E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0438; FRL-11608-05-OCSPP]

Formaldehyde; Updated Draft Risk Calculation Memorandum; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or "the Agency") is announcing the availability of and soliciting public comment on an Updated Draft Risk Calculation Memorandum (or "Draft Memorandum") to inform a Revised Draft Risk Evaluation for Formaldehyde Under the Toxic Substances Control Act (TSCA). The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to human health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use (COUs). Consistent with statutory obligations and Executive Order 14303, Restoring Gold Standard Science, EPA remains committed to the highest standards of scientific integrity and reliance on the best available scientific information. To that end, and after further consideration of comments raised during the scientific peer review process, EPA is reconsidering the use of certain hazard values in the formaldehyde risk evaluation. This Notice, Draft Memorandum, and the materials included in the docket provide the science and science policy basis for determining how the revised draft inhalation point of departure (POD) impacts the corresponding draft margin of exposure (MOE) estimates and the risk determination for formaldehyde under TSCA. Although the Agency is also providing a revised draft occupational exposure value, EPA is not changing its position that formaldehyde poses unreasonable risk of injury to human health. As such, the Agency is continuing work on a proposed risk management rule for formaldehyde as required by TSCA to

ensure statutory deadlines are met and necessary protections are not delayed. EPA is also seeking additional information, specific to how formaldehyde is manufactured and used, which may inform the risk management of formaldehyde. After public comment, the Agency will determine if the proposed revisions discussed in this action warrant updating the Risk Evaluation for Formaldehyde under TSCA.

DATES: Comments must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0438, online at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information: Jeffery Putt, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics (OPPT), Office of Chemical Safety and Pollution Prevention (OCSPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3703; email address: *formaldehydeTSCA@epa.gov*.

For general information: The TSCA Assistance Information Service Hotline, Goodwill Vision Enterprises, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (800) 471-7125 or (202) 554-1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. *Does this action apply to me?*

This action is directed to the public in general and may be of particular interest to those

involved in the manufacture (defined under TSCA section 3(9) to include import), processing, distribution, use, and disposal of formaldehyde, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, state and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all of the specific entities to which this action might apply. If you need help determining applicability of this action, consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is the Agency's authority for taking this action?*

The Agency prepared this Draft Memorandum under the Toxic Substances Control Act (TSCA) (section 6, 15 U.S.C. 2605), which requires that EPA conduct risk evaluations on chemical substances and identifies the minimum components the Agency must include in all existing chemical substance risk evaluations. Each risk evaluation must be conducted consistent with the best available science, be based on the weight of scientific evidence, and consider reasonably available information, pursuant to 15 U.S.C. 2625(h), (i), and (k). See also the implementing procedural regulations at 40 CFR part 702. Consistent with statutory obligations and Executive Order (EO) 14303 (Ref. 1), Restoring Gold Standard Science, EPA is committed to the highest standards of scientific integrity and reliance on the best available scientific information.

C. *What action is the Agency taking?*

EPA is announcing the availability of and soliciting public comment on the Draft Memorandum and supporting materials in the docket. The purpose of the Draft Memorandum, including this Notice and additional draft documents in the docket, is to provide the rationale for why the Agency is considering a revised acute inhalation POD, revised uncertainty factors, and corresponding revised MOE calculations. EPA continues to conclude that exposure to formaldehyde at sufficiently high exposures for sustained duration can lead to cancer in humans.

Additionally, EPA followed the recommendations of federal advisory committees and has concluded that managing acute sensory irritation will be health-protective against other effects, including cancer. Therefore, given the use of a threshold approach, it is not necessary for the Agency to provide a separate quantitative cancer assessment. EPA is seeking comments on all aspects of the Draft Memorandum, including this approach.

D. *What should I consider as I prepare my comments?*

1. *Submitting CBI.* Do not submit Confidential Business Information to EPA through https://www.regulations.gov or email. If you wish to include CBI in your comment, please follow the applicable instructions at https://www.epa.gov/dockets/commenting-epa-dockets#rules and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at https://www.epa.gov/dockets/commenting-epa-dockets.

II. Background

A. *What is formaldehyde?*

Formaldehyde is a colorless, flammable gas at room temperature and has a strong odor. Formaldehyde is found nearly everywhere. People and animals produce and release formaldehyde. Formaldehyde is also produced when organic material including leaves, plants, and woodchips decay. Formaldehyde is also produced and released into the air when things burn, such as when cars emit exhaust, when furnaces and stoves operate, through forest fires, burning candles, and smoking. Finally, formaldehyde is used to make many products and articles such as composite wood products and other building materials, plastics, pesticides, paints, adhesives, and sealants. Industry uses formaldehyde due to its ability to combine and react with many other chemical substances and to make resilient structures that are widely used in manufacturing. Information from the 2016 Chemical Data Reporting for formaldehyde indicates that its

production volume is between 1 billion and 5 billion pounds per year (manufacture and import) (Ref. 2).

Short-term inhalation exposure to high levels of formaldehyde can cause sensory irritation and respiratory effects. Short-term skin contact can cause sensitization. Exposure over longer periods can also cause respiratory effects and cancer. The complex toxicology and exposure profiles for formaldehyde make its evaluation challenging. The formaldehyde sources that EPA evaluated in the TSCA risk evaluation, and this Draft Memorandum, involve, in general, the production and use of products that are subject to TSCA (as opposed to products that are specifically excluded from TSCA under 15 U.S.C. 2602(2)(B), such as pesticides).

B. *Regulatory History for the Formaldehyde Risk Evaluation*

In December 2019, EPA designated formaldehyde as a high-priority substance for risk evaluation under TSCA (84 FR 71924) [FRL-10003-15] (Ref. 3). EPA's OCSPP evaluates risks from formaldehyde under both TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A draft scope of the formaldehyde risk evaluation under TSCA was publicly released in April 2020 (85 FR 22733) [FRL-10008-05] (Ref. 4), and after receiving public comment, EPA issued the final scope of the formaldehyde risk evaluation in September 2020 (85 FR 55281) [FRL-10013-90] (Ref. 5). In March 2024, EPA released a draft risk evaluation (89 FR 18933) [FRL-11608-03-OCSPP] (Ref. 6) for public comment and external scientific peer review. In January 2025, EPA published a final risk evaluation for formaldehyde (90 FR 316) [FRL-11608-04] (Ref. 7). From January 2021 through January 2025, OCSPP leadership directed that OPPT and the Office of Pesticide Programs (OPP) rely upon and use the chronic non-cancer reference concentration (RfC) and cancer inhalation unit risk (IUR) that were being developed and were subsequently finalized by the Integrated Risk Information System (IRIS) program. Consistent with statutory obligations and EO 14303, Restoring Gold Standard Science, EPA is committed to the highest standards of scientific integrity and reliance on the best available scientific information. As such, OCSPP has re-evaluated the use of the IRIS chronic RfC and

cancer IUR.

EPA leveraged work products and resources across the Agency in its development of the Risk Evaluation for Formaldehyde, including consideration of hazard information from EPA's IRIS Toxicological Review of Formaldehyde (Inhalation). A draft version of the IRIS toxicological review was published in April 2022 (Ref. 8) and finalized in August 2024 (Ref. 9). The draft IRIS document was also the subject of external peer review by the National Academies of Sciences, Engineering, and Medicine (NASEM) (Ref. 10).

In addition, EPA leveraged multiple federal advisory committees and their reports to support the external peer review of formaldehyde during the risk evaluation process, including NASEM (Ref. 10), the Human Studies Review Board (HSRB) (Ref. 11), and the Science Advisory Committee on Chemicals (SACC) (Ref. 12).

The formaldehyde risk evaluation includes a series of related assessments called technical support documents (TSDs). Each document contained sub-assessments that inform adjacent, "downstream" TSDs. These TSDs addressed comments from both public and peer review. The components of the Risk Evaluation for Formaldehyde, including (but not limited to) each TSD and responses to peer review and public comments, continue to be available in the docket for this Notice.

The Draft Memorandum is supported by information in the docket which includes this Notice, supporting materials such as risk calculators for workers, consumers, and the general population — all of which are available in the docket. The docket also includes redline versions of the Revised Draft Human Health Hazard Assessment, Revised Draft Human Health Risk Assessment, Revised Draft Executive Summary, and Revised Draft Unreasonable Risk Determination to show the impact of the revisions on the overall evaluation and its components, if the Draft Memorandum were finalized.

C. *Science Policy Context*

As EPA developed and finalized documents for the FIFRA formaldehyde risk assessment

and TSCA risk evaluation from January 2021 through December 2024, as described above, the Agency used, where relevant, the chronic non-cancer RfC and cancer IUR value that were being developed and were subsequently established by EPA's IRIS program. The IRIS draft toxicological review for formaldehyde was released as draft in April 2022 (Ref. 8), reviewed by NASEM (*NASEM, 2023*) (Ref. 10), and subsequently finalized in August of 2024 (*U.S. EPA, 2024a*) (Ref. 9).

Consistent with EPA's Rule for the Protection of Human Subjects, the Agency solicited peer review on four acute inhalation human studies (*Mueller et al., 2013* (Ref. 13); *Lang et al., 2008* (Ref. 14); *Kulle et al., 1987* (Ref. 15); *Andersen and Mølhave, 1983* (Ref. 16)) along with the acute inhalation proposed PODs for formaldehyde and associated rationale from HSRB in October 2022 (Ref. 11), May 2023 (Ref. 17), and July 2023 (Ref. 18). HSRB agreed with EPA's assessment that the four human studies met appropriate scientific and ethical standards and were appropriate for the Agency to rely upon to support decision making. The HSRB also made multiple recommendations to EPA to improve the scientific analysis. Consistent with the findings of the NASEM (*2023*) (Ref. 10), HSRB was critical of observational studies, such as *Hanrahan et al*. (*1984*) (Ref. 19), which were used in the draft EPA IRIS toxicological review for the RfC and did not support using these studies to derive a quantitative POD. Instead, HSRB supported the use of the acute sensory irritation studies performed in the clinical setting for deriving or providing qualitative support for PODs. Included among the recommendations from the HSRB was a recommendation that "EPA conduct a more coordinated approach [to peer review] with other entities (e.g., NASEM, TSCA Science Advisory Committee on Chemicals (SACC))…" (p. 9 of HSRB July 2023 (Ref. 18)).

In March 2024, EPA released the Draft Risk Evaluation for Formaldehyde and the Draft Human Health Hazard Assessment for Formaldehyde (*U.S. EPA, 2024c*) (Ref. 20). The draft TSCA risk evaluation relied upon the chronic RfC and IUR values from the draft IRIS toxicological review because the draft IRIS assessment had not yet been finalized. EPA

specifically solicited input from the SACC on the utility of the EPA IRIS RfC and IUR for use in the TSCA risk evaluation. In response to the HSRB and in accordance with the Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) (40 CFR Part 702) requirement to conduct peer review on risk evaluations, OCSPP convened the SACC in May 2024 to evaluate aspects of the hazard and exposure assessments for formaldehyde (Ref. 21). The SACC minutes and final report were released on August 2, 2024 (*U.S. EPA, 2024b*) (Ref. 12). As described in detail in the following sections, the SACC was critical of the IRIS RfC and IUR and largely advised against using these hazard values in the formaldehyde risk evaluation. Consistent with the direction from EPA leadership at the time, the 2024 TSCA risk evaluation continued to rely on these EPA IRIS values to assess risk from certain exposure scenarios (Ref. 7).

Given the critical scientific concerns on the scientific interpretations of MOA, dose response, and health outcome information in the EPA IRIS assessment (as raised by two federal advisory committees, HSRB and SACC), and to be consistent with EO 14303, OCSPP has revisited the use of the IRIS chronic RfC and cancer IUR values for purposes of the Agency's TSCA risk evaluation of formaldehyde. In addition, OCSPP developed the revised draft POD and uncertainty/extrapolation factor derived from the acute inhalation controlled human exposure studies. The following section describes the scientific rationale and weight of scientific evidence for the hazard identification in the Draft Memorandum.

1. Peer Review Findings and Recommendations

In the Preface to the 2023 NASEM report titled, Review of EPA's 2022 Draft [IRIS] Formaldehyde Assessment (Ref. 10*)*, the Chair stated that "… the committee did not conduct an independent hazard assessment or recommend alternative toxicity values." In other words, the NASEM panel did not perform a thorough review of the individual studies or critically evaluate alternative approaches to the formaldehyde hazard characterization. In contrast, the charge questions to both the HSRB and the SACC did require a critical evaluation of the formaldehyde studies. The NASEM panel did, however, conduct a case study evaluating the *Hanrahan* (*1984*)

study (Ref. 19) and was highly critical of the IRIS evaluation and use of the study. Specifically, the NASEM panel noted that "The committee could not replicate the agency's process with complete fidelity, and we identified inconsistencies in EPA's evaluation" (p. 139 of *U.S. EPA, 2024b*) (Ref. 12).

Both the HSRB and SACC provided detailed, independent critiques of toxicology and epidemiology studies, hazards identified, uncertainty/extrapolation factors, and provided recommendations for alternative POD and hazard identification approach(es). HSRB and SACC peer reviewers called into question whether the EPA IRIS assessment complied with the TSCA requirement to use "best available science" and "weight of scientific evidence" with respect to interpretation to various studies, integration of evidence, and MOA analysis. For example, the SACC report (p. 84 of *U.S. EPA, 2024b*) (Ref. 12) states that "Many Committee members considered that the cancer Inhalation Unit Risk (IUR)… does not integrate all available data, despite the overwhelming weight of scientific evidence (WOSE) that the non-genotoxic mode of action (MOA) predominates and would be protective of any other MOA for formaldehyde carcinogenicity." In addition, the SACC noted that the EPA IRIS assessment contains "an incorrect application of mode of action analysis and an incorrect interpretation of all available data" (p. 63).

With respect to the cancer IUR, the SACC stated that the IUR was "not supported by a proper holistic interpretation of the collected data and should not be used by OPPT for risk assessment." The SACC report also states that "the majority of the information presented in session did not favor a IUR approach and rather supported a threshold approach" (p. 22).

With regards to the RfC, the SACC noted that the studies identified by EPA IRIS are "unreliable for identifying a point of departure" and "do not adequately address the chosen endpoint due to several limitations, including but not limited to the ability to determine causality specific to formaldehyde, confounders that were not addressed and including use of self-completed questionnaires instead of measured health effects which decreases the reliability of

results" (p. 34). The SACC noted the Agency could "consider using sensory irritation as an end point for Points of Departure (POD) as a treatment effect that would protect against all downstream events including a carcinogenic response*"* (p. 84). Similarly, the HSRB stated that "EPA should consider that PODs for sensory irritation could be used as a lower bound for potential adverse effects" (p. 9 of HSRB July 2023) (Ref. 18).

2. *Point of Departure for the OCSPP Formaldehyde Risk Assessments*

a. *Use of Sensory Irritation as an Endpoint*

In the draft and final TSCA risk evaluations for formaldehyde, EPA selected sensory irritation as the basis for acute inhalation POD derivation; use of sensory irritation as the critical effect was supported by the HSRB and SACC. Use of sensory irritation is consistent with other national and international exposure limits (see Appendix A of the Human Health Hazard Assessment for Formaldehyde (Ref. 20)) derived under a range of regulatory and advisory contexts for general population and occupational exposures.

EPA identified four controlled human exposure studies (*Mueller et al., 2013* (Ref. 13); *Lang et al., 2008* (Ref. 14); *Kulle et al., 1987* (Ref. 15); *Andersen and Mølhave, 1983* (Ref. 16)) to inform selection of an acute peak exposure level. The HSRB agreed with EPA's conclusions that each of the studies were scientifically sound and ethically conducted and could be used quantitatively and/or qualitatively to support the acute inhalation weight of evidence (WOE) analysis (July 2023 HSRB report) (Ref. 18).

The sensory irritation effects of formaldehyde are more responsive to the exposure concentration than to exposure duration, which means that formaldehyde does not adhere to Haber's Law (*Shusterman et al., 2006*) (Ref. 22). Based on a review of the WOE analysis presented to the HSRB in May 2023, the HSRB did not recommend duration adjustments for 8- or 24-hour PODs for the sensory endpoint. This was based on the lack of support for this adjustment in the four studies presented in the WOE and the understanding that the existing literature demonstrates that formaldehyde does not follow Haber's Law (p. 9 of the July 2023

HSRB report) (Ref. 18). Therefore, rather than deriving duration-adjusted acute PODs for 8- and 24-hour average concentrations, consistent with the approach recommended by HSRB, EPA's acute inhalation analyses in the draft and final TSCA risk evaluation for formaldehyde focused on identifying air concentrations that may result in sensory irritation at any acute exposure duration.

For the Draft Memorandum and in the Revised Draft Risk Evaluation for Formaldehyde Under the Toxic Substances Control Act (TSCA), OCSPP is continuing to rely upon sensory irritation as the endpoint for evaluating acute inhalation exposures in the Revised Draft.

b. *Revised Draft Uncertainty/Extrapolation Factor for Intra-Human Variability*

Both the HSRB (Ref. 18) and SACC (Ref. 12) recommended that EPA consider an intrapopulation variability uncertainty factor (UF_H) lower than the default 10 times (10x) that was proposed in the draft human health assessment for formaldehyde. Specifically, HSRB noted an uncertainty factor is not necessary when the POD is based on sensory irritation whereas the SACC recommended EPA consider either 1x or 3x.

Sensory irritation is a point-of-contact effect and toxicokinetic differences across people are unlikely to contribute to human variability in the sensory irritation response. As described in Section 2.5 of the National Resource Council (NRC; now NASEM) Standing Operating Procedures for Developing Acute Exposure Guideline Levels for Hazardous Chemicals (*NRC, 2001*) (Ref. 23), direct irritation and/or corrosivity occurs at the point of contact such that absorption, distribution, metabolism, excretion (ADME) characteristics are not factors that would significantly influence the irritant toxicokinetic response. Therefore, EPA concluded that it was appropriate to lower the toxicokinetic component of the UF_H from 3x to 1x in the December 2024 Human Health Hazard Assessment for Formaldehyde (Ref. 20). OCSPP is continuing to use a 1x for the toxicokinetic component of the UF_H in the Draft Memorandum.

With respect to the toxicodynamic portion of the UF_H, in the December 2024 human health hazard assessment of the Risk Evaluation for Formaldehyde, the UF_H of 3x was applied to

account for human variability in toxicodynamics that may not be captured in the controlled human exposure studies used as the basis for dose-response. However, this conclusion does not align with the recommendation of HSRB that specifically notes in the July 2023 report that "younger individuals are more sensitive to sensory irritation than older individuals, and therefore younger individuals are an appropriate population for intentional exposure studies when sensory irritation is the primary objective" (p. 9). The World Health Organization (WHO) supports this conclusion with the following: "There is no evidence indicating an increased sensitivity to sensory irritation to formaldehyde among people often regarded as susceptible (asthmatics, children and older people). Although some studies suggest that formaldehyde plays a role in airway sensitization, an association between formaldehyde and lung effects or sensitization in children have not been convincing owing to confounding factors in the studies, including exposure to traffic-related co-pollutants." (p. 139 of (Ref. 24)).

Similarly, the European Chemicals Agency ECHA (*2019*) (Ref. 25) states that "In general, associations between formaldehyde and lung effects or sensitisation in children in homes and schools have not been convincing owing to confounding factors and chance effects. Well known confounders for asthma are e.g. dust mites, cockroach allergen, pets or mould." The German Umweltbundesamt (UBA) (*2016*) (Ref. 26) also reviewed the results from epidemiological studies investigating if there is an association between formaldehyde exposure and the induction or exacerbation of asthma in children. UBA concluded that there is no clear association between formaldehyde exposure in the indoor environment and asthma in children.

At this time, for the Draft Memorandum to align with the recommendations from the peer review panels, OCSPP is also reducing the toxicodynamic portion of the $UF_{H,}$ to 1x leading to a total UF_H of 1x to evaluate inhalation exposures.

c. *Revised Draft Acute Inhalation POD*

In the EPA's December 2024 human health hazard assessment of the final TSCA risk evaluation for formaldehyde, the acute POD was derived based on sensory irritation effects for

each of the three studies (*Mueller et al.*, 2013 (Ref. 13); *Lang et al.*, 2008 (Ref. 14); *Kulle et al.*, *1987* (Ref. 15)) that HSRB supported using quantitatively (summarized in Table 1). An acute POD of 0.5 ppm (parts per million) was selected in 2024 based on the 95 percent lower confidence limit of the benchmark concentration (BMCL10) and no-observed-adverse-effect concentration (NOAEC) identified for a 3-hour exposure in *Kulle et al. (1*987) (Ref. 15). The acute inhalation POD of 0.5 ppm is provided later in this Notice.

The SACC recommended EPA "Carefully reevaluate the available data to determine if 0.5 ppm or a concentration that is lower or higher" should be used as a POD (p. 28). The SACC further recommended EPA "Follow the HSRB recommendation to rely on *Mueller et al. (2013)* (Ref. 13) and *Lang et al. (2008)* (Ref. 14) to derive a POD consistent with the best available science using a weight of the evidence approach" (p. 35). This recommendation appears to be based on the statement on p. 10 of the HSRB July 2023 report (Ref. 18), which states "Of the studies the HSRB evaluated, the controlled chamber studies (e.g., *Mueller et al. (2013)* (Ref. 13) and *Lang et al. (2008)* (Ref. 14)) have preferred study design and greater scientific rigor than the observational studies (e.g., *Hanrahan et al. (1984)* (Ref. 19) and *Liu et al. (1991)* (Ref. 27))". Therefore, it does not preclude the other two controlled chamber studies *(Kulle et al. 1987* (Ref. 15); *Anderson and Mølhave 1983* (Ref. 16)) from similarly being considered as best available science for the WOE evaluation. The HSRB determined that *Kulle et al. (1987)* (Ref. 15) and *Lang et al. (2008)* (Ref. 14) provided reliable data for use in a WOE analysis to determine a POD for acute inhalation exposure to formaldehyde and that *Mueller et al. (2013)* (Ref. 13) provided reliable semi-quantitative data (p. 5 and p. 6 of July 2023 HSRB report) (Ref. 18).

All the studies tested constant exposure concentrations to formaldehyde and did not observe any effects at 0.5 ppm or below. In addition to constant exposure treatment groups, *Lang et al. (2008)* (Ref. 14) and *Mueller et al. (2013)* (Ref. 13) also included treatment groups with 15-minute peaks to higher concentrations. A NOAEC for these variable exposures was established at 0.3 ppm with 0.6 ppm peaks in *Lang et al. (2008)* (Ref. 14). In *Mueller et al.*

(2013) (Ref. 13), there was an increase in reported irritation in hypersensitive subjects at 0.3 ppm with 0.6 ppm peaks and 0.4 ppm with 0.8 ppm peaks, respectively.

Given the findings in the controlled human exposure studies reviewed by the HSRB, particularly *Mueller et al. (2013)* (Ref. 13), coupled with the reduction of the UF_H to 1x described earlier in this Notice, using the 2024 acute inhalation POD of 0.5 ppm may not be adequately health protective. Specifically, 0.5 ppm POD ÷ 1x UF_H leads to a value of 0.5 ppm where effects in hypersensitive subjects were reported at 0.3 ppm with 0.6 ppm peaks and 0.4 ppm with 0.8 ppm peaks. As noted earlier, there were no effects observed when exposure concentrations were constant at 0.5 ppm or below. Consequently, considering the totality of the evidence, the acute inhalation POD for formaldehyde has been appropriately supplemented. Based on the same four robust controlled human exposure studies, 0.3 ppm is considered a health-protective POD for evaluating acute inhalation exposures where there was a lack of reported findings in the controlled human studies at this constant exposure concentration.

For the Draft Memorandum, OCSPP is updating the draft acute inhalation POD to 0.3 ppm for formaldehyde.

d. Use of the Acute Inhalation POD to Protect for All Durations, Including Cancer

The SACC states (p.84) that "The inhaled formaldehyde is not distributed to an appreciable extent beyond portal-of-entry (POE) to distal tissues/organs based on the currently available experimental evidence. The sensory irritation is a local effect at POE that may progress to adverse effects under repeated and prolonged consumer exposure scenarios at POE. Therefore, the Agency could consider using sensory irritation as an end point for Points of Departure (POD) as a treatment effect that would protect against all downstream events including a carcinogenic response." The conclusion of the SACC is consistent with conclusions previously used by EPA in the 2008 Registration Eligibility Decision and other international bodies. For example, Health Canada (2005, p. 5) states that "Formaldehyde-induced carcinogenicity appears to be a consequence of proliferative regeneration following cytotoxicity, and the risk of cancer

associated with formaldehyde levels sufficiently low to prevent irritation and inflammatory responses appears therefore to be negligible."

WHO (*2010*) (Ref. 24) notes that "Increased cell proliferation due to cell damage is considered a key mechanism for the development of nasal malignancies following exposure to formaldehyde. Overall, indoor air effects of formaldehyde are expected to be limited to the site of contact, generally the nasal and upper airways. Increasing cell proliferation in the nasal mucosa of rats occurs at concentrations at and above 2.5 mg/m^3 formaldehyde. The no-observed-adverse-effect level (NOAEL) for cell proliferation is 1.25 mg/m^3 for long-term exposures. Thus, a threshold approach to setting a guideline for cancer effects is appropriate" (p. 141). Similarly, the SACC stated that "the majority of the information presented in session did not favor an IUR approach and rather supported a threshold approach" (SACC report p. 22) (Ref. 12).

The SACC also stated that "Although the Mueller et al. (2014) study is an acute duration study, formaldehyde does not accumulate in the body and Habers' Law does not apply for formaldehyde. Thus, use of this study may be appropriate for setting a POD for chronic exposures" (p. 58). OCSPP notes that the NOAEL for cytotoxicity and cell proliferation identified by WHO of 1.25 mg/m^3 for long-term exposures in rats is 1.25 mg/m^3 (equivalent to approximately 1 ppm of formaldehyde) and they further state that "In humans, no excess nasopharyngeal cancer has been observed at mean exposure levels at or below 1.25 mg/m^3". Health Canada also described the histopathological effects such as "hyperplasia, squamous metaplasia, inflammation, erosion, ulceration, and disarrangements in the nasal cavity at concentrations of 3.7 mg/m^3 and above (NOAEL 1.2 mg/m^3). These histopathological effects appear to be a function of the formaldehyde concentration in inhaled air rather than of the cumulative dose." As such, the POD of 0.3 ppm is protective of effects for all durations, including cancer. However, if human exposure occurs above 0.3 ppm for a sustained, long-term duration, there is potential for cancer to develop.

Consistent with the recommendations from the SACC and noting consistency with the

science relied upon by other international bodies, OCSPP is proposing that the best available science supports using the revised draft acute inhalation POD of 0.3 ppm as protective of all durations and inhalation hazards, including cancer, for the Draft Memorandum. Consistent with this approach, and OCSPP's understanding of the MOA of formaldehyde in the human body, OCSPP is also no longer relying on the EPA IRIS RfC or IUR.

2. *Weight of Scientific Evidence Conclusions for the Revised Draft Acute Inhalation POD and UF*

As described earlier in this Notice, based on the weight of scientific evidence and informed by the best available science, OCSPP is confident in the following determinations for risk assessment/risk evaluation of formaldehyde:

• an acute inhalation POD of 0.3 ppm is appropriate as the critical effect to protect for all other potential hazards, including cancer;

• the acute inhalation POD can be applied to all durations of exposure (including chronic and cancer) and all populations, including occupational scenarios; and

• a total UF_H of 1x is appropriate.

For the Draft Memorandum, OCSPP is only including the MOE calculations for acute (15-minute) inhalation exposure. Based on the scientific evaluation presented herein, OCSPP proposes to rely on the acute exposure scenarios for determinations of unreasonable risk. Given the MOA of formaldehyde, chronic non-cancer and cancer health effects are not expected if EPA is protecting for acute exposure and effects. Previously estimated chronic exposure values for occupational, consumer, and general population pathways remain in the risk evaluation for formaldehyde. It is important to note that acute exposure was assessed for all COUs and associated exposure scenarios in the risk evaluation for formaldehyde and considered in this Draft Memorandum. There are no exposure scenarios where only chronic exposure was assessed in the risk evaluation for formaldehyde. Because the acute risk estimates are protective of risk presented by chronic exposures, EPA is using the acute risk estimates presented in this Draft

Memorandum to identify COUs that contribute to the unreasonable risk of formaldehyde. Repeated or sustained long-term exposures to formaldehyde above the revised draft POD increases the potential for chronic effects including cancer.

3. Revised Draft Risk Calculations Resulting in Substantial Change

For COUs that the Agency found significantly contribute to the unreasonable risk presented by formaldehyde in the Risk Evaluation for Formaldehyde, the revised POD and corresponding uncertainty factor impacts five COUs for workers where the central tendency or high-end inhalation estimate no longer exceeds the benchmark. These COUs are shown in Table 2.

In addition, three COUs would have central tendency and high-end inhalation estimates for ONUs that no longer show risk above the benchmark. These estimates are shown in Table 3.

4. Revised Draft Unreasonable Risk Determination for Formaldehyde

EPA previously determined that formaldehyde presents an unreasonable risk of injury to human health under the COUs. The Agency also determined that the unreasonable risk to human health presented by formaldehyde is due to (1) non-cancer effects in workers and consumers from acute dermal and inhalation exposures, and (2) cancer effects in workers from long-term inhalation exposure (90 FR 316 (FRL-11608-04-OCSPP)). EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for formaldehyde.

OCSPP maintains its determination that high and prolonged inhalation exposures to formaldehyde can lead to cancer in humans. However, OCSPP has concluded that acute sensory irritation is more sensitive than cancer and therefore health-protective. Specifically, the air concentrations that cause sensory irritation are lower than those that trigger early toxicological events, such as inflammation, cytotoxicity, hyperplasia, squamous metaplasia, and increased cell proliferation in the nasal mucosa of rats, which are involved in cancer development. In other words, developing cancer from inhalation exposure of formaldehyde requires concentrations several times higher than EPA's acute inhalation POD, sustained over weeks to years. Thus, if an

acute risk of concern is identified, then there is also a potential concern for cancer when exposures are higher and sustained.

Risk management efforts to reduce risk from acute inhalation risk will address any potential risks from chronic exposures, including cancer. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory actions to the extent necessary so that formaldehyde no longer presents an unreasonable risk under the COUs. The Agency expects to focus its risk management action on the TSCA COUs that significantly contribute to the unreasonable risk. However, it is important to emphasize that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to contribute significantly to unreasonable risk and may select from among a suite of risk management approaches based on requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) contributing significantly to unreasonable risk—even if the upstream activities do not contribute significantly to the unreasonable risk.

The determination that formaldehyde presents an unreasonable risk of injury to human health would not change as a result of the risk estimates used in this Draft Memorandum, and the same COUs would continue to significantly contribute to the unreasonable risk for formaldehyde as outlined in the Revised Draft Unreasonable Risk Determination of the Risk Evaluation for Formaldehyde available in the docket (EPA-HQ-OPPT-2018-0438). Although there are some changes to the inhalation estimates, as noted above in Section II.C.4, dermal risk findings for these COUs remain unchanged and continue to contribute to unreasonable risks for these COUs.

Because the acute inhalation risk estimates, using an acute POD of 0.3 ppm and UF of 1x, are protective of risk presented by chronic inhalation exposures, the Agency intends to utilize the risk estimates in the Draft Memorandum to safeguard against potential risk for all inhalation

exposure durations and effects, including cancer. Table S2-1 Supporting Basis for the Revised Draft Unreasonable Risk Determination for Human Health (Occupational Conditions of Use) and Table S2-2 Supporting Basis for the Revised Draft Unreasonable Risk Determination for Human Health (Consumer Conditions of Use) (Ref. 28) replace Table 2-1 and Table 2-2 of the Revised Draft Unreasonable Risk Determination of the Risk Evaluation for Formaldehyde available in the docket (EPA-HQ-OPPT-2018-0438). The POD in the Draft Memorandum identifies five COUs that no longer indicate unreasonable risk for workers due to inhalation:

• Inhalation exposure route for workers no longer contribute to the unreasonable risk for the COU, Oxidizing/reducing agent; processing aids, not otherwise listed;

• Inhalation exposure route for workers no longer contribute to the unreasonable risk for the COU, Lawn and garden products;

• Inhalation exposure route for worker no longer contribute to the unreasonable risk for the COU, Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing;

• Inhalation exposure route for worker no longer contribute to the unreasonable risk for the COU, Recycling; and

• Inhalation exposure route for worker no longer contribute to the unreasonable risk for the COU, Laboratory chemicals.

The exact risk estimates for these inhalation routes can be found in the docket accompanying this Notice. Additional scenarios where the central tendency estimates are now above the benchmark include the following:

• Inhalation exposure route for ONUs no longer contribute to the unreasonable risk for the COU, Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing;

• Inhalation exposure route for worker no longer contribute to the unreasonable risk for the COU, Recycling.

• Inhalation exposure route for worker no longer contribute to the unreasonable risk for the COU, Laboratory chemicals.

Because the revised acute inhalation POD of 0.3 ppm is protective of all durations and inhalation hazards, including cancer, EPA anticipates focusing risk management actions related to inhalation on addressing risk from acute inhalation exposures.

For more information about the EPA's process for ensuring the safety of existing chemicals, go to https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals.

Table 1. Key Human Studies Used to Evaluate Peak Air Concentrations of Formaldehyde Associated with Sensory Irritation

Source	Exposure Concentrations	Effects
Kulle et al. (1987) (Ref. 15)*; Kulle (1993)* (Ref. 29)	I: 0.0, 0.5, 1.0, 2.0 ppm, 2.0 ppm exercise II: 0.0, 1.0, 2.0 ppm, 2.0 ppm exercise I: 0, 0.62, 1.23, 2.46, mg/m^3 II: 0, 1.23 3.69 mg/m^3	NOAEL = 0.5 ppm (0.62 mg/m^3) LOAEL = 1.0 ppm (1.23 mg/m^3) for mild to moderate eye irritation BMC = 0.69 ppm (0.85 mg/m^3) BMCL =0.502 ppm (0.617 mg/m^3)
Andersen and Mølhave (1983) (Ref. 16); *Andersen (1979)* (Ref. 30)	0.24, 0.4, 0.81, 1.61 ppm 0.3, 0.5, 1.0, 2.0 mg/m^3	During first 2 hours, no reported irritation discomfort to 0.24 or 0.4 ppm but discomfort to 0.81 and 1.61 ppm within the first hour. During remaining 3 hours exposure, discomfort reported at the 0.24 and 0.4 ppm exposure levels.
Lang et al. (2008) (Ref. 14)	0, 0.15, 0.3, 0.5 ppm 0.3/0.6, 0.5/1.0 ppm peaks (0, 0.3, 0.5 ppm with EA) 0, 0.19, 0.37, 0.62 mg/m^3 0.37/0.74, 0.62/1.23 mg/m^3 peaks (0, 0.37, 0.62 mg/m^3 with EA)	NOAEL = 0.5 ppm continuous (0.62 mg/m^3) and 0.3 ppm with peak 0.6 ppm (0.37/0.74 mg/m^3) LOAEL = 0.5 ppm with peaks of 1 ppm (0.62/1.23 mg/m^3) for blinking frequency, conjunctival redness, eye and nasal irritation, and olfactory symptoms
Mueller et al. (2013) (Ref. 13)	0, 0.5, 0.7 ppm 0.3/0.6 ppm peaks, 0.4/0.8 ppm peaks 0, 0.62, 0.86 mg/m^3 0.37/0.74 mg/m^3 0.49/0.98 mg/m^3	At 0.3/0.6 ppm, increase in reported irritation in hypersensitive individuals. 0.4/0.8 ppm increase in reported irritation in hypersensitive individuals and tear film break-up time. 0.7 ppm statistically significant increase in nasal flow in hypersensitive males. For hyposensitive males: 0.4/0.8 ppm and 0.5 ppm increase in tear film break-up time
NOAEL = no-observed-adverse-effect level; LOAEL = lowest-observed-adverse-effect level; BMC = benchmark concentration; BMCL = benchmark concentration level (lower 95 percent confidence limit).		

Table 2. Acute MOE Calculations for Workers Where Central Tendency Risk or High-End Risk Is No Longer Below the Benchmark for Workers or Occupational Non-Users

COU	Draft Supplement Central Tendency MOE for Acute Inhalation (UF = 1)	Draft Supplement High-End MOE for Acute Inhalation (UF = 1)	Risk Evaluation Central Tendency MOE for Acute Inhalation (UF = 3)	Risk Evaluation High-End MOE for Acute Inhalation (UF = 3)
Lawn and garden products	7.18	1.77	11.9	2.95
Oxidizing/reducing Agent	3.24	1.31	5.40	2.18
Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	2.00	0.10	2.3	0.20
Recycling	1.38	0.51	2.31	0.85
Laboratory chemicals	1.98	0.10	1.99	0.23

Table 3. Acute MOE Calculations for ONUs Where Central Tendency Risk Is No Longer Below the Benchmark

COU	Draft Supplement Central Tendency MOE for Acute Inhalation (UF = 1)	Draft Supplement High End MOE for Acute Inhalation (UF = 1)	Risk Evaluation Central Tendency MOE for Acute Inhalation (UF = 3)	Risk Evaluation High End MOE for Acute Inhalation (UF = 3)
Laboratory chemicals	1.99	0.232	1.19	0.14
Recycling	1.38	0.51	2.31	0.85
Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	1.62	0.46	2.70	0.76

III. Request for Comment

EPA seeks feedback on the Draft Memorandum and associated documents, copies of which are available in the docket, and encourages all potentially interested parties, including individuals, governmental and non-governmental organizations, non-profit organizations, academic institutions, research institutions, and private sector entities to comment on the draft documents. To the extent possible, the Agency asks commenters to please cite any public data related to or that support comments provided, and to the extent permissible, describe any supporting data that is not publicly available. EPA is not seeking peer review for the Draft Memorandum as it relies extensively on multiple existing and relevant peer review reports (Ref. 10, Ref. 12, and Ref. 18).

EPA welcomes specific input on each section of the Draft Memorandum and related supported documents. The following information provided will also be considered for risk management of formaldehyde:

• Personal protective equipment (PPE) use, including the type of PPE worn for different

workplace activities and task durations under the COU, circumstances where it may not be practicable for potentially exposed persons to wear PPE, and feasibility of exposure reduction to formaldehyde sufficient to address the unreasonable risk, including associated monitoring practices to assess exposure reductions;

• Dermal and respiratory workplace controls, such as eliminating dermal contact, engineering controls, and administrative controls that could address the unreasonable risk;

• Emission factors and weight fractions for commercial and consumer products or articles along with the respective uses and applications, and threshold or *de minimus* concentrations in products or articles.

IV. Next Steps

EPA will consider comments received on the Draft Memorandum and associated documents and announce the availability of the Updated Final Risk Calculation Memorandum and Revised Final Risk Evaluation for Formaldehyde Under the Toxic Substances Control Act (TSCA), if warranted. Under TSCA section 6, EPA must use the final risk evaluation as a basis to determine, based on the weight of scientific evidence, whether or not the chemical presents an unreasonable risk to health or the environment under the chemical's COUs. This includes risks to subpopulations who may be at greater risks than the general population, such as children and workers. TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation.

If at the end of the risk evaluation process, EPA determines that a chemical presents an unreasonable risk to health or the environment, the chemical must immediately move to risk management action under TSCA section 6(a). EPA is required to implement, via regulation, regulatory restrictions on the manufacture (including import), processing, distribution, use or disposal of the chemical to eliminate the identified unreasonable risk. The Agency is given a range of risk management options under TSCA, including labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, and a ban of the

chemical or of certain uses. Like the prioritization and risk evaluation processes, there is an opportunity for public comment on any proposed risk management actions.

For more information about the TSCA risk evaluation process for existing chemicals, go to https://www.epa.gov/assessing-and-managing-chemicals-under-tsca.

V. References

The following is a listing of the documents that are specifically referenced in this Notice and other relevant risk evaluation documents. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket.

1. Executive Order 14303. Restoring Gold Standard Science. *Federal Register* (90 FR 22601 May 29, 2025).

2. U.S. EPA. (2020). Use Report for Formaldehyde (CAS RN 50-00-0). Docket ID: EPA-HQ-OPPT-2018-0438.

3. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. *Federal Register*. 84 FR 71924, December 30, 2019 (FRL-10003-15).

4. EPA. Draft Scopes of the Risk Evaluations to be Conducted for Seven Chemical Substances under the Toxic Substances Control Act. *Federal Register.* 85 FR 22733, April 23, 2020 (FRL-10008-05).

5. EPA. Final Scopes of the Risk Evaluations to Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. *Federal Register*. 85 FR 55281, September 4, 2020 (FRL-10013-90).

6. EPA. Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Notice of Availability, Public Meetings, and Request for Comment. *Federal Register.* 89 FR 18933, March 15, 2024 (FRL-11608-03-OCSPP).

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Authority: 15 U.S.C. 2601 *et seq*.

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