



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2026-1189; FRL-13266-01-OCSP]

**1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [ $\gamma$ ]-2-benzopyran (HHCB); Phthalic Anhydride; *o*-Dichlorobenzene (*o*-DCB) and *p*-Dichlorobenzene (*p*-DCB); Science Advisory Committee on Chemicals (SACC) Peer Review; Draft Risk Evaluations; Notice of SACC Meeting; Availability of Draft Documents and Request for Comment**

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is announcing that there will be two virtual public meetings of the Science Advisory Committee on Chemicals (SACC). On May 26, 2026, a preparatory meeting will be held for the SACC to consider the scope and clarity of the draft charge questions for the peer review of the draft risk evaluations for 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [ $\gamma$ ]-2-benzopyran (HHCB) and phthalic anhydride and the draft hazard assessments for *o*-dichlorobenzene (*o*-DCB) and *p*-dichlorobenzene (*p*-DCB). The peer review meeting will be held June 8 through 12, 2026, for the SACC to consider the draft risk evaluations for HHCB and phthalic anhydride, the draft hazard assessments for *o*-DCB and *p*-DCB, the technical support documents, and their public comments. EPA is also announcing the availability of and soliciting public comment on the draft documents and charge questions that will be provided to the SACC for this peer review. The draft risk evaluations and draft hazard assessments were prepared under the Toxic Substances Control Act (TSCA) and will be submitted to the SACC for peer review.

**DATES:**

*Preparatory Public Meeting:*

*Meeting date:* May 26, 2026, 1 p.m. to approximately 4 p.m. (ET).

*Registration:* To request time to present oral comments during the preparatory meeting, you must register by noon (12 p.m. ET) on May 18, 2026, and submit a written version of your oral comments by noon (12 p.m. ET) on May 22, 2026. For those not making oral comments, registration will remain open until the end of this meeting on May 26, 2026.

*SACC Peer Review Public Meeting:*

*Meeting dates:* June 8 through 12, 2026, 10 a.m. to approximately 5 p.m. (ET).

*Registration:* To request time to present oral comments during the SACC peer review meeting, you must register by noon (12 p.m. ET) June 1, 2026, and submit a written version of your oral comments by noon (12 p.m. ET) on June 5, 2026. For those not making oral comments, registration will remain open through the end of this meeting on June 12, 2026.

*Comments:* To ensure proper receipt of comments, it is imperative that you identify docket identification (ID): EPA-HQ-OPPT-2025-1610 in the subject line on the first page of your comments and follow the instructions in this document.

Submit written comments on the draft risk evaluations, draft hazard assessments, and technical support documents for consideration by the SACC for peer review on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

To request time to present oral comments during one of the virtual public meetings, you must register online by the deadlines set in this section of the document. Oral comments during the peer review meeting are limited to five minutes unless arrangements have been made with the Designated Federal Official (DFO), within the constraints of the meeting agenda. In addition, each speaker should submit a written transcript or copy of their oral comments and any supporting materials (e.g., presentation slides) to the DFO prior to the meetings for distribution to the SACC by the deadlines set in this section of the document.

*Special Accommodations:* To allow sufficient time for EPA to process your request for special accommodation before both the preparatory and SACC peer review meetings, please submit the request at least ten business days in advance of the relevant meeting.

**ADDRESSES:**

*Comments:* Submit written comments, identified by docket ID: EPA-HQ-OPPT-2026-1189, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Members of the public should also be aware that personal information included in any written comments may be posted on the internet at <https://www.regulations.gov>. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

*Meeting(s) registration:* Online registration for both the preparatory and the SACC peer review meetings will be available in April 2026. Please refer to the SACC website at <https://www.epa.gov/tsca-peer-review> to complete and submit the registration form(s) approximately one month prior to each meeting. After registering, you will receive the webcast and streaming service meeting links and audio teleconference information.

*Special accommodation requests:* To request an accommodation for a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:**

*DFO:* Dr. Alaa Kamel, Science Advisory Committee Branch, mail code 7602M, Regulatory and Information Services Division, Office of Mission Critical Operations, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-5336 or call the SACC main office: (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 that there will be two virtual public meetings of the SACC. On May 26, 2026, there will be a preparatory meeting for the SACC to consider the scope and clarity of the draft charge questions for the peer review; and on June 8 through 12, 2026, there will be a peer review meeting for the SACC to consider the draft risk evaluations for HHCB and phthalic anhydride, the draft hazard assessments for *o*-DCB and *p*-DCB, the technical support documents, and their public comments. EPA is also announcing the availability of and soliciting public comments on the draft documents and charge questions that will be provided to the SACC for this peer review.

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

EPA established the SACC in 2016 in accordance with TSCA, 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, 5 U.S.C. 10, and supports activities under TSCA, 15 U.S.C. 2601 *et seq.*, the Pollution Prevention Act, 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 and may be of particular interest to those involved in the manufacture, processing, distribution, and disposal of the subject chemical substances, and/or those interested (including members of at-risk communities; non-governmental organizations; and federal, state, and local officials) in the assessment of risks involving chemical substances and mixtures regulated under TSCA.

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

1. *Submitting CBI.* Do not submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. To include information in your comment 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.

2. *Tips for preparing comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>. See also the instructions in Unit III of this document.

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/USAEPAOPPT/subscriber/new?topic\\_id=USAEPAOPPT\\_101](https://public.govdelivery.com/accounts/USAEPAOPPT/subscriber/new?topic_id=USAEPAOPPT_101).

## **II. Background**

A. *What is the purpose of 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 composed of experts in toxicology, environmental risk assessment, exposure assessment, and related sciences (e.g., chemistry, biology, toxicology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). When needed, the SACC 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 high-priority 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 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 did EPA develop these documents?*

HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[ $\gamma$ ]-2-benzopyran (CASRN 1222-05-5)), commonly known by the trade name Galaxolide, phthalic anhydride (CASRN 85-44-9), *o*-DCB (ortho- or 1,2-dichlorobenzene (CASRN 95-50-1)) and *p*-DCB (para- or 1,4-dichlorobenzene (CASRN 106-46-7)), were designated in December 2019 as high-priority substances under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and are currently in the risk evaluation process. EPA published draft and final scopes in April and August 2020, respectively. The scope documents outlined the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expected to consider in its risk evaluations.

On January 22, 2026, EPA leadership re-committed the Agency to phasing out mammalian animal testing and further incorporating New Approach Methods (NAMs) approaches into chemical risk evaluations. These NAMs approaches have been incorporated into forthcoming risk evaluations.

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

EPA is soliciting comments from the SACC on a variety of charge questions related to HHCB, phthalic anhydride, *o*-DCB, and *p*-DCB. Many of the methods and analyses used in these risk evaluations and hazard assessments 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 focusing peer review on critical inputs and novel approaches.

EPA anticipates requesting the SACC to provide feedback on the following documents:

- Complete draft risk evaluation for HHCB, including risk characterization and associated technical support documents related to hazard and exposure assessment.
- Complete draft risk evaluation for phthalic anhydride, including risk characterization and associated technical support documents related to hazard and exposure assessment.
- Draft hazard assessments and technical support documents for human health and ecological hazard for *o*-DCB and *p*-DCB.

In addition, EPA expects to solicit feedback on the following scientific issues, which have been incorporated into forthcoming risk evaluations in alignment with the Agency's recent announcement on phasing out mammalian animal testing.

##### 1. *Use of 5-Day Transcriptomic Studies*

- Interpretation and application of transcriptomic studies for *o*-DCB and *p*-DCB.
- Application of a transcriptomics study and benchmark dose modeling of gene expression in rodent tissues to identify a transcriptomic point-of-departure for *o*-DCB.

##### 2. *Advances in Cancer Risk Assessment*

- Constitutive Androstane Receptor mode of action/adverse outcome pathway analysis and non-human relevance determination for *p*-DCB.
- Application of the Rethinking Carcinogenicity Assessment for Agrochemicals Project weight of evidence framework for HHCB and *o*-DCB.

### *3. Application of In Vitro and Computational NAMs*

- Use of skin sensitization and respiratory sensitization *in vitro* studies and adverse outcome pathways to support hazard characterization of phthalic anhydride.

- Use of skin irritation and dermal absorption *in vitro* studies to support hazard identification of HHCB.

- Computational approaches, including use of the Skin Allergy Risk Assessment-Integrated Chemical Environment model for phthalic anhydride.

- Computational approaches for *o*-DCB.

### *4. Additional Non-Cancer Human Health Hazard Issues*

- Use and interpretation of the Extended One-Generation Reproductive Toxicity Study for HHCB.

### *5. Screening Level Approaches for Occupational and Consumer Exposure Assessment*

- The data and methods utilized in the screening-level occupational and consumer exposure assessments for HHCB, including evidence regarding bioconcentration and bioaccumulation and associated human exposure through fish consumption.

- The use of the thin film model for dermal exposure and the applicability to the chosen exposure scenarios.

### *6. Environmental Hazard Technical Support Documentation*

- The data and methods used to characterize environmental hazards of HHCB and phthalic anhydride.

## **III. Virtual Public Meetings of the SACC**

### *A. What is the purpose of the virtual public meeting(s)?*

The purpose of the preparatory meeting is for the SACC to consider and ask questions regarding the scope and clarity of the draft charge questions. The purpose of the peer review meeting is for the SACC to consider and peer review the draft risk evaluations, draft hazard assessments, and technical support documents. These public meetings are part of the SACC's

peer review of the Agency's methods and novel analyses for the draft risk evaluations and draft hazard assessments. The agenda for these meetings will be posted in the docket and will also be available through the SACC website.

EPA will consider recommendations from this SACC review and public comments in the development of the final TSCA risk evaluations, which may inform other EPA efforts related to the assessment and regulation of the chemical substances. The Agency is seeking peer review of its data analyses and methodologies relevant to human health hazard and exposure analyses that have not been previously peer reviewed.

*B. How can I participate in the virtual public meeting(s)?*

To participate in these virtual public meetings, you must register online to receive the webcast and streaming service meeting links and audio teleconference information for each meeting. Online registration will be available approximately one month prior to the meeting(s) and will remain open until the end of the meeting. To make oral comments during one of these meetings, follow the instructions in this document.

*C. How can I access the documents?*

The draft risk evaluations, draft hazard assessments, related technical supporting materials, and draft charge questions are available in docket ID number EPA-HQ-OPPT-2026-1189 at <https://www.regulations.gov>. EPA will include additional meeting background materials as they become available, (e.g., SACC members and the meeting agenda) in the docket and through the Peer Review of the Draft Risk Evaluations for HHCB and phthalic anhydride and the draft hazard assessments for *o*-DCB and *p*-DCB website at <https://www.epa.gov/tsca-peer-review/peer-review-evaluating-hhcb-phthalic-anhydride-o-dcb-and-p-dcb>.

#### **IV. Next Steps**

After the peer review meeting, the SACC will prepare the meeting minutes and final report document summarizing its recommendations to the EPA, which will also be available in the docket and through the SACC website. EPA will consider the SACC recommendations and

public comments to complete the risk evaluations and unreasonable risk determinations under TSCA for these chemical substances. Under TSCA, EPA must then initiate risk management actions to address the unreasonable risk if identified.

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

Dated: April 10, 2026.

**Douglas M. Troutman,**

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

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