



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2019-0131; FRL-10008-05]**

**Draft Scopes of the Risk Evaluations to be Conducted for Seven Chemical Substances**

**Under the Toxic Substances Control Act; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** As required by the Toxic Substances Control Act (TSCA), which was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016, EPA is announcing the availability of the draft scope documents for the risk evaluations to be conducted for 7 of 20 High-Priority Substances designated in December 2019. The draft 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. EPA is also opening a 45-calendar day comment period on these draft scope documents to allow for the public to provide additional data or information that could be useful to the Agency in finalizing the scope of the risk evaluations; comments may be submitted to this docket and the individual dockets for each of the chemical substances.

**DATES:** Comments must be received on or before [INSERT DATE 45 CALENDAR DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0131, or the applicable docket ID number for the individual chemical substances identified in Unit III., by one of the following methods:

• *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 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](mailto: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](mailto: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 publishing the draft scopes of the risk evaluations for 7 of 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). EPA announced the availability of the draft scopes of the risk evaluations for 13 of 20 chemical substances designated as High-Priority Substances for risk evaluation under TSCA on April 6, 2020 (Ref. 1).

## **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. 2), 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)). 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).

### III. Draft Scopes for 7 of 20 Designated High Priority Chemical Substances

The 7 chemical substances for which EPA is publishing the draft 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: Draft Scopes for 7 of 20 Designated High Priority Chemical Substances**

<b>Chemical Substance</b>	<b>CASRN</b>	<b>Docket ID Number</b>
Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)	85-68-7	EPA-HQ-OPPT-2018-0501
Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester)	84-74-2	EPA-HQ-OPPT-2018-0503
Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester)	84-61-7	EPA-HQ-OPPT-2018-0504
Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	117-81-7	EPA-HQ-OPPT-2018-0433
Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester)	84-69-5	EPA-HQ-OPPT-2018-0434
Formaldehyde	50-00-0	EPA-HQ-OPPT-2018-0438
Phthalic anhydride (1,3-Isobenzofurandione)	85-44-9	EPA-HQ-OPPT-2018-0459

The draft scope of the risk evaluation for each of these 7 chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations the EPA plans to consider. Development of the scope is the first step of a risk

evaluation. The draft scope of each risk evaluation will include the following components (40 CFR 702.41(c)):

- The conditions of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.
- The potentially exposed populations that EPA plans to evaluate; the ecological receptors that 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 will describe 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, to release or 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 will identify 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.

With the publication of the draft scopes, EPA is providing a 45-calendar day public comment period. 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.”

EPA encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. EPA will publish a notice in the Federal Register announcing the availability of the final scopes within six months of the initiation of risk evaluations that occurred on December 20, 2019 (Ref. 2).

#### **IV. 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. 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 FRxx, April 9, 2020 (FRL-10007-11).

2. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act and Initiation of Risk Evaluation on High-Priority Substances; Availability. Federal Register. 84 FR 71924, December 30, 2019 (FRL-10003-15).

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

**Andrew Wheeler,**

*Administrator.*

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