



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0613; FRL-11608-03-OCSP]

### **Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Notice of Availability, Public Meetings and Request for Comment**

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or “Agency”) is announcing the availability of and soliciting public comment on the 2024 draft risk evaluation for formaldehyde prepared under the Toxic Substances Control Act (TSCA). The draft risk evaluation is available for public review and comment. It will also be submitted to the SACC for peer review. EPA is also announcing that there will be two virtual public meetings of the SACC. The SACC will consider and review the draft risk evaluation at a 4-day virtual peer review public meeting that will be held on May 20-23, 2024. In addition, a virtual preparatory public meeting will be held on May 7, 2024, for the SACC to consider the scope and clarity of the draft charge questions for the peer review.

**DATES:** *Virtual Preparatory Public Meeting:* May 7, 2024, from 1 p.m. to approximately 4 p.m. (EST). You must register to receive the webcast meeting link and audio teleconference information. Online registration will be available beginning in April 2024. To request time to present oral comments during the virtual preparatory public meeting, you must register online by noon, May 3, 2024. For those not making oral comments during the virtual preparatory public meeting, registration will remain open through the end of the meeting.

*Virtual Peer Review Public Meeting:* May 20-23, 2024, from 10 a.m. to approximately 5 p.m. (EST) (as needed, updated times for each day may be provided in the meeting agenda that will be posted in the docket at <https://www.regulations.gov> and available through the SACC website at <https://www.epa.gov/tsca-peer-review>). You must register online to receive the

webcast meeting link and audio teleconference information. Online registration will be available beginning in April 2024. To make oral comments during the virtual peer review public meeting and included on the meeting agenda, you must register by noon, May 13, 2024. For those not making oral comments, registration for this meeting will remain open through the last day of the meeting.

*Comments:* Submit comments on the draft risk evaluation on or before **[INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Submit comments intended for the virtual preparatory public meeting on or before noon, May 3, 2024. For additional instructions, see Unit III. of **SUPPLEMENTARY INFORMATION**.

*To request special accommodations:* To allow sufficient time for EPA to process your request before the applicable meetings, please submit your request by April 30, 2024.

**ADDRESSES:** *Virtual Public Meetings:* You must register for each meeting to receive the webcast meeting link and audio teleconference information. Access to these virtual meetings will be provided through a webcast platform such as Zoomgov.com, streaming service, and audio teleconference.

*Meeting Registration:* For information and instructions on how to register and access these virtual public meetings, please refer to the SACC website at <https://www.epa.gov/tsca-peer-review>. After registering, you will receive the webcast meeting link and audio teleconference information.

*Comments:* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0613, through the *Federal eRulemaking Portal* at <https://www.regulations.gov>. to docket ID No. EPA-HQ-OPPT-2023-0613. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

*To request special accommodations:* For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** The Designated Federal Official (DFO) is Tamue Gibson, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-7642 or SACC main office number: (202) 564-8450; email address: gibson.tamue@epa.gov.

For general information: You may subscribe to the Office of Chemical Safety and Pollution Prevention listserv for alerts regarding this and other SACC related activities at [https://public.govdelivery.com/accounts/USAEPAOPPPT/subscriber/new?topic\\_id=USAEPAOPP\\_T\\_101](https://public.govdelivery.com/accounts/USAEPAOPPPT/subscriber/new?topic_id=USAEPAOPP_T_101).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

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

EPA is announcing the availability of and soliciting public comment on the 2024 draft risk evaluation for formaldehyde. EPA is also announcing a 4-day virtual peer review public meeting on May 20-23, 2024, for the SACC to consider and review the draft risk evaluation document. A virtual preparatory public meeting will be held on May 7, 2024, for the SACC and the public to consider and ask questions regarding the scope and clarity of the draft charge questions. EPA will be soliciting comments from the SACC on the Office of Pollution Prevention and Toxics (OPPT) and 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 SACC peer reviews of scientific approaches used in previous TSCA risk evaluations. These

previous peer reviews have informed the 2024 draft risk evaluation for formaldehyde.

This document provides instructions for accessing the materials, submitting written comments, and registering to provide oral comments and attend the public meetings.

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

EPA established the SACC in 2016 in accordance with the TSCA, 15 U.S.C. 2625(o), to provide independent advice and expert consultation, at the request of the Administrator, 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 the 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 and may be of particular interest to those involved in the manufacture, processing, distribution, and disposal of the subject chemical substance, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA.

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

1. *Submitting CBI.* Do not electronically submit any information you consider to be CBI or other information whose disclosure is restricted by statute. Copyrighted material will not be posted without explicit permission of the copyright holder. Members of the public should also be aware that personal contact information, if included in any written comments, may be posted on the internet at <https://www.regulations.gov>. If your comment 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.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets#tips>. See also

the instructions in Unit III.C.

## **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, and 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 did EPA develop these documents?*

TSCA requires EPA to conduct risk evaluations on high priority chemical substances to determine whether a chemical substance presents an unreasonable risk to human health or the environment under the chemical's conditions of use. EPA must also determine whether a chemical substance presents unreasonable risk to potentially exposed or susceptible subpopulations deemed relevant by the Administrator. 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. 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>.

## **III. Public Meeting of the SACC**

### *A. What is the purpose of the virtual peer review public meeting?*

EPA is planning this SACC peer review of the Agency's draft evaluation of the risks

from formaldehyde to inform risk management decisions under TSCA. OPPT collaborated with OPP to develop hazard assessments for human and ecological health. EPA expects to ask the SACC to consider and review these joint hazard assessments in addition to 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 SACC peer reviews of scientific approaches used in previous TSCA risk evaluations. The Agency is leveraging these peer reviews to support further development of the risk evaluation of formaldehyde. The TSCA risk evaluation of formaldehyde is comprised of several modules (i.e., human health hazard, ecological hazard, release and exposure assessments) and two risk assessment documents—the environmental risk assessment and the human health risk assessment. As part of the draft risk evaluation for formaldehyde, OPPT is assessing formaldehyde conditions of use.

Recommendations from the formaldehyde SACC review and public comments will be considered in the development of the final TSCA risk evaluation for formaldehyde 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. For additional information, please see the *Federal Register* notice of December 26, 2023 (88 FR 88910; FRL-11608-01-OCSPP).

#### B. *How can I access the documents?*

The 2024 draft risk evaluation for formaldehyde and related documents, including background documents, related supporting materials, and draft charge questions, are available in the docket. As additional background materials become available, EPA will include those additional background documents (e.g., SACC members and consultants participating in this meeting and the meeting agenda) in the docket. All of these documents will be available at <https://www.regulations.gov> (docket ID No. EPA-HQ-OPPT-2023-0613) and through links on

the SACC website at <https://www.epa.gov/tsca-peer-review>.

After the public meeting, the SACC will prepare the meeting minutes and final report document summarizing its recommendations to the EPA, which will also be available in the docket and through the SACC website.

*C. How can I provide comments?*

To ensure proper receipt of comments, it is imperative that you identify docket ID No. EPA-HQ-OPPT-2023-0613 in the subject line on the first page of your comments and follow the instructions in Unit I.D. and in this unit.

1. *Written comments.* Submit written comments by the deadlines set in the **DATES** section of this document and as described in the **ADDRESSES** section of this document.

2. *Oral comments.* To request time to present oral comments during one of the virtual public meetings, you must register online by the deadlines set in the **DATES** section of this document. Oral comments during the virtual public meetings are limited to 5 minutes. In addition, each speaker should submit a written copy of their oral comments and any supporting materials (e.g., presentation slides) to the DFO prior to the meetings for distribution to the SACC by the DFO.

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

Dated: March 11, 2024.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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