



**[EPA-HQ-OPPT-2024-0114; FRL-11809-01-OCSPP]**

**1,1-Dichloroethane (1,1-DCA); Draft Risk Evaluation under the Toxic Substances Control Act (TSCA); Letter Peer Review; Request for Nominations of Expert Reviewers**

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or the Agency) is seeking nominations of scientific and technical experts to review the draft risk evaluation for 1,1-dichloroethane (1,1-DCA) conducted under the Toxic Substances Control Act (TSCA). The Agency will release the draft risk evaluation for public review and comment in spring of 2024 through a separate *Federal Register* document and subsequently will provide the selected peer reviewers with the draft risk evaluation for letter peer review in the summer of 2024.

**DATES:** Submit your nominations on or before **[INSERT DATE 21 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit your nomination via email to [OCSPP-PeerReview@epa.gov](mailto:OCSPP-PeerReview@epa.gov). Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose public disclosure is restricted by statute. If your nomination may contain any such information, please contact the Peer Review Leader to obtain special instructions before submitting that information.

**FOR FURTHER INFORMATION CONTACT:** The Peer Review Leader is 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 at (202) 564-8450; email address: [muneer.alie@epa.gov](mailto:muneer.alie@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 the EPA can consider for service as experts for the letter peer review of the draft risk evaluation for 1,1-DCA. EPA will be soliciting comments from the experts on the approach and methodologies utilized in the draft risk evaluation. This document provides instructions for submitting such nominations for EPA to consider for the planned letter peer review. EPA will publish a separate document in the *Federal Register* in spring 2024 to announce the availability of the draft risk evaluation and solicit public comments. Comments received and the draft risk evaluation materials will be provided to the letter peer reviewers in the summer of 2024

*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>.

*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 and mixtures 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.

## **II. Nominations of Peer Reviewers**

*A. Why is EPA seeking nominations for peer reviewers?*

EPA is requesting nominations from the public and stakeholder communities for scientific and technical experts who can serve as prospective candidates for letter peer reviews. This is part of a broader process for developing a pool of candidates. Interested persons or

organizations can nominate qualified individuals by following the instructions provided in this document. Individuals are also welcome to self-nominate.

Those who are selected from the pool of prospective candidates will be asked to review the draft risk evaluation for 1,1-DCA and provide their individual comments to EPA.

*B. What expertise is sought for this letter peer review?*

Individuals nominated for this letter peer review should have expertise in one or more of the following areas:

1. Environmental hazard assessment expertise, specifically with experience in analog selection, predictive modeling, and uncertainty analysis.

2. Human health toxicology with expertise in cancer modes of action, reproductive toxicity and derivation of points of departure (PODs) and dose-response values using limited toxicity datasets.

3. Human health toxicology with expertise in the use of read across methodology, the identification of analog, and the application of read across software, such as OECD QSAR Toolbox, GenRA and CompTox.

4. Human exposure assessment experience, especially for industrial hygiene and occupational inhalation exposures, susceptible life stages and subpopulations to environmental contaminants.

5. Expertise in using EPA databases for contaminant concentration estimates in ambient air and/or surface water and sediments.

Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this review.

*C. How do I make a nomination?*

By the deadline indicated under **DATES**, submit your nomination via email to the email identified in **ADDRESSES**. Each nomination should include the following: Contact information

for the person or entity making the nomination; name, affiliation, and contact information for the nominee; and the disciplinary and specific areas of expertise of the nominee.

*D. Will peer reviewers be subjected to an ethics review?*

Peer reviewers are subject to the provisions of the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, conflict of interest statutes in Title 18 of the United States Code and related regulations. In anticipation of this requirement, prospective candidates will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service.

*E. How will EPA select the peer reviewers?*

The selection of scientists to serve as peer reviewers is based on the expertise needed to address the Agency's charge to the peer reviewers. No interested scientists shall be ineligible to serve by reason of their membership on any advisory committee to a federal department or agency or their employment by a federal department or agency, except EPA. Other factors considered during the selection process include availability of the prospective candidate to fully participate in the letter peer review, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in non-selection, the absence of such concerns does not assure that a candidate will be selected to serve as a peer reviewer.

Numerous qualified candidates are often identified for letter peer reviews. Therefore, selection decisions involve carefully weighing a number of factors including the candidates'

areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives across peer reviewers. The Agency will consider all nominations of prospective candidates for service as peer reviewers that are received on or before the date listed in the **DATES** section of this document. However, the final selection of peer reviewers is a discretionary function of the Agency. At this time, EPA anticipates selecting approximately 10–12 peer reviewers for this letter peer review.

EPA plans to make a list of candidates under consideration as prospective peer reviewers for this letter peer review available for public comment by summer of 2024. The list will be available in the docket at <https://www.regulations.gov> (docket ID number EPA–HQ–OPPT–2024–0114).

### **III. Letter Peer Review**

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

The focus of this letter peer review is to review the approach and methodologies utilized in the draft risk evaluation for 1,1-DCA. Feedback from this review will be considered in the development of the final 1,1-DCA risk evaluation.

EPA intends to announce in spring 2024 in the Federal Register, the availability of and solicit public comment on the draft risk evaluation, at which time EPA will provide instructions for submitting public comments. The draft risk evaluation and public comments will be provided to the letter peer reviewers in the summer of 2024.

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

1,1-DCA was designated in December 2019 as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019 (FRL-10003-15), and is currently in the risk evaluation process. In August 2020, the Agency released the final scope document outlining the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the agency expects to consider in its risk evaluation (85 FR 55281, September 4, 2020 (FRL-10013-90).

1,1-DCA is a volatile, colorless, oily liquid with a chloroform-like odor, which is primarily used in organic chemical manufacturing. 1,1-DCA is manufactured and used primarily in industrial applications, such as a reactant for the manufacture of other chemicals or as a laboratory chemical. The reported total production volume (PV) of 1,1-DCA in 2015 and 2020 was between 100 million and 1 billion pounds. EPA assumes that a high percentage of the PV is used for processing as a reactive intermediate, and a small percentage of the PV is used for commercial use as a laboratory chemical. EPA did not identify any consumer uses of 1,1-DCA.

The major exposure pathway to 1,1-DCA is through releases to air. 1,1-DCA is estimated to have high water solubility and once it is released into water, it remains primarily in the water column. EPA, therefore, also assessed relevant surface water and land exposure pathways. EPA relied on databases reporting multi-year 1,1-DCA releases to ambient air, surface water, and disposal to land, such as the Toxic Release Inventory (TRI), the National Emissions Inventory (NEI) and Discharge Monitoring Reports (DMR), among others, to conduct major portions of its exposure analysis. Due to limited empirical data for human health and portions of the environmental hazard assessments, EPA relied on read-across approaches to supplement 1,1-DCA data to develop hazard values.

EPA plans to submit the draft risk evaluation of 1,1-DCA and associated supporting documents for letter peer review in the summer of 2024. The draft risk evaluation includes analyses of physical-chemical properties; the fate and transport in the environment; exposure to workers, and general population including potentially exposed or 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 and the general population.

EPA is focusing its letter peer review charge on specific scientific areas and analyses and is not developing charge questions for all aspects of the risk evaluation. Many of the methods and analyses used in these evaluations are not novel and have been reviewed in the development

of the tools used in various agency work products or in previous TSCA assessments.

EPA is requesting feedback on novel approaches, unique exposure analyses and other calculations, approaches and results associated with the human health and environmental hazard endpoints. Specifically, EPA is seeking comment on the issues below:

- For human health hazard, EPA has limited empirical toxicity data available for 1,1-DCA. EPA has employed an approach for developing the human health hazard values through the utilization of read across to supplement the 1,1-DCA database using information from the identified analog, 1,2-dichloroethane (1,2-DCA). EPA is seeking review of the approach for developing the human health hazard values including the selection and application of a read across using 1,2-DCA as an analog; on the benchmark response (BMR) for the hazard value chosen for the human health hazard value used for the acute, short-term and chronic exposure durations; and on the weight of scientific evidence and confidence for specific hazard endpoints of central nervous system (CNS) depression/sedation, degeneration/necrosis of olfactory mucosa and decreased sperm concentration.

- For environmental hazard for aquatic and benthic organisms, EPA has limited empirical toxicity data available for 1,1-DCA and has employed an approach for developing the environmental hazard values through read across using a method for analog selection. EPA used 1,2-DCA and 1,1,2-trichloroethane as analogs to read across environmental hazard to 1,1-DCA. EPA is seeking comment on the use of analog data in combination with 1,1-DCA data to estimate risk to aquatic vertebrates and invertebrates, including benthic invertebrates.

- EPA obtained primary inhalation exposure monitoring data for 1,1-DCA for the occupational exposure scenario (OES) of Manufacture through a test order and prioritized the use of occupational inhalation monitoring data for the intended condition of use and other appropriate exposure scenarios (e.g., Processing as a Reactant and Laboratory Use OESs). EPA is seeking comment on the use of inhalation exposure monitoring data for these analogous exposure scenarios.

- EPA used surrogate chlorinated solvent inhalation monitoring data to estimate occupational exposures for the OES where there was a lack of inhalation monitoring data and applied a vapor pressure correction factor to account for vapor pressure differences between the surrogate chemical and 1,1-DCA. EPA is seeking comments on the use of surrogate data to estimate occupational exposures.

- For dermal exposures, EPA lacked specific 1,1-DCA dermal absorption data. Therefore, EPA used the Dermal Exposure to Volatile Liquids Model (DEVL) and applied the model to all OES; however, values for fraction absorbed and weight fraction of the chemical can differ among OES. EPA is seeking comments on the application of DEVL to all OESs and is seeking methods to better differentiate the dermal exposure potential and the resulting risks between OES.

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

EPA is planning to release the draft risk evaluation for 1,1-DCA, all background documents and related supporting materials in the spring of 2024. At that time, EPA will publish a separate document in the *Federal Register* to announce the availability of and solicit public comment on the materials and provide instructions for submitting comments. The materials will be available in the docket and through the TSCA Scientific Peer Review Committees website. In addition, as additional background materials become available (e.g., list of experts participating in this letter peer review), EPA will include the additional materials in the docket and through the website.

Dated: March 14, 2024.

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