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*The voice of Maine business*

January 31, 2014

Kerri Malinowski
Maine Department of Environmental Protection
Bureau of Remediation and Waste Management
17 State House Station
Augusta, Maine 04333

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

Dear Ms. Malinowski:

The undersigned organizations are writing in reference to our concerns regarding the proposed Designation of Formaldehyde as a Priority Chemical and Regulation of Formaldehyde in Children's Products ("Proposed Regulation") in Maine's *Toxic Chemicals in Children's Products* law (38 M.R.S.A. §§ 1691-1699-B). The undersigned organizations represent a broad spectrum of the American economy. Each organization is committed to maintaining the safety and integrity of the products our industries produce in order to ensure a safe and healthy product for use by the consumer. Based on the reasons set forth below, we strongly believe that Maine should not move forward with the Proposed Regulation of formaldehyde in children's products.

**A. The products covered under the Proposed Regulation simply do not pose a significant exposure to formaldehyde that would be of concern for an increased cancer risk.**

Formaldehyde is one of the most extensively studied chemicals in use today. It is well-established in the scientific literature that any potential association between formaldehyde and cancer risk is linked to significant and prolonged exposures to inhaled formaldehyde.[1] The products covered under the Proposed Regulation could not plausibly emit formaldehyde at continued and sustained levels to pose any risk of cancer to even the most sensitive populations. In fact, reported concentrations for a majority of the products covered under Washington State's

[1] See, e.g., Kerns, et al. (1983). "Carcinogenicity of Formaldehyde in Rats and Mice after Long-Term Inhalation Exposure." Cancer Research, 43: 4382-92.

Children's Safe Products Act fall at or well below even Maine's 100 ppm cut-off level for regulation of chemical contaminants in children's products.[2]

When considering potential inhalation exposures and risk for children and adults, it is important to remember that formaldehyde is naturally occurring and can be found in every living system, where it is produced as a normal part of metabolism. There is broad agreement that formaldehyde is normally present in all tissues, cells, and bodily fluids and that its natural occurrence complicates any formaldehyde risk assessment. Inhaled formaldehyde is absorbed primarily at the site of first contact because of its high water solubility, metabolism and reactivity. The fate of airborne formaldehyde is an efficient process and is generally considered complete in the upper respiratory tract of the body.

Formaldehyde metabolizes quickly in the body; it breaks down rapidly, is not persistent and does not accumulate in the environment. Furthermore, animal studies show that formaldehyde inhalation in rodents and primates does not alter blood formaldehyde concentrations; thus, it is unlikely for formaldehyde to appear in the blood as an intact molecule. Systemic effects, such as cancer, resulting from formaldehyde inhalation is unlikely since the weight of the scientific evidence indicates that delivery of formaldehyde to distant site tissues does not occur.[3] Finally and importantly, the World Health Organization, among others, has concluded that there is no scientific evidence that children are more or less susceptible to formaldehyde exposures than adults.[4]

**B. Many of the potential industries are already regulated and have, as a result, addressed concerns regarding formaldehyde exposures.**

Under 38 MRSA § 1697(9), the Department is directed to consider the extent to which a chemical is "adequately regulated by the Federal Government or an agency of this State" before exercising its discretionary authority. Formaldehyde has been thoroughly reviewed at the federal and state levels and is sufficiently regulated in those products listed in the Proposed Regulation. Therefore, the use of formaldehyde does not require additional regulation.

Taking for example textiles and apparel, the formaldehyde chemistry used in dyeing and finishing have been extensively studied by CPSC under the Federal Hazardous Substances Act

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[2] Data are available at http://www.ecy.wa.gov/programs/swfa/cspa/.

[3] Lu et al. (2010). "Distribution of DNA adducts caused by inhaled formaldehyde is consistent with induction of nasal carcinoma but not leukemia." Toxicological Sciences, 116(2): 441-51; Moeller et al. (2011). "Determination of N 2-Hydroxymethyl-dG Adducts in the Nasal Epithelium and Bone Marrow of Nonhuman Primates Following 13CD2-Formaldehyde Inhalation Exposure." Chemical Research in Toxicology, 24(2), 162-64.

[4] See, e.g., World Health Organization (WHO). (2010). WHO Guidelines for Indoor Air Quality: Selected Pollutants, at 116. Available at http://www.euro.who.int/__data/assets/pdf_file/0009/128169/e94535.pdf.

(15 U.S. Code 1261-1278). These studies, conducted at Oak Ridge National Laboratory and other locations, determined that formaldehyde content in textiles do not pose acute or chronic health problems for consumers. Based on this research and other work, CPSC has decided that no regulatory standard was necessary for formaldehyde in textiles and apparel.[5]

Maine's Regulation of Chemical Use in Children's products provides that "forest products" are excluded from regulation; however, it is important to recognize that the federal government, following Congressional legislation, is currently finalizing a regulation that would nationalize emission limits set under California's airborne toxics control measure to control formaldehyde emissions from composite wood products.[6] Through many years of voluntary stewardship efforts and as a result of the California regulation, formaldehyde resin producers and panel manufacturers are already now capable of making products that emit at, or near, naturally occurring background levels from wood itself. End-use product manufacturers, such as those that make cribs or wood toys, would be required to purchase certified compliant composite wood and, consequently, abide by those emission limits.

These are just two examples where federal and state government authorities have determined that consumers are adequately protected when formaldehyde-based technologies are used in accordance with existing regulations.

### C. Voluntary efforts have also led to significant reductions in formaldehyde emissions.

The cosmetic industry has worked with the federal government to develop a national scientific organization, known as the Cosmetic Ingredient Review (CIR), which is sanctioned by the U.S. Food and Drug Administration (FDA) to review and assess the safety of ingredients used in cosmetics. Based on its reviews, the CIR classifies formaldehyde in beauty products as 'safe' as long as the substance is no greater than 0.2 percent measured as free formaldehyde, kept to a minimum, and not aerosolized. Formaldehyde was just recently reviewed by the CIR and their current assessment is up to date.[7] We believe that CIR's standards should inform any effort to assess the safety of personal care products that might fall under this Proposed Regulation. Furthermore, recent data show that inhalation of formaldehyde from the use of personal care products poses no risk to human health.[8] Taken together, industry voluntary efforts and existing regulations have led to a wide margin of safety for most uses of formaldehyde chemistry, thereby eliminating the need for Maine to further regulate formaldehyde as a priority chemical.

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[5] See, e.g., U.S. Government Accountability Office (GAO). (2010). Formaldehyde in Textiles (GAO-10-875), at 11. Available at http://www.gao.gov/new.items/d10875.pdf.

[6] See http://www.epa.gov/opptintr/chemtest/formaldehyde/

[7] See http://www.cir-safety.org/ingredient/formaldehyde

[8] Lefebvre, et al. (2012). "Consumer inhalation exposure to formaldehyde from the use of personal care products." Regulatory Toxicology and Pharmacology, 63: 171-76.

**D. The Proposed Regulation would not lead to the production of any new useful information, as the public already has access to any formaldehyde content in children's products through the State of Washington's reporting scheme.**

Washington State's Children's Safe Products Act requires formaldehyde content reporting for many of the same products proposed for listing in this regulation. These reports are publicly available to all stakeholders. (See http://www.ecy.wa.gov/programs/swfa/cspa/search.html.) Therefore, any reporting that might occur under this Proposed Regulation would simply be duplicative and not achieve any additional public health benefit or purpose.

**E. The Proposed Regulation appears to be designed to address predominantly oral, and to some extent dermal, exposures.**

Specifically, section 4.A(1)(b) of the Proposed Regulation states that:

> *A description of the product or products containing formaldehyde, including the overall size of the product and/or the component of the product that contains formaldehyde and whether the product or formaldehyde -containing component of the product, can be placed in the mouth. (If a reportable item is smaller than 5 centimeters in one dimension, it is regarded as mouthable.)*

This provision is clearly intended to identify those products or component parts that may pose oral exposure issues for children. In addition, the Regulation of Chemicals Use in Children's Products establishes a "de minimis" content level of 100 ppm and a reporting level of 0.8 mg/kg for intentionally added formaldehyde, which suggests again regulation of oral or dermal exposures, not inhalation exposures. There is nothing in the Regulation of Chemicals Use in Children's Products or the Proposed Regulation that would provide a framework for looking at thresholds for inhalation exposures, which as noted above, is the only relevant exposure pathway remotely linked with any cancer risk.

**F. Maine's Regulation of Chemical Use in Children's Products Does Not Include "Sensitization" as a Criterion for Listing.**

Maine's Regulation of Chemical Use in Children's Products does not appear to include "sensitization" as a criterion for listing chemicals of concern. Chemicals may be listed as chemicals of concern only if there is credible scientific evidence of the substances being:

- A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;
- Persistent, bio-accumulative and toxic; or
- Very persistent and very bio-accumulative.

Sensitization is clearly not in this list of criteria, and therefore it should not be relied upon as a rationale for identifying any chemical, let alone formaldehyde, as a chemical of high concern, which is a prerequisite for designating priority chemicals. For this reason alone we have not commented on the "sensitization" association you have linked with formaldehyde.

**G. At a minimum, Maine should wait to review formaldehyde until current evaluations by US EPA and the National Academy of Sciences (NAS) are completed.**

Given the vast and complex nature of the formaldehyde science dataset, the EPA is now revising its Integrated Risk Information System (IRIS) assessment for formaldehyde to incorporate the findings and recommendations from the 2011 report of the NAS review of EPA's draft IRIS assessment of formaldehyde. (Available at http://www.nap.edu/catalog.php?record_id=13142). This report provided a number of sharp critiques of process and substance, leading not only to the ongoing revision of the formaldehyde assessment but triggering a larger reform effort for the entire IRIS program.

With regard to cancer, the NAS concluded on pg. 11 that:

> *As with the respiratory tract cancers, the draft IRIS assessment does not provide a clear framework for causal determinations. As a result, the conclusions appear to be based on a subjective view of the overall data, and absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data, and the lack of mechanistic data. Although EPA provided an exhaustive description of the studies and speculated extensively on possible modes of action, the causal determinations are not supported by the narrative provided in the draft IRIS assessment. Accordingly, the committee recommends that EPA revisit arguments that support determinations of causality.....*

The NAS was critical of EPA's analysis for a number of other endpoints as well, reinforcing the fact that despite the robust nature of the scientific literature on formaldehyde, there is still significant work that EPA will need to undertake to reach an assessment that reflects the best available science. As part of that process, we were pleased to see that EPA has announced a workshop on formaldehyde science to be held in April 2014. We certainly hope this workshop will provide a forum for meaningful scientific discussion amongst the most noted experts in the field, and that this in turn will inform EPA's revisions to its draft assessment. We hope you will consider attending.

Equally important, the NAS is currently reviewing the National Toxicology Program's 12$^{th}$ Report on Carcinogens formaldehyde chapter, which reviewed the same data and applied the same general process that was used in EPA's IRIS assessment (and by the International Agency

for Research on Cancer (IARC) for that matter). We expect this report to be released in August 2014.

It is worth noting as well that the European Chemical Agency (ECHA) announced in Dec. 2013 the adoption of the scientific opinion of their Committee for Risk Assessment (RAC), which proposed that formaldehyde be designated as a "presumed human carcinogen" for nasopharyngeal cancer only, which is an extremely rare cancer in the U.S.[9] This is a markedly different assessment than what EPA and NTP have provided in their reviews to date.

All of these reviews should assist in informing Maine's approach to prioritizing formaldehyde. Therefore, at the very least, Maine should refrain from making any decision on whether to designate formaldehyde as a priority chemical until these reviews have been completed.

**Summary**

We **urge** that Maine not move forward with the Proposed Regulation of formaldehyde in children's products. Any approach taken in Maine on formaldehyde should be based on sound science and an assessment of exposure and risk, not just potential hazard. When considering the full weight of the evidence, we do not believe that the science supports designating formaldehyde as a priority chemical for purposes intended for in Maine.

As we have illustrated in our letter, exposures in the products covered by the Proposed Regulation are scant and far below the well documented, concentrations that are necessary to result in cancer. Many of the industries that make these products are already regulated, while others have taken voluntary initiatives to minimize exposures, if they exist at all. The Proposed Regulation appears to address only oral and dermal exposures, and these are not the relevant pathways associated with cancer. We also remain firm in our belief that this regulation is premature at this point, as the U.S. EPA and NAS formaldehyde reviews are still in process.

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[9] See European Chemicals Agency (ECHA). (2013). Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labeling at EU level of Formaldehyde, at 44-46. Available at http://echa.europa.eu/documents/10162/13626/rac_opinion_formaldehyde_en.pdf.

We thank you in advance for considering our concerns and look forward to working with you in enacting science based regulations that advance safety. Should you have any questions, please feel free to contact us.

Sincerely,

Maine State Chamber of Commerce
American Apparel & Footwear Association
American Chemistry Council
American Home Furnishings Alliance
Composite Panel Association
Fashion Accessories Shippers Association
Juvenile Products Manufacturers Association
Travel Goods Association
Toy Industry Alliance