

Rule Chapter 885
Designation of Formaldehyde as a Priority Chemical and
Regulation of Formaldehyde in Children's Products

Supplemental Basis Statement
Response to Comments

List of Commenters

- | | |
|---|---|
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Comments

Defining Scope of Products Regulated

1. Comment: Commenter suggests defining the scope of products subject to regulation so that the focus is on true children's products as much as possible and does not sweep in unintended products. Commenter states that absent this clarification, manufacturers and consumers will face uncertainty regarding which products are covered and potentially face unnecessary costs. Specifically, commenter is concerned about the definition of "Craft Supplies" because it could include products not intended for the arts and crafts market. Commenter cites items not intended to create art, but intended for general use (such as glues, adhesives, and putties), as examples of products that the Consumer Product Safety Commission (CPSC) exempts under its Labeling of Hazardous Art Materials Act (LHAMA) regulation of art materials by not bringing enforcement action against such products unless it is specifically packaged, promoted, or marketed in a manner that would lead a reasonable person to conclude that it is intended for use as an art material. Commenter is concerned that language in the proposed definition "any art supply" is vague and could potentially sweep in unintended products and requires clarification. Commenter is equally concerned with the draft rule definition of "School Supply" and recommends the Department clarify this definition to focus the scope on true children's products and not unintentionally include consumer products that are intended for non-students or adults. (6)
2. Comment: Commenter suggests that the Department maintain language used in prior rulemaking to describe the scope of products that require information submission. Commenter requests that the Department maintain consistency with other rules by adding language to the paragraph describing the timeline for reporting regulated product categories within section 4 "Information required" of the rule to read as follows, "*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 contain intentionally-added formaldehyde shall report to the Department the following information...*" Commenter requests greater clarity with the scope of the rule by including language referring to the specific children's products that require reporting so that the last portion of Section 4(A)(1) of the draft rule include the following, "*...any of which are intended for use by a child under the age of 12 years and...*" (4)(6)

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3. Comment: Commenter is concerned with the inconsistency of the proposal's consideration with what should be defined as a product used by children. Citing Department rule chapters 884, 886, and 887, commenter writes that the Department used language that clearly define that products regulated by the rule were intended for the use of children under the age of 12 years, yet proposed rule chapter 885 lacks this specificity. Commenter requests that the Department mirror language used in section 4 of the above cited rules which would more fully define what would be considered children's products for the purposes of this rule. Commenter notes that a lack of definite scope within chapter 885 potentially makes this proposed regulation include a much broader collection of consumer products that are outside the concern of Maine in related chapters 884, 886, and 887. Commenter states that this important addition to the definition will keep consistency within the Departments regulations and help focus the scope of inquiry to products that are intended for use by children. (2)(1)

Response to Comments 1-3: The Department recognizes the value in further clarifying regulated product categories. For this reason and to achieve consistency with similar rules, the following language is added to 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 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 formaldehyde shall report to the Department the following information:

Redundancy / Federal Regulation

4. Comment: Commenter believes the designation of formaldehyde as a priority chemical and its subsequent regulation of formaldehyde in children's apparel, footwear, and childcare articles such as sleepwear, is unnecessary and should be withdrawn. Commenter states that formaldehyde has been thoroughly reviewed at the federal level and is actively regulated in textiles and apparel. Commenter states that a review by the Consumer Product Safety Commission (CPSC) led the CPSC to determine that formaldehyde content in textiles does not pose acute or chronic health problems for consumers; based on this research and other work, CPSC decided that no regulatory standard is necessary for formaldehyde in textiles and apparel. Commenter goes on to state that the U.S. apparel and footwear brands and retailers already actively monitor formaldehyde through the use of chemical management tools such as the Restricted Substances List which helps set internal corporate limits on formaldehyde. Commenter states that the information required by the proposed rule can undermine the goal of consumer safety by failing to acknowledge that the presence of a chemical in a product does not inherently mean that the product is unsafe. Commenter

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urges the Department to withdraw the rule designating formaldehyde as a priority chemical.
(5)

5. Comment: Commenter states that toy manufacturers do not intentionally add formaldehyde to products, and goes on to explain that formaldehyde is naturally occurring and can be found in every living system, all of which produce formaldehyde as a normal part of metabolism. Commenter uses the example of wood, which comes from natural sources and is often a primary material used to make toys, which must already comply with the California Air Resources Board Formaldehyde Airborne Toxic Control Measure (CARB ATCM). Commenter states that toys sold across the nation comply with this California standard, toy companies that use composite wood have diligently worked to ensure product compliance with this requirement. Commenter notes that the U.S. EPA is evaluating proposed formaldehyde wood emission limits in the Formaldehyde Standards for Composite Wood Products Act (FSCWPA) and anticipates publishing a final rule by the end of 2015. Commenter cites Minnesota as the only other state to regulate formaldehyde in children's products and cosmetics, noting that toys were not included in the scope of their legislation – due to the fact that toys are extensively regulated in California for formaldehyde and also stringently regulated for safety at the federal level. Commenter included language from the Minnesota law which specifically excludes, "...children's toys that are covered by the ASTM International F963 standard for Toy Safety,..." Commenter requests that the Department add language to be consistent with Minnesota law by acknowledging the CARB ATCM within proposed rule Section B (Exemptions) by adding the following:

(4) Regulated products. A product that is in compliance with all requirements of the California Air Resources Board Formaldehyde Airborne Toxic Control Measure § 93120 through 93120.12 of title 17, California Code of Regulations or regulations promulgated under the Formaldehyde Standards for Composite Wood Products Act under § 601 of the Toxic Substances Control Act, 15 U.S.C. 2697.

(4)

6. Comment: Commenter states that formaldehyde has been thoroughly reviewed at the federal and state levels and is sufficiently regulated in those products potentially regulated by the proposed rule. Commenter notes that since 2008, the toy and juvenile products industries have been required by the Consumer Product Safety Improvement Act to follow the technical requirements within the toy safety standard ASTM F963. Commenter notes that this standard incorporates the Federal Hazardous Substances Act, which sets specific thresholds for formaldehyde content in products, which applies to a wide variety of children's products. Commenter goes on to note that the use of formaldehyde by the textiles and apparel sector has been extensively studied by the Consumer Product Safety Commission, which determined that formaldehyde content in textiles does not pose acute or chronic health problems for consumers and concluded that no regulatory standard was

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necessary for formaldehyde in textiles and apparel. Commenter states that the textiles and apparel industry goes beyond this determination and has set voluntary restrictions on the use of formaldehyde in clothing. Commenter states that the cosmetics industry has worked with the federal government to develop a national scientific organization (the Cosmetic Ingredient Review (CIR)), which classifies formaldehyde in beauty products as "safe" when measured under 0.2 percent. Commenter states that recent studies show that inhalation of formaldehyde from the use of personal care products poses no risk to human health. (7)

7. Comment: Commenter notes that "forest products" are excluded from Maine's Regulation of Chemical Use in Children's Products; however, commenter believes it important to recognize that the federal government is currently finalizing a regulation nationalizing the formaldehyde emission limits from composite wood products set under California's airborne toxics control measure. Commenter states that end-use manufacturers, such as those that make cribs or wood toys, would be required to purchase certified compliant composite wood and abide by those emission limits. Commenter believes that industry's voluntary efforts and existing regulations have led to a wide margin of safety for most uses of formaldehyde chemistry, which eliminates the need for Maine to further regulate formaldehyde as a priority chemical. (7)
8. Comment: Commenter states that the proposed reporting requirement would be duplicative of information gathered by Washington State through their similarly structured Children's Safe Products Act. Commenter notes that at last year's public hear for this same proposed rule, representing Maine's Environmental Health Strategy Center, Emma Halas-O'Connor testified that, "[l]ittle to no new information on chemical use in consumer products will result from the proposed rule...It is unnecessary for DEP to propose a rule to require the state to gather information that is already provided by authoritative sources and searchable on the internet." Commenter agrees with Ms. Halas-O'Connor on this point and goes on to state that reporting under this proposal would be duplicative and not achieve any additional public health benefit or purpose. (7)
9. Comment: Commenter states that the National Academy of Sciences National Research Council (NRC Committee) published its review of the 12th Report on Carcinogens (12th ROC) chapter on formaldehyde in August 2014, and that this review does not change the science regarding the safety of formaldehyde and products made from formaldehyde. Commenter notes that much more information than what was considered by the NRC Committee is needed to understand potential risk of formaldehyde in every-day use. Commenter notes that the charge question which predicated the NRC Committee's review was flawed and lacked the rigor necessary to support a credible hazard assessment, as existing ROC listing criteria do not take into account the totality of the evidence nor do they integrate all studies when making a hazard determination. Commenter goes on to differentiate the NRC Committee's 2011 review of EPA's draft IRIS assessment for

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formaldehyde. Commenter notes that during this 2011 review the NRC Committee was called upon to review procedural and substantive elements of EPA's draft IRIS assessment. Commenter states that the 2011 NRC Committee's final report strongly criticized EPA's failure to demonstrate a causal association with leukemia as problematic given the generally weak evidence to support such an associations. Commenter notes the inconsistencies between these two reviews cause more confusion than clarity, which reinforces the need for a comprehensive and fully integrative analysis of formaldehyde science in the U.S. Commenter also notes that the World Health Organization has indicated that normal human exposures do not present a risk of cancer and that there is no scientific evidence that concludes that children are more or less susceptible than adults to inhaled formaldehyde from household exposures. (7)

Response to Comments 4-9: The Department seeks to obtain information about how and in what products formaldehyde is intentionally added to children's products offered for sale in the State of Maine. The limited information currently available in the public domain indicates that formaldehyde is still being used by manufacturers of some children's products; however, in the absence of a federal program providing timely information on the use of formaldehyde 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 children's products available for sale in the State of Maine. 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.

Other

10. Comment: Commenter believes that, "formaldehyde is widely used in a variety of children's products," citing data reported to Washington State Department of Ecology as confirmation that, "a great number of products sold in that state contain formaldehyde." Commenter claims that there is no safe level of human exposure to a carcinogen, and commenter notes that, according to the U.S. Department of Health and Human Services, formaldehyde is known to be a human carcinogen. Commenter states that the rule should be revised to ensure disclosure of formaldehyde in all consumer products that are children's products in order to expand mandatory reporting to include those products to which a fetus is exposed through maternal exposure during pregnancy. Commenter cites the authority of current law clearly as providing for disclosure of a priority chemical for any consumer product that is a children's product which likely results in a child under 12 years of age or a fetus being exposed to the regulated chemical, not limiting the rule's authority to products intended for or marked to children under the age of 12 years. Commenter states that a body of credible scientific evidence has amassed that establishes that much of the origin of health and disease relates to multiple risk factors affecting the fetal environment during pregnancy. Commenter states that the currently proposed rule eliminates protection of the

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fetus from toxic chemical exposure, an idea that was unanimously rejected by the Environment and Natural Resources Committee when amendments to the law were approved in 2011. Commenter strongly urges the Department to revise its proposed rule to expand the scope of reporting to provide information helpful to protect the vulnerable fetus.
(3)

Response: The Department notes the inconsistency between commenter's assertion here and the comments provided at the time this same rule was deliberated in 2014. At the public hearing on this rule held January 14, 2014, Emma Halas-O'Conner, representing Maine's Environmental Health Strategy Center, provided testimony which did not support the proposed rule requiring formaldehyde reporting.

In addition to the testimony of Ms. Halas-O'Conner, Maine's Environmental Health Strategy Center provided an analysis of the proposed rule requiring reporting of formaldehyde as a priority chemical, dated November 22, 2013, and asserted the following, "[v]ery little potential remains to further reduce exposure to...formaldehyde from consumer products still sold in Maine. Instead, the major remaining sources of exposure to these hazardous chemicals are from...air pollution from combustion sources (formaldehyde)."¹

The Department has determined that the most appropriate course of action for this reporting rule is to maintain consistency with recently adopted, and currently effective, rules which are specifically focused on children's products.

No change to the rule.

11. Comment: Commenter believes that Maine should not move forward with this reissued proposed regulation of formaldehyde in children's products. Commenter notes that during 2014 rulemaking proceedings for this same proposal not one participant at the hearing spoke in support of the regulation, and many made the case that the proposed regulation would be duplicative and unnecessary. Commenter states that the following points clearly support the assertion that the proposed rule would not provide any public health benefit. Commenter states that formaldehyde is not directly added to most consumer products, and that when formaldehyde is used directly there is little or no formaldehyde present in the final product. Commenter cites a study conducted by the Washington State Department of Ecology, published in March 2014, which evaluated compliance with the state's Children's Safe Product Act by testing for the presence of formaldehyde; the results of this study concluded that 93.8% of the products tested resulted in presence below the non-detect level and the remaining 6.2% of products tested showed presence at less than 1 part per million. Commenter notes that during the 2014 rulemaking proceeding for this rule and three others

¹ "Analysis of Proposed Rules to Require Reporting of the Use of Mercury, Arsenic, Cadmium and Formaldehyde as Priority Chemicals in Certain Consumer Products," Environmental Health Strategy Center, submitted as supplemental documentation to the testimony of Emma Halas-O'Connor during rule deliberations (2014), www.preventharm.org, dated November 22, 2013, page 1.

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proposed at the time, Maine's Environmental Health Strategy Center testified that, "none of these chemicals has a major source of exposure that is a consumer product," and "formaldehyde persists in some consumer products as a preservative, but is still in limited use in children's products." Testimony from Maine's Environmental Strategy Center, provided by Emma Halas-O'Connor, during this same proceeding concluded that, "these proposed rules target chemicals that are mostly irrelevant when it comes to household products." Commenter states that formaldehyde is one of the most extensively studied chemicals in use today, and that the primary exposure routes addressed by this proposed rule (oral and dermal exposures) do not post toxicological risk at the levels contained in the children's products captured by this proposed rule. Commenter notes that products covered by this proposed rule could not plausibly emit formaldehyde at continued and sustained levels to pose any risk of cancer to even the most sensitive populations. (7)

12. Comment: Commenter writes that it is remarkable that not one organization or individual that testified at the 2014 hearing on this same proposal spoke in support of its adoption. Commenter goes on to state that many of those who testified at that time, which includes the public health community and industry, noted that the proposed regulation would be duplicative and unnecessary. Commenter notes that the science behind formaldehyde and its uses have not changed over the course of a year such that the position of those who testified in 2014 should be any different now than it was at last year's public hearing. (7)

Response to comments 11-12: The Department believes moving forward with this reporting requirement is of value because the information obtained is not currently available through any other source. Information reported through this rule will assist the Department's Safer Chemicals Program in gaining a better understanding of how formaldehyde, which is intentionally added to children's products, may affect public health. See also Response to comments 4-9. No change to the rule.