EPA Issues Draft Risk Evaluation for Formaldehyde, Preliminarily Finds That Formaldehyde Poses Unreasonable Risk to Human Health

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The U.S. Environmental Protection Agency (EPA) announced on March 15, 2024, the availability of and solicited public comment on the 2024 draft risk evaluation for formaldehyde prepared under the Toxic Substances Control Act (TSCA). 89 Fed. Reg. 18933. EPA states that it “preliminarily finds that formaldehyde poses unreasonable risk to human health. The risk evaluation notes that these risks may not apply to everyone, everywhere and describes some of the sources of uncertainties in EPA’s findings.” EPA will submit the draft risk evaluation to the Science Advisory Committee on Chemicals (SACC) for peer review. EPA also announced that there will be two virtual public meetings of SACC. Written comments on the draft risk evaluation must be submitted by May 14, 2024.

Draft Risk Evaluation Findings

On its web page regarding the risk evaluation for formaldehyde, EPA states it “evaluated the risks that arise from ways in which people may be exposed to formaldehyde from the production and use of products that are subject to TSCA — as opposed to exposures from those products that are excluded from TSCA (such as pesticides and exposures from sources of formaldehyde that are biogenic such as breathing and the decomposition of leaves) and exposures from other sources of formaldehyde.” EPA found that workers in workplaces where formaldehyde is used are at the most risk from formaldehyde exposure. According to EPA, workers may be exposed to formaldehyde by inhaling it after it is released into the air or by making skin contact with formaldehyde-containing materials. EPA notes that it made these conclusions without assuming that worker protections, such as wearing personal protective equipment (PPE), were in place, “although EPA is aware that many employers do take measures to protect the safety of their workers.”

EPA states that it also found that people who frequently use certain consumer products containing formaldehyde are at risk. According to EPA, these products include car waxes, some crafting supplies, and fabrics or leather goods treated with formaldehyde. EPA notes that a person’s risk from these products depends on how long and how frequently the products are used, however, and in many cases, exposures from these products are at the same or lower levels than exposures from
other sources of formaldehyde in the home, such as candles or cooking. EPA states that people may also be exposed to more formaldehyde in their homes if the homes are newer or contain newer furniture because building products and furniture can release formaldehyde at higher levels when newly formulated. Finally, people living near facilities releasing formaldehyde may have higher exposures than those located further away.

EPA notes that it also evaluated formaldehyde’s impact on the environment and found that formaldehyde is not expected to last long in water, sediment, or soil based on its physical and chemical properties. EPA “did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for formaldehyde.”

Uses of Formaldehyde

EPA states that in the final scope, it identified conditions of use (COU) associated with the importing; processing; distribution in commerce; industrial, commercial, and consumer uses; and disposal of formaldehyde, for example:

- Adhesive and sealants;
- Pesticides and agricultural chemicals;
- Lawn and garden products;
- Personal care products;
- Plastic materials;
- Resins, glues, and binders;
- Paper manufacturing;
- Various petrochemical processes and products;
- Wood product manufacturing; and
- Textiles, apparel, and leather.

The above listed COUs are ways that a person or the environment could be potentially exposed to formaldehyde.

Next Steps

EPA states that it will solicit comments from SACC on the Office of Pollution Prevention and Toxics (OPPT) and Office of Pesticide Programs (OPP) joint hazard assessments for human and ecological health and the OPPT exposure and risk characterizations. EPA notes that the SACC peer review is in addition to prior external peer reviews by the National Academies of Science, Engineering, and Medicine (NASEM), EPA’s Human Studies Review Board (HSRB), and SACC peer reviews of scientific approaches used in previous TSCA risk evaluations. According to EPA, these previous peer reviews have informed the 2024 draft risk evaluation for formaldehyde.

SACC will consider and review the draft risk evaluation at a four-day virtual peer review public meeting that will be held May 20-23, 2024. A virtual preparatory public meeting will be held May 7, 2024, for SACC to consider the scope and clarity of the draft charge questions for the peer review. According to EPA, to request time to present oral comments during the virtual preparatory public meeting, registration must be completed by 12:00 p.m. (EDT) on May 3, 2024. For those not making oral comments during the virtual preparatory public meeting, registration will remain open through the end of the meeting. To make oral comments during the virtual peer review public meeting and be included on the meeting agenda, registration must be completed by 12:00 p.m. (EDT) on May 13, 2024. For those not making oral comments, registration for this meeting will remain open through the
Commentary

Bergeson & Campbell, P.C. (B&C®) was surprised to see that EPA released the draft risk evaluation on formaldehyde prior to issuing in final the draft Integrated Risk Information System (IRIS) Toxicological Review of Formaldehyde – Inhalation (the Draft IRIS Assessment), along with other critical support documents, which are still in draft form and are referenced in the draft risk evaluation. We anticipate that readers will find interest in EPA’s release of the draft risk evaluation on formaldehyde, in part, due to EPA’s reliance on the Draft IRIS Assessment and its recently issued draft updates to its Scientific Integrity Policy. We also believe that the draft risk evaluation will serve as a cautionary reminder to regulated entities about the importance of developing data, particularly occupational monitoring data, on chemical substances identified as high-priority substances under TSCA Section 6. EPA’s draft risk evaluation on formaldehyde provides examples of the perils of EPA’s use of modeling data in the absence of measured data. We elaborate on each of these statements below.

Recall that EPA released draft updates to its Scientific Integrity Policy for public comment on January 24, 2024. For further discussion, see our memorandum dated February 2, 2024. As part of EPA’s draft updates, it stated that it is the policy of EPA to:

Ensure peer review charge questions address all relevant scientific questions, including those raised in DSOs, and are free from any interference, especially interference that may inappropriately limit the scope of the review.

Compare that scientific integrity standard with the statement from the NASEM committee in its final report in response to EPA’s sponsored peer review of the Draft IRIS Assessment:

The committee…was not charged with commenting on other interpretations of scientific information relevant to the hazards and risks of formaldehyde, nor did its statement of task call for a review of alternative opinions on EPA’s formaldehyde assessment.

The NASEM committee’s response is a fair representation of the charge questions from EPA, but those charge questions do not fit well with EPA’s Scientific Integrity Policy. Furthermore, EPA is not requesting peer review from the TSCA SACC on all sections of the Draft IRIS Assessment that EPA incorporated into the draft risk evaluation on formaldehyde. For example, EPA stated the following in the draft risk evaluation on formaldehyde:

For cancer and non-cancer hazards associated with chronic inhalation exposures, the joint hazard assessment relies upon the analysis already completed in the draft IRIS assessment on formaldehyde inhalation (U.S. EPA, 2022b) and peer reviewed by the National Academies of Sciences, Engineering, and Medicine (NASEM) (NASEM, 2023).

EPA seems to be bootstrapping a limited review by NASEM to conclude that NASEM reviewed broadly EPA’s approach, even though EPA’s charge questions and NASEM’s own statements clearly document the limit of NASEM’s review.
We acknowledge that EPA is under challenging timeframes to complete its risk evaluations on high-priority substances. We are, however, concerned about the lack of consistency of EPA’s statements on peer review, given that EPA’s exclusion of “other interpretations” and “alternative opinions” goes against its prevailing view of scientific integrity, which according to EPA, includes “consideration of differing scientific opinions (DSOs) and their transparent documentation...” As we stated in our memorandum dated December 27, 2023, a fundamental reason for requesting the TSCA SACC’s peer review on the Draft IRIS Assessment is because of a legal challenge filed on the NASEM peer review, based on alleged violations of the Federal Advisory Committee Act. This suit was subsequently dismissed, but it serves as a reminder of the types of challenges that may be filed on EPA’s peer review of formaldehyde under TSCA.

Formaldehyde also presents significant challenges because of the breadth of sources of formaldehyde. For example, EPA’s model shows significantly higher concentrations from secondary sources (e.g., combustion byproducts or biodegradation) and biogenic sources (e.g., trees and humans) than point sources (industrial or commercial facilities). It is, however, unclear if EPA will conclude that even though point sources are minor contributors to general population air exposures, that such sources contribute to the overall exposures, thereby increasing the risk, even if marginally so, and thus warranting a ban on formaldehyde from all uses.

B&C again observed scientific issues in the draft risk evaluation on formaldehyde that are reoccurring themes from EPA’s previous risk evaluations with exposure monitoring values. For example, EPA stated that it followed its 1994 Guidelines for Statistical Analysis of Occupational Exposure Data (the 1994 Guidelines) when evaluating data sets that include exposure data reported as below the limit of detection (LOD). EPA summarized the approaches used as follows:

That report [i.e., the 1994 Guidelines] recommends using the ???/?2 if the geometric standard deviation of the data is less than 3.0 and ???/2 if the geometric standard deviation is 3.0 or greater.

We note that the 1994 Guidelines also state: “If 50% or more of the monitoring data are nondetectable, substitution of any value for these data will result in biased estimates of the geometric mean and the geometric standard deviation [citation omitted].” It is unclear, however, if EPA addressed this potential bias, since many of the monitoring data sets, particularly for the 15-minute worker values, consisted of more than 50% of samples below the LOD (e.g., 81% of the samples were below the LOD for composite material manufacturing). This is especially problematic given EPA’s view that absent data to show that exposures are not an unreasonable risk, EPA will seek to ban the substance rather than impose an exposure limit.

EPA did not identify reasonably available data to inform its dermal exposure assessment to workers for any of the conditions of use evaluated. EPA informed this data gap using modeling estimates. We have previously discussed the issues with EPA’s dermal exposure models, which account for the quantity of a chemical substance remaining on the skin, following exposures that may include immersion. The issue here is that EPA’s default estimates are based on values obtained using highly viscous substances (e.g., mineral oil and cooking oil), which are of questionable relevance for informing the quantity of a substance remaining on skin from substances that are gases at room temperature (e.g., formaldehyde) or low viscosity solutions of those substances (e.g., formaldehyde/methanol solutions). For further discussion, see our memorandum dated July 21, 2022.

B&C encourages interested readers to review EPA’s draft risk evaluation on formaldehyde. We note
that EPA’s approach will inform its decision making on other chemical substances identified as high-priority substances that are also endogenously produced. We note, as we have previously, that EPA’s IRIS assessment will continue to take a more prominent role in EPA’s decision making under TSCA. We, therefore, encourage interested stakeholders to stay mindful of EPA’s IRIS evaluations.

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