



Submitted Via Email

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Dr. Jonathan M. Samet  
Committee Chair  
Committee on Review of EPA's 2022 Draft Formaldehyde Assessment  
National Academies of Science Engineering and Medicine  
Board on Environmental Studies and Toxicology  
500 Fifth St., N.W.  
Washington, D.C. 20001  
[jon.samet@cuanschutz.edu](mailto:jon.samet@cuanschutz.edu); [formaldehyde@nas.edu](mailto:formaldehyde@nas.edu)

**RE: January 30<sup>th</sup> Public Meeting of the NASEM Committee to Review the 2022 Draft IRIS Formaldehyde Assessment**

Dear Dr. Samet,

On behalf of the American Chemistry Council (“ACC”) Formaldehyde Panel (“Panel”), I am writing to express our disappointment with the continued lack of meaningful opportunities for public engagement in the National Academies of Sciences, Engineering and Medicine (“NASEM”) Committee (“Committee”) review of EPA’s 2022 draft formaldehyde assessment (“2022 draft assessment”). The open sessions thus far have not been designed to solicit public engagement in any meaningful way on the critically important scientific and procedural flaws in the 2022 draft assessment. Therefore, we urge the Committee to immediately rectify these deficiencies, several of which appear inconsistent with Section 15 of the Federal Advisory Committee Act (“FACA”), in subsequent open sessions of the Committee.

The main topic of the open session portion of the January 30<sup>th</sup> public meeting was to discuss the written responses EPA provided to a set of four questions received from the Committee on January 6, 2023.<sup>1</sup> Neither the Committee questions to EPA nor the written responses to those questions were shared with the public until the day of the public meeting. If this information was shared with the public in advance, the Committee could have benefited from hearing public input on the questions that were posed to EPA. In addition, if the EPA responses were shared, then the public commenters could have also commented on EPA’s responses and their implications for the assessment. Instead, the public was left in the dark again without any prior information to help inform and target their comments to the Committee. This gives the perception that the Committee does not place any value on the input of the public.

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<sup>1</sup> [Questions-Responses NASEM Formaldehyde Panel Meeting January 30, 2023 \(nationalacademies.org\)](https://www.nationalacademies.org/2023/01/questions-responses-nasem-formaldehyde-panel-meeting-january-30-2023)



The January 30<sup>th</sup> public meeting was not designed to solicit meaningful public engagement in several aspects, including:

- NASEM committee members met in-person, yet all public speakers were disadvantaged because they were limited to providing oral comments virtually and only via audio;
- Public speakers were denied the opportunity to use slide presentations, which is typically allowed in order to facilitate communication of information in a virtual format;
- Public speakers were rushed to make comments on complex scientific and procedural issues in mere 3-minute intervals and were cut-off if they exceeded the 3-minute arbitrary deadline, despite there being plenty of extra time available for public commenters,
- Engagement with the public speakers appeared to be discouraged, in stark contrast to the almost 60 minutes dedicated to questions-and-answers with the EPA presenters;
- Committee members were never asked if they had questions for any of the speakers;
- Several speakers were excluded from being allowed to provide comments based on their organizations, without consideration of the possibility that multiple speakers from one organization may be speaking on completely different topics;
- All public commenters were relegated to the end of a full day meeting, after the committee had met for several hours, and with no time allotted for dialogue by the committee with public speakers; and
- NASEM directed registered public commenters, verbally and in writing on the day of the meeting, to not comment on certain topics, including concerns around balance, independence, and transparency of the committee. As ACC has previously noted,<sup>2</sup> the process for soliciting public comment on the committee composition was significantly limited and these directives are inconsistent with FACA requirements.<sup>3</sup> Furthermore, NASEM's limitations on public participation related to the public meetings are inconsistent with FACA requirements.<sup>4</sup> Additionally, important correspondence has been excluded from NASEM's public access file, decisions inconsistent with FACA.

Furthermore, the Panel seeks opportunities to fully correct the record on statements made by EPA during the January 30<sup>th</sup> NASEM public meeting:

- EPA asserted that Agency leadership suspended all work on a complete formaldehyde draft assessment in 2017 and that work restarted in 2021. This characterization is at odds

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<sup>2</sup> <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-panel-extension-request-to-nasem>; <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/response-to-nasem-on-extension-denial>; <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/nasem-committee-procedural-comment>; <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/nasem-committee-composition-comment>.

<sup>3</sup> Under Section 15(b)(1) of FACA NASEM must “provide a reasonable opportunity to comment on such appointments...”, including in some cases “in the period immediately following the appointments.” As we noted in prior communications, NASEM’s actions have raised serious questions as to if it is “make[ing] its best efforts to ensure that... the committee membership is fairly balanced” and “the final report of the Academy will be the result of the Academy’s independent judgment.”

<sup>4</sup> Section 15(b)(3) of FACA requires NASEM to “ensure that meetings of the committee to gather data from individuals who are not officials, agents, or employees of the Academy are open to the public” and to “make available to the public... written materials presented to the committee by individuals who are not officials, agents, or employees of the Academy.”

with the Agency's own statements about the process announced in April 2019 to prioritize assessments identified by program offices, in which EPA suspended the formaldehyde assessment because it was **not** identified as a priority.<sup>5</sup> Indeed, no EPA program office identified the formaldehyde assessment as priority. In addition, all of the other four assessments deprioritized through this process (chloroform, ethylbenzene, naphthalene, and uranium) were all restarted by following step one of the EPA's IRIS process.

- The NASEM 2011 review of the 2010 Draft Assessment identified significant deficiencies in how EPA evaluated the available science, specifically in the areas of toxicokinetics, mode of action, systemic and port-of-entry health effects, derivation of reference concentrations and unit risk estimates, the systematic review process, and the use of a weight of evidence approach. EPA indicated in their written response to the NASEM questions that “the methods and approaches recommended in the 2011 [NASEM] report were core components of the methods applied to develop the current draft...” Contrary to this assertion, as discussed extensively in the previous Panel comments, the 2022 draft assessment does not fully incorporate NASEM's 2011 systematic review recommendations or current best practices for implementing systematic review.<sup>6</sup> As the Panel has documented in significant detail, EPA has attempted to narrow the scope of this review to exclude important related issues related to resolving these matters and their characterization does not constitute good faith communication with the Committee.<sup>7</sup>

NASEM peer review panels, including the committee to review the EPA draft assessment, should seek to be as inclusive as possible. Public input can assist the committee in its deliberations by offering clarifying information and alternative scientific interpretations and perspectives. Public engagement bolsters public confidence in the committee's deliberations and the objectivity of its decisions. Thus, NASEM should explicitly solicit public comments on all technical materials prepared for or by an advisory committee.

Much to our dismay, the January 30<sup>th</sup> public meeting failed to meet these expectations. Despite these shortcomings, more than 40 public speakers have raised concerns on fundamental issues that need to be addressed by the Committee. To explore these issues more fully, we urge the Committee to provide robust opportunities for public engagement. As such, the Panel reiterates its September 20, 2022, request that NASEM convene a public information gathering session to

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<sup>5</sup> “In April 2019, the IRIS Program announced under the Program Outlook that in an effort to modernize its workflow, IRIS has moved away from one-size-fits-all assessments to a portfolio of chemical evaluation products to meet specific decision needs. This approach optimizes the application of best practices of systematic review in the IRIS Program.” ([EPA IRIS Program Outlook April 2019-Suspended/Discontinued Assessment](#)); “The IRIS assessment of formaldehyde (inhalation) announced as suspended in April 2019 has recently been unsuspended.” [A Message from the IRIS Program March 2021 \(epa.gov\)](#)

<sup>6</sup> See ACC Formaldehyde Panel Comments for examples: <https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0100>

<sup>7</sup> <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/acc-comments-on-the-charge-questions-and-committee-task-for-peer-review-of-draft-formaldehyde-assessment>; <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-panel-follow-up-letter-to-epa>.

facilitate the committee's consideration of the breadth of scientific information submitted through public comments.<sup>8</sup>

We request and look forward to future open sessions of the committee that do not repeat the deficiencies apparent in the past public meetings. Should you have any questions regarding this submission, I can be reached at [sahar\\_osman-sypher@americanchemistry.com](mailto:sahar_osman-sypher@americanchemistry.com).

Sincerely,



Sahar Osman-Sypher  
Senior Director  
Chemical Products & Technology Division  
American Chemistry Council  
On Behalf of the ACC Formaldehyde Panel

cc: Marcia McNutt (NASEM), Audrey Mosley (NASEM), Elizabeth Eide (NASEM), Clifford Duke (BEST), Kathryn Guyton (NASEM Staff Officer), [formaldehyde@nas.edu](mailto:formaldehyde@nas.edu)

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<sup>8</sup> ACC Formaldehyde Panel Letter to NASEM On Information Gathering Session, September 20, 2022: <https://www.americanchemistry.com/content/download/11908/file/Letter-to-NASEM-on-Information-Gathering-Session.pdf>