

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

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

Dated: December 12, 2024.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0601; FRL-11581-07-OCSPP]

High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Under the Toxic Substances Control Act (TSCA) and related implementing regulations, EPA is designating five chemicals as High-Priority Substances for risk evaluation. This document provides the identity of five chemical substances for final designation as High-Priority Substances for risk evaluation, EPA's rationale for final designation as High-Priority Substances, and instructions on how to access the chemical-specific information, analysis, and basis EPA used to support final designations for the chemical substances. A designation of a substance as a High-Priority Substance is not a finding of unreasonable risk. Rather, the designation of these chemical substances as high priority constitutes the initiation of evaluation of associated risk.

DATES: The designations of High-Priority Substances for risk evaluation in this notice are effective December 18, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0601, is available online at <https://www.regulations.gov>. In addition, the docket ID numbers for the individual chemical substances designated in Unit IV. are as follows: Acetaldehyde (EPA-HQ-OPPT-2018-0497); Acrylonitrile (EPA-HQ-OPPT-2018-0449);

Benzenamine (EPA-HQ-OPPT-2018-0474); Vinyl Chloride (EPA-HQ-OPPT-2018-0448); and 4,4'-Methylene bis (2-chloroaniline) (MBOCA) (EPA-HQ-OPPT-2018-0464). Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information: Sarah Au, Data Gathering, Management and Policy 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: 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, and users, non-governmental organizations in the environmental and public health sectors, state and local government agencies, Tribes, and members of the public. Since other entities may also be interested, EPA 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 finalizing the designation of five chemical substances as High-Priority Substances for risk evaluation pursuant to section 6(b) of TSCA, 15 U.S.C. 2605(b). This document includes a high-level summary of comments received during the two 90-day comment periods during which the public submitted comments on EPA's initiation of prioritization (Ref. 1) and the proposed designations of those five chemicals as High-Priority Substances for risk evaluation (Ref. 2), as well as a high-level summary of Agency responses to those comments received during both 90-day public comment periods. The comments and EPA's responses are discussed in more depth

in the response to comments document (Ref. 3). EPA also considered comments received during and following the prioritization public webinar that occurred in February 2024, during which EPA explained the prioritization process and provided an overview of information that may be used to inform the considerations that ultimately support a High- or Low-Priority Substance designation, such as information on conditions of use and health effects resulting from exposure to the chemicals of interest.

C. Why is the Agency taking this action?

TSCA section 6(b) and implementing regulations at 40 CFR part 702, subpart A require EPA to carry out a prioritization process for chemical substances that may be designated as high priority for risk evaluation. EPA generally expects to complete five risk evaluations per year over the next several years, and TSCA section 6(b)(3)(C) requires EPA to designate at least one High-Priority Substance upon completion of each risk evaluation for a High-Priority Substance. Pursuant to TSCA section 6(b)(2)(B), EPA is finalizing the designation of the five chemical substances as High-Priority Substances for risk evaluation identified as candidates for High-Priority Substance designation when EPA initiated the prioritization process on December 18, 2023 (Ref. 1). As required under TSCA section 6(b)(3)(C), EPA is specifying the designation of: MBOCA to replace the final risk evaluation for 1,1-dichloroethane; acetaldehyde to replace the final risk evaluation for 1,3-butadiene; acrylonitrile to replace the final risk evaluation for dicyclohexyl phthalate; benzenamine to replace the final risk evaluation for formaldehyde; and vinyl chloride to replace the final risk evaluation for tris(2-chloroethyl) phosphate.

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

This document is issued pursuant to TSCA section 6(b)(1) and 6(b)(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 risk evaluation process and the five chemical substances that have already or will have risk evaluations completed which they will replace. 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.

II. Background

TSCA section 6(b)(1) requires EPA to prioritize chemical substances for risk evaluation. In accordance with TSCA section 6(b) and 40 CFR 702.7, on December 18, 2023 (Ref. 1) EPA initiated the prioritization process for five chemical substances identified as candidates for High-Priority Substance designation. On July 25, 2024, EPA proposed to designate the same five chemical substances as High-Priority Substances for risk evaluation (Ref. 2). That notice included a summary of the approach used by EPA to support the proposed designations, links to the proposed designation document for each of the chemical substances, and instructions on how to access the chemical-specific information, analysis, and basis EPA used to make the proposed designation for each chemical substance.

Under TSCA section 6(b)(1)(B) and implementing regulations (40 CFR 702.3), a High-Priority Substance is defined as “a chemical substance that EPA concludes, without consideration of costs or other non-risk factors, 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 a potentially exposed or susceptible subpopulation identified as relevant by EPA.”

A designation of a substance as a High-Priority Substance is not a finding of unreasonable risk. Rather, when prioritization is complete, for those chemicals designated as High-Priority Substances, the Agency will have evidence on hazards and exposures that supports a finding that the substances may present an unreasonable risk of injury to health or the environment 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 the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use.

As described in the notice proposing to designate the five chemical substances as High-Priority Substances for risk evaluation (Ref. 2), “EPA will generally use reasonably available information to screen the candidate chemical substance[s] against 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;
- Storage of the chemical substance near significant sources of drinking water;
- The chemical substance’s conditions of use or significant changes in conditions of use;
- The chemical substance’s production volume or significant changes in production volume; and
- Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance’s priority” (40 CFR 702.9(a)).

When selecting candidates for prioritization, the Agency also generally intends to consider (1) Agency priorities (with consideration of the priorities of other Federal agencies), (2) Quantity and quality of information (to ensure that information necessary to prioritize the substance is reasonably available), and (3) Overall workload (the Agency will be mindful of the complexity associated with the assessment of the chemical substance to ensure timely completion of prioritization and risk evaluation of each substance) (Ref. 5).

A more detailed discussion of the information, analysis, and basis used to support the proposed High-Priority Substance designation can be found in Unit IV.A of the July 25, 2024, notice (Ref. 2).

As described in 40 CFR 702.9(b), in conducting the screening review during the prioritization process, EPA considered sources of reasonably available information relevant to the 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), and did not consider costs or other non-risk factors in making a proposed High-Priority Substance designation (see TSCA Section 6(b) and 40 CFR 702.9).

After considering additional information collected from the proposed designation process, described in Unit III., EPA is finalizing the High-Priority Substance designations of the same five chemical substances proposed for High-Priority Substance designations, consistent with the scientific standards of TSCA section 26(h) and (i). EPA did not consider costs or other non-risk factors in making the final priority designations. Instructions on how to access the chemical-specific

information, analysis, and basis used by EPA to support the final designation for each chemical substance can be found in Unit IV. A general statement of the condition(s) of use that were the primary basis for each designation is contained in Unit IV. Pursuant to TSCA section 6(b)(3)(A) and 40 CFR 702.17, the designation of these chemical substances as High-Priority Substances constitutes the initiation of the risk evaluations on the substances.

III. Information and Comments Received

A. Overview of Public Comments

EPA provided a 90-day comment period for the public to submit comments on the list of candidate High-Priority Substances immediately following the initiation of prioritization (Ref. 1) and provided a second 90-day comment period for the public to submit comments on the documents supporting the proposed designations of High-Priority Substances for risk evaluation (Ref. 2). The two comment periods are required by TSCA section 6(b)(1)(C) and implementing regulations (40 CFR 702.7(d) and 702.9(g)).

Under TSCA section 6(b)(1)(C)(i), EPA must “request interested persons to submit relevant information on a chemical substance that EPA has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided” (Ref. 1). At initiation of the prioritization process, EPA published a **Federal Register** notice identifying five chemical substances and provided a general explanation for why the Agency chose to initiate prioritization on those chemical substances. During this comment period, the public was invited to submit relevant information on the chemical substances undergoing prioritization, including, but not limited to, any information that may inform the screening review conducted pursuant to 40 CFR 702.9(a). The information received was considered when developing the proposed designations for the High-Priority Substances. The required 90-day comment period was extended for an additional 30 days to receive chemical-specific comments and information for MBOCA (docket ID No. EPA-HQ-OPPT-2018-0464). The second 90-day comment period following the proposed High-Priority Substance designations of the same five chemical substances identified as candidates for High-Priority Substance designation. Under TSCA section 6(b)(1)(C)(ii), EPA must “publish each proposed designation of a chemical

substance as a High- or Low-Priority Substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation” (Ref. 2). The **Federal Register** notice proposing the designations of these substances as High-Priority for risk evaluation identified how to access the chemical-specific information, analysis, and basis used to support the proposed designations and announced the availability of a proposed designation document for each of the chemical substances undergoing prioritization. Interested persons were invited to submit comments, including additional information relevant to the chemical substances that were proposed as high priority for risk evaluations.

To the extent that comments from the first comment period provided information on additional conditions of use for the candidate High-Priority Substances, those conditions of use were discussed in the proposed designation documents for each chemical substance. Other information received specific to High-Priority Substances (*e.g.*, relevant studies and assessments) was considered when making the final priority designations and will be considered as reasonably available information in the subsequent risk evaluation for each High-Priority Substance.

Following a public webinar on February 20, 2024, EPA also received comments on the prioritization process and data considered up until that date for the five chemical substances for which EPA initiated prioritization in December 2023. The comments received were considered when developing the proposed and final designations for the High-Priority Substances.

EPA created one general docket to receive comments regarding the prioritization process (docket ID No. EPA-HQ-OPPT-2023-0601) and additional dockets to receive chemical-specific information (as identified under **ADDRESSES**). During the first public comment period, EPA also opened the pre-prioritization docket (docket ID No. EPA-HQ-OPPT-2023-0606) to welcome potentially relevant information and comments on the candidate chemical substances that were not selected for prioritization.

EPA received 96,011 comment submissions to inform prioritization; several of these comments were mass mailing campaigns with identical submissions. There were also many comments that could not be posted publicly due to inappropriate language, copyright violations, and empty

submissions. Upon review, EPA received 977 unique submissions across both public comment periods. Some commenters included comments for multiple chemical substances in one submission and submitted the same comment to multiple dockets while other commenters chose to submit different sets of comments to each chemical-specific docket. EPA received submissions from individuals, Tribes, potentially affected businesses or trade associations, environmental and public health advocacy groups, academia, and other organizations. Comments addressed the overall prioritization process (*e.g.*, the collection and consideration of relevant information, basis for designation, etc.), the review process (*e.g.*, the use of data and approaches for screening review), information specific to the candidate chemical substances (*e.g.*, relevant studies, previous assessments, and conditions of use information), as well as topics beyond the scope of this prioritization action or not related to the prioritization process in general (*e.g.*, scheduling future chemicals for prioritization, risk evaluation, and risk management). EPA also received a few comments which were not related to TSCA. All comments received are identified by their respective docket ID number and are available at <https://www.regulations.gov>.

EPA responded to comments related to the High-Priority Substance designations in two general categories: (1) General comments, including overarching and cross-cutting policy and process comments, received for the candidate High-Priority Substance designations; and (2) Chemical-specific comments received on each proposed High-Priority Substance designation (Ref. 3). A high-level summary of the comments received related to the prioritization process and Agency responses follows in this unit. The comments and the Agency’s responses are discussed in more depth in the response to comments document (Ref. 3), a copy of which is included in docket ID No. EPA-HQ-OPPT-2023-0601.

B. Comments on Candidate High-Priority Designations

EPA received 748 unique comments during the first public comment period between December 18, 2023, and March 18, 2024, and 229 unique comments during the second comment period from July 25, 2024, to October 23, 2024, resulting in a total of 977 unique comment submissions. An additional two comment submissions were received for MBOCA during the 30-day

extension of the first public comment period for Docket ID number: EPA-HQ-OPPT-2018-0464.

EPA received several mass-mailing campaigns, totaling over 13,000 signatures. All mass-mailing campaigns expressed their support for the prioritization process and encouraged EPA to prioritize one or all of the chemicals. Specifically, many of the mass mailing campaigns encouraged EPA to designate vinyl chloride as a High-Priority Substance under TSCA. In addition to the mass-mailing campaigns and 17 commenters who attended the prioritization public webinars in February 2024, EPA received over 100 comments expressing support for EPA’s prioritization actions.

Commenters expressed their concern regarding human health hazards and exposure potential of all five of the High-Priority Substances and asked that EPA consider specific potential health outcomes and exposure scenarios. Several commenters urged EPA to identify relevant potentially exposed or susceptible subpopulations (PESS), including infants, children, pregnant women, workers, the elderly, and people living in proximity to sources of contamination, as well as consider environmental justice concerns in the prioritization process. In addition, several commenters, including some of the mass-mailing campaigns, urged the Agency to consider all potential exposures and risks, including those from accidents, spills, and leaks, specifically potential exposure resulting from transportation incidents such as derailments and collisions, which may pose significant risk to fence line communities.

Over 600 commenters asked EPA to ban vinyl chloride and emphasized the availability of hazard and exposure data demonstrating harm posed by vinyl chloride releases. Many commenters also cited the February 3, 2023, train derailment that resulted in the release of and potential exposure to vinyl chloride by residents in East Palestine, Ohio.

Each data submission and potentially relevant data source was screened using systematic review approaches for applicability and considered for the final designation of these chemical substances as High-Priority Substances and will be considered as reasonably available information.

The Agency appreciates all comments and information submitted by the public for this action. For additional information regarding specific topics and EPA’s responses to these comments, please see the Agency’s full response to comments received (Ref. 3).

IV. Designation as High-Priority Substances for Risk Evaluation

Based on the information provided in the proposed designation documents, as referenced in the document that appeared in the **Federal Register** of July 25, 2024 (Ref. 2), and public comments received, including information pertaining to individual chemical substances, EPA is designating the same five chemicals as High-Priority Substances for risk evaluation under TSCA. Pursuant to 40 CFR 702.11, which states: “For High-Priority Substances, EPA generally expects to indicate which condition(s) of use were the primary basis for such designations.” For all five High-Priority Substances the conditions of use which formed the primary basis for the designation were included in the proposed designation documents. The final High-Priority Substance designations are as follows:

- Acetaldehyde, CASRN 75–07–0, Docket ID number: EPA–HQ–OPPT–2018–0497;
- Acrylonitrile, CASRN 107–13–1, Docket ID number: EPA–HQ–OPPT–2018–0449;
- Benzenamine, CASRN 62–53–3, Docket ID number: EPA–HQ–OPPT–2018–0474;
- Vinyl chloride, CASRN 75–01–4, Docket ID number: EPA–HQ–OPPT–2018–0448; and
- 4,4'-Methylene bis(2-chloroaniline) (MBOCA), CASRN 101–14–4, Docket ID number: EPA–HQ–OPPT–2018–0464.

The final designations are based on the conclusion that each chemical substance satisfies the definition of High-Priority Substance in TSCA section 6(b)(1)(B) and 40 CFR 702.3. EPA developed a document for each substance to identify the information, analysis and basis used to support the proposed designations as a High-Priority Substance for risk evaluation. These documents are available in the docket of each of the chemical substances. Also included in each document is an explanation of the approach used by EPA to conduct the review. Each document includes an overview of the requirements in TSCA section 6(b)(1)(A) and a regulatory section addressing the review criteria and considerations (40 CFR 702.9).

These designated High-Priority Substances will fulfill the statutory requirement to designate at least one high-priority substance upon completion of each risk evaluation for a High-Priority Substance, under TSCA section 6(b)(3)(C). Pursuant to TSCA section 6(b)(3)(A) and 40 CFR 702.17, the designation of these chemical

substances as High-Priority Substances constitutes the initiation of the risk evaluations on the substances.

A designation of a chemical substance as a High-Priority Substance is not a finding of unreasonable risk; rather, a final designation as a High-Priority Substance initiates the risk evaluation for the chemical substance. This is a three-year process that will culminate in a finding of whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. The chemical-specific designation documents containing the information, analysis and basis used to support the proposed designations are located in the docket for each chemical substance. As previously discussed, to the extent that comments provided information on additional conditions of use for the candidate High-Priority Substances for risk evaluation, those conditions of use were noted in the proposed designation documents for each chemical substance and may be reflected in the draft scope of the risk evaluation for each chemical substance, which will include the conceptual model and analysis plan for carrying out the evaluation. As such, EPA will not amend the proposed designation documents. Instead, additional submitted potentially relevant information specific to High-Priority Substances (e.g., relevant studies and assessments) will be considered in subsequent phases of risk evaluation, including draft scope documents and draft risk evaluation documents, both of which will be subject to public comment opportunities.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket for this action includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket. For assistance in locating these referenced documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Initiation of Prioritization Under the Toxic Substances Control Act (TSCA). Notice. **Federal Register**. 88 FR 87423, December 18, 2023 (FRL–11581–01–OCSP).
2. EPA. Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA). **Federal Register**. 89 FR 60420, July 25, 2024 (FRL–11581–03–OCSP).
3. EPA. EPA Response to Public Comments Received on the “Initiation of Prioritization Under the Toxic

Substances Control Act” and “Proposed High-Priority Substance Designations Under the Toxic Substances Control Act.” December 18, 2024.

4. EPA. “A Working Approach for Identifying Potential Candidate Chemicals for Prioritization.” (https://www.epa.gov/sites/production/files/201809/documents/preprioritization_white_paper_9272018.pdf). September 27, 2018.

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

Dated: December 12, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2023–0601; FRL–11581–06–OCSP]

Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Under the Toxic Substances Control Act (TSCA) and related implementing regulations, EPA is initiating the prioritization process for five chemical substances as candidates for designation as High-Priority Substances for risk evaluation. This action 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 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 March 18, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. For comments not related to a specific chemical, including general comments on Unit IV.A., use docket ID number EPA–HQ–OPPT–2023–0601; submit information on the candidates for which EPA is initiating the prioritization process to the applicable chemical-specific docket ID number identified in Unit III.B.; submit information on the potential candidates for which EPA is not currently initiating the prioritization