CENTER FOR ENVIRONMENTAL ACCOUNTABILITY

COMMENTS OF THE CENTER FOR ENVIRONMENTAL ACCOUNTABILITY

Comments on Draft Formaldehyde Risk Evaluation under the Toxic Substances Control Act (TSCA)

89 Fed. Reg. 18,933 (March 15, 2024)
Docket No. EPA-HQ-OPPT-2023-0613;
RL-11608-03-OCSPP

SUBMITTED MAY 14, 2024

The Center for Environmental Accountability (CEA) submits these comments on the United States Environmental Protection Agency's (EPA) draft risk evaluation for formaldehyde, as described in EPA's Notice for *Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Notice of Availability, Public Meetings and Request for Comment*, 89 Fed. Reg. 18,933 (March 15, 2024).

CEA is a 501(c)(3) organization devoted to educating the public and government on the importance of transparency and accountability in the areas of environmental and energy policy. CEA's work is driven by its core principles, including a commitment to the rule of law, to a clean environment, and to a healthy human environment founded on a strong economy and vibrant communities animated by people gainfully employed in all the occupations of human flourishing. CEA understands that adherence to law requires respect for the proper roles of each branch of government and for the respective roles of the federal government and of state governments. CEA recognizes that the public interest requires a balance of environmental stewardship, resource development, and energy access and security, and that environmental remediation functions best when targeted at those communities injured by unlawful pollution.

I. Introduction

Formaldehyde is normally present in all tissues, cells and bodily fluids and that natural occurrence complicates any formaldehyde risk assessment.

National Academies of Sciences, Engineering, and Medicine (2011).

Throughout our daily lives, all of us are exposed to formaldehyde and always will be. After all, formaldehyde is an integral part of normal metabolism in humans and other animals; a product of all sorts of combustion, including wildfires; a natural decomposition byproduct of organic matter; and a product of the degradation of other chemicals. Formaldehyde is also a remarkably versatile chemical used to make a multitude of industrial and consumer products that we all rely on, from composite wood products to electronics.

EPA recognizes the ubiquitous nature of formaldehyde and that conducting a TSCA risk evaluation of formaldehyde poses unique challenges. Not only must EPA overcome the challenge of distinguishing formaldehyde exposures traceable to certain conditions of use (COUs) from all other sources, but it must evaluate the hazards from these exposures, all of which must be based on the best available science and the weight of scientific evidence. EPA fails to meet these challenges as made abundantly clear in the draft risk evaluation for formaldehyde (hereinafter "Draft RE").

EPA confidently asserts that formaldehyde as a whole chemical presents unreasonable risk. In rendering this unreasonable risk determination, EPA clearly failed to assess potential risk from conditions of use of formaldehyde "within the broader context of all sources of

formaldehyde, some of which people have been exposed throughout the course of human existence."[1]

In the Draft RE, EPA did not separate background combustion sources from the TSCA COUs, nor was EPA able to distinguish formation of formaldehyde as a result of the degradation of other chemical compounds from the COUs. In its evaluation of specific COUs, EPA's exposure estimates are riddled with uncertainties and unrealistic assumptions that only serve to exaggerate the estimated exposures and exacerbate the challenges of assessing and addressing unreasonable risk. Similarly, EPA's overly conservative interpretation of the available hazard information – repeatedly criticized upon review by various scientific bodies – further obfuscates the Agency's evaluation of real-life, actual risks associated with the COUs.

The Draft RE is plagued by fatal scientific and procedural deficiencies that cannot be corrected during the risk management phase as EPA appears to signal in an appendix tucked away in one of the documents that constitute the sprawling Draft RE. Indeed, TSCA's legislative history makes clear that demonstrating "the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture," which is a required element of any risk management rule under TSCA Section 6(c)(2)(A), does "not require EPA to conduct a second risk evaluation-like analysis to identify the specified information, but rather, can satisfy these requirements on the basis of the conclusions regarding the chemical's health and environmental effects and exposures in the risk evaluation itself."[2] EPA cannot abdicate its duty to accurately evaluate the risks associated with each COU during risk evaluation, in hopes that the Agency will develop "new information collection or development" during the risk management stage.[3]

The stakes could not be higher. EPA's preliminary determination that formaldehyde presents unreasonable risks, if left unaltered, will have profound impacts on the entire economy as EPA unleashes its regulatory arsenal to address those unreasonable risks, however unreal. EPA recognizes it is at a critical juncture in the development of the Draft RE, as it awaits public and peer review comments on both the formaldehyde hazard and exposure assessments, the two key ingredients of any risk evaluation. In finalizing the formaldehyde risk evaluation, EPA has the choice to either fulfill its obligations under TSCA and ensure that the risk evaluation truly reflects the TSCA scientific standards of best available science and weight of the scientific evidence, or to hold fast to its current approach that EPA rightly fears "compounds conservative assumptions, leading to unrealistic or un-addressable outcomes."[4]

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[1] *See* EPA, *Executive Summary of the Draft Risk Evaluation for Formaldehyde*, at 4 (March 2024) (hereinafter "Executive Summary"), *available at* https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-executive-summary-public-release-hero-march2024.pdf.

[2] 162 Cong. Rec. S3511-01, at *S3517.

[3] *Id.*

[4] *Executive Summary* at 7.

II. EPA's single "unreasonable risk" determination for formaldehyde, as a whole, contradicts TSCA's implementing regulations and undermines the statutory scheme.

A. A single determination for the entire chemical is contrary to TSCA's existing regulations.

EPA's current procedural regulations for chemical risk evaluation require that, "[a]s part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment ***under each condition of uses*** [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents."[5] The Draft RE does not include separate determinations applicable to each condition of use, as required by the regulation. Instead, EPA brands the entire chemical with an "unreasonable risk" determination and subsequently asserts whether each condition of use "contributes to" this unreasonable risk, without clearly defining the criteria the Agency uses to determine such "contribution."[6]

EPA appears to have ignored the procedural regulations applicable during the drafting of the risk evaluation and has instead tailored the Draft RE to be consistent with the Agency's recently amended regulations – effective July 22, 2024 – which will remove the requirement to make a determination for each COU and instead require "a single determination as to whether the chemical substance presents an unreasonable risk." EPA's reliance on these recent regulatory changes is not only contrary to the purpose and intent of TSCA as explained below, but also unlawfully disregards the mandates imposed by the regulations at the time of the drafting of the risk evaluation.[7]

B. A single risk determination undermines the purpose of TSCA and eviscerates key preemption provisions.

TSCA explicitly states in its introductory "findings" section that "among the many chemical substances and mixtures which are constantly being developed and produced, there are some ***whose manufacture, processing, distribution in commerce, use, or disposal*** may present an unreasonable risk of injury to health or the environment."[8] Thus, the purpose of TSCA is *not* to assess whether chemical substances *themselves* may pose an unreasonable risk, but to determine whether *particular applications* of chemical substances have the potential to pose

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[5] 40 C.F.R. § 702.47 (emphasis added).

[6] *See* EPA, *Unreasonable Risk Determination of the Draft Risk Evaluation for Formaldehyde* (March 2024) (hereinafter "Unreasonable Risk Determination"), *available at* https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-unreasonable-risk-determination-public-release-hero-march-2024.pdf.

[7] *See, e.g.*, *Santomenno ex rel. John Hancock Tr. v. John Hancock Life Ins. Co. (U.S.A)*, 768 F.3d 284, 298 (3d Cir. 2014) ("[A] proposed regulation does not represent an agency's considered interpretation of its statute, … and therefore it does not supplant a prior regulation that was the result of the agency's considered interpretation.").

[8] 15 U.S.C. § 2601(a)(2) (emphasis added).

unreasonable risk, and to take action to address those specific applications.[9] This intent is further evidenced by Congressional floor statements made on the day of passage of the 2016 TSCA Amendments: "To be clear, every condition of use identified by the Administrator in the scope of the risk evaluation must, and will be either found to present or not present an unreasonable risk."[10] Thus, Congress knew that individual risk determinations for each COU were necessary for EPA to take targeted, actionable steps to address any potential unreasonable risk. A determination that an entire chemical, as a whole, presents unreasonable risk, is meaningless when EPA's ultimate charge is to regulate "the manufacture, processing, or distribution in commerce of such substance or mixture," including "particular use[s]" of the chemical substance.[11]

In addition to complicating EPA's risk management obligations, a single risk determination undermines the balance struck between federal and state authority over the regulation of chemicals as intended under TSCA. The Draft RE's single risk determination could severely limit TSCA's preemption provisions, which were critical to the negotiations that led to the enactment of the 2016 TSCA amendments. Congressional floor statements recognized that "the preemption section […] was the most contentious issue of the negotiations as well as the most important linchpin in the final deal" and that preemption would "further Congress's legislative objective of achieving uniform, risk-based chemical management nationally in a manner that supports robust national commerce."[12]

TSCA Section 18(c) states that federal preemption applies "***only to*** … ***the hazards, exposures, risks, and uses or conditions of use*** of such chemical substances ***included in any final action*** the Administrator takes," either to prevent an identified unreasonable risk under Section 6(a), or to make a determination of "no unreasonable risk" under Section 6(i)(1).[13] Thus, under EPA's "single risk determination" approach for formaldehyde, states could take the position that preemption only applies to those conditions of use that are included in a Section 6(a) rule, or that are the subject of a no unreasonable risk determination under Section 6(i). This approach would exclude from the scope of preemption those conditions of use that are included in a risk evaluation, but are not ultimately included in a Section 6(a) rule or Section 6(i) order.

Such a situation is likely to arise with formaldehyde. The Draft RE evaluates 62 separate conditions of use. The Draft RE explains that it has varying degrees of certainty regarding the contribution of each of these conditions of use to the unreasonable risk of formaldehyde. The Agency concludes that it has "less certainty" about the contribution of dozens of these conditions of use to the unreasonable risk due to cancer and non-cancer effects. The Draft RE further determines that four of the conditions of use are not expected to contribute to the unreasonable

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[9] The actions available to EPA include, for example, requirements on "a particular use," a "manner or method of commercial use," or a "manner or method of disposal." 15 U.S.C. § 2605(a).

[10] 162 Cong. Rec. S3511-01, at *S3520.

[11] 15 U.S.C. § 2605(a).

[12] 162 Cong. Rec. S3511-01, at *S3520-3521.

[13] 15 U.S.C. § 2617(c)(3) (emphasis added).

risk at all. However, under EPA's approach to risk evaluations, none of these conditions of use – which are unlikely to present an unreasonable risk by EPA's own criteria – will benefit from preemption. This is because these conditions of use are unlikely to be addressed in a Section 6(a) rulemaking (to prevent the unreasonable risk) or a Section 6(i) order (a "no unreasonable risk" determination). Thus, states will inevitably argue that they are free to regulate these uses even though they have been evaluated by EPA,[14] contrary to Congressional intent, which assumes that every condition of use will be found either to present or not present an unreasonable risk.

C. A single risk determination is ultimately unhelpful for the purposes of risk management.

As noted above, the Draft RE does not include individual determinations of unreasonable risk *for each COU*, as required by the current (2017) regulations. Instead, EPA states with varying levels of confidence whether each COU *contributes to* the overall unreasonable risk that the Agency has assigned to formaldehyde as a whole chemical. The criteria that EPA uses to determine the contribution of each COU to the unreasonable risk are not well-defined. EPA simply states that it "examined whether the contribution of formaldehyde exposure from a COU was greater than or within typical expected exposures from indoor air to inform EPA's preliminary determination of whether that COU contributes to unreasonable risk."[15] Elsewhere, EPA states that "For the risks […] to workers and people who use formaldehyde-containing products or have formaldehyde-containing products or have formaldehyde-containing furnishings or materials in their homes, those risks may not be any greater than" the risks from biogenic, combustion and secondary sources of formaldehyde."[16]

The Agency "has high level of certainty of the contribution to the unreasonable risk of formaldehyde from a COU when the risk from such COU is much greater than the risk expected from the formaldehyde based on monitored concentrations in the indoor air."[17] Thus, EPA's confidence in its determinations of the contribution of each COU to unreasonable risk appears to be based on a comparison to background levels of formaldehyde, rather than a substantive assessment of the estimated exposures from each COU in comparison to the derived hazard values. EPA's approach fails to meet the statutory mandate that the risk evaluation "***integrate***

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[14] In the preamble to the final procedural rule, EPA strains to make the argument that a single risk determination will not impact the scope of preemption because it will apply "to any condition of use within the scope of the risk evaluation… irrespective of whether those uses contribute to the unreasonable risk and/or are targeted for risk management." 89 Fed. Reg. at 3706. EPA fails to read the plain language of TSCA Section 18(c)(3), which limits the scope of preemption "only to … the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any ***final action*** the Administrator takes pursuant to section 2605(a) or 2605(i)(1)" (emphasis added). States are likely to argue that the risk evaluation is not a "final action" and that they are therefore free to regulate those conditions of use included in a risk evaluation but not included in a final risk management rulemaking.

[15] *See Unreasonable Risk Determination*, at 4.

[16] *See Executive Summary*, at 4.

[17] *Id.* at 6.

and assess available information on ***hazards and exposures for the conditions of use*** of the chemical substance."[18]

EPA's vague "contribution" approach to the COUs also casts doubt on the Agency's overall determination that formaldehyde, as a whole chemical, presents an unreasonable risk. If certain of EPA's determinations regarding contribution to unreasonable risk are found to be inaccurate following peer review, at what point is the overall determination of unreasonable risk implicated? If, for example, inaccuracies are found in EPA's exposure estimates for workers, such that it is clear that existing regulations from other agencies drastically reduce such exposures in practice, does formaldehyde, as a whole, still present unreasonable risk? It is impossible to tell from EPA's approach. Similarly, there is no way for EPA quantitatively determine whether it has imposed requirements "to the extent necessary" to address the unreasonable risk, as required by TSCA.[19]

III. EPA unlawfully excludes key portions of the Draft RE from SACC Peer Review

The regulations on the procedures for risk evaluations under TSCA explicitly mandate that "[p]eer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A)" and that "[t]he EPA Peer Review Handbook (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), and other available relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities."[20]

As discussed in the preamble to the 2017 final procedural rule establishing the existing peer review provisions, "[i]n addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment[21] will also undergo peer review, as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination."[22] The preamble goes on to state that "[t]he peer review will address aspects of the science underlying the assessment, including, but not limited to hazard assessment, assessment of dose-response, exposure assessment, and risk characterization."[23] Peer review of the Draft RE, therefore, helps

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[18] 15 U.S.C. § 2605(b)(4)(F) (emphasis added).

[19] 15 U.S.C. § 2605(a).

[20] 40 C.F.R. § 702.45. The OMB Peer Review Bulletin does discuss "circumstances when peer review of influential products may not be necessary," none of which apply to the "product" (*i.e.*, the Draft RE) in this instance. The circumstances include, for example, if the product was developed by NASEM or if the product had already been peer-reviewed. But the Draft RE has never been peer reviewed.

[21] The "risk assessment" and the unreasonable risk determination together constitute the risk evaluation. Although the regulations refer to peer review of the "risk evaluation" EPA notes in the preamble to the final rule, "Consistent with the proposed rule, EPA will not seek review of any determination as to whether the risks are 'unreasonable,' which is an Agency policy determination." 82 Fed. Reg. 33726, 33744 (July 20, 2017).

[22] *Id.*

[23] *Id.*

ensure that the risk evaluation fully meets the scientific standards of best available science and weight of scientific evidence.

EPA claims throughout the Draft RE that it will be peer reviewed in accordance with the 2017 regulations.[24] Yet, despite these public pronouncements and regulatory requirements, EPA has requested that the Agency's Science Advisory Committee on Chemicals (SACC)[25] peer review only select portions of the comprehensive Draft RE. "The Agency will be seeking SACC review of its data analyses and methodologies relevant to human health hazard and exposure analyses that have not been previously peer reviewed."[26] With respect to "formaldehyde human health hazard identification and dose-response analysis for acute inhalation and dermal routes," EPA will rely on the peer review by the Human Studies Review Board (HSRB).[27] Similarly, "[f]or chronic inhalation exposure and the cancer inhalation unit risk (IUR), the Agency intends to defer to the draft 2022 Integrated Risk Information System [IRIS] Toxicological Review of Formaldehyde and associated 2023 review by the [National Academies of Sciences, Engineering, and Medicine (NASEM)]."[28]

NASEM conducted a review of the draft formaldehyde IRIS assessment and HSRB reviewed only a handful of studies. EPA plans to "leverage[e] these peer reviews to support further development of the risk evaluation of formaldehyde," but neither this "further develop[ed]" formaldehyde risk evaluation nor the current version of the Draft RE – in its entirety - will be subject to peer review by the SACC or any other peer review body.[29] EPA, however, will ask the SACC to review the chronic inhalation reference concentration (RfC), in

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[24] *See, e.g.*, *Final Scope of the Risk Evaluation for Formaldehyde*, at 13, 77 (August 2020) *available at* https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf ("The draft risk evaluation for formaldehyde will be peer reviewed, … will … address aspects of the underlying science … such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization … [and] will be conducted ***in accordance with EPA's regulatory procedures for chemical risk evaluations***, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45).") (emphasis added); *see also Draft Human Health Risk Assessment for Formaldehyde*, at 113 (the "draft risk evaluation will be reviewed by the SACC in 2024").

[25] The SACC is established under TSCA Section 26(o) (15 U.S.C. § 2625(o)). The SACC must be composed of representatives of science, government, labor, public health, public interest, animal protection, and industry, with the purpose of providing independent advice and expert consultation on the scientific and technical aspects of issues relating to TSCA implementation. *Id.* at Section 2625(o)(2)-(3).

[26] 89 Fed. Reg. 18933, 18935 (March 15, 2024).

[27] 88 Fed. Reg. 88910, 88911 (Dec. 26, 2023). "The HSRB is a federal advisory committee that operates in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. §10. The HSRB is required to review and comment on all proposed and completed third-party research […] involving intentional human subject exposure that is subject to the coverage of EPA's regulations […]." *See* https://www.epa.gov/scientific-leadership/human-studies-review-board#:~:text=The%20Human%20Studies%20Review%20Board,%C2%A7%2010%20.

[28] *Id.*

[29] *Id.* at 88910. EPA also states that "it is relying on the [NASEM] peer review[] […] on certain aspects of the human hazard assessment" but it is unclear *what* EPA is relying or *when* this reliance will occur. *See Draft Human Health Risk Assessment for Formaldehyde* at 9.

light of the HSRB's recommendation "that EPA conduct a more coordinated peer review approach."[30]

Rather than comply with the current regulatory requirements for peer review as promulgated in 2017, EPA instead is applying the standard described in its proposed rule revising 40 C.F.R. § 720.41 regarding peer review, in which EPA "expects that peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)(4)(A), **or portions thereof**, will be consistent with the applicable peer review policies, procedures, guidance documents, and methods pursuant to guidance promulgated by Office of Management and Budget, EPA, and in accordance with 15 U.S.C. 2625(h) and (i)."[31] Notably, EPA's final rule amending Section 720.41 removes this "or portions thereof" language, such that the new regulation, effective on July 2, 2024, will state that "EPA will conduct peer review activities on risk evaluations …."[32] Thus, EPA's decision to exclude portions of the risk evaluation from peer review is contrary to the plain language of both the current and forthcoming regulations, and demonstrates the Agency's misplaced reliance on a proposed regulation.[33]

IV. EPA's significant uncertainties and unreasonably conservative assumptions undermine the Agency's exposure estimates.

EPA readily admits that there are key uncertainties that "cast doubt on whether all risk estimates presented in this draft evaluation … are reflective of real-life exposure to formaldehyde in the workplace, outdoor ambient air, and inside homes and other indoor situations."[34] Moreover, "EPA also acknowledges that it is often difficult -if not impossible- to understand what contribution various conditions of use are making to the total level of formaldehyde to which a person is exposed in any given place at any given time."[35] Rather than substantively resolving these uncertainties, EPA instead errs on the side of extreme conservatism, resulting in exaggerative exposure estimates and overcautious interpretations of the available toxicity data.

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30 *Id.* at 88911 – 88912. EPA tasked the HSRB with peer reviewing a weight-of-evidence for acute inhalation endpoints for formaldehyde exposure. Based on this WOE, EPA proposed points of departure for three exposure durations – 15-min peak, 8-hr, and 24-hr. In its peer review report to EPA, HSRB expressed obvious frustration with EPA's approach to peer review. HSRB recommended a "more coordinated approach" with other peer review entities, including the SACC and NASEM, "regarding advice in establishing PODs for formaldehyde as well as reviewing recommendations from these and other entities on formaldehyde exposure. To further this recommendation, the HSRB recommends that the EPA share this HSRB report with the NASEM and TSCA SACC […]." In an effort to demonstrate a more coordinated approach to peer review, "EPA intends to solicit comment [from the SACC] on the chronic reference concentration (RfC)." *Id.*

31 *See* 88 Fed. Reg. at 74323 (emphasis added).

32 *See* 89 Fed. Reg. 37028, 37055 (May 3, 2024).

33 *See supra* Section II.A.

34 *See Executive Summary* at 2.

35 *Id.* at 2, 9, 29.

A. Occupational exposures

EPA's determination that formaldehyde presents an unreasonable risk appears to be driven by the Agency's assessment of occupational exposures. In its *Executive Summary of the Draft Risk Evaluation for Formaldehyde*, EPA states that "[w]orkers who are in workplaces where formaldehyde is used are at the most risk from formaldehyde exposure."[36] EPA's *Draft Human Health Risk Assessment for Formaldehyde* further states that "[w]orker exposure to formaldehyde via inhalation and dermal are expected to result in the highest formaldehyde exposures among the assessed populations."[37] EPA's *Draft Unreasonable Risk Determination for Formaldehyde* module also indicates that the vast majority of the COUs for which EPA has a "high level of certainty" regarding contribution to the unreasonable risk are occupational. Specifically, this module states that EPA has a high level of certainty that:

- 41 occupational COUs contribute to unreasonable risk due to non-cancer effects, specifically sensory eye irritation associated with **acute inhalation** of formaldehyde;

- 10 occupational COUs contribute to the unreasonable risk due to non-cancer effects, specifically respiratory and non-respiratory health effects in workers, including reduced pulmonary function, increased asthma prevalence, reduced asthma control, allergy-related conditions, male and female reproductive toxicity, and developmental effects, associated with **chronic inhalation** exposures.

- 47 occupational COUs contribute to unreasonable risk due to non-cancer effects, specifically dermal sensitization associated with **acute dermal** exposure, meaning that skin contact can result in an allergic response.

Most of the other COUs that drive the unreasonable risk determination, for which the Agency has "less certainty" regarding the contribution to the unreasonable risk, are occupational as well. Indeed, the Agency highlights only 10 COUs that are *not occupational* as drivers of unreasonable risk, 7 of which carry the "high level of certainty" designation, and 3 of which carry the "less certainty" designation.

The outsized impact of EPA's estimated occupational exposures discredits the Agency's overall determination that formaldehyde presents an unreasonable risk because of the significant uncertainties and unrealistic assumptions underlying these exposure estimates.

For example, EPA readily admits that the data underlying its inhalation exposure estimates for occupational COUs are limited due to "uncertainties in the representativeness of the data due to some scenarios having limited exposure monitoring data in literature."[38] In these

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[36] *See Executive Summary* at 4.

[37] *See* EPA, *Draft Human Health Risk Assessment for Formaldehyde*, at 10 (March 2024) (hereinafter "Draft Human Health Risk Assessment"), *available at* https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-risk-assessment-public-release-hero-march-2024.pdf.

[38] *See* EPA, *Draft Occupational Exposure Assessment for Formaldehyde*, at 30 (March 2024) (hereinafter "Draft Occupational Exposure Assessment"), *available at* https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-occupational-exposure-assessment-for-formaldehyde-public-release-hero-march2024.pdf.

instances, "[w]here few data are available, the assessed exposure levels are unlikely to be representative of worker exposure across the entire job category or industry."[39] Indeed, EPA concedes that the weight of evidence is only "slight" for many of the occupational inhalation exposure estimates."[40] Despite these glaring, unresolved uncertainties, EPA later claims that it has a "high level of certainty" that all but two occupational COUs contribute to unreasonable risk for workers due to inhalation exposures.[41]

1. EPA assumes that no PPE is worn, contrary to existing regulatory requirements.

EPA's inhalation exposure estimates for manufacturing COUs assume that no personal protective equipment (PPE) is used, despite the Agency's recognition that the monitoring data underlying the exposure estimates "include job tasks where workers wore respiratory protection."[42] In dismissing the use of PPE, EPA relies on a 2003 survey indicating that 619,400 U.S. establishments used respirators for voluntary or required purposes.[43] EPA states that 45% of these establishments were estimated to have had respirator use within the 12 months prior to the survey, representing approximately 4.5 percent of all private industry establishments at the time. EPA fails to recognize that this survey, taken only a few years after the adoption of OSHA's updated respirator requirements for formaldehyde in 1998,[44] is likely not reflective of current respirator usage rates. EPA similarly dismisses the potential for reduced dermal exposure due to glove protection based on the assumption that the types of gloves worn in the workplace are ineffective. Notably, this determination is "not based on experimental values or field investigations of PPE effectiveness," but rather "professional judgments" used in the development of theoretical modeling.[45] Despite evidence to the contrary, EPA dismisses any mitigating effects of PPE that may significantly drive down exposure estimates for workers – the primary driver of EPA's unreasonable risk determination.

EPA's failure to apply the mitigating impact of OSHA's existing standards for formaldehyde in its risk assessment also highlights a broader issue with the Agency's lack of coordination and cooperation with other federal agencies – which are critical requirements under TSCA. TSCA Section 9(d) requires EPA to "consult and coordinate with" other Federal agencies "for the purpose of achieving the maximum enforcement of this chapter while imposing the least burdens of duplicative requirements on those subject to the chapter and for other

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[39] *Id.*

[40] *See id.* at 44.

[41] *See* EPA, *Unreasonable Risk Determination* at 17-24.

[42] *See Draft Occupational Exposure Assessment* at 36.

[43] *Id.* at 239.

[44] *Respiratory Protection*, 63 Fed. Reg. 1152-01 (January 8, 1998).

[45] *See Draft Occupational Exposure Assessment* at 241.

purposes."[46] These provisions were intended, in large part, to address potential overlap between EPA and OSHA, as Congress did "not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls."[47] Yet, the Draft RE does just that.

2. Other uncertainties and assumptions

In addition, for the occupational COUs for which no monitoring data were available, EPA similarly incorporated exaggeratively conservative assumptions into its models. EPA's model for the occupational COU "Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products," which "showed formaldehyde concentrations above other scenarios," assumed that no engineering controls were in place, and that all formaldehyde within the automotive care product is completely evaporated during application of the product and available for the worker to inhale.[48] For dermal exposures, EPA's model assumed, without explanation, that worker activities involving spray applications (which also resulted in the "highest dermal exposure estimate") were equivalent to immersive exposures to formaldehyde.[49]

These uncertainties underlying the occupational exposure estimates are compounded by additional conservatisms incorporated into EPA's hazard and risk assessments. For example, EPA's hazard value for the chronic non-cancer exposure scenario is based on a study of reduced pulmonary function in children.[50] Despite the Agency's reliance on a study that examined a population more sensitive than the adult worker population, EPA nonetheless applied an additional uncertainty factor of 3 to derive a hazard value that is then used as a benchmark to support EPA's conclusion (designated with a "high degree of certainty") that 10 occupational COUs contribute to the unreasonable risk due to chronic non-cancer effects from inhalation.[51]

EPA's acute inhalation hazard value also incorporates an uncertainty factor of 10, despite recommendations from the HSRB that the use of an uncertainty factor "is not necessary when the

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[46] 29 U.S.C. § 655(b)(5).

[47] HR Rep. 114-176 (June 23, 2015), at 28-29.

[48] *See Draft Occupational Exposure Assessment* at 36.

[49] *Id.*

[50] *See* EPA, *Draft Human Health Hazard Assessment for Formaldehyde*, at 38 (March 2024), *available at* https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-hazard-assessment-for-formaldehyde-public-release-hero-march2024.pdf. For further discussion of the deficiencies in Krzyzanowski *et al.,* (1990), see *supra* Section V.A.1.

[51] *Id.*

POD is based on sensory irritation."[52] The result is that far more conditions of use were preliminarily determined to contribute to unreasonable risk than if the UF of 10 were not used.[53]

EPA even recognizes that the uncertainties underlying its risk assessment for occupational exposures "may be great enough to change risk estimates for specific conditions of use."[54] The Agency does not discuss in any greater detail *which* risk estimates for specific COUs might change due to these uncertainties, or how it can reconcile these uncertainties with its "high degree of certainty" that the occupational exposures contribute to unreasonable risk. Instead, EPA blanketly states that "[w]hile there are some uncertainties in the assessment, these uncertainties are not expected to change risk estimates enough to shift the overall risk assessment conclusions."[55] We see no evidence for this conclusion. To the contrary, if these uncertainties jeopardize the validity of EPA's conclusions with respect to enough occupational COUs, the primary driver of EPA's unreasonable risk determination may be eliminated.

In preparing the final risk evaluation, EPA should re-examine the uncertainties related to its assessment of each occupational COU to determine which COUs may, in fact, not present an unreasonable risk when taking into account more realistic exposure scenarios and scientifically justifiable interpretations of the available hazard data.

B. Consumer and general population exposures

1. EPA inappropriately assesses the strength of modeling data by comparing it to monitoring data.

In assessing indoor air exposure to formaldehyde, EPA relied on both monitoring and modeling information. So far so good. Monitoring reflects formaldehyde measured in air from multiple sources of formaldehyde, including contributions from both TSCA COUs and potentially scores of other non-TSCA regulated sources. The American Healthy Home Survey II, published in 2021, "is the most current nationally representative survey of formaldehyde in indoor air in American homes," and according to EPA is "likely the best representation of the current range of aggregate exposures and risk from all sources of formaldehyde in indoor air."[56] The survey was based on a nationally representative sample of nearly 700 homes of various ages,

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[52] *See Report of the U.S. Environmental Protection Agency Human Subjects Review Board*, at 8-9 (October 5, 2023), *available at* https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde.pdf.

[53] *See Draft Human Health Risk Assessment* at 83. For further discussion of the uncertainties underlying EPA's assessment of sensory irritation, *see supra* Section V.A.2.

[54] *Id.* at 13.

[55] *Id.*

[56] *Id.* at 94. And formaldehyde sources included "tobacco smoke or the use of fireplaces, gas-burning appliances, candles, and air purifiers." *Id.* at 56. Gas-ovens alone, for example, have been shown to produce formaldehyde concentrations as high as over 400 ug/m^3. *Id.* The survey, however, does not represent the full impact of TSCA Title VI regulation of wood products has not been felt. *Id.* at 94.

types, conditions, and climates; 95% of which had formaldehyde concentrations less than 47 ug/m^3.[57]

Modeling indoor air, however, is specific to the COUs EPA selects to model, and therefore, does not reflect the input from any other sources of formaldehyde.[58] For example, based on modeling data, EPA concluded that "[o]ver the span of a year, the highest TSCA COU contributor to the residential indoor air environment was building wood products," which is graphically depicted in Figure 2-5 (of the Draft Human Health Risk Assessment) to be considerably higher than 100 ug/mg^3 (represented as the chronic average daily concentration).[59]

Data derived from monitoring is demonstrably not comparable to data derived from modeling. The proverbial apples and oranges. The Draft RE recognizes this disparity – "Monitored concentrations are expected to reflect aggregate concentrations resulting from multiple sources of formaldehyde of formaldehyde and are therefore not directly comparable to modeled concentrations estimated for specific sources."[60] Nonetheless, EPA persists. In rationalizing its reliance on both modeling and monitoring data, EPA touts its observation that "[r]esidential indoor air modeled and measured concentrations of formaldehyde were generally within the same order of magnitude."[61] But this observation underscores the fact that modeling data is wildly conservative. In modeling just a single COU, projected emissions of formaldehyde are 10x higher than what was measured in the residential air of 95% of surveyed homes representing all indoor sources of formaldehyde!

EPA opted not to aggregate the modeled air concentrations for various COUs but ultimately "concluded that, due to variability among homes and over time within a given home, uncertainties were too great to support a quantitative aggregate analysis across multiple COUs."[62] But don't these same uncertainties point EPA away from relying on data for any of the COUs modeled? Moreover, EPA opted not to rely on the Consumer Exposure Model (CEM) data to calculate cancer risk from chronic indoor air exposures for certain COUs because "there is substantial uncertainty related to the degree of dissipation of formaldehyde over time […]."[63]

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57 *Id.* at 53.

58 *Id.* at 50, 56.

59 *Id.* at 57-58.

60 *Id.* at 71.

61 *Id.* at 52. Elsewhere in the HHRA module, EPA doubles down on its reliance on modeling data. Once again, EPA recognizes that incomparability of modeling and monitoring data, but yet states the following: "However, the fact that modeled concentrations are within the same order of magnitude of monitored concentrations increases confidence in modeled concentrations." *Id.* at 71.

62 *Id.* at 59.

63 *Id.* at 95. EPA's indoor air models do not take into account the expected decline in household exposure due to the half-life of formaldehyde. *Id.* at 96.

Again, doesn't this uncertainty also apply to EPA's assessment of chronic non-cancer risks from CEM data?

Of course, uncertainties also accompany monitoring data. As recognized by EPA, "formaldehyde concentrations in indoor environments are expected to vary over longer time periods (*e.g.,* an individual's lifetime) and are highly dependent on an individual's propensity to move to new homes as well as their purchasing behaviors."[64] In assessing indoor air exposures for the general population, EPA does not account for the expected decline in indoor air concentrations due to the promulgation of EPA's 2018 emission standards for household products under TSCA Title VI (15 U.S.C. §2697).[65] In sum, "the many factors that may contribute to overall indoor air concentrations and relative concentrations from TSCA and other uses introduce a significant source of uncertainty in the indoor air exposure."[66]

Yet, despite these significant uncertainties, EPA nonetheless "has medium confidence in the overall findings for the indoor air exposure assessment due to a high confidence in the CEM [consumer exposure model] used …." These overall findings warrant nothing more than a "low confidence" which renders them unusable for risk evaluation.

2. The 1987 Westat survey is grossly outdated and does not represent current consumer use behaviors.

EPA continues to rely on the outdated Westat Survey from 1987, nearly 40 years ago! In previous peer reviews of draft risk evaluations, such as trichloroethylene (TCE), the SACC voiced ongoing concerns with EPA's reliance on the Westat Survey. Specifically, in response to EPA's draft risk evaluation for TCE, the SACC implored EPA to "consider updating the Westat survey data (U.S. EPA, 1987) to verify that use patterns and building-related parameters reflect current consumer use patterns and housing construction."[67] The SACC continued:

> With respect to model inputs, the Committee was unanimous in their opinion that at least some consumer use patterns are likely to have changed since the Westat survey (U.S. EPA, 1987) data were collected, about 30 years ago from the present time. The Committee has made this same comment in prior TSCA chemical reviews. The size of homes has also changed in the last few decades with a trend to larger homes and more open floor designs, as well as a trend to increasingly tighter structures that may affect air exchange rates.

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64 *Id.* at 11, 12.

65 *Id.* at 5.

66 *Id.* at 15. Although "EPA has confidence it is not underestimating formaldehyde exposure resulting from TSCA conditions of use or across all sources of formaldehyde" *Id.* The point we emphasize in these comments is that EPA is in fact grossly overestimating formaldehyde exposures attributable to COUs relative to other sources of formaldehyde.

67 *See* TSCA Science Advisory Committee on Chemicals, *Peer Review for EPA Draft Risk Evaluation for Trichloroethylene (TCE)*, at 57 (March 24-27, 2020).

The SACC's comments make clear that the Westat survey no longer represents the best available science. Regrettably, EPA has chosen to ignore the SACC's repeated recommendations and relies on this survey in the draft RE.

3. Other uncertainties and assumptions

EPA also inflates consumer dermal exposures by assuming that consumers ignore label recommendations and assume "occlusion or immersion of hands using liquid or spray consumer products."[68] EPA also recognizes that risk estimates are based on modeled exposure estimates and thus it is not possible "to determine how frequently these exposures may occur for consumers or ground-truth these estimates."[69] EPA nonetheless concludes that it has "medium confidence" rather than low confidence in its risk estimates for indoor air and dermal exposures. In the final risk evaluation, EPA should re-examine the uncertainties related to its assessment of each consumer/general population COU to determine which COUs do not present an unreasonable risk when taking into account more realistic and scientifically supportable exposure scenarios.

V. The Hazard Assessment of the Draft RE fails to comport with TSCA's mandate to rely on the best available science and apply a weight of evidence approach.

TSCA section 26 mandates, "[i]n carrying out section 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, […] consistent with the best available science […]." These decisions must also "be based on the weight of the scientific evidence."[70] Risk evaluations developed under section 6, including the Draft RE, therefore, must be based on the best available science and the weight of scientific evidence.[71]

A. The Draft RE improperly relies on a flawed, draft IRIS assessment.

In developing the Draft RE, EPA relies on the ***draft*** formaldehyde IRIS assessment, notwithstanding that the current draft remains in Step 5 ("Revise Assessment") of the 7 step IRIS process and has been extensively criticized by NASEM, industry stakeholders, and other experts.[72] EPA has yet to incorporate any of the numerous NASEM recommendations from its review of the draft IRIS assessment, let alone any of the public comments, in either revising the

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[68] *Id.* at 93. For occupational exposures, EPA also assumed "immersive dermal loading."

[69] *Executive Summary* at 5.

[70] 15 U.S.C. § 2625(i).

[71] The risk evaluation procedural rule expands on the legislative language of section 26 to underscore that, "[h]azard information related to potential health and environmental hazards of the chemical substance will be reviewed in a manner consistent with best available science and weight of scientific evidence as defined in § 702.33 and all assessment methods will be documented. This process includes the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical substance." 40 C.F.R. § 702.41(d)(2).

[72] *See* https://iris.epa.gov/ChemicalLanding/&substance_nmbr=419#status.

draft IRIS assessment or in the Draft RE.[73] NASEM, for example, noted a key fundamental deficiency - "the assessment does not satisfactorily follow recommendations for problem formulation and protocol development. EPA did not develop a set of specific protocols for the 2022 Draft Assessment in a fashion that would be consistent with the general state of practice that evolved during the prolonged period when the assessment was being developed."[74]

EPA relies on the draft IRIS Assessment for the chronic hazard values (both cancer and non-cancer), which serve as EPA's key benchmarks in the Draft RE.[75] Some of these effects, according to the draft IRIS Assessment, are systemic and occur at distant sites (*e.g.*, reproductive effects). Yet, the draft IRIS Assessment also acknowledges that inhaled formaldehyde is not distributed beyond the respiratory tract.[76] In failing to reconcile these alleged effects with a lack of formaldehyde distribution, the draft IRIS assessment ignores biological plausibility, a critical aspect of the risk evaluation process, to explain these alleged systemic effects, including male reproductive effects discussed below.[77] EPA nonetheless claims, without sufficient explanation, that the weight of the scientific evidence and overall confidence in EPA's hazard assessment is based in part on the "biological plausibility of the effects observed."[78]

Other comments on the draft IRIS assessment submitted by academic experts – who have spent decades researching the exposures and effects of formaldehyde – pointedly observe the omission of key datasets and scientific methodologies from the draft IRIS assessment. EPA has

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[73] https://nap.nationalacademies.org/catalog/27153/review-of-epas-2022-draft-formaldehyde-assessment. In the Draft RE, EPA states that it "is relying on the peer reviews provided by the National Academies of Sciences, Engineering, and Medicine [NASEM] and the Human Studies Review Board on certain aspects of the human hazard assessment." *See Draft Human Health Risk Assessment* at 9. It is unclear, however, what EPA means by this, since EPA has yet to revise the current draft IRIS assessment to reflect NASEM recommendations.

[74] *Id.* at 5. The American Chemistry Council (ACC), among other stakeholders, noted numerous substantive and procedural deficiencies with the Draft RE. For example, ACC notes that "[s]cores of studies were either dismissed, not considered, or only considered superficially in the Draft." ACC goes on to state that this deficiency "seriously calls into question the completeness of EPA's systematic review process and if the 2022 Draft Assessment represents the best available science." *See Comment submitted by American Chemistry Council (ACC) Formaldehyde Panel*, at 79 (March 19, 2024), *available at* https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0074. Although in developing the Draft RE, EPA identified a dozen additional studies not reflected in the draft IRIS assessment, none of those studies are on the list identified by ACC as missing from the draft IRIS assessment.

[75] *See Executive Summary* at 3.

[76] The Draft RE notes that "The draft IRIS report also includes a robust discussion of the potential for systemic delivery of inhaled formaldehyde to distant sites. IRIS cited several studies supporting that exogenous formaldehyde is neither systematically distributed nor significantly absorbed into blood." *Draft Human Health Hazard Assessment* at 9.

[77] *See Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Virtual Meeting "Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0" held on April 19-21, 2022*, at 109.

[78] *See Draft Human Health Risk Assessment* at 76.

wholly failed to address these comments.[79] In addition, notable experts provided comments to a review committee of NASEM tasked by EPA to review the draft IRIS assessment.

Among the many submissions to NASEM, we discuss below certain aspects of Dr. Debra Kaden's critique. Dr. Kaden served as an integral part of the WHO working group that developed the WHO indoor air guideline for formaldehyde.

1. Krzyzanowski *et al.*, (1990) suffers from significant uncertainties and lack of transparency.

In selecting a point of departure to assess potential non-cancer risk from chronic inhalation of formaldehyde, the Draft RE relies on the draft IRIS assessment. In particular, the Krzyzanowski *et al.,* (1990) study's value of 0.021 mg/m^3 (equivalent to 0.017 ppt) served as the POD and the attendant uncertainty factor of 3 from this study served as the benchmark MOE to assess whether any of the COUs "contributed to" an unreasonable risk from chronic exposures to formaldehyde.[80] Krzyzanowski *et al.,* (1990) as discussed in the draft IRIS assessment is "[a] cross-sectional study of residential formaldehyde exposure in a large (298 children), population-based sample observed a linear relationship between increased formaldehyde exposure and decreased peak expiratory flow rate (PEFR) among children exposed to average concentrations of 0.032 mg/m^3 (26 ppb)."

Given the significance of this study in EPA's preliminary determination that formaldehyde presents unreasonable risk, Dr. Debra Kaden's recent critique warrants review by EPA. Kaden underscores several important issues with the Krzyzanowski *et al.*, study, including that nearly half the number of children in the study lived in households with environmental tobacco smoke. Although the authors state in their study that "[t]he statistical model adjusted for potential confounders including […] smoking status," Kaden asserts that "this is an incorrect statement, as the authors did not adjust the model but rather stated that they did not find an association between these factors and PEFR (data not shown)." Kaden continues that "[t]he lack of a smoking variable (ETS) in modeling of 15-year olds and younger adds uncertainty to the analysis" and "it seems implausible that PEFR was not affected by ETS, and [the] authors should have included it as a potential effects modifier in the model."[81]

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[79] *See, e.g., Comments on IRIS Toxicological Review of Formaldehyde-Inhalation (external review draft, 2022). Submitted by Kun Lu, Ph.D.*, at 1 (June 9, 2022), *available at* https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0076 (commenting on EPA's failure to integrate the rich datasets generated by UNC's laboratory over the last decade into the draft IRIS Assessment); *see also Technical Comment on Portions of the Environmental Protection Agency's (EPA's) draft IRIS Toxicological Review of Formaldehyde (Inhalation), prepared by Chad Thompson, Ph.D.* (June 13, 2022), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0098 (commenting on EPA's omission of several key studies, including a study on the mode of action of formaldehyde-induced nasal tumors).

[80] *See Draft Human Health Hazard Assessment* at 19 – 20.

[81] *See* Debra Kaden, Ph.D., DABT, ATS, Ramboll US Corporation, Inc., *Peer-review of Krzyzanowski et al.,: An evaluation of EPA's Use of the Study for Hazard Classification and Derivation of a cRfC for Pulmonary Effects (PEFR) of Inhaled Formaldehyde*, at 3 – 7 (May 17, 2023).

For all these reasons and others further discussed in her submission to NASEM, Dr. Kaden would have assigned a "low" rather than the draft IRIS Assessment classification as "high" confidence in this study.[82] Yet, the draft RE relies on the study to derive a point of departure (POD) that drives many of the Agency's unreasonable risk determinations.

2. Sensory irritation is irrelevant to unreasonable risk because it does not lead to "injury."

In the Draft RE, EPA asserts that it has a "high level of certainty" that sensory irritation, an acute formaldehyde inhalation effect identified for scores of COUs, contributes to formaldehyde's "unreasonable risk." Indeed, no other effect contributes as much to EPA's unreasonable risk determination.[83]

Dr. Kaden also noted in her recent submission to NASEM that sensory irritation is "transient, reversible, and do[es]not affect the form or function of the tissue or organism."[84] She goes on to emphasize that:

> These sensory irritation responses are without functional impairment or pathological change – thus, the sensory recognition of formaldehyde is not adverse and is no different than sensory responses to other chemicals or environmental stimuli such as taring when exposed to fumes from cut onions or blinking when suddenly exposed to sunlight. This 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.[85]

In sum, sensory irritation does not constitute an adverse effect. Even if it were viewed as adverse, EPA's risk value for sensory irritation is overly conservative and inconsistent with risk values derived by other international scientific bodies. For example, in 2010, the World Health Organization (WHO) established guidelines, "for the protection of public health from risks due to a number of chemicals commonly present in indoor air," including formaldehyde.[86] The guideline for formaldehyde was set at 0.1 mg/m^3 (0.08 ppm), based on sensory irritation, the same endpoint EPA selected in the Draft RE as the acute non-cancer effect from inhalation of formaldehyde. In its lengthy scientific report supporting the guideline, WHO notes that "[t]he threshold for objective sensory irritation appears to be about 1 mg/m^3 for workers. For the

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[82] *Id.* at 7.

[83] *See Unreasonable Risk Determination* at 17-27.

[84] *See* Debra A. Kaden, PhD, ATS, *Comments on Sensory Irritation in the EPA's 2022 Draft Formaldehyde Assessment*, at 2 (December 21, 2022).

[85] *Id.*

[86] *See* WHO, *Guidelines for Indoor Air Quality: Selected Pollutants* (2010), *available at* https://iris.who.int/bitstream/handle/10665/260127/9789289002134-eng.pdf?sequence=1.

indoor environment (24 hours), a value of 0.125 mg/m^3 was considered safe for the entire population against sensory irritation, including chronic sensory irritation."[87] This value was selected based on the Lang *et al.*, and Kulle *et al.,* studies, and is considered protective for even the "more sensitive part of the population."[88] WHO rounded down to derive the ultimate guideline of 0.1 mg/m^3.

Although EPA relied on the same chamber studies relied on by WHO, heeding to the strong peer review recommendation of the HSRB, EPA's comparable value is set at 0.062 mg/m^3, clearly lower than the WHO guideline. The fact that WHO's guideline value is higher than EPA's is especially jarring, given that the WHO guideline is not predicated on avoiding "unreasonable risk;" rather it ensures public health protection from even the most sensitive effect from formaldehyde exposures. Thus, EPA's comparable value of 0.062 mg/m^3, coupled with overly conservative exposure assumptions discussed throughout these comments, effectively transform TSCA's unreasonable risk standard into an impermissible zero risk standard, contrary to the purpose of the risk evaluation process under TSCA.[89]

3. Male reproductive effects are not supported by the best available science and should not be included in the Draft RE.

Among other health effects attributed to long-term formaldehyde inhalation, EPA includes male reproductive effects as contributing to the unreasonable risk for as many as 45 occupational COUs and 3 consumer COUs.[90] The POD EPA selected for chronic non-cancer endpoints "is expected to be protective of" male reproductive effects.[91]

EPA draws upon the draft IRIS assessment to support its inclusion of male reproductive effects in the Draft RE. But what EPA chooses not to include in the Draft RE are the considerable uncertainties associated with male reproductive effects. "Uncertainties include a lack of well-conducted animal studies testing formaldehyde exposure levels below 6 mg/m3 and

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87 *Id.* at 115.

88 *Id.*

89 EPA calculated a point of departure (POD) based on chamber studies. The HSRB recommended that the use of an uncertainty factor "is not necessary when the POD is based on sensory irritation." *See Report of the U.S. Environmental Protection Agency Human Subjects Review Board*, at 8-9 (October 5, 2023), *available at* https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde.pdf. The HSRB's recommendations mirrors that of the EU-SCOEL in which it established occupational exposure value without applying UFs. *See Draft Human Health Hazard Assessment* at 48.

Despite these recommendations, the Draft RE retains an uncertainty factor (UF) of 10. This is not a trivial matter, as retaining the factor of 10 means that estimated exposures would need to be at least 10 times lower than the POD to conclude that the particular condition of use does not contribute to unreasonable risk. The result is that far more conditions of use were preliminarily determined to contribute to unreasonable risk than if the UF of 10 were not used. *See Draft Human Health Risk Assessment* at 83.

90 *Unreasonable Risk Determination* at 3, 6.

91 *See Draft Human Health Risk Assessment* at 132.

no plausible, experimentally verified MOA explaining such effects without systemic distribution of formaldehyde; however, some support for indirect effects in rodents is provided by relevant mechanistic changes in male reproductive organs."[92] In the draft IRIS assessment, however, EPA also underscores its low confidence in the database – "**while there are a number of published studies that evaluated reproductive toxicity in males, the interpretation of study results is complicated by their methodological limitations and exclusive use of formaldehyde concentrations above 6 mg/m^3, and data are lacking regarding functional endpoints.**"[93]

Simply, EPA cannot comply with TSCA's scientific standards by relying on EPA's draft IRIS assessment to support its conclusions that male reproductive effects can be attributed to formaldehyde exposure.

4. Nasopharyngeal cancer risks do not contribute to unreasonable risk from chronic formaldehyde inhalation.

Out of the scores of COUs EPA evaluated in the Draft RE, EPA preliminarily determined that it "is less certain about the contribution from 1 [one] occupational COU to the unreasonable risk of formaldehyde due to nasopharyngeal cancer from chronic inhalation exposures."[94] But the uncertainty is even less than EPA acknowledges, which renders NPC entirely irrelevant to any unreasonable risk determination.

Once again, EPA relies entirely on the draft IRIS assessment and the Beane-Freeman *et al.*, (2013) cohort study in selecting nasopharyngeal cancer (NPC) as the cancer hazard endpoint upon which to base the inhalation unit risk (IUR) estimate. With respect to NPC's mode of action, "the IRIS assessment concluded that a mutagenic action contributes to risk of nasopharyngeal cancer from inhaled formaldehyde."[95] But the NASEM committee that peer-reviewed an earlier version of the IRIS formaldehyde assessment, recommended that EPA reconcile EPA's selection of a non-threshold MOA "with the observations that formaldehyde is endogenous, that nasal tumors are very rare in both rats and humans, and that no increases in tumor frequency have been observed in animal studies at formaldehyde exposure concentrations that do not also cause cytotoxicity [a threshold-based MOA]."[96]

Similarly, the Committee for Risk Assessment in 2020, "agreed in accordance with the RAC conclusion of [formaldehyde] carcinogenicity (2012) that experimental results and mechanistic data support 'the existence of a threshold type does-response for induction of nasal

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92 *See* EPA, *Toxicological Review of Formaldehyde-Inhalation (External Review Draft),* at 1-557 (April 2022), *available at* https://iris.epa.gov/Document/&deid=248150.

93 *Id.* at 2-36 (emphasis added).

94 *Unreasonable Risk Determination* at 5.

95 *Draft Human Health Risk Assessment* at 9.

96 NASEM, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011)*, at 55.

tumors, with regenerative cell proliferation being the predominant feature in the carcinogenic process. The genotoxicity of formaldehyde is also expected to play a role above this threshold.'"[97] EPA has yet to offer any reconciliation that meets the TSCA scientific standard of best available science.

Even the epidemiological evidence linking formaldehyde with NPC is fraught with inconsistencies. Numerous studies cited by Chang *et al.,* (2021), including occupational studies in the U.S., Italy, Hong Kong, and a combined study from Finland, Sweden, Norway and Iceland all "found no excess risk of NPC."[98] And with respect to the Beane Freeman *et al.*, study, Chang *et al.*, note that the positive findings in the NCI cohort study by Beane Freeman *et al.*, "were driven by a single plant where six of the 11 observed NPC deaths occurred, whereas the remaining nine plants exhibited a nonsignificant deficit of NPC mortality. An unusually small proportion of deaths coded as unspecified pharyngeal cancer at that single site suggests that diagnostic or death certificate coding bias, along with shared exposures encountered elsewhere, probably contributed to the apparent excess of NPC."[99]

VI. EPA has unlawfully interpreted "unreasonable risk" as "zero risk."

Perhaps the most important term in all of TSCA is the term "unreasonable risk of injury to health or the environment" (or simply "unreasonable risk"). Under Section 6 of TSCA, EPA evaluates the risk of chemicals to determine whether uses present "unreasonable risk." A determination of unreasonable risk triggers risk management regulations to ensure that the chemical no longer presents unreasonable risk. Thus, knowing what is and isn't unreasonable risk is critical to effectively eliminating that risk. Although TSCA does not define unreasonable risk, legislative history makes clear that "'unreasonable risk does not mean no risk; it means that EPA must determine, on a case-by-case basis, whether the risks posed by a specific high priority substance are reasonable in the circumstances of exposure and use."[100]

In 2017, EPA promulgated regulations on procedures for chemical risk evaluation under TSCA. (These regulations were recently revised by EPA, as noted above.) EPA could have defined the term "unreasonable risk," but like Congress, it opted not to. Instead, EPA delineated a list of "relevant factors" it will consider, in rendering an unreasonable risk determination, including the following:[101]

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[97] *See* European Chemicals Agency Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC), *Opinion on an Annex XV dossier proposing restrictions on Formaldehyde and formaldehyde releasers*, at 19-20 (March 13, 2020).

[98] Chang, Ellen T., *et al.,* "The evolving epidemiology of nasopharyngeal carcinoma." *Cancer Epidemiology, Biomarkers & Prevention* 30.6 (2021): 1035-1047, at 1040.

[99] *Id.*

[100] *See* 162 Cong. Rec. S3511-01, at *3522.

[101] *See* 83 Fed. Reg. 33726, 33735 (July 20, 2017).

- The effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks);

- The effects of the chemical substance on the environment and environmental exposure under the conditions of use;

- The population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties.

In the Draft RE, EPA relied in part on these risk-related factors in making its finding "that formaldehyde presents an unreasonable risk of injury to human health."[102] As noted, scores of conditions of use underly EPA's unreasonable risk determination. For some, EPA has high level of certainty of their contribution to unreasonable risk; for others, EPA has *less certainty* of their contribution to unreasonable risk.

With respect to non-cancer risks, EPA relies on so-called benchmark margins of exposure (MOEs), which "are typically the total UF [uncertainty factor] for each non-cancer POD [point of departure]. If the numerical value of the [calculated] MOE [for a condition of use] is less than the benchmark MOE, this relationship is a starting point to determine if there are unreasonable non-cancer risks."[103] In the Draft RE, EPA also "consider[ed] contributions from all sources as part of a pragmatic and holistic evaluation of formaldehyde hazard and exposure in making its unreasonable risk determination. If an estimate of risk for a specific scenario exceeds the benchmarks, then the decision of whether those risks are unreasonable is both case-by-case and context driven."[104]

For example, in assessing occupational COUs, "some inhalation exposure concentrations for workers and ONUs are within the outdoor and indoor air concentrations, and some, are greater than what would be expected from total indoor and outdoor exposures. In this preliminary risk determination EPA has high level of certainty of the contribution of an occupational COU when the risk from such occupational COUs is much greater than the risk expected from the formaldehyde based on monitored concentrations in the indoor air […]."[105] The indoor air concentrations EPA refers to are based on residential environments, which begs the question, why would formaldehyde levels in homes be in any way comparative to occupational environments? And it is unclear what "much greater" means quantitatively? (EPA engaged in a similar exercise when interpreting inhalation risk estimates of the consumer COUs.)[106]

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[102] *See Executive Summary* at 2.

[103] *See Draft Human Health Risk Assessment* at 80-81.

[104] *Id.* at 79.

[105] *See Draft Unreasonable Risk Determination* at 11.

[106] *Id.* at 12.

In its recently issued risk management rule for methylene chloride, EPA provides greater clarity as to how it defines what is and isn't unreasonable risk through its reliance on an "ECEL" – existing chemical exposure limit. "EPA has determined that ensuring exposures remain at or below the 8-hour TWA ECEL of 2 ppm will eliminate the unreasonable risk of injury to health resulting from acute and chronic exposures for certain occupational conditions of use of methylene chloride."[107] Thus, the 8-hour time-weighted average (TWA) ECEL of 2 ppm, and the 15-minute short-term exposure limit (STEL) of 16 ppm serve as the benchmarks of unreasonable risk. Above these numbers = unreasonable risk; at or below these values = no unreasonable risk.

In the Draft RE, EPA calculates an 8-hr "existing chemical occupational exposure value [of 0.011 ppm] to summarize the occupational exposure scenario and sensitive health endpoints into a single value."[108] This value is considerably higher than indoor formaldehyde concentrations in nearly all U.S. homes from all sources of formaldehyde, not just COUs. Clearly, EPA's calculated exposure value of 0.011 ppm if relied on to eliminate unreasonable risk from COUs transforms the unreasonable risk standard into a no risk standard.

The occupational exposure value, like the ECEL for methylene chloride, "represents the exposure concentration below which workers and occupational non-users are not expected to exhibit any appreciable risk of adverse toxicological outcomes, accounting for potentially exposed and susceptible populations (PESS)."[109] Moreover, EPA relies on the same algorithm to calculate the ECEL and the occupational exposure value.

It would appear then that EPA has replaced the term "ECEL" with "existing chemical occupational exposure value." Alas, that is not the case, for EPA goes on to caution that the occupational exposure of 0.011 ppm could differ from "any existing chemical exposure limit (ECEL) used for occupational safety risk management purposes […] based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c)."[110] Indeed, EPA concedes that "this is certain to be the case for formaldehyde."[111] Contrary to the clear language of TSCA section 6, however, EPA plans to revise what it deems to be unreasonable risk in any forthcoming risk management rule on formaldehyde.

Further underscoring EPA's interpretation of "unreasonable risk" as "no risk," EPA relies on the draft IRIS reference concentration (RfC) to assess inhalation chronic non-cancer effects. Given the conservate nature of the definition of RfC – "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

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[107] 89 Fed. Reg. 39254, 39275 (May 8, 2024).

[108] *Draft Human Health Risk Assessment*, at 142.

[109] *Id.*

[110] *Id.*

[111] *Id.*

effects during a lifetime," compounded by EPA's unrealistic exposure assumptions, EPA's view of unreasonable is utterly detached from reality.

The ultimate objective of any risk evaluation under TSCA section 6 "is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors […] under the conditions of use."[112] If EPA finds unreasonable risk, then under TSCA 6(a), "[EPA] shall by rule, and subject to section 18 [preemption], and in accordance with subsection (c)(2) [which delineates factors for EPA to consider in selecting risk management requirements] apply one or more of the following requirements […] to the extent necessary so that the chemical substance no longer presents such risk."[113] In a nutshell, TSCA demarcates risk evaluation from risk management; an unreasonable risk determination is the purview of risk evaluation, and the role of risk management is to eliminate that unreasonable risk. Under TSCA section 6, therefore, EPA cannot revise what it considers to be unreasonable risk from formaldehyde exposures in any subsequent risk management rule.[114]

VII. Conclusion

The Draft RE is utterly insufficient in serving TSCA's ultimate purpose of addressing unreasonable risk. EPA should revisit each component of the risk evaluation to resolve the considerable uncertainties that plague the exposure estimates, particularly where the exaggeratively high exposures serve as drivers of the unreasonable risk determination (*e.g.*, worker exposures). EPA should more seriously consider the recommendations of reviewing scientific bodies and public comments on the sufficiency of key studies and surveys underlying the risk evaluation and driving the unreasonable risk determination.

Finally, EPA should restructure the risk evaluation so that a separate risk determination is made for each COU – based on the best available science and the weight of scientific evidence - which will allow the Agency to fulfil its obligations under TSCA Section 6(a) to target the specific COUs that actually present unreasonable risk, rather than having to guess based on vague determinations of "contributions" to unreasonable risk.

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112 15 U.S.C. § 6(b)(4)(A).

113 *Id.* at § 6(a).

114 *See* 162 Cong. Rec. S3511-01, at *S3517, *supra* note 3. ("The effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture," which is a required element of any risk management rule under TSCA Section 6(c)(2)(A), does "not require EPA to conduct a second risk evaluation-like analysis to identify the specified information, but rather, can satisfy these requirements on the basis of the conclusions regarding the chemical's health and environmental effects and exposures in the risk evaluation itself.")