

response and may make final updates to all relevant materials, if deemed necessary. Finally, EPA will submit all relevant materials for OMB for review and approval under the PRA and issue a final PR Notice.

(Authority: 7 U.S.C. 136 *et seq.*)

Dated: December 23, 2025.

**Nancy B. Beck,**

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

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2025-3358; FRL-13124-01-OCSPP]

### Science Advisory Committee on Chemicals (SACC); Request for Nominations of Ad Hoc Peer 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 that EPA can consider for service as *ad hoc* peer reviewers assisting the Science Advisory Committee on Chemicals (SACC). EPA is considering peer review for ten Toxic Substances Control Act (TSCA)-designated High-Priority chemicals. EPA will convene two SACC peer review meetings anticipated to occur in early and mid-2026. EPA is conducting these chemical review evaluations to help inform whether the chemical substances present unreasonable risks to human health and/or the environment under the conditions of use, as required by TSCA. Any interested person or organization may nominate qualified individuals to be considered prospective candidates for these reviews by following the instructions provided in this document. Individuals may also self-nominate.

**DATES:** Submit your nominations on or before February 4, 2026.

**ADDRESSES:** Submit your nomination via email to [SACC@epa.gov](mailto:SACC@epa.gov) following the instructions in Unit III. 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 Designated Federal Officer (DFO) in **FOR FURTHER**

**INFORMATION CONTACT** to obtain special instructions before submitting that information.

**FOR FURTHER INFORMATION CONTACT:** The DFO and Executive Secretary for the SACC is Tamue Gibson, Regulatory & Information Services Division (7602M), 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 at (202) 564-8450; email address: [gibson.tamue@epa.gov](mailto:gibson.tamue@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. 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. 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.

#### B. What should I consider as I prepare my nominations for EPA?

1. *Submitting CBI.* Do not submit 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 in **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting that information.

2. *Request for Nominations to Serve as ad hoc Expert Reviewers to Assist the SACC.* 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 to serve as *ad hoc* reviewers assisting the SACC with 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 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 chemical evaluation documents and to help finalize the meeting minutes and final report.

#### 1. Peer Review Topics Anticipated for 2026

Individuals nominated for the two SACC peer reviews anticipated for early and mid-2026 should have expertise in one or more of the chemicals and/or areas of expertise identified below.

*Early-2026 Chemicals Undergoing Risk Evaluation that EPA is Considering for SACC Review:*

- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)

- Phthalic anhydride (PAD)
- o-Dichlorobenzene (o-DCB)
- p-Dichlorobenzene (p-DCB)

Individuals nominated for peer review for the early-2026 chemical review should also have expertise in one or more of the following areas:

Aquatic exposure modeling; aquatic exposures from ships/ports; cancer mechanism of action (MOA); cancer weight-of-evidence (WoE); chemical engineering; chemical transport and fate; computational toxicology; consumer exposure; dermal exposure modeling (including probabilistic modeling) and estimation for workers; dermal sensitization; dose-response modeling; epidemiology; inhalation toxicology; metabolism; physiologically based pharmacokinetics (PBPK); probabilistic modeling for environmental exposures; read-across; respiratory sensitization; risk assessment; sediment dynamics; toxicokinetics; transcriptomics; and worker exposure.

*Mid-2026 Chemicals Undergoing Risk Evaluation that EPA is Considering for SACC Review:*

- 1,2-Dichloropropane (1,2-DCP)
- 1,1,2-Trichloroethane (1,1,2-TCA)
- trans-1,2-Dichloroethylene (trans-DCE)
- Ethylene dibromide (EDB)
- 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)
- Phosphoric acid, triphenyl ester (TPP)

Individuals nominated for peer review for the mid-2026 chemical review should have expertise in one or more of the following areas:

Aquatic exposure modeling; aquatic toxicology; amphibian toxicology; avian toxicology; cancer mechanism of action (MOA); cancer weight-of-evidence (WoE); chemical engineering (processing as a reactant and processing as a plastic processes); chemical transport and fate; computational toxicology; consumer exposure; dermal exposure modeling (including probabilistic modeling) and estimation for workers; dermal sensitization; dose-response modeling; epidemiology;

exposure modeling—releases from industrial and commercial facilities; exposures to firefighters; industrial hygiene; inhalation exposure modeling and estimation for workers; inhalation toxicology; metabolism; physiologically based pharmacokinetics (PBPK); respiratory sensitization; risk assessment; sediment dynamics; toxicokinetics; and worker exposure.

## 2. Nominations

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

Submit your nomination as directed under **ADDRESSES** by the deadline indicated under **DATES**.

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

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. Selected candidates are required to complete an ethics training prior to conducting their reviews.

## 3. Selection of 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.

At this time, EPA is seeking nominations to create a pool of *ad hoc experts* who can be available to the SACC to assist in reviews conducted by the Committee. EPA anticipates selecting experts from this pool, as needed, to assist the SACC in their review of the chemicals listed in Units II B1. and II.B2. The Agency will consider all nominations of prospective candidates for service as *ad hoc* reviewers for the SACC that are received on or before February 4, 2026. However, final selection of *ad hoc* reviewers is a discretionary function of the Agency.

EPA plans to make a list of candidates under consideration as prospective *ad hoc* reviewers for these reviews available for public comment. The list will be available in the docket at <https://www.regulations.gov> (docket identification number EPA-HQ-OPPT-2025-3358) and through the SACC website at <https://www.epa.gov/tsca-peer-review>.

## 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 19 members. When needed, the committee will be assisted by *ad hoc* reviewers with specific expertise in the topics under consideration.

### B. Background on Each Chemical

#### 1. Early 2026 Chemicals Under Consideration

- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB): HHCB is a synthetic polycyclic musk used in fragrances found in cleaners, detergents, and personal care products. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. HHCB is released primarily via wastewater pathways and may persist in aquatic and sediment environments. EPA's risk evaluation will address ecological toxicity, environmental fate, bioaccumulation, general population exposures, and human health impacts across conditions of use.

- Phthalic Anhydride (PAD): PAD is an industrial intermediate used to manufacture alkyd resins, plasticizers, polyester resins, pigments, and coatings. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. The draft risk evaluation will examine industrial releases, occupational inhalation and dermal exposures (including sensitization), consumer exposures, environmental fate, and human health hazards.

- o-Dichlorobenzene (o-DCB): o-DCB is used as a solvent, degreasing agent, and chemical intermediate. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. Its evaluation will focus on inhalation exposures to workers and consumers, multimedia environmental transport, and potential health risks associated with acute and chronic exposures.

- p-Dichlorobenzene (p-DCB): p-DCB is used in deodorant blocks, air fresheners, repellents, and other industrial applications. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. It presents inhalation exposure concerns due to its volatility and widespread consumer uses. EPA's risk evaluation will address health hazards, exposure

pathways, environmental fate, and risks associated with indoor and ambient exposures.

## 2. Mid-2026 Chemicals Under Consideration

- **1,2-Dichloropropane (1,2-DCP):** 1,2-DCP is a chlorinated solvent used in consumer and industrial cleaning, chemical synthesis, and as an intermediate. EPA designated it as a High-Priority substance due to concerns for inhalation and dermal exposure and potential carcinogenicity. EPA's draft risk evaluation will assess general population, occupational and consumer exposures, environmental releases, fate and transport, and human health and environmental hazards.

- **1,1,2-Trichloroethane (1,1,2-TCA):** 1,1,2-TCA is used as a solvent and chemical intermediate. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. Its evaluation will address general population, occupational and consumer exposures via inhalation and dermal exposure pathways; environmental releases from industrial use; and potential human and environmental health hazards including systemic toxicity and carcinogenicity.

- **trans-1,2-Dichloroethylene (trans-DCE):** trans-DCE is a highly flammable, colorless liquid. It is a synthetic chemical with no known natural sources, and it is used as a solvent in processing and in formulations for cleaning and degreasing, among other uses. EPA designated it as a High-Priority Substance for risk evaluation under TSCA in 2019. EPA's risk evaluation will address potentially exposed or susceptible subpopulations (PESS), environmental and human health hazards, and exposures and impacts across conditions of use.

- **Ethylene Dibromide (EDB):** EDB is primarily used in chemical synthesis and as a fuel additive. It was historically used as a fumigant. EDB has known toxicity and potential carcinogenic effects. EPA designated it as a High-Priority Substance under TSCA. EPA's draft evaluation will consider inhalation and dermal exposures during manufacturing, processing and use, environmental fate, ecological effects, and health hazards associated with occupational, consumer, and general population exposures.

- **Tetrabromobisphenol A (TBBPA):** TBBPA is a brominated flame retardant used in printed circuit boards, resins, and polymer systems. EPA designated it as a High-Priority Substance due to potential ecological hazards, persistence, and possible endocrine-related effects. The risk evaluation will

address aquatic and sediment exposure pathways, environmental fate, bioaccumulation, and human health risks associated with occupational and consumer uses.

- **Triphenyl Phosphate (TPP):** TPP is used as a flame retardant and plasticizer in polymers, electronics, and consumer products. EPA designated it as a High-Priority Substance under TSCA. TPP may be released to air, water, or dust during use and disposal. EPA's risk evaluation will consider exposure to workers and consumers, environmental fate, ecological effects, and potential risks across conditions of use.

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

Dated: December 30, 2025.

**Nancy B. Beck,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-E-1289]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; AUGTYRO

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AUGTYRO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by March 6, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 6, 2026. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 6, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2024-E-1289 for "Determination of Regulatory Review Period for Purposes of Patent Extension; AUGTYRO." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for