

PRE-PUBLICATION NOTICE

On December 12, 2023, Michal Freedhoff, the EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, signed the following document:

Action: **Notice**
Title: **Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment**
FRL #: **11581-01-OCSP**
Docket ID #: **EPA-HQ-OPPT-2023-0601**

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming daily issue of the FR (<https://www.federalregister.gov/> and <https://www.govinfo.gov/app/collection/fr>).

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <https://www.regulations.gov>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT- 2023-0601; FRL-11581-01-OCSP]

Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the initiation of and soliciting public comment on the prioritization process for five chemical substances as candidates for designation as High-Priority Substances for risk evaluation under the Toxic Substances Control Act (TSCA) and related implementing regulations. This document provides the identity of the chemical substances being initiated for prioritization, a general explanation of why the Agency chose these chemical substances, and information on the data sources that EPA plans to use to support the designation. EPA is providing a 90-day comment period, during which interested persons may submit relevant information on these chemical substances.

DATES: Comments must be received on or before **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*]**.

ADDRESSES: Submit your comments through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Submit comments on the chemicals identified in Unit III.B. to the applicable chemical-specific docket ID number provided in Unit III.B. Submit comments on the chemicals identified in Unit IV.B. and comments not related to a specific chemical, including general comments on Unit IV.A., to Docket ID No. EPA-HQ-OPPT- 2023-0601. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets

generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Sarah Au, Data Gathering and Analysis Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0398; email address: au.sarah@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that currently or may manufacture (including import) a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, users, non-profit organizations in the environmental and public health sectors, state and local government agencies, and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What action is the Agency taking?

EPA is initiating the prioritization process under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, for five chemical substances as candidates for designation as High-Priority Substances for risk evaluation. This document includes the identity of the chemical substances entering the prioritization process before designation, and a general explanation of

why the Agency choose to initiate prioritization on these chemical substances. In addition, EPA is providing a 90-day comment period during which interested persons may submit relevant information on these chemical substances. Relevant information might include, but is not limited to, any information that may inform the prioritization screening review conducted pursuant to 40 CFR 702.9(a).

C. Why is the Agency taking this action?

TSCA section 6(b) requires that EPA initiate the prioritization process for chemical substances that may be designated as high priority and low priority for risk evaluation. In December 2019, EPA designated 20 High-Priority Substances pursuant to TSCA section 6(b)(2)(B), which are currently undergoing risk evaluation. Because EPA generally expects to complete five risk evaluations per year over the next several years, EPA is initiating the prioritization process for five chemical substances per TSCA section 6(b)(3)(C), which requires EPA to designate at least one High-Priority Substance upon completion of each risk evaluation for a High-Priority Substance. By initiating this group of High-Priority Substance candidates, EPA intends to begin building a sustainable pipeline of existing chemical risk evaluations under TSCA section 6(b). The request for interested persons to submit relevant information on a chemical substance for which EPA has initiated the prioritization process is required by TSCA section 6(b)(1)(C)(i).

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

This document is issued pursuant to the authority in TSCA section 6(b)(1) and (3)(C).

E. What are the estimated incremental impacts of this action?

This document identifies the five chemical substances for which EPA is initiating the prioritization process, provides a general explanation of why the Agency chose to initiate prioritization on these chemical substances, and provides a 90-day comment period for interested

persons to submit relevant information. This document does not establish any requirements on persons or entities outside of the Agency. No incremental impacts are therefore anticipated, and consequently EPA did not estimate potential incremental impacts for this action.

F. What should I consider as I prepare my comments for EPA?

1. Submitting CBI.

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2 and/or 40 CFR part 703, as applicable.

2. Tips for preparing your comments.

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets.html>.

II. Background

TSCA section 6(b)(1) requires EPA to prioritize chemical substances for risk evaluation and to establish a process for prioritizing chemical substances. Under TSCA section 6(b) and as described in 40 CFR 702.7, EPA is initiating the prioritization process for five chemical substances as candidates for High-Priority Substances for risk evaluation.

Under TSCA section 6(b)(1)(B) and its implementing regulations (40 CFR 702.3), a High-Priority Substance is defined as a chemical substance that EPA determines, without consideration of costs or other non-risk factors, that may present an unreasonable risk of injury to

health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Initiation of prioritization for chemical substances as High-Priority Substance candidates is not a finding of risk. Rather, when prioritization is complete, for those chemicals designated as high priority, the Agency will have evidence that this substance may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use. Final designation of a High-Priority Substance initiates the risk evaluation process (40 CFR 702.17), which culminates in a finding of whether or not the chemical substance presents an unreasonable risk under the conditions of use.

This document is intended to fulfill the TSCA section 6(b)(1)(C)(i) requirement that the Administrator request interested persons to submit relevant information on chemical substances for which the Administrator has initiated the prioritization process. As described in 40 CFR 702.7, this document initiates the prioritization process and provides 90 days during which interested persons may submit relevant information.

As described in 40 CFR 702.9(b) *Information sources*, in conducting the screening review during the prioritization process, EPA will consider sources of information relevant to the screening review criteria as outlined in the statute (TSCA section 6(b)(1)(A)) and implementing regulations (40 CFR 702.9(a)) and consistent with the scientific standards of TSCA section 26(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the TSCA Work Plan Chemicals: Methods Document (February 2012).

Consistent with the approach in our *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization* (September 27, 2018) and prioritization process (40 CFR 702.7), EPA consulted with other federal agencies and intends to continue to collaborate with

them to identify information that is useful throughout the prioritization process.

III. High Priority Candidate Chemical Substances for Which EPA Is Initiating

Prioritization

A. How did EPA select these candidates for prioritization for potential designation as High-Priority Substances for risk evaluation?

In general, EPA's working approach to select candidates for designation as High-Priority Substances for risk evaluation is outlined in the document, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, released to the public on September 27, 2018, available at https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf. To identify candidates for designation as High-Priority Substances, the Agency primarily looked to the TSCA Work Plan for Chemical Assessments: 2014 Update (2014 TSCA Work Plan), available at https://www.epa.gov/sites/default/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf. TSCA requires the Agency to preferentially consider chemicals on the 2014 TSCA Work Plan, as these chemicals were selected due to their potential risk to human health and the environment. EPA also consulted with other EPA program offices and partner federal agencies to inform the Agency's prioritization efforts. With these considerations, the chemicals for which prioritization is initiated in this notice were selected based on a variety of factors and reflect Agency priorities. While data availability was a significant driver of the Agency's selections, EPA also considered the complexity of evaluating broad chemical categories such as metal compounds. In order for EPA to build a sustainable TSCA prioritization, evaluation, and (when appropriate) risk management pipeline, chemicals ultimately designated as High-Priority Substances for risk evaluation should have a robust data landscape. In future rounds of prioritization, EPA intends to use its data gathering authorities earlier and commits to regular stakeholder engagement to

ensure that the Agency has the information it needs to meet its statutory mandates.

Using data sources such as those described in the document, *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*, EPA considered various types of information and data from existing databases (and dashboards) such as EPA's National Center for Computational Toxicology's Chemistry Dashboard (CompTox Chemicals Dashboard), available at <https://comptox.epa.gov/dashboard>. EPA also conducted initial searches of additional sources of information within the public and gray literature domains (e.g., searches in PubMed, Web of Science, other US government and international websites).

Existing information from public and non-public (i.e., confidential business information) sources that are maintained by authoritative sources, such as other EPA program offices, state and federal agencies and various U.S. and international organizations are also considered (e.g., including but not limited to EPA's Office of Water, EPA's Office of Air and Radiation, EPA's Office of Research and Development, California Environmental Protection Agency (Cal EPA), National Toxicology Program (NTP), National Institute for Occupational Safety and Health (NIOSH), Agency for Toxic Substances and Disease Registry (ATSDR), International Agency for Research on Cancer (IARC), European Chemicals Agency (ECHA), Health Canada and Organisation for Economic Co-operation and Development (OECD)).

After identifying evidence of information from reasonably available sources, the information was screened across several data elements including physical and chemical properties, environmental fate and transport properties, hazard, exposure, and use information to determine the breadth of data availability for a chemical substance. Using experience gained from TSCA implementation activities to date, EPA considered previous and planned Agency activities related to a given chemical substance, including how to better leverage experience gained from previously conducted or ongoing risk evaluations. EPA also considered whether

analyses from existing risk assessments could be used to better understand the chemical substance's potential exposure and/or hazard characteristics.

In the absence of measured data on chemicals being evaluated, EPA may use alternative means or new approach methods (NAMs) to obtain relevant data. These NAMs can reduce vertebrate testing, consistent with TSCA section 4(h)(1)(A). EPA intends to use this approach to the extent practicable and scientifically justified.

To identify chemical substances, EPA considered information such as the data submitted to EPA in 2020 under the Chemical Data Reporting (CDR) rule under TSCA regarding reported uses and products as a surrogate for complexity of information to inform prioritization and risk evaluation. EPA considered the release and use information for these chemicals and screened them according to the types of industrial uses and types of products where the chemicals were used, as reported in the 2020 CDR.

EPA intends to update and refine its initial review based on data sources identified by the public during the comment period (see EPA's request for data in Unit IV.) and, where permitted by TSCA section 14 and subject to EPA confidentiality regulations at 40 CFR part 2, subpart B and 40 CFR part 703, intends to make this information publicly available for the initiated chemicals when we publish the proposed priority designation.

B. What chemicals are being initiated?

EPA is initiating the prioritization process for the following five chemicals as candidates for designation as High-Priority Substances:

1. *Acetaldehyde, CAS RN 75-07-0, Docket ID No.: EPA-HQ-OPPT-2018-0497.*

This chemical was listed in the 2014 TSCA Work Plan with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in the 2020 CDR. EPA also receives information annually on

this chemical through the Toxics Release Inventory (TRI). Information is available from assessments conducted by the state of California, international organizations, and other countries.

2. Acrylonitrile, CAS RN 107-13-1, Docket ID No.: EPA-HQ-OPPT-2018-0449.

This chemical was listed in the 2014 TSCA Work Plan with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in the 2020 CDR. EPA also receives information annually on this chemical through the TRI. Information is available from assessments conducted by other federal agencies, the state of California, international organizations, and other countries.

3. Benzenamine, CAS RN 62-53-3, Docket ID No.: EPA-HQ-OPPT-2018-0474.

This chemical was listed in the 2014 TSCA Work Plan with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 1. Data regarding the use of this chemical was reported to EPA in the 2020 CDR. EPA also receives information annually on this chemical through the TRI. Information is available from assessments conducted by the Center for Disease Control (CDC), the state of California, international organizations, and other countries.

4. Vinyl Chloride, CAS RN 75-01-4, Docket ID No.: EPA-HQ-OPPT-2018-0448.

This chemical was listed in the 2014 TSCA Work Plan with a hazard score of 3; an exposure score of 3; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in the 2020 CDR. EPA also receives information annually on this chemical through the TRI. Information is available from assessments conducted by other federal agencies, the state of California, international organizations, and other countries.

5. 4,4'-Methylene bis(2-chloroaniline) (MBOCA), CAS RN 101-14-4, Docket ID No.: EPA-HQ-OPPT-2023-0464.

This chemical was listed in the 2014 TSCA Work Plan with a hazard score of 3; an

exposure score of 2; and a persistence and bioaccumulation score of 2. Data regarding the use of this chemical was reported to EPA in the 2020 CDR. EPA also receives information annually on this chemical through the TRI. Information is available from assessments conducted by other federal agencies, the state of California, international organizations, and other countries.

IV. Relevant Information

A. What additional information is relevant to the five candidate chemical substances for which EPA is initiating prioritization?

Through this initiation of prioritization for chemical substances, EPA is providing a 90-day comment period as required by the statute (TSCA section 6(b)(1)(C)(i)) and implementing regulations (40 CFR 702.7(d)), and requests that interested persons voluntarily submit relevant information. Relevant information might include, but is not limited to, information that may inform the screening review conducted pursuant to 40 CFR 702.9(a), consistent with the scientific standard of TSCA section 26(h), about the following criteria and considerations:

- The chemical substance's hazard and exposure potential;
- The chemical substance's persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the submitter believes are relevant to the prioritization;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- The chemical substance's conditions of use or significant changes in conditions of use, including information regarding trade names;
- The chemical substance's production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance that

might be relevant to the designation of the chemical substance's priority for risk evaluation.

If the information is publicly available, citations are sufficient (including, but not limited to: title, author, date of publication, publication source), and the submission does not need to include copies of the information.

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B. What information is relevant to 10 additional chemical substances that EPA considered for the current round of prioritization?

During the pre-prioritization process, EPA met with federal partners, industry, environmental organizations, labor organizations, state and local governments, and tribes to discuss the prioritization process and presented a list of 15 chemical substances that EPA was considering for prioritization. EPA took feedback from these discussions into consideration when selecting the five chemicals for prioritization listed in Unit III.B. Interested persons may submit relevant information on the following chemical substances that are not currently undergoing prioritization by using Docket ID No. EPA-HQ-OPPT-2023-0606.

- 4-tert-Octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol), CAS RN 140-66-9;
- Benzene, CAS RN 71-43-2;
- Bisphenol A, CAS RN 80-05-7;
- Ethylbenzene, CAS RN 100-41-4;
- Napthalene, CAS RN 91-20-3;
- Styrene, CAS RN 100-42-5;
- Tribromomethane, CAS RN 75-25-2;
- Triglycidyl isocyanurate, CAS RN 2451-62-9;

- Hydrogen fluoride, CAS RN 7664-39-3; and
- N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine, CAS RN 793-24-8.

C. How will confidential business information be protected?

A person seeking to protect from disclosure as “confidential business information” any information that person submits under TSCA must assert and substantiate a claim for protection from disclosure concurrent with submission of the information in accordance with the requirements of TSCA section 14 and 40 CFR 703, with limited exceptions provided in the statute. TSCA section 14(b) limits confidentiality protections for health and safety studies and information from such studies, however, and while EPA considers confidential business information when conducting its review under 40 CFR 702.9(a), the Agency encourages submitters to minimize claims for protection from disclosure wherever possible to maximize transparency in EPA’s screening review. More information on asserting and submitting confidential business information claims under TSCA can be found at 40 CFR 703 and <https://www.epa.gov/tsca-cbi>.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 12, 2023.

Michal Freedhoff,

Assistant Administrator Office of Chemical Safety and Pollution Prevention.