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Please see attached comments from the American Chemistry Council Formaldehyde Panel.



July 14, 2023

Safer Products for WA
Hazardous Waste and Toxics Reduction Program
WA Department of Ecology
Olympia, WA 98504-7600

Submitted Electronically to: SaferProductsWA@ecy.wa.gov and online comment form.

RE: Draft Identification of Priority Chemicals Report to the Legislature: Safer Products for Washington Cycle 2, Implementation Phase 1

Dear WA Department of Ecology Staff,

The American Chemistry Council (ACC)¹ Formaldehyde Panel (Panel) appreciates the opportunity to comment on the Washington State Department of Ecology (the Department) Draft Identification of Priority Chemicals Report to the Legislature: Safer Products for Washington Cycle 2, Implementation Phase 1 (Draft Phase 1 Report). The Formaldehyde Panel represents producers, suppliers and users of formaldehyde products, as well as trade associations representing key formaldehyde applications.

Ensuring the safety of consumers and the environment is an important objective of Safer Products for Washington. To effectively accomplish this objective, the Department must prioritize chemical hazards demonstrated by the best available science and applications that present a real risk to consumers and the environment. The Panel offers the Department the following comments related to its proposed identification of formaldehyde and formaldehyde releasers in Phase 1 of Cycle 2 of the Safer Products for Washington program. As a threshold issue, the Panel observes that many key studies regarding the risks presented by formaldehyde are not cited, described, or taken into account in the Draft Phase 1 Report. In order to ensure that the Department's actions are consistent with the best available science and with the Department's statutory obligations, these studies and their conclusions must be included in the final report and in the Department's analysis of formaldehyde throughout Cycle 2.

These comments include the following key points:

- natural production of formaldehyde in the body,
- safe thresholds that exist for formaldehyde exposure,
- threshold like dose-response for nasal tumor formation,
- lack of biological plausibility between inhaled formaldehyde and leukemia,

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®; common sense advocacy designed to address major public policy issues; and health and environmental research and product testing. The business of chemistry is a \$486 billion enterprise and a key element of the nation's economy. It is among the largest exporters in the nation, accounting for ten percent of all U.S. goods exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

- inaccurate classification of formaldehyde as an asthmagen,
- use of third-party chemical hazard assessments to support the proposed identification of formaldehyde and formaldehyde releasers,
- existing formaldehyde standards and regulations, and
- ongoing formaldehyde risk evaluation at the federal level.

Formaldehyde is Naturally Produced in the Body

Formaldehyde is widespread in nature and is present in every living thing. It is present in food that we consume every day. For example, formaldehyde is found naturally occurring in apples (6.3-22.3 ppm), bananas (16.3 ppm), grapes (22.4 ppm) and pears (38.7-60 ppm)². During the June 21, 2023, Safer Products for Washington webinar, the Department made a statement regarding endogenous and exogenous formaldehyde. The Department recognized endogenously produced formaldehyde, however stated that exogenous formaldehyde acts differently. The Panel would like to take the opportunity to correct that statement. Formaldehyde is made endogenously because it is essential to the one-carbon metabolism, which supports life. Often exogenous (inhaled) and endogenous formaldehyde are thought to be different when they are the exact same molecule. There is no data to support endogenous and exogenous formaldehyde are different. As such, at concentrations that do not upset normal variability in metabolic processes, inhaled exogenous formaldehyde presents no added risk. Furthermore, metabolic detoxification mechanisms and pathways have been well studied and prevalent in the case of formaldehyde toxicity.³ The Department should not consider banning formaldehyde in consumer products when the concentrations in those products are lower than the concentrations naturally present in our own bodies and in the foods we eat. Any contrary action would be inconsistent with the Department's statutory obligations. Further, neither of the studies described in this section are cited in the Draft Phase 1 Report.

Formaldehyde is Well Studied and Safe Thresholds for Exposure Exist

The available scientific literature provides considerable evidence of an observed threshold for effects from formaldehyde exposure. In 2010, the World Health Organization (WHO) recognized that a threshold-based approach is appropriate for establishing indoor air quality guidelines for formaldehyde.⁴ In 2018, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) also recognized a threshold for formaldehyde exposure when establishing its values for safe long-term exposure.⁵ Neither of these studies are cited in the Draft Phase 1 Report.

There is a Threshold-Like Dose Response for Nasal Tumor Formation in Rats, an Updated Mode of Action and Inconclusive Epidemiological Evidence

There is a wealth of scientific evidence supporting a threshold between formaldehyde exposure and nasopharyngeal cancer (NPC). In 2011, Lu et al.⁶ generated the first molecular dosimetry data using

² Centre for Food Safety. (2017, May 2). Foods Known to Contain Naturally Occurring Formaldehyde. Hong Kong. The Government of the Hong Kong Special Administrative Region. Retrieved from https://www.cfs.gov.hk/english/programme/programme_rafs/programme_rafs_fa_02_09.html;

³ European Food Safety Authority. (2014). Endogenous formaldehyde turnover in humans compared with exogenous contribution from food sources. Parma, Italy. EFSA Journal, 12(2), 3550. Retrieved from <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2014.3550>.

⁴ World Health Organization (WHO). 2010 Formaldehyde. In: Selected pollutants. WHO Guidelines for Indoor Air Quality. WHO, Regional Office for Europe, Copenhagen, Denmark, pp. 103-156.

⁵ The French Agency for Food, Environmental and Occupational Health & Safety. (2018). Opinion on the revision of ANSES's reference values for formaldehyde: occupational exposure limits (OELs), derived no-effect levels (DNELs) for professionals, toxicity reference values (TRVs) and indoor air quality guidelines (IAQGs)

⁶ Lu, K., B. Moeller, M. Doyle-Eisele, J. McDonald, & J. Swenberg (2011) Molecular Dosimetry of N2-hydroxymethyl-dG DNA adducts in rats exposed to Formaldehyde Chemical Research in Toxicology 24(2):159-161

formaldehyde-specific DNA biomarkers and reported the formation of exogenous formaldehyde DNA adducts was highly non-linear. And in 2019, Leng et al.⁷ detected endogenous but not exogenous adducts in rats exposed to low doses of formaldehyde by inhalation. In 2020, the mode of action (MOA) framework for nasal tumors was updated by Thompson et al.⁸ It was found that there are exposure concentrations below which there are no detectable biomarkers of exposure in rats. Finally, Marsh et al. analyzed (2014)⁹ and re-analyzed (2016)¹⁰ NPC mortality and formaldehyde exposure in one of ten factories reported in the 2004 follow-up of the National Cancer Institute (NCI) formaldehyde cohort study. The Marsh analyses found the NPC mortality and formaldehyde exposure in the one factory reported in the NCI study was neither consistent with the available data nor with other research findings based on this group of U.S. formaldehyde workers. None of the studies described in this section are cited in the Draft Phase 1 Report.

There is a Lack of Biological Plausibility for a Causal Association Between Inhaled Formaldehyde and Lymphohematopoietic Cancers

The Department specifically references the National Toxicology Program's (NTP) conclusion of an association between formaldehyde exposure and leukemia. However, NTP's classification of formaldehyde as a "known human carcinogen" was issued without conducting a causation evaluation. In fact, NTP states this "only indicates a potential hazard and does not establish the exposure conditions that would pose cancer risks to individuals in their daily lives."¹¹

Other authoritative bodies, particularly in the EU, have reached vastly different conclusions regarding formaldehyde and leukemia. The European Chemicals Agency's (ECHA) Committee for Risk Assessment (RAC) found that "the epidemiology data do not show consistent findings across studies for leukemia rates" and "the lack of biological plausibility argue against formaldehyde as the cause of the increased rates".¹² Similarly the EU Scientific Committee on Occupational Exposure Limits (SCOEL) concluded, "there is no biological plausibility for an induction of human leukemia by formaldehyde exposure" and "systemic genotoxic action of inhaled FA is not likely".¹³

Lastly, there is extensive scientific literature that also does not support a causal association between formaldehyde and leukemia. For example, in 2020, Gentry et al.¹⁴ critically evaluated the plausibility of the association between formaldehyde inhalation exposure and leukemia. Their

⁷ Leng, J., Liu C., Hartwell, J.H., Yu, R., Lai, Y., Bodnar, W.M., Lu, K., and Swenberg, J.A. (2019). "Evaluation of inhaled low-dose formaldehyde-induced DNA adducts and DNA-protein cross-links by liquid chromatography-tandem mass spectrometry." *Archives of toxicology*: 1-11

⁸ Thompson, C. M., Gentry, R., Fitch, S., Lu, K., & Clewell, H. J. (2020). "An updated mode of action and human relevance framework evaluation for Formaldehyde-Related nasal tumors." *Critical Reviews in Toxicology*, 50(10), 919-952.

⁹ Marsh, G., Morfeld, P., Collins, J., Symons, JM. (2014). Issues of methods and interpretation in the National Cancer Institute formaldehyde cohort study. *Journal of Occupational Medicine and Toxicology* 9, no. 1: 1.

¹⁰ Marsh, G., Morfeld, P., Zimmerman, S., Liu, Y., and Balmert, L. (2016). An updated re-analysis of the mortality risk from nasopharyngeal cancer in the National Cancer Institute formaldehyde worker cohort study." *Journal of Occupational Medicine and Toxicology* 11, no. 1: 1.

¹¹ NTP. 2010. Report on Carcinogens, Twelfth Edition. Introduction. p.3 Available at <http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40DBA9EC0928DF8B15>

¹² RAC (Risk Assessment Committee), 2012. Opinion Proposing Harmonised Classification and Labelling at EU Level of Formaldehyde. European Chemicals Agency, Helsinki 30 November 2012

¹³ European Commission, Directorate-General for Employment, Social Affairs and Inclusion, Klein, C., Nielsen, G., Johanson, G. et al., SCOEL/REC/125 formaldehyde – Recommendation from the Scientific Committee on Occupational Exposure Limits, Publications Office, 2017, <https://data.europa.eu/doi/10.2767/399843>

¹⁴ Gentry, R., Thompson, C.M., Franzen, A., Salley, J., Albertini, R., Lu, K., and Greene, T. (2021). "Using mechanistic information to support evidence integration and synthesis: a case study with inhaled formaldehyde and leukemia." *Critical Reviews in Toxicology*, 1-34

analysis focused on the postulated MOA for leukemia following inhalation exposure to formaldehyde and the research relevant to the key events using the WHO/International Programme on Chemical Safety (IPCS) MOA framework. The authors concluded that none of the four postulated MOAs evaluated was biologically plausible, using the IPCS MOA framework, and the weight of evidence did not support the postulated MOAs. None of the studies described in this section, except for the NTP report, are cited in the Draft Phase 1 Report.

Typical Formaldehyde Exposures are Not Associated with Asthma

A number of reviews do not support the classification of formaldehyde as an asthmagen. In ECHA's 2019 substance evaluation report on formaldehyde, it was concluded that "a very limited number of case reports have been published on formaldehyde-related asthma but these data do not provide sufficient evidence that formaldehyde should be considered a risk factor for respiratory tract sensitization."¹⁵ The National Academy of Sciences (NAS) reviewed asthma and indoor air exposures.¹⁶ In this review NAS only found limited or suggestive evidence of an association between formaldehyde exposure and exacerbations of asthma. Finally, in 2017 Golden and Holm¹⁷ evaluated the literature and found that studies reviewed incorrectly concluded that there was a significant positive association between formaldehyde exposure and childhood asthma. None of the studies described in this section are cited in the Draft Phase 1 Report.

The Third-Party Chemical Hazard Assessments Should Not be Used to Screen the Formaldehyde Literature

Ecology's reliance on third-party assessments to screen relevant formaldehyde literature is misplaced. Such an approach introduces bias and subjectivity into Ecology's rulemaking process, which is clearly inconsistent with Ecology's statutory obligations. It is also contrary to Ecology's commitment in the Draft Phase 1 Report that it will evaluate chemicals in a consistent, non-biased manner. Ecology's reliance on third-party chemical hazard assessments to screen formaldehyde literature is also unnecessary. The available formaldehyde literature is vast and complex.

Consumer Exposure to Formaldehyde is Low and Adequately Regulated

The Department describes several potential exposures to formaldehyde including indoor and outdoor air as well as dermal exposure. There are a number of publications and reviews that demonstrate consumer exposure does not pose cancer risk. In a 2017 publication, Sheehan et al.¹⁸ evaluated formaldehyde concentrations in approximately 18,000 residences and found that formaldehyde emissions posed virtually no cancer risk. The typical indoor exposure levels are between 16 and 32 ppb.¹⁹ The WHO reviewed epidemiological studies from the NCI and concluded that "for purposes of indoor air guideline setting, that no excess nasopharyngeal cancer was reported at a mean formaldehyde exposure at or below 1.25 mg/m³ [1,020 ppb] and with peak exposures

¹⁵ European Chemicals Agency (June 2019). Substance Evaluation Conclusion as required by REACH Article 48 and Evaluation Report for Formaldehyde. See: <https://echa.europa.eu/documents/10162/cc0acabf-6e82-f2ed-5dbe8058f48ce6c4>

¹⁶ National Academy of Sciences (NAS) (2000) Institute of Medicine (IOM). Clearing the Air: Asthma and Indoor Air Exposures. Washington, DC: National Academy Press.

¹⁷ Golden, R., and Holm, S. (2017). Indoor Air Quality and Asthma: Has Unrecognized Exposure to Acrolein Confounded Results of Previous Studies? Dose Response. Feb 15;15(1).

¹⁸ Sheehan, P., Singhal, A., Bogen, K.T., MacIntosh, D., Kalmes, R.M., McCarthy, J. 2017. Potential Exposure and Cancer Risk from Formaldehyde Emissions from Installed Chinese Manufactured Laminate Flooring. Risk Analysis. 38(6): 1128-1142

¹⁹ Salthammer, T., Mentese, S., & Marutzky, R. (2010). Formaldehyde in the indoor environment. Chemical Reviews, 110(4), 2536-72.

below 5 mg/m³ [4,100 ppb]".²⁰ Taking the average indoor exposure levels of 16-32 ppb, which again is for all sources in the home, it is abundantly clear that average indoor air exposures fall very far below the threshold for cancer risk. Lastly, although dermal exposure to formaldehyde-containing liquid is possible for some applications, routine skin contact is not likely. This is because the irritating and absorptive properties preclude ongoing skin contact and systemic effects.²¹ Further, NIOSH states that "data on in vivo toxicokinetics in animals suggest that formaldehyde has limited potential to be absorbed through the skin (i.e., percent absorption of less than 10%)." ²² None of the studies described in this section are cited in the Draft Phase 1 Report.

As highlighted below, there are federal agencies that have reviewed and, in some cases, regulated formaldehyde.

- In December 2016, the Environmental Protection Agency (EPA) issued a final rule to implement the Formaldehyde Emission Standards for Composite Wood Products Act. This rule includes formaldehyde emission standards applicable to hardwood plywood, medium density fiberboard (MDF), and particleboard, and finished goods containing composite wood products, that are sold, supplied, offered for sale, or manufactured (including imported) in the United States. EPA worked with the California Air Resources Board to ensure the final federal rule set emission levels consistent with California's requirements for composite wood products.
- The Department of Housing and Urban Development (HUD) has standards in place that limit formaldehyde emissions from wood products used in manufactured housing. HUD also requires that all such products be certified by a nationally-recognized testing laboratory to verify compliance with HUD's formaldehyde emissions limits.
- The Consumer Product Safety Commission (CPSC) has extensively studied formaldehyde emissions in the home environment and has not recommended additional regulation or limits based on the available science.
- The Food and Drug Administration (FDA) has reviewed the safety of formaldehyde and approved its use as an indirect food additive in a number of materials having contact with food.

The state of Washington has already taken steps to regulate formaldehyde in certain products. It recently passed its Toxics Free Cosmetics Act on May 15, 2023. This bill bans formaldehyde and formaldehyde releasers in cosmetics and personal care products.

Formaldehyde is Currently Being Evaluated by EPA's Under the Toxic Substances Control Act

Formaldehyde was designated as a high priority chemical for risk evaluation under the Toxic Substances Control Act (TSCA) in December of 2019. Since then, EPA has been scoping and drafting its risk evaluation for formaldehyde. A final scope of the risk evaluation was released in August 2020 and a draft of the risk evaluation should be released this year. The scope of the risk evaluation includes any potential consumer exposures from a broad range of products, including: floor coverings; foam seating and bedding products; cleaning and furniture care products; furniture;

²⁰ World Health Organization (WHO). 2010 Formaldehyde. In: Selected pollutants. WHO Guidelines for Indoor Air Quality. WHO, Regional Office for Europe, Copenhagen, Denmark, pp. 103-156.

²¹ ECHA (2019). Worker exposure to formaldehyde and formaldehyde releasers. Available at: https://echa.europa.eu/documents/10162/13641/investigationreport_formaldehyde_workers-exposure_final_en.pdf/ac457a0c-378d-4eae-c602-c7cd59abc4c5

²² NIOSH Skin Notation Profiles: Formaldehyde/Formalin, April 2011. Available at 2011-145.pdf (cdc.gov)

fabric, textile, and leather products (including clothing); water treatment products; laundry and dishwashing products; personal care products; adhesives and sealants; paint and coatings; building and construction materials; electrical and electronic products; automotive care products; lubricants and greases; fuels and related products; lawn and garden products; paper products; plastic and rubber products; toys; playground and sporting equipment; arts, crafts, and hobby materials; ink, toner, and colorant products; and photographic supplies.²³ The risk evaluation and any subsequent risk management will thus very likely take into account any applications the Department would evaluate for formaldehyde, if designated as a priority chemical under its program. Therefore, any regulatory action the Department sought to impose restricting or prohibiting the presence of formaldehyde in products could be preempted pursuant to 15 U.S.C. § 2617.

The Panel urges the Department to consider the wealth of scientific information and reviews described in these comments when considering its final designation of priority chemistries under the Safer Products program. It is also important for the Department to consider existing and potential future regulations for formaldehyde during this prioritization exercise so that Department resources can be effectively used to protect consumer and environmental health. Please feel free to contact me at julianne_ogden@americanchemistry.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Julianne Ogden". The signature is fluid and cursive, with the first name being more prominent than the last.

Julianne Ogden
Associate Director, American Chemistry Council
On behalf of the Formaldehyde Panel

²³ EPA (2020). Final Scope of the Risk Evaluation of Formaldehyde, Table 2-2, available at https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf.