

Rule Chapter 887
Designation of Arsenic as a Priority Chemical and
Regulation of Arsenic in Children's Products

Supplemental Basis Statement
Response to Comments

List of Commenters

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|---|---|
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Comments

Other State Requirements

1. Comment: Commenter states that this rule will not provide the Department with any new information as the Washington State Department of Ecology has already collected the information this proposed rule seeks and has made this information available to the public online. Commenter argues that the proposed regulation is unnecessary and duplicative, as other state and federal laws already require the reporting and collection of information which is widely available in the public domain. Requiring manufacturers to submit such a report to Maine is costly and redundant. The information that the proposed rules would require the State of Maine to collect is already largely available to the public from other sources. Commenter states that, "...even if there were significant exposure to this chemical through children's products, Maine residents purchase products in retail that are part of the global economy...the DEP has offered no justification that the consumer product use patterns in Maine are any different than in Washington State." Commenter states that the DEP is wasting resources on this rule as its implementation would have virtually no public health benefit. Commenters (1)(5)(3)(6)(7)(8)

Response: Information reported to the Washington State Department of Ecology ("WDOE") to date covers only 3 of the 6 manufacturer categories (based on gross annual sales as specified in rule) that will eventually be required to report to WDOE annually. WDOE's program staggered which manufacturers are obligated to report by categorizing them based on sales data, and WDOE also limited the type of products regulated manufacturers must report by describing products in a 3 tiered system. Of the 3 manufacturer categories that have reported to WDOE as of October 2013, only 1 category of manufacturers have reported on all 3 product tiers. Eventually full implementation of the WDOE reporting rule will provide reports from all 6 manufacturer categories on all 3 product tiers. WDOE began implementing this reporting cycle in August 2012, and manufacturer categories will have reported on all product tiers in August 2018. Therefore, the information required by Maine's rule may have some overlap, but is not duplicative of information made available by WDOE.

Commenters did not identify any other state or federal program which requires manufacturers to report the same categories of information the Department seeks through this rule. Therefore, due to its uniqueness, the information the Department would collect through this rule will serve to inform future policy in a manner otherwise unattainable through any other source. No change to the rule.

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2. Comment: Commenter states that this rule would contribute to the patchwork of chemical regulations throughout the country. Commenter is concerned that this regulation carries the tremendous potential to create uncertainty, delay, and cost to impacted businesses. The result would stifle innovation and defeat the shared goal of protecting children and delivering safer, more innovative products to the marketplace. Commenter (5)

Response: The Department recognizes that this reporting rule has some similarities to other regulatory schemes manufacturers must respond to and rejects the notion that this rule would cause confusion and stifle innovation. Arsenic has been a known human carcinogen for many years, and reporting of arsenic under some state programs should encourage innovation to eliminate remaining uses that cause exposure to children. The Department also recognizes that fees associated with Maine's Safer Chemicals Program may be considered a negative impact on regulated manufacturers. However, in the absence of a federal program providing current information on the use of arsenic in the categories of products regulated by the Toxic Chemicals in Children's Products law, the Department finds no other avenue through which to gain a detailed understanding of its use in certain consumer products. Therefore, the information the Department will obtain through this reporting rule holds a value which is not duplicated by any other state or federal program. No change to the rule.

State and Federal Regulatory Overlap

3. Comment: Commenter states that the federal Consumer Product Safety Improvement Act ("CPSIA"), signed in 2008, provides preemptive mandatory consumer product safety rules - including limits with regard to arsenic - for toys sold in the United States. With the incorporation of the ASTM F-963 Toy Safety Standard, the CPSIA specifically limits the amount of soluble arsenic to 25 parts per million ("ppm") in the surface coatings and substrates of toys. Commenter states that given the federal restrictions and controls under the Toxic Chemicals in Children's Products Act this chemical would be considered a "contaminant" under this rule. The potential need for testing to make a reporting determination and any potential future restrictions which may result could run in conflict with the preemptive impact of the CPSIA 2008. Specifically, a state requirement that attempts to regulate the amount of arsenic in toys in a manner that is inconsistent is preempted by federal law. Commenter details the following reference, 15 U.S.C. 2075 provides as follows: "*Whenever a consumer product safety standard under this chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or*

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labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.” Commenter states that whereas the purpose of Maine's Toxic Chemicals in Children's Products Act is to protect children from harm and this rule is designed to meet that purpose, the rule does not align with this stringent federal requirement. Therefore, commenter requests the rule be amended in Section 1 (B) to include that:

Federal Regulation. Toys that are in compliance with requirements of ASTM F-963 for arsenic are not subject to this rule.

Commenter (4)

Response: The Department does not believe the CPSIA (2008) safety rules cited by the commenter create a preemption issue for the Department's rule. The Department's rule, as written, only serves to gather information about the use of arsenic in certain categories of children's product. Therefore, the rule would not obstruct the cited federal regulation, and would not be subject to conflict preemption. The language within CPSIA (2008) does not explicitly preempt any state law pertaining to chemicals in children's products, therefore express preemption does not apply to the rule either. Lastly, CPSIA (2008) does not offer language which would lead a state regulatory agency to assume federal occupation of this particular area of law, therefore field preemption does not apply to the rule.

No change to the rule.

Other

4. Comment: Commenter states that other states and the federal government have already banned or severely restricted most uses of arsenic in consumer products. Commenter states that there are no new products which provide a major source of exposure to arsenic. Commenter goes on to state that the exposure reduction potential from this rule is so limited that the benefits are negligible. Commenter states that the products selected for reporting under the proposed rule do not address exposure to this chemical. Commenter (3)

Response: Initial reports to WDOE indicate arsenic remains in use in some children's products. The Department seeks information about the use of arsenic which is beyond data currently available in the public domain, to clarify how and in what products arsenic is intentionally added. The Department believes that what the commenter refers to as the "limited" use of arsenic is worth the investigatory effort, as any product intended to be used by children which is within the scope of the Department's Safer Chemicals Program, is of value. No change to the rule.

Reporting Threshold/PQL

5. Comment: Commenter believes that the use of the practical quantification limit (“PQL”) as the reporting threshold is not practical and provides additional uncertainty for regulated entities. Because the PQL for any given chemical will vary based on the matrix in which the chemical is contained as well as the specific test being utilized. This will lead to differing thresholds for manufacturers reporting the same chemical, depending on the laboratory used for analysis. Analytical testing methods and detection limits will improve over time, causing a change in regulatory thresholds which have absolutely no correlation with public or environmental hazard or risk. Using the PQL as the threshold creates testing uncertainty and compliance challenges, and will require regulated manufacturers to undertake expensive and unnecessary alternatives analyses. Commenter (5)

Response: The Department must adhere to the framework of Maine law, 38 M.R.S.A. Chapter 16-D. In this case, the use of practical quantification limit as a threshold for disclosure of information is detailed in statute, which guides the Department's program implementation. No change to the rule.

6. Comment: Commenter states that this chemical is a naturally occurring element in the environment, making a “zero” limit unattainable and not health-risk based. Federal requirements for arsenic in consumer products have been based on risk and exposure to prevent the potential for harm to children. Commenter (4)

Response: Through this rule the Department seeks only information regarding the use of arsenic in specific children's product categories. This does not translate to a regulatory requirement of a non-detection limit or “zero” limit as specified by the commenter. No change to the rule.

Clarify Products to be Reported

7. Comment: Commenter is concerned that the definition of “consumer product,” as it relates to consumer electronic products, will lead to inconsistencies between existing laws and regulations. Manufacturers may not know whether their products will be used by children. Commenter suggests guidance on this issue may help avoid cumbersome reporting requirements on a manufacturer's products that are sold in Maine. Commenter (5)

Response: The Department believes it is clear that the intent of the rule is to capture product categories that meet the statutory definition of consumer product as set forth in 38 M.R.S.A. § 1691(7) through (8), and advises the commenter, and any other potentially

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regulated party, to contact program staff to discuss specific details regarding the applicability of product categories captured by this rule. No change to the rule.

8. Comment: Commenter states that science has demonstrated that early exposures to toxic chemicals can be especially harmful and lead to life-long neurological and learning challenges. In order to ensure a safe and healthy pregnancy, the mother must be protected from toxic chemicals and requests that the rule include products the mother is exposed to in order to reduce prenatal exposure to arsenic. Commenter states that fetal exposure to toxic chemicals can impact a child's health throughout their lives. The Toxics in Children's Products (*sic*) law clearly gives the Department the authority to regulate consumer products intended for home use if they may expose a fetus to Chemicals of High Concern [38 MRSA § 1691(7)]. Commenter states that prenatal exposure of pregnant women to toxic chemicals has long been recognized as a serious threat to fetal development during a critical window of vulnerability, and many chemicals have been found in the bodies of women who are pregnant. Commenter states that the product categories cited in the proposed rule are routinely used in homes, thus providing opportunities for exposure to pregnant women and requests the rule be amended to include language which would protect potential fetal exposures. Commenter requests that future priority chemical rules specify reporting requirements for "any household products."
Commenters (1)(2)(3)(6)(7)(8)

Response: The Department notes the disparity between commenter's claim that the rule is irrelevant due to the negligible use of arsenic in consumer products and the commenter's request that the Department expand the scope of product categories included in the proposed rule. The Department believes it is appropriate to limit reporting to products intended for use by children, because a broadening of this category by the inclusion of fetuses and pregnant women effectively includes all products intended for use by adult females. The Department is focusing, at this time, on a narrow scope of product categories to begin evaluating the remaining uses of intentionally added arsenic. No change to the rule.

9. Comment: Commenter requests greater clarity with the scope of rule language referring to the specific children's products that require reporting. Understanding that the underlying statutory definition of children's product is broad and can include both general use consumer and commercial products, the age limit of "12 years of age" is used in the statutory definition of "children's product" (Title 38, Chapter 16-D §§1691(8)). Therefore, commenter requests this specificity be used in the proposed rule to ease reporting confusion. Specifically, the commenter requests the following modification to the rule:

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(1) No later than 180 days after the effective date of this chapter, the manufacturer of any ~~of the following~~ bedding, childcare articles, clothing, cosmetics, craft supplies, footwear, games, jewelry and embellishments, safety seat, occasion supplies, personal accessories, personal care products, school supplies, or toys, any of which are intended for use by a child under the age of 12 years and that contain intentionally-added mercury shall report to the department the following information:

Commenter (4)

Response: The Department recognizes the value in further clarifying regulated product categories and proposes the following change to the rule:

Section 4. A.

(1) No later than 180 days after the effective date of this chapter, the manufacturer of any ~~of the following~~ bedding, childcare articles, clothing, cosmetics, craft supplies, footwear, games, jewelry and embellishments, safety seats, occasion supplies, personal accessories, personal care products, school supplies, or toys, any of which are intended for use by a child under the age of 12 years and that contain intentionally-added mercury shall report to the department the following information:

Confirmation of Arsenic in Products

10. Comment: Commenter agrees that arsenic is in a group of some of the worst chemicals out there. Commenter states that no one can dispute that arsenic poses a serious health threat.
Commenter (6)

Response: The commenter affirms the Department's concern for childhood exposure to arsenic and the need to gather information about its use in products which are used by Maine children. No change to the rule.

Alternatives Assessment

11. Comment: Commenter suggests that the DEP should use its authority under Maine's Toxic Chemicals in Children's Products law to require an alternatives assessment and use that information to initiate a rule before the Board of Environmental Protection to phase out toxic chemicals from products where safe and affordable alternatives are available.
Commenters (1)(3)

Response: Maine state law provides a step-wise approach which lists alternatives assessment as information which may be supplemental to the disclosure of information on a priority chemical (i.e. reported use information) which the Department does not believe

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necessary for this stage of analysis. As detailed in 38 M.R.S.A. § 1695 (2), the Department may request 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 as "additional information" from a manufacturer which has reported its use of a priority chemical. No change to the rule.