

2020 Annual Plan for Chemical Risk Evaluations under TSCA

Background

The Frank R. Lautenberg Chemical Safety for the 21st Century Act amendments to the Toxic Substances Control Act (TSCA) signed on June 22, 2016, required EPA to implement new authorities and obligations. One of the Act's new requirements was the evaluation of existing chemical substances. Section 26(n) of amended TSCA requires the EPA to publish an annual plan at the beginning of each calendar year that identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion, describes the status of each risk evaluation that has been initiated but not yet completed, and includes an updated schedule for completion of risk evaluations, if appropriate. This plan has been developed in fulfillment of that requirement, following development of similar plans for 2017, 2018 and 2019.

[Find the 2019 Annual Report on Risk Evaluations](#)

[Find the 2018 Annual Report on Risk Evaluations](#)

[Find the 2017 Annual Report on Risk Evaluations](#)

Chemical Risk Evaluation Process

As required by TSCA Section 6(b)(4)(B), on June 22, 2017, EPA issued a final rule entitled *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (Risk Evaluation Process Rule) specifying procedures for chemical risk evaluation under TSCA. This final rule established the process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including unreasonable risks to potentially exposed or susceptible subpopulations, under the conditions of use. This process incorporates the science requirements of the amended statute, including use of best available science and weight of the scientific evidence. As part of each risk evaluation, EPA will conduct a peer review following public release of the draft evaluation to obtain expert feedback on the science that underlies the risk determination and increase public transparency in the risk evaluation process. This will provide greater surety that the risk determination is supported by the best available science and weight of the scientific evidence. The agency will identify aspects of the analysis upon which peer review will be conducted, and the planned methodologies, as part of the draft scoping document that will undergo public comment. Peer reviews will be informed by executive branch peer review directives including OMB's Final Information Quality Bulletin for Peer Review and EPA's Peer Review Handbook.

[Read the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act](#)

First 10 Chemicals Undergoing EPA-Initiated Risk Evaluation

EPA was required under the statute to commence ten EPA-Initiated risk evaluations in December 2016, and risk evaluations for at least 20 high-priority chemicals 3.5 years after enactment of the Lautenberg Act (December 2019). EPA's designation of the first ten chemical substances on December 19, 2016, pursuant to the requirements of TSCA Section 6(b)(2)(A), constituted the commencement of the risk evaluation for each of these chemical substances. These chemicals are: 1, 4-Dioxane, Methylene Chloride, 1-Bromopropane (1-BP), N-Methylpyrrolidone, Asbestos, Pigment Violet 29, Carbon Tetrachloride, Trichloroethylene, Cyclic Aliphatic Bromide Cluster (HBCD), and Tetrachloroethylene.

[Find the webpages for each of the ten chemicals](#)

In November 2018 EPA released the first draft risk evaluation on Pigment Violet 29 and provided the public with a 60-day public comment period as required in the Risk Evaluation Process Rule. In March and April 2019, EPA provided the public with additional information that informed this risk evaluation and re-opened the docket for an additional public comment period to July 2019, in light of the newly publicly available information. Since then, EPA in 2019 issued five additional draft risk evaluations for 60-day public comment periods, for the chemicals 1,4-Dioxane (June 2019); HBCD (June 2019); 1-BP (August 2019); Methylene Chloride (October 2019) and N-methylpyrrolidone (November 2019). Peer review meetings have been conducted for all six draft evaluations released in 2019. From January through April 2020, EPA released the remaining four draft risk evaluations, Carbon Tetrachloride, Trichloroethylene (TCE), Asbestos, and Perchloroethylene (Perc, PCE). The peer review meetings for all four chemicals have occurred or have been scheduled and will conclude by early June 2020. In FY 2020, EPA intends to finalize all risk evaluations for the first 10 chemicals.

[Read the Draft Risk Evaluation for all of the chemicals for which drafts have been released to date](#)

20 EPA-Initiated Risk Evaluations Commenced in 2019

TSCA, as amended, requires the EPA to conduct a prioritization process to identify low-priority chemicals, for which risk evaluation is not warranted at this time, and high-priority chemicals which must immediately begin the risk evaluation process. In July 2017 EPA issued a final rule entitled *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* (Risk Prioritization Process Rule) laying out the procedures for prioritization of chemicals for risk evaluation under TSCA. EPA implemented the Prioritization Process during 2018 and 2019. In August 2019, EPA released proposed designations of 20 low-priority chemicals, followed by proposed designations of 20 high-priority chemicals. After reviewing public comments, EPA in December 2019 finalized the designations of 20 high-priority chemicals for risk evaluation and commenced the evaluations immediately afterward. The agency released draft scope documents for each of these chemicals for public comment in March and April 2020 and expects to finalize them in June 2020. In accordance with statutory

timelines, EPA will publish final risk evaluations within 3 years of initiation, with a possible 6-month extension.

EPA carefully reviewed public comments on the proposed designations of 20 low-priority chemicals and finalized the low-priority designation of these chemicals in February 2020.

[Read the list of the 20 high-priority chemicals for risk evaluation](#)

[Read the list of the 20 low-priority chemicals](#)

Manufacturer-Requested Risk Evaluations (MRREs)

In May 2019, EPA received manufacturer requests to conduct risk evaluations of diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP). These belong to a family of chemicals called phthalates and are commonly used as plasticizers in the production of plastic and plastic coating to increase flexibility. In August 2019 EPA asked for public comment on the two manufacturer requests and, based on the comments received and EPA's review of the requests, EPA granted both requests in December 2019 and the risk evaluations are now in progress. The agency expects to release draft scope documents in the third quarter of FY 2020, complying with statutory timelines.

In March 2020 EPA received a facially complete manufacturer request to conduct a risk evaluation on octamethylcyclotetrasiloxane (D4). EPA expects to ask for public comment on this request and make a final determination as to whether to grant this request within FY 2020. The agency may receive additional requests in FY 2020 and will conduct the process to review these requests as directed in the Risk Evaluation Process Rule.

Resources Necessary for Risk Evaluations

On September 27, 2018, EPA finalized the *Fees for the Administration of the Toxic Substances Control Act* (Fees Rule), thereby implementing through notice and comment rulemaking the fee provisions of amended TSCA. The 2016 amendments to TSCA provide EPA with authority to collect fees from certain chemical manufacturers (including importers) and processors to defray a portion of TSCA implementation costs (up to 25% of agency costs for implementing TSCA Section 4, 5, 6 and 14, averaged over three-year periods of time). The final rule became effective on October 18, 2018. Under the final rule, affected businesses began incurring fees on October 1, 2018. The rule requires payment from manufacturers who submit information to EPA under TSCA Section 4, submit a notice, exemption application, or other information under TSCA Section 5 and who manufacture a chemical substance that is the subject of a risk evaluation under TSCA Section 6(b). Fees also apply to processors in certain circumstances under Sections 4 and 5. For each EPA-initiated risk evaluation, including those commenced for 20 high-priority chemicals in December 2019, a flat fee of \$1.35 million is due 120 days after publication of the final scope documents. The required fee payment will be shared among manufacturers of the chemical substance. In addition, the rule establishes fees for MRREs at either 50% or 100% of the actual costs associated with the evaluation, depending on whether

or not the chemical is included in the TSCA Work Plan for Chemical Assessments: 2014 Update. For each of the two manufacturer-requested evaluations commenced in December 2019, a down payment of \$1.25 million has been collected by EPA, with the remainder due upon completion of the evaluations in three years.

TSCA requires EPA to review fees and consider updating the fees rule every three years to ensure fees are adequate to defray 25% of the costs for implementing TSCA Section 4, 5, 6 and 14, and to consult with stakeholders again if fees change. In 2020 EPA expects to begin this process to review fees and propose certain exemptions to the current rule's self-identification requirements associated with EPA-initiated risk evaluations for manufacturers that Import the chemical substance in an article, produce the chemical substance as a byproduct, and produce or import the chemical substance as an impurity.

[Read the TSCA Work Plan for Chemical Assessments: 2014 Update](#)

On January 27, 2020, EPA published preliminary lists of manufacturers (including importers) of the 20 chemicals designated as high-priority for risk evaluation to help determine the appropriate division of fees. The agency is providing a 60-day comment period during which manufacturers/importers are required to self-identify as a manufacturer of a high-priority substance irrespective of whether they are included on the preliminary lists.

[Read the Fees Rule Here](#)

Estimates of the resources necessary to complete risk evaluations, the draft and final rule, public comments and other supporting documents are found in docket EPA-HQ-OPPT-2016-0401 at [regulations.gov](https://www.regulations.gov).

[Read Cost Estimates in the Technical Background Document](#)

This report serves as the 2020 annual plan for risk evaluations as required under TSCA Section 26(n).