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EPA Unveils Scoping Analysis for Risk Evaluations under Amended TSCA, Requests Comments on the First Ten Chemicals

The Environmental Protection Agency (EPA) has issued the three framework rules called for by the amended Toxic Substances Control Act (TSCA) to direct future review of chemical risks. Without waiting for those rules, however, EPA had previously launched risk evaluations for the initial ten chemical substances. On June 22, 2017, EPA posted the [scope documents](#) (follow the links under “First ten chemicals for Risk Evaluation”) for those substances. They present a less complete scoping process than what the scope analysis will look like in the future. For each of the ten chemicals, EPA has opened dockets for public comments. The next step for these ten chemical substances is problem formulation .

Background

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSEA) revamped TSCA’s section 6 regulatory scheme by requiring a risk evaluation process for high-priority chemicals before any section 6(a) regulation. Three groups of chemical substances will be subject to risk evaluations:

- The initial ten EPA-selected chemicals from the 2014 TSCA Work Plan;
- High-Priority substances designated in the prioritization process; and
- Chemical substances for which EPA has granted requests by manufacturers for risk evaluations.¹

For each covered chemical, section 6(b)(4)(D) requires EPA to publish the scope of the risk evaluation that identifies the “hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations [EPA] expects to consider.” Scope documents must be published no later than 6 months after the initiation of the risk evaluation process.

The scope documents published on June 22 are for the ten initial risk evaluation chemicals. Section 6(b)(2)(A) requires that EPA select ten chemicals from the 2014 TSCA Work Plan for the initial risk evaluations; none of the ten chemicals was subject to prioritization. To start the evaluation process, EPA designated

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¹ TSCA § 6(b)(4)(C).

the chemicals on December 19, 2016, assigning each chemical its own rulemaking docket.² It then held a public meeting and accepted written comments in early 2017 for initial public inputs.³ The ten selected chemicals are listed below (with links to the EPA webpages with corresponding scope documents and supplemental files):⁴

- [Asbestos \(CAS No. 1332-21-4\)](#)
- [1-Bromopropane \(CAS No. 106-94-5\)](#)
- [1,4-Dioxane \(CAS No. 123-91-1\)](#)
- [Carbon Tetrachloride \(CAS No. 56-23-5\)](#)
- [Cyclic Aliphatic Bromide Cluster \(Hexabromocyclododecane or HBCD\) \(CAS Nos. 25637-99-4, 3194-55-6, and 3194-57-8\)](#)
- [Methylene Chloride \(CAS No. 75-09-2\)](#)
- [N-Methylpyrrolidone \(NMP\) \(CAS No. 872-50-4\)](#)
- [Pigment Violet 29 \(Anthra\[2,1,9-def:6,5,10-d'e'f\] diisoquinoline-1,3,8,10\(2H,9H\)-tetrone\) \(CAS No. 81-33-4\)](#)
- [Tetrachloroethylene \(also known as perchloroethylene\) \(CAS No. 127-18-4\)](#)
- [Trichloroethylene \(TCE\) \(CAS No. 79-01-6\)](#)

The publication of the scope documents was the latest step of the risk evaluation process, intended to satisfy the section 6(b)(4)(D) requirements. The scope documents (and the scope publication process) for these ten chemicals will have both similarities and differences in comparison with later scoping work. In announcing the scope documents, EPA explained that it “has aligned these scope documents with the approach set forth in the risk evaluation process.”⁵ However, citing the absence of prioritization and the “compressed” timeframe, EPA also recognized that these first scope documents are “not as refined or specific as future scope documents are anticipated to be.” Procedurally, EPA issued no draft scope document for any of these chemicals, which it intends to do in future risk evaluations. The scope documents likely reflect EPA’s general scoping approaches, but EPA’s practices in future scoping work may deviate somehow from its actions here.

General Approach

EPA took a highly uniform approach for the ten scoping documents chemicals. One common core message is that EPA’s scoping analysis focuses on individual “conditions of use,” instead of the chemical substance in its entirety. EPA’s scoping work started with information gathering and integration, which resulted in the scope documents. The scope documents themselves have three primary components: statutorily-required information, conceptual models, and analysis plans.

EPA collected and evaluated data prior to issuing the scope documents. These initial surveys investigated the regulatory and assessment history of the chemicals, as well as the data and information relevant to the specific subjects to be addressed in the scope documents. For the latter, EPA drafted a separate *Strategy for Conducting Literature Searches* protocol for each chemical. The collected data are categorized into “on-topic” and “off-topic” references, based on their presumed relevance to subsequent risk evaluations. Subcategories are also assigned as part of the screening process. EPA, however, stated that these designations are subject to change.

² 81 Fed. Reg. 91927 (Dec. 19, 2016).

³ A transcript of EPA’s February 14 public meeting is at [EPA-HQ-OPPT-2017-0002-0025](#). EPA’s presentation during the meeting is at [EPA-HQ-OPPT-2017-0002-0005](#). Submitted written comments can be located in individual rulemaking dockets.

⁴ For each chemical, EPA released scope documents, *Strategy for Conducting Literature Searches* documents, and the initial lists of literature references. As explained below, the *Strategy* documents and the initial lists of references concern EPA’s preliminary data collection and processing work leading to the scope documents.

⁵ See *Scopes of the Risk Evaluations to be Conducted for the First Ten Chemical Substances under the Toxic Substances Control Act; Notice of Availability*, 82 Fed. Reg. 31592 (July 7, 2017) (“[Notice of Availability](#)”).

The scope documents lay out the basic information of the chemical substances, mostly required under section 6(b)(4)(D). Such information covers four subjects: Physical and chemical properties of the substance, conditions of use, exposures, and hazards (effects). Issues relating to potentially exposed or susceptible subpopulations, which TSCA directs EPA to consider, are addressed in exposures and hazards sections.

EPA integrated the above data into conceptual models, which “describe the actual or predicted relationships between the chemical substance and receptors.” In all ten scope documents, EPA provided three conceptual models: for industrial and commercial activities and uses, for consumer activities and uses, and for environmental releases and wastes. Finally, EPA developed analysis plans. These plans are EPA’s checklists of key considerations and action items that presumably would be taken in further risk evaluation analysis.

Conditions of Use

In section 2.2 of each scope document, EPA provided detailed characterization of various conditions of use for that chemical, with references to separate “use documents” in the docket. It also provided life-cycle diagrams to provide comprehensive overviews of potential scopes of risk evaluations in terms of likely affected life cycle stages. More detailed information relating to life-cycle analysis is in each scope document’s Appendix B.

Other than asbestos, each chemical will be evaluated for risks at five different life cycle stages: manufacturing, processing, use (industrial, commercial, and consumer), distribution, and disposal. EPA further specified different categories of use for each chemical with information from the Chemical Data Reporting and other sources.

EPA classified conditions of uses subject to risk evaluation for non-asbestos chemical substances in a highly standardized format for four life-cycle stages.⁶ “Manufacturing” includes domestic manufacturing and import. “Processing” mostly includes uses as reactants or intermediates; incorporation of the chemical into formulation, mixture, or reaction products; incorporation of the chemical into articles; repackaging; and recycling. “Distribution” is evaluated throughout the entire life cycle instead of based on single use scenarios. “Disposal” covers emissions to air, wastewater, liquid wastes, and solid wastes. Scenarios under the “Use” stage, on the other hand, vary more considerably depending on chemical. Below, for example, is the scope of the carbon tetrachloride risk evaluation. Other non-asbestos chemicals follow a similar pattern, although the level of details may vary for individual life cycle stages.

- Manufacturing
 - Domestic manufacturing
 - Import
- Processing
 - Reactant / Intermediate
 - HCFCs, HFCs, and HFOs
 - PCE;
 - Inorganic chlorinated compounds
 - Chlorinated paraffins
 - Incorporation into formulation, mixture, or reaction product
 - Petrochemical manufacturing
 - Agricultural products manufacturing
 - Solvents for cleaning and degreasing

⁶ Under TSCA, the term “conditions of use” refers to “the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” TSCA § 3(4) (definition of “conditions of use”). Therefore, “conditions of use” cover more than just “use” in a chemical substance’s life cycle.

- Adhesives and sealants
 - Paints and coatings
 - Incorporation into article
 - Repackaging
 - Recycling
- Distribution
- Uses
 - Industrial use
 - Catalyst regeneration (petrochemical manufacturing)
 - Processing aid (petrochemical manufacturing)
 - Additive (petrochemical manufacturing)
 - Fertilizers and other agricultural products manufacturing (Agricultural products manufacturing)
 - Industrial/commercial/consumer uses
 - Machinery cleaning (solvents for cleaning and degreasing)
 - Textile cleaning (solvents for cleaning and degreasing)
 - Brake cleaning (solvents for cleaning and degreasing)
 - Rubber cement (adhesives and sealants)
 - Arts and crafts (adhesives and sealants)
 - Asphalt (adhesives and sealants)
 - Industrial adhesives (adhesives and sealants)
 - Paints and coatings (paints and coatings)
 - Laboratory chemicals (laboratory chemicals)
 - Other uses
 - Reactive ion etching
 - Processing aid (e.g. metal recovery, nitrogen trichloride removal in chlor-alkali production)
- Disposal
 - Emissions to air
 - Wastewater
 - Liquid wastes
 - Solid wastes

For asbestos, although the life-cycle diagram reflects similar stages, EPA identified asbestos conditions of uses by “use status” and individual product categories:

- Known use
 - Asbestos diaphragms (example: chlor-alkali industry);
 - Sheet gaskets (example: chemical manufacturing);
- Evidence of use
 - Industrial friction products (example: brake blocks in oil industry)

- Aftermarket automotive brakes (example: passenger vehicles)
- Other vehicle friction products (non-passenger vehicles)
- Adhesive and sealants (examples: mirror adhesive; tile cement);
- Roof and non-roof coatings (examples: roofs / foundations; mastics);
- Other gaskets and packing (example: washers);
- Reasonably foreseen use
 - Building materials (example: imported cement)
 - Woven products (example: imported textiles)
 - Other (not specified articles)

EPA elaborated several general principles relating to conditions of use in the Introduction to each scope document. One was that EPA generally will not “reach[] back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.” EPA explained that it interprets section 6 to mean that it must focus on “uses for which manufacture, processing or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e. is prospective or on-going).” For instance, under the trichloroethylene scoping document, EPA left open the issue of whether dermal exposure is the result of legacy uses or legacy and ongoing uses.⁷ Thus, “legacy uses, associated disposal, and legacy disposals” will only be considered in terms of background exposures in aggregate exposure assessment or evaluation of risk of exposures from non-legacy uses. This is consistent with EPA’s position in the preamble to the risk evaluation final rule.

EPA repeated this principle as specifically applicable in at least two scope documents. Asbestos-containing materials (ACMs) remaining in older buildings are excluded from the asbestos risk evaluation based on the “legacy use” principle. Similarly excluded are those ACMs that are part of older products that are no longer intended, or known or reasonably foreseen, to be manufactured, processed, or distributed in commerce.⁸ EPA also asserted the applicability of the “legacy use” principle to carbon tetrachloride.

In addition, EPA excluded certain uses covered by previous section 6(a) actions. These include the uses of methylene chloride⁹ and N-methylpyrrolidone (NMP)¹⁰ for paint and coating removal and the use of trichloroethylene for vapor degreasing and aerosol degreasing.¹¹

Next Steps

Section 6(b)(4)(G) of the amended TSCA requires EPA to complete risk evaluations “not later than 3 years” after the initiation of the risk evaluation, but gives EPA the discretion to extend the deadline for no more than 6 months. Therefore, final risk evaluations for these ten chemicals will be due in June 2020 at the latest. Prior to releasing any final risk evaluation, under section 6(b)(4)(H), EPA must first issue a draft risk evaluation and provide a notice-and-comment period no less than 30 days.

In addition to these long-term statutorily-mandated requirements, EPA has planned a series of actions on the first ten chemicals in the near future. Per a June 9 EPA [memo](#) available in each rulemaking docket, interested persons may submit information from until September 19 on these chemicals as EPA prepares for problem formulation, which will refine the scope documents as an interim step. After the problem formulation, EPA will publish the problem formulation documents for additional comments toward draft risk evaluations.

⁷ See EPA, [Scope of the Risk Evaluation for Trichloroethylene](#), at 34.

⁸ Section 2.2.2 of the Asbestos scope document provides a more detailed scope and explanation of the excluded legacy uses. See EPA, [Scope of the Risk Evaluation for Asbestos](#), at 24-25.

⁹ EPA, [Scope of the Risk Evaluation for Methylene Chloride \(Dichloromethane, DCM\)](#), at 30. See also 82 Fed. Reg. 7464 (Jan. 19, 2017).

¹⁰ EPA, [Scope of the Risk Evaluation for N-Methylpyrrolidone \(2-Pyrrolidinone, 1-Methyl-\)](#), at 19-20. See also 82 Fed. Reg. 7464 (Jan. 19, 2017).

¹¹ EPA, [Scope of the Risk Evaluation for Trichloroethylene](#), at 27. See also 82 Fed. Reg. 7432 (Jan. 19, 2017).



Stakeholders will have at least three additional opportunities (on the scope documents, on the problem formulation documents, and on the draft risk evaluations) before EPA finalizes the risk evaluation of the first ten chemicals. Stakeholders who would be affected by EPA risk management rules for these chemicals may want to take advantage of those opportunities.

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