Moreover, cost is only one factor considered in determining if a safer alternative is "available" within the meaning of the term; the board also considers the extent to which the alternative is currently

available in the marketplace and the affordability of the product as demonstrated by sales volume.

The Department considers the price a consumer pays for a product to be the best measure of how much it cost the manufacturer to produce it, and therefore a legitimate basis for comparing technically feasible alternatives. The rule does not preclude a manufacturer from submitting information bearing on other factors they consider when making a substitution for a priority chemical. The introductory language to section 4(B) states, "…the board shall consider all relevant evidence…including, but not limited to, alternatives assessments ***submitted by product manufacturers****…" (emphasis added).*

Product manufacturers in developing their alternatives assessments may, at their discretion, examine the factors listed by the commenter and follow the informed substitution guidelines suggested. This type of information is implicitly invited under the proposed rule in section 3(B)(3)(b) as an element of an alternatives assessment. Under that section, the manufacturer is asked to describe the specific chemical and non-chemical alternatives considered in lieu of the priority chemical, and to describe why the priority chemical was selected over the alternatives considered. However, developing this information as suggested by the commenter may not be cost effective in all instances and therefore should not be required by the Department.

No change to the rule.

119. Comment: The commenter expresses concern that the rule limits the Department to restricting use of hazardous chemicals unless the agency has identified a safer and cost-effective alternative. The commenter contends that this provision will encourage manufacturers to defend current, potentially dangerous products while discouraging research and innovation to make these products safer. The commenter recommends that, regardless of known available alternatives, the Department publish on its website a list of priority chemicals and the products that contain them. The commenter contends that such a list will speed the process of developing alternatives and allow parents to avoid the listed products. (105)

Response: The Chemicals of High Concern list is published on the department website. Priority Chemicals must be selected from that list and designated as such in a rule adopted by the Board of Environmental Protection and, once adopted, will be posted on the website of the Secretary of State. Rules banning the sale of products containing a priority chemical will also be posted on the Secretary of State's website. The Department will evaluate the practicality of maintaining a list of products that contain priority chemicals as the program develops. No change to the rule.

4(B) Assessment of Alternatives; scope of review

120. Comment: The commenter points out that listing as a priority or banning one chemical could cause manufacturers to make a substitution with another chemical that could be potentially more harmful than the banned chemical. (1, 3, 87, 119)

Response: The alternatives analysis required in subsection 4(B) of the proposed rule is intended to avoid such an unfortunate outcome. The safety criteria in subsection 4(B)(2) should identify whether actually safer alternatives exist and provide manufacturers with guidance to help them avoid less desirable alternatives. No change.

121. Comment: The commenter recommends that the Department delete this subsection and replace it with a new section, entitled "Section 5. Alternatives Assessment." The commenter provides suggested language that delineates the process the Department would follow to identify potential alternatives to a priority chemical and criteria used to conduct that assessment. (2)

122. Comment: The commenter contends that successful alternatives must: provide an improved profile for health and environmental issues; be technologically feasible and commercially available in sufficient quantity; deliver the same or better value in cost and performance; be accepted by the consumer; account for economic and social considerations and have potential to result in lasting change, avoiding the potential for unintended consequences. (2, 10)

123. Comment: The commenter recommends that alternative assessments be submitted to the Department and be give the opportunity for more elaborate, open and iterative stakeholder comments, including appropriate CBI provisions to protect trade secrets. (10)

124. Comment: The commenter contends that there is not enough information as to what constitutes an acceptable assessment for the sake of potential ban. (103)

Response to comments # 121-124: The Department appreciates the commenters' suggestions and Commenter #2's detailed description for how a request for alternatives assessments could be carried out. The elements of such an assessment are covered in a more general way in paragraph 3(B)(3) of the proposed rule, under Supplemental Information and the recommendations suggested by the commenters could readily be carried out under the provisions of subsection 3(D). While the Department will keep the commenter's suggestion in mind when developing future requests for alternative assessment information, it also sees the value in keeping the language in the rule more general, to allow for flexibility when requesting information on alternatives, depending on the nature and use of individual chemicals. No change.

4(B)(1) Availability

125. Comment: The commenter points out that Section 4(B)(1) considers only the economic impact on the end consumer without consideration of the costs of and burdens imposed on manufacturers and distributors. The commenter suggests that not taking these costs into consideration could lead to unintended consequences, such as the removal of certain children's products from the stream of commerce in Maine, and businesses being forced to stop production and lay off employees. The commenter recommends that the impact of potential increased cost, as well as burdens of retooling and redesign to manufacturers and distributors, should be considered by the Board throughout this process, to ensure that safe products of all kinds are available to the children of Maine. (1)

126. Comment: The commenters take issue with the statement after 4(B)(1)(d) that states that "redesign, retooling or other costs" incurred in replacing a chemical may not be considered by the Board. The commenters contend that these costs, especially for more complex products, represent the vast majority of the costs necessary to substitute a chemical whereas the actual price of the chemical is a minor concern and recommend that the paragraph be removed from the regulation. (10, 103)

Response to comments # 125-126: While the rule states that the Board is not obligated to consider the costs of redesign and retooling, it does not preclude the Board from doing so.

Presumably, costs incurred by the manufacturer to switch to an alternative will be passed on to consumers and therefore be reflected in the purchase price differential. The "burdens" of redesign and retooling will be addressed when considering the "ease with which the alternative could be substituted for the priority chemical" as stated in subparagraph 4(B)(1)(d). While it would be unfortunate to remove certain products from the stream of commerce in Maine, the intent of the rule is to reduce children's exposure to hazardous chemicals; if an alternative product is available without the priority chemical, or if the product containing the priority chemical is a novelty, then the Department is obligated by statute to exercise caution and eliminate the potential exposure. No change to the rule.

127. Comment: The commenter recommends that this section address issues other than affordability, purchase price differential, and ease of substitution in determining whether an alternative is available. The commenter suggests that the Department incorporate factors about product efficacy and affordability at a minimum. Additionally, the commenter expresses concern that mere availability of an alternative does not address the potential health, environmental, social and economic risks that use of the alternative might cause, nor how those risks compare to the priority chemical. (16)

Response: The proposed rule provides for consideration of each of the issues raised in the comment. Product efficacy is addressed in paragraph 3(B)(3), authorizing the commissioner to consider the performance of an alternative. Affordability is addressed in subparagraphs 4(B)1)(b) and (c). Paragraph 4(B)(2) addresses potential health and environmental risks of potential alternatives. No change to the rule.

4(B)(2) Safety

128. Comment: The commenter suggests that this section appropriately address the concept of safety to include the notion of "potential for harm." The commenter considers this concept to imply both inherent toxicity at certain doses and exposure at levels of concern, and suggests that the Department state these concepts more explicitly in this subsection. (16)

Response: The basis for the development of this rule and the statute that directed its creation is a movement away from a chemical policy framework based on risk analysis and management to a new framework focused on reducing hazards. Underlying this new policy approach is an assumption that the presence of harmful chemicals in products to which consumers (especially susceptible populations such as children and fetuses) are exposed poses a "potential for harm." No change to the rule.

129. Comment: The commenter contends that many considerations besides simple toxicity and exposure must be considered, such as product performance (for example, the strength of a child safety device). (103)

Response: The intent of this rule is to address chemical exposures to children. Other safety considerations (such as the commenter's example of a child safety device) are addressed by other agencies and regulations (for example the Consumer Products Safety Commission). It goes without saying that products using alternative chemicals must meet the same state and federal safety requirements outside the bounds of this rule that the product with the priority chemical had to meet. No change.

4(B)(3) Presumptions

130. Comment: The commenter expresses concern with the presumptions made in Section 4(B)(3). The commenter states that alternatives should be subject to the same level of

scrutiny that priority chemicals are being judged by under the proposed regulation. The commenter recommends that studies be done to ensure that an alternative is not a CMR, PBT, VPVB, present at levels of concern, etc. (16)

131. Comment: The commenter objects to the presumptions of safety. (10)

Response to comments # 130-131: Response: The presumptions are limited in scope and will not be pertinent in all cases. Where they do not apply, the proposed rule requires a full assessment of safety of alternatives [see section 4(B)(2) of the rule] as recommended in these comments. Where the presumptions do apply, they reduce the burden on the board to show safer alternatives are available. The burden is shifted to makers of the priority chemical and the products targeted by the proposed ban, to show that, contrary to the presumptions, safer alternatives are not available. If the board, in a proposed rule to ban the sale of a children's product, invokes a presumption in support of the ban, any person who has evidence contrary to the presumption can submit that evidence to the board during the rulemaking comment period. No change to the rule.

Product Liability

132. Comment: The commenter recommends that the Department add another subsection to this section concerning product liability. The commenter suggests the following language: "Liability for alternatives. Upon the commissioner prohibiting the manufacture, sale or distribution of one or more children's product containing a priority chemical, the manufacturer of a children's product shall not be responsible for the environmental or human health impact of the alternative to the prohibited priority chemical." (2)

Response: Manufacturers are responsible for ensuring that any alternative chemical that replaces a priority chemical is safe for humans and the environment. The alternatives assessment in section 4(B) is intended to avoid the most obvious of unintended results from a chemical substitution. However, it is not inconceivable that safety concerns arise at a later date about a product that appears to be a promising candidate in an alternatives assessment. Even if the Department had the authority (which it does not) to exempt manufacturers from liability when replacing a priority chemical, such an action would be inadvisable, as it would discourage manufacturers from continuing to research the relative safety of components used in children's products. No change to the rule.