



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0131; FRL-9998-29]

Proposed High-Priority Substance Designations under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As required under section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations, EPA is proposing to designate 20 chemical substances as High-Priority Substances for risk evaluation. This document and supporting docket materials identify the proposed designation for each of the chemical substances and instructions on how to access the chemical-specific information, analysis and basis used by EPA to support the proposed designation for each chemical substance. EPA is providing a 90-day comment period during which interested persons may provide comments on the proposed designations of High-Priority Substances for risk evaluation.

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

ADDRESSES: Use one of the following methods to submit comments. For comments not related to a specific chemical, including comments on Unit V., direct your comments to docket identification (ID) number EPA-HQ-OPPT-2019-0131. For comments on one or more of the 20 chemical substances, use the applicable chemical specific docket ID number(s) identified in Unit IV.B.:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions

for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information about the High-Priority Substances contact:* Ana Corado, Chemical Control Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency (Mailcode 7408M), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-0140; email address: corado.ana@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.

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; 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 proposing to designate 20 chemical substances as High-Priority Substances for risk evaluation pursuant to section 6(b) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(b). This document includes a summary of the approach used by EPA to support the proposed designations, the proposed designation for each of the chemical substances, and instructions on how to access the chemical-specific information, analysis and basis used by EPA to make the proposed designation for each chemical substance. EPA is providing a 90-day comment period during which interested persons may submit comments on the proposed designations.

C. Why is the Agency taking this action?

TSCA section 6(b) and EPA implementing regulations at 40 CFR 702.9 require EPA to carry out a prioritization process for chemical substances that may be designated as high priority for risk evaluation. TSCA section 6(b)(2)(B) requires that EPA be conducting risk evaluations on at least 20 High-Priority Substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182). EPA is proposing to designate as High-Priority Substances for risk evaluation the same 20 chemical substances for which EPA initiated the prioritization process required by TSCA section 6(b) on March 21, 2019 (Ref. 1). EPA is providing a 90-day comment period during which the

public may submit comments on EPA's proposed designations of High-Priority Substances for risk evaluation, as required by TSCA section 6(b)(1)(C)(ii) and implementing regulations (40 CFR 702.9(g)).

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

This document is issued pursuant to TSCA section 6(b)(1).

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

This document identifies 20 chemical substances for proposed designation as High-Priority Substances for risk evaluation. 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 Confidential Business Information (CBI).* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as 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.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

TSCA section 6(b)(1) requires EPA to prioritize chemical substances for risk evaluation.

As required by TSCA section 6(b) and described in 40 CFR 702.7, on March 21, 2019 (Ref. 1) EPA initiated the prioritization process for 20 chemical substances identified as candidates for High-Priority Substance designation.

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 determines, 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 potentially exposed or susceptible subpopulations identified as relevant by EPA.

A proposed 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 that the substances 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 of injury to health or the environment under the conditions of use.

This document is intended to fulfill the requirement in TSCA section 6(b)(1)(C)(ii) that the Administrator propose the designation of 20 chemical substances as High-Priority Substances for risk evaluation after conducting a review, as required by TSCA section 6(b)(1)(A) (see also 40 CFR 702.9(a)). This document is also intended to fulfill the requirement in TSCA section 6(b)(1)(C)(ii) that the Administrator request public comments on proposed priority designations (see also 40 CFR 702.9(g)).

EPA generally used reasonably available information to screen the candidate chemical substances against the following criteria and considerations (40 CFR 702.9(a)):

- 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.

As described in 40 CFR 702.9(b), in conducting the review during the prioritization process, EPA considered sources of 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). In addition, as required by 40 CFR 702.9, EPA considered the hazard and exposure potential of the chemical substances and did not consider costs or other non-risk factors in making a proposed priority designation.

III. Information and Comments Received

The initiation of the prioritization process (Ref. 1) included a 90-day comment period during which interested persons were able to submit relevant information on the 20 chemical substances identified as candidates for High-Priority Substance designation. EPA received 125

submissions from commenters, including private citizens, potentially affected businesses, trade associations, environmental and public health advocacy groups, and academia. Comments addressed the overall prioritization process (e.g., the collection and consideration of relevant information), the review process (e.g., the use of data and approaches in risk evaluation), information specific to the candidate chemical substances (e.g., relevant studies, assessments and conditions of use), and topics not germane to this prioritization process (e.g., scheduling future chemicals for prioritization and concerns about risk evaluation fees). To the extent that comments provided information on additional conditions of use for these candidate High-Priority chemical substances, those conditions of use are discussed in the proposed designation documents for each chemical substance. EPA will respond to those and any additional comments in conjunction with the final priority designation of these chemical substances.

IV. Chemical Substances for which EPA is Proposing a High-Priority Substance

Designation for Prioritization

A. Information, Analysis and Basis Used to Support the Proposed High-Priority Substance

Designation

EPA used reasonably available information, including public comments received during the 90-day comment period following initiation of the prioritization process (Ref. 1), to analyze the candidate chemical substances against the criteria and considerations in TSCA section 6(b)(1)(A) and 40 CFR 702.9 (see Unit III.). 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 with a proposed designation as a High-Priority Substance for risk evaluation. The proposed designations and docket references are presented in Unit IV.B., along

with the docket references.

Also included in each document is an explanation of the approach used by EPA to conduct the review. Each of the documents includes an overview of the requirements in TSCA section 6(b)(1)(A) and the regulatory section addressing the following review criteria and considerations (40 CFR 702.9):

1. *Production volume or significant changes in production volume.* EPA considered reasonably available information on the current volume or significant changes in volume of the chemical substance using reported information from manufacturers (including importers) under the Chemical Data Reporting (CDR) rule. EPA assembled information reported to the Agency from 1986 through 2016 on the production volume under the Inventory Update Rule (IUR) and CDR. The most recent principal reporting year for which CDR data are available is 2015 information, reported in 2016.

2. *Conditions of use or significant changes in conditions of use.* EPA assembled information on conditions of use or significant changes in conditions of use of the chemical substance using reported CDR data, the Toxics Release Inventory (TRI) and chemical-specific information received from public commenters. TSCA section 3(4) defines the term “conditions of use” to mean the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. For CDR data, EPA assembled information submitted by manufacturers (including importers) under the 2012 and 2016 CDR reporting cycles. CDR requires manufacturers (including importers) to report information on the chemical substances they produce domestically or import into the United States, generally more than 25,000 lbs per site. For candidate priority chemicals included on the TRI chemical list, information disclosed by

reporting facilities in Part II Section 3 (“Activities and Uses of the Toxic Chemical at the Facility”) of their TRI Form R reports was used to supplement the CDR information on conditions of use. In addition to the information disclosed in Part II Section 3 of the TRI Form R, information pertaining to waste management activities (e.g., disposal, treatment, recycling) disclosed in other sections of the TRI Form R was also used to supplement the CDR information on conditions of use. Based on the manufacturing information, industrial processing and use information, and consumer and commercial use information reported under CDR and TRI as well as information associated with waste management activities reported under TRI, as well as chemical-specific information received from public commenters, EPA developed a list of conditions of use from data reported during the 2012 and 2016 CDR reporting cycles and the 2011, 2015 and 2017 TRI reporting cycles, as appropriate. Should the Agency decide to make a final decision to designate a chemical substance as a high-priority substance for risk evaluation, further characterization of relevant TSCA conditions of use will be identified during the risk evaluation process as part of EPA’s scope document.

3. *Potentially exposed or susceptible subpopulations.* In this review, EPA considered reasonably available information to identify potentially exposed or susceptible subpopulations. At this stage, EPA analyzed information regarding children, women of reproductive age, and workers (note that consumers are considered as part of the criterion for “7. Exposure potential”):

- For children, EPA evaluated the chemical substance’s use in products and articles regulated under TSCA and intended for children, using CDR information reported during the 2012 and 2016 CDR cycles. EPA presented information regarding those commercial and consumer uses where the chemical substance was used in products intended for children. EPA also identified the potential for developmental hazards that could negatively impact children.

- For women of reproductive age (e.g., pregnant women) EPA identified exposure conditions and hazard information for the chemical substance which indicated potential for reproductive or developmental adverse effects.

- For workers, EPA identified the potential for occupational exposures to workers based on the conditions of use of each chemical.

4. *Persistence and bioaccumulation.* EPA considered reasonably available information of the chemical substance and assessed physical-chemical properties for persistence and bioaccumulation based on best available science. EPA presented a summary of the physical and chemical properties and the environmental fate characteristics of each chemical substance.

5. *Storage near significant sources of drinking water.* To support the proposed designation, EPA analyzed each chemical substance, under its conditions of use, with respect to the seven criteria in TSCA section 6(b)(1)(A) and 40 CFR 702.9. The statute specifically requires the Agency to consider the chemical substance's storage near significant sources of *drinking water*, which EPA interprets as direction to focus on the chemical substance's potential human health hazard and exposure. EPA reviewed reasonably available information, specifically looking to identify certain types of existing regulations or protections for the proposed chemical substances. EPA considered the chemical substance's potential human health hazards, including to potentially exposed or susceptible subpopulations, by identifying existing National Primary Drinking Water Regulations (40 CFR Part 141) and other regulations under the CWA (40 CFR 401.15). In addition, EPA considered the consolidated list of chemicals subject to reporting requirements under the EPCRA (Section 302 Extremely Hazardous Substances and Section 313 Toxic Chemicals), CERCLA (Hazardous Substances), and the CAA (Section 112(r) Regulated Chemicals for Accidental Release Prevention). Regulation by one of these authorities is an

indication that the substance is a potential health or environmental hazard which, if released near a significant source of drinking water, could present unreasonable risk to health or the environment.

6. *Hazard potential.* EPA considered reasonably available information to identify potential hazards for each chemical substance. EPA surveyed information from previous peer-reviewed assessments and databases and summarized the reasonably available information for potential human health and environmental hazards by endpoints of concern. If endpoint-specific hazard information was not available for the chemical substance subject to the review, then EPA considered isomer analog data.

7. *Exposure potential.* EPA considered reasonably available information to identify potential environmental, worker/occupational, consumer, and general population exposures for each chemical substance:

- For environmental exposures, EPA considered the conditions of use and activities associated with those conditions of use and considered monitoring data and fate properties of each chemical substance to anticipate its presence in different environmental media.

- For worker or occupational exposure, EPA identified the conditions of use that are likely to result in workers exposures, such as manufacturing, processing, industrial and commercial use, distribution in commerce, and disposal.

- For consumer exposure, EPA identified consumer uses using CDR information, information from the NIH Household Products Database and the EPA's Chemical and Products Database (CPDat).

- For general population exposure, EPA considered releases from certain conditions of use as reported in TRI, such as manufacturing, that may result in general population exposures

via drinking water ingestion and/or inhalation from air releases.

8. *Other risk-based criteria that EPA determined to be relevant to the designation of the chemical substance's priority.* EPA did not identify other risk-based criteria relevant to the proposed designations of the candidate chemical substances as High-Priority Substance for risk evaluation.

B. Proposed Designation as High-Priority Substances for Risk Evaluation

EPA is proposing to designate the 20 chemicals listed in Unit IV.C. as High-Priority Substances for risk evaluation. The proposed designations are based on the conclusion that the chemical substance satisfies the definition of High-Priority Substance in TSCA section 6(b)(1)(B) and 40 CFR 702.3. As mentioned previously, a proposed designation of a chemical substance as a High-Priority Substance is not a finding of unreasonable risk; rather, when prioritization is complete, a final designation as a High-Priority Substance will initiate the risk evaluation for the chemical substance, which will culminate in a finding of whether or not the chemical substance presents an unreasonable risk to health or the environment under the conditions of use. Based on the information provided in the Proposed Designation documents, the Agency is proposing the chemical substances listed in Unit IV.C. as High-Priority Substances for risk evaluation. The chemical-specific designation documents containing the information, analysis and basis used to support the proposed designation are located in the docket for each chemical substance.

C. Request for Comments

EPA is interested in comments that would inform the exposure and hazard assessments and the identification of conditions of use for the following chemicals:

1. *1,3-Butadiene, CASRN 106-99-0, Docket ID number: EPA-HQ-OPPT-2018-0451.*

2. *Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester), CASRN 85-68-7, Docket ID number: EPA-HQ-OPPT-2018-0501.*
3. *Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester), CASRN 84-74-2, Docket ID number: EPA-HQ-OPPT-2018-0503.*
4. *o-Dichlorobenzene (Benzene, 1,2-dichloro-), CASRN 95-50-1, Docket ID number: EPA-HQ-OPPT-2018-0444.*
5. *p-Dichlorobenzene (Benzene, 1,4-dichloro-), CASRN 106-46-7, Docket ID number: EPA-HQ-OPPT-2018-0446.*
6. *1,1-Dichloroethane, CASRN 75-34-3, Docket ID number: EPA-HQ-OPPT-2018-0426.*
7. *1,2-Dichloroethane, CASRN 107-06-2, Docket ID number: EPA-HQ-OPPT-2018-0427.*
8. *trans-1,2- Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-), CASRN 156-60-5, Docket ID number: EPA-HQ-OPPT-2018-0465.*
9. *1,2-Dichloropropane, CASRN 78-87-5, Docket ID number: EPA-HQ-OPPT-2018-0428.*
10. *Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester), CASRN 84-61-7, Docket ID number: EPA-HQ-OPPT-2018-0504.*
11. *Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester), CASRN 117-81-7, Docket ID number: EPA-HQ-OPPT-2018-0433.*
12. *Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester), CASRN 84-69-5, Docket ID number: EPA-HQ-OPPT-2018-0434.*
13. *Ethylene dibromide (Ethane, 1,2-dibromo-), CASRN 106-93-4, Docket ID number: EPA-HQ-OPPT-2018-0488.*

14. *Formaldehyde, CASRN 50-00-0, Docket ID number: EPA-HQ-OPPT-2018-0438.*
15. *1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB), CASRN 1222-05-5, Docket ID number: EPA-HQ-OPPT-2018-0430.*
16. *4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA), CASRN 79-94-7, Docket ID number: EPA-HQ-OPPT-2018-0462.*
17. *Phosphoric acid, triphenyl ester (TPP) CASRN 115-86-6, Docket ID number: EPA-HQ-OPPT-2018-0458.*
18. *Phthalic anhydride (1,3-Isobenzofurandione), CASRN 85-44-9, Docket ID number: EPA-HQ-OPPT-2018-0459.*
19. *1,1,2-Trichloroethane, CASRN 79-00-5, Docket ID number: EPA-HQ-OPPT-2018-0421.*
20. *Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1',1''-phosphate), CASRN 115-96-8, Docket ID number: EPA-HQ-OPPT-2018-0476.*

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other 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**. (84 FR 10491, March 21, 2019) (FRL-9991-06).

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

Dated: August 16, 2019.

Andrew R. Wheeler,

Administrator.

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