E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0905; FRL-10798-01-OCSPP]

Science Advisory Committee on Chemicals (SACC); Draft Supplement to the 1,4 Dioxane Risk Evaluation; Request for Nominations of *ad hoc* Expert Reviewers and Notice of Public Meeting

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 "2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation." The draft supplement will be released for public review and comment in June of 2023. EPA is also planning to submit the draft supplement to the SACC for peer review and is scheduling a 4-day virtual public meeting for the SACC to consider and review the draft supplement in September of 2023.

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

ADDRESSES: *Nominations*: Submit your nominations to the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

Special accommodations: For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Contact the DFO, 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 the EPA can consider for service as *ad hoc* reviewers assisting the SACC with the peer review of the "2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation." EPA is also planning a 4-day virtual public meeting for the SACC to consider and review the draft supplement. EPA will be soliciting comments from the SACC on the methodologies utilized in the draft 2023 1,4-dioxane supplemental risk evaluation that have not been previously peer reviewed.

This document provides instructions for submitting nominations for EPA to consider for *ad hoc* reviewers. EPA will publish a separate document in the *Federal Register* in June of 2023 to announce the availability of the draft supplement and solicit public comments. Additional instructions and information regarding the virtual public meeting will be provided at that time.

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

The SACC was established by EPA in 2016 in accordance with the Toxic Substances Control Act (TSCA), 15 U.S.C. 2625(o), to provide independent advice and expert consultation, at the request of the Administrator, 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 the 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 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.

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

Submitting CBI. Do not submit CBI or other sensitive information to EPA through *https://www.regulations.gov* or 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.

II. Nominations for *ad hoc* Reviewers

A. What is the purpose of the SACC?

The SACC provides 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 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 modeling (PBPK), computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). The SACC currently consists of 17 members. When needed, the committee will be assisted by *ad hoc* reviewers with specific expertise in the topics under consideration.

B. 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 stakeholder communities 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.

C. 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: Engineering (experience in environmental exposure release from industrial sources for review of Monte Carlo release assessment methods, risk assessment experience preferred); Industrial Hygiene (experience with evaluating the application of occupational exposure modeling approaches and monitoring data for industrial and commercial operations); Statistics (experience in water quality data for review of novel application of Monte Carlo methods in release assessment and water model); Exposure science and contaminant hydrology (experience in aquatic monitoring and modeling for groundwater and surface water with background in risk assessment); Exposure science with experience in air modeling (for review of air exposure analysis); Petroleum engineering (experience in evaluating sources of environmental releases from hydraulic fracturing operations); Risk assessment (experience in chemicals and environmental fate of chemicals for review of exposure factors, averaging time assumptions, etc. with background in risk 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.

D. How do I make a nomination?

By the deadline indicated under **DATES**, submit your nomination to the DFO listed under **FOR FURTHER INFORMATION CONTACT**. 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.

E. 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.

F. 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, 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 a number of 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 on or before the date listed in the **DATES** section of this document. However, the final selection of *ad hoc* reviewers

is a discretionary function of the Agency. At this time, EPA anticipates selecting 10-15 *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 late May or early June 2023. The list will be available in the docket at *https://www.regulations.gov* (docket ID number EPA-HQ-OPPT-2022-0905) and through the *SACC website*. You may also subscribe to the following listserv for alerts regarding this and other SACC-related activities: *https://public.govdelivery.com/accounts/USAEPAOPPT/subscriber/new?topic_id=USAEPAOPPT_101*.

III. Virtual Public Meeting of the SACC

A. What is the purpose of this public meeting?

The focus of the 4-day virtual public meeting is the SACC peer review of the methodologies that have not been previously peer reviewed and are utilized in the 2023 1,4-dioxane supplemental risk evaluation. Feedback from this review will be considered in the development of the final supplement to the 1,4-dioxane risk evaluation. In addition, SACC reviewer feedback may help refine EPA's methods for conducting release assessments and evaluating general population exposures in risk evaluations of other chemicals under TSCA.

In addition, EPA intends to publish a separate document in the *Federal Register* to announce the availability of and solicit public comment on the draft supplement, at which time EPA will provide instructions for submitting written comments and registering to provide oral comments at the peer review meeting planned for September. EPA also intends to provide a meeting agenda for each day of the meeting, and as needed, may provide updated times for each day in the meeting agenda that will be posted in the docket and on the SACC website.

B. Why did EPA develop these documents?

TSCA requires the U.S. Environmental Protection Agency (EPA or the Agency) 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. 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.

1,4-Dioxane is one of the first 10 chemical substances undergoing the TSCA risk evaluation process after passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA. 1,4-Dioxane is primarily used as a solvent in a variety of commercial and industrial applications such as the manufacture of other chemicals (*e.g.*, adhesives, sealants) or as a processing aid or laboratory chemical. Although there are no direct consumer and commercial uses of 1,4-dioxane, it is also produced as a byproduct in commercial and consumer products from several manufacturing processes, including ethoxylation, sulfonation, sulfation, and esterification.

In the 2019 draft 1,4-dioxane risk evaluation, EPA reviewed the exposures and hazards of 1,4-dioxane direct commercial uses assessing risk from occupational exposures and surface water exposures to environmental organisms. This assessment, which included the physical and chemical properties, lifecycle information, environmental fate and transport information, and hazard identification and dose-response analysis was reviewed by the SACC. The Agency considered the SACC feedback and is not seeking additional review at this time as this information has not changed.

In October of 2020, a supplement to the draft 1,4-dioxane risk evaluation was released for public comment. The October 2020 supplement assessed eight conditions of use (COUs) of 1,4-dioxane as a byproduct in consumer products and general population exposure from incidental

contact with surface water. The Agency determined that the additional analysis did not warrant SACC review.

The 2019 draft and 2020 supplement were both incorporated into the final *Risk Evaluation for 1,4-Dioxane* published December 2020. After publication, EPA determined an additional supplement to the final *Risk Evaluation for 1,4-Dioxane* was needed to consider critical exposure pathways not previously assessed. Specifically, the more recent supplement (2023) includes evaluation of additional conditions of use in which 1,4-dioxane is present as a byproduct in industrial processes and commercial products and evaluates risks from general population exposures to 1,4-dioxane released to ambient surface water and groundwater, ambient air, and land. To evaluate these additional exposure pathways, the Agency used new methods and novel applications of existing methods. These new methods described below have not been the subject of public comment or peer review for applications in TSCA risk evaluations.

In the 2023 supplemental, EPA is relying on the physical and chemical properties, lifecycle information, environmental fate and transport information, and hazard identification and dose-response analysis presented in the final *Risk Evaluation for 1,4-Dioxane*, thus, is not seeking feedback on these topics. However, EPA is seeking review of the methodologies listed below that have not been previously peer reviewed and are utilized in the 2023 1,4-dioxane supplemental risk evaluation.

EPA applied Monte Carlo modeling in the assessment of 1,4-dioxane occupational exposures and environmental releases.

The Agency has utilized Monte Carlo approaches in TSCA risk evaluations previously for specific conditions of use; however, the application of Monte Carlo methods in the draft 2023 1,4-dioxane supplemental risk evaluation was expanded to capture additional exposure and release models for additional conditions of use. The expanded application of these methods incorporates randomness and variability to improve the representativeness of the resulting model outputs. This was done to further improve exposure and release estimates and is in response to

previous SACC review comments received on the first 10 risk evaluations.

EPA assessed hydraulic fracturing as a condition of use.

This evaluation required consideration of new field operations data that have not yet been considered in TSCA risk evaluations to estimate occupational exposures and environmental releases from these operations. EPA has developed a new generic exposure scenario for hydraulic fracturing and applied it in the draft 1,4-dioxane supplemental risk evaluation along with the Monte Carlo modeling to estimate a range of potential releases.

EPA assessed the ambient air pathway to determine exposures and associated risks to fenceline communities (a subset of the general population).

The Agency assessed general population exposures via the inhalation route through both single- and multi-year analyses.

The single-year analysis utilized the Fenceline 1.0 methodology described in the "Draft TSCA screening level approach for assessing ambient air and water exposures to fenceline communities, Version 1.0" (see "Peer Review of the EPA TSCA Screening Level approach for Assessing Ambient Air and Water Exposures to Fenceline Communities March 15-17, 2022," https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0415/document*)* previously reviewed by the SACC. Although that methodology has been peer reviewed, the results from application of the methodology to 1,4-dioxane is first presented in the 2023 supplemental risk evaluation.

In response to SACC recommendations, EPA expanded on the methodology reviewed by the SACC to evaluate multiple years of release data and to consider the combined risks from multiple facilities releasing 1,4-dioxane to a single media (ambient air). The methods used to evaluate combined exposure and risks from multiple facilities releasing 1,4-dioxane have not previously been applied in the context of TSCA risk assessments. The multi-year analysis applies the "pre-screening" methodology described in the SACC-reviewed draft Fenceline report with some modifications to focus the analysis on a single exposure scenario found to represent a higher-end exposure estimate. While the pre-screening methodology has been reviewed by

SACC, neither the modification to the approach nor the results from applying the modified pre-screening methodology have been presented prior to this supplemental risk evaluation.

EPA assessed general population exposures via drinking water sourced from groundwater and surface water.

Although the 2020 1,4-dioxane risk evaluation considered incidental oral and dermal exposures to surface water, the 2020 analysis did not consider drinking water exposures through sourcing of 1,4-dioxane contained in surface water or groundwater.

Surface Water

• 1,4-Dioxane concentrations in surface water reported in the 2023 draft supplemental risk evaluation were modeled based on known facility and publicly owned treatment works releases directly to surface water. This methodology is generally consistent with what was previously done to aquatic exposures and presented in the draft Fenceline 1.0 methodology previously reviewed by the SACC.[1] However, this analysis was modified to include consideration of multiple years of release data, as recommended by SACC, and integrated NHDPlus flow networks and flows to modernize approaches previously utilized in TSCA risk evaluations. This assessment is the first time the modified approach has been employed in a TSCA risk evaluation.

• 1,4-Dioxane concentrations resulting from consumer and commercial down-the-drain releases of 1,4-dioxane through publicly owned treatment works to surface water were estimated. EPA used the Stochastic Human Exposure and Dose Simulation Model (SHEDS) for high-throughput (HT) (SHEDS-HT) model (see Environ. Sci. Technol. 2014, 48, 21, 12750–12759) predictions to estimate down-the-drain disposals (Isaacs, 2014). SHEDS-HT was developed by EPA under the ExpoCast program for evaluating chemicals based on the potential for biologically relevant human exposure. This is the first TSCA risk evaluation incorporating down-the-drain estimates based on SHEDS-HT model predictions and is the first time the down-the-drain model has been used for one of the first 10 chemicals.

• 1,4-Dioxane concentrations in surface water were modeled based on multiple upstream sources, including releases from facilities and publicly owned treatment works and down-the-drain releases. In addition, EPA compared the modeled concentrations to drinking water monitoring data for community water systems. This approach to considering the contribution of multiple sources to drinking water exposures is novel. EPA has not previously considered multiple releases when estimating exposure concentrations in surface water for a TSCA risk evaluation.

Groundwater

• 1,4-Dioxane concentrations in groundwater were modeled for two disposal pathways by applying the Delisting Risk Assessment Software (DRAS) model in a novel way. DRAS is a multi-pathways model developed by the EPA that calculates the potential human health risks associated with disposing a specific facility's given waste stream in a landfill or surface impoundment (see EPA's "Hazardous Waste Delisting Risk Assessment Software Version 4. Lenexa"). DRAS was specifically designed to address the Criteria for Listing Hazardous Waste. The supplemental 1,4-dioxane risk evaluation presents a novel application of this model and first application in a TSCA risk evaluation.

Specifically, EPA compared the modeled concentrations to monitoring data from groundwater contaminations around the nation to consider if they are within a reasonable range. A second model, EPA's Composite Model for Leachate Migration with Transformation Products (EPACMTP), was also utilized in the 1,4-dioxane assessment to characterize the potential impact that different landfill liners might have when accounting for increasing amounts of data in a Monte Carlo analysis. This model has also not been previously used in any TSCA risk evaluations.

• EPA is also seeking review of the overall synthesis of the results of these novel methodologies and the integration of the results into the 1,4-dioxane supplemental risk evaluation. Feedback from this review will be considered in the development of the final

supplement to the 1,4-dioxane risk evaluation. In addition, SACC reviewer feedback may help refine EPA's methods for conducting release assessments and evaluating general population exposures in risk evaluations of other chemicals under TSCA.

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

EPA is planning to release the draft supplement mentioned above and all background documents, related supporting materials, and draft charge questions provided to the SACC in June 2023. At that time, EPA will publish a separate document in the *Federal Register* to announce the availability of and solicit public comment on the draft supplement and provide instructions for submitting written comments and registering to provide oral comments. These materials will also be available in the docket through *https://www.regulations.gov* (docket ID number EPA-HQ-OPPT-2022-0905) and through the SACC website. In addition, as additional background materials become available and are provided to the SACC, EPA will include those additional background documents (*e.g.*, SACC members and consultants participating in this meeting and the meeting agenda) in the docket and on the SACC website.

D. How can I participate in the virtual public meeting?

The public virtual meeting will be held via a webcast platform such as "*Zoomgov.com*" and audio teleconference. You must register online to receive the webcast meeting link and audio teleconference information. Please follow the registration instructions that will be announced on the SACC website in the summer of 2023.

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

Dated: March 20, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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