



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2024-0551; FRL-12418-02-OCSP]

Science Advisory Committee on Chemicals (SACC) Peer Review; High-Priority Phthalates; Draft Risk Evaluations and Technical Support Documents; Notice of SACC Meeting; Availability of Draft Documents and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing that there will be two virtual public meetings of the Science Advisory Committee on Chemicals (SACC). On July 21, 2025, a preparatory meeting for the SACC to consider the scope and clarity of the draft charge questions for the peer review; and on August 4 through 8, 2025, a peer review meeting for the SACC to consider the dibutyl phthalate (DBP), the dicyclohexyl phthalate (DCHP), and the di(2-ethylhexyl) phthalate (DEHP) draft risk evaluations, as well as the technical support documents for butyl benzyl phthalate (also known as benzyl butyl phthalate, BBP) and diisobutyl phthalate (DIBP), and public comments. The charge questions will address scientific and technical issues identified for peer review in all five phthalate risk evaluations scheduled to be finalized in 2025. EPA is also announcing the availability of and soliciting public comment on the draft documents and charge questions that will be provided to the SACC for this peer review. The draft risk evaluations and technical support documents were prepared under the Toxic Substances Control Act (TSCA) and will be submitted to the SACC for peer review.

DATES:

Preparatory Public Meeting:

Meeting date: July 21, 2025, 1 p.m. to approximately 4 p.m. (EDT).

Registration: To request time to present oral comments during the preparatory meeting,

you must register by noon (12 p.m. EDT) on July 14, 2025, and submit a written version of your oral comments by noon (12 p.m. EDT) on July 18, 2025. For those not making oral comments, registration will remain open through the end of this meeting on July 21, 2025.

SACC Peer Review Public Meeting:

Meeting dates: August 4 through 8, 2025, 10 a.m. to approximately 5 p.m. (EDT).

Registration: To request time to present oral comments during the peer review meeting, you must register by noon (12 p.m. EDT) July 28, 2025, and submit a written version of your oral comments by noon (12 p.m. EDT) on August 1, 2025. For those not making oral comments, registration will remain open through the end of this meeting on August 8, 2025.

Comments:

Submit written comments on the draft risk evaluation and technical support documents for consideration by the SACC for peer review, on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. To be considered by the SACC during the peer review meeting, the comments must be submitted to the peer review docket by July 21, 2025.

Special accommodations:

To allow sufficient time for EPA to process your request for special accommodations before the meeting, please submit the request at least ten business days in advance of the relevant meeting.

ADDRESSES:

Comments: Submit written comments, identified by docket identification (ID) number EPA-HQ-OPPT-2024-0551, through <https://www.regulations.gov>. 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 information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

Meeting registration: Online registration will be available in July 2025. Please refer to the SACC website at <https://www.epa.gov/tsca-peer-review>. After registering, you will receive the webcast and streaming service meeting links and audio teleconference information.

Special accommodation requests: To request an accommodation for a disability, please contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Designated Federal Official (DFO): Dr. Alaa Kamel, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-5336 or call the SACC main office at (202) 564-8450; email address: kamel.alaa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing that there will be two virtual public meetings of the Science Advisory Committee on Chemicals (SACC). On July 21, 2025, a preparatory meeting for the SACC to consider the scope and clarity of the draft charge questions for the peer review; and on August 4 through 8, 2025, a peer review meeting for the SACC to consider the draft risk evaluations and technical support documents and public comments. The charge questions associated with these draft risk evaluations will address scientific and technical issues identified for peer review of all five phthalate risk evaluations scheduled to be finalized in 2025. The charge questions will be available in EPA docket ID No. EPA-HQ-OPPT-2024-0551 on or before June 16, 2025.

EPA is also announcing the availability of and soliciting public comment on the draft documents that will be provided to the SACC for this peer review, including the draft charge questions that will be provided to the peer reviewers; the draft risk evaluations to inform risk management decisions under TSCA for DBP, DCHP, and DEHP; the non-cancer human health

and environmental hazard draft technical support documents for BBP and DIBP; and three cross-phthalate technical support documents, specifically the:

- Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone Technical Support Document;

- Draft Cancer Human Health Hazard Assessment Technical Support Document; and

- Revised Draft Technical Support Document for the Cumulative Risk Analysis (CRA).

EPA recently announced the availability of the draft risk evaluations for DBP and DEHP, and two cross-phthalate technical support documents (the Draft Cancer Human Health Hazard Assessment Technical Support Document and the Revised Draft Technical Support Document for the Cumulative Risk Analysis (CRA)) for public comment (see <https://www.epa.gov/chemicals-under-tsca/epa-releases-draft-tsca-risk-evaluations-phthalates-dbp-and-dehp-public> (FRL-12808-01-OCSPP)). In January 2025, EPA released the draft risk evaluations for DCHP, along with the draft technical support documents for BBP and DIBP; and the cross-phthalate Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone Technical Support Document. The draft risk evaluations were prepared under the Toxic Substances Control Act (TSCA) and will be submitted to the SACC for peer review.

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

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

EPA established the SACC in 2016 in accordance with TSCA, 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 and may be of particular interest to those involved in the manufacture, processing, distribution, and disposal of the subject chemical substances, and/or those interested (including members of at-risk communities, non-governmental organizations (NGOs), and federal, state, and local officials) 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 submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. To include information in your comment 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 comments.* When preparing and submitting your comments, see <https://www.epa.gov/dockets/commenting-epa-dockets>. See also the instructions in Unit III.C.

E. *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/USAEPAOPPT/subscriber/new?topic_id=USAEPAOPPT_101.

II. Background

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

The SACC provides independent 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 composed of experts in toxicology; environmental risk assessment; exposure assessment; and related sciences (e.g., chemistry, biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic (PBPK) modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). When needed, the SACC committee will be assisted by *ad hoc* reviewers with

specific expertise in the topics under consideration.

B. Why is EPA conducting these risk evaluations?

TSCA requires EPA to conduct risk evaluations on high-priority chemical substances and identifies the minimum components EPA 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 conditions of use (COUs). These evaluations include assessing risks to relevant potentially exposed or susceptible subpopulations. As part of this process, EPA: (1) Integrates hazard and exposure assessments using the best available science that is reasonably available to assure decisions are based on the weight of the scientific evidence, and (2) Conducts peer review for risk evaluation approaches that have not been previously peer reviewed. 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. Why did EPA develop these documents?

EPA designated the following chemicals as High-Priority Substances for risk evaluation under TSCA (84 FR 71924, December 30, 2019 (FRL-10003-15)): butyl benzyl phthalate (also known as benzyl butyl phthalate, CASRN 85-68-7), dibutyl phthalate (CASRN 84-74-2), dicyclohexyl phthalate (CASRN 84-61-7), di(2-ethylhexyl) phthalate (CASRN 117-81-7), and diisobutyl phthalate (CASRN 84-69-5). For these chemicals, EPA published draft and final scope documents (85 FR 22733, April 23, 2020 (FRL-10008-05) and 85 FR 55281, September 4, 2020 (FRL-10013-90)). The scope documents outlined the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expected to consider in its risk evaluations. Although there are some differences in conditions of use and exposures, these chemical substances are primarily used as plasticizers in polyvinyl chloride (PVC) products and in adhesives, sealants, paints, coatings, rubbers, and other applications.

Given the significant similarities in exposure and physical chemical properties of these phthalates, EPA is developing these risk evaluations, and the cross-phthalate draft technical support documents in parallel. Di-isodecyl phthalate (DIDP) and di-isononyl phthalate (DINP) were reviewed previously by the SACC (89 FR 43847, May 20, 2024 (FRL-11760-02-OCSPP)); the draft risk evaluations for BBP, DBP, DCHP, DEHP, and DIBP are incorporating many of the SACC recommendations from this previous peer review. Draft risk evaluations for BBP and DIBP will be released prior to the SACC peer review meeting and announced subsequently in the *Federal Register*.

In this SACC peer review of the draft risk evaluations for DBP, DCHP, and DEHP, EPA is soliciting comments from the SACC on the draft risk evaluations, including analyses of physical chemical properties, fate and transport in the environment, exposure to workers, consumers and general population including potentially exposed susceptible subpopulations, releases to the environment, environmental hazard and risk characterization for terrestrial and aquatic species, and human health hazard and risk characterization for workers, consumers, and the general population. Along with the full draft risk evaluations for DBP, DCHP, and DEHP, EPA is also soliciting feedback on its BBP and DIBP non-cancer human health hazard, and environmental hazard, draft technical support documents and the three cross-phthalate technical support documents (specifically, the Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone Technical Support Document, the Draft Cancer Human Health Hazard Assessment Technical Support Document, and the Revised Draft Technical Support Document for the Cumulative Risk Analysis). The Revised Draft Technical Support Document for the Cumulative Risk Analysis was developed based on the Draft Proposed Approach for Cumulative Risk Assessment under TSCA including recommendations from the May 2023 SACC review (see docket ID No. EPA-HQ-OPPT-2022-0918).

D. *What is the topic of the planned SACC peer review?*

EPA anticipates that the SACC peer review will focus on the complete draft risk

evaluations for DBP, DCHP, and DEHP; the non-cancer human health and environmental hazard draft technical support documents for BBP and DIBP; and the three cross-phthalate technical support documents (specifically, the Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone Technical Support Document, the Draft Cancer Human Health Hazard Assessment Technical Support Document, and the Revised Draft Technical Support Document for the Cumulative Risk Analysis). EPA anticipates requesting SACC peer review of the questions pertaining to critical inputs and novel approaches contained in these documents to constitute full peer review of all high priority substance phthalate risk evaluations.

III. Public Meeting of the SACC

A. What is the purpose of the virtual public meeting(s)?

The purpose of the preparatory public meeting is for the SACC to consider and ask questions regarding the scope and clarity of the draft charge questions, and the public peer review meeting is for the SACC to consider, and peer review the draft risk evaluations and technical support documents. These public meetings are part of the SACC's peer review of the Agency's methods and novel analyses for the draft risk evaluations. The agenda for these meetings will be posted in the docket and will also be available through the SACC website.

Recommendations from this SACC review and public comments will be considered in the development of the TSCA risk evaluations and may inform other EPA efforts related to the assessment and regulation of the chemical substances. 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.

B. How can I participate in the virtual public meeting(s)?

To participate in these virtual public meetings, you must register online to receive the webcast and streaming service meeting links and audio teleconference information for each meeting. Online registration will be available approximately one month prior to the meeting and will remain open through the end of the meeting. To make oral comments during one of these

meetings, follow the instructions in this document.

C. How can I access the documents?

The draft risk evaluations, related supporting materials and draft charge questions are available in docket ID No. EPA-HQ-OPPT-2024-0551. EPA will include additional meeting background materials as they become available, (e.g., SACC members and the meeting agenda) in the docket and through the Peer Review of High-Priority Phthalates website at <https://www.epa.gov/tsca-peer-review/peer-review-evaluating-risk-high-priority-phthalates>.

D. How can I provide comments?

To ensure proper receipt of comments, it is imperative that you identify docket ID No. EPA-HQ-OPPT-2024-0551 in the subject line on the first page of your comments and follow the instructions in this document.

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 five minutes unless arrangements have been made, within the constraints of the meeting agenda, prior to July 24, 2025. 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 deadlines set in the **DATES** section of this document.

IV. Next Steps

After the SACC public meeting, the SACC will prepare the meeting minutes and a final report document summarizing its recommendations to the EPA, which will also be available in the docket and through the SACC website. EPA will consider the SACC recommendations and public comments to complete the risk evaluations and unreasonable risk determinations under TSCA for these chemical substances. Under TSCA, EPA must then initiate risk management

actions to address the unreasonable risk it identified.

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

Dated: June 5, 2025.

Nancy B. Beck,

Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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