Supplemental Basis Statement
Re-opened 06-096 CMR Chapter 880
Regulation of Chemical Use in Children's Products

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COMMENTS

Section 1. Definitions

1. Comment: The commenter supported the definition of "contaminant" proposed in the amended rule Chapter 880 draft (published by the Department October 7, 2011). At the time of the October, 2011, publication the definition was consistent with the Washington State Children's Safe Products Act (CSPA) (Chapter 173-334 WAC) rule, and it was Washington State's law that provided the basis for amendments made to statute through LD 1129 (recorded as *Public Law 2011, Chapter 319*) which were unanimously approved by the Maine Legislature in June 2011. The commenter contends that legislative intent, and all stakeholders involved, clearly indicated a desire for consistency with Washington State CSPA, as demonstrated by published statements recorded during the Environment and Natural Resource Committee consideration of LD 1129. The re-opened rule draft (published February 6, 2012) removed the definition of "contaminant" that was consistent with Washington State rule and replaced it with vague and unclear language the commenter strongly opposes. The commenter requests the Department restore the definition of "contaminant" published in the October 7, 2011, amended draft rule, or remove the currently published definition entirely, allowing the Legislature to define "contaminant" unencumbered by language used in Department rule. (1)(2)(6)(7)

2. Comment: The commenter applauds the new proposed definition of "contaminant," which flows logically from the statutory changes imposed by LD 1129 in 2011. (3)(4)

   Response comment 1-2: Due to the need for clarity from the Legislature regarding this definition, the Department has removed the definition of contaminant from the rule.

3. Comment: The commenter applauds the proper inclusion of the term "de minimis level" throughout the amended draft text of Chapter 880. This definition is consistent with the Washington State Children's Safe Products Act (Chapter 173-334 WAC) definitions and is critical to implementing Maine's amendments to statute (*PL 2011, Chapter 319*). (2)

   Response: No change to the rule.

4. Comment: The commenter proposes amending the rule to fulfill the statutory intent to protect children's health by re-focusing regulatory attention on priority chemicals that have the greatest potential for significant exposure to children. The focus of Maine's regulatory efforts under this statute needs to target manufacturers' intentional addition of priority chemicals at a level in children's product that could potentially elicit a negative

health response. The commenter asserts the need to establish a *de minimis* threshold in products at the internationally recognized level of 0.1% to focus regulatory efforts on meaningful levels of priority chemicals to which children are exposed and provide certainty to the regulated community for reporting obligations. The commenter suggests that without the *de minimis* threshold for intentionally-added chemicals, manufacturers will need to chase molecules through analytical testing to determine reporting obligations. This regulatory framework will lead to a climate of over-reporting that will blur the cases deserving of further assessment and possible risk management. (5)

5. Comment: The commenter states that the currently written "de minimis", in the draft rule, is inconsistent with international standards that set a default level of 0.1% used in a number of state, federal and global regulations, including the European Union's implementation of the Globally Harmonized System (GHS) for product classification. In addition to applying a default of 0.1% by weight, the EU GHS establishes chemical-specific de minimis that may be lower or higher than 0.1% based on sound science and reliable information. Additionally, the de minimis level set should be the same for all chemicals irrespective of whether they were "intentionally-added" or "contaminants". The commenter proposes the following revisions:

   "De minimis level" means:
   ~~A.~~ For a chemical of high concern or priority chemical ~~that is an intentionally-added chemical to a children's product or component of a children's product, the practical quantification limit; or B. For a chemical of high concern or priority chemical that is a contaminant~~ present in a children's product or component of a children's product, a concentration of ~~100~~ 1000 parts per million. (8)

   Response comments 4-5: The definition of de minimis presented in the draft rule reflects current statutory language. No change to the rule.

6. Comment: The commenter is highly concerned that the scope of the proposed amended rule is overly broad and fails to focus on exposures that present the greatest risk to children's health. Specifically, the commenter points to the inclusion of traditional children's products, which manufacturers intentionally design and market for use by children, and finished products that manufacturers design and market for segments of the consumer population other than children. The commenter asserts that manufacturers go to great lengths to *prevent* use by children of many of the latter category of consumer products, through the utilization of protective packaging features, precautionary labeling and use instructions. However, the proposed amended rule obfuscates the true focus of this "Children's Product" regulation by pulling all consumer products that are distributed for sale in Maine into scope. The broadly written definition of "children's product"

accomplishes this feat by including the phrasing of "…*will likely result in…a fetus being exposed to that chemical.*" By the very nature of this definitional construct, the proposed amended rule could place hundreds of thousands of products on the path for alternative assessment and potential phase-out *regardless of whether the low level exposure presents a meaningful risk to children's health or safety*. (5)

Response: During the 2011 legislative session, the legislature amended statute to redefine both "children's product" and "consumer product" in 38 MRSA § 1691 (7) and (8) respectively. Therefore, the Department cannot substantively expand or narrow the range of products that are considered for inclusion in the required information submission. However, the Department is empowered to take into account information on the likelihood of children's exposure when determining product categories that manufacturers are required to report, and when assessing whether safer alternatives should be substituted in a product that uses a priority chemical. No change to the rule.

7. Comment: The commenter cites the lack of a recognized *de minimis* threshold, failure to limit regulatory efforts to intentionally-added ingredients, and the Practical Quantification Limit (PQL) concept as the trifecta in this proposed amended rule that works with the poorly constructed "children's product" definition, to effectively condemn any consumer product distributed in the state of Maine that happens to contain trace, intentional levels of a priority chemical. The commenter states that mere presence of an intentional priority chemical in a consumer product, or a low-level contaminant present at 100ppm, thrusts a manufacturer into a situation of 1) reporting to the Department; 2) costly and time-consuming alternatives assessment; 3) possible re-formulation and substitution with an alternate chemical that may not be commercially available or function as well as the priority chemical in the complex formula matrix; and 4) likely phase-out of the original formulation containing the priority chemical because of rallied public pressure from the Maine activist community. The commenter suggests an efficient solution to this quandary is to amend the Chapter 880 rule with a weight-of-evidence approach.

   The commenter suggests that in this weight-of-evidence approach to designation would mandate that Maine's regulatory action is focused on chemicals that have the highest known health hazards AND have the most extensive uses AND have the greatest potential for significant exposure to children. Safety assessments and evaluation of alternatives for the highest priority chemicals will result in meaningful and measureable improvements in product safety and achieve the statutory intent of protecting children's health. (5)

Response: The Department has employed the weight-of-evidence approach in its determination of the list of chemicals of high concern, from which a priority chemical is designated. In addition, many of the chemicals on the source lists consulted in developing Maine's chemicals of high concern (CHC) list originally appear on source lists based on a weight-of-evidence analysis conducted by the listing authority. Maine law does not speak to the need to independently analyze the hazard traits of candidate chemicals, through a weight-of-evidence approach or otherwise, by drawing on the analyses already performed by other authoritative governmental entities. Any chemical that is a candidate for priority designation will undergo further evaluation by the Department. It should be noted that the presence of a chemical on the CHC list does not have regulatory consequences. The Department only has regulatory authority through formal designation as a priority. Law requires that the Department designate a priority chemical by rule, providing opportunity for concerned parties to comment on the appropriateness of this action. No change to the rule.

8. Comment: The commenter cites increasingly sophisticated analytical techniques and sensitivities that are capable of detecting trace levels of chemicals in consumer products to extremely low levels as a source of confusion for the regulated community attempting to be compliant with Maine's practical quantification limit (PQL) requirement. Presence of a priority chemical in a consumer product at parts per billion (ppb) or parts per trillion (ppt) levels is often below normal background, environmental levels, and does nothing to jeopardize the safety of the finished product to children. The commenter points out that manufacturers may analyze priority chemicals in products at different sensitivities, leading to uneven reporting obligations. The PQL creates extensive data auditing and reporting requirements for a manufacturer, followed by massive alternatives assessment requirements, without any correlation to a positive benefit to children's health. The PQL creates the perfect environment for the activist community to challenge the consumer product industry for presence of extremely trace and insignificant levels of priority chemicals that may serve an intentional purpose, but are present via complex sub-mixtures within the finished formulation. The commenter points to PQL language offered in the draft rule as an easy tool with which to stoke the flames of public concern without appropriate risk context and to burden already stretched resources within the regulated community and at the Department with limitless reporting. The commenter argues that the PQL creates confusion and distraction from the real cases of significant exposures to children of harmful chemicals that warrant regulatory action to deliver a health benefit. (5)

Response: Department rule is guided by law, the language of PQL must remain consistent with 38 MRSA, § 1691(10-A). No change to the rule.

9. Comment: The commenter requests the Department clarify the universe of consumer products that are impacted by this regulation versus those products that are exempted from regulatory consideration. The definition of consumer products in the proposed draft rule includes an exemption for, "…paper or forest products or a pesticide regulated by the United States Environmental Protection Agency…" leaving its meaning unclear. Specifically, the commenter points to the "paper or forest product" language as particularly ambiguous. If this exemption extends to all consumer products made from paper or forest products, then the argument can be made that all consumer products formed from cellulosic materials may be considered eligible for this exemption. Many consumer products made from cellulosic materials are eligible for this exemption, these same products also contain inks, additives and non-cellulosic components that raise the question of whether such products fit the "paper" exemption. The commenter states that it is very likely that the consumer product industry has a broader interpretation of "paper" than the proposed amendment authors envision with this exemption. Additional clarity is needed in this section to guide the regulated community in an accurate interpretation of compliance responsibility. Additionally, the commenter states that the exemption paragraph for "consumer product" fails to address medical devices and over-the-counter drugs regulated federally by the Food and Drug Administration. The definition of "children's product" specifically includes personal care products (i.e. cosmetics), which are also under the federal jurisdiction of FDA. However, the proposed amendments are silent throughout the regulation on the appropriate classification of medical devices and over-the-counter drugs in the context of compliance obligations. The commenter asks that the final regulation resolve this ambiguity and specifically address the appropriate context for these FDA consumer products. (5)

Response: The products cited are products otherwise regulated. Public Law 2011, Chapter 316, provides the Department with the authority to effectively address the commenters concerns about duplicated regulatory requirements, which may cause an excessive burden on manufacturers required to submit information to the Department under the rule, by outlining the Department's discretionary authority to consider whether a chemical is adequately regulated by the Federal Government or agency of the state. No change to the rule.

10. Comment: The commenter suggests that the definition of credible scientific evidence, as currently written, does not address quality, reliability, adequacy, and relevance to human health. "Credible" peer-reviewed scientific literature ought to be clearly defined and

include some notion of reliability – a more appropriate definition for "credible scientific evidence" would be:

"The results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are reliable, adequate, and relevant to human health and the environment that have been published in a peer-reviewed journal or in a publication of an authoritative federal or international governmental agency…" (8)

Response: The definition of "credible scientific evidence" reflects current law. No change to the rule.

Section 2. List of chemicals of concern

11. 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 if they are exempted under applicable statute Section 1697. The commenter continues to believe that the entirety of the proposed Chapter 880, Section 2(B) should be included in Section 3 to ensure consistency with the revised law. The commenter recommends inserting the same petition process currently proposed in Chapter 880, Section 2(B) in Section 3, as a new subsection "E". (2)

12. Comment: The commenter requests the Department reinsert parts (3) and (4) of Section 2(B), "Removal by petition," as it existed in the draft rule published in October 2011. Specifically, the commenter points to the underlying statutory authority providing for a petition process to remove a chemical from the List of Chemicals of Concern, and states that it is unclear why the Department chose to delete two criteria previously afforded to manufacturers to remove a chemical from the list by petition. The Department's proposed revisions reduce the opportunities to utilize the petition process, which only serves to weaken the integrity of the petition process. Appropriate provisions for addition and removal from lists of concern reflect the reality that scientific information may develop in support of the safety of a chemical, and that changes in the product composition and the regulatory decisions of federal and state agencies can obviate the need for action by the Department under this rule. Where the sections formerly published as Sections 2(B)(3) and 2(B)(4) have been removed the commenter suggests reinstating these sections as previously written. (7)

Response comments 11-12: Statute provides interested parties the process of Removal by Petition specifically for the list of chemicals of concern (38 MRSA § 1693(3)), language not duplicated in the law for either the list of chemicals of high concern or priority chemicals. Department rule must reflect the process detailed in law and avoid a

broadening of scope outside of the current boundaries of law. No change to the rule.

13. Comment: The commenter suggests an "or" be inserted in the list of criteria by which the Department may remove a chemical from the list of chemicals of concern in Section 2(B) of the draft rule. The commenter states that this word insertion would clarify that any of the criteria can be met to justify granting a petition to remove a chemical from the list. Without this addition, the commenter asserts, this section currently reads as if all three criteria must be met, which would be in error. (3)(4)

    Response: To be consistent with Maine law, section 2(B) of the draft rule has been amended to read "…meets one or more of the following criteria."

14. Comment: The commenter requests that Sections 2(A) and 3(B) be revised to reinstate the qualifier word "known" to be CMRs (carcinogenic, mutagenic, reproductive disruptor). (8)

    Response: The law does not require the qualifier "known" to be CMRs in its description of criteria for chemical listing. Rather, the words "identified...as being…"(38 MRSA § 1693(1)), and "…is a…"(38 MRSA § 1693-A(2)) are used to describe the degree of certainty that the chemical must meet. To provide consistency, this language is reflected in rule, therefore, no change to the rule.

Section 3. Identification of chemicals of high concern

15. Commenter: The commenter suggests replacing "authorizes" with "requires" in the first sentence of Section 3 of the proposed draft rule. As currently revised, the draft makes it sounds as if adopting a list of up to 70 candidate priority chemicals is a discretionary duty, which would be an incorrect conclusion but rather, a mandate that must be accomplished by July 1, 2012. (3)(4)

    Response: The Department has amended the rule to reflect the suggested change.

16. Comment: The commenter states that there remains no credible, clearly defined, systematic prioritization process to move a compound from the list of "chemicals of concern" to the list of "chemicals of high concern" and help relatively rank chemical and product use pairs of greater potential concern to identify priority chemicals in priority products, as the mere presence of a chemical in humans, consumer products, or indoor environments does not necessarily equate with any real safety concerns. (8)

Response: Maine statute does not require the Department to rank chemicals, as suggested, nor is a comprehensive risk analysis required in order to promote a chemical from the list of concern to either high concern or priority. In fact, it is due to a lack of available information that the Department seeks disclosure of information by manufacturers on the use of a priority chemical, which will assist the Department in making an informed decision regarding the appropriateness of risk management. The Department intends to proceed with priority designation thoughtfully, taking into consideration the potential for exposure and the spectrum of dose response data available for review when making its determination to require the regulated community to submit information. No change to the rule.

Section 4. Designation of priority chemicals

17. Comment: The commenter requests that the Department reinsert Section 4(D)(3) from the October 7, 2011 draft rule. The deletion of the former Section 4(D)(3) removes the requirement for the Department to articulate the children's products or product categories subject to the disclosure requirement. Manufacturers will experience a greater level of certainty from the Department having clearly articulated what children's products are subject to disclosure, given that a transparent product prioritization methodology is not part of this process as currently written. The former Section 4(D)(3) also provided an indicator to manufacturers of children's products when the Department will communicate this information, "at least 180 calendar days after the effective date of the rule." (7)

    Response: The Department's request for information on the use of a priority chemical is based on a lack of currently available documentation on exposure source. Whereas the Department is unable to predict future priority chemical designations, and the products that priority chemicals may be constituents of, it is consistent with Maine law and appropriate to allow flexibility in rule for future rulemaking to outline product categories for which manufacturers are required to report. During the rulemaking process the public is provided the opportunity to comment, it is at that time that a regulated entity may gain a preview of regulated categories and prepare for compliance. No change to the rule.

18. Comment: The commenter cites sections 1695 and 1696 of MRSA 38 Chapter 16-D as specifically exempting inaccessible components from reporting and action under Maine law. Therefore, the commenter supports the Department removal of the previously published draft rule Section 4(D)(4). (2)

    Response: No change to the rule.

19. Comment: The commenter supports the removal of Section 4(D)(5) from the previous draft rule, stating that the reporting of contaminants is governed by the de minimis level definition, whether the manufacturer had in place a control program, and exercised due diligence to minimize the presence of the contaminant, as is stated in Section 1697(11) in the relative statute. These provisions, combined, give clear direction to a manufacturer to determine if the presence of a priority chemical in their product, as a contaminant, should be reported. (2)(6)(7)

    Response: No change to the rule.

20. Comment: The commenter applauds the inclusion of references to "credible scientific evidence" throughout the rule, and believes that this reference is needed in one other provision. The commenter urges DEP to also include this concept in the opening Section 4(B) of the rule so that it reads: "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)(6)(7)

    Response: The rule will be amended to add "credible scientific evidence" to the opening of Section 4(B) of the draft rule, as suggested.

Section 5. Disclosure of information on priority chemicals

21. Comment: The commenter suggests that language from *PL 2011, Chapter 319 Section 1697(11)* be added to the initial statements of Section 5 of the draft rule. Adding detail regarding what information must be disclosed within a report will reduce the burden on DEP of estimating if a chemical is considered a contaminant and ensure consistent application of the reporting requirement. (2)(6)

    Response: After review, the Department has amended the rule to reflect the suggested modification within Section 5.

22. Comment: The commenter highlights the structure of provisions within the draft rule Chapter 880 which do not allow for appropriate sell-through of the products available to consumers before the effective date of a priority chemical designation; and upon designating a priority chemical, the reporting company has the minimum (180 days) amount of time allowable by law to compile sales data for the most recent calendar year or fiscal year. The commenter states the structure of this provision applies reporting retroactively, prior to any legal obligation having been created under a priority chemical designation and reporting rule. The commenter states that the relative statute does not

stipulate that a full calendar year or fiscal year of sales data must be submitted to the Department with a priority chemical report. In addition, the current rule (chapter 880, Section 5(C)) provides the Commissioner with broad authority to extend or waive data submission requirements. Already having established that the Commissioner has this authority, there similarly is the authority for the Commissioner and DEP to allow additional time for reporting, and reasonably modify the current requirement of a full-year of data with only 180-days notice. The commenter strongly urges the Department to amend the proposed reporting structure; as it creates both great confusion in the market-place and a dichotomy between the legal reporting obligation and retroactive sales data-keeping requirements. Similar reporting required under the Washington State Children's Safe Products Act (Chapter 173-334 WAC), allows 12-months from the effective date of a 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 precedes the applicable due date for first notices." (WAC 173-334-100). The commenter urges the Department to amend Chapter 880 to allow for an effective reporting date to be 12-months from when the designation and reporting rule is adopted, or only to stipulate a 180-day data submission requirement. Additionally, reporting should occur for products "manufactured for sale" in Maine after the effective date of a reporting rule. The commenter suggests the following specific amendments:

Section 4(D)(3)(*sic*) should indicate that the disclosure deadline would "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) should be amended to read:
"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 are provided for reporting, the most recent full year (fiscal or calendar is dependent on filer accounting system) prior to the specified deadline of the chemical requirement."
(2)

23. Comment: The commenter states that the proposed amendments to rule chapter 880 need to resolve the lingering uncertainty encountered during the first experience of priority chemical reporting to the Department in October, 2011. Specifically, the commenter states that rulemakings under the applicable statute are silent on a manufacturer's reporting responsibility for discontinued products which are present in Maine merely as a consequence of inventory sell-through. Because Chapter 880 provides no distinction between currently manufactured products containing a priority chemical and discontinued

products in a sell-through situation, as currently written, reporting is required for both. No alternative assessment or risk management effort is needed in a sell-through situation because the manufacturer has already made these product stewardship decisions. The regulated community will find greater reporting certainty through the addition of a specific provision to Chapter 880 that clarifies the Department's intent for sell-through inventory. (5)

Response comments 22-23: Submission of a priority chemical report for products captured by the reporting rule, and remaining in the market after a modification of the manufacturing process, remains of value to the Department. The purpose of this program is to ensure full disclosure of any priority chemical used in a consumer product available for sale within the state of Maine. No change to the rule.