

enumerated in TSCA section 6(a), 15 U.S.C. 2605(a). The Agency is given a range of risk management options under TSCA—including labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, and a ban of the chemical or of certain uses. EPA will not be revisiting the risk management for the unreasonable risk that was identified in the Asbestos Part 1 Risk Evaluation (Ref. 4) and that was addressed in the final rule that was issued in March 2024 (89 FR 21970, March 28, 2024; FRL–8332–01–OCSPF).

Like the prioritization and risk evaluation processes, there is an opportunity for public comment on any proposed risk management actions.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. **Federal Register**. 84 FR 71924, December 30, 2019 (FRL–10003–15).
2. EPA. Asbestos (Part 1: Chrysotile Asbestos); Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability. **Federal Register**. 86 FR 89, January 4, 2021 (FRL–10017–43).
3. EPA. Asbestos Part 2 Supplemental Evaluation Including Legacy Uses and Associated Disposals; Draft Risk Evaluation Under the Toxic Substances Control Act; Notice of Availability, Webinar and Request for Comment. **Federal Register**. 89 FR 26878, April 16, 2023 (FRL–9347–06–OCSPF).
4. EPA. Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos. December 2020. Office of Chemical Safety and Pollution Prevention. Washington, DC. December 2020. (EPA Document ID No. EPA–HQ–OPPT–2021–0057–0007). <https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0057-0007>.
5. EPA. Letter Peer Review; White Paper: Quantitative Human Health Approach To Be Applied in the Risk Evaluation for Asbestos Part 2; Notice of Availability and Request for Comment. **Federal Register**. 88 FR 51309, August 3, 2023 (FRL–10017–43).
6. EPA. Nontechnical Summary of the TSCA Risk Evaluation for Asbestos (Part 2) November 2024. (EPA Document ID No. EPA–740–S–24–006).
7. EPA. Asbestos Part 1; Chrysotile Asbestos; Regulation of Certain Conditions of Use Under the Toxic Substances Control Act (TSCA). **Federal Register**. 89 FR 21970, March 28, 2024 (FRL–8332–01–OCSPF).
8. EPA. Draft Comment Summary and Responses for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos; Regulation Under the Toxic Substances Control Act. November 2024.
9. EPA. Draft Comment Summary and Responses for Letter Peer Review of White Paper: Quantitative Human Health Approach To Be Applied in the Risk Evaluation for Asbestos Part 2. November 2024.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: November 26, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2024–0425; FRL–12241–02–OCSPF]

1,3-Butadiene; Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Science Advisory Committee on Chemicals (SACC) Peer Review; 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 the availability of and soliciting public comment on the draft risk evaluation for 1,3-butadiene. The draft risk evaluation was prepared under the Toxic Substances Control Act (TSCA) and will be submitted to the Science Advisory Committee on Chemicals (SACC) for peer review. EPA is also announcing that there will be two virtual public meetings of the SACC: On February 4, 2025, a preparatory meeting for the SACC to consider the scope and clarity of the draft charge questions for the peer review; and on February 25 through 28, 2025, the peer review meeting for the SACC to consider the draft documents and public comments.

DATES:

Preparatory Public Meeting:

Meeting date: February 4, 2025, 1:00 p.m. to approximately 4:00 p.m. (ET).

Registration: To request time to present oral comments during the

preparatory meeting, you must register by noon (12:00 p.m. ET) on January 31, 2025. For those not making oral comments, registration will remain open through the end of this meeting on February 4, 2025.

Comments: Submit written comments on the scope and clarity of the charge questions, by noon (12:00 p.m. ET) on January 28, 2025. (Submit a written version of your oral comments by noon (12:00 p.m. ET) on January 31, 2025.)

SACC Peer Review Public Meeting:
Meeting dates: February 25 through 28, 2025, 10:00 a.m. to approximately 5:00 p.m. (ET).

Registration: To request time to present oral comments during the peer review meeting, you must register by noon, February 18, 2025. For those not making oral comments, registration will remain open through the end of this meeting on February 28, 2025.

Comments: Submit written comments on the draft documents, and written version of your oral comments, on or before February 3, 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–2024–0425, 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/>.

Meeting Registration: Online registration will be available beginning in January 2025. Please refer to the SACC website at <https://www.epa.gov/tsc-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): Alie Muneer, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564–

6369 or call the main office number: (202) 564-8450; email address: muneer.alie@epa.gov.

Technical information: Brooke Porter, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-6388; email address: porter.brooke@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing the availability of and soliciting public comment on the draft risk evaluation for 1,3-butadiene. The draft risk evaluation was prepared under the Toxic Substances Control Act (TSCA) and will be submitted to the Science Advisory Committee on Chemicals (SACC) for peer review. EPA is also announcing that there will be two virtual public meetings of the SACC: On February 4, 2025, a preparatory meeting for the SACC to consider the scope and clarity of the draft charge questions for the peer review; and on February 25 through 28, 2025, the peer review meeting for the SACC to consider the draft risk evaluation and public comments.

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 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 in the assessment of risks involving chemical substances and mixtures regulated under TSCA (including members of at-risk communities, non-governmental organizations (NGOs), federal, state, and local officials). Since

other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested.

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/USAEPAOPPPT/subscriber/new?topic_id=USAEPAOPPPT_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., synthetic 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 prioritized chemical substances and allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical substance (or category of chemical substances) using the procedures established in 40 CFR 702.37. TSCA also 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 unreasonable 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 ensure 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 TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

C. Why is EPA evaluating this chemical substance?

In 2020, EPA issued final scope documents for the 20 chemical substances designated in December 2019 as High-Priority Substances for the TSCA risk evaluation process, which included 1,3-butadiene. The final scope documents outline the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expected to consider in its risk evaluation for the substances (85 FR 55283, September 4, 2020 (FRL-10013-90)).

1,3-Butadiene (CASRN 106-99-0) is a volatile, colorless gas with a total U.S. production volume between 1 and 5 billion pounds. It is produced in petrochemical processing and extracted and further processed as a building block for several polymers and elastomers that do not readily depolymerize. Air is expected to be the major pathway of exposure for 1,3-butadiene in the environment. Although 1,3-butadiene is moderately soluble in water, monitoring data indicate that it is not detected in water. Environmental release data show that more than 98 percent of 1,3-butadiene facility releases are to air. Once in air, 1,3-butadiene will not deposit to land or adsorb to organic matter due to its chemical properties. Long-range transport in air is not expected, in part, because 1,3-butadiene has a short half-life (<8 hours) and will degrade into formaldehyde and acrolein.

Reduced fetal body weight and hematological effects are indicated as the most sensitive and robust non-cancer human health hazards. EPA has classified 1,3-butadiene as a human carcinogen and epidemiology studies have demonstrated an association between 1,3-butadiene exposure and

increased incidence of leukemia in workers.

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

EPA is submitting the draft risk evaluation of 1,3-butadiene and associated supporting documents to the SACC for peer review, along with the public comments received. The draft risk evaluation includes analyses of physical chemical properties, the fate and transport in the environment, releases to the environment, exposure to workers and the general population, including potentially exposed susceptible subpopulations, environmental risk characterization, and human health hazard and risk characterization for workers and the general population.

EPA is focusing its peer review charge on specific scientific areas and analyses. Many of the methods and analyses used in these evaluations are not novel and have been reviewed in the development of previous TSCA assessments. EPA is requesting feedback on approaches, results and calculations associated with the exposure, human health hazard, and environmental hazard analyses. EPA is releasing the draft risk evaluation for public comment and independent, expert peer review. Once EPA receives comment and input from public comment and peer review, revisions will be made, and the Agency will finalize the 1,3-butadiene risk evaluation.

EPA is requesting a focused panel discussion and feedback on novel approaches, unique exposure analyses and other calculations, and selection of key hazard endpoints for 1,3-butadiene:

- No exposure to aquatic and terrestrial species is expected due to the physical and chemical properties of 1,3-butadiene, which is primarily released to air and does not partition, deposit, or persist in or on water or soil. Monitoring data indicate that 1,3-butadiene is not detected in water. Exposure of terrestrial organisms via ambient air will be brief due to the reactive nature of 1,3-butadiene. EPA is seeking comment on the preliminary determination that quantitative risk assessment for ecological taxa is not needed for 1,3-butadiene.

- Reduced fetal body weight (the basis of the acute Reference Concentration (RfC) in the 2002 IRIS Assessment) is observed in both mice and rats following gestational exposure but is not expected to result from a single dose of 1,3-butadiene. Further, EPA did not identify effects of teratogenicity or any other relevant endpoint following single exposures at

doses relevant to human exposure scenarios. Therefore, EPA did not derive an acute point of departure (POD) or quantify risks from acute exposures. EPA is seeking comment on the preliminary determination that there is no appropriate POD to support acute risk estimates.

- Ovarian atrophy is an adverse effect observed only in mice and can be attributed to a specific 1,3-butadiene metabolite (diepoxybutane) that is less prevalent in rats and humans. EPA has evaluated the relevance of ovarian atrophy for assessing human risk and determined that the ovarian atrophy endpoint is not appropriate for extrapolating to human risk due to differences in species-specific metabolites. EPA is proposing to use decreased fetal body weight as the basis for the intermediate and chronic points of departure for 1,3-butadiene. EPA is seeking comment on these preliminary conclusions to establish intermediate and chronic points of departure based on reduced fetal body weight.

- OPPT revised the inhalation unit risk (IUR) for 1,3-butadiene presented in the IRIS 2002 assessment to incorporate updated epidemiological cohort data. EPA is seeking comment on the mathematical approach and new epidemiological cohort data used in the revised IUR. OPPT also derived bladder cancer risk estimates using the same epidemiological cohort and is seeking comment on the appropriate IUR for evaluating cancer risk.

- EPA has conducted a mutagenic mode of action analysis and evaluating whether the use of an age-dependent adjustment factor (ADAF) for leukemia is appropriate. EPA has preliminarily concluded that a mutagenic mode of action is applicable to 1,3-butadiene and use of an age-dependent adjustment factor (ADAF) for leukemia is appropriate. EPA is seeking comment on this analysis and preliminary conclusion.

- The majority of occupational exposure sampling data points, collected from OSHA, NIOSH, and ACC's report, were not quantifiable values but were identified as being below the limit of detection (LOD). For datasets including exposure data that were reported as below the LOD, EPA estimated exposure concentrations, following EPA's *Guidelines for Statistical Analysis of Occupational Exposure Data*. Based on these guidelines, EPA used the LOD value as the high-end estimate and half the LOD as central tendency. EPA is seeking comment on this approach and the relevance of this dataset for risk characterization.

- General population exposure to 1,3-butadiene was modeled using the Human Exposure Model (HEM) to estimate ambient air concentrations based on releases reported to the Toxic Release Inventory (TRI) for years 2016 to 2021. Exposure concentrations were modeled at discrete distances from releasing facilities and surrounding census blocks. EPA is seeking comment on this analysis and preliminary conclusions.

III. Public Meeting of the SACC

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

EPA is planning two virtual public meetings: (1) A preparatory public meeting for the SACC to consider and ask questions regarding the scope and clarity of the draft charge questions; and (2) a public peer review meeting for the SACC to consider and peer review the draft risk evaluation. These public meetings are part of the SACC's peer review of the Agency's methods and novel analyses for the draft risk evaluation of 1,3-butadiene. 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 evaluation and may inform other EPA efforts related to the assessment and regulation of the chemical substance. 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 beginning 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 evaluation for 1,3-butadiene 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

materials (e.g., SACC members and consultants participating in this meeting and the meeting agenda) in the docket and through links on the SACC website at <https://www.epa.gov/tsca-peer-review>.

D. How can I provide comments?

To ensure proper receipt of comments, it is imperative that you identify docket ID No. EPA-HQ-OPPT-2024-0425 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 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.

E. What happens after the SACC meeting(s)?

After the SACC 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. EPA will consider the SACC recommendations and public comments to complete the risk evaluation and unreasonable risk determination under TSCA for this chemical substance. 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: November 26, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024-28286 Filed 12-2-24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2024-0551; FRL-12418-01-OCSPPT]

Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Di(2-ethylhexyl) Phthalate (DEHP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP); Technical Support Documents; Science Advisory Committee on Chemicals (SACC) Peer Review; Request for Nominations of Ad Hoc Reviewers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) 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 technical support documents for benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), di(2-ethylhexyl) phthalate (DEHP), diisobutyl phthalate (DIBP), and dicyclohexyl phthalate (DCHP) and the cross-phthalate technical support documents for human health benchmark dose (BMD) analysis, cancer analysis, and cumulative risk analysis. 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. EPA is planning to convene a virtual public meeting of the SACC in the spring of 2025 to review the technical support documents.

DATES: Submit your nominations on or before January 2, 2025.

ADDRESSES: Submit your nominations to SACC@epa.gov.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Official (DFO) for the SACC is 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. 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 technical support documents for the evaluation of the risks from BBP, DBP, DEHP, DIBP and DCHP to inform risk management decisions under TSCA. EPA is planning to hold a virtual public meeting in the spring of 2025 for the SACC to consider and review technical support documents. At that time, EPA will solicit comments from the SACC on the critical inputs and novel approaches for a variety of charge questions related to individual, draft chemical risk evaluations and the draft cumulative risk analysis.

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.

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

TSCA section 6(b) requires that EPA conduct risk evaluations on existing chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations (15 U.S.C. 2605(b)). The risk evaluation must not consider costs or other non-risk factors (15 U.S.C. 2605(b)(4)(F)(iii)). The specific risk evaluation process is addressed in 40 CFR part 702 and summarized on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

The SACC was established by EPA 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. This action may, however, be of particular 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. Members of at-risk communities, non-