ALLIANCE FOR AUTOMOTIVE INNOVATION

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Submitted through https://www.regulations.gov

Jeffrey Putt
Existing Chemicals Risk Management Division (7404M)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
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RE: Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Notice of Availability, Public Meetings and Request for Comment, EPA-HQ-OPPT-2023-0613

Dear Mr. Putt:

The Alliance for Automotive Innovation[1] (Auto Innovators) appreciates the opportunity to provide comments on EPA's draft risk evaluation for formaldehyde.[2] Auto Innovators represents the auto manufacturing sector, including automakers that produce and sell approximately 95% of the new light-duty vehicles in the United States. Our mission is to work with policymakers to realize a future of cleaner, safer, and smarter personal transportation and to work together on policies that further these goals, increase U.S. competitiveness, and ensure sustainable, well-paying jobs for citizens throughout the country.

EPA is requesting comment on the scope of the draft risk evaluation, the Office of Pollution Prevention and Toxics and Office of Pesticide Programs' joint hazard assessments for human and ecological health, and the exposure and risk characterizations.

EPA's draft risk evaluation assessed the risks that may arise from ways in which people may be exposed to formaldehyde from the production and use of products that are subject to TSCA. EPA determined that workers who are in workplaces where formaldehyde is used are at the most risk from formaldehyde exposure. EPA also found that people who frequently use certain consumer products that contain formaldehyde are at risk. These products included car waxes, some crafting supplies, and fabrics or leather goods treated with formaldehyde, including seat cushions and covers in automobiles. EPA found no unreasonable risk to the environment.

As EPA is aware, formaldehyde is a basic building block chemical that is essential to the manufacturing and processing of many products that serve as components of thousands of everyday consumer products. In the automotive sector, "formaldehyde-based technologies are used to make interior molded and under-the-hood components that allow for higher fuel efficiency by reducing

[1] From the manufacturers producing most vehicles sold in the U.S. to autonomous vehicle innovators to equipment suppliers, battery producers and semiconductor makers – Alliance for Automotive Innovation represents the full auto industry, a sector supporting 10 million American jobs and five percent of the economy. Active in Washington, D.C. and all 50 states, the association is committed to a cleaner, safer, and smarter personal transportation future. www.autosinnovate.org.
[2] 89 Fed. Reg. 18,933 (Mar. 15, 2024).

vehicle weight. It is also used in the production of highly durable exterior primers, clear coat paints, tire-cord adhesives, brake pads and fuel system components."[3] When used in the production or processing of these uses, its end use is primarily in a converted form, where the formaldehyde is spent or consumed in the production of the final product.

The last point in the statement above is critical when assessing consumer exposure to the articles and components that EPA considered conditions of use (COUs) for formaldehyde. Recognizing that TSCA requires that EPA take action to mitigate any risk(s) that it finds to be unreasonable, if EPA assumes there is exposure to formaldehyde from a consumer product where no formaldehyde is present in the final product, that flaw in its exposure assessment could result in EPA imposing risk mitigation requirements that are not only unnecessary but potentially disruptive to commerce.

Given the short amount of time to review all the documents associated with this risk assessment, our comments are focused predominantly on concerns with EPA's approach to assessing exposure. These include:

- Uncertainties in the Exposure Assessment
- TSCA Section 6(2)(E) – Articles
- TSCA Section 6(c)(2)(D) – Replacement Parts
- Inclusion of Composite Wood and Laminate Products

A. Uncertainties in the Exposure Assessment

As outlined in EPA's ExpoBox, uncertainty in an exposure assessment can be qualitative or quantitative. "Qualitative uncertainty may be due to a lack of knowledge about the factors that affect exposure, whereas quantitative uncertainty may come from the use of non-precise measurement methods."[4] In this draft assessment, both qualitative and quantitative uncertainties decrease the level of reliability of the exposure component of EPA's determinations of unreasonable risk. Specific examples of these uncertainties are listed below.

1. Combustion and Secondary Sources of Formaldehyde

Because combustion and secondary formation are so abundant and likely result in co-occurring exposures, this draft risk assessment could not practically or reasonably differentiate secondary formation, formation from combustion, and direct releases of formaldehyde with certainty for this draft risk evaluation. Secondary formation and combustion are the largest contributor of formaldehyde to ambient air and indoor air concentrations. A full quantitative evaluation of exposure and risk from formaldehyde produced during secondary formation and combustion was not practicable and would impede efforts to conduct a scientifically sound and fit-for-purpose evaluation under TSCA within statutory timeframes. For purposes of this TSCA draft risk evaluation for

[3] *Formaldehyde: Automotive Applications*, American Chemistry Council, https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-automotive-applications.
[4] *Uncertainty and Variability*, U.S. Environmental Protection Agency, https://www.epa.gov/expobox/uncertainty-and-variability.

> formaldehyde, EPA considered these as background exposures that are accounted for in the outdoor and indoor air exposure assessment.[5]

The overwhelming influence of background exposures, such as those acknowledged by EPA above, is perhaps the most significant of the quantitative uncertainties. However, when combined with a confluence of additional uncertainties, the cumulative impact on the exposure assessment of those background exposures has resulted in a serious overestimation of risk.

2. Dissipation Over Time

EPA has not taken into consideration that formaldehyde (when present) dissipates over time, and ignoring the fact that formaldehyde dissipates over time is another critical quantitative flaw in EPA's exposure assessment. As EPA describes its modeling:

> While measured formaldehyde concentrations from AHHS II represent homes that have a combination of new and old materials that have off gassed over time (and potentially several decades), CEM does not incorporate chemical half-life (EPA, 2019). COU-specific estimates represent formaldehyde air concentrations from new articles only. Hence, total modeled estimates may represent formaldehyde air concentrations from a newly built home (or automobile), based on the TSCA COUs assessed.[6]

Use of only the concentrations at time of a new article overstates the acute or chronic exposure concentration for receptors for a given exposure scenario. Any assessment of exposure should reflect an ever-decreasing level of formaldehyde that may be present. If an exposure assessment assumes a steady state of the highest possible chemical concentration in the media (in this case, air), the resultant risk assessment overestimates the potential risk.

The choice to not address dissipation is doubly confusing given that EPA has included a clear dissipation curve that shows a rapid decrease in formaldehyde emissions after initial installation of an article or component.

> Figure_Apx F-1 displays the general formaldehyde dissipation in residential indoor air [EPA's surrogate of choice for vehicle cabins]. The figure shows an initial spike in concentration from off-gassing following the initial installation of new articles. This is followed by a rapid decrease in concentrations over the first few months.[7]

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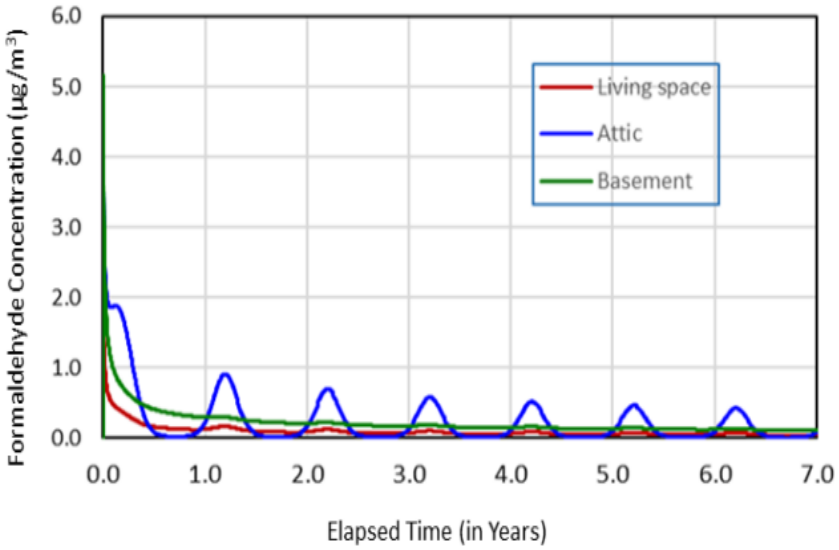
[5] U.S. Environmental Protection Agency, Conditions of Use of the Draft Risk Evaluation of Formaldehyde (Mar. 2024) at 15, *available at* https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-conditions-of-use-public-release-hero-march2024.pdf (hereinafter Conditions of Use Document).
[6] U.S. Environmental Protection Agency, Draft Indoor Air Exposure Assessment for Formaldehyde (Mar. 2024) at 46, *available at* https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-indoor-air-exposure-assessment-for-formaldehyde-public-release-hero-march2024.pdf (hereinafter Draft Indoor Air Exposure Assessment).
[7] *Id.* at 52.



Figure_Apx F-1. General Formaldehyde Dissipation in a Residence

Auto Innovators recommends that EPA revise its risk evaluation, taking into account the dissipation curve, as well as factors such as air flow, turnover, etc., since a home's (or automobile's) air does not remain static.

3. Assessing Real versus Assumed Exposure

While formaldehyde may be used in the production of any specific product or article, its use does not mean that formaldehyde is present in the final product or that, even if bound up in the final article, there is a potential for exposure. EPA's exposure assessment assumes that formaldehyde is being released from all the COUs regardless of whether there is any demonstrated off-gassing. A fuller discussion of exposure potential from articles is presented below in section B.

4. Specific Uncertainties to Consumer Exposure Associated with Automobiles

EPA relied on two studies (Lawryk and Weisel, 1996; Lawryk et al., 1995) to assess exposure to formaldehyde in the cabins of automobiles. The two automobiles used in this study were from the 1988 and 1987 model years. EPA recognizes that "it is possible the materials used in these two older automobiles were relatively strong and persistent off-gassers of formaldehyde being manufactured in the late-1980s to the mid-1990s" and further states "[v]ehicular air circulation systems and the materials used to build the indoor cabin of automobiles have likely changed significantly since the publication of this study in 1996."[8] Auto Innovators agrees with EPA's noted limitations of these studies.

[8] *Id.* at 32.

5. Lack of Scientific Review

We are also concerned that EPA "rushed" this assessment and released this document before the Science Advisory Committee on Chemicals (SACC) had an opportunity to review EPA's approaches to this relatively novel situation and to provide constructive advice and guidance on how to better incorporate and address all the uncertainties in this assessment. As EPA stated, "A full quantitative evaluation of exposure and risk from formaldehyde produced during secondary formation and combustion was not practicable and would impede efforts to conduct a scientifically sound and fit-for-purpose evaluation under TSCA within statutory timeframes."[9]

Releasing this draft risk assessment before a SACC review is an unusual sequencing and not reflective of past review practices. This rushed approach makes public a draft risk assessment that has not had the benefit of review by the SACC, an advisory committee mandated by the Lautenberg Chemical Safety Act (LCSA) amendments and specifically charged with providing independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated by TSCA. Given the unique exposure issues surrounding this draft assessment, EPA, the public and the regulated community would have been better served by being informed by the scientific and technical expertise of this independent group of advisors.

B. TSCA Section 6(c)(2)(E) – Articles

It is challenging to determine where EPA stands on the potential exposure to formaldehyde from articles where formaldehyde may have been an input but is no longer present or present only in minimal concentrations. On the one hand, EPA has stated that new formaldehyde-based materials introduced to homes or automobiles and construction of new residences and automobiles using formaldehyde-based materials are expected to be among the highest concentrations.[10] On the other, EPA has stated that for articles, its Consumer Exposure Model (CEM) did not yield any expected inhalation exposures, and does not expect dermal (skin loading) or oral exposures from use of such products.[11]

One reason that accurately assessing potential exposures from articles is critical is that the statutory language in LCSA directs EPA to take a more focused and narrow approach when identifying articles that EPA believes need to be managed under TSCA sections 4, 5 or 6 based on their unique contribution to overall risk.

> In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or the category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).[12]

[9] Conditions of Use Document at 15 (emphasis added).
[10] Draft Indoor Air Exposure Assessment at 5.
[11] Draft Consumer Exposure Assessment at 26.

The intent of this new provision was to recognize that for the most part, articles do not pose the same exposure (and subsequent risk) concerns as the chemicals that may have been used in the manufacture (including import), processing and use of those articles. TSCA section 6(c)(2)(E) provides EPA with the authority to regulate articles, but only "to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or the category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation."

In this draft risk evaluation, EPA has not identified what exposure(s) are occurring as a direct result of the "exposure to the chemical substance or mixture from the article." EPA does not appear to have recognized the distinction between the exposures, risks, and impacts associated with direct chemical exposure versus any potential limited or negligible exposure to a manufactured article. By ignoring the direction of TSCA section 6(c)(2)(E) in this draft risk assessment, EPA is fundamentally making it "inapplicable," a precedent that undermines the very intent of this section of LCSA.

Auto Innovators urges EPA to clarify its interpretation of the applicability of TSCA section 6(c)(2)(E) and conduct the analyses required by the statute. We request that EPA clearly assess any potential exposure from articles used in the automotive sector, the predicted exposure to the article itself, not use exposure to the chemical formaldehyde as a default, and finally, characterize the contribution of these articles to overall risk. We request this be done at the risk assessment stage, so that when formaldehyde moves to the risk management phase, EPA's risk management staff will have the information they need to appropriately apply the requirements of TSCA section 6(c)(2)(E).

C. TSCA Section 6(c)(2)(D) – Replacement Parts

Auto Innovators cannot find any recognition of TSCA section 6(c)(2)(D) in this draft risk assessment. TSCA section 6(c)(2)(D) states that the Administrator "shall" exempt replacement parts unless the Administrator finds that replacement parts contribute significantly to the risk identified in a risk evaluation:

> The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.[13]

If EPA has not specifically conducted a risk assessment to determine whether replacement parts contribute significantly to any potential formaldehyde unreasonable risk determination, we question how EPA will be able to make the required determination under TSCA section 6(c)(2)(D) to exempt this critical group of articles. Therefore, as part of the final risk assessment, EPA should clearly state that replacement parts were not assessed and therefore remain exempt per TSCA section 6(c)(2)(D).

[13] 15 U.S.C. § 2605(c)(2)(D) (emphasis added).

D. Inclusion of Composite Wood and Laminated Products

In the 2020 final scope document for formaldehyde,[14] EPA determined that three types of composite wood products[15] and laminated products would not be included in the scope of the risk evaluation. Those three products are currently regulated under the Formaldehyde Emission Standards for Composite Wood Products final rule,[16] promulgated under TSCA Title VI.

For reasons not clearly articulated in this draft risk assessment, EPA determined that it will now include all composite wood products, including those regulated under TSCA Title VI. This appears to be at odds with an additional uncertainty expressed by EPA:

> However, the Agency also recognizes that allocating exposures due to emissions from finished goods in indoor environments might be difficult due to the monitoring data available for this draft risk evaluation which does not necessarily reflect information after the implementation of TSCA Title VI.[17]

While we recognize that EPA stated in its recent final rule Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)[18] that it intends to consider exposures already regulated under other EPA and federal statutes, it is unclear why EPA is also including a use already regulated by TSCA. In effect, EPA is overriding its existing TSCA regulations, and possibly running counter to statutorily defined measures. Such an approach is concerning, as the unintended consequences could be far-reaching and the potential exists to circumvent the requirements of the Administrative Procedures Act (APA). For example, previously, new vehicles were excluded from the scope of the final 2016 Formaldehyde Emission Standards for Composite Wood Products rule. If EPA determines that composite wood products pose an unreasonable risk to consumers based on its risk assessment for formaldehyde, will EPA override the exclusion for new vehicles in that rule by opting to regulate under TSCA section 6 rather than revisiting under TSCA Title VI? Auto Innovators recommends that EPA not revisit here the ground it previously covered in its Formaldehyde Emission Standards for Composite Wood Products final rule.

E. Workplace Exposures

EPA stated in its final scope that it will "consider and incorporate applicable [engineering controls] and/or [personal protective equipment] into exposure scenarios."[19] Auto Innovators here affirms that the auto industry implements engineering controls and personal protective equipment (PPE) requirements published from the Occupational Health & Safety Administration, ACGIH, and other known industry standards; therefore, they should be considered when evaluating exposure and the reduced risk associated with the use of formaldehyde.

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[14] U.S. Environmental Protection Agency, Final Scope of the Risk Evaluation or Formaldehyde (Aug. 2020), *available at* https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf (hereinafter Final Scope).
[15] Hardwood plywood, particleboard, and medium density fiberboard (including thin-medium density fiberboard).
[16] 81 Fed. Reg. 89,674 (Dec. 12, 2016).
[17] Conditions of Use Document at 16.
[18] 89 Fed. Reg. 37,028 (May 3, 2024).
[19] Final Scope at 67.

We thank you for your consideration of these comments and recommendations. If you have any questions, please feel free to reach out to me.

Sincerely,

Catherine Palin
Senior Attorney & Director of Environmental Policy
Alliance for Automotive Innovation