



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0235; FRL-9997-25]

### **1-Bromopropane (1-BP); Draft Toxic Substances Control Act (TSCA) Risk Evaluation and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Notice of Availability and Public Meetings**

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

**ACTION:** Notice.

**SUMMARY:** EPA is announcing the availability of documents and dates for the peer review of the draft risk evaluation for 1-Bromopropane (1-BP). The purpose of the risk evaluations under the Toxic Substances Control Act (TSCA) is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. EPA is also submitting these same documents to the TSCA Science Advisory Committee on Chemicals (SACC) for peer review and is announcing that there will be a 3-day in-person meeting of the TSCA SACC to consider and review these draft risk evaluations. Preceding the in-person meeting, there will be a 3-hour preparatory virtual meeting for the panel to consider the scope and clarity of the draft charge questions for the peer reviews.

**DATES:** *Comments:* Comments on the draft risk evaluation must be received on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

Please submit comments on the draft risk evaluation by August 30, 2019 to allow the SACC time to review and consider them before the peer review meeting. Comments received after August 30, 2019 will still be provided to the SACC for their consideration. For additional instructions,

see Unit II.A. and Unit II.B. of the **SUPPLEMENTARY INFORMATION**.

*Meetings:* The preparatory virtual meeting will be held on August 21, 2019, from 1 p.m. to approximately 4 p.m. (EDT). The 3-day in-person meeting will be held on September 10-12, 2019 from 9:00 a.m. to approximately 5:30 p.m. (EDT).

**ADDRESSES:** *Virtual Meeting:* The preparatory virtual meeting will be conducted via webcast and telephone. Registration is open to the public and is required to participate during the preparatory virtual meeting. Please visit <https://www.epa.gov/tsca-peer-review> website for additional information including how to register.

*In-Person Meeting:* The location of the in-person meeting will be announced on the TSCA SACC website at <http://www.epa.gov/TSCA-Peer-Review>. The in-person meeting may also be webcast. Please refer to the TSCA SACC website at <https://www.epa.gov/tsca-peer-review> for information on how to access the webcast. Please note that for the in-person meeting, the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the in-person meeting will continue as planned.

*Comments.* Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0235, by one of the following methods:

- *Federal eRulemaking Portal:* <http://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.

- *Mail:* OPPT Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed

information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

*Requests to present oral comments and requests for special accommodations.* Submit requests for special accommodations, or requests to present oral comments (*in-person or over the telephone*) during the webcast and/or the public portion of the peer review meeting to the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT** by the deadline identified in the **DATES** section. Comments received after the date set in the **DATES** section and prior to the end of the oral public comment period during the meeting for each chemical will still be provided to the SACC for their consideration.

**FOR FURTHER INFORMATION CONTACT:** *TSCA SACC meetings:* Tamue Gibson, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7642; email address: [gibson.tamue@epa.gov](mailto:gibson.tamue@epa.gov).

*Risk Evaluations:* Dr. Stan Barone, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-1169; email address: [barone.stan@epa.gov](mailto:barone.stan@epa.gov).

*Special accommodations for the SACC meeting:* For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

*A. Does this action apply to me?*

This action is directed to the public in general. This action may be of interest to persons who are or may be required to conduct testing and risk evaluations of chemical substances under the TSCA, 15 U.S.C. 2601 *et seq.* Since other entities may also be interested in these risk evaluations, the EPA has not attempted to describe all the specific entities that may be affected by this action.

*B. What action is the EPA taking?*

EPA is announcing the availability of and seeking public comment on the draft risk evaluation for 1-Bromopropane (1-BP). EPA is seeking public comment on all aspects of the draft risk evaluation, including any conclusions, findings, and determinations, and the submission of any additional information that might be relevant to the science underlying the risk evaluation and the outcome of the systematic review associated with the chemical. This 60-day comment period on the draft risk evaluations satisfies TSCA section 6(b)(4)(H), which requires EPA to “provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation” and 40 CFR 702.49(a), which states that “EPA will publish a draft risk evaluation in the *Federal Register*, open a docket to facilitate receipt of public comment, and provide no less than a 60-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.” In addition to any new comments on the draft risk evaluation, the public should resubmit or clearly identify any previously filed comments, modified as appropriate, that are relevant to the draft risk evaluation and that the submitter feels have not been addressed. EPA does not intend to respond to comments submitted prior to the release of the draft risk evaluation unless they are clearly identified in comments on the draft risk evaluation.

EPA is also submitting these same documents to the TSCA SACC for peer review and announcing the meetings for the peer review panel. All comments submitted to the dockets for consideration by the TSCA SACC by the deadline identified in the **DATES** section will be provided to the TSCA SACC peer review panel, which will have the opportunity to consider the comments during its discussions.

*C. What is the EPA's authority for taking this action?*

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.” 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an EPA risk evaluation, and the timelines for public comment and completion of the risk evaluation. The law also requires that EPA operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must

also: (1) integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure. 15 U.S.C. 2605(b)(4)(F)(i)-(ii) and (iv)-(v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

The statute requires that the risk evaluation process last no longer than three years, with a possible additional six-month extension. 15 U.S.C. 2605(b)(4)(G). The statute also requires that the EPA allow for no less than a 30-day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

## **II. TSCA SACC Meetings**

The focus of the public meeting is to peer review EPA's draft risk evaluation of 1-BP. After the peer review process, EPA will consider peer reviewer comments and recommendations and public comments, in finalizing the risk evaluation. The draft risk evaluation contains: discussion of chemistry and physical-chemical properties; characterization of conditions of use; environmental fate and transport assessment; human health exposures; environmental hazard assessment; risk characterization; risk determination; and a detailed description of the systematic review process developed by the Office of Pollution Prevention and Toxics to search, screen, and evaluate scientific literature for use in the risk evaluation process.

*A. How may I participate in the in-person meeting?*

You may participate in the in person meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify the corresponding docket ID number for 1-BP (EPA-HQ-OPPT-2019-0235) in the subject line on the first page of your request.

1. *Written comments.* To provide TSCA SACC the time necessary to consider and review your comments, written comments must be submitted by the date set in the **DATES** section and using the instructions in the **ADDRESSES** section and Unit II.C. Comments received after the date set in the **DATES** section and prior to the end of the oral public comment period during the meeting for each chemical will still be provided to the SACC for their consideration.

2. *Oral comments.* In order to be included on the meeting agenda, submit your request to make brief oral comments to the TSCA SACC during the in-person meeting to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before the date outlined in the **DATES** section. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. Oral comments before TSCA SACC during the in-person meeting are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of his or her comments and presentation for distribution by the DFO to the TSCA SACC at the meeting.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

*B. How may I participate in the preparatory virtual meeting?*

Registration for the August 21, 2019, preparatory virtual meeting is required. To participate by listening or making a comment during this meeting, please visit:

<https://www.epa.gov/tsca-peer-review> website to register. Registration online will be confirmed

by email that will include the webcast meeting link and audio teleconference information.

1. *Written comments.* Written comments for consideration during the preparatory virtual meeting should be submitted, using the instructions in **ADDRESSES** and Unit II.C., on or before August 20, 2019.

2. *Oral comments.* Requests to make brief oral comments to the TSCA SACC during the preparatory virtual meeting should be submitted when registering online or with the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before noon on August 20, 2019. Oral comments before TSCA SACC during the preparatory webcast are limited to approximately 5 minutes due to the time constraints of this webcast.

3. *Webcast.* The preparatory virtual meeting will be webcast only and will be open to the public. Please refer to the TSCA SACC website at <http://www.epa.gov/tsc-peer-review> for information on how to access the webcast. Registration is required.

*C. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit CBI to EPA through [regulations.gov](http://www.regulations.gov) or email. If your comments contain 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 your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

### **III. Background**

*A. What is EPA's risk evaluation process for existing chemicals under TSCA?*

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As this chemical is part of the first

ten chemical substances undergoing risk evaluation, the chemical substance was not required to go through prioritization (81 FR 91927, December 19, 2016) (FRL-9956-47). The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out 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>. As explained in the preamble to EPA's final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL-9964-38), the specific regulatory process set out in 40 CFR part 702, subpart B will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

#### *B. What is 1-Bromopropane?*

1-Bromopropane (1-BP) is primarily used as a solvent cleaner in vapor and immersion degreasing operations to clean optics, electronics and metals, and it has also been reported to be used as a solvent vehicle in industries using spray adhesives such as those used in foam cushion manufacturing. Information from the 2016 Chemical Data Reporting (CDR) for 1-BP indicates the reported production volume is 25.9 million lbs/year (manufacture and import).

Information about the problem formulation and scope phases of the risk evaluation for this chemical is available at <https://www.epa.gov/assessing-and-managing-chemicals-under->

*tscs/risk-evaluation-1-bromopropane-1-bp.*

*C. What is the purpose of the TSCA SACC?*

The TSCA SACC was established by EPA in 2016 and operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix 2 *et seq.* The SACC supports activities under TSCA, the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.*, and other applicable statutes. The TSCA SACC provides expert 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 TSCA SACC is comprised of experts in: toxicology; human health and environmental risk assessment; exposure assessment; and related sciences (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, PBPK modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). The TSCA SACC currently consists of 24 members. When needed, the committee will be assisted in their reviews by ad hoc participants with specific expertise in the topics under consideration.

*D. TSCA SACC Documents and Meeting Minutes*

EPA's background paper, related supporting materials, and draft charge questions to TSCA SACC are available on the TSCA SACC website and in the docket established for the specific chemical. In addition, the EPA will provide additional background documents (e.g., TSCA SACC members participating in this meeting and the meeting agenda) as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available, at <http://www.regulations.gov> and the TSCA SACC

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

TSCA SACC will prepare meeting minutes summarizing its recommendations to the EPA. The meeting minutes will be posted on the TSCA SACC website and in the relevant docket.

**Authority:** 15 U.S.C. 2601 *et seq.*; 5 U.S.C. Appendix 2 *et seq.*

Dated: August 5, 2019.

**Andrew R. Wheeler,**

*Administrator.*

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