

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, at 38 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 from 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, an assessment of the availability, cost, feasibility and performance, including potential for harm to human health and the environment, of alternatives to the priority chemical and the reason the priority chemical is used in the manufacture of the children's product in lieu of identified alternatives."

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 requested 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.