



January 17, 2024

Michal Freedhoff, Ph.D.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

RE: Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Request for Nominations of *ad hoc* Expert Reviewers; Docket ID EPA-HQ-OPPT-2023-0613

Dear Assistant Administrator Freedhoff,

The American Chemistry Council (ACC) Formaldehyde Panel (Panel)¹ appreciates the opportunity to provide comments on the Environmental Protection Agency (EPA) December 26, 2023 solicitation of nominees² for an *ad hoc* Science Advisory Committee on Chemicals (SACC)³ review of its forthcoming draft risk evaluation of formaldehyde under the Toxic Substances Control Act (TSCA) as well as formaldehyde review under the Fungicide, Insecticide, Fungicide, and Rodenticide Act (FIFRA) in 2024. We write to seek an extension of the nomination period, which expires January 25, 2024. The Panel intends to separately nominate several experts for this opportunity as well as to identify myriad scientific and legal issues with EPA's forthcoming peer review of limited elements of a draft risk evaluation for formaldehyde.

The Panel supports EPA's plans to solicit public comment "on the candidate list of *ad hoc* expert reviewers for this peer review" as well as the draft documents and related materials submitted to the SACC for peer review" (although, as noted below, EPA failure to seek comment on draft "charge" questions as well as establish the membership of the standing, chartered SACC prior to soliciting peer reviewer nominations for this review is inconsistent with EPA's Peer Review Handbook and the Federal Advisory Committee Act). However, the December 26 solicitation and advance notice of other planned activities raise several major concerns for the Agency's forthcoming formaldehyde activities:

The Panel requests that EPA extend this nomination period by at least 30 days and, in turn consider, sequencing other "planned actions" prior to the close of the nomination period to better reflect EPA's peer review policies. EPA should take this action for several reasons:

¹ The ACC Formaldehyde Panel represents producers, suppliers and users of formaldehyde and formaldehyde products, as well as trade associations representing key formaldehyde applications. Its primary activities are scientific research, regulatory and legislative advocacy, and outreach. The Panel is also committed to informing and educating regulators, policymakers, the value chain and the media on the weight of the scientific evidence surrounding formaldehyde exposure and safety.

² 88 Federal Register 88910. While this nonrulemaking docket does not contain an option for public comments, ACC and the Panel ask EPA to include this comment in relevant documents prior to the close of the nomination period: <https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613>.

³ The SACC was established in Section 26(o) of the 2016 amendments to TSCA (15 U.S.C. § 2625(o)).



- EPA indicates that it anticipates a public meeting of the standing SACC and these *ad hoc* reviewers in May 2024,⁴ providing several months to thoroughly seek and select experts. In addition, the SACC “expects to meet approximately four (4) to six (6) times a year”⁵ including approximately every two months,⁶ thus eliminating the need for EPA to rush overlapping peer review processes.
- This extension would be consistent with related EPA actions. EPA has previously extended the nomination period for the SACC,⁷ provided greater than 30 days for nominations to the standing SACC as well as *ad hoc* SACC panels,⁸ and (seemingly in recognition of the low likelihood of meaningful feedback in late December 2023), extended the deadline for public comment on peer reviewers for EPA’s draft TSCA risk evaluation for Tris(2-chloroethyl) Phosphate (TCEP).⁹ EPA has also provided more than 60 days for nominations for numerous EPA advisory committees since late 2022.¹⁰ EPA should follow these precedents and extend the nomination period.
- EPA also indicates that it “plans to publish separate documents in the Federal Register in early 2024,” including “draft documents and related materials submitted to the SACC for peer review.”¹¹ These documents, which presumably include peer review questions and a more detailed charge for the SACC, should be issued prior to the close of solicitation of nominees. EPA’s current Peer Review Handbook recommends this path and identified two benefits: “the Agency can consider public comments on the scope of the charge before the selection of 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.”¹²
- It is premature to close the nomination period for this activity prior to filling “up to eight” appointments on the 18-member standing SACC, openings for which EPA solicited nominations through December 11, 2023 and indicated “EPA anticipates appointing new SACC members by mid-2024 due to expiring membership terms.”¹³ In addition to the improved efficiency of seeking nominations for formaldehyde experts “for service as *ad hoc* reviewers assisting” the SACC upon selection of the updated SACC roster, this sequencing is essential to ensure that EPA is achieving TSCA, Federal Advisory Committee Act (FACA), and EPA policy requirements related to a “fairly balanced” panel as well as identifying gaps in expertise or diversity for the suite of reviewers who will be involved in review of formaldehyde.
- An extension of the nomination period may enable EPA to fulfill required steps (many previously identified by the Panel) prior to issuance and peer review of the draft risk evaluation of formaldehyde, including:

⁴ 88 FR 88911.

⁵ 88 FR 88910.

⁶ <https://www.epa.gov/system/files/documents/2022-04/2022-sacc-charter-renewal-final-0.pdf>.

⁷ 85 FR 50020.

⁸ 83 FR 46487; 81 FR 58925.

⁹ <https://www.epa.gov/tsca-peer-review/toxic-substances-control-act-tsca-letter-peer-review-2023-draft-risk-evaluation>.

¹⁰ 88 FR 40818; 88 FR 2614; 87 FR 79301.

¹¹ 88 FR 88913.

¹² https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf (pg. 86).

¹³ 88 FR 77308.

- Listing on EPA’s peer review agenda as well as publication and public comment on a peer review plan for its draft risk evaluation for formaldehyde, as required by the White House Office of Management and Budget’s (OMB) Final Information Quality Bulletin for Peer Review and EPA Peer Review Handbook.¹⁴
- Finalization, including incorporation of peer review and public comments, for the formaldehyde IRIS assessment,¹⁵ for which “the Agency intends to defer” for chronic inhalation exposure and the cancer inhalation unit risk.¹⁶ Indeed, the Agency should wait for completion of litigation related to its failure to comply with FACA in developing the IRIS assessment as this failure means that EPA cannot rely on NAS’s peer review. Further, reliance on the IRIS toxicity values is inappropriate since the NAS indicated that it did not conduct a comprehensive review of the science.
- Requirement to “consult and coordinate” on the draft risk evaluation with other federal agencies, consistent with Section 9 of TSCA¹⁷ and long-standing Executive Orders and OMB guidance regarding “significant” and “influential” actions.¹⁸
- Response to formal request from small business trade associations to convene a small business advisory panel ahead of the issuance of the draft formaldehyde risk evaluation pursuant to the Small Business Regulatory Enforcement Fairness Act.¹⁹
- Carrying out EPA’s December 2019 commitment “to consultation and coordination with Tribes” as part of the high-priority chemical risk evaluation process,²⁰ which has not taken place for formaldehyde or other forthcoming TSCA risk evaluations.²¹

Thank you for your consideration of our request to extend the nomination period for at least 30 days. Please feel free to contact me at (202) 249-6721 or Sahar_Osman-Sypher@americanchemistry.com if you have any questions. I look forward to your response.

Sincerely,



Sahar Osman-Sypher
Senior Director

¹⁴ https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0130/attachment_1.pdf (pg. 4); <https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0249> (pg. 39).

¹⁵ https://iris.epa.gov/ChemicalLanding/&substance_nmbr=419#status. See also: <https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0130>.

¹⁶ 88 FR 88911.

¹⁷ 15 U.S. Code § 2608.

¹⁸ <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>; <https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-13.pdf>; <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>; <https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0208>.

¹⁹ <https://nfda.org/Portals/0/HCHO%20SBREFA%20LETTER%20FINAL%2010-6-23.pdf>. See also: <https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0249> (pg. 43-44) and <https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0208>.

²⁰ <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0438-0021>.

²¹ <https://tcots.epa.gov/ords/tcotspub/f?p=106:1>.

Chemical Products & Technology Division
American Chemistry Council
On Behalf of the ACC Formaldehyde Panel

cc:

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