



Submitted Via Email

September 20, 2022

Dr. Kathryn Guyton
Study Director, Review of EPA's 2022 Draft Formaldehyde Assessment
National Academies of Science Engineering and Medicine (NASEM)
Board on Environmental Studies and Toxicology (BEST)
500 Fifth St., N.W.
Washington, D.C. 20001
kguyton@nas.edu

Re: Stakeholder Engagement with the NASEM Committee Peer Reviewing the Draft IRIS Formaldehyde Assessment

Dear Dr. Guyton:

The American Chemistry Council's Formaldehyde Panel¹ ("Panel") and a number of other key stakeholders submitted voluminous comments to the U.S. Environmental Protection Agency ("EPA") on its draft Integrated Risk Information System ("IRIS") formaldehyde assessment.² Importantly, the comments referenced separate submissions by numerous scientists with expertise in scientific issues on formaldehyde. Together, these submissions provide critical information that will benefit the members of the NASEM committee tasked with reviewing and evaluating the draft assessment and potential risks from low level exposures to formaldehyde. Of particular relevance to the NASEM committee's task are the scores of studies that EPA dismissed, failed to consider, or considered only superficially.³ In order to facilitate the NASEM committee's consideration of the breadth of scientific information submitted through public comments, we are requesting that NASEM convene a public information gathering session, as described below. The Panel also requests that NASEM designate at least 4 hours of oral public comments during the peer review public meetings.⁴

It is our understanding that the EPA's Task Order for the NASEM peer review specifies that public comments will be provided to the NASEM committee as "background information." We contend, however, that the scientific issues discussed in the Panel's extensive comments and those submitted separately by scientists should receive much greater focus and attention by the NASEM committee, pursuant to both EPA's Peer Review Handbook ("Handbook") and OMB Information Quality Bulletin for Peer Review ("OMB Bulletin").

The Handbook notes, for example, that peer reviewers should be provided "with materials relevant to the work product, including [...] **significant scientific and technical comments**" (emphasis added).⁵ Similarly, the OMB Bulletin requires agencies to "ensure that peer reviewers receive copies of comments that address significant scientific issues **with ample time to consider them in their review**" (emphasis added).⁶

To facilitate the NASEM committee's consideration of public comments submitted to EPA on the 2022 draft IRIS formaldehyde assessment, the Panel requests that NASEM convene a public information gathering session in which pivotal scientific issues can be publicly presented to and considered by the NASEM committee. The public session would be separate and distinct from the oral comments presented



during the NASEM peer review public meetings. Some of the scientific issues to be discussed at the session would include the following topics:

- Mode of action for formaldehyde-induced nasal tumors.
- Potential for systemic effects, considering the lack of systemic distribution of inhaled formaldehyde.
- The update to the Biologically Based Dose Response (BBDR) model. The BBDR model was the subject of extensive discussion in the 2011 NASEM report on the 2010 draft IRIS formaldehyde assessment.
- The role of endogenous formaldehyde in assessing low level exposure to exogenous formaldehyde.
- The novel “bottom up” approach to bounding human cancer risks from chronic inhalation exposure to formaldehyde, developed by Drs. Tom Starr and James A. Swenberg. Results from the application of this approach bound the potential risks for cancer, especially in consideration of the endogenous production of formaldehyde.
- New science generated, including epidemiology studies, since the NASEM review of the 2010 draft IRIS formaldehyde assessment that is critical to evaluating formaldehyde leukemogenicity.

The Panel would welcome an opportunity to discuss and further delineate the full complement of scientific issues to be presented and considered at an information gathering session. The session also would be an ideal forum in which to highlight for the benefit of the NASEM committee the implications of failing to consider scores of studies that EPA dismissed, failed to consider, or considered only superficially in the 2022 draft IRIS formaldehyde assessment.

Opportunities for robust public participation are especially critical given EPA denials of requests to provide adequate opportunity for public comment and a rigorous interagency comment process on the 2022 draft IRIS formaldehyde assessment, the history of public engagement on the 2010 draft of the IRIS formaldehyde assessment, and the experience of other BEST committees. EPA denied requests from a variety of stakeholders to conduct rigorous interagency review of the 2022 draft IRIS formaldehyde assessment before public dissemination⁷ as well as to hold a public listening session and extend the comment period for the draft assessment.⁸ The lack of a public listening session is particularly striking given that EPA held a public listening session on the 2010 draft formaldehyde assessment. NASEM also denied a request to extend public comment on the NASEM provisional panel.⁹

Holding a public information gathering session to consider scientific information, especially new information not incorporated into the 2022 draft IRIS formaldehyde assessment, is consistent with the practices of other BEST committees. For example, another current EPA-sponsored BEST consensus study is focused on human health risks associated with certain uses of electric arc furnace slag has included six public meetings over an eight-month period,¹⁰ including a 4-hour session for information gathering focused solely on trade association scientific information relevant to the review.¹¹ Similarly, the EPA-sponsored BEST consensus study related to the National Ambient Air Quality Standards has included 14 sessions, webinars, or multi-day events over a nine-month period with several sessions dedicated to information gathering from key stakeholders.¹²

The EPA Task Order also states that “The public peer review meeting(s) shall not exceed 8 total hours and shall include an opportunity for written and oral public comments to the external peer review committee.” What is not stated, however, is the amount of time that should be allotted for oral public comments. Given the extensive critical review of the 2010 draft IRIS formaldehyde assessment by a previous NASEM peer review committee, the nearly 2000 pages of the current 2022 draft IRIS formaldehyde assessment (including its many appendices), the Panel requests that at least an additional 4

hours should be allotted for oral public comments. Further, we recommend that each speaker should be given no less than 5 minutes to present oral comments to the NASEM committee. Additional time could be afforded each speaker depending on the total number of registered public presenters.

Thank you for your consideration of the Panel's request. We look forward to hearing from you. If you have any questions, please contact Sahar Osman-Sypher at sahar_osman-sypher@americanchemistry.com.

Regards,



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

cc: Elizabeth Eide, Executive Director, Division on Earth and Life Studies, NASEM, eeide@nas.edu
Clifford Duke, Ph.D., Director, Board on Environmental Studies and Toxicology, cduke@nas.edu
Audrey Mosley, General Counsel, NASEM, amosley@nas.edu

Public Access File Request at: publicac@nas.edu

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. The ACC Formaldehyde Panel represents producers, suppliers and users of formaldehyde and formaldehyde products, as well as trade associations representing key formaldehyde applications.

² Docket ID # EPA-HQ-ORD-2010-0396 for the Formaldehyde (Inhalation) IRIS Assessment, Available at: <https://www.regulations.gov/docket/EPA-HQ-ORD-2010-0396>

³ See Appendix A on pages 107-114 in the Panel comments available at <https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0103> for a list of more than 70 important studies, reviews, or responses which are not referenced in the external review draft for EPA's toxicological review or supplemental information.

⁴ We recognize that there was a recent event posted on the NASEM website for a first multiday event for October 12-13, 2022 for review of EPA's 2022 draft formaldehyde assessment. However, there was no further information posted with regards to the agenda topics or how much time would be allotted for public comments.

⁵ US EPA Peer Review Handbook, 4th Edition, October 2015, Available at: https://www.epa.gov/sites/default/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf (pg. 35)

⁶ OMB Information Quality Bulletin for Peer Review, Dec 2004, Available at: https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-03.pdf (p. 26)

⁷ https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0065/attachment_2.pdf;

https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0065/attachment_1.pdf;

https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0065/attachment_4.pdf;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0091>;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0066>.

⁸ For example, see: <https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0050> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0061> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0066> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0054> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0058> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0051> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0052> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0059> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0055> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0071> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0064> ;

<https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0060>.

⁹ <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/letter-to-nasem-on-info-request>.

¹⁰ <https://www.nationalacademies.org/our-work/electric-arc-furnace-slag-understanding-human-health-risks-from-unencapsulated-uses>.

¹¹ <https://www.nationalacademies.org/event/06-29-2022/electric-arc-furnace-slag-understanding-human-health-risks-from-unencapsulated-uses-meeting-4>.

¹² <https://www.nationalacademies.org/our-work/assessing-causality-from-a-multidisciplinary-evidence-base-for-national-ambient-air-quality-standards>.