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EPN Comments on the Draft TSCA Risk Evaluation for Formaldehyde
Docket No.: EPA-HQ-OPPT-2023–0613
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The Environmental Protection Network (EPN) harnesses the expertise of more than 600 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

Background

On March 15, 2024, EPA released the draft risk evaluation for formaldehyde for public comment and the forthcoming peer review by the Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC) during a virtual public meeting scheduled for the latter part of May 2024. Formaldehyde was designated a high-priority substance for TSCA evaluation in 2019 during the second round of prioritization. This is the second chemical on that list of 20 for which a draft risk evaluation has been issued. In addition to being a chemical regulated under TSCA, formaldehyde is also a registered pesticide. As such, it is currently undergoing registration review under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The draft FIFRA risk assessment, which evaluates the pesticidal uses of the chemical (and paraformaldehyde), was released for public comment on April 19, 2024. It should be noted that the two programs (OPPT and OPP) jointly developed the human health and environmental *hazard* assessments as well as the chemistry, fate, and transport assessment which appear in this draft Risk Evaluation (RE). The RE, in turn, relies heavily upon the hopefully soon-to-be-released updated Integrated Risk Information System (IRIS) Toxicological Review–Inhalation, which focuses solely on inhalation exposure, the primary route of exposure to formaldehyde related to TSCA Conditions of Use for most humans.

Formaldehyde (CASRN 50-00-0) is a colorless, flammable gas at room temperature and has a strong odor with an ability to cause significant eye and respiratory tract irritation. The presence of formaldehyde in the internal and external environment is ubiquitous. As EPA points out, "People and animals produce and release formaldehyde." Accounting for and incorporating this endogenous source into a risk assessment poses an interesting challenge to the risk assessor.

EPA has made a preliminary determination that formaldehyde *poses unreasonable risk to human health* (but not to the environment).

EPN Review and Comments

As noted above, the agency is planning to subject the draft Risk Evaluation to external peer review by its TSCA SACC during a virtual public meeting scheduled for May 20-23, 2024. As is the agency's traditional practice, it has developed a series of charge questions to focus the SACC's attention on specific components of the draft Risk Evaluation, although the Committee is free to address other aspects, if so inclined. EPA is specifically asking for comment and recommendations on the agency's analyses and methodologies relevant to the derivation of human health hazard values (for both non-cancer and cancer effects), (human and

environmental) exposure assessments that have not been previously (externally) peer reviewed, and additional topics that are unique to formaldehyde.

The charge questions provide a convenient structure for organizing our comments on the draft Risk Evaluation. We will begin with the Human Health Hazard, Exposure, and Risk Assessments, since those areas are the focus of the Charge questions and then follow up with comments on other aspects of the Risk Evaluation.

1. Human Health Hazard

Charge Question 1.1. Acute inhalation hazard value. Please comment on the updated weight of evidence used to establish the point of departure (POD) for acute inhalation of formaldehyde and the application of an extrapolation/uncertainty factor for intraindividual (*sic*) variability as well as the characterization of the overall confidence in the value presented in the draft human health hazard assessment.

EPN Comments:
A plethora of controlled human exposure studies have shown that irritation of the eyes and respiratory tract, including itching, burning, stinging sensations, watering eyes, sneezing, rhinitis, sore throat, coughing, and bronchoconstriction can begin immediately upon exposure to formaldehyde. Given the immediacy of this effect, sensory irritation is an appropriate endpoint upon which to base acute inhalation hazard values.

"The acute response to formaldehyde appears to be more responsive to the exposure concentration than to exposure duration and may not adhere to Haber's law (Shusterman et al., 2006). EPA's Human Studies Review Board (HSRB) evaluation of the weight of evidence analysis led the Board to *not* recommend duration adjustments for 8- or 24-hour PODs for the sensory endpoint, based on the lack of support for this adjustment in the four studies presented in the WoE and the existing literature (HSRB, 2023a)," as might be done for other chemicals that do conform to Haber's law. As a result, multiple hazard values have not been developed to reflect differences in durations of short-term exposure. The HRSB supported the use of three of those four studies for dose response analysis. The agency selected an acute threshold POD based on the 0.5 ppm no-observed-adverse-effect concentration (NOAEC) (and corresponding benchmark concentration level (BMCL), also 0.5 ppm) identified for a 3-hour exposure in Kulle[1] and Kulle *et al.*[2].

In EPN's view, the updated weight of evidence, which argues that it is not appropriate to develop duration-adjusted acute hazard values, as informed by feedback from the HRSB, is scientifically sound and well-supported by the available data.

EPA appropriately applied an uncertainty/extrapolation factor of 10X to account for what should be identified as INTER-individual variability. "INTRA-individual" is not an appropriate term to use in this context. In fact, EPA does not employ the term in any of its assessments. This error of language is repeated elsewhere in the draft Human Health Hazard Assessment as well. EPA should search and replace the term intra-individual with inter-individual.

[1] Kulle, T.J. 1993. Acute odor and irritation response in health nonsmokers with formaldehyde exposure. Inhal. Toxicol. 5(3):323-332.
[2] Kulle, T.J., L.R. Sauder, J.R. Hebel, D.J. Green, and M.D. Chatham. 1987. Formaldehyde dose-response in healthy nonsmokers. JAPCA 37(8):919-924.

While we could not find any agency characterization of its overall confidence in the acute inhalation hazard value in the draft human health hazard assessment, we would rate it "Medium to High," some modest uncertainties notwithstanding.

Charge Question 1.2. Chronic, non-cancer inhalation hazard value. Please comment on OCSPP's use of the chronic reference concentration (RfC) from the draft IRIS assessment as described above and in Section 4.1.2.2 of the Draft Human Health Hazard Assessment. In your comments, please consider the strengths and uncertainties of the underlying studies identified by ORD IRIS for the weight of evidence for chronic human health non-cancer hazard.

EPN Comments:
The Draft Human Health Hazard Assessment appropriately uses the chronic, non-cancer inhalation hazard endpoints and PODs derived in the draft IRIS assessment[3]. The IRIS assessment identified a POD of 0.017 ppm based upon a series of five human inhalation studies showing evidence of sensory irritation, adverse effects on pulmonary function, allergy-related conditions, or degree of asthma control/prevalence of current asthma. Coupled with an uncertainty factor (UF) of 3X, an RfC of 0.007 mg/m^3 was derived.

In this draft human health hazard assessment, EPA chose to use the same POD of 0.017 ppm (or 0.021 mg/m$^{3)}$ from just one of the five studies[4] and the same UF of 3X. This would yield the equivalent of the IRIS RfC of 0.007 mg/m^3, if that calculation were to be done for this assessment. However, OPPT does not ordinarily derive RfCs in its TSCA Risk Evaluations, but employs the uncertainty factor as the benchmark margin of exposure (MOE) when making unreasonable risk determinations.

The dataset available for the qualitative and quantitative analysis underlying the derivation of a chronic, non-cancer hazard value is more robust than is often seen. Among its positive attributes is that all of the candidate studies considered most useful were based upon observations in humans. The observed results recapitulated the range of sensory irritation and respiratory system effects observed in the human studies available for generating the acute inhalation hazard value. Furthermore, the Krzyzanowski et al. (1990) study was an analysis of the degree of asthma control in children with current asthma, obviating the need for consideration of an uncertainty factor greater than 3X to assure adequate protection of this susceptible subpopulation.

Charge Question 1.3. Dermal hazard value. Please comment on selection of the dermal sensitization POD, draft weight of scientific evidence (WOSE) narrative, application of uncertainty/extrapolation factors, and characterization of overall confidence.

EPN Comments
No dermal hazard values were included in the 2022 draft IRIS document, nor are there any in OPP's 2008 Registration Eligibility Document (RED)[5]. Furthermore, OPP's Formaldehyde and Paraformaldehyde Final Work Plan for registration review states "Dermal endpoints were not selected for the registered antimicrobial uses of formaldehyde and paraformaldehyde. Uses do not involve purposeful contact with the

[3] US EPA. 2022. Toxicological Review of Formaldehyde Inhalation (Review draft). Washington, DC: Integrated Risk Information System. https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=248150
[4] Krzyzanowski, M., Quackenboss, JJ., Lebowitz, MD. 1990. Chronic respiratory effects of indoor formaldehyde exposure. Environ Res 52: 117-125.
[5] https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-043001_30-Jun-08.pdf

skin and a dermal risk assessment is not expected to be required" [6]. However, the recently-released human health and environmental risk assessment for formaldehyde and paraformaldehyde does include a dermal exposure/risk assessment for residential handlers. Thus, the dermal hazard values presented in the draft risk evaluation will be useful both for OPPT in its TSCA risk evaluation for formaldehyde and OPP's registration renewal risk assessment.

A sizable number of animal and human studies of adequate quality are available that describe the potential for formaldehyde to exert adverse effects at the site of contact following dermal exposure to the substance. While both the animal and human studies reveal similar effects such as skin irritation, skin sensitization, and other immune effects, the human studies are preferred for dose response analysis because cross-species extrapolation need not be carried out, reducing at least one element of uncertainty.

EPN agrees with the agency's determination that skin sensitization is the most sensitive non-cancer effect following dermal exposure and that sufficient data are available to use in the dose response analyses. Four studies were used to inform the derivation of PODs for skin sensitization: two studies employing a human patch test, one employing the local lymph node assay in mice, and one employing non-animal artificial neural network (ANN) prediction models using various combinations of descriptors from several *in vitro* sensitization tests. Candidate PODs were identified separately from each study. A candidate elicitation POD was selected from among the PODs generated from data from the first three studies noted above. A candidate induction POD was derived employing the ANN prediction models using *in vitro* data.

The results are as follows:

Elicitation POD= 10.5 $\mu g/cm^2$

UF = 10X (UF_H = 10) = Benchmark MOE

Induction POD= 100 $\mu g/cm^2$

UF = 100X (UF_A =10, UF_H = 10) = Benchmark MOE

If dermal reference doses (RfDs) were to be generated for Elicitation and Induction of effects, they would be essentially the same (1 ug/m^2).

The draft risk evaluation includes description of a significant number of useful studies, which in total, provides a robust Weight of Evidence argument. EPN agrees with the agency's conclusions that "while there are some uncertainties associated with the human studies related to lack of clarity in methods and data reporting, the concordance in effect levels across multiple streams of evidence increases confidence in the POD(s)."

Charge Question 1.4. Oral hazard values. Please comment on selection of the oral POD, draft WOSE narrative, and characterization of overall confidence.

EPN Comments:
While the agency asks for comment on the selection of *the* oral POD, it actually has selected *two* PODs, one to address subchronic or shorter-term exposure scenarios and the other to address long-term or chronic

[6] https://www.regulations.gov/document/EPA-HQ-OPP-2015-0739-0004

exposure scenarios. Two questions come to mind. The first is: Are there no exposure scenarios that would warrant the selection of an *acute* oral POD for use in this risk evaluation? In 1993, the Office of Water (OW) issued Health Advisories (HA) for formaldehyde in drinking water: a 1-day (acute) HA of 10 mg/L and a 10-day (short-term, subacute) HA of 5 mg/L. OW also calculated a long-term, lifetime HA of 1 mg/L, based upon an RfD of 0.2 mg/kg/day derived from the Til et al (1989) study[7]. This RfD is the same as that in the 1990 IRIS assessment, but different from the RfD generated in this draft risk evaluation. Because we were not able to access the background document for the formaldehyde HAs, we are not able to judge whether the information used to derive the 1-day and 10-day HAs would be useful in deriving acute oral hazard values for use in the TSCA risk evaluation or the Registration Review human health risk assessment. We recommend that EPA follow up on this.

The second question is: Is it necessary to select *any* POD for oral exposure for the purposes of this risk evaluation? The exposure scenarios for which assessments have been conducted in this risk evaluation appear to pay overwhelming, if not exclusive, attention to the inhalation route.

EPN finds a possible answer to these two questions may be that, while oral hazard values may not be particularly relevant for the TSCA risk evaluation, they could be relevant for registration renewal. OPP appears to be reconsidering the necessity for conducting dietary assessments of indirect food uses[8].

The candidate subchronic POD is 25 mg/kg/day, based upon the NOAEL identified in a 28-day drinking water study in rats (Til et al 1988). This POD was adjusted by the application of a data adjustment factor (DAF) of 0.24 to produce a Human Equivalent Dose (HED) of 6 mg/kg/day. The DAF accounts for the pharmacokinetic differences between rats and humans. The (combined) uncertainty factor of 30x (3x for interspecies extrapolation, 10x for intraspecies variation) can be used to derive a subchronic RfD of 0.2 mg/kg/day or used as the Benchmark MOE.

The candidate chronic oral POD selected is 15 mg/kg-day based on the NOAEL in rats following two years of formaldehyde exposure through drinking water[9]. This POD also was adjusted by the application of a DAF of 0.24 to produce an HED of 3.6 mg/kg/day. The (combined) uncertainty factor of 30x (3x for interspecies extrapolation, 10x for intraspecies variability) can be used to derive a chronic oral RfD of 0.12 mg/kg/day or used as the Benchmark MOE.

General EPN Comments on the Human Health Hazard Assessment:
It is unfortunate that OCSPP did not have a final IRIS assessment document available for use in preparing this draft TSCA risk evaluation, instead having to depend upon the 2021 draft IRIS document for selection of PODs, uncertainty factors, and risk estimates for use in the qualitative and quantitative assessment of chronic, non-cancer, and cancer effects. The National Academies of Sciences, Engineering, and Medicine (NASEM) issued a review of the 2021 draft in August 2023. While the NASEM committee was generally supportive of the choices ORD IRIS made with respect to PODs, UFs, and cancer risk estimates, it did present a number of findings and recommendations. It would have been helpful for the SACC peer

[7] Til, HP, Woutersen, RA, Feron, VJ, Hollanders, VHM, Falker, HE; Clary, JJ. 1989. Two-year drinking-water study of formaldehyde in rats. Food Chem Toxicol 27: 77-87.
[8] See Table 9 – Studies Anticipated as Needed for the Registration Review of Formaldehyde and Paraformaldehyde in the Formaldehyde and Paraformaldehyde Final Work Plan (US EPA 2017).
[9] il, HP, Woutersen, RA, Feron, VJ, Hollanders, VHM, Falker, HE; Clary, JJ. 1989. Two-year drinking-water study of formaldehyde in rats. Food Chem Toxicol 27: 77-87.

reviewers and other public commenters to know if and how the IRIS program responded to those findings and recommendations, and whether any significant changes were made.

3. Occupational Assessment

Charge Question 3.1. To assess occupational inhalation exposures for formaldehyde, workplace inhalation monitoring data from governmental agencies such as the Occupational Safety and Health Administration (OSHA), monitoring data found in published literature, and other monitoring data submitted to the agency were considered. As described in Section 2.5.1 and Appendix E of the Draft Occupational Exposure Assessment for Formaldehyde (U.S. EPA, 2024i), monitoring data from OSHA with sampling duration greater than 5.5 hours were used to estimate the 8-hour time-weighted average exposures. It was assumed that for any unsampled time, the exposure was zero. Please comment on the strengths and limitations of this approach and underlying assumptions for estimating full-shift exposure concentrations from the OSHA data. In your response, please consider the available monitoring data and if there are other potential sample durations (e.g., 4 hours) that should be considered to understand threshold effects data and associated risks. Furthermore, discuss what information should be considered when assuming the concentration for any unsampled period.

EPN Comments:
EPN believes that the Occupational Assessment was extremely well done. It was well organized overall and consistently organized for each condition of use (COU) and exposure scenario. All of the assumptions and data used were thoroughly documented. We agree that the approaches EPA described in Charge Questions #3.1 and #2 are appropriate.

Charge Question 3.2. As described in Section 4.2.1 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g), occupational monitoring data were used as the best available data to estimate occupational exposures. Specifically, monitoring data with 15-minute samples were compared to the acute (threshold) inhalation hazard information. Please comment on the strengths and limitations of this approach and underlying assumptions for estimating acute risk to workers from inhaling formaldehyde. Please comment on the alignment of the health effect (i.e., sensory irritation) with the 15-minute samples intended to represent peak exposures. In your response, please consider the available monitoring data and if there are other potential sampling and averaging times that should be considered to understand threshold effects data and associated risks.

EPN Comments:
See response to Charge Question 3.1.

Charge Question 3.3. The Draft Human Health Risk Assessment (U.S. EPA, 2024g) relies on the chronic inhalation hazard endpoints and PODs derived in the draft IRIS assessment on formaldehyde (U.S. EPA, 2022). The IRIS assessment considered a range of respiratory and non-respiratory health effects in humans including reduced pulmonary function, increased asthma prevalence, decreased asthma control, allergy-related conditions, sensory irritation, male and female reproductive toxicity, and developmental effects. Section 4.2.1 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the chronic inhalation POD to assess risks to workers with occupational exposure to formaldehyde. Please comment on the strengths and uncertainties associated with use of the chronic non-cancer POD from the draft IRIS assessment for evaluation of formaldehyde risks to workers.

EPN Comments:
Given the strengths (while acknowledging the uncertainties) of the data available for determination of a chronic inhalation hazard value, we agree with OCSPP that the robustness of the data set, selection of the appropriate endpoint, and calculation of a chronic non-cancer inhalation hazard value as presented in the IRIS assessment reflect the best use of the available information and provide a suitable basis for assessing the long-term inhalation risks to workers.

Charge Question 3.4. The draft human health hazard assessment (U.S. EPA, 2024f) relies on the cancer inhalation unit risk (IUR) derived in the draft IRIS assessment on formaldehyde (U.S. EPA, 2022). Section 4.2.1 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the cancer IUR to assess risks to workers with occupational exposure to formaldehyde. Please comment on the strengths and uncertainties associated with use of the cancer IUR from the draft IRIS assessment for evaluation of formaldehyde risks to workers.

EPN Comments:
Given the strengths (while acknowledging the uncertainties) of the data available for characterization of formaldehyde's carcinogenic potential and the calculation of the IUR, we agree with OCSPP that the robustness of the data set, selection of the appropriate endpoint, and calculation of the IUR as presented in the IRIS assessment reflect the best use of the available information and provide a suitable basis for assessing the cancer risks to workers.

4. Consumer Assessment

Charge Question 4.1. Please comment on the applicability of the standard scenarios modeled in the draft consumer exposure assessment (U.S. EPA, 2024c) to represent current uses of formaldehyde-based consumer products.

EPN Comments:
EPA's Consumer Exposure Model (CEM) is an appropriate model to use to estimate acute and chronic inhalation exposures to formaldehyde, and EPA's Thin Film Model is an appropriate model to use to estimate dermal exposures to users of products that contain formaldehyde. As with all models, the assumptions made and the input data used will greatly influence the confidence in the model estimates. EPN presumes that EPA is relying primarily on steady state emission modeling to generate these exposure estimates because there are few, if any, studies that measured emission rates of formaldehyde or room concentrations of formaldehyde from the consumer product types identified.

Charge Question 4.2. Please comment on additional information relevant to formaldehyde and not considered in the draft consumer exposure assessment (U.S. EPA, 2024c) that may support evaluation of current consumer activities and use patterns. In your comments, please describe the strengths and uncertainties associated with these identified sources.

EPN Comments:
EPA has successfully relied upon the 1987 Westat Survey data for many years for the assessment of consumer exposures. Although those data are still relevant to many of the exposures being assessed in this document, EPA acknowledges that the survey data "may not be reflective of current use patterns for the

specific product types assessed." There may be more recent and more reliable data available, though likely for a cost, to EPA. For example, in the 1980s, EPA did utilize Simmons Market Research Bureau (now known as MRI-Simmons) for detailed consumer product usage information. Perhaps, if additional funding is available, EPA could purchase this type of survey data again. Or, perhaps some of the relevant trade associations or NGOs may be able to provide additional reliable data to EPA for free.

Table 2-1 provides a good compilation of many of the major model inputs for the different consumer product types. The Table notes that formaldehyde weight fractions and product densities of formaldehyde containing products were compiled from publicly available product material safety data sheets (MSDS) or safety data sheet (SDS) documents. It is somewhat surprising that so few products were identified by EPA for each consumer product type (no more than five and many less than three), which makes it a bit difficult to confidently select the low, mid, and high weight fractions for use in the CEM modeling. Also, it is not clear what the term "formaldehyde weight fraction" means. Please provide a clear definition. For example, the table indicates that "toys, playground and sporting equipment" and "furniture/seat covers" contained up to 30% formaldehyde by weight and that "furniture & furnishings" contained up to 10% formaldehyde by weight. This seems exceedingly high for free formaldehyde that would readily volatilize or be emitted from these products. Presumably, this weight percentage includes the amount of formaldehyde reacted in resin systems and thus emitted very slowly or not at all. However, these consumer product types had some of the highest estimated acute exposure concentrations. Again, perhaps some of the relevant industries, trade associations, or NGOs may be able/required to provide additional reliable data to EPA.

One more minor issue. Given the problematic history associated with prior use of Urea Formaldehyde Foam Insulation (UFFI) in the 1980s (banned by the Consumer Product Safety Commission (CPSC) in 1982 for use in residences and schools), EPN suggests that EPA provide a more detailed explanation of EPA's lack of concern for "foam insulation." EPA's statement, "Not assessed as formaldehyde content in finished good insulation is expected to be minimal," is not an adequate explanation without providing rationale/data supporting the statement.

Charge Question 4.3. The draft human health hazard assessment (U.S. EPA, 2024f) describes uncertainties regarding chronic cancer consumer exposure estimates associated with assumptions on duration of use/exposures over a longer period (e.g., lifetime exposures from photo processing solutions), given that consumer habits and products may change over time. Uncertainty in such exposure estimates (e.g., to liquid photo processing solutions or arts and craft materials) contributes to uncertainty in cancer risk estimates for those consumer conditions of use. Please comment on information or approaches the Agency may want to consider that will increase confidence in long-term exposure estimates and corresponding cancer risk estimates (where appropriate) for consumer products.

EPN Comments:
Perhaps some of the major producers, relevant trade associations, or NGOs may be able/should be required to provide additional reliable data to EPA on current usage and formaldehyde emission rates (and the most appropriate models to use) of those product types that have the highest estimated cancer risks (e.g., liquid photo processing solutions, arts and craft materials, furniture & furnishings, floor coverings, foam seating, and bedding products).

Charge Question 4.4. The Draft Human Health Hazard Assessment (U.S. EPA, 2024f) relies on the chronic inhalation hazard endpoints and PODs derived in the draft IRIS assessment on formaldehyde (U.S.

EPA, 2022). Section 4.2.2 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the chronic inhalation POD to assess risks to people with exposure to formaldehyde through use of consumer products. Please comment on the strengths and uncertainties associated with use of the chronic non-cancer POD from the draft IRIS assessment for evaluation of formaldehyde risks from use of consumer products.

EPN Comments:
Given the strengths (while acknowledging the uncertainties) of the data available for determination of a chronic inhalation hazard value, we agree with OCSPP that the robustness of the data set, selection of the appropriate endpoint, and calculation of a chronic non-cancer inhalation hazard value, as presented in the IRIS assessment, reflect the best use of the available information and provide a suitable basis for assessing the long-term inhalation risks to consumers.

Charge Question 4.5. The Draft Human Health Hazard Assessment (U.S. EPA, 2024f) relies on the cancer IUR derived in the draft IRIS assessment on formaldehyde (U.S. EPA, 2022). Section 4.2.2 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the cancer IUR to assess risks to people with exposure to formaldehyde through use of consumer products. Please comment on the strengths and uncertainties associated with use of the cancer IUR from the draft IRIS assessment for evaluation of formaldehyde risks from use of consumer products.

EPN Comments:
Given the strengths (while acknowledging the uncertainties) of the data available for characterization of formaldehyde's carcinogenic potential and the calculation of the IUR, we agree with OCSPP that the robustness of the data set, selection of the appropriate endpoint, and calculation of the IUR as presented in the IRIS assessment reflect the best use of the available information and provide a suitable basis for assessing the cancer risks to consumers.

5. Indoor Air Assessment

Charge Question 5.1. The draft indoor air exposure assessment (U.S. EPA, 2024h) focused the four TSCA conditions of use that are expected to be consistent contributors of formaldehyde exposure in homes, mobile homes, and vehicles. Please comment on the metrics and data used by EPA to focus its risk assessment on these four TSCA conditions of use. In addition to the consideration of relatively high emission rate and persistence (rather than temporary transient emissions), please provide feedback on additional criteria or information EPA may want to consider in its identification of major contributors to indoor air concentrations of formaldehyde.

EPN Comments:
Based on the emission rate information gathered by EPA from the literature for formaldehyde-emitting products and activities (e.g., combustion-related activities), EPN agrees the EPA has appropriately focused on the four general COUs that are likely to be the major current TSCA contributors to formaldehyde exposure in homes and vehicles.

Charge Question 5.2. The CEM has primarily been used to estimate short-term chemical exposures from consumer products in previous TSCA existing chemical risk evaluations. As described in Section 2.1.1 of the draft indoor air exposure assessment (U.S. EPA, 2024h), the CEM was used to estimate long-term

concentrations of formaldehyde in residential indoor air. Please comment on the strengths and limitations of using the CEM to estimate long-term indoor air exposures to formaldehyde resulting from TSCA conditions of use.

EPN Comments:
EPN does not have any specific concerns that CEM cannot or should not be used for estimating long-term concentrations of formaldehyde in residential indoor air. However, we are curious to better understand why EPA did not use EPA's Formaldehyde Indoor Air Model (FIAM) rather than CEM to conduct this modeling effort or at least to use FIAM to model the emissions from products that exhibit a concentration-dependent emission rate. EPA had used FIAM in the rulemaking to implement TSCA Title VI regarding control of formaldehyde emission rates from pressed wood products. This exposure document would benefit from addition of a clear explanation as to why CEM rather than FIAM was used, as well as an explanation as to why dated emission rate information using Oak Ridge National Laboratory (ORNL) Formaldehyde Surface Emission Monitoring devices was used to estimate emissions from hardwood flooring for use in the risk assessment rather than chamber emission rate data for actual hardwood flooring products or for particleboard as an analog.

Charge Question 5.3. The CEM was used to model the contribution of specific TSCA conditions of use to indoor air when products and articles containing formaldehyde are newly introduced to homes, mobile homes, and vehicles. Due to the uncertainty in model input assumptions related to a person's likelihood to move into newly constructed homes, what products they acquire while they live in the home, and the uncertainty in the rate formaldehyde may be released from those products, the draft indoor air exposure assessment (U.S. EPA, 2024h) did not quantify chronic cancer risks associated with specific indoor conditions of use that contribute to indoor air exposures. Please comment on EPA's assumptions and conclusion not to assess chronic-cancer risks for formaldehyde in indoor air based on uncertainties in exposure estimates beyond 1 year. Please also comment on information or approaches that may increase confidence in modeled COU-specific estimates for long-term exposures relevant to cancer risks.

EPN Comments:
EPN agrees that there is uncertainty related to the degree of dissipation of formaldehyde over time and how exposures from specific products (primarily wood products) change over the course of several years. However, we are not convinced that EPA should have such low confidence in these exposure estimates that potential cancer risks should not be evaluated. EPA evaluated this uncertainty back in the 1980s when it was initially working on formaldehyde exposure from pressed wood products with CPSC, Department of Housing and Urban Development (HUD), National Institute of Standards and Technology (NIST), and ORNL[10]; again in 2012 when it issued version 2.0 of the Formaldehyde Indoor Air Model for Pressed Wood Products[11]; and again in 2016 when it published the Formaldehyde from Composite Wood Products: Exposure Assessment for TSCA Title VI Final Rule[12]. Those three reports consistently estimated the formaldehyde half-life in residential settings from pressed wood products to be on the order of 1.5 to 3 years.

[10] See, for example, EPA (1985) – Formaldehyde Exposure in Residential Settings: Sources, Levels and Effectiveness of Control Options – EPA Contract no. 68-02-3698
[11] https://www.epa.gov/sites/default/files/2015-09/documents/fiam-pwp_v2_0_user_guide.pdf
[12] https://www.epa.gov/formaldehyde/formaldehyde-emission-standards-composite-wood-products

Charge Question 5.4. The Draft Indoor Air Exposure Assessment (U.S. EPA, 2024h) characterizes the available indoor air monitoring data as representing aggregate exposure from all sources of formaldehyde in indoor air including TSCA conditions of use. Several sources of indoor air monitoring data were considered, and the American Healthy Homes Survey II (AHHS II) (QuanTech, 2021) was determined to be the source of the most current nationally representative indoor air data. Please comment on the strengths and limitations of AHHS II, its application for this formaldehyde risk evaluation, and the conclusions that the data represent aggregate sources of formaldehyde in American residences. Please comment on the appropriateness of the other indoor air monitoring data considered in the assessment and the extent to which the weight of evidence narrative is supported by current indoor air monitoring information for formaldehyde.

EPN Comments:
Based on the sets of monitoring data presented in the report (i.e., age of data sets, number of homes monitored, etc.), EPN agrees that the AHHS II are likely to be the most current and nationally representative indoor air data and that the data represent aggregate sources (both TSCA sources and other non-TSCA sources such as combustion sources) of formaldehyde in American residences. We also agree that these data do not, *per se*, provide information about the relative contribution of each source.

Charge Question 5.5. The identified wood article-specific emission rates used in the draft indoor air exposure assessment (U.S. EPA, 2024h) predate EPA's 2016 final rule to reduce emission rates of formaldehyde from composite wood products and may not represent current and future emissions of formaldehyde from these products. A supplementary assessment of wood articles assuming the new emission standards as described in Appendix D of the draft indoor air exposure assessment (U.S. EPA, 2024h) was completed. Please comment on the strengths and weaknesses of this approach to better characterize future risks from formaldehyde products that reflect the new emissions standard.

EPN Comments:
EPA stated that it only considered products that are currently available on the consumer market but also stated that "the assessed wood products (*i.e.*, hardwood floor and wood furniture) are unlikely to be compliant with the TSCA Title VI Formaldehyde Emission Standards for Composite Wood Products given the wood product emission rates identified are from literature published from 2009 and prior." Using emissions data from 2009 and earlier does not convincingly justify the claim that such wood products are not likely to be Title VI compliant today. Perhaps relevant trade associations and/or individual companies may provide, in their comments on this risk evaluation, more recent emission rate data for hardwood flooring and furniture as well as other products assessed in the indoor air assessment. Appropriate chamber emission testing data sets for current Title VI-compliant hardwood plywood (HWPW), particle board (PB), and medium-density fiberboard (MDF), and appropriate chamber emission testing of kitchen cabinets and pressed-wood door panels that could be used in the FIAM would also be useful. To better ensure that any such data provided to EPA would be considered valid, reasonably current, and without bias, Third Party Certifiers (TPCs) could be given permission by the companies they represent to provide the data to EPA directly. Or, perhaps EPA could undertake its own emission rate studies (perhaps with a TPC laboratory) or issue an immediate final TSCA Section 8(a) rule requiring such existing information to be submitted. Presumably, EPA would want some assurances from interested parties that they would not object to such an immediate final rule to ensure that such data would be available to inform any risk management rule that would be issued to manage any unreasonable risks associated with formaldehyde exposure.

In Appendix D, EPA utilized emission limits set for Title VI for HWPW, MDF, and PB to estimate potential indoor air exposures for each of these individual product types under one product loading rate to simulate use as flooring, one air exchange rate, and one air temperature using the model underlying EPA's FIAM. EPA states, however, that "due to uncertainties related to whether the assessed wood products are made entirely of HWPW, MDF, or PB, whether the identified products are compliant with the relevant emission standards, and whether the approach to estimating emission rates from the set emission limits, sufficiently represent products on the consumer market, there was a low confidence in such analysis which is qualitatively detailed in Appendix D." EPN agrees that these are valid concerns but, as noted above, EPA could likely obtain or require the needed data to address these shortcomings to better assess the impacts of hardwood flooring and furniture than by using the limited (i.e., few data points) and very dated emission rate data in the current exposure assessment.

Charge Question 5.6. The draft human health hazard assessment (U.S. EPA, 2024f) relies on the chronic inhalation hazard endpoints and PODs derived in the draft IRIS assessment on formaldehyde (U.S. EPA, 2022). Section 4.2.3 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the chronic inhalation POD to assess risks to people with exposure to formaldehyde through indoor air. Please comment on the strengths and uncertainties associated with use of the chronic non-cancer POD from the draft IRIS assessment for evaluation of formaldehyde risks to indoor air.

EPN Comments:
As noted in earlier comments to previous questions: Given the strengths (while acknowledging the uncertainties) of the data available for determination of a chronic inhalation hazard value, we agree with OCSPP that the robustness of the data set, selection of the appropriate endpoint, and calculation of a chronic inhalation hazard value as presented in the IRIS assessment reflects the best use of the available information and provides a suitable basis for assessing the long-term non-cancer inhalation risks to people with exposure to formaldehyde through indoor air.

Charge Question 5.7. The Draft Human Health Hazard Assessment (U.S. EPA, 2024f) relies on the cancer IUR derived in the draft IRIS assessment on formaldehyde (U.S. EPA, 2022). Section 4.2.3 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the cancer IUR to assess risks to people with exposure to formaldehyde through indoor air based on air monitoring data. Please comment on the strengths and uncertainties associated with use of the cancer IUR from the draft IRIS assessment for evaluation of formaldehyde risks to indoor air.

EPN Comments:
As noted in earlier comments on previous questions: Given the strengths (while acknowledging the uncertainties) of the data available for characterization of formaldehyde's carcinogenic potential and the calculation of the IUR, we agree with OCSPP that the robustness of the data set, selection of the appropriate endpoint, and calculation of the IUR as presented in the IRIS assessment reflect the best use of the available information and provide a suitable basis for assessing the cancer risks from formaldehyde exposure in indoor air. However, as noted above in Charge Question 5.3, EPA has not quantified chronic cancer risks associated with specific indoor conditions of use that contribute to indoor air exposures in this draft indoor air exposure assessment. EPN reiterates our comments above on Charge Question 5.3 that EPN is not convinced that EPA should have such low confidence in these long-term exposure estimates that potential cancer risks should not be evaluated.

6. Ambient Outdoor Air Assessment

Charge Question 6.3. This is the first time EPA has used the Human Exposure Model (HEM 4.2). in a TSCA risk evaluation. Please comment on the application of the HEM for the purpose of identifying communities with elevated ambient air exposures to formaldehyde from industrial facilities and characterizing the exposed populations. In your response, please comment on the strengths and uncertainties associated with EPA's presentation of HEM results in Section 2.4.2.3 and Section 4.2.4.2 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g), including Figures 2-8 and 2-9 and Tables 4-2 and 4-3 of that assessment.

EPN Comments:
Why is there no mention or use in the formaldehyde ambient outdoor air exposure assessment of the 2022 Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0? While two of the models employed in the draft formaldehyde ambient air exposure assessment (HEM and IIOAC) are components of the above-mentioned document, they are not acknowledged as such. Has this approach been disavowed and/or set aside?

Charge Question 6.5. The Draft Human Health Hazard Assessment (U.S. EPA, 2024f) relies on the chronic inhalation hazard endpoints and PODs derived in the draft IRIS assessment on formaldehyde (U.S. EPA, 2022). Section 4.2.4 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the chronic inhalation POD to assess risks to people with exposure to formaldehyde in outdoor air. Please comment on the strengths and uncertainties associated with use of the chronic non-cancer POD from the draft IRIS assessment for evaluation of formaldehyde risks to outdoor air.

EPN Comments:
Please see the EPN Comments on Charge Question 5.6.

Charge Question 6.6. The Draft Human Health Hazard Assessment (U.S. EPA, 2024f) relies on the cancer IUR derived in the draft IRIS assessment on formaldehyde (U.S. EPA, 2022). Section 4.2.4.1 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) outlines the use of the cancer IUR to assess risks to people with exposure to formaldehyde in outdoor air. Please comment on the strengths and uncertainties associated with use of the cancer IUR from the draft IRIS assessment for evaluation of formaldehyde risks to outdoor air.

EPN Comments:
Please see the EPN comments on Charge Question 5.7 related to indoor air.

7. Aggregate Exposure

The Draft Human Health Risk Assessment for Formaldehyde (U.S. EPA, 2024g) considered how aggregate exposures to formaldehyde from multiple sources and across multiple routes, groups of people, or pathways,may increase the risk to formaldehyde exposure for some people.

Charge Question 7.1. Section 4.3 of Draft Human Health Risk Assessment (U.S. EPA, 2024g) qualitatively considered the combined exposures that may result from multiple sources releasing formaldehyde to air in

specific indoor or outdoor environments. For example, EPA's HEM analysis estimated exposures and risks from formaldehyde released to ambient air from all TRI facilities present in a particular location. EPA also used monitoring data to estimate aggregate exposures and risks from all sources of formaldehyde in a range of indoor and outdoor settings. Please comment on the strengths and uncertainties of EPA's approaches for estimating aggregate exposure and risk from multiple sources of formaldehyde through a specific pathway (i.e., indoor or outdoor air).

EPN Comments:
EPA states that inhalation is the route of exposure most likely to occur (and, also likely, at higher intakes than other routes) in most formaldehyde duration-defined (e.g., acute, longer term) exposure scenarios. The agency has conducted exposure/risk analyses for several categories of scenarios: occupational, consumer, general population, water and land, indoor air, outdoor/ambient air. As noted, both monitoring and modeled data were used in these analyses, when available, with a stated preference for monitoring data. In some cases, existing data were insufficient or completely lacking.

This is an unfortunate situation. It leaves the overall exposure assessment in a weakened state and likely will lead to an underestimation, perhaps significant, of the actual risk to humans from formaldehyde exposure.

Formaldehyde has been the subject of prior regulatory action (e.g, the establishment of the TSCA Title VI Formaldehyde Emission Standards for Composite Wood Products). It possesses a robust hazard database. It was identified as a TSCA chemical of concern years before the amended TSCA established the Existing Chemicals Review Program. It was included on the second list of high-priority chemicals in the 2017 prioritization round, finalized in 2019. The Scoping document was finalized in 2020 and acknowledged data gaps. Ample opportunity has been available to the agency to use its data-gathering authorities to fill some of the exposure data gaps by requiring the generation of empirical/monitoring data for those scenarios within reach of TSCA.

We recommend that the agency revisit the level of effort it has made to date on aggregate exposure and develop and implement more robust aggregate analyses.

Absent a more robust aggregate exposure and risk assessment, we might expect to see inadequate risk mitigation measures imposed.

Charge Question 7.2. Section 4.3 of the Draft Human Health Risk Assessment (U.S. EPA, 2024g) qualitatively considered the aggregate exposures individuals may experience from multiple exposure scenarios. For example, individuals exposed to formaldehyde through work or through use of consumer products are expected to also have exposure to formaldehyde through outdoor air or through indoor air at home. EPA concluded that there is too much uncertainty in exposure and risk estimates for individual sources to support quantitative aggregation across more than one exposure scenario. Please comment on the extent to which qualitative approach is supported by the available information. In your response, specifically describe the data that could potentially support an alternative approach and how that approach could be implemented.

EPN Comments:
We disagree with the agency that there is too much uncertainty to do more than a qualitative aggregate exposure/risk assessment. As stated above, we recommend that the agency revisit the level of effort it has made to date on aggregate exposure and develop and implement more robust aggregate analyses.

Additional EPN Comments

I. Environmental Hazard, Exposure, and Risk Assessment

In evaluating the effects of formaldehyde on the environment, EPA found that formaldehyde is not expected to last long in water, sediment, or soil based on its physical and chemical properties; i.e, it is highly reactive in nature. Specifically, formaldehyde in water hydrates quickly to methylene glycol and can further transform to oligomers and paraformaldehyde, all of which are structurally and chemically dissimilar to both formaldehyde and methylene glycol.

Formaldehyde will react rapidly with proton donors on soil particle surfaces and transform into many other substances that cannot be effectively characterized. Similar to surface water, formaldehyde will hydrate rapidly in groundwater and further transform to oligomers of various chain lengths, and continue to react unpredictably with other chemical substances which are expected to be less toxic than formaldehyde. By this reasoning, formaldehyde is not expected to be found in aquatic systems.

Environmental hazard and risk to aquatic and soil organisms
Formaldehyde toxicity to aquatic and terrestrial organisms ranged from slight to moderate to high depending on, among other factors, species and route and duration of exposure. Nevertheless, EPA did not assess risk to aquatic and soil-dwelling organisms in their evaluation of formaldehyde because aquatic and soil exposures to formaldehyde are not expected. Consequently, risks to these organisms are not expected.

Environmental hazard and risk to terrestrial organisms via ambient air
EPA used information from all reasonably available sources to characterize exposure, hazard, and risk posed by formaldehyde in air to terrestrial organisms.

Environmental fate and transport data indicate formaldehyde does not bioaccumulate[13]. Briefly, supporting evidence includes its reactivity, high water solubility (~ 400 g/L at 20 °C), and lack of persistence in water and on land. Also, formaldehyde has a log KOW of 0.35, which confers low potential for bioaccumulation (BAF <1) in both aquatic and terrestrial organisms. Based on these considerations, EPA concludes formaldehyde poses no risk to terrestrial organisms via bioaccumulation and, by extension, via the dietary pathway to terrestrial organisms.

The highest formaldehyde concentrations in ambient air, whether measured (60.1 $\mu g/m^3$) or modeled (50.5 $\mu g/m^3$) from possible TSCA COU, were lower by a factor of 7 than the concentration that yielded no observed adverse effects (NOAEC = 438 $\mu g/m^3$) to the common bean, *Phaseolus vulgaris*, a representative of the most sensitive terrestrial receptor group, i.e., vascular plants. Rats were found to be the most sensitive terrestrial vertebrate as a result of exposing them for 26-weeks to formaldehyde via the inhalation route; this

[13] U.S. EPA. 2024. Draft Chemistry, Fate, and Transport Assessment for Formaldehyde. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics.

testing yielded a NOAEC of 1,230 $\mu g/m^3$, which is an order of magnitude above the highest exposure level (60.1 $\mu g/m^3$) measured in ambient air. Moreover, the most sensitive endpoints identified are likely to be protective across taxa. Tables 2-1 and 2-2 in EPA's draft environmental risk evaluation summarize these data and demonstrate that formaldehyde poses no risk to terrestrial organisms.

Confidence in EPA's environmental risk assessment
EPN concurs with EPA's expression of high confidence in their draft environmental risk evaluation for the following reasons:

Consistent with the agency's approach to supporting risk evaluations for chemical substances under TSCA[14], the environmental risk posed by formaldehyde was carefully determined only after weighing the scientific evidence using the following criteria: database quality, consistency, strength, precision, biological gradient/dose response, and relevance of the data. These criteria are evident throughout the risk evaluation and well summarized in Section 2.3.3 of that document.

We also agree there are multiple lines of evidence supporting the agency's high level of confidence in concluding there is (1) no risk to aquatic organisms relative to toxicity endpoints; (2) no risk to terrestrial organisms relative to toxicity endpoints via the land pathway; (3) no risk to terrestrial organisms via the dietary pathway; and (4) no risk to terrestrial organism via the air pathway.

EPA does express uncertainty in the exposure estimates but these are expected to be transient due to the reactive nature of formaldehyde. Toxicity endpoints associated with longer exposure durations are expected to be protective of shorter exposures, and this does not present any increased risk. Again, we concur with this assessment.

Bottom line: We think the agency makes a sound case for concluding there is no unreasonable risk posed by formaldehyde to the environment as presented in Section 2.2 Unreasonable Risk to the Environment in the document entitled "Unreasonable Risk Determination of the Draft Risk Evaluation for Formaldehyde."[15].

II. Human Health Risk Assessment

This document is often difficult to read and follow. More detailed explanations and justifications would have been very helpful. Given that there are so many separate documents making up the draft formaldehyde risk evaluation, one gets the impression that perhaps what one wants to see in "this document" may be in another one, but inadequate reference is made to where to go for answers. It might be helpful to do some revision/embellishment to include more references to the primary source document keeping in mind that "this document" is the only one the reader will read.

We will focus our attention on Section 4. Human Health Risk Characterization and the subsections on the risk estimates.

[14] USEPA, 2021, Draft systematic review protocol supporting TSCA risk evaluations for chemical substances, Version 1.0: A generic TSCA systematic review protocol with chemical-specific methodologies, Office of Chemical Safety and Pollution Prevention, Washington, DC (EPA Document #EPA-D-20-031).
[15] USEPA, 2024, Draft Chemistry, Fate, and Transport Assessment for Formaldehyde, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington, DC, Updated 15 April 2024.

Section 4.2.1 Risks to Workers
EPA states: "For many TSCA COUs, EPA did not identify inhalation exposure data for ONUs, and therefore evaluated chronic risks using the central tendency estimates for workers." What is the rationale/justification for this? Why could likely exposures not be modeled, using existing TSCA-relevant tools, as has been done in the past?

EPA also states that "EPA did not identify information for potential peak exposures by ONUs and therefore did not quantify acute inhalation risks for ONUs. Risks to ONUs are assumed to be equal to or less than risks to workers who handle materials containing formaldehyde as part of their job." Does this mean EPA chose the same risk values for ONUs as for workers or none at all? The answer is not in this document. If it is a different one, the citation should be included here.

We are aware that risk estimates for all exposure scenarios evaluated in the risk assessment are provided in the "Supplemental file: Occupational Risk Calculator." However, information in the supplemental file is not readily accessible. The Excel file we downloaded from the docket displayed no data displayed when opened; thus, it was useless. Perhaps, these estimates should also be included in an appendix in the risk assessment.

Section 4.2.1.1 Risk Estimates for Inhalation Exposures
This section and all subsequent ones, including those for consumers, indoor, outdoor/ambient air, and releasing facilities, often include a statement summarizing how many TSCA COUs have risk estimates below the benchmark MOE and perhaps an order of magnitude lower than the benchmark, or have cancer risk estimates above the "acceptable" threshold. This summary should also contain a reiteration of whether that risk estimate was based upon a median or high-end exposure and the rationale/justification for the choice.

Section 4.2.1.2 Overall Confidence in Worker Inhalation Risks
This section presents a litany of uncertainties surrounding the exposure data used in this assessment. EPA acknowledges that the uncertainties may result in either overestimation or underestimation of exposures depending on the actual distribution of formaldehyde air concentrations and the variability of work practices among different sites. The uncertainties with respect to exposure may result in either overestimation or underestimation of the risk. This uncertainty argues against depending on central tendency estimates to serve as the decision metric for the unreasonable risk determinations. The more responsible and health-protective approach would be to use the high-end estimates, data permitting. It is far better to be overprotective than underprotective. If a regulated party objects to this approach, then it can/should provide empirical data to support a more accurate exposure (and risk) assessment.

Section 4.2.4 Risk Estimates for Ambient Air
Estimating risks to formaldehyde in ambient (outdoor) has some interesting aspects to it. EPA evaluated cancer and acute and chronic non-cancer risks resulting from human exposure to formaldehyde via the ambient air pathway.

Twenty-six of 29 TSCA COUs linked with releasing facilities evaluated have cancer risk estimates greater than 11×10^{-6}, and 19 COUs have risk estimates greater than 11×10^{-5}. Additionally, 21 of the 29 TSCA COUs have risk estimates greater than relative risk estimates for biogenic sources. Estimates were based upon sampling done in the range of 100 to 1000 m away from the release point. This could represent an exposure zone for populations living/working within that space, in other words, fenceline communities.

Section 4.2.4.2 Risk Estimates Based on Modeled Concentrations near Releasing Facilities
Another way of looking at the risks: In total, 19 of the 29 TSCA COUs (65.5%) have cancer risk estimates within the same order of magnitude greater than 1×10^{-5}. An additional seven TSCA COUs have cancer risk estimates within the same order of magnitude greater than 1×10^{-6} and less than 1×10−5, equating to 26 of the total of 29 evaluated. Two COUs have cancer risk estimates within the same order of magnitude greater than 1×10^{-7} and less than 1×10^{-6}, and one TSCA COU has a cancer risk estimate in the 1×10^{-9} range.

EPN is pleased that the agency is giving a significant degree of attention to these fenceline communities, showing, once again, the disparate burden of pollution that Black, brown, and marginalized populations and other disadvantaged communities bear when compared with majority-white communities. Table 4-2 shows the disproportionate (roughly 1.5 to 2-fold higher) cancer burden on African-Americans and Native Americans when compared to Whites, Other, and Multiracial and Latino/Hispanic subpopulations. Coupled with likely downside socioeconomic and other factors, the true negative consequences could actually be a greater issue to be reckoned with during the risk management phase of the review process.

This reality is reinforced in Table 4-3 presenting the Demographic Details of Population with Estimated Cancer Risk Higher than or Equal to 1 in 1 Million, Compared with National Proportions. The disparity holds even though no subpopulation is free from risks at or greater than 10^{-6}, when parsing the percentage or population by race/ethnicity, income, education, or linguistic isolation. When you add the number and nature of health conditions, lifestyle, and other factors into the mix, the disparities could be even greater.

Section 4.2.4.4 Overall Confidence in Exposures, Risk Estimates, and Risk Characterizations for Ambient Air
EPA states that "its overall confidence in risk estimates based on air concentrations modeled near release sites is high for non-cancer estimates and moderate for cancer estimates based on the hazard values. As described in Section 3.2, overall confidence in the chronic, non-cancer hazard POD is high, while overall confidence in the inhalation unit risk for formaldehyde is medium. The cancer risk estimates presented here do not include risks for some of the tumor sites. Although the draft IRIS assessment concluded that the evidence demonstrates that formaldehyde inhalation causes myeloid leukemia and sinonasal cancer in humans, EPA was not able to quantify those risks with confidence. The draft IRIS assessment estimated that the IUR used to estimate lifetime cancer risks may underestimate total cancer risk by as much as 4-fold."

EPN generally agrees with the agency's level of confidence in exposures, risk estimates, and risk characterizations for ambient air. While we are not aware of any scientific evidence that would confirm or counter EPA's speculation that the actual cancer risk to formaldehyde inhalation exposure could be 4-fold higher than that derived using the current IUR, there is strong evidence that formaldehyde exposure causes myeloid leukemia in humans. However, uncertainties in the available dose-response data led to insufficient confidence in the quantitative IUR estimate derived for this outcome to combine the estimated risks for cancer in the respiratory system with the multiple myeloma risk at this time, a conclusion with which we agree. However, we would urge that efforts be continued towards resolving the multiple myeloma conundrum so that this target site can be integrated into the risk assessment.

III. Unreasonable Risk Determination

Section 2. Unreasonable Risk Determination
Page 4: "EPA is preliminarily determining that formaldehyde presents an unreasonable risk of injury to human health under the COUs. Risk of injury to the environment does not contribute to EPA's preliminary determination of unreasonable risk. The formaldehyde sources that EPA evaluates in this draft risk evaluation involve, in general, the production and use of products that are subject to TSCA (as opposed to those products that are excluded from TSCA, such as pesticides). The unique challenge associated with this evaluation is that the formaldehyde released from commercial activities and products that are subject to TSCA is mixed in with the naturally-formed formaldehyde released from all the activities and processes mentioned above."

EPN Comments:
ALL ambient exposures should be incorporated into the exposure assessment without regard to source. Reality requires recognition and inclusion.

Page 4: "EPA has a high level of certainty that 41 occupational COUs and has less certainty that 5 additional occupational COUs contribute to unreasonable risk due to non-cancer effects, specifically sensory eye irritation associated with acute inhalation of formaldehyde.
EPA has a high level of certainty that 7 consumer COUs contribute to the unreasonable risk due to non-cancer effects, specifically sensory eye irritation associated with acute inhalation of formaldehyde."

EPN Comments:
What is the total number of occupational COUs? What is the total number of consumer COUs?

Why does EPA use the terms "high level of certainty" or "has less certainty" when describing degree to which COUs contribute to unreasonable risk due to various effects (e.g., page 4), but uses the terms "high, medium or low" when judging the confidence in the robustness of a health or exposure assessment or dose response analysis (e.g., page 7)? It is confusing.

Page 8: "If in the final TSCA risk evaluation for formaldehyde, EPA determines that formaldehyde presents an unreasonable risk of injury to health or the environment under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate."

EPN Comments:
The agency states in this and other documents that it cannot affirmatively determine all of the source(s) of exposure to formaldehyde in the ambient environment (e.g., indoor or outdoor air). The goal of risk mitigation is/should be to reduce exposure to "acceptable" levels, however one defines that term. Therefore, if/when designing a risk mitigation strategy for a specific unreasonable risk scenario, it should be assumed that those unidentified sources are TSCA-related and should be combined with the confirmed

COU-related exposure when setting an exposure value that reflects an "acceptable" level. To do otherwise is not health-protective and leaves the exposed parties subject to unacceptable risk.

Section 2.1.3. Basis for Unreasonable Risk to Human Health
Page 10: "Risk estimates based on high-end exposure levels (e.g., 95th percentile) are generally intended to cover individuals with sentinel exposure levels whereas risk estimates at the central tendency exposure are generally estimates of average or typical exposure. EPA aggregated exposures across certain routes and exposure scenarios for consumers and bystanders for COUs with quantitative risk estimates."

EPN Comments:
Cite the document after the last sentence quoted above where one can find the outputs of the aggregation of exposures noted there. The agency should display both the median and the high-end value here, along with reconsideration of which provides the most accurate assessment of reality.

Section 2.1.4 Unreasonable Risk in Occupational Settings
Page 11: "Chronic cancer risk estimates include an exposure time frame over a 40-year work tenure for the high-end exposure and a 31-year work tenure for the central tendency exposure."

EPN Comments:
Please recapitulate in this document the rationale for the approach described on page 11.

Section 2.3 Additional Information Regarding the Basis for the Unreasonable Risk
Table 2-1 needs to include a note at the top reminding readers what blank boxes mean: either risk estimates were derived but did not meet threshold of concern ,or no assessment was done at all? And why is there no subacute column in this table given that risk estimates were derived for this duration of inhalation exposure?

Similarly, Table 2-2 should also include a note at the top reminding readers what blank boxes mean.

Finally, while it would be preferable to have these tables include the numerical estimates for each COU/endpoint/duration as was done in most of the first ten risk evaluations, it would be very helpful if the document where they can be found is cited with the tables.