
# American Chemistry Council Comments on the

# Updated Draft Risk Calculation Memorandum to Inform a Revised Draft Risk Evaluation for Formaldehyde Prepared Under the Toxic Substances Control Act Docket ID Number: EPA–HQ–OPPT–2018–0438

Submitted by:

**The American Chemistry Council's**
**Formaldehyde Panel**

Washington, DC

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## Executive Summary

The American Chemistry Council (ACC) Formaldehyde Panel submits these comments on EPA's Updated Draft Risk Calculation Memorandum (Draft Memorandum) for formaldehyde. ACC supports EPA's commitment, consistent with TSCA and Executive Order 14303, Restoring Gold Standard Science, to rely on the best available science and to respond to peer review comments.

EPA's Draft Memorandum reflects meaningful scientific progress. EPA justifiably moves away from reliance on flawed IRIS-derived values and instead grounds inhalation risk calculations in controlled human exposure studies, integrated mode of action (MOA) evidence, and a threshold-based framework. This approach aligns the formaldehyde risk evaluation with TSCA's statutory scientific standards and the weight of the scientific evidence.

The best available science for formaldehyde supports several core conclusions: (1) sensory irritation is the most sensitive and health-protective endpoint and, under a threshold MOA, is protective of downstream effects, including cancer; (2) controlled human chamber studies provide the most rigorous and reliable basis for selecting points of departure; (3) additional uncertainty factors are not scientifically warranted when sensory irritation is used as the point of departure; and (4) duration adjustments are inappropriate because formaldehyde does not follow Haber's Law and effects are driven by concentration rather than exposure duration.

Consistent with this evidence, ACC supports EPA's derivation of a 0.3 ppm occupational exposure value (OEV) based on controlled human exposure studies and an uncertainty factor of 1. Because formaldehyde-induced sensory irritation is driven by exposure concentration rather than duration, this value should be applied as an 8-hour time-weighted average (TWA), not as a short-term exposure limit (STEL), if used to inform risk management. Established industrial hygiene practice, including OSHA's longstanding formaldehyde standard, provides a practical and protective model for managing short-term exposure variability without creating an unsupported *de facto* ceiling limit.

EPA's revised inhalation framework is also consistent with conclusions reached by authoritative international scientific bodies, including the European Union and the World Health Organization, which have similarly relied on controlled human exposure data and MOA-based evidence integration to derive health-protective exposure limits. This consistency reinforces the scientific basis for applying concentration-driven benchmarks, such as an 8-hour TWA, and helps ensure that U.S. regulatory decisions remain durable and U.S. businesses remain internationally competitive.

While ACC strongly supports EPA's inhalation course correction, some issues remain. EPA should revisit its dermal hazard characterization and dermal exposure assumptions, which continue to be overly conservative, are not grounded in the best available science, and now drive unreasonable risk determinations. In addition, EPA should establish a 0.1 percent regulatory *de minimis* threshold as part of the TSCA Section 6 rulemaking to promote regulatory certainty and practical implementation, consistent with long-standing regulatory practice and recent EPA precedent.

## Introduction

The American Chemistry Council (ACC) Formaldehyde Panel (the Formaldehyde Panel) appreciates the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA or "the Agency") on EPA's Updated Draft Risk Calculation Memorandum (Draft Memorandum) to inform a Revised Draft Risk Evaluation for Formaldehyde under the Toxic Substances Control Act (TSCA).[1] As EPA explains in the Draft Memorandum, the purpose of the TSCA risk evaluation is to determine whether formaldehyde presents an unreasonable risk of injury to human health or the environment under its conditions of use, without consideration of costs or other non-risk factors, including risks to potentially exposed or susceptible subpopulations identified as relevant by EPA.

ACC recognizes and supports EPA's stated commitment, consistent with TSCA and Executive Order 14303, Restoring Gold Standard Science, to uphold the highest standards of scientific integrity and to rely on the best available scientific information. In this regard, ACC appreciates EPA's decision, following scientific peer review and public comment, to reconsider the use of certain hazard values in the formaldehyde risk evaluation. As EPA notes, the Draft Memorandum provides the scientific basis for evaluating how the revised draft inhalation point of departure affects margin of exposure estimates and risk determinations under TSCA.

EPA's Draft Memorandum reflects meaningful progress toward a science-based framework by reconsidering prior hazard assumptions, relying on controlled human exposure data, integrating mode of action (MOA) evidence, and moving away from default extrapolation approaches that are not supported by the formaldehyde evidence base. Consistent with EPA's stated commitment to rely on the best available science, the weight of the scientific evidence for formaldehyde supports the following conclusions:

- No causal association between inhaled formaldehyde and myeloid leukemia is supported by the available evidence or biological plausibility;
- Formaldehyde exhibits a threshold, non-linear dose response MOA, below which adverse effects, including cancer, are not expected to occur;
- Sensory irritation is the most sensitive endpoint and is protective of all other effects, including acute, chronic non-cancer, and chronic cancer outcomes;
- Controlled human exposure (chamber) studies provide a preferred study design and greater scientific rigor than observational epidemiological studies for evaluating inhalation hazards;
- Additional uncertainty factors are not scientifically warranted when sensory irritation is used as the point of departure, as it represents a conservative lower bound for adversity; and

[1] The Updated Draft Risk Calculation Memorandum is available at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-formaldehyde, and the supporting information is also available at: https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438.

- Duration adjustments are not necessary because formaldehyde does not follow Haber's Law, meaning concentration, not duration, is the primary driver of whether effects will be seen.

Formaldehyde is a naturally occurring substance composed of carbon, hydrogen, and oxygen and is an integral component of normal biological metabolism. It is also one of the most extensively studied industrial chemicals and, through decades of innovation and safe use, has become a critical building block in products essential to modern life, including automobiles and electric vehicles, engineered wood products, medical devices, vaccines, fertilizers, and antimicrobials. Formaldehyde-based technologies support critical supply chains and, in 2023, contributed to approximately 1.5 million jobs and $1.6 trillion in U.S. sales across sectors such as housing and construction, food and agriculture, aerospace, semiconductors, automotive manufacturing, national security, and medical technologies.[2]

ACC understands that, although EPA has issued a revised draft occupational exposure value (OEV) and has reconsidered aspects of the inhalation hazard assessment, the Agency is continuing work on a proposed risk management rule to meet TSCA statutory deadlines. These comments are intended to support EPA's ongoing evaluation by acknowledging areas where the Draft Memorandum reflects meaningful scientific progress, while also identifying remaining issues that warrant further refinement so that the final TSCA risk evaluation fully reflects the best available science and the weight of the scientific evidence.

The Formaldehyde Panel's members include producers, suppliers, and users of formaldehyde and formaldehyde-based products, as well as trade associations representing key downstream applications. The Panel is committed to advancing high-quality science, protecting workers and community health, and helping ensure that EPA's regulatory decisions are grounded in robust, transparent, and fit-for-purpose scientific analyses. ACC and the Formaldehyde Panel have actively engaged with EPA throughout this process and incorporate by reference prior technical submissions and peer-review comments.[3] In addition, Appendices D, E, and F include excerpts from key submissions by EPA peer reviewers, Members of Congress, federal and state agencies, scientific experts, and other stakeholders that raise concerns with EPA's prior approach on the

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[2] ACC, Formaldehyde Producers Boost U.S. Economy, available at: https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-producers-boost-us-economy; Summary descriptions of formaldehyde's essential role in each of these sectors are available at: https://www.americanchemistry.com/industry-groups/formaldehyde/benefits-applications.

[3] *See* ACC Formaldehyde Panel Comments on the 2024 Draft TSCA Risk Evaluation for Formaldehyde, May 14, 2024, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0235 and included as Appendix A of this submission; ACC Formaldehyde Panel Comments on the 2022 Draft Formaldehyde IRIS Assessment, June 13, 2022, available at: https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0127/attachment_7.pdf; NAS public access file materials available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0113; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0114; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0115; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0116; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0117; and ACC Comments on Scientific and Legal Issues with EPA's Forthcoming Peer Review of Draft Evaluation of Formaldehyde under the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Mar. 8, 2024, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0007.

formaldehyde risk evaluation. The comments that follow build on that record, and focus on EPA's revised inhalation hazard framework, remaining concerns with dermal hazard characterization and exposure assumptions, and issues relevant to finalizing a TSCA risk evaluation that complies with statutory requirements and Executive Order 14303.

## I. EPA's Decision to Not Rely on IRIS Is Consistent with the Best Available Science for the Formaldehyde TSCA Risk Evaluation

Formaldehyde is a unique chemical substance and one of the most extensively studied compounds in commercial use. More than four decades of scientific research and practical experience have informed numerous evaluations by authoritative bodies worldwide assessing its safe use. As ACC has explained in prior submissions, a standard IRIS-based approach, which separates acute and chronic exposures and relies on a chronic reference concentration (RfC), is not appropriate for informing a TSCA risk evaluation for formaldehyde. We therefore agree with EPA's revised position, as reflected in the Draft Memorandum, which moving away from reliance on IRIS-derived values is scientifically appropriate. This course correction is consistent with TSCA's statutory scientific standards and with Executive Order 14303, which directs agencies to adhere to the highest standards of scientific integrity and reliance on the best available scientific information.[4]

### A. Formaldehyde's Unique Toxicological and Pharmacokinetic Properties

Although formaldehyde is classified as a volatile organic compound (VOC), it exhibits properties that distinguish it from typical VOCs. Formaldehyde is naturally produced as a metabolic byproduct by all living organisms. At room temperature, it is a colorless, flammable gas with a distinct, pungent odor typically detectable above 1 ppm. Dermal contact to formaldehyde solutions at sufficient concentration can cause severe injury to the skin accompanied by drying, cracking, and scaling. Inhalation exposures have been extensively characterized by controlled studies with human volunteers, including asthmatics and other sensitive individuals. As ACC has previously noted, these controlled studies provide a robust and reliable database for identifying an appropriate point of departure.

The kinetics of formaldehyde inside the body have also been well studied.[5] Formaldehyde is a normal product of intermediary metabolism in mammals and is formed endogenously from serine, methionine, choline, and glycine through demethylation of N-, O-, and S-methyl compounds. It is present at concentrations of approximately 0.1- 0.2 mM in blood and tissues.[6] Due to its high reactivity with water, formaldehyde is readily taken up into epithelial tissues in the upper respiratory tract, resulting in a pronounced anterior-to-posterior concentration gradient

[4] Executive Order 14303. Restoring Gold Standard Science. 90 Fed. Reg 22601 (May 29, 2025).
[5] Golden, R., *Identifying an indoor air exposure limit for formaldehyde considering both irritation and cancer hazards*, Crit. Rev. in Toxic, 2011: 41(8): 672-721; available at: https://www.tandfonline.com/doi/full/10.3109/10408444.2011.573467?role=tab&tab=permissions&aria-labelledby=reprints-perm&scroll=top.
[6] Heck, et al., *Determination of formaldehyde in biological tissues by gas chromatography/mass spectrometry, Biomed Mass Spectrom*.1982 Aug;9(8):347-53; Heck, et al., *Formaldehyde (CH2O) concentrations in the blood of humans and Fischer-344 rats exposed to CH2O under controlled conditions*, Am Ind Hyg Assoc J. 1985, Jan;46(1): 1-3.

along the nasal epithelium.[7] Because nasal tissues already contain endogenous formaldehyde, low-level exogenous exposures are not expected to produce any appreciable increase above background levels. Dosimetry modeling further demonstrates that, at exposure concentrations up to 1.9 ppm, any increase in endogenous formaldehyde attributable to exogenous exposure remains far below existing endogenous concentrations.[8] This is an important consideration that ACC has repeatedly emphasized in evaluating biological plausibility for systemic effects.

Consistent with the findings of both the EPA Human Studies Review Board (HSRB), which reviewed portions of the formaldehyde literature for the Office of Chemical Safety and Pollution Prevention (OCSPP),[9] and the Science Advisory Committee on Chemicals (SACC), which peer-reviewed the 2024 Draft Formaldehyde Risk Evaluation,[10] formaldehyde does not follow Haber's Law and does not exhibit meaningful differences in sensory irritation across acute versus chronic exposure durations. [11] ACC has long raised concerns that treating acute and chronic sensory irritation as distinct effects is not supported by the evidence. The Draft Memorandum appropriately reflects this scientific understanding.

Importantly, the Draft Memorandum also acknowledges, consistent with ACC's prior comments, that sensory irritation is the most sensitive and biologically relevant endpoint for inhalation exposure and that protecting against sensory irritation is protective of all other adverse effects of formaldehyde, including nasal tumors, when a threshold-based MOA is applied. In reaching this conclusion, EPA applies core principles of MOA analysis and evidence integration that are foundational to EPA's *Framework for Human Health Risk Assessment to Inform Decision Making*.[12] Under this framework, upstream effects observed at lower concentrations and earlier time points are understood to precede and protect against downstream effects observed at higher concentrations and longer durations, a relationship that is well established for formaldehyde, including for the MOA underlying nasal tumor formation.

Accordingly, EPA's conclusion in the Draft Memorandum that managing acute sensory irritation will be health-protective against other effects, including cancer, is consistent with the available scientific evidence and supports the application of a threshold-based approach. Moreover, by moving away from reliance on IRIS-derived values and conducting a more holistic evaluation of hazard, dose response, and MOA information, EPA has corrected the prior fundamental flaw of parsing of acute and chronic assessments. This integrated approach supports the conclusion that

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[7] Kimbell et al., *Application of computational fluid dynamics to regional dosimetry of inhaled chemicals in the upper respiratory tract of the rat*, Toxicol Appl Pharmacol. 1993 Aug;121(2):253-63.
[8] Lu et al., *A Review of Stable Isotope Labeling and Mass Spectrometry Methods to Distinguish Exogenous from Endogenous DNA Adducts and Improve Dose-Response Assessments,* 2022, Chem Res Toxicol. Available at: https://pubmed.ncbi.nlm.nih.gov/34910474/.
[9] HSRB Final Report, Oct. 5, 2023, available at: https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde_0.pdf.
[10] SACC Meeting Minutes and Final Report; Peer review of the 2024 Draft Risk Evaluation for Formaldehyde, May 20-23, 2024. SACC noted 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); available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0298
[11] Golden. 2011.
[12] EPA, *Framework for Human Health Risk Assessment to Inform Decision Making* (2014), https://www.epa.gov/sites/default/files/2014-12/documents/hhra-framework-final-2014.pdf.

there is no meaningful distinction between protective levels for acute and chronic sensory irritation and that controlling exposures to prevent sensory irritation is protective against other effects at higher concentrations, including cancer.

### B. TSCA Addresses "Unreasonable" Risk, Not "No Appreciable" Risk

TSCA section 6(a) directs EPA to manage *unreasonable* risks of injury to health or the environment to the extent necessary so that the chemical substance no longer presents such risks.[13] "Unreasonable risk" does not mean no risk; rather, TSCA requires EPA to determine, on a case-by-case basis, whether the risks posed by a chemical substance are unreasonable under the circumstances of exposure and use.[14]

As ACC has previously explained, hazard values developed under the IRIS program are designed to identify exposure levels that are likely to be without an appreciable risk of deleterious effects over a lifetime.[15] Such values are not intended to inform TSCA unreasonable risk determinations and, when applied in that context, effectively seek to mitigate risks well beyond what the statute mandates. RfC values are commonly described as levels below which there is "no appreciable risk."[16] Also, when EPA has converted RfCs into health-based occupational exposure levels for other chemicals, the Agency has characterized those values as concentrations below which an adult would be unlikely to experience adverse effects during a single 8-hour workday.[17] As such, when based on RfCs, these occupational exposure values therefore function as essentially a zero risk level.

Consistent with TSCA, EPA's Draft Memorandum appropriately moves away from reliance on IRIS-derived hazard values and instead grounds its revised risk calculations in an acute sensory irritation point of departure and an uncertainty factor of 1. This shift better aligns the risk evaluation with TSCA's statutory requirement to address *unreasonable* risk rather than to regulate to a "no appreciable risk" standard. As illustrated in Figure 1 below, risk exists along a continuum ranging from zero risk to unreasonable risk. TSCA requires mitigation only at the point where risk becomes unreasonable, whereas IRIS-based values are derived to mitigate to a level of "no appreciable risk."

This distinction is particularly important for formaldehyde. Sensory irritation is a reversible effect that is not considered an adverse effect,[18] and the scientific record demonstrates that

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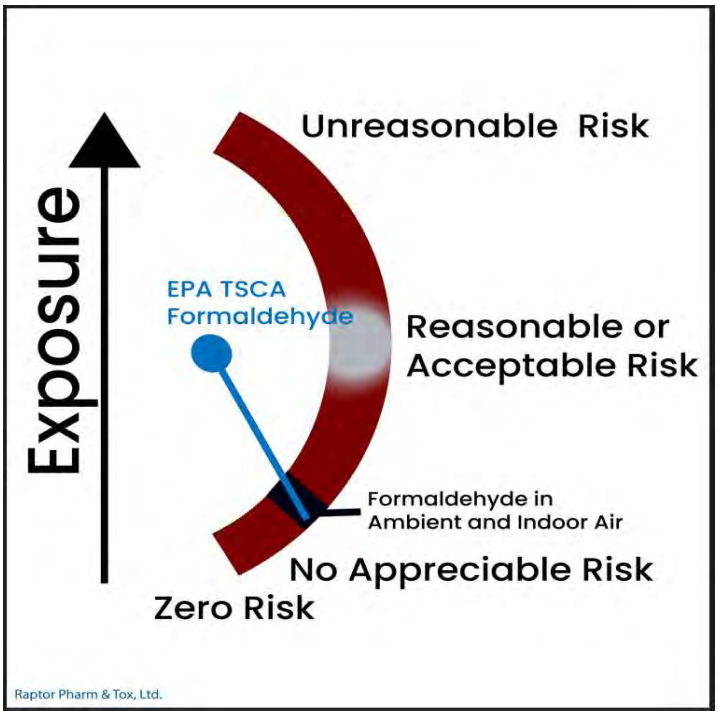
[13] 15 U.S.C. § 2605(a).
[14] Id. § 2605(b)(4)(A).
[15] See: https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.
[16] EPA, *IRIS Glossary*, where EPA defines an RfC as "An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." Available at: https://www.epa.gov/iris/iris-glossary#r.
[17] 88 Fed. Reg. 74712, 74721 (Oct. 31, 2023).
[18] *See,* for example, Comments from James Sherman to the HSRB, which state: "Odor detection and sensory irritation are normal physiological responses to environmental stimuli, including formaldehyde at ≤1 ppm, and do not reduce functioning or ability to respond to additional environmental challenge;" available at: https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0106/attachment_7.pdf; and additional discussion of "adverse effects" in section III.A.3 of these comments.

effects of concern, including cancer, occur at concentrations higher than those associated with sensory irritation. Accordingly, EPA's revised approach appropriately recognizes that protecting against sensory irritation provides health-protective control of all other effects that occur at higher exposure levels. While additional issues remain regarding exposure assumptions and risk characterization, EPA's move away from IRIS-based benchmarks represents an important and necessary correction toward an unreasonable risk framework that is consistent with the statute.

**Figure 1. Understanding the Risk Continuum[19]**




## C. The Peer Review Record Supports EPA's Decision to Not Rely on IRIS

EPA's decision, reflected in the Draft Memorandum, to move away from reliance on the IRIS Formaldehyde Assessment is supported by the administrative record and the nature of the peer review conducted by EPA's advisory bodies. As an initial matter, it is important to distinguish the scope of the National Academies of Sciences, Engineering, and Medicine (NASEM) reviews from the other reviews conducted by the Human Studies Review Board (HSRB) and the Science Advisory Committee on Chemicals (SACC).

In the Preface to the 2023 NASEM report, Review of EPA's 2022 Draft IRIS Formaldehyde Assessment, 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 comprehensive evaluation of individual studies, alternative hazard identification approaches, or dose response frameworks. By contrast, the charge questions to both the HSRB and the SACC explicitly required a critical evaluation of the underlying toxicology and

[19] *See* comments submitted to the SACC from Dr. Lyle Burgoon, Raptor Pharm & Tox, Ltd., May 2024, available at: https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613.

epidemiology studies, uncertainty and extrapolation assumptions, mode of action considerations, and the appropriateness of EPA's hazard identification approach.

Although limited in scope, the NASEM panel did conduct a case study evaluation of the Hanrahan (1984) study and was highly critical of EPA's evaluation of the study, noting that "the committee could not replicate the agency's process with complete fidelity, and we identified inconsistencies in EPA's evaluation."[20] This finding underscores concerns regarding transparency and reproducibility in the IRIS assessment, even within the constrained scope of the NASEM review.

Both the HSRB and the SACC went substantially further. Each provided detailed, independent critiques of the studies relied upon by IRIS, the hazards identified, the uncertainty and extrapolation factors applied, and the overall integration of evidence. In doing so, HSRB and SACC peer reviewers directly called into question whether the IRIS assessment satisfied TSCA's requirements to use the best available science and a weight of scientific evidence approach, particularly with respect to MOA analysis and evidence integration.

For example, the SACC concluded 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." The SACC further found that the IRIS assessment reflects "an incorrect application of mode of action analysis and an incorrect interpretation of all available data." With respect to use of the IUR in TSCA risk assessment, 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," and noted that "the majority of the information presented in session did not favor an IUR approach and rather supported a threshold approach."[21]

The SACC raised similar concerns regarding the IRIS chronic RfC, concluding that the studies relied upon by IRIS were "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 the use of self-completed questionnaires instead of measured health effects." The SACC further noted that EPA 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 HSRB reached conclusions consistent with the SACC. In its July 2023 report, the HSRB stated that "EPA should consider that PODs for sensory irritation could be used as a lower bound for potential adverse effects." The HSRB also rejected the IRIS duration assumptions,

[20] NASEM, Review of EPA's 2022 Draft Formaldehyde Assessment (2023), available at: https://nap.nationalacademies.org/catalog/27153/review-of-epas-2022-draft-formaldehyde-assessment.
[21] SACC Meeting Minutes and Final Report; Peer review of the 2024 Draft Risk Evaluation for Formaldehyde, May 20-23, 2024, available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0298.

concluding that "the HSRB disagreed with EPA's assumption of Haber's Law for formaldehyde and recommends that EPA not make duration adjustments to develop the PODs."[22]

Taken together, these peer review findings demonstrate that EPA's decision to move away from reliance on IRIS-derived chronic hazard values and cancer IURs is not only scientifically justified, but directly responsive to the critiques and recommendations of its scientific advisory bodies. EPA's revised approach, grounded in controlled human exposure studies, integrated MOA analysis, and a threshold-based framework, is therefore consistent with Executive Order 14303 and reflects appropriate adherence to TSCA's scientific standards for use of the best available science and weight of evidence approach.

### D. EPA's Revised Integrated Framework Appropriately Evaluates Inhalation Hazards Without Parsing Out Acute and Chronic Effects

EPA's Draft Memorandum appropriately reflects an integrated approach to evaluating formaldehyde inhalation hazards that no longer artificially separates acute and chronic effects. By grounding its analysis in controlled human exposure studies and MOA-based evidence integration, EPA has corrected prior inconsistencies associated with compartmentalized hazard evaluations and reliance on IRIS-derived values for chronic exposures.

EPA's reliance on high-quality controlled human exposure studies, including Lang et al. (2008) and Mueller et al. (2013), provides a scientifically robust basis for informing both short-term and longer-term exposure scenarios. These studies involved multi-hour exposures conducted over multiple days, reasonably approximating occupational conditions. As EPA now recognizes, because formaldehyde does not follow Haber's Law and concentration, not exposure duration, is the primary driver of sensory irritation, duration adjustments are not scientifically warranted for hazard derivation or occupational exposure values.

Consistent with EPA's revised conclusions, sensory irritation is the most appropriate and health-protective endpoint for formaldehyde inhalation exposure. It occurs at lower concentrations than other non-cancer or cancer effects, is reversible, and is non-adverse. The use of controlled human exposure studies involving younger, generally healthy adults appropriately captures the most sensitive population and supports the application of an integrated, threshold-based framework without additional adjustment factors.

Finally, EPA's revised approach appropriately considers the broader exposure context for formaldehyde, including endogenous production and its ubiquitous presence in indoor and outdoor environments. This framework is consistent with the weight of the evidence approach applied by authoritative international bodies, including the EU Scientific Committee on Occupational Exposure Limits (SCOEL), which derived an 8-hour time-weighted average occupational exposure limit of 0.3 ppm based on controlled human exposure data and MOA

[22] HSRB Final Report, Oct. 5, 2023, available at: https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde_0.pdf

considerations.[23] EPA's revised inhalation hazard framework therefore reflects the best available science for evaluating formaldehyde risks as required by TSCA.

## II. EPA's Revised Approach Relies on Scientifically Sound Hazard Endpoints and Points of Departure

### A. EPA Appropriately Does Not Rely on Observational Epidemiology for Inhalation Hazards

As reflected in the Draft Memorandum, EPA has appropriately moved away from reliance on the IRIS Formaldehyde Assessment, which did not reflect best available science, for purposes of characterizing inhalation hazards under TSCA. In doing so, EPA has corrected prior shortcomings associated with the IRIS Assessment, including its reliance on observational epidemiological studies to derive points of departure, rather than on controlled human exposure studies that represent the gold standard for evaluating inhalation risks in humans.

EPA's revised approach appropriately recognizes formaldehyde's unique chemistry, including the well-established finding that it does not follow Haber's Law, and evaluates hazard and dose response information using a weight of the scientific evidence framework. By grounding its analysis in controlled human exposure data and integrating information across exposure durations, EPA has aligned its assessment with the best available science and with what is known about formaldehyde's effects at typical background concentrations.

The discussion below provides context for why reliance on the IRIS Assessment did not meet TSCA's scientific standards and explains why EPA's revised approach, focused on sensory irritation as the most sensitive endpoint and supported by controlled human studies, provides a more scientifically defensible basis for deriving hazard values and occupational exposure benchmarks.

#### 1. Controlled Human Exposure Studies Provide Greater Scientific Rigor Than Observational Studies

As reflected in the Draft Memorandum, EPA has determined that reliance on observational epidemiological studies for identifying points of departure for inhalation effects is not appropriate and has instead grounded its analysis in controlled human exposure studies and MOA-based evidence integration. This approach reflects best available science as required by TSCA.

As discussed in detail in ACC's prior comments on the Draft Risk Evaluation and the Draft IRIS Formaldehyde Assessment, observational epidemiological studies are inherently limited for dose response characterization due to confounding, exposure misclassification, and the inability to

[23] EU, SCOEL/REC/125 Formaldehyde, Recommendation from the Scientific Committee on Occupational Exposure Limits, 2016, available at: https://op.europa.eu/en/publication-detail/-/publication/7a7ae0c9-c03d-11e6-a6db-01aa75ed71a1.

establish causality.[24] These studies do not provide a reliable basis for identifying points of departure for regulatory risk assessment. In contrast, controlled human exposure studies provide a substantially stronger scientific foundation for evaluating inhalation hazards because subjects, exposure concentrations, durations, and potential confounders are known and controlled, allowing for direct assessment of cause-and-effect relationships. When such studies are available, they are widely recognized as the gold standard for evaluating human inhalation risks.

In the case of formaldehyde, multiple high-quality controlled human exposure studies are available and have been evaluated by EPA and other authoritative bodies. EPA's reliance on these studies appropriately reflects the best available science and is consistent with findings from the EPA HSRB and other expert bodies that formaldehyde does not follow Haber's Law, that concentration, not duration, is the primary driver of sensory irritation, and that protection against sensory irritation is protective of downstream effects, including cancer.

EPA should be aware of forthcoming human exposure studies being conducted by the Monell Chemical Senses Center and the Leibniz Research Centre which are evaluating the effects of formaldehyde to inform setting standards for formaldehyde.[25] Results from the recently completed controlled human exposure study conducted by the Leibniz Research Centre have already been submitted to EPA (*See* Appendix C) and complement the existing chamber studies, further reinforcing a threshold mode of action for formaldehyde with no concentration-dependent sensory irritation at exposures up to 1 ppm. Together with prior chamber studies, these findings confirm sensory irritation as the most sensitive and health-protective endpoint, demonstrate that controlled human exposure data provide greater scientific rigor than observational epidemiology, and support use of a threshold-based point of departure without additional uncertainty factors or duration adjustments.

Because EPA has revised its approach and no longer relies on observational epidemiological studies to derive points of departure for non-cancer inhalation hazards, ACC does not restate its detailed critiques of those studies here and instead incorporates those prior comments by reference.[26] ACC supports EPA's decision to rely on controlled human exposure data as a more scientifically defensible basis for hazard characterization and derivation of protective exposure benchmarks for formaldehyde that meets TSCA's scientific standards.

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[24] ACC Formaldehyde Panel Comments on the 2024 Draft TSCA Risk Evaluation for Formaldehyde; ACC Formaldehyde Panel Comments on the 2022 Draft Formaldehyde IRIS Assessment.

[25] *See*, for example a research plan for studies at the Monell Chemical Senses Center available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0117, and comments submitted to the SACC, May 2024, from Christoph van Thriel (IfADo - Leibniz Research Centre for Working Environment and Human Factors, Dortmund, Germany), available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0179.

[26] Detailed comments by independent experts have been provided to EPA and the SACC on the weaknesses of these studies. *See* Comments submitted, May 2024, from Dr. Dennis Paustenbach (P&A): https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0222; Linda Dell (Ramboll): https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0236; Dr. Stewart Holm (AF&PA): https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0190; and Renee Kalmes and Dr. Pamela Dopart (Exponent): https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0221.

### a) Sensory Irritation Is the Critical Endpoint: Biology, Sensitive Populations, and Application of Haber's Law

EPA's revised approach appropriately reflects the scientific consensus regarding formaldehyde's sensory irritant effects, sensitive populations, and the inapplicability of Haber's Law. Extensive controlled human exposure studies demonstrate that the odor detection threshold for formaldehyde generally occurs at concentrations lower than those associated with ocular or nasal irritation (chemesthesis).[27] To date, no chemical has been identified as having an irritation threshold that is lower than its odor threshold, and formaldehyde is no exception.[28] Formaldehyde can be sensed at 100-500 ppb, and existing studies do not show sensory irritation occurring until 500-1000 ppb.[29] Multiple well-conducted chamber studies show no evidence of ocular or nasal irritation at concentrations of 300–500 ppb, supporting the conclusion that maintaining exposures at or below these levels is protective of sensory irritation.

Consistent with EPA's revised analysis, sensory irritation provides the appropriate lower bound on potential risk from adverse effects because any cytotoxic irritation and other adverse effects will occur at concentrations higher than those where sensory irritation is observed.[30] The HSRB, which questioned whether sensory irritation meets the EPA definition of adverse, not only agreed that using this endpoint as a lower bound is appropriate, but also recommended that no uncertainty factor need be applied when sensory irritation is used as the point of departure.[31] Other inhalation experts have also questioned the adversity of the sensory irritation endpoint, noting that the chemesthesis response to formaldehyde is a normal physiological response and does not reflect adverse health effects unless the sensory organs are overwhelmed to the point of being functionally impaired or objectively incapacitating.[32] Similarly, the SACC noted that although sensory irritation is the most sensitive endpoint, "mild sensory irritation may not be an adverse effect," is "a reversible effect," and the sensory irritation effects used to establish the point of departure "could reasonably be defined as not adverse."[33]

The evidence also demonstrates that potentially exposed or susceptible subpopulations are not more sensitive to formaldehyde-induced sensory irritation than the general population. Age-related declines in olfactory and trigeminal sensitivity mean that younger, healthier individuals,

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[27] Doty, R. L., J. E. Cometto-Muñiz, A. A. Jalowayski, P. Dalton, M. Kendal-Reed and M. Hodgson (2004). *Assessment of upper respiratory tract and ocular irritative effects of volatile chemicals in humans*, Critical Review in Toxicology 34(1): 85-142.

[28] Dalton, P., comments to NASEM 2022, PAF-20, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0114 and also comments at: https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0086, and https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613/comments.

[29] *Id*.

[30] See Celanese comments to EPA, Oct. 13, 2023, in particular the summary discussion of the SCOEL opinion regarding the mechanistic support for threshold effects, at page 8, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0128.

[31] HSRB Final Report.

[32] Kaden, D., comments to NASEM 2022, PAF-43, available at: https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0115/attachment_10.pdf; and Kaden, D. (2026) comments on EPA Draft Risk Calculation Memorandum: Formaldehyde, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0416; and Dalton, P. (2026) comments on EPA Draft Risk Calculation Memorandum: Formaldehyde, available at: https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438.

[33] SACC Meeting Minutes and Final Report; Peer review of the 2024 Draft Risk Evaluation for Formaldehyde.

who are typically represented in controlled exposure studies, are likely to be the most sensitive to odor and irritation.[34] This conclusion is consistent with findings from other authoritative bodies. The National Academy of Sciences (NAS)[35] concluded that at exposure concentrations at or below 3 ppm, asthmatic individuals do not appear to be at greater risk of airway dysfunction than non-asthmatics, and the World Health Organization (WHO)[36] determined that there is no evidence of increased sensitivity to sensory irritation among populations often considered susceptible.

In addition, chemosensory expert Dr. Pamela Dalton[37] has reviewed numerous studies, controlled and observational, that included asthmatics and other sensitive individuals, and these studies do not show that asthma and other health conditions predispose individuals to be more sensitive to formaldehyde.[38] Thus, when it comes to formaldehyde, consistent with the findings of the HSRB,[39] a younger and generally healthier population will be the most sensitive. Thus, there is no disproportional effect on populations that could be considered to be potentially exposed or susceptible subpopulations.

Critically, the Draft Memorandum appropriately reflects the well-established conclusion that formaldehyde does not follow Haber's Law. This finding has been repeatedly documented in peer reviewed literature and confirmed by peer review bodies. The HSRB explicitly rejected EPA's earlier assumption that Haber's Law applies to formaldehyde and recommended that "EPA not make duration adjustments to develop the PODs."[40] Because Haber's Law does not apply, short-term controlled human exposure studies are scientifically appropriate for informing longer-term exposure scenarios, and there is no scientific basis for applying duration adjustments or additional uncertainty factors.

Consistent with this understanding, NAS, which considered sensory irritation the primary health effect of concern, agreed with the literature that found that exposure to concentrations that do not produce short-term sensory irritation also do not result in sensory irritation after repeated exposure.[41] Cytotoxic irritation only occurs at concentrations higher than those that elicit sensory irritation. Recognizing the sequence of effects at increasing air concentrations, NAS also stated that at air concentrations that did not produce chronic tissue irritation, risk of cancer and other health effects (including asthma) appeared negligible.[42]

EPA's revised conclusion that managing sensory irritation is protective against downstream effects, including cancer, aligns with the weight of the scientific evidence, the findings of the

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[34] Dalton, P., comments to EPA 2026 and Dalton, P., comments to NASEM 2022, PAF-20.
[35] NAS, *Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants Volume 1*, 2007, at page 108, available at: https://nap.nationalacademies.org/download/11170#.
[36] World Health Organization (WHO) (2010): Regional Office for Europe. *WHO Guidelines for Indoor Air Quality: Selected Pollutants*. Copenhagen, Denmark: World Health Organization.
[37] Dalton, P., comments to EPA 2026.
[38] Dalton, P, Comments to EPA on the Draft IRIS Formaldehyde Assessment, June 13, 2023, available at: https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0086 and https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613/comments.
[39] HSRB Final Report.
[40] *Id*.
[41] NAS, 2007, at page 105.
[42] *Id*.

HSRB, and the conclusions reached through SACC peer review.[43] Together, this body of evidence recognizes sensory irritation as the most sensitive and health-protective endpoint, identifies younger and generally healthier individuals as the most sensitive population, and demonstrates that concentration, not duration, is the driver of whether effects will be seen.

### b) Controlled Human Exposure Studies Are Best Available Science and Supported by EPA Scientific Advisory Bodies

In the Draft Memorandum, EPA appropriately relied on controlled human exposure studies as the primary basis for characterizing formaldehyde inhalation hazards. As part of this process, EPA asked the HSRB to evaluate the ethical acceptability and scientific rigor of key controlled chamber studies, including Mueller et al. (2013), Lang et al. (2008), Kulle et al. (1987), and Andersen and Mølhave (1983). The HSRB did not identify ethical concerns with these studies and concluded that controlled human exposure studies represent "a preferred study design and greater scientific rigor than the observational studies."[44] As noted above, these studies provide clear advantages over observational epidemiology because subjects, exposure concentrations, durations, and potential confounders are known and controlled.

Consistent with this evaluation, the HSRB recommended particular reliance on Mueller et al. (2013) and Lang et al. (2008), with emphasis on Lang et al., for deriving a scientifically defensible point of departure using a weight of the evidence approach. The Office of Pesticide Programs (OPP) Data Evaluation Records (DERs) similarly concluded that both studies provide data suitable for quantitative use in point of departure derivation.[45] The SACC further recommended EPA "[f]ollow the HSRB recommendation to rely on Mueller et al. (2013) and Lang et al. (2008) to derive a POD consistent with the best available science using a weight of the evidence approach."[46]

Although the HSRB's formal charge focused on acute inhalation exposures, EPA's revised approach appropriately recognizes that, for formaldehyde, findings from controlled human exposure studies are informative for both acute and longer-term exposure scenarios. As reflected in the Draft Memorandum, this conclusion is supported by the well-established evidence, affirmed by both the HSRB and the SACC, that formaldehyde does not follow Haber's Law and that concentration, rather than exposure duration, drives sensory irritation. Accordingly, EPA's integrated reliance on these controlled human exposure studies represents an appropriate application of the best available science and provides a sound basis for informing both short-term and chronic exposure assessments under TSCA.

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[43] Dalton, P., comments to EPA 2026.
[44] HSRB Final Report.
[45] *See* DERs for Lang et al. 2008 and Mueller et al. 2013, available at 42. DER Lang 2008 Draft Risk Evaluation for Formaldehyde and 43. DER Mueller 2013 Draft Risk Evaluation for Formaldehyde, and Debra Kaden presentation to the HSRB on Lang et al. and Mueller et al., available at: https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0106/attachment_3.pdf and https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0106/attachment_2.pdf.
[46] SACC Meeting Minutes and Final Report; Peer review of the 2024 Draft Risk Evaluation for Formaldehyde.

### c) EPA's Approach Is Consistent with Conclusions of Other Authoritative Bodies

EPA's revised approach is consistent with the determinations of other authoritative scientific bodies that have evaluated formaldehyde for the purpose of establishing health-protective exposure limits. Specifically, when evaluating formaldehyde for the determination of occupational limits, other authoritative bodies have chosen to rely on controlled human exposure studies over observational epidemiological studies and in doing so relied upon sensory irritation effects as protective of all other non-cancer and cancer effects.[47] In 2017, ACGIH relied upon Lang et al., and in 2016, SCOEL relied on Mueller et al. and Lang et al. In 2010, for general population exposures, WHO also relied on controlled human exposure studies (Lang et al.), and in 2007, the NAS also recommended controlled human exposure studies when evaluating formaldehyde exposures in submarines. These organizations evaluated the weight of the evidence and determined that studies where the populations, exposures, and confounders were controlled were best available science.

## 2. Application of an Uncertainty Factor of 1 to the Acute Point of Departure is Scientifically Justified and Reflects Best Available Science

In the Draft Memorandum, EPA appropriately revised its application of uncertainty factors to the acute inhalation point of departure for formaldehyde by applying an uncertainty factor (UF) of 1. EPA selected the appropriate controlled human exposure studies and consistent with the weight of the scientific evidence, concluded that an additional uncertainty factor for human variability is not warranted when sensory irritation is used as the point of departure.

This revised approach reflects the well-established understanding that since sensory irritation is a transient and reversible effect that does not affect the form or function of the tissue or organism, it does not meet EPA's definition of an adverse effect.[48] This is consistent with past EPA practice of not applying uncertainty factors when relying on a non-adverse effect as a point of departure.[49] The EPA HSRB similarly questioned whether sensory irritation meets the EPA definition of adversity and recommended that no uncertainty factor be applied when this endpoint is used.

EPA's application of UF = 1 is further supported by the evidence on population sensitivity. As discussed above and reflected in the HSRB's findings, younger, generally healthy adults are likely to be the most sensitive to formaldehyde-induced sensory effects, and the available evidence does not support large differences in sensitivity across population groups.[50] International authorities have reached the same conclusion. In deriving its occupational exposure

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[47] *See* Goyak and Holm (2024). *Sensory irritation and use of the best available science in setting exposure limits: Issues raised by a scientific panel review of formaldehyde human research studies.* Reg Tox Pharm., available at: https://doi.org/10.1016/j.yrtph.2024.105587; and Celanese comments, to EPA, Oct. 13, 2023, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0128.

[48] EPA, IRIS Glossary, where adverse effect is defined as "A biochemical change, functional impairment, or pathologic lesion that affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge." https://www.epa.gov/iris/iris-glossary.

[49] *See* for example EPA's IRIS assessment for perchlorate and also the EPA OPP assessment of chloropicrin.

[50] Goyak and Holm (2024).

value for formaldehyde, the EU SCOEL likewise determined that no additional uncertainty factor was necessary when relying on controlled human exposure studies.

Finally, EPA's use of UF = 1 is consistent with considerations related to background concentrations and analytical variability.[51] Controlled human exposure studies report standard deviations up to 50 ppb to 60 ppb, including under nominal zero exposure conditions, underscoring the importance of deriving exposure benchmarks that are meaningfully distinguishable from background levels and greater than the maximum standard deviations in these studies.[52] Applying an additional uncertainty factor would risk establishing exposure values at or below background concentrations, which would not be scientifically meaningful for risk characterization for a particular source.

Taken together, the lack of adversity associated with sensory irritation, the absence of evidence supporting substantial interindividual variability, the recommendations of the HSRB, and international and agency precedent support EPA's revised conclusion that application of UF = 1 to the acute point of departure is consistent with the best available science and appropriate for the formaldehyde TSCA risk evaluation.

### B. EPA Appropriately Does Not Rely on the IRIS Assessment for Characterization of Inhalation Cancer Hazards

As reflected in the Draft Memorandum, EPA has appropriately moved away from reliance on the IRIS Formaldehyde Assessment, which does not reflect best available science, for purposes of characterizing inhalation cancer hazards under TSCA. This change is consistent with Executive Order 14303, which emphasizes scientific integrity, transparency, and reliance on the best available scientific information as well as TSCA's statutory requirements to use the best available science and consider reasonably available information.

Importantly, EPA's revised approach is also consistent with EPA's 2005 Guidelines for Carcinogen Risk Assessment (Cancer Guidelines), which recognize that default linear extrapolation is not appropriate in all cases. For substances classified as "likely" or "carcinogenic to humans," where the weight of the scientific evidence supports a non-mutagenic mode of action, the Cancer Guidelines explicitly allow application of a threshold, non-linear approach. This framework is routinely applied by EPA's Office of Pesticide Programs (OPP) and provides clear support for EPA's decision here to move away from IRIS-derived linear approaches that are not fit for purpose under TSCA.[53]

Recent EPA practice further reinforces this approach. In a January 2024 Cancer Assessment Review Committee (CARC) determination for methyl isothiocyanate (MITC), EPA concluded

[51] As EPA reports in the Dec. 2025 Revised Draft Human Health Risk Assessment of Formaldehyde, the AHHS II study finds typical indoor air levels to be 0.3 ug/$m^3$ to 124.2 ug/$m^3$.

[52] The studies by Kulle et al., Lang et al., and Mueller et al. reported the standard deviations in the measurements of formaldehyde concentrations, with all three studies reporting standard deviations up to 50 ppb to 60 ppb for at least one concentration for real-time and/or HPLC measurements. Lang et al. reported a standard deviation of 50 ppb at a nominal concentration of 0 ppb when measured in real time.

[53] *E.g.*, EPA-HQ-OPP-2013-0242-0050, EPA-HQ-OPP-2019-0232-0008, EPA-HQ-OPP-2012-0415-0046, EPA-HQ-OPP-2010-0498-0072, EPA-HQ-OPP-2009-0326-0022, EPA-HQ-OPP-2008-0042-0010.

no concern for mutagenicity and that a threshold-based, non-linear approach was warranted, classifying MITC as "not likely to be carcinogenic to humans below concentrations that induce regenerative [cell] proliferation of the nasal cavity epithelium."[54] This determination is directly relevant to formaldehyde, as both chemicals share a similar mode of action framework in which nasal tumor formation occurs only at concentrations that produce cytotoxicity and sustained regenerative cell proliferation. The MITC CARC decision is clear and recent precedent for EPA's revised approach to formaldehyde and further supports alignment with a threshold-based framework, consistent with international assessments like the EU, rather than continued reliance on a linear no-threshold approach derived from IRIS, which does not reflect best available science.

As ACC and numerous external experts have previously documented, the IRIS IUR analysis for nasopharyngeal cancer (NPC) suffers from fundamental scientific flaws, including failure to conduct an independent analysis of key epidemiological data, lack of consideration of alternative and non-linear dose response models consistent with EPA's Cancer Guidelines,[55] and disregard of a well-established, threshold-based mode of action (cytotoxicity with regenerative cell proliferation) that has been adopted by authoritative international bodies.[56] Robust mechanistic evidence, including molecular dosimetry and biologically based dose–response modeling, demonstrates that protecting against sensory irritation is protective of downstream effects, including NPC, and that linear extrapolation from low-dose background exposures substantially overestimates cancer risk.

Similarly, ACC and others have raised longstanding concerns regarding the IRIS Assessment's conclusions related to myeloid leukemia, including the absence of a biologically plausible mode of action, lack of systemic distribution of inhaled formaldehyde, negative findings in animal bioassays, and inconsistent epidemiological evidence.[57,58] Multiple independent reviews applying recognized MOA frameworks have concluded that a causal association between inhaled formaldehyde and lymphohematopoietic (LHP) cancers is not supported by the weight of the scientific evidence. Most recently, Vincent et al., 2024, conducted a systematic review focusing

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[54] EPA Cancer Assessment Review Committee (CARC), Methyl Isothiocyanate (MITC) Cancer Classification Reassessment, Feb 2024, available at: https://www.regulations.gov/document/EPA-HQ-OPP-2013-0080-0059

[55] NAS, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde,* 2011, at page 134, available at: https://nap.nationalacademies.org/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.

[56] *See* comments from Dr. Chad Thompson and Dr. Robinan Gentry (2026) on EPA Draft Risk Calculation Memorandum: Formaldehyde, available at: https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438; Comments to the SACC, May 2024, from Dr. Chad Thompson and Dr. Robinan Gentry, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0213.

[57] *See*, for example references in ACC Formaldehyde Panel comments on Draft 2022 Formaldehyde Assessment to Gentry/Checkoway/Mundt/Rhomberg papers, and comments submitted to the SACC from Dr. Harvey Checkoway, May 1, 2024, where he states "Based on my review of the draft EPA report, I do not find that its conclusions are grounded in the best available science and also fails to fully incorporate key recommendations from previous peer reviews, " available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0140.

[58] Gentry, R., Thompson, C.M., Franzen, A., Salley, J., Albertini, R., Lu, K. and Greene, T., 2020. *Using mechanistic information to support evidence integration and synthesis: a case study with inhaled formaldehyde and leukemia*. Critical reviews in toxicology, 50(10), pp. 885-918.

on the relationship between formaldehyde and LHP cancers, including myeloid leukemia.[59] This systematic review found "no credible explanation linking inhaled formaldehyde to LHP cancers, and no evidence of formaldehyde entering the bone marrow or blood when inhaled" and determined that causation is unlikely.[60]

In light of these issues, EPA's revised approach appropriately integrates mode of action-based evidence within the weight of the scientific evidence framework, rather than relying on the IRIS Formaldehyde Assessment, which failed to integrate the available scientific information for purposes of a TSCA risk evaluation. Because EPA has moved away from reliance on IRIS, ACC does not restate its detailed critiques here and instead incorporates its prior technical submissions by reference.[61, 62]

ACC supports EPA's decision to ground its TSCA risk evaluation in controlled human exposure data, mechanistic evidence, and a threshold-based framework that is consistent with EPA's Cancer Guidelines, TSCA's statutory scientific standards, and the best available science.

## III. EPA's Revised OEV is Based on Best Available Science

### A. EPA's OEV Derivation Is Appropriate When Applied as an 8-Hour TWA

EPA's Draft Memorandum reflects a scientifically sound and well-supported approach to deriving an occupational exposure value (OEV) for formaldehyde. EPA appropriately selected a POD of 0.3 ppm based on controlled human exposure studies identifying sensory irritation as the most sensitive and relevant endpoint, and correctly applied an uncertainty factor of 1, consistent

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[59] M J Vincent, S Fitch, L Bylsma, C Thompson, S Rogers, J Britt, D Wikoff, *Assessment of associations between inhaled formaldehyde and lymphohematopoietic cancer through integration of epidemiological and toxicological evidence with biological plausibility*, Toxicological Sciences, 2024, kfae039, https://doi.org/10.1093/toxsci/kfae039.

[60] Truth in Science, *Why Robust Methods in Systematic Review Matter: The Case of Formaldehyde and Myeloid Leukemia*, available at: https://truthinscience.org/why-robust-methods-in-systematic-review-matter-the-case-of-formaldehyde-and-myeloid-leukemia%ef%bf%bc/.

[61] ACC Formaldehyde Panel Comments on the 2024 Draft TSCA Risk Evaluation for Formaldehyde; ACC, *Summary of Insufficient U.S. Environmental Protection Agency (EPA) Responses to the Recommendations From the National Academy of Sciences (NAS) 2011 Review of EPA's 2010 Draft IRIS Assessment of Formaldehyde*, Mar. 31, 2023, at pages 4-7, available at: https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0117/attachment_7.pdf; ACC, Formaldehyde Panel Comments on the 2022 Draft IRIS Assessment for Formaldehyde, which provides additional information about scientific studies which EPA misinterpreted when evaluating the epidemiological data and mode of action information relating to NPC.

[62] As described in previous comments, robust scientific information that has been provided to EPA, but not considered in the IRIS Formaldehyde Assessment, supports a non-genotoxic mode of action where protecting against sensory irritation would also be protective of cancer. *See* MacGregor 2006, and Panel 2010 comments at: https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0029, document 5 etc. In addition, the CIIT Formaldehyde Biologically Based Dose Response (BBDR) model has been updated to address uncertainties associated with modeling DNA adducts and nasal tumors due to formaldehyde exposure. This model predicts that the probability of tumors from chronic exposure of rats to 1 ppm formaldehyde would be indistinguishable from controls, *See* Conolly RB, Schroeter J, Kimbell JS, Clewell H, Andersen ME, Gentry PR. 2023. *Updating the biologically based dose-response model for the nasal carcinogenicity of inhaled formaldehyde in the F344 rat*. Toxicol Sci. 193(1):1-17. https://doi.org/10.1093/toxsci/kfad028. PMID: 36912747; PMCID: PMC10176246

with the robustness of the underlying human data. This approach is consistent with TSCA scientific standards and with conclusions from peer reviewers and other authoritative bodies.

Importantly, while sensory irritation is not an adverse health effect, it represents a well-recognized and appropriate biological response for establishing occupational exposure limits. Sensory irritation is the single most common critical endpoint used in OEL derivation across substances, reflecting its direct relevance to impaired comfort, distraction, reduced task performance, and increased risk of accidents and safety incidents in occupational settings.[63, 64] Accordingly, protection against sensory irritation serves a clear preventive function by maintaining worker performance and safety, in addition to health protection.

EPA further recognizes that sensory irritation from formaldehyde is driven primarily by exposure concentration rather than exposure duration, and that irritation responses do not increase with longer exposure periods. Based on this scientific understanding, EPA concludes that the resulting 0.3 ppm OEV is health-protective for other endpoints, including cancer.

While EPA characterizes the 0.3 ppm OEV as an "acute" value, the scientific rationale articulated by the Agency supports application of this value as an 8-hour TWA rather than as a 15-minute short-term exposure limit (STEL).[65] This "acute" OEV is based on sensory irritation, which is a normal physiological response mediated by activation of trigeminal nerve receptors. Trigeminal nerve activation triggers a reversible cascade of defensive reflexes, such as eye-blinking.[66]

As noted by EPA peer review panels, observance of this normal physiological response to irritants provides a lower bound on potential risk from adverse effects associated with the well-described MOA leading to nasal tumors after formaldehyde exposure, because the key events in this MOA (e.g., cytotoxic irritation, regenerative cell proliferation) occur at higher doses (>2 ppm).[67]

At these higher doses, typical detoxification and repair mechanisms are overwhelmed and true adverse effects that represent functional impairment are observed.[68] While it is distinct from the cytotoxicity/regenerative cell proliferation MOA, sensory irritation is considered protective with

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[63] Brüning T, Bartsch R, Bolt HM, Desel H, Drexler H, Gundert-Remy U, Hartwig A, Jäckh R, Leibold E, Pallapies D, Rettenmeier AW. 2014. Sensory irritation as a basis for setting occupational exposure limits. Archives of Toxicology, 88(10): 1855-1879, Available at: https://doi.org/10.1007/s00204-014-1346-z.

[64] *See* comments from Andy Maier and Heather Lynch of Integral (2026) on EPA Draft Risk Calculation Memorandum: Formaldehyde, available at https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438.

[65] *Id.*

[66] *See* ACC Formaldehyde Panel Comments on the 2024 Draft TSCA Risk Evaluation for Formaldehyde, pg. 10 "Understanding formaldehyde, sensory irritation, sensitive populations, and Haber's Law; and Brüning et al. 2014.

[67] *See* Thompson et al. 2020 for a detailed summary of key events and dose levels: Thompson CM, Gentry R, Fitch S, Lu K, Clewell HJ. 2020. An updated mode of action and human relevance framework evaluation for Formaldehyde-Related nasal tumors. Critical Reviews in Toxicology, 50(10): 919–952. DOI: https://doi.org/10.1080/10408444.2020.1854679

[68] Kaden, D. (2026) comments to EPA.

regards to cancer because sensory irritation effects are observed at lower concentrations (~1 ppm) relative to the adverse effects associated with this MOA (>2 ppm).[69]

This approach is consistent with international precedent, including the European Union's establishment of a formaldehyde occupational exposure limit of 0.3 ppm as an 8-hour TWA, derived from controlled human exposure studies and based on the conclusion that irritation responses are driven by exposure concentration rather than duration.

In summary, EPA's derivation of a 0.3 ppm OEV is scientifically robust and well justified. However, to implement the Agency's stated scientific rationale, the 0.3 ppm value should be applied as an 8-hour TWA, not as a 15-minute STEL. Doing so ensures internal consistency in the risk evaluation, consistency with international benchmarks, and appropriately reflects the formaldehyde-specific human evidence demonstrating that protection against sensory irritation at this concentration is protective across exposure durations.

### B. A Short-Term Value Should Be Based on a Peak Exposure Approach

Where short term exposure management is warranted, established industrial hygiene practice relies on peak or excursion approaches, rather than direct conversion of an 8-hour TWA into a STEL. Such approaches are designed to address brief exposure variability while maintaining protection against transient sensory irritation.[70]

From an industrial hygiene and toxicological perspective, this distinction between continuous exposure and short-term peak exposure supports establishment of a STEL that is higher than the 8-hour TWA. A higher STEL reflects the biological reality that higher concentrations may be tolerated for limited periods without increasing health risk, provided that exposure duration and frequency are appropriately controlled.

Accordingly, a STEL that exceeds the 8-hour TWA is scientifically consistent with the available data on formaldehyde. A short-term limit that is equal to the TWA would instead function as a *de facto* ceiling limit, implying that any momentary exceedance is hazardous - an interpretation that is not supported by the human evidence base relied upon by EPA. In particular, both Lang et al. 2008 and Mueller et al. 2013 found no evidence of sensory irritation effects after exposure to 0.3 ppm with 0.6 ppm peaks, and Mueller et al. found no evidence of sensory irritation effects exposure to 0.4 ppm with 0.8 ppm peaks.

OSHA's longstanding 2 ppm 15-minute STEL for formaldehyde exemplifies the appropriate approach to short-term exposure management. The OSHA STEL was established to prevent

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[69] *See* the following controlled human chamber studies that show sensory irritation is concentration-dependent and not observed at or below ~0.3 ppm under typical continuous or peak exposure scenarios: Mueller et al. 2013, Lang et al. 2008, and Kulle et al. 1987.

[70] ACGIH provides the most well-known example of this approach and defines it as a "pragmatic precautionary approach." It is generally defined as limiting exposures to no more than 3 times the threshold limit value (TLV) exposure. *See* ACGIH. 2025. Formaldehyde.8DOC-278-CS. https://www.acgih.org/science/tlv-bei-guidelines/tlv-chemical-substances-introduction/

unacceptable sensory irritation from brief peak exposures and has been applied successfully for decades across diverse occupational settings.

Incorporating OSHA's 2 ppm STEL by reference would provide EPA with a practically proven mechanism to manage short-term exposure variability while maintaining protection against continuous exposure through the 0.3 ppm 8-hour TWA. This approach aligns with established industrial hygiene practice, avoids creation of an EPA-unique short-term limit not supported by the formaldehyde-specific evidence base, and ensures internal consistency with EPA's irritation-driven hazard characterization.

### C. The OSHA PEL Remains Health-Protective

As discussed above, short term exposure management for formaldehyde is appropriately addressed through peak or excursion-based approaches, rather than by converting an 8-hour TWA into a short-term limit. OSHA's existing formaldehyde standard exemplifies this approach.

In 1992, OSHA established an 8-hour TWA PEL of 0.75 ppm, an action level of 0.5 ppm, and a 15-minute STEL of 2 ppm (29 CFR §1910.1048(c)). Together, these elements provide a comprehensive framework for managing both routine and short-term exposures. OSHA concluded that this combination of limits was necessary to eliminate significant risk to workers, based on the weight of the evidence available at the time, including nasal tumor data in animals and human sensory irritation studies.

Subsequent scientific evidence reinforces OSHA's conclusions. Updated interspecies modeling demonstrates that rodents are more sensitive than humans to formaldehyde-induced nasal effects, and newer controlled human exposure studies show that objective sensory irritation occurs only at peak concentrations well above the OSHA TWA of 0.75 ppm, with cytotoxic effects occurring at still higher concentrations.[71] These studies confirm that OSHA's existing approach to short-term transient exposures with a 2 ppm STEL is protective against both transient sensory irritation and longer-term adverse effects.

Accordingly, OSHA's long-standing standard provides a science-based, practical example of how short-term peaks can be effectively managed within a TWA-based framework, without the need to establish a new or lower STEL that is not supported by the formaldehyde-specific evidence base.

[71] A relatively new study, Thompson et al. (2020), which was not considered in the previous 2024 Draft TSCA Evaluation, observes that exposure of rats to 2 ppm formaldehyde for 6 hours results in estimated nasal tissue concentrations equivalent to endogenous formaldehyde production. Conolly et al. 2023a, b, uses pharmacokinetic modeling to predict that exposure up to 2 ppm would result in minimal changes in tissue GSH, whereas exposures above 4 ppm would deplete GSH, resulting in formaldehyde reaction with other cellular components (Andersen et al. 2010). Conolly also observes that exposure at 2 ppm does not result in cytotoxicity and regenerative cell proliferation in rodent nasal tissue which occurred with exposures at 6 ppm; *See* comments from Dr. Chad Thompson and Dr. Robinan Gentry submitted to EPA, February 2026, available at: https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438.

### D. EPA's Approach Should Be Consistent with the EU 8-Hour TWA

In addition to OSHA's longstanding formaldehyde standard, international authorities have reached conclusions that further support application of 0.3 ppm as an 8-hour TWA rather than as a STEL. In 2016, the European Union's Scientific Committee on Occupational Exposure Limits (SCOEL) evaluated the formaldehyde database and established a binding occupational exposure limit of 0.3 ppm as an 8-hour TWA, based on controlled human exposure studies identifying sensory irritation as the most sensitive and relevant endpoint.[72]

Consistent with EPA's revised OEV rationale, SCOEL concluded that formaldehyde-induced sensory irritation is driven by exposure concentration rather than duration, and that protection against this effect is protective of other adverse outcomes, including carcinogenic effects at the portal of entry. Accordingly, the EU selected an 8-hour TWA derived from controlled human exposure studies, without application of additional uncertainty factors, reflecting the robustness of the human data.

If, as a matter of policy, EPA elects to identify an occupational benchmark below the OSHA PEL for purposes of TSCA risk management, consistency with the EU's 8-hour TWA of 0.3 ppm is scientifically appropriate. However, neither the EU's scientific rationale nor the underlying human evidence supports converting that value into a STEL. Rather, as discussed above, short-term exposures are appropriately addressed through peak or excursion-based exposure management approaches.

This approach is consistent with the existing U.S. occupational framework, under which OSHA's 8-hour TWA PEL is complemented by a longstanding 2 ppm STEL that effectively manages short-term peaks without converting a concentration-based TWA into a short-term limit.

In summary, the best available science supports application of the 0.3 ppm OEV as an 8-hour TWA, not as a STEL. Short term exposures are appropriately addressed through established peak exposure approaches, and for formaldehyde this need is already met by OSHA's longstanding and protective 2 ppm STEL.

## IV. EPA's Dermal Hazard Value and POD are Not Based on Best Available Science

While we recognize that the Draft Memorandum does not revise EPA's dermal hazard characterization or dermal exposure assumptions, and its scope is limited to inhalation hazard and dose response issues, we reiterate our previous comments since these issues remain unresolved.

As EPA has previously recognized, formaldehyde's dermal effects are largely localized, primarily involving allergic contact dermatitis in a small subset of sensitized individuals, and do not result in systemic effects. Occupational controls already in place, such as those required under OSHA standard 1910.1048 for solutions ≥1% formaldehyde, are specifically designed to prevent routine skin contact. Consistent with evaluations by European Chemicals Agency

[72] EU, SCOEL 2016.

(ECHA) and National Institute of Occupational Safety and Health (NIOSH), dermal exposure to formaldehyde is expected to be acute, accidental, and self-limiting due to its irritating properties, with rapid metabolism at the site of contact and negligible potential for systemic distribution.

ACC previously provided EPA with extensive occupational exposure information demonstrating that routine dermal exposure is implausible for the manufacturing and processing conditions of use evaluated under TSCA, which typically involve closed systems and engineering controls.[73] EPA's earlier scoping documents correctly recognized inhalation, not dermal contact, as the dominant exposure pathway for workers, given formaldehyde's high volatility.

Notwithstanding this, EPA derived a dermal point of departure based on a combination of animal induction and human elicitation studies that do not reflect realistic exposure conditions. In particular, reliance on occluded patch-test studies (e.g., Flyvholm et al.) and assumptions embedded in dose–response modeling (e.g., inferred monotonicity across concentrations) do not align with accepted risk assessment practices for skin sensitizers. These approaches overstate dermal risk by compounding conservatisms, including the application of unnecessary uncertainty factors, despite the fact that sensitization benchmarks (e.g., NESILs) are typically derived without uncertainty factors and are already protective by design.[74]

ACC also noted that EPA's use of elicitation endpoints is of limited relevance for occupational settings, where the emphasis is on preventing induction, and where sensitized individuals would be promptly removed from exposure. Available evidence, including controlled human data, local lymph node assay results, and in vitro assays, supports a substantially higher and more realistic induction threshold than the benchmark ultimately selected by EPA.

### A. Direct Dermal Contact with Formaldehyde is Limited by Irritancy and Occupational Exposure Controls

As outlined in ACC's comments on the draft formaldehyde risk evaluation, although dermal exposure to formaldehyde-containing liquids is theoretically possible during manufacturing (e.g., during a spill or leak), routine skin contact with formaldehyde is generally not plausible for several reasons.[75]

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[73] See ACC Formaldehyde TSCA Risk Evaluation Consortium comments, submitted to EPA May 11, 2023, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0118.

[74] *See* Comments submitted to the SACC from Dr. Joel Cohen of Gradient, May 2024, available at https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613, *See* Comments submitted to the SACC from Heather Lynch and Andrew Maier of Integral, May 2024, available at https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613; and comments from Dr. Elaine Freeman of E[x]ponent, *Occupational and Consumer Exposures Related to Wood Products*, May 2024, available at: https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613

[75] ACC. 2023. Memo to Mr. Jeffery Putt, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Re: Industrial Hygiene Monitoring Data for Formaldehyde Manufacturing and Processing - Docket ID # EPA-HQ-OPPT-2018-0438. May 11, 2023. Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0118

First, the irritating and, at higher concentrations, corrosive properties of formaldehyde that preclude prolonged skin contact are well recognized.[76] Formaldehyde solutions may cause transient discomfort and irritation, which is concentration-dependent, precluding prolonged dermal exposure. ECHA noted in its assessment of occupational exposure to formaldehyde that "[d]ermal exposure to formaldehyde solutions is expected to occur only acutely or accidentally, but duration is expected to be short due to the irritating property."[77]

Moreover, its high local reactivity minimizes the contribution of dermal formaldehyde exposure to systemic exposure. Specifically, "[a]bsorption appears to be limited to cell layers immediately adjacent to the point of contact, and formaldehyde is rapidly metabolized at the initial site of contact. Due to rapid metabolism, distribution of formaldehyde molecules to other more distant organs is not likely, except from exposure to high concentrations."[78] NIOSH concluded that in vivo toxicokinetic studies demonstrate that formaldehyde absorption is less than 10% of the exposure dose.[79] As a result, EPA recognized in its scoping document for the formaldehyde risk evaluation that "[d]ue to formaldehyde's high volatility, EPA expects the inhalation pathway to be most likely source of exposure to workers and ONUs."

Finally, the nature of the operations and tasks in some COUs, including but not limited to the manufacturing and processing COUs, which often involve closed systems with no direct worker interaction, preclude significant dermal contact with formaldehyde. See below for specific examples of processes limiting dermal exposure noted by multiple companies in their submissions to the formaldehyde TSCA docket.

## B. PPE Selection Guidance is Available to the Formaldehyde Industry

Glove selection procedures are well-established and publicly available from authoritative entities such as OSHA, NIOSH, the American Industrial Hygiene Association (AIHA), and the peer-reviewed literature. Employers covered by OSHA regulations are required to adhere to OSHA's 29 CFR 1910.138, Hand Protection.[80] Proper glove selection methods are critical, as personal protective equipment (PPE) is considered the last line of defense between workers and chemical/physical hazards if engineering and work practice controls cannot eliminate the hazard.[81]

Further, it is well-known that different hazard/task combinations may require different gloves; identification of the intended tasks, associated hazards, and necessary gloves is typically conducted during a job hazard analysis. Factors such as the chemical hazards present during a

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[76] NIOSH. 2011. NIOSH Skin Notation (SK) Profile: Formaldehyde/Formalin [CAS No. 50–00–0]. DHHS (NIOSH) Publication No. 2011–145.
[77] 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.
[78] *Id*.
[79] NIOSH. 2011.
[80] Nelson, D.I., and R.N. Phalen. 2022. Review of the performance, selection, and use of gloves for chemical protection. ACS Chem. Health Saf. 29:39−48. https://doi.org/10.1021/acs.chas.1c00084
[81] OSHA. 2023. Personal Protective Equipment. OSHA 3151-02R 2023. Occupational Safety and Health Administration.

specific task, the nature of the contact, duration of contact, area requiring protection, grip requirements, size and comfort, and dexterity are all considered when selecting the proper glove for a specific task.[82]

Importantly, the limitations of different gloves are also considered during glove selection.[83] In the case of formaldehyde, OSHA reports that neoprene, latex/rubber, butyl, and nitrile gloves all offer "very good" protection.[84] OSHA's PPE guidance document is intended to assist both employers and employees. It provides a comprehensive understanding of the various types of PPE, selecting the appropriate PPE for a wide range of occupational scenarios, and an understanding of the necessary training requirements for the correct use, maintenance, and care of PPE. This guidance also contains a comprehensive table outlining glove selection properties and strategies for employers based on chemical resistance. This table evaluates the protective performance of various glove types against specific chemical agents, including formaldehyde. It is intended to assist in the selection of the most suitable glove type for safeguarding workers, and the performance ratings are defined as VG = Very Good; G = Good; F = Fair; and P = Poor (not recommended).[85]

Testing protocols to determine glove permeation resistance are also well-established.[86] The American Society of Testing and Materials (ASTM International), the International Organization for Standardization (ISO), and the European Union's European Center for Standardization (CEN) are the main organizations that have developed glove testing standards. These standards are used by glove manufacturers to test their glove materials in a controlled lab setting and measure the effects of penetration, degradation, and permeation under continued chemical exposures. Such testing yields glove performance parameters, including breakthrough time, standardized breakthrough time, steady state permeation rate, and cumulative penetration. Literature on whole-glove permeation testing to reflect the influence of hand movement on chemical permeation also exists; however, these methods are less widespread.[87]

Below are two examples of company-specific PPE selection guides.

Ansell Guardian Chemical—Permeation and Degradation Database

This database provides data pertaining to the barrier (permeation/degradation) efficacy of specific PPE materials against selected chemicals. This information is designed to support and guide occupational and safety hazard (OSH) professionals in making evidence-based PPE selection decisions aligned with the chemical or chemical mixtures in use. OSH professionals can use this database to inform selection of hand and body protection PPE products.

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[82] Nelson and Phalen (2022).
[83] *Id*.
[84] OSHA. 2023. Table 4.
[85] *Id*.
[86] Banaee, S., and S.S. Que Hee. 2019. Glove permeation of chemicals: The state of the art of current practice, Part 1: Basics and the permeation standards. J. Occup. Environ. Hyg. 16(12): 827–839. doi:10.1080/15459624.2019.1678754.
[87] *Id*.

| CHEMICALS | | | | PRODUCT | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| CAS | Chemical Name | % | Physical State | Thickness (mm): 0.062 mm 2.5 mil<br>Material: LLDPE<br>Brand: AlphaTec® | Thickness (mm): N.A.<br>Material: Neoprene<br>Brand: AlphaTec® | Thickness (mm): N.A.<br>Material: PVA<br>Brand: AlphaTec® | Thickness (mm): 0.38 mm 15 mil<br>Material: Nitrile<br>Brand: AlphaTec® Solvex® | Thickness (mm): 0.56 mm 22 mil<br>Material: Nitrile<br>Brand: AlphaTec® Solvex® | Thickness (mm): 0.35 mm 14 mil<br>Material: Butyl<br>Brand: AlphaTec® |
| | | | | 02-100 | 08-352.354 | 15-554 | 37-155 | 37-185.165/58-008 | 38-001 |
| 50-00-0 | Formaldehyde | 37 | Liquid | > 480' C | 240-480' | < 10' | > 360' C | > 480' | > 480' |

PERMEATION BREAKTHROUGH TIMES

| Good Protection | Medium Protection | Splash Protection | Not Recommended |
|---|---|---|---|
| > 480 | 120-240 | 30-60 | < 10 |
| 240-480 | 60-120 | 10-30 | |

Honeywell & North Safety—Chemical Resistance Guide

This guide helps employers through the process of determining what type of PPE glove to wear and its permeation resistance to the selected chemical, formaldehyde included.

Specifically, this guide incorporates degradation, permeation rates, and breakthrough time, and provides a color-coded recommendation guide and other useful information.[88]

### C. Company Dermal SOPs and Trainings are Prevalent

Examples provided in the public comments on the draft TSCA formaldehyde risk evaluation demonstrate that numerous companies representing multiple formaldehyde COUs have robust PPE programs to protect their workers from potential exposures to formaldehyde. Select excerpts from comments submitted to the formaldehyde docket are included below.

Celanese

Celanese submitted comments to the docket in 2024 that detailed information on its PPE program, including requirements for potential dermal exposures. Celanese noted in its comments that COUs relevant to its use of formaldehyde include 1) Domestic manufacture of formaldehyde, 2) Processing of formaldehyde as a reactant (intermediate) in plastic materials and

[88] Honeywell and North Safety, Chemical Resistance Guide, available at: https://prod-edam.honeywell.com/content/dam/honeywell-edam/sps/his/en-us/products/hand-protection/documents/HS_silver_shieldc2ae_-_ssca_2940.pdf?download=false

resin manufacturing, and 3) Distribution of formaldehyde.[89] Celanese stated that "[t]he OSHA formaldehyde standard requires the use of protective clothing to prevent dermal exposure where needed. The Celanese data presented to EPA during a site visit and in the docket establishes that Celanese workers wear dermal-protective PPE when engaged in higher exposure activities."

Celanese described the stringency of its PPE program for workers, including occupational non-users (ONUs): "Celanese requires as a condition of employment that specific types of PPE are worn by all workers at the manufacturing facility; ONUs in other manufacturing, maintenance, and utilities areas; and by any ONUs when they enter production areas.

Required PPE includes fire resistant clothing, cut resistant gloves, safety glasses and/or goggles, ear plugs, and non-permeable steel-toed boots. PPE requirements are specified in site or company policies; compliance is a condition of employment. Celanese ensures employee compliance through regular training, visual monitoring, and corrective action for any non-compliance."

Covestro

Covestro submitted comments to the docket in 2024, including multiple attachments detailing the different trainings, tools, and guidance utilized as part of its PPE program. In its comments, Covestro noted that its processes fall under processing as a reactant in chemical production (specifically in production of methylene diphenyl diisocyanate).[90]

Attachment 4 to Covestro's comments highlights the consideration of breakthrough time in selecting PPE for specific tasks: "Chemical Resistant Suits and Gloves – There are many chemical compounds used in the [redacted] Plant, and the most common are identified in the Minimum Required Personal Protective Equipment list. Allowances have been made for exposure time, e.g., a minimum of a 30-minute exposure time has been used for glove selection when possible. However, after chemical contact has occurred, an individual should remove the suit or gloves as soon as possible to prevent chemical breakthrough. While planning tasks that require chemical resistant clothing, the breakthrough time of the chemical or mixture with the chosen PPE should be considered. Work breaks may be required to change out contaminated PPE. Other work task conditions that may affect breakthrough times are temperature and presence of solvents. When a chemical comparison cannot be made from the data in the Minimum Required PPE list, consult with Industrial Hygiene." [91]

[89] Celanese Corporation. 2024. Comments of Celanese Corporation on the Draft Risk Evaluation for Formaldehyde. Docket No. EPA-HQ-OPPT-2018-0438, Docket No. EPA-HQ-OPPT-2023-0613. May 14, 2024. Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0286

[90] Covestro LLC. 2024b. Comments of Covestro LLC, submitted to Science Advisory Committee on Chemicals (SACC) Peer Review of 2024 Draft Formaldehyde Risk Evaluation (Docket No. EPA-HQ-OPPT-2023-0613). May 13, 2024. Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0277

[91] Covestro LLC. 2024a. Attachment 4: Minimum Personal Protective Equipment Requirements. Location: HSEQ Site Procedures. Revision No. 20. Revision Date February 21, 2024. Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0277

Further, Attachment 5 to Covestro's comments contains a printout of Covestro's dashboard for selecting the necessary PPE, including glove types, by chemical and intended task.[92] The tool indicates that potential exposures to formaldehyde when starting equipment or operating valves, nitrile, butyl, neoprene, rubber/latex, or Viton gloves are acceptable.

Dow

Dow submitted comments to the formaldehyde docket in 2024, highlighting its workers' use of PPE when around formaldehyde.[93] Dow notes that its uses of formaldehyde are represented under the processing as a reactant: manufacturing of basic chemicals COU. Dow also states how it considered breakthrough time when selecting gloves for use around formaldehyde: "While Dow understands that EPA does not consider PPE as part of their risk evaluation process, PPE is required to be used in this industrial setting because formaldehyde is corrosive at these concentrations. Again, PPE is only used as a precaution since exposure to the hands is not expected to occur. In the unlikely event that exposure to the hands did occur, gloves that are worn (widely available from many vendors) demonstrate 0% breakthrough of formaldehyde after 8-hour of exposure (Ansell 2003 Chemical Resistance Guide). Therefore, actual dermal exposure would be zero. Lastly, as an added precaution, if exposure did occur, our employees would be required to enter a safety shower immediately."

Hexion

Hexion, representing the manufacturing COU, submitted comments to the docket in 2024.[94] Hexion's comments describe its worker health and safety program, including the use of formaldehyde-resistant gloves when needed: "For example, Hexion manages any worker dermal and inhalation exposures through long-standing and robust health and safety programs… Exposure to formaldehyde in the workplace is readily controlled by good engineering and process controls, sufficient ventilation and proper handling and storage techniques. Examples include local exhaust ventilation systems; proper protective equipment such as eye protection; suitable work clothing which covers arms and legs; formaldehyde-resistant gloves; and NIOSH-approved respirators in situations where exposure exceeds allowable exposure limits and/or ventilation alone is not sufficient."

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[92] Covestro LLC. no date. Attachment 5: Minimum Required Personal Protective Equipment Table. Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0277

[93] Dow. 2024. Memo from Mike LaFore, Americas Product Regulatory Services Senior Leader, to Tamue Gibson, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, U.S. Environment Protection Agency RE: Comments on EPA's Draft Formaldehyde Risk Evaluation; Docket: EPA-HQ-OPPT-2023-0613. May 14, 2024. Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0269.

[94] Hexion, Inc. 2024. Memo from Clint Woods, Global Director, Product Stewardship & Regulatory Affairs, to Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency (U.S. EPA or EPA), RE: Comments on U.S. EPA's Draft Toxic Substances Control Act (TSCA) Risk Evaluation of Formaldehyde and Peer Review by the Science Advisory Committee on Chemicals (SACC); Docket ID: EPA–HQ–OPPT–2023–0613; 88 Federal Register (FR) 18933 (March 15, 2024). May 14, 2024. Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0260.

The Scotts Company, LLC

The Scotts Company, LLC submitted comments in 2023 describing its use of formaldehyde in a closed system, representing a processing as a reactant COU.[95] The Scotts Company's comments describe the use of formaldehyde within a closed system, and the PPE required in the event of a spill or leak: "The production of methylene urea is the result of reacting to Urea Formaldehyde Concentrate (UFC) and urea. Prior to reaction, UFC 85 (60% formaldehyde, 25% urea and 15% water) is transferred via a closed system from bulk tanks to a reaction vessel that is equipped with a scrubber to mitigate potential gases from venting and minimize worker exposure. During the reaction of UFC with additional urea, free formaldehyde is completely and irreversibly consumed. If leaks or spills occur or UFC feeders require calibration, respirators with organic vapor cartridges are required in addition to standard personal protective equipment (PPE), such as hard hats, safety glasses and gloves."

In summary, while ACC supports EPA's revised, science-based approach for inhalation hazards reflected in the Draft Memorandum, EPA has not revisited or corrected its dermal hazard analysis, which remains overly conservative and does not reflect the best available science or standard methodologies for evaluating skin sensitization. Because dermal exposure assumptions now drive unreasonable risk determinations for many conditions of use, it is particularly important that this aspect of the risk evaluation be scientifically sound and fit for purpose. ACC therefore incorporates its prior detailed dermal comments by reference and encourages EPA to subject its dermal hazard framework to the same level of scientific rigor and evidence integration that it has now appropriately applied to inhalation risks.[96]

In addition, as documented in comments submitted by Integral, EPA's dermal risk determinations are driven by inflated permeability assumptions (Qu values), an elicitation-based benchmark that ignores SACC recommendations, and fail to consider standard NESILs (No Expected Sensitization Induction Level) or real-world exposure controls - each of which independently biases the analysis toward unreasonable risk conclusions.[97]

## V. Additional Information Relevant to Informing Risk Management Decisions

### A. Consideration of ACC IH Monitoring Data Previously Submitted to EPA

Industrial hygiene monitoring data from U.S. formaldehyde manufacturing and processing facilities demonstrate that current occupational exposures are far below the levels OSHA's PEL and action level. An analysis previously provided to EPA evaluated nearly a decade (2012–2020) of personal breathing-zone industrial hygiene monitoring data representing more than 80 percent

[95] The Scotts Company, LLC. 2024. Memo from Janelle Restum, Vice President – Regulatory Affairs and Environmental, Health and Safety, to Tamue Gibson, Designated Federal Office, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, RE: EPA-HQ-OPP-2023-0613, The U.S. Environmental Protection Agency's (EPA) Draft Evaluation of Formaldehyde under the Toxic Substances Control Act (TSCA). Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0250.

[96] ACC Formaldehyde Panel Comments on the 2024 Draft TSCA Risk Evaluation for Formaldehyde, *see* pages 24-27: EPA's dermal hazard value and POD are not best available science (charge question 1.3).

[97] Andy Maier and Heather Lynch of Integral. (2026).

of U.S. formaldehyde manufacturing capacity.[98] Across 4,688 full-shift (8-hour TWA) samples covering multiple manufacturing and processing conditions of use, median worker exposures ranged from approximately 0.04 to 0.07 ppm, with an overall median of 0.05 ppm and a conservative 95th-percentile estimate of 0.25 ppm, well below OSHA's PEL and action level. Temporal analyses showed exposures to be stable or declining over time, with reduced variability reflecting modern engineering controls and mature industrial hygiene programs. Notably, these estimates were derived without accounting for the use of PPE, which would further reduce actual inhalation exposures.

The monitoring data used in this assessment were collected from major formaldehyde manufacturing and processing facilities in the United States. Monitoring data were reported from 17 formaldehyde manufacturing facilities, 15 formaldehyde and resin production facilities, 16 facilities incorporating formaldehyde into an article, 2 facilities processing formaldehyde as a reactant, and 14 facilities incorporating formaldehyde into a formulation, mixture, or reaction product. Given the number and breadth of facilities evaluated, the exposure estimates developed from the monitoring data are therefore reflective of current domestic formaldehyde manufacturing and processing facilities.

Unfortunately, EPA does not appear to have incorporated this data into its occupational exposure assessment, and we encourage the Agency to incorporate this information into its analysis and any future risk management decisions.

### B. EPA Should Establish a Regulatory *De Minimis* Threshold for Formaldehyde in Products

As part of the TSCA Section 6 risk management rulemaking for formaldehyde, EPA should establish a regulatory *de minimis* threshold excluding from future restrictions products containing less than 0.1 percent formaldehyde by weight, and should extend this threshold to relevant upstream activities, including manufacturing, import, and processing. Adoption of such a threshold would be consistent with EPA's recent TSCA risk management rules, long-standing regulatory practice across federal programs, and the scientific understanding of formaldehyde.

The 0.1 percent threshold is already widely recognized across federal regulatory programs as a practical benchmark. Under OSHA's Hazard Communication Standard and the Toxics Release Inventory (TRI) reporting requirements, concentrations below 0.1 percent for carcinogens are generally exempt from additional regulatory obligations. Formaldehyde is also classified as an irritant and sensitizer, and OSHA applies *de minimis* thresholds of 0.1 percent or higher for those hazard endpoints as well. These thresholds reflect a long-standing regulatory judgment that trace levels below 0.1 percent do not warrant additional risk management measures.

A regulatory *de minimis* threshold provision is particularly appropriate for formaldehyde given its unique biological and environmental context. Formaldehyde is ubiquitous in the natural environment and is also produced endogenously in the human body as part of normal metabolic

[98] ACC. 2023. Memo to Mr. Jeffery Putt, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Re: Industrial Hygiene Monitoring Data for Formaldehyde Manufacturing and Processing - Docket ID # EPA-HQ-OPPT-2018-0438. Also attached as Appendix B.

processes. As a result, trace quantities of formaldehyde in products at levels below 0.1 percent will not meaningfully alter ambient concentrations or materially increase exposure or risk beyond background levels.

Establishing a regulatory *de minimis* threshold would also address practical realities associated with polymers and other materials that may contain very low levels of residual or byproduct formaldehyde. In both cases, manufacturers make efforts to remove formaldehyde to the extent practical. In processing, many polymers are melted and molded to shape. This practice releases virtually all of the residual formaldehyde. Polymers are solid substances while formaldehyde is a gas at ambient conditions. Any formaldehyde that remains is largely encapsulated in layers of polymer chains. Any risk of exposure is truly *de minimis*.[99]

Adoption of a 0.1 percent regulatory threshold for formaldehyde would be consistent with EPA's interpretations under the proposed 2025 TSCA risk evaluation framework rule.[100] It would also align with numerous other federal regulatory programs, including:

- Appendix A to OSHA's Health Hazard Criteria at 29 CFR 1910.1200;
- EPA's 2023 National Emissions Standards for Hazardous Air Pollutants for the Plywood and Composite Wood Products Sector, which treat amino-phenolic resins containing less than 0.1 percent formaldehyde as non-HAP resins; [101]
- TRI *de minimis* reporting thresholds; [102]
- OSHA exemptions from safety data sheet reporting under the Hazard Communication Standard; [103] and
- Products and uses not affected by the Consumer Product Safety Commission's strong sensitizer interpretation under the Federal Hazardous Substances Act. [104]

In summary, EPA should establish a 0.1 percent regulatory *de minimis* threshold for formaldehyde as part of the Section 6 risk management rulemaking. Doing so would be grounded in existing regulatory precedent, consistent with the best available science, and

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[99] For an example of how extremely low emissions from a polymer might be, see Celanese Comment letter of December 7, 2023, which on pp. 5-6, describes a long-term sample found to release only about 0.0000019 ppb per minute, https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0132.

[100] In the Proposed 2025 Framework Rule, EPA "proposes that experience in conducting risk evaluations under TSCA section 6(b) has made clear that at least some discretion to tailor the scope of risk evaluations is necessary to accomplish the objective of making meaningful progress in comprehensively evaluating the risks presented by existing chemicals while also complying with TSCA's ambitious statutory deadlines. As mentioned in the 2017 final rule, excluding *de minimis* uses and uses with minimal exposure potential are two examples of how EPA might choose to focus risk evaluations."

[101] National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products, 88 Fed. Reg. 31856, 31872 (proposed May 18, 2023) (to be codified at 40 C.F.R. 63); Memorandum from Katie Hanks, U.S. EPA to Docket ID No. EPA-HQ-OAR-2016-0243 (May 18, 2023), https://www.regulations.gov/document/EPA-HQ-OAR-2016-0243-0420; Memorandum from Katie Hanks, U.S. EPA, to Docket ID No. EPA-HQ-OAR-2016-0243 (May 18, 2023), https://www.regulations.gov/document/EPA-HQ-OAR-2016-0243-0409.

[102] U.S. EPA, Office of Pollution Prevention and Toxics, EPA 740-B-22-005, Toxic Release Inventory: Basis of OSHA Carcinogens (Sept. 2022), https://www.epa.gov/system/files/documents/2023-01/Toxics%20Release%20Inventory%20Basis%20of%20OSHA%20Carcinogens.pdf.

[103] 29 C.F.R. § 1910.1200(b)(5)(ii) (2024).

[104] 15 C.F.R. § 1500.13 (2025).

essential to providing regulatory certainty while focusing risk management measures on uses and exposures that meaningfully contribute to risk.

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Thank you for considering our comments. Should you have any questions, please reach out to Sahar Osman-Sypher, Senior Director, Formaldehyde Panel, at sahar_osman-sypher@americanchemistry.com or 202-249-6721.