



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0131; FRL-10013-90]

Final Scopes of the Risk Evaluations to be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Toxic Substances Control Act (TSCA), which was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016, and implementing regulations, EPA is announcing the availability of the final scope documents for the risk evaluations to be conducted for the 20 High-Priority Substances designated in December 2019. The scope document for each chemical substance includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations the EPA plans to consider in conducting the risk evaluation for that chemical substance.

DATES: The scope documents announced in this notice are dated August 27, 2020.

ADDRESSEES: The docket for this action is identified by docket identification (ID) number EPA-HQ-OPPT-2019-0131, and the docket ID numbers for the individual chemical substances are listed with the chemical substance in Unit IV. All the dockets are available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Ross Geredien, Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency (Mailcode 7403M), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-1864; email address: geredien.ross@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. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that 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 is the Agency's authority for taking this action?

This action directly implements TSCA section 6(b)(4)(D), 15 U.S.C. 2605(b)(4)(D).

C. What action is the Agency taking?

EPA is announcing the availability of the final scope documents of the risk evaluations for the 20 chemical substances designated as High-Priority Substances for risk evaluation under TSCA. Through the risk evaluation process, EPA will determine whether the chemical substances present an unreasonable risk of injury to health or the environment under the conditions of use, in accordance with TSCA section 6(b)(4).

II. Background

TSCA section 6(b)(1) requires EPA to prioritize chemical substances for risk evaluation (15 U.S.C. 2605(b)(1)). Effective December 20, 2019, EPA designated 20 chemical substances as High-Priority Substances for risk evaluation (Ref. 1), which initiated the risk evaluation process for those chemical substances (15 U.S.C. 2605(b)(3)(A); 40 CFR 702.17). The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence (15 U.S.C. 2605(b)(4)(F), 2625(h) and (i)). This process will culminate in a determination of whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (40 CFR 702.47).

Pursuant to 40 CFR 702.41(c)(7), EPA announced the availability of and sought public comment on the draft scope documents for the risk evaluations to be conducted for 13 of 20 High-Priority Substances under TSCA (85 FR 19941, April 9, 2020) (FRL-10007-11) (Ref. 2) and the remaining 7 of 20 High-Priority Substances under TSCA (85 FR 22733, April 23, 2020)

(FRL-10008-05) (Ref. 3).

III. Information and Comments Received

A. Overview of public comments

Comments were received during two 45-day comment periods following the announcement of the draft scope documents for the risk evaluations to be conducted for 13 of 20 High-Priority Substances under TSCA (Ref. 2) and the remaining 7 of 20 High-Priority Substances under TSCA (Ref. 3). During both comment periods, the public was invited to submit comments on EPA's draft scope documents, including additional data or information relevant to the chemical substances or that otherwise could be useful to the Agency in finalizing the scope of the risk evaluations. To the extent that comments provided information on conditions of use, as well as other elements of the draft scope documents, those comments and other submitted information (e.g., relevant studies and assessments) were used to inform revisions to the draft scope documents and may be considered in subsequent phases of the risk evaluation process.

EPA created one general docket to receive comments regarding the risk evaluation process and additional, individual dockets on each of the 20 High-Priority Substances undergoing risk evaluation to receive chemical-specific information. From all 21 dockets, EPA received 245 submissions; however, some commenters opted for one submission describing all their comments and submitted it to multiple dockets, other commenters chose to submit different comments to specific chemical-specific dockets, and some commenters did both. Therefore, EPA considered 78 of those submissions unique. EPA received submissions from 66 different entities, including potentially affected businesses or trade associations, environmental and public health advocacy groups and academia (some submissions were signed by more than one group), a group of state attorneys general, and other organizations.

Comments addressed the overall approach to the risk evaluation process (e.g., collection, consideration, and systematic review of relevant information), the specific elements of the scope documents (e.g., hazard, exposure, and potentially exposed or susceptible subpopulations (PESS)), information specific to the chemical substances (e.g., relevant studies, assessments, and conditions of use (COUs)), and topics beyond the draft scope document phase of the process (e.g., risk management). One comment (EPA-HQ-2018-0465-0028) was not related to the risk evaluation of the 20 High-Priority Substances. EPA considered those comments, as applicable and appropriate, in developing the final scope documents. Concurrently with the publication of the 20 final scope documents, EPA is publishing a response to comments document that contains a comprehensive summary of and response to public comments received on the 20 draft scope documents. The comprehensive response to comments document is available in the docket EPA-HQ-OPPT-2019-0131 (Ref. 4).

IV. Final Scopes for the 20 Designated High-Priority Chemical Substances

The chemical substances for which EPA is publishing the final scopes of the risk evaluations are identified in the following Table, along with the corresponding Chemical Abstract System Registry Number (CASRN) and docket ID numbers.

Table: List of the 20 Designated High Priority Chemical Substances

Chemical Substance	CASRN	Docket ID Number
1,3-Butadiene	106-99-0	EPA-HQ-OPPT-2018-0451
o-Dichlorobenzene (Benzene, 1,2-dichloro-)	95-50-1	EPA-HQ-OPPT-2018-0444
p-Dichlorobenzene (Benzene, 1,4-dichloro-)	106-46-7	EPA-HQ-OPPT-2018-0446
1,1-Dichloroethane	75-34-3	EPA-HQ-OPPT-2018-0426
1,2-Dichloroethane	107-06-2	EPA-HQ-OPPT-2018-0427
trans-1,2-Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-)	156-60-5	EPA-HQ-OPPT-2018-0465
1,2-Dichloropropane	78-87-5	EPA-HQ-OPPT-2018-0428
Ethylene dibromide (Ethane, 1,2-dibromo-)	106-93-4	EPA-HQ-OPPT-2018-0488
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222-05-5	EPA-HQ-OPPT-2018-0430
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	79-94-7	EPA-HQ-OPPT-2018-0462

Phosphoric acid, triphenyl ester (TPP)	115-86-6	EPA-HQ-OPPT-2018-0458
1,1,2-Trichloroethane	79-00-5	EPA-HQ-OPPT-2018-0421
Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1',1"-phosphate)	115-96-8	EPA-HQ-OPPT-2018-0476
Butyl benzyl phthalate (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)	85-68-7	EPA-HQ-OPPT-2018-0501
Dibutyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester)	84-74-2	EPA-HQ-OPPT-2018-0503
Dicyclohexyl phthalate	84-61-7	EPA-HQ-OPPT-2018-0504
Phthalic anhydride (1,3-Isobenzofurandione)	85-44-9	EPA-HQ-OPPT-2018-0459
Formaldehyde	50-00-0	EPA-HQ-OPPT-2018-0438
Di-ethylhexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	117-81-7	EPA-HQ-OPPT-2018-0433
Di-isobutyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester)	84-69-5	EPA-HQ-OPPT-2018-0434

The final scope document for the risk evaluation for each of these 20 chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider. Development of the scope is the first step of a risk evaluation. The final scope document for each risk evaluation includes the following components (40 CFR 702.41(c)):

- The conditions of use, as determined by the Administrator, that EPA plans to consider in the risk evaluation.
- The potentially exposed populations that EPA plans to evaluate; the ecological receptors EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.
- A description of the reasonably available information and the science approaches that the Agency plans to use.
- A conceptual model that describes the actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and the receptors, either human or environmental, with consideration of the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, and disposal – and

identification of human and ecological health hazards EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

- An analysis plan, which identifies the approaches and methods EPA plans to use to assess exposure, hazards, and risk, including associated uncertainty and variability, as well as a strategy for using reasonably available information and science approaches.
- A plan for peer review.

Based on public comments received, the Agency was able to update conditions of use presented in the draft scope documents and accept additional data or information from stakeholders that was useful to the Agency in finalizing the scope of the risk evaluations. In addition, public comments were considered to better inform the exposure pathways, routes, receptors, PESS, and hazards that EPA plans to consider in the risk evaluations for the 20 High-Priority Substances. Note that, as a result of the Ninth Circuit Court of Appeals' decision in *Safer Chemicals, Healthy Families v. U.S. EPA*, 943 F.3d 397, 425 (9th Cir. 2019), EPA will no longer exclude legacy uses or associated disposal from the definition of "conditions of use." Rather, when these activities are intended, known, or reasonably foreseen, these activities will be considered uses and disposal, respectively, within the definition of "conditions of use."

V. References

The following is a listing of the documents that are specifically referenced in this *Federal Register* notice. 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. High-Priority Substance Designations Under the Toxic Substances Control Act

(TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. *Federal Register*. (84 FR 71924, December 30, 2019) (FRL-10003-15).

2. EPA. Draft Scopes of the Risk Evaluations to Be Conducted for Thirteen Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. *Federal Register*. (85 FR 19941, April 9, 2020) (FRL-10007-11).

3. EPA. Draft Scopes of the Risk Evaluations to Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. *Federal Register*. (85 FR 22733, April 23, 2020) (FRL-10008-05).

4. EPA. Summary of Public Comments Received on the Draft Scopes of the Risk Evaluations for Twenty Chemical Substances Under the Toxic Substances Control Act (TSCA). (August 2020).

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

Andrew Wheeler,

Administrator.

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