



August 15, 2022

Marcia McNutt, Ph.D.
President
National Academy of Sciences
National Academies of Sciences, Engineering, and Medicine
Washington, DC 20001

Dear Dr. McNutt,

On the afternoon of Friday, August 5, the National Academies of Sciences, Engineering, and Medicine (NASEM) and the Board on Environmental Studies and Toxicology (BEST) released a provisional committee for the review of the 2022 U.S. Environmental Protection Agency (EPA) draft assessment of formaldehyde under the Integrated Risk Information System (IRIS) with a deadline to comment of August 25 (20 calendar days). The American Chemistry Council's ("ACC")¹ Formaldehyde Panel ("the Panel")² requests that NASEM extend the comment period on the provisional committee for no less than 20 additional calendar days. Extending this comment period is critical to provide a reasonable opportunity for the public to comment on such appointments and that the provisional committee adheres to current standards for independence, transparency, balance, turnover, and impartiality.

Section 15 of FACA requires that NASEM meet certain requirements for transparency, balance, and independence in the peer review process and prohibits agencies like EPA from using NASEM committee advice if these standards are not met. NASEM must provide "a reasonable opportunity for the public to comment on such appointments...." Given the timing of this provisional committee's announcement, the size and limited opportunity for comment on the underlying draft assessment, NASEM's failure to produce a "public access file" for this review, and the dearth of nomination information accompanying this announcement, NASEM should extend the comment period to provide that reasonable opportunity for the public to engage. In addition, multiple other NASEM requirements under FACA may be relevant for this committee and its composition, including:

- "no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed...;"
- "the final report of the Academy will be the result of the Academy's independent judgment;"
- "the committee was not subject to any actual management or control by an agency or an officer of the Federal Government;" and

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry.

² The ACC Formaldehyde Panel represents producers, suppliers and users of formaldehyde and formaldehyde products, as well as trade associations representing key formaldehyde applications.



- “The Academy shall make available to the public... written materials presented to the committee by individuals....”

Additional background on the nominations and conflicts of interest for selected committee members is essential for meaningful public comment and adherence with FACA. This information is especially important given recently released records showing EPA participation and potential control and management of the selection of committee members for this review.³ NASEM should also ensure that the biographical information is accurate and sufficiently comprehensive to allow for meaningful public comment. Importantly, some of the current biographical information on provisional committee members is inaccurate and/or missing critical information regarding potential bias and conflict of interest.

Multiple other guidelines, policies, and directives may also apply to the committee, including requirements from NASEM, EPA,⁴ and the White House Office of Management and Budget.⁵ The reasonable opportunity for public comment may also be affected by confusion and inconsistency for NASEM’s own policy for committee composition. On September 7, 2021, NASEM (without taking public comment and on the same day that EPA and NASEM signed the task order for this review) released a new version of its Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations.⁶ However, EPA and OMB peer review requirements still reference and rely on the 2003 policy that was in effect through September 2021.⁷ NASEM and BEST should provide clarity on which resources should guide the public’s comments on key issues like expertise, balance, independence, and impartiality.

Extending the deadline is consistent with past NASEM efforts to encourage public participation. For example, NASEM extended the deadline to nominate experts for this committee in October 2021.⁸ As the Panel has documented in several communications to EPA and NASEM,⁹ the nomination process fails to address direction in EPA’s Peer Review Handbook to solicit and consider public comment on the draft work product and accompanying charge questions prior to soliciting peer reviewers “so that appropriate expertise is included to address all charge questions” and “the Agency’s public comment process is kept distinct from the peer review panel’s comment process.”¹⁰

NASEM and BEST’s failure to extend the comment period would be yet another failure to provide meaningful public participation in the development and review of IRIS assessment. In

³http://web.archive.org/web/20220414101314/https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006489_00000125.pdf/a2e0ef78-2b13-4cc3-893d-4718f9bace52.

⁴ https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

⁵ https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-03.pdf.

⁶ <https://www.nationalacademies.org/docs/D4D336B1CB9047B19928EA8785ED2E43C913B841539A>.

⁷ https://web.archive.org/web/20170129021618/http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

⁸ <https://mailchi.mp/nas/formaldehyde-assessment-call-for-nominations-1322427?e=55eb0046ef>.

⁹ <https://www.americanchemistry.com/content/download/10864/file/ACC-EPA-NASEM-Charge-Questions.pdf>; <https://www.americanchemistry.com/industry-groups/formaldehyde/resources/extension-request-on-draft-iris-toxicological-review-of-formaldehyde>.

¹⁰ https://www.epa.gov/sites/default/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf (pg. 86).



comment letters to EPA, we have previously outlined failures by EPA in the development of the 2022 draft assessment of formaldehyde. NASEM should chart a different course in its review process and invite meaningful public participation. As outlined previously, EPA's failures include:

- By not releasing nor seeking public comment¹¹ on a chemical-specific IRIS assessment plan or systematic review protocol, the Agency failed to comply with its 7-step IRIS process.¹² In EPA's most recent IRIS program outlook, formaldehyde is the only one of the eighteen chemicals under review by the IRIS Program for which EPA has not released an IRIS Assessment Plan or Systematic Review Protocol for public comment prior to the release of a draft assessment.¹³
- Rejecting numerous requests to extend the 60-day comment period¹⁴ on the draft assessment from Members of Congress from both parties, agricultural & animal groups, trade associations, and key end users.¹⁵
- Failing to extend the interagency review period in order to allow affected federal agencies to provide meaningful feedback on the draft assessment. These requests for a more robust interagency review and coordination process came from multiple Members of Congress from both parties, who characterized the interagency process as sharing a copy of the draft assessment "with some federal agencies in late 2021, with a deadline to comment of a few short weeks and over the holidays."¹⁶

NASEM has noted that "[t]he quality and integrity of the work of these committees is essential to the reputation of the National Academies and to continuation of the institution's role as an advisor to the government and the nation. . . . Work that is of high quality and integrity requires that the membership of these committees be qualified, inclusive, and appropriately balanced. Members must be free of conflicts of interest, transparent about their relevant relationships and publications, and independent from the sponsors of the committee's work."¹⁷ It is, therefore, imperative that the comment period is extended to ensure that stakeholders have adequate time to evaluate whether the provisional committee:

- has the appropriate range of knowledge, perspective, and expertise to fully address the committee's charge,
- is absent of strongly held views or biases or is closely associated with a group that has taken a strong position on an issue, and

¹¹ <https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0103> (pg. 75-77).

¹² <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process>.

¹³ <https://www.epa.gov/iris/iris-program-outlook>.

¹⁴ <https://www.regulations.gov/document/EPA-HQ-ORD-2010-0396-0032/comment>.

¹⁵ Extension requests denied from American Veterinary Medical Association, American Feed Industry Association, National Chicken Council, National Pork Producers Council, National Turkey Federation, US Poultry & Egg Association, United Egg Producers, American Chemistry Council, American Forest & Paper Association/ American Wood Council, Composite Panel Association, Methanol Institute, Independent Lubricant Manufacturers Association, Louisiana Chemical Association.

¹⁶ <https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0066>; https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0065/attachment_1.pdf; https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0065/attachment_2.pdf; https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0065/attachment_4.pdf.

¹⁷ <https://www.nationalacademies.org/docs/D4D336B1CB9047B19928EA8785ED2E43C913B841539A>.

- has balance and diversity.

Consistent with Section 15(b) of the Federal Advisory Committee Act, we also request written materials¹⁸ provided to NASEM on these nominees, including conflict-of-interest forms, nomination materials, and a full list of participation by provisional committee members on other NASEM or EPA peer review bodies (information inconsistently reported in the August 5 biographies). Additionally, we request any amendments made to the contract between EPA and NASEM to conduct the review as well as any memoranda of understanding (MOU) between any of the institutions in which the provisional committee members are employed and EPA, the sponsoring federal agency.

Thank you for your consideration of the ACC Formaldehyde Panel's request regarding the extension of the comment period for the NASEM provisional committee. If you have any questions, please contact Lynn Dekleva at lynn_dekleva@americanchemistry.com.

Regards,



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American Chemistry Council
On Behalf of the ACC Formaldehyde Panel

cc:

John L. Anderson, Ph.D., President, National Academy of Engineering
Victor J. Dzau, MD, National Academy of Medicine
Elizabeth A. Eide, Ph.D., Executive Director, Division on Earth and Life Sciences
Clifford Duke, Ph.D., Director, Board on Environmental Studies and Toxicology (BEST)
Raymond Wassel, Scholar and Director of Environmental Studies, BEST
Kathryn Guyton, Ph.D., Study Director, BEST

¹⁸ If the Academy has determined that releasing any of these materials "would disclose matters described in Section 552(b) of title 5, United States Code," please advise the Panel of these determinations in writing.

