

Prepublication Copy Notice:

The EPA Acting Principal Deputy Assistant Administrator signed the following *Federal Register* document on May 31, 2018:

Title: **Problem Formulations for the Risk Evaluations to be Conducted under the Toxic Substances Control Act, and General Guiding Principles To Apply Systematic Review in TSCA Risk Evaluations; Notice of Availability**

Action: Notice

FRL: 9978-40

Docket No.: **EPA-HQ-OPPT-2018-0210**

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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-2018-0210; FRL-9978-40]

Problem Formulations for the Risk Evaluations to be Conducted under the Toxic Substances Control Act, and General Guiding Principles To Apply Systematic Review in TSCA Risk Evaluations; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is publishing and taking comments on the problem formulation documents for the first 10 chemical substances undergoing risk evaluation under the Toxic Substances Control Act (TSCA). Comments received will inform the development of draft risk evaluation documents for these 10 chemical substances. The 10 problem formulation documents announced in this document refine the scope documents published in June 2017 and are an additional interim step, prior to publication of the draft risk evaluations. EPA is also publishing and taking comments on a document entitled: “*Application of Systematic Review in TSCA Risk Evaluations*,” which sets out general principles to guide EPA’s application of systematic review for TSCA risk evaluations. The Office of Pollution Prevention and Toxics (OPPT) generally intends to apply systematic review principles in the development of risk evaluations under TSCA. The systematic review document includes a structured process of identifying, evaluating and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process. This document may be revised periodically. EPA welcomes public input on the document.

DATES: Comments on the problem formulations must be received on or before [*insert date 45 days after date of publication in the Federal Register*].

EPA specifically requests comments on the *Application of Systematic Review in TSCA Risk Evaluations* document for 45 days *after date of publication in the Federal Register*. In addition, because this document is a living document which may be revised periodically, EPA welcomes public input on this document at any time.

ADDRESSES: Submit your comments, identified by the appropriate docket identification (ID) numbers as provided in Unit IV., 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. When submitting comments, please be as specific as possible, and please include any supporting data or other information.

- *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 in general is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information on the Problem Formulation documents contact:* Christina Motilall, Risk Assessment Division,

Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1287; email address: *motilall.christina@epa.gov*.

For technical information on Application of Systematic Review in TSCA Risk Evaluations contact: Iris Camacho, Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-1229; email address: *TSCA-systematicreview@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. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use or dispose of any of the 10 chemical substances identified in this document for risk evaluation, or any future existing chemical substances undergoing risk evaluation under TSCA. This action may be of particular interest to entities that are regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110, among others). 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.

II. What is the Agency's Authority for this Action?

As amended in June 2016, TSCA requires that EPA prioritize and evaluate existing chemical substances and manage identified risks (15 U.S.C. 2605). TSCA section 6(b) specifies the requirements for risk evaluation.

III. Background

A. The first 10 chemical substances for risk evaluations under TSCA

On December 19, 2016 (81 FR 91927) (FRL-9956-47), EPA released its designation of the first 10 chemical substances for risk evaluations under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA section 6(b)(4).

On June 22, 2017, EPA released scope documents for the first 10 chemical substances (see 82 FR 31592, July 7, 2017) (FRL-9963-57). Each scope document includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation.

EPA has prepared a Response to Comments document addressing overarching comments received on the scope documents, which is available in the docket (see docket ID number EPA-HQ-OPPT-2017-0736). Chemical substance-specific comments on the scope documents are addressed in the respective problem formulation documents.

B. Systematic Review

In the development of TSCA risk evaluations, the Agency generally intends to apply systematic review principles. EPA described systematic review in the preamble of the final rule *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017), and in the preamble of the proposed rule (82 FR 7562, January 19, 2017) (FRL-9957-75). EPA intends to apply systematic review to pre-specify the

criteria, methods/approaches for data collection, data evaluation and data integration to meet the TSCA science standards. TSCA requires EPA to make scientific decisions in a manner consistent with the best available science and base decisions on the weight of the scientific evidence.

Supplemental documents to the scope documents of the first 10 chemical substances, published in June 2017 (e.g. *Strategy for Conducting Literature Searches for Asbestos: Supplemental Document to the TSCA Scope Document*, CASRN: 1332-21-4) already document the initial methods for identifying, compiling and screening publicly available information. These data collections and screening activities are described in the *Strategy for Conducting Literature Searches* document and the *Bibliography* document supporting each of the TSCA scope documents for the first ten chemical substances.

IV. What Action is the Agency Taking?

A. Problem Formulation Documents

To refine the scope documents, EPA is publishing and taking public comment on problem formulation documents for the first 10 chemical substances. As indicated in the scope documents, time constraints resulted in scope documents that were not as refined or specific as future scope documents are anticipated to be. The 10 problem formulation documents announced in this document are an additional interim step, prior to publication of the draft risk evaluations, that refine the scope documents. These refinements may apply to the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA expects to consider in the risk evaluation. EPA has incorporated scope document comments specific to each chemical substance into the respective problem formulation document. While EPA does not intend to revise these problem formulation

documents, comments and information provided will inform the development of the draft risk evaluation documents.

The following table identifies the docket ID numbers and EPA contact for each of the 10 problem formulations that EPA is taking comments on.

Chemical Name	Docket ID Number	Agency Contact
Asbestos	EPA-HQ-OPPT-2016-0736	Robert Courtnage, <i>courtnage.robert@epa.gov</i> , 202-566-1081
1-Bromopropane	EPA-HQ-OPPT-2016-0741	Ana Corado, <i>corado.ana@epa.gov</i> , 202-564-0140
1,4-Dioxane	EPA-HQ-OPPT-2016-0723	Cindy Wheeler, <i>wheeler.cindy@epa.gov</i> , 202-566-0484
Carbon Tetrachloride	EPA-HQ-OPPT-2016-0733	Stephanie Jarmul, <i>jarmul.stephanie@epa.gov</i> , 202-564-6130
Cyclic Aliphatic Bromide Cluster (HBCD)	EPA-HQ-OPPT-2016-0735	Sue Slotnick, <i>slotnick.sue@epa.gov</i> , 202-566-1973
Methylene Chloride	EPA-HQ-OPPT-2016-0742	Ana Corado, <i>corado.ana@epa.gov</i> ,

		202-564-0140
N-Methylpyrrolidone (NMP)	EPA-HQ-OPPT-2016-0743	Ana Corado, <i>corado.ana@epa.gov</i> , 202-564-0140
Pigment Violet 29 (Anthra[2,1,9-def:6,5,10- d'e'f] diisoquinoline- 1,3,8,10(2H,9H)-tetrone)	EPA-HQ-OPPT-2016-0725	Hannah Braun, <i>braun.hannah@epa.gov</i> , 202-564-5614
Tetrachloroethylene (also known as perchloroethylene)	EPA-HQ-OPPT-2016-0732	Tyler Lloyd, <i>lloyd.tyler@epa.gov</i> , 202-564-4016
Trichloroethylene (TCE)	EPA-HQ-OPPT-2016-0737	Toni Krasnic, <i>krasnic.toni@epa.gov</i> , 202-564-0984

EPA invites the public to provide additional comment and information that would be useful in conducting the risk evaluation for each of the 10 chemical substances.

B. The Application of Systematic Review in TSCA Risk Evaluations

The *Application of Systematic Review in TSCA Risk Evaluations* document is a supplemental publication which sets out general principles to guide EPA's application of systematic review in the risk evaluation process for the first 10 chemical substances that EPA initiated on December 19, 2016, as well as future assessments. It also provides the intended

strategy for assessing the quality of information that the Agency plans to use for the TSCA risk evaluations.

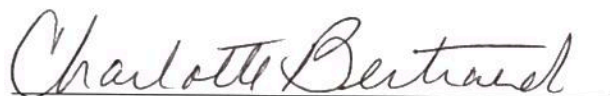
The Agency intends to implement a structured process of identifying, evaluating and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process. As needed, EPA will develop new approaches and methods to address specific assessment needs for the relatively large and diverse chemical space under TSCA. Hence, the Agency will document the progress of implementing systematic review in the draft risk evaluations and through revisions of this document and publication of supplemental documents. The systematic review document provides the *general expectations* for evidence integration. Further additional information will be published with the publication of the draft TSCA risk evaluations.

Ultimately, the goal is to establish a pragmatic systematic review process that generates high quality, fit-for-purpose risk evaluations that rely on the best available science and the weight of the scientific evidence within the context of TSCA.

This document is a living document which may be revised periodically. EPA welcomes public input on this document at any time.

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

Dated: 5.31.2018

A handwritten signature in cursive script, reading "Charlotte Bertrand", written in dark ink over a horizontal line.

Charlotte Bertrand

*Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution
Prevention.*