November 17, 2023

Sent Electronically

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Research Triangle Park, NC 27711

RE: Comments of the American Chemistry Council on EPA Proposed "Revisions to the Air Emissions Reporting Requirements [EPA-HQ-OAR-2004-0489; 88 Fed. Reg. 54118, Aug. 9, 2023].

Dear Sir or Madam,

The American Chemistry Council (ACC)[1] appreciates the opportunity to submit comments on the U.S. Environmental Protection Agency's (EPA) proposed technical amendments to its "Revisions to the Air Emissions Reporting Requirements" (AERR) rulemaking.[2] ACC appreciates EPA's efforts to advance regulatory requirements that protect our employees, communities, and the environment.

ACC members operate facilities across the country in compliance with existing state and federal statutory requirements. Our facilities routinely report air emissions information for hazardous air pollutants (HAP) under several existing state and federal regulatory requirements and operating permits. Separately, many of our members also have longstanding commitments to transparently interact with community residents about processes and products through important tools like Community Advisory Panels, which help facilities build relationships with members of their communities, share information about operations, identify any community concerns, and work with community stakeholders to try to resolve community concerns.

[1] *The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®; common sense advocacy designed to address major public policy issues; and health and environmental research and product testing. The business of chemistry is a $768 billion enterprise and a key element of the nation's economy. It is among the largest exporters in the nation, accounting for fourteen percent of all U.S. goods exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.*

[2] 88 Fed. Reg. 54118.

While we appreciate EPA's efforts to generate information to support its Clean Air Act (CAA) activities and advance its overall mission to protect public health and the environment, we have concerns that the rulemaking as proposed presents a sweeping and overly broad attempt to address these goals. Specifically, EPA's proposed rulemaking is a significant and precedential effort that will dramatically overhaul air emissions reporting requirements. The resulting additional regulatory burden, duplication, and complexity is foreseeable, but EPA has not properly quantified any associated environmental benefits. ACC is particularly concerned about EPA's proposed updates and expansion of HAP reporting thresholds outlined in Table 1 to Appendix A of the rulemaking, some of which are based on flawed and technically impractical toxicity values like unit risk estimates (UREs) generated by EPA's Integrated Risk Information System (IRIS) program, two of which are embroiled in litigation. Additionally, the framework of EPA's requirements as proposed would subject smaller area sources of HAP emissions to the same burdensome requirements as major sources, which is inconsistent with how these sources have been historically regulated through narrower and more tailored requirements suitable to their size.

ACC supports the separate comments on this rulemaking submitted by several key stakeholders and trade associations that will be directly impacted by the proposed requirements, including those from the Texas Chemical Council, the Small Business Administration, and our broader industry coalition.[3] In addition to those comments, ACC provides the comments herein to address important issues like the potential for duplication with existing regulatory programs covering our member facilities and several chemical-specific comments raised by EPA's approach to HAP reporting thresholds. ACC's comments and our associated recommendations are intended to offer suggestions for the Agency to take that would tailor proposed reporting obligations to comply with the CAA, obtain information that enhances environmental protection, and allow state agencies to continue to collect relevant information in the time and manner they have established.

I. Potentially Duplicative Requirements

As proposed, EPA's rulemaking will result in a vast new reporting program some of which will duplicate requirements for facilities to report different sets of emissions information to both their state regulatory authority or EPA in different systems, all of which may involve different and potentially conflicting objectives, program requirements, formats, technical details, statistical

[3] *See* comments to EPA Docket EPA-HQ-OAR-2004-0489 from joint coalition Alliance for Chemical Distribution, the Aluminum Association, American Chemistry Council, American Coke and Coal Chemicals Institute, American Composites Manufacturers Association, American Forest & Paper Association, American Fuel & Petrochemical Manufacturers, American Petroleum Institute, American Public Power Association, American Road & Transportation Builders Association, American Wood Council, Corn Refiners Association, Essential Minerals Association, The Fertilizer Institute, International Liquid Terminals Association, Interstate Natural Gas Association of America, National Asphalt Pavement Association, National Lime Association, National Mining Association, National Oilseed Processors Association, National Stone, Sand, & Gravel Association, the Petroleum Alliance of Oklahoma, Portland Cement Association, PRINTING United Alliance, U.S. Chamber of Commerce, and The Vinyl Institute. November 27, 2023.

treatments, etc. ACC members are already subject to reporting requirements for HAP emissions to state authorities for certain sizes of facilities. It should be noted that many of these existing programs appropriately include exemptions for insignificant sources or *de minimis* reporting thresholds, in contradiction with EPA's proposed "all HAP" requirement in this proposal.

a. EPA Federal Databases and Regulatory Programs

As a general matter, ACC notes that EPA already is subject to separate express statutory requirements to collect some of the information that it proposes to collect in the present rulemaking. Specifically, EPA administers the "Toxics Release Inventory" program under Section 313 of the 1986 Emergency Planning and Community Right to Know Act to collect source-specific reporting of toxics releases to the environment, information that already includes air emissions for a wide range of substances. The TRI program specifies among other things, the chemicals to be reported, provisions for threshold reporting levels, criteria to identify affected facilities, and other relevant program elements.[4] Congress has several times amended this program to add additional specific limitations and requirements.[5] Similarly, the CAA Title V operating permit program prescribes a detailed and elaborate permitting program that has the primary purposes of requiring the identification of CAA requirements applicable to each affected facility and issuing publicly available permits that allow for all interested parties to have access to this information.[6] It would be unreasonable (and, indeed, impermissible) to interpret the general authority conferred by CAA § 114 as requiring or authorizing EPA to effectively amend and augment overlapping statutory programs such as the TRI and the Title V operating permit program.

In addition to the routine reporting requirements that may be included in a facility's permit, a site may also be required to evaluate and report emissions under other EPA databases, including TRI-MEweb or EPA's electronic Greenhouse Gas Reporting Tool (e-GGRT). Further, some facilities may also report additional fenceline monitoring data to EPA in compliance with other source-specific CAA regulatory requirements. EPA's proposed requirements to report HAP emissions into CAERS will only serve as yet another duplicative annual exercise for a facility's reporting obligations.

EPA proposes to gather some information from facilities that is already available in the Agency's own files and state-level permitting agency databases: certain release point information, Title V permit number, applicable regulations, etc. Much of the requested information was obtained during EPA's risk reviews for Maximum Achievable Control Technology (MACT) standards and associated technology reviews. Many of these reviews have been completed.. EPA has already completed many of these reviews. Major source facilities already provide nearly all the information EPA says it needs as part of an information collection request (ICR) or as part of comments or industry data gathering exercises during Risk and Technology Review (RTR) rulemakings. In fact, RTRs involve modeling, which means EPA obtains more information than

[4] 42 U.S.C. § 11023
[5] https://www.epa.gov/toxics-release-inventory-tri-program/tri-laws-and-regulatory-activities.
[6] 42 U.S.C. § 7661-7661f

emissions data as part of the RTR process. We recommend that EPA use the vast amount of data already available to it through the states and existing databases before unnecessarily expanding the AERR.

Although it is unclear what states will accept HAP reporting responsibilities, EPA's proposed timeline for the first required HAP report will prevent most from doing so, at least initially.[7] It will be difficult for companies that operate in multiple states to navigate whether their facilities must report to the state, EPA, or both. It will also mean a duplicative review process for corporate personnel who assist individual facilities if they must review the state report and an EPA report with different (and potentially conflicting) requirements. Having two emissions reports to review increases the risk of error.

b. Coordination with States

In Section IV of the proposal, EPA seeks comment on its proposed approaches to collecting HAP annual emissions, including the extent to which some of those requirements may overlap with existing state-level requirements and ways that the Agency may avoid or eliminate the possibility of duplication.[8] ACC strongly encourages EPA to continue to collect data from states instead of proceeding with a new set of requirements that companies and facilities will have to interpret and implement, that will be inconsistent with existing reporting requirements, and a system into which over 130,000 facilities will be required to enter detailed information. ACC believes that EPA should allow states to first coordinate this information internally and develop and implement their own emissions reporting requirements in the manner and time most suited to their current emissions inventory requirements. This approach is more efficient, as facilities could submit one air emissions report to states, not separate potentially disparate reports to multiple agencies in different systems.

Moreover, SLTs, which have information on facilities' emissions and other operating parameters from air permits and other submittals, are familiar with the facilities they permit, and are well-suited to identify whether there are localized air toxics issues that must be addressed, outside of the federal residual risk process. Our members value their good working relationships with SLT regulators. Facilities can more easily collaborate with and access their state agency personnel to raise questions and concerns or provide input on emissions data, estimation methods, and reporting platforms. EPA should collaborate with SLTs to collect only the information that is necessary, in the manner that works for each SLT, not require industry to report emissions inventory data to both their SLT and to EPA on multiple platforms with different requirements and identifiers.

If there are specific chemicals of concern to EPA, EPA could undertake separate, targeted sets of rulemakings that specifically identify the chemicals or industries where additional data are needed to evaluate risk and require those industries to report releases to the TRI.

[7] 88 Fed. Reg. 54180.
[8] *Id*. at 54131.

c. Consideration of PFAS Reporting Requirements

In Section IV.16 of EPA's proposal, the Agency solicits comment on an option to include "mandatory reporting on per- and polyfluoroalkyl substances (PFAS) in the final rule," which could potentially require reporting for PFAS to states and EPA along with broader HAP reporting requirements.[9] ACC strongly opposes the suggestion to require reporting of PFAS included on the Toxic Release Inventory (TRI) list under the AERR proposal. As noted by the Agency, no PFAS have been identified as a HAP or as a criteria air pollutant. EPA has conducted a toxicity assessment for only a limited number of these substances and has yet to develop health benchmarks for the inhalation toxicity of any PFAS. Moreover, analytical methods are unavailable to measure many of the individual PFAS subject to TRI reporting. In light of these limitations, EPA has suggested that owners/operators use estimation techniques for reporting when measurements are not available.

Since facilities would no doubt use the same techniques to estimate emissions of the individual PFAS under AERR as they do for TRI reporting, it is not clear what additional "level of detail" the Agency hopes to collect as a result of adding PFAS to this proposal. The Agency should avoid such a speculative requirement for reporting of releases of individual PFAS until it has resolved the multiple issues it has identified. Future additions of any individual PFAS should be limited to those for which the Agency has listed as a HAP.

II. Concerns with general approach to calculating proposed risk thresholds and use of IRIS values.

a. EPA's Modeling Approach to Threshold Calculation

In Table 1B in the proposed rulemaking, EPA provides HAP emissions reporting thresholds in tons per year (tpy). Yet, many thresholds are lower than 10 tpy (the level included in the HAP major source definition). We note that requiring reporting of all HAPs, regardless of emissions level, for both major and area sources would be even more burdensome than the proposed approach for facilities, SLTs, and EPA. On this point, ACC supports and incorporates by reference the comments provided by the separate industry trade coalition as detailed in Section [XX]. As noted in those comments and echoed here, EPA can improve the clarity of its proposal and streamline its implementation if the Agency were to require reporting of any HAP with actual emissions of 10 tpy or more. This simplification would also focus attention on the largest sources of HAP. We believe that EPA has underestimated the number of sources that will need to develop HAP emissions inventories because the proposed thresholds for multiple HAPs are very low. Even sources with emissions lower than the proposed thresholds will need to estimate HAP emissions to show that the emissions are below the very low thresholds.

ACC notes that the proposed thresholds are unnecessarily low for many HAPs, and in many cases are much lower than SLT permitting, modeling and/or reporting thresholds for the same

[9] 88 Fed. Reg. 54148.

HAPs. The thresholds for HAPs such as naphthalene, formaldehyde, benzene, and acetaldehyde would cause small facilities, including many small businesses and area sources with multiple small combustion units, that no agency has ever identified as health risks, to fall under this burdensome proposal. ACC believes that the approach EPA has used to calculate its proposed thresholds for many HAPs lacks an adequate basis in sound scientific principles.

In its general approach, EPA's use of a threshold of one in one million cancer risk in the hypothetical modeling used to establish the thresholds is overly conservative. That level of risk is one percent of the threshold typically used in risk assessment to identify a level of risk that is acceptable[10]. This threshold is inappropriate for many types of sources. HAPs emitted at a very low concentration that would only contribute 1 percent of an acceptable level of risk should not be considered to contribute significantly to the overall cancer risk from a facility, or even to the cumulative risk when nearby facilities are taken into account. ACC believes that EPA should more closely consider threshold approaches that can screen out chemicals with a low contribution to overall risk, a contention that has found support in an international context at the European Food Safety Authority International Workshop on Risk Assessment of Combined Exposure to Multiple Chemicals.[11]

In addition, EPA typically applies overly conservative assumptions in its risk analyses, such as the assumption that the entire population continuously breathes outdoor air with a constant HAP concentration at a fixed receptor for a standard 70-year lifetime. This and other assumptions made by EPA in its hypothetical modeling continue to compound the level of conservatism beyond reason or justification. For example, EPA assumes a hypothetical fenceline of just 100 meters. While that might be appropriate for some types of facilities it is highly inappropriate for others. Mines, for instance, often have fencelines that are miles from any actual emission points. Moreover, EPA's focus on fencelines is misguided because members of the public are rarely located right at a fenceline, and certainly not for the lifetime duration assumed in risk assessments. Even with facilities that have fencelines that are relatively close to emission points, actual receptors in the general public are still far more likely to be located much further away. EPA should recognize exceptions to its highly conservative thresholds for facilities with dramatically different physical characteristics than those assumed in the overly conservative

[10] Benzene NESHAP, 54 Fed. Reg. 38045, September 14, 1989. "EPA will generally presume that if the risk to [the maximum exposed] individual is no higher than approximately one in 10 thousand, that risk level is considered acceptable."

[11] "A combined risk-based approach generates risk metrics using hazard metrics for a common effect or target organ and exposure metrics for individual chemicals using dose addition as the default assumption. Chemicals with a marginal contribution to the combined risk can be identified and excluded from grouping. A threshold value can be used to quantify the marginal contribution to a combined risk for defining low priority chemicals. Such threshold values will depend on the context of the assessment, and the prioritisation method used should be documented. EFSA's SC had recommended threshold values of 10% i.e any chemical contributing more than 10% to the combined risk (threshold value) is retained for refinement of the assessment group using hazard-driven criteria. However, this threshold might not perform well under all circumstances, e.g., when a high number of chemicals have a contribution slightly below the threshold value and would need to be further assessed." **EFSA International Workshop on RA of Combined Exposure to Multiple Chemicals.** APPROVED: 30 June 2022. EFSA Supporting publication 2022:EN-7422.

hypothetical modeling used to set the HAP applicability thresholds. The inherent conservatism in EPA's analysis further supports use of a higher threshold than EPA has proposed.

These low thresholds also place an undue burden on facilities, particularly small or medium-sized, to report insignificant emissions. Additionally, the use of an unnecessarily low threshold of one-in-one million cancer incidence, considering the exceedingly small amounts of some HAP that may generate this level of risk, would cause small facilities with minor permits or even simple registrations to have to understand and implement the requirements of the revised AERR, when they have never had reporting requirements in the past. Although we do not agree with the approach EPA has taken to set the proposed HAP emissions thresholds, a higher risk threshold (*e.g.*, at least the 20-in-1 million threshold EPA considered for small entities) could greatly reduce the reporting burden on small facilities, while having little or no impact on the overall risk presented by a facility or group of facilities.

In addition to the unreasonably low threshold of one-in-one million cancer risk as the reporting threshold, EPA's use of the 10th percentile of the emissions distribution causes a one-in-one million cancer risk across all sources modeled to establish the threshold adds compounded conservatism and subjects facilities with emissions resulting in significantly less than one-in-one million cancer risk to an overly broad and permanent reporting program. By definition, using the 10th percentile to set these thresholds means that 90 percent of the facilities modeled, if they emitted at the established reporting threshold, would <u>not</u> contribute a one-in-one million cancer risk from that HAP. EPA should reevaluate its proposed thresholds to be less conservative, such that HAP emissions reporting is not required from over 130,000 facilities for little or no benefit.

We believe that EPA's proposed requirement for major sources to report emissions of all HAPs emitted, rather than allowing the use of the same thresholds for individual HAPs as for area sources, is overly burdensome and unnecessary and will not result in meaningful improvements to public health. EPA should only require reporting of HAPs that exceed the major source thresholds, not all HAPs.

b. EPA's Application of Flawed Risk Values like IRIS to Inform Potential Regulatory Requirements

As ACC has explained in other CAA regulatory actions, the use of IRIS values as drop-in regulatory values is inconsistent with prior EPA statements on what IRIS values can be used for, representations to Congress, and ignores numerous problems associated with their development. For those reasons, ACC urges EPA to not use IRIS values for setting risk-based reporting thresholds. If, however, EPA continues down this path, it should not impose reporting requirements until it has evaluated each IRIS value for appropriateness of use in this regulatory context, provided clear notice to impacted entities and evaluated the scientific validity of each IRIS value through notice and comment rulemaking. If EPA intends to incorporate any other values, including from new draft or final IRIS assessments, it should re-propose the affected requirements and provide justification consistent with Section 307(d)(3).

Primarily we urge the Agency to not use the values since IRIS values which are not legally binding, and are the product of a process that, on the advice of the National Academy of Sciences ("NAS") and at the direction of Congress, EPA has been working to reform for over a decade. We reiterate and expand on some of these concerns below:

1. IRIS values are not binding regulatory values.

IRIS is an EPA database that summarizes information on the potential adverse human health effects of certain chemicals. IRIS Background Paper (Feb. 1993) ("Background Paper") at 1.[12] For an individual chemical the database generally contains information on potential dose response relationships. *Id.* at 1. IRIS was designed as a starting point for understanding this relationship prior to its use in a regulation, not as an end point to be used directly in the regulation without an evaluation of all the science. *Id.* at 2, 5. As the EPA Background paper explained IRIS "as *one* source in evaluating potential public health risks of or from environmental contaminants," *id.* 3 (emphasis added), not the source. These cautions have been often repeated by EPA. For example, EPA has stated, "IRIS values are not entitled to conclusive weight" and that "[i]f an outside party questions IRIS values during the course of an EPA proceeding . . . EPA will consider all credible and relevant information before it in that proceeding."[13] And indeed, in other regulatory actions, EPA has emphasized that regulators "should not rely exclusively on IRIS values but should consider all credible and relevant information that is submitted in any particular rulemaking[.]"[14]

Historically, EPA understood the limitation of IRIS values in air rules developed under the hazardous air pollutant provisions on the CAA. For example, in promulgating the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for benzene, 54 Fed. Reg. 38044 (Sept. 14, 1989), (Benzene NESHAP), one of only a few air toxics rules prior to the 1990 CAA amendments, EPA did not use the benzene IRIS value, let alone rely on it exclusively. Instead, EPA evaluated the broader scientific record and chose a risk value based on that record as a while. *See* 53 Fed. Reg. 28496, 28506 (July 28, 1988) For example, EPA indicated that it "believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information." 54 Fed. Reg. at 38044, 38046; *see id.* at 38045-38057. Thus, at this early stage of the program, EPA made clear, in words and actions that IRIS values need not be considered at all by the Agency, let alone be given preclusive effect. To the contrary, EPA's approach called for the consideration of a wide range of scientific information. This is not mere prologue or a policy that the Agency can simply step away from, especially without even acknowledging it is doing so.[15]

Subsequently Congress amended Section 112 of the Clean Air Act in 1990 to address air toxics. In doing so, it explicitly embedded the approach taken by EPA in the Benzene NESHAP. *See* 42

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[12] *Available at*: EPA Background Paper, https://nepis.epa.gov (last visited Aug. 14, 2023).
[13] Water Rule, 66 Fed. Reg. at 46929.
[14] Water Rule, 66 Fed. Reg. at 46929.
[15] Even if Congress had not incorporated the Benzene NESHAP framework, EPA would still have needed to explained its change in policy, which to date it has not done. [EZ TO ADD FC VS. FOX CITATION]

U.S.C. 7412(f)(2)(B) (providing that nothing in Section 112 "shall be construed as affecting, or applying to" EPA's interpretation of Section 112 as set forth in the 1989 benzene rule). The incorporation of the benzene NESHAP rule's approach into the Clean Air Act demonstrates that Congress recognized that the consideration of multiple scientific views and technical analyses (beyond an IRIS value) was the appropriate way to regulate air toxics. This nuanced approach used by EPA and adopted by Congress stands in sharp contrast to EPA's approach here.

Moreover, Congress recognized that it, rather than EPA, should be the entity seeking to regulate residual risk after imposition of the MACT standards. To facilitate such action by Congress, it required that EPA submit within three years a report, which included, among other things, "methods to calculate risk" and "recommendations as to legislation regarding such risk". 112(f)(1). In this report to Congress, EPA indicated that it would "not be relying exclusively on IRIS values" but instead would "be considering all credible and readily available assessments."[16] Having received EPA's explanation on how the program would be implemented and recommendations, Congress decided not to act. Similarly, Congress has never authorized the Office of Research and Development's IRIS program. While not only raising significant non-delegation issues, this history also makes clear that EPA's interpretation of relying on IRIS values is unreasonable if not clearly inconsistent with the statute.[17]

This history makes clear that: (1) EPA's interpretation that was subsequently incorporated into the statue did not give preclusive effect to IRIS values and, indeed reflected a view that all credible information needed to be considered; (2) EPA's roughly contemporaneous understanding of its statutory obligations tracked this understanding; (3) EPA represented to Congress that the program would be implemented consistent with such understanding. This last point was explicitly made in the context of Congress deciding to exercise its authority. Under these circumstances, EPA cannot reasonably interpret 112 as authorizing EPA to rely on IRIS values without giving full consideration of all scientific information.

2. Congress and Independent Scientific Organizations Have Raised Concerns that the IRIS Development Process has Scientific and Procedural Flaws

In addition to the limitations noted above regarding the use of IRIS values, Congress and other outside bodies have raised significant concerns with the methodology used to derive IRIS values

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[16] EPA, *Residual Risk Report to Congress*, at 57 (Mar. 1999). *Available at*: https://www.epa.gov/sites/default/files/2013-08/documents/risk_rep.pdf (last visited Aug. 14, 2023). EPA's guidelines for ensuring data quality in influential scientific risk assessments take a similar approach, stating that EPA intends to "use all relevant information," "evaluate that information based on sound scientific practices," and "reach a position based on careful consideration of all such information. EPA, *Guidelines for Ensuring and Maximizing Information Quality*, at 26 (Oct. 2002). *Available at*: https://www.epa.gov/sites/default/files/2019-08/documents/epa-info-quality-guidelines_1.pdf (last visited Aug. 14, 2023).

[17] ACC incorporates by reference the non-delegation arguments raised in the Petitioners' brief in *Huntsman v. EPA*, no 23-1045 at 57-59 (D.C. Cir July 24, 2023)

as well as their accuracy.[18] None have been so vocal about underlying methodological and substantive issues as the National Academies of Sciences, a body whose relevant recommendations EPA is obligated to address in conducting rulemakings under Section 307 of the Clean Air Act.

In connection with its 2011 review of the draft IRIS Assessment for Formaldehyde, NAS raised concerns with IRIS' methodology, including a critique of "recurring methodologic problems" with EPA's IRIS assessments, including "problems with clarity and transparency of the methods" EPA used.[19] Following upon the NAS concerns, Congress requested that the National Research Council ("NRC") within the NAS assess EPA's planned and implemented changes and recommend further improvements. EPA did make some programmatic changes to "ensure that EPA adequately considere[d] the [NAS'] recommendations." NAS assessed those changes in a 2014 report, finding significant programmatic issues in multiple areas, including, problem formulation, evidence identification, evidence evaluation, evidence integration, public participation and calculation of IRIS values.[20] NAS explicitly called for EPA revise its IRIS program by, among other recommendations:

- improving evidence integration and transparency,
- developing specific criteria to determine when evidence is sufficient to derive toxicity values,
- and preparing a quality-management plan for future IRIS assessments.[21]

Agreeing with the recommendations of the 2014 NAS Report EPA and has sought tooverhaul the IRIS process, including, most recently, issuing a 243-page peer-reviewed handbook for conducting IRIS assessments.[22] While a recent peer review of the Handbook noted that EPA had made significant steps to address the 2011 and 2014 recommendations, substantial work remains even with respect to developing a handbook that would "'provide a single detailed guidance document for all those involved in the development of IRIS assessments' and make the IRIS process transparent to stakeholders."[23] Areas identified for additional work included: clarifying the role of mechanistic data in evidence integration, and provide a step-by-step description of the process for appropriate study selection.[24]

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[18] *See, e.g.*, Integrated Risk Information System (IRIS); Announcement of Availability of Background Paper, 58 Fed. Reg. 11490 (Feb. 25, 1993) ("IRIS Announcement"); H.R. Doc. No. 106-379, at 129 (Oct. 13, 1999) ("The conferees are concerned about the accuracy of information contained in the Integrated Risk Information System (IRIS) data base"); *Cf.* H.R. 120, 118th Congress (Jan. 9, 2023) (proposing to require chemical assessments to be performed by the relevant EPA program office rather than the IRIS program to improve science).

[19] NAS, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde* (2011) at 4.

[20] NAS, *Review of EPA's Integrated Risk information System (IRIS) Process*, at 3-9 (2014) ("2014 NAS Report").

[21] *Id.* at 23, 37, 58, 77, 105, 129-130.

[22] *See generally ORD Staff Handbook for Developing IRIS Assessments*, EPA/600/R-22/268 (Dec. 2022).

[23] IRIS Handbook Peer Review at 13-14 (quoting (NRC, 2014 at 23)).

[24] *Id.* (*e.g.*, Recommendation 6.3, 7.1).

While these initial NAS recommendations were issued in the context of addressing formaldehyde NAS made clear that the recommendations were directed at the IRIS program more generally – with an entire chapter devoted to non-Formaldehyde specific recommendations applicable to all IRIS assessments[25]. EPA has recognized that these were programmatic recommendations and has been working to implement them a in a programmatic matter. This of course means that EPA has not fully implemented or addressed the NAS recommendations with respect to any of the IRIS values that it is relying on in this rule. As ACC has noted previously, CAA section 307(d)(3) explicitly requires that any rulemaking subject to 307(b) shall "summarize and provide a reference to any pertinent findings, recommendations and comments" by NAS and explain how the proposal differs in any important respect from any of the recommendations, and an explanation for such differences." The NAS recommendations are pertinent to the rule. They lay out fundamental concerns with both the process that EPA was using to develop IRIS values and the substantive outcomes thereof. EPA has not acknowledged the NAS recommendations in this rule. It has not described its basis for ignoring them. It has not shown why considering all scientifically relevant data, which as noted above was EPA's historical approach-and the one it represented to Congress it would take, would not address these recommendations. Addressing these recommendations would allow full consideration of all scientific information, including the problems with the IRIS program and addressing them in the same way that any limitations and uncertainties in information would be address. By failing to do so, EPA has failed to meet its obligations under 307 and the portion of the rule relying on IRIS values should be withdrawn or a supplement issued.

3. Issues with EPA's Consideration of Formaldehyde Science

As discussed in the previous section, it is not reasonable to interpret Section 112 as authorizing or requiring EPA to rely on IRIS values. The significant scientific and procedural flaws of the IRIS development process have already been addressed. However, beyond the concerns with the process for developing IRIS values, for a number of chemistries, there is a strong scientific record that provides additional support for not defaulting to consideration of IRIS values in this rulemaking. Formaldehyde is one of these chemistries. This section of comments addresses EPA's inappropriate choice of values for the development of reporting thresholds for formaldehyde and why EPA should consider alternative peer reviewed values and values developed by other authoritative bodies.

A. EPA's Existing IRIS Value for Formaldehyde Is Not Best Available Science

EPA proposes to use a unit risk estimate (URE) of 0.00013 ug/m^3 for the consideration of cancer risks for formaldehyde. This URE, developed in 1991, based on a rodent study conducted in 1983, does not represent the best available science. EPA recognized this in 2004 when the agency determined that "the dose-response value in IRIS is based on a 1987 study, and no longer

[25] See Samet 2011 testimony at page 4: https://republicans-science.house.gov/_cache/files/8/f/8f105f38-2eef-487d-bfec-9862239be561/699D2C53E8AB774A43FD706DCE8464FC.071411-samet-0.pdf

represents the best available science in the peer reviewed literature."[26] EPA acknowledged that new data and analysis had become available and instead recommended that EPA rely on research published by the CIIT Centers for Health Research (CIIT).[27] As described by EPA "[t]he CIIT model is based on computational fluid dynamics (CFD) models of airflow and formaldehyde delivery to the relevant parts of the rat and human respiratory tract, which are then coupled to a biologically-motivated, two-staged clonal growth model that allows for incorporation of different biological effects. These biological effects, such as interaction with DNA and cell proliferation, are processes by which formaldehyde may contribute to development of cancer at sites exposed at the portal of entry (e.g., respiratory tract). The two-staged model is a much more advanced approach for examining the relevance of tumors seen in animal models for human populations."[28] EPA went on to state that "the CIIT modeling effort represents the best available application of the available mechanistic and dosimetric science on the dose-response for portal of entry cancers due to formaldehyde exposure."[29]

In 2005, for the National-Scale Air Toxics Assessment (NATA), consistent with the concerns identified in 2004, EPA again reiterated that "EPA no longer considers the formaldehyde URE reported in IRIS, which is based on a 1987 study, to represent the best available science in the peer-reviewed literature."[30] EPA determined that the CIIT data, published in 1999, was the "best application of available mechanistic and dosimetric science on the dose-response for portal of entry cancers due to formaldehyde exposures."[31] Other EPA Office of Air and Radiation statements accompanying final agency actions reflect fundamental issues with the 1991 IRIS assessment of formaldehyde and the use of alternatives:

- "Furthermore, where the IRIS assessment substantially lags the current scientific knowledge, we have committed to consider alternative credible and readily available assessments. For our use, these alternatives need to be grounded in publicly available, peer-reviewed information. Formaldehyde is an example of this situation…. For formaldehyde, we do not use the dose-response value reported in IRIS. The dose-response value in IRIS is based on a 1987 study, and no longer represents the best available science in the peer-reviewed literature."[32]
- "In the case of formaldehyde, we have determined that the cancer potency derived using the approach developed by CIIT, which has been peer reviewed by an external review panel sponsored by EPA and the Canadian government, represents an appropriate alternative to EPA's current IRIS URE for formaldehyde. Therefore, this potency represents the best available peer-reviewed science at this time."[33]

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[26] 69 Fed. Reg. 18327, 18333 (Apr. 7, 2004).
[27] *Id* at 18333.
[28] *Id* at 18333.
[29] *Id.*
[30] EPA, Health Effects Information Used In Cancer and Noncancer Risk Characterization For the 1999 National-Scale Assessment, Nov. 2005, available at: https://web.archive.org/web/20170201124639/https:/archive.epa.gov/airtoxics/nata1999/web/pdf/healtheffectsinfo.pdf.
[31] *Id.*
[32] 69 FR 45993.
[33] 71 FR 8348, 8349.

- "We believe that the CIIT modeling effort represents the best available application of the available mechanistic and dosimetric science on the dose-response for portal of entry cancers due to formaldehyde exposures. We note here that other organizations, including Health Canada, have adopted this approach. Accordingly, we have used risk estimates based on the CIIT airflow model coupled to a two-staged clonal growth model as the basis for the dose-response values for this analysis. This model incorporates state-of-the-art analyses for species-specific dosimetry, and encompasses more of the available biological data than any other currently available model. As with any model, uncertainties exist, and this model is sensitive to the inputs, but we believe it represents the best available approach for assessing the risk of portal-of-entry cancers due to formaldehyde exposures."[34]

Other federal bodies have come to similar conclusions about the 1991 formaldehyde URE. The Government Accountability Office stated, "The IRIS cancer risk factor had been subject to criticism because it was last revised in 1991 and was based on data from the 1980s," noting that decisions on EPA final rules that did not use the 1991 value "did not specifically address EPA's reliance on the CIIT study."[35] In the most recent Reregistration Eligibility Decision for Formaldehyde and Paraformaldehyde, EPA's Office of Pesticide Programs highlighted concerns with the exclusive use of the 1991 URE and OAR's use of the CIIT model, noting that "Health Canada, Australia, the World Health Organization, and the German Maximale Arbeitsplatzkonzentrationen (MAK) Commission have also used the CIIT model" and "[m] strengths include consideration of the mode of action data for formaldehyde and a conservative approach to account for potential direct DNA interaction and mutation induction."[36]

Other stakeholders, including ACC, have extensively documented the scientific, procedural, and information quality issues with reliance on the 1991 URE for EPA and state actions.[37]

Recognizing that the 1991 IRIS URE was outdated, since 2003 EPA has been undertaking efforts to better understand risks from exposures to formaldehyde.[38] EPA released an updated draft IRIS Toxicological Review of Formaldehyde in 2010 (2010 Draft Formaldehyde Assessment).[39] In this draft evaluation, EPA changed course and rejected the use of the CIIT modelling (also referred to as biologically based dose-response (BBDR) modelling). Consistent with this approach, in January 2011, for use in the 2011 NATA assessment, EPA reverted back to using

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[34] 69 Fed. Reg. 45994.
[35] https://www.gao.gov/assets/gao-08-440.pdf (pg. 39).
[36] https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-043001_30-Jun-08.pdf (pg. 14-15).
[37] https://downloads.regulations.gov/EPA-HQ-OAR-2010-0786-0051/attachment_3.pdf; http://data.oregon.gov/views/dv6h-8bqc/files/5b8168da-cda3-4403-896c-2a8fcbf6878a.
[38] *See* formaldehyde science activities and documents available at: https://iris.epa.gov/ChemicalLanding/&substance_nmbr=419 .
[39] EPA's draft 2010 Formaldehyde IRIS Assessment is available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614.

the outdated 1991 Formaldehyde URE.[40] However, a review of the EPA 2010 Draft Formaldehyde Assessment by the National Academy of Sciences National Research Council (NAS) found significant methodological problems and problems with clarity and transparency and noted many substantive concerns with EPA's scientific evaluation.[41] In particular, NAS disagreed with EPA's rejection of the use of the BBDR modelling, stating that "[g]iven that the BBDR model for formaldehyde is one of the best-developed BBDR models to date, the positive attributes of BBDR models generally, and the limitations of the human data, the committee recommends that EPA use the BBDR model for formaldehyde in its cancer assessment, compare the results with those described in the draft assessment, and discuss the strengths and weaknesses of each approach."[42]

Equally important, in the 2010 Draft Formaldehyde Assessment, EPA considered using the 1983 study (Kerns et al. 1983) that is the basis of the 1991 IRIS URE to derive a cancer risk estimate. While the 2011 NAS review identified concerns that were so great that they led to a 12-year effort by EPA to improve its practices and procedures for toxicological assessments, nothing in the 2011 NAS review, nor anything in a more recent 2022 NAS review of yet another updated draft IRIS Formaldehyde Review (discussed in further detail below), suggest that the Kerns et al. 1983 study used by EPA to develop the 1991 URE represents the best available scientific information.

In the wake of NAS' highly critical 2011 report on EPA's 2010 draft formaldehyde IRIS assessment, EPA's Office of Air and Radiation committed to implementing several key recommendations, none of which are incorporated in this proposal and subsequent reporting requirements. These include commitments made in conjunction with the National Emission Standards for Wood Furniture Manufacturing Operations (2011),[43] National Emission Standards for Hazardous Air Pollutants for Friction Materials Manufacturing Facilities; Residual Risk and Technology Review (2018),[44] National Emission Standards for Hazardous Air Pollutants: Wet-Formed Fiberglass Mat Production Residual Risk and Technology Review (2018),[45] and National Emission Standards for Hazardous Air Pollutants: Generic Maximum Achievable Control Technology Standards; and Manufacture of Amino/Phenolic Resins (2014)[46] that: "The EPA will follow the NAS report recommendation and will present results obtained by implementing the biologically based dose response (BBDR) model for formaldehyde"; "The EPA will compare these estimates those currently presented… and will discuss their strengths and weaknesses"; and "As recommended by the NAS committee, appropriate sensitivity and uncertainty analyses will be an integral component of implementing the BBDR."

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[40] EPA, An Overview of Methods for EPA's National-Scale Air Toxics Assessment, Jan. 2011, available at: https://www.epa.gov/sites/default/files/2015-10/documents/2005-nata-tmd.pdf.
[41] NAS, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011), available at: https://nap.nationalacademies.org/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.
[42] *Id* at page 6.
[43] 76 Fed. Reg. 72061.
[44] 83 Fed. Reg. 19506.
[45] 83 Fed. Reg. 14991.
[46] 79 Fed. Reg. 1686.

For rulemaking activities where EPA has elected to use IRIS-related formaldehyde values (either in conjunction with the CIIT model or independently), the decision did not result in unacceptable risk determinations and subsequent standards.[47] OAR also stated that "EPA will fully address all the NRC recommendations on formaldehyde."[48] None of these steps have taken place in conjunction with this proposed rule, nor has EPA provided a detailed justification for their dramatic change of position.

As described above, while EPA has released multiple draft assessments updating the 1991 URE, none of the evaluations in any of the draft assessments, nor anything in the peer review reports, suggests that the 1991 URE that is currently on the IRIS database represents the best available science. This value should not be used to support this proposed rulemaking. OAR must provide a reasoned explanation, notice, awareness that it is changing position, good reasons for the new policy, and a more detailed justification for this about-face.[49] The Clean Air Act Section 307(d)(3) also requires that such a proposed rule provide statement of basis and purpose that includes "the methodology used in… analyzing the data" and the major legal interpretations and policy considerations underlying the proposed rule," which is lacking for the decision to include an unscientific IRIS value for formaldehyde.

B. *ATSDR's Minimal Risk Value for Formaldehyde Non-Cancer Respiratory Effects Does Not Represent Best Available Science*

EPA proposes to use a non-cancer reference concentration (RfC) of 0.0098 mg/m^3 (0.008 ppm) for the consideration of non-cancer risks for formaldehyde. The source of this value is the 1999 Toxicological Profile for Formaldehyde developed by the Agency for Toxic Substances and Disease Registry (ATSDR). The ATSDR minimal risk value (MRL) for chronic inhalation of formaldehyde is based on a 1989 study (Holmstrom et al. 1989) which evaluated nasal tissue specimens from a group of 70 workers.[50]

ATSDR's process for the development of MRL values in 1999 was not robust. While the document was reviewed internally, it did not undergo review through an interagency process, nor is there any discussion of the consideration of comments from the public.[51] Additionally while there was a peer review, it consisted of only 3 experts, and neither the experts' comments nor ATSDR's response to their comments are publicly available. The ATSDR toxicological profiles are not a valid substitute for the rigorous scientific review that is required to support rulemaking. Equally important, in describing how to use ATSDR minimal risk levels, ATSDR describes these values as "[i]ntended to serve as screening levels, are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at

[47] 85 Fed. Reg. 41281; 76 FR 72061.
[48] 78 Fed. Reg. 34823.
[49] FCC v. Fox Television Stations, Inc., 556 U.S. 502 (2009) as well as Clean Air Act Section 307(d)(3).
[50] ATSDR, Toxicological Profile For Formaldehyde, Jul. 1999, available at: https://www.atsdr.cdc.gov/toxprofiles/tp111.pdf.
[51] *Id* at page ix-xi.

hazardous waste sites. **It is important to note that MRLs are not intended to define cleanup or action levels for ATSDR or other Agencies"** (emphasis added by ATSDR).[52] ATSDR values are not appropriate for use in this rulemaking.

While the IRIS database does not currently provide a value for non-cancer inhalation effects, EPA proposed, in both 2010 and in 2022, RfC values for the respiratory effects of formaldehyde. Neither of these proposals suggested that Holmstrom et al. 1989 should be relied upon for development of the formaldehyde RfC. Similarly, while NAS has conducted two separate reviews of EPA formaldehyde science (in 2011 and 2023), neither NAS report has suggested that the Holmstrom et al. 1989 study should be used to derive an RfC for respiratory effects of formaldehyde. The ATSDR value that EPA proposes to use does not represent today's best available science, and in its place, EPA should consider other peer-reviewed values and final values developed by other authoritative bodies.

C. EPA's 2022 Draft IRIS Formaldehyde Assessment Does Not Represent the Best Available Science

Recognizing that the 1991 IRIS cancer assessment for formaldehyde and the 2010 Draft IRIS Formaldehyde Assessment were not scientifically robust, EPA began a multi-year process to update the Draft Assessment and potentially address the scientific comments from the 2011 NAS review. As part of the scientific process, EPA held a workshop in 2014 and continued to work on developing a new assessment for formaldehyde. In 2022, EPA released another draft Formaldehyde IRIS Assessment. EPA sought review of the 2022 Draft Formaldehyde IRIS Assessment from NAS. NAS reviews are typically used for the most controversial and highest-visibility products.[53] Unfortunately, this review suffered from three major flaws which are described below.

While the 2022 Draft Formaldehyde IRIS Assessment was undergoing NAS review, EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) sought review of a weight-of-evidence analysis of formaldehyde to inform a safe level for formaldehyde use under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This review was conducted by EPA's Human Subject Review Board (HSRB). The HSRB review, as described below in further detail, identified scientific shortcomings in EPA's analysis that highlight the need for major revisions to EPA's 2022 Draft Formaldehyde IRIS Assessment.

Considering the fatal flaws of the NAS review process, and the shortcomings identified by EPA's HSRB, the scientific analyses presented in the 2022 Draft IRIS Formaldehyde Assessment cannot be considered best available science and should not be used to inform this rulemaking.

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[52] See ATSDR description of minimal risk levels at: https://www.atsdr.cdc.gov/mrls/index.html.
[53] EPA Peer Review Handbook, 2015, available at: https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

i. NAS Review Flaw One: Violations of FACA Balance and Independence Requirements

The first major flaw of the 2022 NAS review relates to violations of the Federal Advisory Committee Act (FACA) that compromised the entire review process. These violations impacted the independence and membership of the NAS review panel and its staff. Importantly, FACA requires that members of the NAS committee do not have conflicts of interest and that the committee is fairly balanced. The NAS review panel fell short in both aspects, and the shortcomings were worsened by a lack of independence of the NAS staff.

Section 1014(b)(1)(B) of FACA requires that NAS committee be fairly balanced and appropriate for the functions to be performed.[54] The 2022 NAS committee was not appropriately balanced. Members included 2 state representatives and 11 members from the academic sector. There were no members from industrial/commercial, small business, or consulting sectors. As described in EPA's Peer Review Handbook, including member(s) with industry perspective helps to ensure the appropriate balancing of peer-reviewers with "diverse work history and affiliation."[55] Scientists with expertise in private sector industrial toxicology and industrial epidemiology are uniquely poised to consider real-world usage of and exposure to formaldehyde and similarities or differences from scenarios in various studies. However, there were no scientists with these perspectives on the NAS committee.

In addition, the NAS committee lacked the necessary expertise to address the complex scientific issues in the draft assessment. For instance, despite certain disciplines being mentioned in the EPA task order,[56] the NAS committee lacked expertise in occupational epidemiology, biological modeling including mechanisms of carcinogenicity, physiologically based pharmacokinetic ("PBPK") modeling, hematology, and reproductive and developmental toxicity.

Furthermore, the NAS policy on composition and balance includes consideration of objectivity, including whether "an individual may have strongly held views or biases, or may be closely associated with a group that has taken a strong position, on an issue before the committee."[57] And guidance from the Office of Management and Budget on peer review for scientific information cautions against the "repeated use of the same reviewer on multiple assessments

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[54] https://casetext.com/statute/united-states-code/title-5-government-organization-and-employees/part-i-the-agencies-generally/chapter-10-federal-advisory-committees/section-1014-requirements-relating-to-national-academy-of-sciences-and-national-academy-of-public-administration.

[55] EPA Peer Review Handbook, 2015, available at: https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

[56] Performance Work Statement for Task Order #68HERC21F0401 under NAS Contract #68HERC19D0011, at 4 (Sept. 7, 2021).

[57] NAS, Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations, Sept. 2021, available at: https://www.nationalacademies.org/documents/embed/link/LF2255DA3DD1C41C0A42D3BEF0989ACAECE3053A6A9B/file/D4D336B1CB9047B19928EA8785ED2E43C913B841539A?noSaveAs=1#:~:text=Members%20must%20be%20free%20of,must%20conform%20to%20this%20policy.

unless his or her participation is essential and cannot be obtained elsewhere."[58] This guidance is reiterated in EPA's Peer Review Handbook, which states "[t]the principle is to avoid the repeated use of the same reviewer on multiple assessments unless his/her participation is essential and the expertise cannot be obtained elsewhere."[59] Within the NAS committee of 13 members, 6 of the members served on a previous NAS committee in 2011 that reviewed EPA's previous formaldehyde draft assessment. Another NAS committee member was also a reviewer of the previous formaldehyde draft assessment. An analysis conducted by the American Chemistry Council (ACC) determined that these 13 members have served on over 220 federal advisory committees.[60] These relationships compromise the objectivity of the NAS review.

Compounding the concerns about independence and objectivity, the NAS study director, who was the staff lead overseeing the 2022 NAS review, had previously worked at EPA within the IRIS program and played a role in developing and reviewing drafts of EPA's formaldehyde assessment.[61] Her roles at EPA included being a disciplinary workgroup co-chair for the draft formaldehyde assessment and as a point of contact for IRIS reforms stemming from the 2011 NAS Review of the 2010 Draft Formaldehyde IRIS Assessment. The NAS biography of the study director, which is posted on the NAS webpage, does not disclose this involvement in developing the 2022 Draft Formaldehyde IRIS Assessment.

ii. NAS Review Flaw Two: Violations of FACA Requirements for Meaningful Input

FACA also requires that reasonable opportunity be provided for the public to comment on appointments to committees before they are made, that meetings are open to the public, and that written materials are made available.[62] Despite these requirements, the NAS committee did not allow for meaningful public input regarding committee appointments and was not sufficiently transparent with the public. For example, NAS only provided brief biographies of proposed committee members and, despite multiple requests to NAS to obtain additional information, this information was not provided.[63] This withholding of key information about NAS committee members unreasonably limited stakeholders' opportunity to comment on the proposed NAS committee composition.

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[58] OMB, Final Information Quality Bulletin for Peer Review, Jan. 2005, available at: https://www.federalregister.gov/documents/2005/01/14/05-769/final-information-quality-bulletin-for-peer-review.
[59] EPA Peer Review Handbook, 2015, available at: https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.
[60] *See* ACC's analysis here: https://www.americanchemistry.com/industry-groups/formaldehyde/resources/nasem-committee-procedural-comment.
[61] Details on the conflicts of the NAS study director are provided in a, ACC letter to Dr. Marcia McNutt, President of the NAS, Aug. 25, 2022 available at: https://www.americanchemistry.com/industry-groups/formaldehyde/resources/nasem-committee-procedural-comment.
[62] 5 U.S.C. § 1014(b)(1), (2), (3), (4).
[63] *See* for example, ACC's letter to Dr. Marcia McNutt, President of the NAS, Aug. 25, 2022 available at: https://www.americanchemistry.com/industry-groups/formaldehyde/resources/nasem-committee-procedural-comment.

NAS also limited public discourse regarding NAS committee appointments by failing to disclose comments about the NAS committee, including those provided by EPA, and failing to provide the public with an adequate summary of committee meetings. Indeed, the NAS "summary" for the NAS committee's September 1, 2022 meeting to address its composition, balance, and conflicts of interest consisted of only the statement: "The following topics were discussed in the closed sessions. Topics: Composition, balance, and conflict of interest discussion."[64] Contrary to FACA, the "summary" of this meeting that NAS placed on its website is not a summary at all; it does not summarize any discussion or conclusion.

iii. NAS Review Flaw Three: A Constrained Charge

The charge to a peer review panel is perhaps the most important part of any peer review contract because it contains the instructions to the peer reviewers regarding the objective of the peer review and the specific advice sought. Due to the limited scope of the charge that EPA provided to NAS, NAS did not conduct an independent assessment of the 2022 Draft IRIS Formaldehyde Assessment.[65] Instead, NAS evaluated whether the 2022 Draft IRIS Formaldehyde Assessment "adequately and transparently" evaluated the scientific literature and used appropriate methods to synthesize the state of the science. The NAS committee was not charged with commenting on the full body of literature relevant to the hazards and risks of formaldehyde, nor was it charged with reviewing alternative scientific opinions.[66] The NAS committee merely focused on whether EPA's approaches were consistent with EPA guidance documents. In addition, the NAS committee report, beyond mentioning that they had public comment periods, makes no mention of whether or how public input was used to inform its report.[67] Considering the limited nature of the NAS committee charge, and that the NAS report states that the committee "was not charged with…reviewing alternative opinions of EPA's assessment,"[68] it is doubtful that public comments were considered relevant to the NAS committee.

While the NAS review was limited to methods and approaches, and the NAS committee was not asked to conduct an independent assessment of the science, the NAS committee did recommend that "EPA should revise its assessment to ensure that users can find and follow the methods used

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[64] NAS, Review of EPA's 2022 Draft Formaldehyde Assessment BCOI Discussion (Sept. 1, 2022), https://www.nationalacademies.org/event/09-02-2022/review-of-epas-2022-draft-formaldehyde-assessment-bcoi-discussion.

[65] NAS, Review of EPA's 2022 Draft Formaldehyde Assessment, Aug 2023, available at: https://www.nationalacademies.org/our-work/review-of-epas-2022-draft-formaldehyde-assessment.

[66] The NAS committee task was to assess "whether EPA's draft document adequately and transparently evaluated the scientific literature, used appropriate methods to synthesize the current state-of-the science, and presented conclusions regarding the hazard identification analysis and dose-response analysis of formaldehyde that are supported by the scientific evidence." As noted by the NAS committee, "[t]he committee did not conduct an independent hazard evaluation or dose-response assessment, and therefore does not recommend alternative hazard identification conclusions or toxicity values. The committee also was not charged with commenting on other interpretations of scientific information relevant to the hazards and risks of formaldehyde, nor did its statement of task call for a review of alternative opinions on EPA's formaldehyde assessment."

[67] NAS, Review of EPA's 2022 Draft Formaldehyde Assessment, Aug. 2023, available at: https://www.nationalacademies.org/our-work/review-of-epas-2022-draft-formaldehyde-assessment.

[68] *Id*.

in each step of the assessment for each health outcome."[69] This Tier 1 recommendation speaks to the lack of clarity and transparency in EPA's assessment process. Indeed, a detailed review of the NAS committee report shows that EPA's 2022 Draft Formaldehyde IRIS Assessment does not represent the best available science.[70] Most importantly, because an independent evaluation of the science was not conducted, it is inappropriate to consider the science in the 2022 Draft Formaldehyde IRIS Assessment as having undergone the necessary robust peer review.

Additionally, if EPA intends to use the 2022 draft formaldehyde IRIS assessment or any subsequent final assessment as the basis for deriving annual monitoring requirements, they should issue a supplemental notice and provide a justification for such a change. Such an important scientific, legal and policy decision, especially given the Office of Air and Radiation's prior positions and commitment to incorporate peer review recommendations, new modeling, and other components of the best available, would not be a logical outgrowth from this proposal.

iv. The 2023 HSRB Review

In contrast to the NAS review of the 2022 Draft Formaldehyde IRIS Assessment, the HSRB, when charged with reviewing EPA's weight-of-the-evidence evaluation of the science related to formaldehyde induced sensory irritation, conducted a deep dive into the literature.[71] The HSRB also considered material provided by EPA and public commenters and publicly available information including research articles. This robust review, in contrast to the NAS review, was consistent with FACA requirements and was consistent with the requirements of the EPA Peer Review Handbook for the review of highly influential scientific assessments.[72]

The HSRB looked closely at the underlying data in each study it evaluated, while also looking closely at methods, statistics, author conclusions, and EPA's conclusions. HSRB conducted its own evaluation to inform EPA's weight-of-evidence evaluation on the acute endpoints related to sensory irritation. Stemming from its in-depth review, the HSRB made many important recommendations to EPA that also inform the science in the 2022 Draft Formaldehyde IRIS Assessment.[73] For instance, the HSRB found that the controlled chamber studies had a "preferred study design and greater scientific rigor" compared to the observational epidemiology studies and recommended that EPA rely on the controlled chamber studies rather than observational epidemiology studies. The HSRB also determined that formaldehyde does not follow Haber's

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[69] *Id.*
[70] https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/national-academies-buries-the-lede-in-review-of-epa-formaldehyde-assessment.
[71] A comparison of the NAS and HSRB reviews can be found here: https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/epa-human-studies-review-board-peer-review-shows-that-not-all-peer-reviews-are-equal-a-tale-of-two-peer-reviews-on-formaldehyde.
[72] *Id.*
[73] The HSRB report can be found here: https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde_0.pdf; a summary of some of the HSRB recommendations can be found here: https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/the-epa-human-studies-review-board-scientific-peer-review-highlights-that-major-revisions-are-needed-to-epa-s-draft-iris-formaldehyde-assessment.

Rule, and exposure adjustments are not necessary when calculating a point of departure. The HSRB provided additional recommendations related to which populations are most sensitive to sensory irritation from formaldehyde. While these comments were made in the context of acute endpoints, each of the recommendations are relevant for the chronic endpoints evaluated in the 2022 Draft Formaldehyde IRIS Assessment. This review reveals fundamental blind spots in EPA's approach that extend to other endpoints and other durations.

When considering the NAS review committee concerns about the lack of transparency in the 2022 Draft Formaldehyde IRIS Assessment, and the substantive scientific concerns identified by the HSRB, significant revisions are necessary before the 2022 Draft Formaldehyde IRIS Assessment can be considered to represent the best available science.

D. EPA has Violated Section 307(d)(3) of the Clean Air Act regarding Scientific, Legal, and Policy Justifications for the Proposal, including Advice from the National Academy of Science

The proposed rule's use of the 1991 URE fails to follow requirements under Section 307(d)(3). EPA has failed to include "the factual data on which the proposed rule is based" for deriving annual monitoring requirements from decades-old or scientifically questionable IRIS values. EPA has not explained the major legal interpretations and policy considerations underlying the proposed rule and its reliance on IRIS assessments that the Office of Air and Radiation has previously rejected, and the National Academy of Science has extensively critiqued. EPA has failed to "set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments" by the National Academy of Science regarding EPA's IRIS process and, specifically, the Agency's IRIS assessments of formaldehyde.

The 2022 formaldehyde IRIS assessment has also failed to fully address numerous still-relevant recommendations of a similar draft IRIS assessment. ACC has previously compiled these recommendations and explained in detail why they are legally required to be incorporated by EPA.[74] In addition, the 2022 NASEM Committee acknowledged that "[t]he present committee did not review specific changes in the 2022 Draft Assessment against the recommendations in the 2011 NRC report…"[75]

E, For Best Available Science, EPA Should Consider Alternative Authoritative Body and Peer-Reviewed Values

As described above, EPA's 1991 URE value and ATSDR's 1999 MRL value do not represent the best available science and are not consistent with EPA's own guidance, Clean Air Act requirements, and Federal Information Quality Guidelines. Similarly, the proposed values in

[74] https://www.americanchemistry.com/content/download/10668/file/Formaldehyde-Panel-Follow-Up-Letter-to-EPA-031022.pdf.
[75] https://nap.nationalacademies.org/catalog/27153/review-of-epas-2022-draft-formaldehyde-assessment.

EPA's 2022 Draft Formaldehyde IRIS Assessment are also flawed. These values should not be used by EPA in this rulemaking.

While EPA has struggled to finalize a formaldehyde assessment that peer reviewers have supported, other authoritative bodies have completed more robust formaldehyde assessments. Most recently, EPA has identified many of these values in its supporting documentation for the May 2023 HSRB review of the formaldehyde weight of the evidence.[76] In particular, scientific experts in the EU have found that formaldehyde has a threshold below which nasopharyngeal cancer and other adverse effects do not occur.[77] The EU Scientific Committee on Occupational Exposure Limits (SCOEL), consistent with these findings, recommends a value of 0.369 mg/m^3 (0.3 ppm) as protective for exposures to workers,[78] which EPA considers to be one of the most sensitive subpopulations. As EPA has acknowledged, two EU scientific bodies (ECHA and SCOEL) did not find associations between formaldehyde exposure and leukemia to be biologically plausible. The World Health Organization (WHO) also reached this same conclusion.[79]

In addition to considering recent values from authoritative bodies, such as from the EU SCOEL and ECHA, EPA should also consider using peer-reviewed values that the Agency has relied upon in the past, such as the value from CIIT, which EPA identified as best available science in 2005, and which also received a favorable review from NAS in 2011. While EPA's latest attempt to characterize the formaldehyde science, as presented in the 2022 Draft Formaldehyde Assessment, is fatally flawed (as discussed above), robust scientific evaluations exist to support a move away from the 1991 IRIS URE and the 1999 ATSDR MRL.

F. EPA's Derivation of Annual Reporting Requirements for Entities Emitting Small Amounts of Formaldehyde Lacks a Rational Basis Given EPA Scientific Determinations about Sources of Formaldehyde.

[76] EPA, Weight of Evidence for Acute and Peak Inhalation Exposures, May 2023, at page 3-4, available at: https://www.epa.gov/system/files/documents/2023-04/3a.%20Formaldehyde%20WOE%20for%20Acute%20and%20Peak%20Inhalation%20Endpoints_2023-04-23.pdf.

[77] *See* for example, French and Dutch Competent Authorities, Substance Evaluation Conclusion as required by REACH Article 48 and Evaluation Report for Formaldehyde (June 7, 2019), (Evaluation) (Attachment 5), available at: https://echa.europa.eu/documents/10162/cc0acabf-6e82-f2ed-5dbe-8058f48ce6c4; ECHA, Annex XV Restriction Report; Proposal for a Restriction – Formaldehyde and formaldehyde releasers (Mar. 3, 2019), https://echa.europa.eu/documents/10162/8ee35676-a94c-53b0-1e89-b2aef767bdd2; and Commission Regulation (EU) 2023/1464 of 14 July 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R1464.

[78] SCOEL. 2016. SCOEL/REC/125 Formaldehyde. Recommendation from the Scientific Committee on Occupational Exposure Limits.

[79] For a robust discussion of authoritative body consideration of leukemia, see comments submitted by the American Chemistry Council Formaldehyde TSCA Risk Evaluation Consortium to EPA on the 2022 Draft Formaldehyde IRIS Assessment, available at: https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0100.

The proposed rule, which incorporates outdated and unscientific toxicity values and admittedly questionable modeling, would result in an enormous number of entities, including many small entities which may be disproportionately impacted, to annually report extremely small emissions of formaldehyde (0.83 short tons per year). While the Agency claims this might improve emissions inventories and modeling capabilities, EPA's own scientific determinations demonstrate the insignificance of these sources and low likelihood of improved risk characterization for the microscopic contributions of all stationary sources.

In response to frequently asked questions on its AirToxScreen, EPA note that biogenic sources – including from "trees, plants, and soil microbes" – emit formaldehyde, acetaldehyde, and methanol as well as "large amounts of other volatile organic compounds." EPA also notes the significance of secondary formation of formaldehyde, which the Agency estimates using the CMAQ model.[80]

EPA's National Emissions Inventory and EPA publications and presentations demonstrate the overwhelming contribution of biogenic and fire sources and the insignificant role of stationary sources affected by this rule. One EPA presentation concludes that biogenic contributions of formaldehyde "dominate at most locations in the continental US."[81] EPA's National Emissions Inventory demonstrates that fires (primarily wildfires) and biogenic emissions representing over 90 percent of emission.[82] Wildfires alone emit three times more formaldehyde than all stationary and mobile sources in the country combined. Biogenic emissions contribute nearly 2,500 times more formaldehyde than chemical manufacturing. Even within the less than 10 percent of direct formaldehyde emissions associated with mobile and industrial source, EPA may be barking up the wrong tree. For example, locomotives produce more than 20 times more formaldehyde than all chemical manufacturing processes.

Several studies also show very low correlations between modeled formaldehyde, including CMAQ-modeled secondary concentrations, and in situ of satellite measurements.[83] These issues are unlikely to be resolved by annual reporting of de minimis formaldehyde emissions by stationary sources.

Similarly, Georgia's Environmental Protection Division underscored this concern in 2022 comments on EPA's AirToxScreen, noting: "Based on information provided to GEPD by your staff, the formaldehyde risk identified in AirToxScreen is mostly attributed to the 'Secondary' emission source group, meaning that it's formed in the atmosphere through photochemical

[80] https://www.epa.gov/AirToxScreen/airtoxscreen-frequent-questions; https://19january2021snapshot.epa.gov/national-air-toxics-assessment/nata-frequent-questions_.html.
[81] https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=88282&Lab=NERL.
[82] https://enviro.epa.gov/envirofacts/embed/nei?pType=SECTOR&pReport=nation&pState=&pPollutant=&pPollutant=50000&pSector=&pYear=2017&pCounty=&pTier=&pWho=NEI.
[83] https://acp.copernicus.org/preprints/acp-2018-496/acp-2018-496-manuscript-version4.pdf; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8353957/; https://arxiv.org/abs/2209.07414.

reactions. AirToxScreen estimates higher formaldehyde and secondary contributions across the southeast, including Georgia, due to biogenic emissions."[84]

v. Ethylene Oxide

ACC has previously provided detailed comments in multiple venues explaining why the IRIS value for ethylene oxide cannot be used for regulatory purposes. Given the comprehensive and technical, legal, and procedural nature of these comments, ACC incorporates them into these comments as attachments.[85]

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We appreciate EPA's consideration of these comments. If you have any questions or need further clarification, please feel free to contact me at (202) 249-6423 or.

Sincerely,

Brendan Mascarenhas
Senior Director
American Chemistry Council

<<ATTACHMENT 1: Comments of the American Chemistry Council Ethylene Oxide Panel on EPA Proposed Amendments to "National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Source Category." EPA-HQ-OAR-2018-0746-0098. Docket ID No. EPA-HQ-OAR-2018-0746 (84 Fed. Reg. 69182; Dec 17, 2019).>>

<<ATTACHMENT 2: Comments of the American Chemistry Council Ethylene Oxide Panel on EPA Proposed "New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry." EPA-HQ-OAR-2022-0730-0174. Submitted to Docket ID No. EPA-HQ-OAR-2022-0730, 88 Fed. Reg. 25080 (April 25, 2023).>>

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[84] https://epd.georgia.gov/document/document/georgia-epd-comments-2017-airtoxscreen-pdf/download.

[85] *See* Comments of the American Chemistry Council Ethylene Oxide Panel on EPA Proposed Amendments to "National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Source Category." EPA-HQ-OAR-2018-0746-0098. Submitted to Docket ID No. EPA-HQ-OAR-2018-0746 (84 Fed. Reg. 69182; Dec 17, 2019); Comments of the American Chemistry Council Ethylene Oxide Panel on EPA Proposed "New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry." EPA-HQ-OAR-2022-0730-0174. Submitted to Docket ID No. EPA-HQ-OAR-2022-0730, 88 Fed. Reg. 25080 (April 25, 2023).