



**[EPA-HQ-OPPT-2023-0265; FRL-11109-02-OCSPP]**

**Tris(2-chloroethyl) Phosphate (TCEP); Draft Risk Evaluation under the Toxic Substances Control Act (TSCA); Letter Peer Review; Notice of Availability, Public Meeting and Request for Comment**

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on the document titled: “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)” and related draft charge questions. EPA will be submitting the Draft Risk Evaluation and public comments to peer reviewers who will consider the approach and methodologies utilized. The letter peer review will include review of the analysis of physical-chemical properties, the fate of TCEP in the environment, releases of TCEP 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. The letter peer review is expected to begin on March 13, 2024, and end on April 12, 2024. A preparatory virtual public meeting will be held on March 5, 2024, for reviewers and the public to comment on and ask questions regarding the scope and clarity of the draft charge questions. Feedback from the letter peer review will be considered in the development of the final TCEP risk evaluation.

**DATES:** *Virtual Public Meeting:* March 5, 2024, 1 – 4 p.m. EST. To receive the webcast meeting link and audio teleconference information before the meeting, you must register by 5 p.m. EST on March 1, 2024.

*Special Accommodations:* To allow EPA time to process your request for special accommodations, please submit the request by February 23, 2024.

*Written Comments:* Comments must be received on or before **[INSERT DATE 60 DAYS**

**AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

**ADDRESSES:** Submit written comments identified by docket identification (ID) number EPA-HQ-OPPT-2023-0265, 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>.

**FOR FURTHER INFORMATION CONTACT:** The Peer Review Leader (PRL), Alaa Kamel, PhD, Mission Support Division, Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-5336 or call the main office number: (202) 564-8450; email address: [kamel.alaa@epa.gov](mailto:kamel.alaa@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 document titled: “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)”. A letter peer review is expected to begin on March 13, 2024, and end on April 12, 2024, to review the approach and methodologies utilized in this document. A preparatory virtual public meeting will be held on March 5, 2024, for reviewers and the public to comment on and ask questions regarding the scope and clarity of the draft charge questions.

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

Section 6(b) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2605(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. 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 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>.

*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 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 comments to EPA?*

1. *Submitting Confidential Business Information (CBI)*. Do not submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. If you'd like to include information in your comment that you consider to be CBI or otherwise protected, please contact the PRL 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 Tips for Effective Comments at <https://www.epa.gov/dockets>.

## **II. Request for Comment**

EPA is seeking public comment on both the draft risk evaluation and the draft charge questions for the letter peer review. Both documents are available in EPA Docket ID No. EPA-HQ-OPPT-2023-0265 at <https://www.regulations.gov> and may also be accessed through EPA's website at <https://www.epa.gov/tsca-peer-review>. As additional background materials become available, EPA will include those additional background documents (e.g., reviewers participating in this letter peer review) in the docket and on the website.

## **III. Preparatory Meeting**

EPA will publish instructions on how to register for the virtual public meeting that will be held on March 5, 2024, from 1-4 p.m. EST. After registering, you will receive the webcast

meeting link and audio teleconference information for this public meeting. You may register and participate as a listen-only attendee at any time up to the end of the meeting on March 5, 2024. Requests to make brief (up to five minutes) oral comments during the preparatory meeting can be submitted when registering and will be accepted until Friday, March 1, 2024.

#### **IV. Letter Peer Review**

##### *A. What is the purpose of this Letter Peer Review?*

The focus of this Letter Peer Review is on the approach and methodologies utilized in the “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP).” Feedback from this review will be considered in the development of the final TCEP risk evaluation.

##### *B. Why did EPA develop these documents?*

TCEP is a High-Priority substance undergoing the TSCA risk evaluation process. TCEP has been primarily used in paint and coating manufacturing, and in polymers used in aerospace equipment and products. In the past it has also been used in commercial and consumer products, including fabric and textile products, foam seating, and construction materials. TCEP may also be imported in articles intended for consumer use.

In August 2020, EPA published a final scope document for 20 High-Priority substances, including TCEP, outlining the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expects to consider in its risk evaluation.

EPA is submitting the “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)” and associated supporting documents for Letter Peer Review. The Letter Peer Review will include review of the analysis of physical chemical properties, the fate of TCEP in the environment, releases of TCEP 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. Specifically, EPA is seeking comment on the following issues:

- The list of considerations EPA used to arrive at the human health hazard confidence

levels and the specific confidence levels chosen for individual human health hazard outcomes (neurotoxicity, reproductive/developmental effects, kidney effects, and cancer) in the TCEP risk evaluation.

- Whether the approach used to estimate anaerobic degradation in the absence of data is appropriate for assessing anaerobic degradation in sediment.

- Use of the model, Web-based Interspecies Correlation Estimation (Web-ICE), to predict acute toxicity hazard values for aquatic species not represented in the available studies.

This is the first time EPA has used Web-ICE in a TSCA risk evaluation. These predictions were used with available empirical data to create a Species Sensitivity Distribution (SSD). The SSD was used to calculate a hazardous concentration for 5% of species ( $HC_{05}$ ). EPA is also using a data-driven way of accounting for uncertainty for environmental hazard and is soliciting comment on its characterization of this uncertainty, specifically its use of the lower bound of the 95% confidence interval of the hazardous  $HC_{05}$ .

- Human health hazard benchmark dose modeling of animal toxicity data for TCEP.

- The list of considerations EPA used to arrive at the human health hazard confidence levels and the specific confidence levels chosen for individual human health hazard outcomes (neurotoxicity, reproductive/developmental effects, kidney effects, and cancer) to quantitatively evaluate risk from TCEP.

- Use of several approaches for estimating exposures to humans and environmental receptors: (1) The use of Verner 2008 Multi-compartment model, which was used to assess TCEP exposure to infants through human milk for the first time in a TSCA risk evaluation; (2) the use of Verner 2008 Multi-compartment model and associated uncertainties in extrapolating from the inhalation to oral routes of exposure; (3) the use of the American Meteorological Society/Environmental Protection Agency Regulatory Model (AERMOD) to estimate air deposition of TCEP. EPA has used AERMOD in previous TSCA risk evaluations; however, its use in estimating air deposition is novel for TSCA risk evaluations.

- Approach for modeling drinking water contamination from wells near municipal solid waste landfills, which is a new approach for TSCA risk evaluations.

*C. How can I access the documents submitted for review?*

The “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)” and all background documents, related supporting materials, and draft charge questions are available at <https://www.regulations.gov> in Docket ID No. EPA-HQ-OPPT-2023-0265 and through the TSCA Scientific Peer Review Committees website at <https://www.epa.gov/tsca-peer-review>. In addition, as additional background materials become available (*e.g.*, reviewers participating in the letter peer review), EPA will include those additional background documents in the docket and through the website.

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

Dated: December 12, 2023.

**Michal Freedhoff,**

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

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