

## 2025 Annual Plan for Chemical Risk Evaluations Under TSCA

January 17, 2025

### Background

*The Frank R. Lautenberg Chemical Safety for the 21st Century Act* (Public Law [P.L.114-182]),<sup>1</sup> amended the Toxic Substances Control Act (TSCA) to enhance public health and chemical safety by providing the U.S. Environmental Protection Agency (EPA) with significant authorities and obligations. TSCA section 26(n) requires: At the beginning of each calendar year, the Administrator shall publish an annual plan that— (A) identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion; (B) describes the status of each risk evaluation that has been initiated but not yet completed; and (C) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

This plan fulfills the requirement of TSCA section 26(n) for 2025.

### Chemical Substances Currently Undergoing Risk Evaluation

As required under section 6(b) of TSCA, EPA must conduct a prioritization process to determine if chemical substances are a high- or low-priority for risk evaluation. A high-priority substance may present unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure, and a low-priority substance is one for which a risk evaluation is not warranted at the time. At the end of the prioritization process, if a chemical is designated as a High-Priority Substance, EPA will initiate a risk evaluation for that chemical substance. EPA will then publish a draft scope for public comment, followed by a final scope document within six months of initiating the risk evaluation. Table 1 lists the chemicals undergoing risk evaluation and the actual or expected “no later than” date of the final scope, draft risk evaluation, and final risk evaluation. In the table, EPA grouped the risk evaluations by initiation date.

### *High-Priority Chemical Risk Evaluations Initiated in 2019*

In August 2019, EPA proposed High-Priority Chemical Substance designations for 20 chemicals. In December 2019, EPA finalized the designations and commenced risk evaluations for the chemicals.<sup>2</sup> The agency finalized scopes for these chemicals in August and September 2020.

On November 22, 2024, EPA entered a consent decree with Community in Power and Development Association Inc. in which EPA agreed to schedules for completing the final risk

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<sup>1</sup> See <https://www.epa.gov/sites/default/files/2016-06/documents/bills-114hr2576eah.pdf>.

<sup>2</sup> See <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluationunder-tsca>.

evaluations for the 20 High-Priority Chemical Substances initiated in 2019.<sup>3</sup> The timeline for these final risk evaluations range from the end of calendar year 2024 through the end of calendar year 2026. Pursuant to a consent decree, EPA did complete the final risk evaluations for Formaldehyde<sup>4</sup> and Tris(2-chloroethyl) Phosphate (TCEP)<sup>5</sup> by December 31, 2024.

### ***Manufacturer-Requested Risk Evaluations (MRREs)***<sup>6</sup>

In March 2020, EPA received a manufacturer request to conduct a risk evaluation of octamethylcyclotetrasiloxane (D4). In October 2020, EPA granted the request based on public comment and EPA's review of the requests. In March 2022, EPA released a draft scope document for D4 for 45-day public review.

In November 2020, EPA received an updated manufacturer request to conduct a risk evaluation of four chemical substances as a single category, the octahydro-tetramethyl-naphthalenyl-ethanone (OTNE) chemical category. In light of this request being submitted under TSCA section 6(h) and prior to the finalization of the EPA's 2017 risk evaluation rule and associated requirements for a manufacturer requested risk evaluation submission, EPA is still working with the manufacturer to ensure the agency has the information necessary to perform a risk evaluation.

Pursuant a separate consent decree also filed November 22, 2024, Consent Decree Regarding Manufacturer-Requested Risk Evaluation Deadlines,<sup>7</sup> EPA did complete the final risk evaluations for DIDP<sup>8</sup> and DINP<sup>9</sup> by December 31, 2024.

### ***High-Priority Chemical Risk Evaluations Initiated in 2024***

In December 2023, EPA announced that it was initiating the process to prioritize five chemicals for potential risk evaluation under TSCA.<sup>10</sup> On December 18, 2024, EPA finalized the designations of these chemical substances as High-Priority Substances for risk evaluation.

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<sup>3</sup> *Community In-Power and Development Assoc., Inc., et al. v. U.S. Environmental Protection Agency*, No. 1:23-cv-02715-DLF, Dkt. # 39, "Consent Decree Regarding High-Priority Chemical Risk Evaluation Deadlines," (D.D.C. Nov. 22, 2024).

<sup>4</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-formaldehyde>

<sup>5</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-tris2-chloroethyl-phosphate-tcep>

<sup>6</sup> For more information, see: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturerrequested-risk-evaluations-under-tsca>.

<sup>7</sup> *Community In-Power and Development Assoc., Inc., et al. v. U.S. Environmental Protection Agency*, No. 1:23-cv-02715-DLF, Dkt. # 40, "Consent Decree Regarding Manufacturer-Requested Evaluation Deadlines," (D.D.C. Nov. 22, 2024).

<sup>8</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-di-isodecyl-phthalate-12-benzene>

<sup>9</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-diisononyl-phthalate-12-benzene>

<sup>10</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritization-actions-under-tsca>

## Status of Chemical Risk Evaluations Underway

Table 1. Status of chemicals undergoing risk evaluation in 2025.

Chemical Name	Final Scope (Publication date/estimated no later than date)	Draft Risk Evaluation (Publication date/estimated no later than date)	Final Risk Evaluation (Publication date/estimated no later than date)
High-Priority Chemicals Initiated in 2019*			
<a href="#">1,3-Butadiene</a>	Aug. 27, 2020	Dec. 12, 2024	Dec. 2025
<a href="#">Butyl benzyl phthalate – 1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester (BBP)</a>	Aug. 27, 2020	April 2025	Dec. 2025
<a href="#">Dibutyl phthalate (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester) (DBP)</a>	Aug. 27, 2020	March 2025	Dec. 2025
<a href="#">Dicyclohexyl phthalate (DCHP)</a>	Aug. 27, 2020	Jan. 6, 2025	Dec. 2025
<a href="#">Di-ethylhexyl phthalate – (1,2-Benzene-dicarboxylic acid, 1,2-bis-(2-ethylhexyl) ester) (DEHP)</a>	Aug. 27, 2020	April 2025	Dec. 2025
<a href="#">Di-isobutyl phthalate – (1,2-Benzene-dicarboxylic acid, 1,2-bis-(2methylpropyl) ester) (DIBP)</a>	Aug. 27, 2020	March 2025	Dec. 2025
<a href="#">1,1-Dichloroethane</a>	Aug. 27, 2020	July 7, 2024	April 2025
<a href="#">1,2-Dichloroethane (also known as Ethylene Dichloride)</a>	Aug. 27, 2020	May 2025	Dec. 2025
<a href="#">o-Dichlorobenzene</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">p-Dichlorobenzene</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">Phosphoric acid, triphenyl ester (TPP)</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">Phthalic anhydride</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">1,1,2-Trichloroethane</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">trans-1,2-Dichloroethylene</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">1,2-Dichloropropane</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
<a href="#">Ethylene dibromide</a>	Aug. 27, 2020	Dec. 2025	Dec. 2026
Manufacturer Requested Risk Evaluations			
<a href="#">Octamethylcyclotetra-siloxane (D4)</a>	March 7, 2022	May 2025	April 2026

High-Priority Chemicals Initiated in 2024			
Acrylonitrile	June 2025	Dec. 2026	Dec. 2027
Acetaldehyde	June 2025	Dec. 2026	Dec. 2027
Benzenamine (a.k.a. Aniline)	June 2025	Dec. 2026	Dec. 2027
MBOCA [4,4'-Methylene bis(2-chloroaniline)]	June 2025	Dec. 2026	Dec. 2027
Vinyl chloride	June 2025	Dec. 2026	Dec. 2027

\* The deadlines for the 20 high-priority chemicals initiated in 2019 are subject to consent decree.

## Resources Necessary to Complete Risk Evaluations

TSCA provides EPA with authority to collect fees from eligible TSCA activities to defray up to 25% of the costs associated with overall TSCA implementation efforts. TSCA requires EPA to establish its fee structure by rule. EPA finalized the fees rule in 2018 and an updated rule in February 2024.<sup>11</sup> In developing the 2024 rule, EPA thoroughly reviewed its anticipated workload for fiscal years 2024, 2025, and 2026 and explained its estimated costs for TSCA sections 4, 5, 6 and 14 activities in a technical support document - *Technical Support Document: Final Rulemaking; Fees for the Administration of the Toxic Substances Control Act (TSCA)*.<sup>12</sup> EPA's analysis included updates to TSCA activities, the resources necessary for contractor support, and payroll costs associated with the federal workforce.

TSCA section 6 cost estimates were informed by EPA's experience conducting evaluations for the first 10 chemicals undergoing risk evaluation under amended TSCA; by the Agency's experience developing the scopes of the risk evaluations of the 20 chemicals designated as High-Priority Substances in December 2019; and by the Agency's experience with risk management actions addressing unreasonable risks identified from the first 10 risk evaluations. For purposes of the Fees rule, the estimated annual cost to EPA of administering relevant risk evaluation activities under TSCA section 6 is \$43,320,378. This may not be the actual cost for 2025 risk evaluation activities. EPA's Office of Inspector General (OIG) identified TSCA risk evaluations as a "Top Management Challenge" in November 2021,<sup>13</sup> estimating that EPA would need to increase its capacity by 140 percent in order to meet deadlines for just the 24 risk evaluations EPA had ongoing at that time. While additional resources from the fiscal year (FY) 2022 and FY 2023 budgets helped to an extent, cuts to Office of Chemical Safety and Pollution Prevention's (OCSPP) operating budget in FY 2024 have inhibited some ongoing efforts and further constrained EPA's ability to accelerate progress. In addition, the availability of resources for FY 2025 remains uncertain as a full-year appropriation is not expected to be received until at least March of 2025, half-way through the FY. Nonetheless, EPA continues to focus on opportunities

<sup>11</sup> *Fees for the Administration of the Toxic Substances Control Act*. <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0493>

<sup>12</sup> <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0118>

<sup>13</sup> [https://www.epa.gov/system/files/documents/2021-11/certified\\_epaoig\\_20211112-22-n-0004.pdf](https://www.epa.gov/system/files/documents/2021-11/certified_epaoig_20211112-22-n-0004.pdf)

to create additional efficiencies by applying fit-for-purpose approaches and frontloading data collection efforts.

### **Conclusion**

This report serves as the 2025 Annual Plan for Chemical Risk Evaluations under TSCA as required under TSCA Section 26(n).