



**[EPA-HQ-OPPT-2023-0613; FRL-11608-01-OCSPP]**

**Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Request for Nominations of *ad hoc* Expert Reviewers**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is seeking public nominations of scientific and technical experts that EPA can consider for service as *ad hoc* reviewers assisting the Science Advisory Committee on Chemicals (SACC) with the peer review of the Agency's evaluation of the risks from formaldehyde being conducted to inform risk management decisions under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) programs. EPA expects to ask the SACC to consider and review the Office of Pollution, Prevention, and Toxics (OPPT) and the Office of Pesticide Programs (OPP) joint hazard assessments for human and ecological health; and the OPPT exposure and risk characterizations. This SACC peer review is in addition to prior external peer reviews by the National Academies of Science, Engineering, and Medicine (NASEM), the EPA's Human Studies Review Board (HSRB) and the SACC. The Agency is leveraging these peer reviews to support further development of the risk evaluation of formaldehyde. To facilitate nominations, this document provides information about the SACC, the intended topic for the planned peer review, the expertise sought for this peer review, instructions for submitting nominations to EPA, and the Agency's plan for selecting the *ad hoc* reviewers for this peer review.

**DATES:** Submit your nominations on or before **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit your nominations to the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** The DFO is Tamue Gibson, MS, Mission

Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-7642 or call the SACC main office at (202) 564-8450; email address: *gibson.tamue@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. What action is the Agency taking?*

The Agency is seeking public nominations of scientific and technical experts that EPA can consider for service as *ad hoc* reviewers assisting the SACC with the peer review of the Agency's evaluation of the risks from formaldehyde being conducted to inform risk management decisions under TSCA and FIFRA programs. EPA expects to ask the SACC to consider and review the OPPT and OPP joint hazard assessments for human and ecological health; and the OPPT exposure and risk characterizations. This SACC peer review is in addition to prior external peer reviews by the National Academies of Science, Engineering, and Medicine (NASEM), the EPA's Human Studies Review Board (HSRB) and the SACC. The Agency is leveraging these peer reviews to support further development of the risk evaluation of formaldehyde. To facilitate nominations, this document provides information about the SACC, the intended topic for the planned peer review, the expertise sought for this peer review, instructions for submitting nominations to EPA, and the Agency's plan for selecting the *ad hoc* reviewers for this peer review.

In addition, this document provides advance notice that EPA's plans to publish in the *Federal Register* in early 2024 separate documents to: 1) Announce the availability of and solicit public comment on the candidate list of *ad hoc* expert reviewers for this peer review; 2) Announce a 4-day public meeting of the SACC anticipated to be scheduled for May 2024; and 3) Announce the availability of and solicit public comment on the draft documents and related materials submitted to the SACC for peer review. In these future notices, EPA will also provide instructions for submitting written comments and for registering to provide oral comments at the

SACC meeting.

*B. What is the Agency's authority for taking this action?*

EPA established the SACC in 2016 in accordance with TSCA section 26(o), 15 U.S.C. 2625(o), to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. The SACC operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. 10, and supports activities under TSCA, 15 U.S.C. 2601 *et seq.*, the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.*, and other applicable statutes.

*C. Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, and disposal of chemical substances and mixtures, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

*D. What should I consider as I submit my nominations to EPA?*

Do not submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. If your nomination contains any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting that information.

## **II. Background**

*A. What is the purpose of the SACC?*

The SACC provides independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. The SACC is comprised of experts in toxicology; environmental risk assessment; exposure assessment; and related sciences

(e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic (PBPK) modeling, computational toxicology, epidemiology, environmental fate, environmental engineering and sustainability).

The SACC currently consists of 18 members. When needed, the committee will be assisted by *ad hoc* reviewers with specific expertise in the topics under consideration.

*B. Why is EPA conducting the risk evaluation?*

TSCA requires EPA to conduct risk evaluations on prioritized chemical substances and identifies the minimum components the Agency must include in all chemical substance risk evaluations. The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk to human health or the environment under the chemical's conditions of use (COUs). These evaluations include assessing risks to relevant potentially exposed or susceptible subpopulations. As part of this process, EPA integrates hazard and exposure assessments using the best available science and reasonably available information to assure decisions are based on the weight of the scientific evidence (WoSE). For more information about the three stages of EPA's process for ensuring the safety of existing chemicals (i.e., prioritization, risk evaluation, and risk management), go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals>.

*C. What is the focus of this SACC peer review?*

EPA is planning this SACC peer review of the Agency's evaluation of the risks from formaldehyde being conducted to inform risk management decisions under TSCA and FIFRA programs. EPA expects to ask the SACC to consider and review the OPPT and OPP joint hazard assessments for human and ecological health; and the OPPT exposure and risk characterizations. This SACC peer review is in addition to prior external peer reviews by the NASEM, the EPA's HSRB and the SACC. The Agency is leveraging these peer reviews to support further development of the risk evaluation of formaldehyde. The TSCA risk evaluation of formaldehyde is expected to comprise several modules (i.e., human health hazard, ecological hazard, release

and exposure assessments) and two risk assessment documents—the ecological risk assessment and the human health risk assessment. As part of the TSCA risk evaluation for formaldehyde, OPPT is assessing formaldehyde COUs (e.g., composite wood products, plastics, rubber, toys, and various adhesives and sealants).

Recommendations from the formaldehyde SACC review will be considered in the development of the TSCA and FIFRA risk evaluations and may inform other EPA efforts related to the assessment and regulation of formaldehyde. The Agency will be seeking SACC review of its data analyses and methodologies relevant to human health hazard and exposure analyses that have not been previously peer reviewed.

With respect to the formaldehyde human health hazard identification and dose-response analysis for acute inhalation and dermal routes, EPA is relying on peer review from three HSRB meetings: October 2022, May 2023, and October 2023. The HSRB reviewed the WoSE for EPA's acute inhalation point of departure (POD). Because the Agency's updated hazard characterization takes into consideration the HSRB's recommendations, EPA will not be soliciting review of the acute inhalation POD or WoSE. The HSRB reviewed relevant dermal studies, but not the WoSE for establishing the dermal POD. As such, EPA will seek review of the dermal POD and WoSE.

For chronic inhalation exposure and the cancer inhalation unit risk (IUR), the Agency intends to defer to the draft 2022 Integrated Risk Information System Toxicological Review of Formaldehyde and associated 2023 review by the NASEM. In part due to overlapping discussion of specific studies under review by NASEM and the HSRB, the latter recommended in its July 2023 report that EPA conduct a more coordinated peer review approach with other entities (e.g., NASEM, HSRB, SACC) regarding advice in establishing PODs for formaldehyde. In response to this recommendation, EPA intends to solicit comment on the chronic inhalation reference concentration (RfC).

The Agency intends to seek review of the oral POD and WoSE including the Agency's

assessment of the strengths and uncertainties in the underlying data and the utility of the data for risk assessment purposes. The Agency anticipates several areas of peer review related to human and environmental exposure to formaldehyde. EPA intends to request SACC review of how the environmental fate and monitoring data are used to support the qualitative assessment of formaldehyde exposure via water and land pathways to human and ecological populations. The Agency intends to seek SACC review related to EPA's assessment of formaldehyde air exposure via inhalation to terrestrial species based on fate, exposure modeling, monitoring, and toxicity data.

EPA intends to request SACC review on the Agency's interpretation of the available occupational monitoring data utilized in the formaldehyde occupational exposure assessment. The request for SACC review will focus on unique attributes considered and relied upon in the exposure assessment, including use of short-term exposure estimates, application of data relevancy, and evidence integration strategies.

EPA intends to seek review on its qualitative assessment of consumer exposure via the oral route. The Agency based this assessment on available data for TSCA COUs, indicating that formaldehyde is not expected to be released from consumer products or, if released, will not be available for uptake via an oral exposure route (*e.g.*, mouthing).

EPA intends to seek SACC review of the approach used to assess indoor air exposures, which considers both modeled and monitored formaldehyde concentrations.

EPA intends to seek review on the interpretation and assessment of ambient air monitoring data and its use in the risk evaluation. However, the Agency is not intending to request review on the modeling methods used to estimate formaldehyde exposure in ambient (outdoor) air as the methods used have been previously peer reviewed. SACC already reviewed both the Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities, Version 1.0 and the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation. Furthermore, feedback from these reviews have been incorporated into

the draft formaldehyde risk assessment.

EPA intends to request review of the assessment of aggregate exposure to formaldehyde.

### **III. Nominations of *ad hoc* Reviewers**

#### *A. Why is EPA seeking nominations for ad hoc reviewers?*

As part of a broader process for developing a pool of candidates for SACC peer reviews, EPA is asking the public and stakeholder communities for nominations of scientific and technical experts that EPA can consider as prospective candidates for service as *ad hoc* reviewers assisting the SACC with the peer reviews. Any interested person or organization may nominate qualified individuals for consideration as prospective candidates for this review by following the instructions provided in this document. Individuals may also self-nominate.

Those who are selected from the pool of prospective candidates will be invited to attend the public meeting and to participate in the discussion of key issues and assumptions at the meeting. In addition, they will be asked to review and to help finalize the meeting minutes.

#### *B. What expertise is sought for this peer review?*

Individuals nominated for this SACC peer review, should have expertise in one or more of the following areas: Indoor air quality; ambient air quality; exposure science with experience in air modeling and monitoring (for review of air exposure analysis); risk assessment (experience in chemicals and environmental fate of chemicals with background in risk assessment, aggregate exposure and risk assessment, industrial hygiene, ecological/terrestrial exposure); inhalation toxicology; dermal sensitization; statistics (experience in air quality data for review of interpretation of available monitoring data, experience in interpretation of environmental release data (*e.g.*, Toxic Release Inventory (TRI) and National Emissions Inventory (NEI))); epidemiology; and toxicology with expertise in interpreting gastrointestinal toxicity data associated with oral chemical exposure. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this review.

*C. How do I make a nomination?*

By the deadline indicated under **DATES**, submit your nomination to the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Each nomination should include the following information: Contact information for the person making the nomination; name, affiliation, and contact information for the nominee; and the disciplinary and specific areas of expertise of the nominee.

*D. Will ad hoc reviewers be subjected to an ethics review?*

SACC members and *ad hoc* reviewers are subject to the provisions of the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, conflict of interest statutes in Title 18 of the United States Code and related regulations. In anticipation of this requirement, prospective candidates for service on the SACC will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on the SACC.

*E. How will EPA select the ad hoc reviewers?*

The selection of scientists to serve as *ad hoc* reviewers for the SACC is based on the function of the Committee and the expertise needed to address the Agency's charge to the Committee. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a federal department or agency or their employment by a federal department or agency, except EPA. Other factors considered during the selection process include availability of the prospective candidate to fully participate in the Committee's reviews, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of

loss of impartiality, lack of independence, and bias may result in non-selection, the absence of such concerns does not assure that a candidate will be selected to serve on the SACC.

Numerous qualified candidates are often identified for SACC reviews. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications, and achieving an overall balance of different scientific perspectives across reviewers. The Agency will consider all nominations of prospective candidates for service as *ad hoc* reviewers for the SACC that are received on or before the date listed in the **DATES** section of this document.

#### **IV. Advance Notice of Other Planned Activities**

As indicated previously, EPA's plans to publish separate documents in the *Federal Register* in early 2024 to announce the planned activities related to this peer review that are briefly discussed in this unit

##### *A. Planned public review of a candidate list of ad hoc reviewers being considered.*

Although the final selection of *ad hoc* reviewers is a discretionary function of the Agency, EPA plans to make available for public comment a candidate list of *ad hoc* expert reviewers for this peer review in early 2024. The "List of Candidates" provides the names and biographical sketches of all interested and available nominees identified from respondents to this solicitation, other nominations received, and any additional candidates identified by EPA staff.

##### *B. Planned public meeting.*

EPA plans to announce a 4-day public meeting of the SACC that is anticipated to be scheduled for May 2024. At that time, EPA will provide logistical information and instructions for registering to attend and/or provide oral comments at the SACC meeting.

##### *C. Planned public review of materials submitted for peer review.*

EPA plans to announce the availability of and solicit public comment on the draft documents and related materials submitted to the SACC for peer review. At that time, EPA will provide instructions for accessing the materials provided to the SACC and will provide

instructions for submitting written comments and instructions for registering to provide oral comments at the SACC meeting. These materials will also be available in Docket ID No. EPA-HQ-OPPT-2022-0613 at <https://www.regulations.gov> and through the SACC website at <https://www.epa.gov/tsca-peer-review>. As additional background materials become available and are provided to the SACC, EPA will include those additional background documents (e.g., SACC members and consultants participating in this meeting and the meeting agenda) in the docket and through the SACC website.

*D. How can I stay informed about SACC activities?*

You may subscribe to the following listserv for alerts regarding this and other SACC-related activities: [https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic\\_id=USAEPAPPT\\_101](https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101).

(Authority: 15 U.S.C. 2625(o); 5 U.S.C 10)

Dated: December 20, 2023.

**Michal Freedhoff,**

*Assistant Administrator,*

*Office of Chemical Safety and Pollution Prevention.*

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