Supplemental Basis Statement
Chapter 880
Regulation of Chemical Use in Children's Products

List of Commenters

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COMMENTS

Section 1. Definitions

1. Comment: The commenter supports the rule as amended. (1)

   Response: No change to the rule.

2. Comment: The commenter supports an added provision on exposure. (6)

   Response: The Department is proposing these routine technical rules as necessary to implement PL 2011, ch 319. The legislature considered the issue of exposure, which resulted in the rule as proposed. No change to the rule.

3. Comment: The commenter supports the consistency between state and federal regulations in defining "children's product" as a product specifically made for or marketed for a child 12 years of age or younger. (5)(6)

   Response: No change to the rule.

4. Comment: The commenter supports the clarification of de minimis level as applying science-based knowledge to the determination of concentration level. A detectable level does not equal a concentration harmful to humans. (5)(6)

   Response: No change to the rule.

5. Comment: The commenter states that the proposed de minimis threshold for reporting is unnecessary and inappropriate, as it results in a varying disclosure threshold for every compound on the Chemicals of High Concern list. The commenter states that this variable threshold, "…has nothing to do with the purposes of interest to the Department or the citizens of Maine." The commenter believes a default de minimis of 1,000 parts per million should be adopted. (7)

   Response: In 2011, an early version of LD 1129 included a proposed de minimis of 1,000ppm. This statutory language was replaced by the current de minimis definition, and the threshold for contaminants of 100ppm, as agreed upon by the active stakeholders. In June 2011, LD 1129 was voted on and passed by the Maine Legislature to become PL 2011, ch 319. No change to the rule.

6. Comment: The commenter outlines the federal bench mark for disclosure of hazardous chemicals in consumer products, and specifies that the Federal Hazardous Substances Act mandates consideration of actual risk from exposure to hazardous chemicals, before requiring public disclosure. The commenter emphasizes, that at the federal level, degree of exposure from use of consumer products is critical to determining whether disclosure is necessary. The commenter states, "the proposed rule would entirely do away with the concept of exposure by requiring all intentionally-added components to be disclosed down to the practical quantification limit. It is hard to imagine what benefit consumers in Maine will obtain, presence is not exposure and consumers will not benefit from an arbitrarily variable and vastly over-inclusive threshold." (7)

   Response: The Department is proposing these routine technical rules as necessary to implement PL 2011, ch 319. The legislature considered the issue of exposure, which resulted in the rule as proposed. No change to the rule.

7. Comment: The commenter supports the definition provided in rule of "inaccessible component" as a clarification of applicability of the rule, as frequently an internal component is not accessible and would never come in contact with a child. (5)

   Response: No change to the rule.

8. Comment: The commenter acknowledges the definition of "inaccessible component" does match that of statute and requests that only reasonably foreseeable uses be targeted. Product manufacturers should not and cannot be held accountable for the abuse of their products, commenter requests the Department strike "and abuse" from this definition as manufacturers should only be held responsible for reasonably foreseeable uses of their products, not abuses. (7)

   Response: Because the use of the word "abuse" is presented in statute 38 MRSA § 1697(10), this term will remain in place. No change to the rule.

9. Comment: The commenter supports narrowing the definition of "children's product." A second commenter requests clarification of the definition of "consumer product" to add "within the State of Maine." While the commenter supports the exclusion of pharmaceuticals, food additives, pesticides, and specific packaging already regulated by federal agencies, the commenter describes the definition as needing to clearly demonstrate the scope of regulated children's products sold, or offered for sale, are within the State of Maine. Commenter (7), requests the addition of "within the State of Maine," following Section 1(J)(2). (6)(7)

Response: Maine law regulates activities within State borders exclusively. Therefore, the Department does not consider the language suggested to substantively add meaning or applicability to the law or rule. No change to the rule.

10. Comment: The commenter applauds the inclusion of the definition of contaminant that is consistent with Washington State Children's Safe Products Act (Chapter 173-334 WAC). The commenter requests this consistency with Washington State be preserved. (2)

11. Comment: The commenter expresses concern with the added definition of contaminant, stating the definition conflicts with legislative intent and is not defined in statute. Rather there are references to "contaminant" in statute that clearly spell out the policy implications through "de minimis." In addition, a contaminant can escape regulation if the manufacturer had in place a control program and exercised due diligence to minimize the contaminant. The commenter is concerned that the proposed definition is so broadly defined, that it becomes easy for a manufacturer to avoid being regulated under the statute by declaring a chemical as a contaminant.

    The commenter provides an example of a manufacturer using "back door means" to become exempt from the priority chemical reporting requirement. Comments provided state that, "…according to DEP staff another toy manufacturer who claimed confidentiality initially filed a report on its use of BPA in its toys, then the same manufacturer withdrew its report, claiming that the BPA in its plastic toy was a "contaminant" and therefore the BPA levels fell below the de minimis level for reporting."

    The commenter cites §1691(8-A)(*sic*), "…which states that a priority chemical is *either* intentionally-added *or* a contaminant." The commenter provides this citation to prove the Legislature clearly intended to define "contaminant" to mean a priority chemical in a product or product component that is not intentionally-added. The commenter states that inclusion of a definition of contaminant would produce an outcome that would conflict with the legislative intent to require manufacturers to disclose the presence of all intentionally-added chemicals in children's products. The commenter requests the Department reject the proposed definition of "contaminant" and replace with the following: "**Contaminant means a chemical that is present in a product or product component but is not an intentionally-added chemical."** (4)

Response comment 10-11: The commenter's example of a manufacturer using "back door means" to withdraw a chemical use report is inaccurate. The manufacturer referenced in this example reported a single product as having a priority chemical known to be present as a contaminant. The manufacturer reported the chemical function as "contaminant" upon its initial filing to the Department. After having submitted this particular chemical report, the

manufacturer received chemical analysis with results proving the amount of chemical present was below de minimis, resulting in an appropriate withdrawal of the manufacturer's report. The manufacturer did not, at any time, change the function of the chemical reported, as is claimed by the commenter.

The Department revised the definition of "contaminant," to be consistent with section 1691 (8-B) and has modified amendments to rule chapter 880 to reflect the change.

12. Comment: The commenter requests the hypotheticals published by the Department in its Reporting Guidance document become incorporated into the definition of "contaminant" by reference and supports the definition as proposed. (7)

    Response: The Department provided hypotheticals in published Reporting Guidance as a reference for those in the regulated community to use in the necessary review of applicability. The published rule, implementing PL 2011, ch 319, remains the appropriate regulatory rule. No change to the rule.

13. Comment: The commenter supports the definition of "credible scientific evidence" as a useful step toward a more risk-based decision making process, which employs statistical power and weight-of-the-evidence risk assessment, as proper foundations for chemical management and public health protection. The commenter supports the specificity in rule of credible scientific evidence as it is defined and specified in rule as a determining factor to establish the list of chemicals of concern (originally published as a list of over 1,700 compounds). The commenter states that applying credible scientific evidence will provide predictability for businesses regulated under the law and improve the effort of the underlying statute to protect Maine's vulnerable population. (5)(6)(7)

    Response: No change to the rule.

14. Comment: The commenter supports the proper inclusion of the term "de minimis level" throughout the amended text of the proposed rule. This definition is consistent with the Washington State Children's Safe Products Act (Chapter 173-334 WAC), and as this consistency between states was urged by all stakeholders that agreed to LD 1129, it must be continued in Chapter 880 and the implementation of this program. (2)

    Response: No change to the rule.

Section 2. List of chemicals of concern

15. Comment: The commenter disagrees with the proposed amendments as written in Section 2(B). The proposed amendments to chapter 880 Section 2(B) would add two additional criteria for removal of chemicals from the list of chemicals of concern which contradict statute and legislative intent. The concept of authorizing delisting of chemicals of concern that are "adequately regulated by the federal government" was included in the originally proposed LD 1129 and was unanimously rejected by the Environment and Natural Resources Committee and the Maine Legislature. The statutory authority in this section is apparently meant to refer to the "chemicals of high concern" list, rather than the larger "chemicals of concern list." The proposal compounds the regulatory ambiguity of the proposed definition of "contaminant" by adding the authority to delist a chemical of concern that "occurs in a product…as a contaminant." The commenter requests that sections 2(B)(3) and 2(B)(4) be deleted from the final rule. The commenter adds, "no statutory authority exists to deviate from or add to the criteria by which a chemical may be considered for removal from the list of chemicals of concern under Section 1693." (4)

Response: The final rule is modified to delete §2(B)(3) and §2(B)(4).
38 MRSA § 1693(3) specifically details the process to remove a chemical from the chemicals of concern list by petition. To remain consistent with statute, there will be no change in the use of the title "chemicals of concern list" in section 2(B).

16. Comment: The commenter supports the reasonable provision the rule provides in allowing for the removal of a chemical on the list of concern by either agency action or petition. (5)

Response: No change to the rule.

17. Comment: The commenter supports the language within the removal by petition section as it reflects the reality that scientific consensus can evolve, changes occur in product composition, as well as federal and state agencies, and all can obviate the need for action by the Department. In addition, commenter expresses appreciation for the opportunity for public review and comment of the petition process. The commenter supports the language in section 2(B)(4) recognizing the due diligence by product manufacturers to minimize the presence of a chemical of concern in the final product. (7)

18. Comment: The commenter expresses concerns regarding "loopholes" in the amended rule. Specifically, the commenter is concerned with section 2(B)(3) as the language used was not passed in statute, and section 2(B)(4) stating this language is too broad and does not correspond with final language in statute. (3)

19. Comment: The commenter supports the Department's attempt to incorporate "regulatory efficiency" into its removal by petition section, however, suggests modification of this section. The commenter outlines three primary concerns with this section: first, concurrence from the Maine CDC is required before a petition for chemical removal may be granted, dilutes the Department's discretionary authority; second, the rule only allows for removal of a chemical that is used "solely" in a consumer product regulated by a federal or state agency which would burden the petitioner by needing to know every commercial usage of the chemical, the chemical makeup of every consumer product on the market, and whether a product is already regulated by a state or federal agency; third, commenter points to regulatory efficiency having its own provision in statute yet is shown in the amended rule as part of the petition process. Commenter suggests creating a stand-alone provision within rule to simply exempt chemicals used in consumer products regulated by another state or federal agency. (6)

20. Comment: The commenter supports a clear process and criteria whereby chemicals can be removed from the chemicals of concern and chemicals of high concern lists for "regulatory efficiency" interests and because a chemical is a "contaminant". The commenter suggests that Section 2(B) should be included in Section 3 also, to ensure consistency with the revised law. Commenter supports these as reasonable factors to consider via petition. (2)

Response comments 17-20: To maintain consistency with law, section 2(B) has been amended to remove "regulatory efficiency." 38 MRSA § 1693(3) Removal by Petition does not include this language. Creating a stand-alone provision within rule, as suggested by the comment, would reach beyond statutory authority. Therefore, it will not be added to rule.

Section 3. Identification of chemicals of high concern.

21. Comment: The commenter supports the listing of no more than 70 chemicals of high concern as a means of providing a more predictable process for industry and anticipates this will lead to a better system of addressing specific concerns within the more reduced chemical list. Also stating that the original list of over 1,700 chemicals of concern (from which the first two priority chemical designations were made) consisted of compounds there are commonly found and do not cause harm. (5)

Response: No change to the rule.

22. Comment: The commenter expresses concern that the criteria to identify a Chemical of High Concern relies on the presence of a chemical in human tissue, the home environment, or in consumer products, stating that presence of a chemical does not equate to harm, or

necessarily create an exposure at a level of concern, as is reflected in the Department's treatment of inaccessible components. (7)

Response: The Department is proposing these routine technical rules as necessary to implement PL 2011, ch 319. The legislature considered the issue of exposure, which resulted in the rule as proposed. No change to the rule.

23. Comment: The commenter states that periodic review of the list of chemicals of high concern, every three years, is a beneficial amendment. (7)

Response: No change to the rule.

Section 4. Designation of priority chemicals

24. Comment: The commenter supports the reference to the use of "credible scientific information" through the proposed rule. The commenter urges DEP to also include this concept in the opening of Section 4(B) of the rule to read: "The commissioner board may designate a priority chemical if the commissioner finds there is **strong credible scientific evidence**, in concurrence with the Maine CDC, that:..." (2)

25. Comment: The commenter points to the statutory criteria for designating priority chemicals does not meaningfully restrict its discretion in promoting chemicals from the high concern list, as "all chemicals on the list of the chemicals of high concern are likely to meet the prerequisites for designation as priority chemicals." The commenter requests the Department exercise discretion in its choice of priority chemicals, with an emphasis on the benefit the public will derive from the designation. (7)

Response comment 24-25: The Department acknowledges the commenters concerns and intends to proceed thoughtfully, using the most current credible scientific evidence, peer reviewed study, and risk assessment information available. At this time there is no change to the rule.

26. Comment: The commenter urges the Department to add "credible scientific evidence" to §4(B) prerequisites for designation. Stating, "…data and information used to determine the hazard characteristics of chemicals in children's products and the exposure and use data of chemicals in children's products, should be held to strict scientific standards. Incorporating the statutory and regulatory definition of "credible scientific evidence" in section 4(B) would ensure a more robust level of scientific rigor in the designation process." (7)

Response: The Department acknowledges the commenters concerns. However, the chemical compounds presented as candidates for priority designation have already gone through the rigors of criteria set forth by the legislature, which includes credible scientific evidence. No change to the rule.

27. Comment: The commenter expresses appreciation for the removal of §4(B)(2)(c) and §4(B)(2)(f), stating that these deletions streamline the rule by focusing on the core of the regulation. (7)

Response: No change to the rule.

28. Comment: The commenter requests Section 4(D)(5) be removed from the proposed rule, stating that only the manufacturer will have the knowledge to determine if the presence of a priority chemical is a contaminant or intentionally-added to their product. The commenter requests that language from PL 2011, c. 319 be added to the initial statements of Section 5 regarding what must be disclosed within a report. To ensure consistency with statute and reduce the burden to the Department of trying to estimate if the presence of a chemical exists and the intent with which it became present. (2)

29. Comment: The commenter cites the section language is 4(D) as an increased burden on the DEP as it requires DEP to know more about chemical use than can be reasonably obtained prior to any information disclosure. The commenter requests sections 4(D)(3) and 4(D)(4) be removed. (4)

30. Comment: The commenter requests the removal of Section 4(D)(4) because it appears to require that inaccessible components be subject to a rulemaking decision during the designation of every priority chemical subject to reporting. The commenter points to PL 2011 ch 319 Section 1697(10) which specifically exempted inaccessible components from reporting. Commenter requests amending Section 5 to include the language referenced above so that confusion regarding what must be disclosed within a report may be avoided and consistency maintained. (2)

Response to comments 28-30: Sections 4(D)(3), 4(D)(4), and 4(D)(5) have been removed to remain consistent with statute.

31. Comment: The commenter expresses concern that the structure of sales information requested for reporting does not allow for appropriate sell-through of products before the effective date of a priority chemical designation rule. The current structure of this provision applies the reporting requirement to products that were sold prior to any legal obligation being created under a priority chemical designation and reporting rule. The commenter

urges the Department to reconsider this reporting structure; as it creates great confusion in the market-place and creates a dichotomy between the legal reporting obligation and retroactive sales data-keeping requirements. The commenter points to language in the Washington State Children's Safe Products Act (Chapter 173-334 WAC), which allows 12-months from the effective date of the reporting requirement until the due date for data submission and reporting. Specifically, this method focuses on products, "manufactured for sale in Washington during the twelve-month period that proceeded the applicable due date for first notices." The commenter suggests modifying this section to allow for an effective date reporting to be 12-months from when the designation and reporting rule is adopted; or only stipulate a 180-day data submission requirement. Reporting should occur for products "manufactured for sale" in Maine after the effective date of a reporting rule. The commenter offers the following language:

Section 4(D)(3) "be at least 180 calendar days after the effective date of the rule; **or up to 365 calendar days after the effective date of the rule if necessary to allow collection of sales data."**

Section 5(A)(2) "(2) The **approximate** number of **products manufactured and offered for** sale ~~units sold or distributed for sale~~ in the State or nationally during the **180 calendar days preceding the reporting deadline; or if 365 calendar days is provided for reporting**, the most recent full year (fiscal or calendar year is dependent on filer accounting system) prior to the specified ~~effective date~~ **deadline** of the chemical reporting requirement. (2)

32. Comment: The commenter recommends the Department revise the timeframe during which relevant information must be reported, suggesting the use of a different data metric of six months of sales data or one year of reported sales data. Adding that in the context of children's products it is best to report in terms of sales data timelines. (7)

Response comment 31-32: The Department has determined that 180 days provides sufficient reporting time. No change to the rule.

33. Comment: The commenter suggests that the last sentence of Section 4(A) should be modified to read "The commissioner ~~board~~ may designate any chemical on the list of chemicals of **high** concern as a priority…" to be consistent with statute. This change would avoid the potential of a "chemical of concern" from becoming a "priority chemical" without being designated as a "chemical of high concern" first. The commenter states that continuity of this three-step process is essential. (2)

Response: The Department's omission of the word "high" was inadvertent and has been corrected to read as the commenter recommends.

Regulatory Efficiency

34. Comment: The commenter points to the stringent regulation by state and federal entities of ingredients used in personal care products and over-the-counter (OTC) drugs. Commenter believes these items should be exempt from the scope of the proposed regulation, referencing the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) as the base structure from which Congress intended to "occupy the field" of regulation for this category of product. Additionally, commenter references the Federal Hazardous Substances Act of 1960, Consumer Product Safety Act of 1972, the Toxic Substances Control Act of 1976, the Child Safety Protection Act of 1994, all of which specifically exempt food, drugs, cosmetics and medical devises (including the Toxic Substance Control Act which regulates pesticides). The commenter stresses the Food and Drug Administration (FDA) maintains strict oversight of imported cosmetics and ingredients and monitors domestically produced cosmetic products via the Voluntary Cosmetic Registration Program (VCRP) through which companies report cosmetic ingredients available for commercial distribution in the U.S. Indeed the FDA has the authority to ban an unsafe chemical from use in U.S. and regulates that a cosmetic manufacturer must substantiate the safety of each chemical ingredient in the product and of the product as a whole prior to marketing. (6)

Response: Regulatory efficiency is a new provision, added pursuant to LD 1129 in June, 2011. The Department intends to examine this discretionary authority closely as chemical lists are reviewed and modified. No change to the rule.

5. Disclosure of information on priority chemicals

35. Comment: The commenter notes that disclosure of information regarding product ingredients and chemical formulations could potentially jeopardize a large quantity of confidential business information; making it important for the Department to determine information that is essential while affording protections to the intellectual property of manufacturers. The commenter also expresses concern that the Department is requiring manufacturer's report the amount of the chemical in each unit of the product, as well as the chemical's function in the product. The commenter suggests that there are methods the Department should explore by which manufacturers could provide this type of formulation information in a format that would provide confidentiality. (7)

36. Comment: The commenter finds section 5(A)(2) "particularly troublesome". Citing that the Department may reasonably request "the number of product units sold or distributed for sale in the State," although the Department does not have the authority to require manufacturers to report the number of product units sold or distributed nationally; making the distinction between the regional and national sales data. The commenter argues this request is outside of the scope of the regulation and raises confidential business information (CBI) concerns. (7)

Response 35-36: The Department acknowledges the commenters concerns. It becomes incumbent upon the reporting manufacturer to provide properly documented CBI requests to the Department. All requests for information (submitted to the Department) to remain confidential must reference Maine law and be applicable to 38 MRSA § 1310-B(2).

37. Comment: The commenter supports the addition of "in an amount greater than de minimis" in Section 5. (7)

Response: No change to the rule.