



[EPA-HQ-OPPT-2024-0073; FRL-11760-01-OCSPP]

**Di-isodecyl Phthalate (DIDP) and Di-isononyl Phthalate (DINP); Draft Risk Evaluations; Science Advisory Committee on Chemicals (SACC) Peer Review; Request for Nominations of *ad hoc* Expert Reviewers**

**SUMMARY:** The Environmental Protection Agency (EPA) 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 evaluation of the risks from di-isodecyl phthalate (DIDP) and di-isononyl phthalate (DINP) being conducted to inform risk management decisions under the Toxic Substances Control Act (TSCA). 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 summer of 2024 to review the draft risk evaluations.

**DATES:** Submit your nominations on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your nominations to the SACC at [SACC@epa.gov](mailto: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](mailto: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 evaluation of the risks from DIDP and DINP being conducted to inform risk management decisions under TSCA. EPA is planning a virtual public meeting to be held in the summer of 2024 for the SACC to consider and review the draft risk evaluations. At that time, EPA will be soliciting comments from the SACC on the novel approaches used, the unique exposure analyses and other calculations, and selection of key hazard endpoints.

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?*

The SACC was established by EPA in 2016 in accordance with TSCA section 26(o), 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-governmental organizations (NGOs) (particularly those with an interest in protecting health for at-risk communities), and Federal, State and local officials may also be interested. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities

to which this action may apply.

*D. What should I consider as I submit my nominations to EPA?*

Do not submit confidential business information (CBI) or other sensitive information to EPA through email. If your nomination contains 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 that information.

*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/USAEPAPPT/subscriber/new?topic\\_id=USAEPAPPT\\_101](https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_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 comprised 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, environmental engineering and sustainability). The SACC currently consists of 18 members. When needed, the 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 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 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 is EPA evaluating the risks from DIDP and DINP?*

On May 24, 2019, EPA received requests to conduct risk evaluations for DIDP and DINP from ExxonMobil Chemical Company, Evonik Corporation, and Teknor Apex, through the American Chemistry Council's High Phthalates Panel (ACC HPP). In December 2019, EPA notified ACC HPP that the Agency had granted their manufacturer requested risk evaluations.

DIDP is a common chemical name for the category of chemical substances that includes the following substances: 1,2-benzenedicarboxylic acid, 1,2-diisodecyl ester (CASRN 26761-40-0) and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (CASRN 68515-49-1). Both CASRNs contain mainly C10 dialkyl phthalate esters.

DINP is a common chemical name for the category of chemical substances that includes the following substances: 1,2-benzenedicarboxylic acid, 1,2-isononyl ester (CASRN 28553-12-0) and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C9-rich (CASRN 68515-48-0). Both CASRNs contain mainly C9 dialkyl phthalate esters. Both DIDP and DINP are primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer, commercial, and industrial applications.

DIDP and DINP are both structurally phthalates, and therefore many aspects of physical-chemical (p-chem) properties and exposure (to humans and ecological species) are similar. Because of the similar exposure and physical chemical properties of DIDP and DINP, EPA is

developing these individual risk evaluations in parallel, and similarly the SACC peer review of the draft risk evaluations will occur concurrently. Both have extremely low water solubility and will be preferentially sorbed into sediments, soils, and suspended solids in surface water and wastewater. Both are expected to be persistent in anaerobic environments. Therefore, ecological risk will be assessed primarily considering exposure via sediment and soil pathways. Under indoor settings, DIDP and DINP are expected to partition to airborne particles and are expected to have extended lifetime compared to outdoor settings.

For both DIDP and DINP, liver and developmental toxicity are indicated as the most sensitive and robust non-cancer hazards. However, these two phthalates differ in several important respects regarding their human health hazard profiles. For DIDP, the developmental toxicity is not characterized by androgen insufficiency, and data are insufficient to determine the carcinogenicity. For DINP, developmental toxicity results in androgen insufficiency (phthalate syndrome), and the effects on the liver include cancer.

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

EPA is planning this SACC peer review of the Agency's risk evaluations for DIDP and DINP. EPA expects to ask the SACC to consider and review the novel approaches, unique exposure analyses and other calculations, and selection of key hazard endpoints for the risk evaluations of DIDP and DINP. Feedback from this review will be considered in the development of the final risk evaluations of the two phthalates under TSCA.

EPA continues to work on risk evaluations of additional high-priority substance phthalates, in addition to the cumulative risk assessment (CRA) for the phthalates. The subsequent five individual risk evaluations and the CRA are not part of this peer review but will be brought to the SACC at a future date.

EPA intends to publish a separate document in the *Federal Register* to announce the availability of and solicit public comment on the draft risk evaluations that are submitted to the SACC for peer review, at which time EPA will provide instructions for submitting written

comments and registering to provide oral comments at the peer review meeting planned for the summer of 2024.

### **III. Nominations for ad hoc Reviewers**

#### *A. Why is EPA seeking nominations for ad hoc reviewers?*

As part of a broader process for developing a pool of candidates for SACC peer reviews, EPA is asking the public and stakeholders for nominations of scientific and technical experts that EPA can consider as prospective candidates for service as *ad hoc* reviewers assisting the SACC with the peer reviews. Any interested person or organization may nominate qualified individuals for consideration as prospective candidates for this review by following the instructions provided in this document. Individuals may also self-nominate.

Those who are selected from the pool of prospective candidates will be invited to attend the public meeting and to participate in the discussion of key issues and assumptions at the meeting. In addition, they will be asked to review and to help finalize the meeting minutes.

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

Individuals nominated for this SACC peer review should have expertise in one or more of the following areas: Risk assessment; ecological risk assessment, including terrestrial hazard/wildlife toxicology for feedback on Toxicity Reference Value (TRV) approach, bioaccumulation and fate/physical chemistry (p-chem) for trophic transfer, and analogue selection; General exposure, particularly, consumer products and indoor air; Ingestion exposure for mouthing/ingestion route and chemical migration to saliva, surface water concentrations, water solubility, and acute aquatic hazard (fate/P-chem and aquatic toxicology), and use of European Union (EU) percentages to assign production volumes for the Conditions of Use (engineering); Human health, including liver toxicity and developmental toxicology for DIDP (toxicology), cancer and peroxisome proliferator-activated receptor alpha (PPARα mode of action), and dose response assessment.

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?*

Submit your nomination as directed under **ADDRESSES** by the deadline indicated under **DATES**. Each nomination should include the following information: Contact information for the person making the nomination; Name, affiliation, and contact information for the nominee; and, The disciplinary and specific areas of expertise of the nominee.

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

SACC members and *ad hoc* 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 for service on the SACC 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 on the SACC.

*E. How will EPA select the ad hoc reviewers?*

The selection of scientists to serve as *ad hoc* reviewers for the SACC is based on the function of the Committee and the expertise needed to address the Agency's charge to the Committee. No interested scientists shall be ineligible to serve by reason of their membership on any other 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 Committee's reviews, ability to be hired as an EPA Special Government Employee (SGE), 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 on the SACC.

Numerous qualified candidates are often identified for SACC reviews. Therefore, selection decisions involve carefully weighing several factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives across reviewers. The Agency will consider all nominations of prospective candidates for service as *ad hoc* reviewers for the SACC that are received by the deadline listed under **DATES**. However, the final selection of *ad hoc* reviewers is a discretionary function of the Agency.

EPA anticipates selecting 8-10 *ad hoc* reviewers to assist the SACC in their review of the designated topic. EPA plans to make a list of candidates under consideration as prospective *ad hoc* reviewers for this review available for public comment in April 2024. The list will be available in the docket at <https://www.regulations.gov> (docket ID No. EPA-HQ-OPPT-2024-0073) and through the SACC website at <https://www.epa.gov/tsca-peer-review>.

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

Dated: February 23, 2024.

**Michal Freedhoff,**

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

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