September 16, 2016

Ms. Kara Steward
HWTR Program
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Submitted via email to: Kara.Steward@ecy.wa.gov

RE: Washington State Department of Ecology Review of the Children's Safe Products Reporting Rule (Chapter 173-334 WAC)

Dear Ms. Steward:

The American Chemistry Council (ACC) Formaldehyde Panel (the Panel) appreciates the opportunity to comment on the Washington State Department of Ecology (DoE) review of the Children's Safe Products Reporting Rule (CSPRR) language and the status of formaldehyde on the Chemicals of High Concern to Children (CHCC) list. The Formaldehyde Panel represents producers, suppliers and users of formaldehyde products, as well as trade associations representing key formaldehyde applications. ACC and the Panel submitted detailed comments in 2010[1] and 2011[2] focused on: (1) ensuring that the final rule utilized a risk based process to prioritize chemicals of potential concern, (2) evaluating selected chemicals using the best available scientific data and approaches, (3) setting a science based minimum reporting threshold of 1,000 parts per million for formaldehyde and (4) adequately communicating the utility and relevance of the reporting thresholds in order to avoid confusion in the market place.

Ensuring the safety of children's products and addressing the potential risks from possible exposure to chemicals is an important objective of the DoE. To effectively accomplish this task the DoE should revise the rule and its process for identifying CHCC so that the approach is science based and incorporates current knowledge about hazard and relevant human exposures. We appreciate the DoE's consideration of our 2010 and 2011 comments as it finalized the rule. However, the rule as it currently stands continues to lack a risk based foundation and the designation of formaldehyde (CASRN 50-00-0) as a CHCC is not transparent. Below we offer: (1) recommendations for changes to the rule, (2) comments on the criteria used to prioritize and include chemicals on the CHCC list and (3) information indicating low exposure to formaldehyde from children's products.

I. The designation of a CHCC should be a risk based process that takes both hazard and exposure into account.

Section 173.334.70 of the CSPRR includes guidance for how the DoE will identify chemicals for inclusion in the CHCC list. Specifically, a chemical that the DoE determines to meet the toxicity, persistence and bioaccumulation criteria in RCW

[1] American Chemistry Council Comments on Proposed WAC 173-334 (December 17, 2010).
[2] Formaldehyde Panel of American Chemistry Council Comments on Proposed WAC 173-334 (January 7, 2011)

70.240.010(6) and the exposure criteria in RCW 70.240.030(1) will be included on the CHCC. While the CSPRR identifies both hazard and exposure criteria, as defined in the statutory language, the CSPRR appears to consider these items in isolation and does not take into consideration relevant human exposures that could result in the hazards identified in the rule. Accordingly, the exposure criteria state that the DoE "*shall identify high priority chemicals that are of high concern for children after considering a child's or developing fetus's potential for exposure to each chemical.*" However, all of the criteria identified in RCW 70.240.030 indicate that chemicals should be added to the CHCC list if the mere presence of the chemical is found in a product or in biological or environmental media, regardless of whether the hazard identified is plausible at relevant exposure levels.

We therefore request that DoE include additional language in the rule to conduct a margin of exposure assessment for each substance that has been identified to meet both the hazard and exposure criteria in order to determine if current exposure levels present an unreasonable risk. If the results of the margin of exposure assessment indicate an unreasonable risk, then DoE should include these chemicals on the CHCC list. The DoE should immediately conduct a margin of exposure assessment for formaldehyde to determine if it warrants inclusion on the CHCC list based on relevant exposures in children's products. In addition to this recommended revision to the rule, we also note that the criteria for toxicity, persistence, or bioaccumulation are in RCW 70.240.010**(9)**, not RCW 70.240.010(6) as identified in the CSPRR.

II. The prioritization process lacks transparency and robustness.

An article by Smith et al. (2016), titled "A Toxicological Framework for the Prioritization of Children's Safe Product Act Data,"[3] sought to summarize the process utilized under the Washington State Children's Safe Products Act (CSPA) to prioritize the 10 most frequently reported substances. The framework generates a total priority index score by adding the exposure scores (which assess lifestage, exposure duration, primary, secondary and tertiary exposure routes, toxicokinetics and chemical properties) and toxicity scores (which assess reproductive and developmental toxicity, endocrine disruption, neurotoxicity and carcinogenicity). Based on this evaluation, formaldehyde was deemed the highest priority chemical with a total priority score of 297.8. However, this score lacks transparency as highlighted below.

- The average exposure score for formaldehyde was noted at 14.2 but it is difficult to determine how this number was calculated because lifestage, concentration, exposure duration, dermal exposure and applied directly to skin scores were not included in the document or the supplemental material. If this information is available, it should be made a part of the supplemental materials. Additionally, the Phase 3 scoring sheets,

[3] Smith, M. N., Grice, J., Cullen, A., & Faustman, E. M. (2016). A Toxicological Framework for the Prioritization of Children's Safe Product Act Data. International journal of environmental research and public health, 13(4), 431.

which were used by DoE to prioritize substances, were not readily available on the DoE's website.[4]

- The total average toxicity score for formaldehyde is not included in the framework so it is difficult to determine if this information had been accurately quantified. Notably, in reviewing Table 2 it appears that some information was inaccurately calculated. For example, neurotoxicity scores were assessed based on Grandjean and Landrigan (2014)[5] and the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. If chemicals were listed as neurotoxicants in Grandjean and Landrigan (2014), they received a score of 3, if not they received a score of 0. Chemicals were also classified as neurotoxicants based on their GHS classification. In the framework, formaldehyde received a neurotoxicity certainty score of 3; however, it was not classified as a neurotoxicant by Gradjean and Landrigan,[6] and it is unclear what GHS information was relied upon to assign formaldehyde a score of 3.

  It is important to note that available scientific data illustrates that formaldehyde is absorbed primarily at the site of first contact. Normal indoor air formaldehyde concentrations do not pass beyond the respiratory epithelium and the relatively small amounts of formaldehyde that might remain in the nose and upper respiratory tract are expired or quickly metabolized. Therefore formaldehyde's direct effects are limited to the portal-of-entry. , Consequently, a 2011 review of formaldehyde by the National Academy of Sciences[7], that evaluated neurotoxicity, found the scientific evidence lacking and the available studies not sufficiently robust in design to be considered well executed for the purpose of neurotoxicity hazard identification. Given DoE's lack of adequate justification for the neurotoxicity certainty score, the score of 2 for neurotoxicity potency should also be re-evaluated.

III. Washington State's own evaluation illustrates low exposure from formaldehyde in children's products.

Based on the results from an evaluation conducted by DoE, published in March 2014,[8] formaldehyde is not present in significant concentrations in children's products. The study tested for the presence of formaldehyde in twelve children's products. Of the products tested, 93.8% were below the non-detect level for formaldehyde and in the remaining 6.2% of products, formaldehyde was found at very low levels.

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[4] DoE Phase 3 Summary. The final report submitted was unavailable when we attempted to access the weblink (http://www.ecy.wa.gov/programs/swfa/rules/pdf/p3doh.pdf) on September 6, 2016.
[5] Grandjean, P., & Landrigan, P. J. (2014). Neurobehavioural effects of developmental toxicity. The Lancet Neurology, 13(3), 330-338.
[6] Supplement to: Grandjean P, Landrigan PJ. Neurobehavioural effects of developmental toxicity. Lancet Neurol 2014; Weblink: file:///C:/Users/kwhite/Downloads/NIHMS683046-supplement-Supp.pdf
[7] National Academy of Sciences (NAS). National Research Council (NRC). 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. Board of Environmental Studies and Toxicology. Division of Earth and Life Sciences.
[8] Washington State Department of Ecology (March 2014). Formaldehyde and 15 Volatile Organic Chemicals in Children's Products. See https://fortress.wa.gov/ecy/publications/SummaryPages/1404015.html

As summarized above, the CSPRR must be a science based and serve to improve public health in a transparent and objective way. The DoE should: (1) revise the CSPRR language to include provisions regarding exposure and potential for adverse health impact from foreseeable use of a product, (2) review the exposure and toxicity scoring for formaldehyde to ensure it is accurate, (3) make all the underlying information available that was used to prioritize formaldehyde as discussed in Smith et al. (2016) and (4) conduct a margin of exposure assessment for formaldehyde to justify its inclusion on the CHCC.

We thank you for your consideration of these comments.

Regards,

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Senior Director
Chemical Products & Technology Division