

2019 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.

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

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

Chemical Risk Evaluations

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* on 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.

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

Scope and Problem Formulation Documents on the First 10 Chemicals Undergoing Risk Evaluation

EPA was required to initiate ten risk evaluations in 2016, and at least 20 more for High Priority chemicals within 3.5 years after enactment of the Lautenberg Act, or by 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 initiation of the risk evaluation for each of these chemical substances. These chemicals are: 1, 4-Dioxane, Methylene Chloride, 1-Bromopropane, N-Methylpyrrolidone, Asbestos, Pigment Violet 29, Carbon Tetrachloride, Trichloroethylene, Cyclic Aliphatic Bromide Cluster (HBCD), and Tetrachloroethylene.

TSCA Section 6(b)(4)(D) requires that not later than 6 months after the initiation of a risk evaluation, EPA publish the scope of the risk evaluation to be conducted, including the hazards,

exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. EPA published the scope documents for the first 10 chemicals on June 22, 2107.

Because of time constraints in issuing 10 scope documents in 6 months under a new statute, EPA took an additional step of issuing problem formulation documents, which are refinements to the scope documents. Future scope documents will include the additional elements, such as conceptual models, found in the problem formulation documents for the first 10 chemicals. EPA published and took comments on the problem formulation documents in June 2018. The comments on the problem formulation documents have informed the draft risk evaluations. The scope and problem formulation documents are available on each of the ten chemical webpages.

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

Draft Risk Evaluations for the First 10 Chemicals Undergoing Risk Evaluation

The *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* requires 60-days of public comment on the draft risk evaluations and that each draft risk evaluation be peer reviewed by the Science Advisory Committee on Chemicals (SACC). 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 Rule. In March and April EPA provided the public with additional supplemental information that informed the risk evaluation and re-opened the docket for an additional public comment period in light of the newly publicly available information. EPA expects to hold the SACC peer review in the spring of 2019 and finalize the risk evaluation in December 2019.

[Read the Draft Risk Evaluation for Pigment Violet 29](#)

EPA expects to publish the remaining nine draft risk evaluations in the summer of 2019, followed by a 60-day public comment period, and hold the SACC peer reviews in summer and early fall of 2019. EPA intends to publish the final risk evaluations for these nine chemicals by December 2019 which adheres to the statutory requirement to complete the risk evaluations within 3 years of initiation.

Prioritization of Chemical Substances

Prioritization, as required under TSCA Section 6(b)(1)(B), is the initial step in the process of existing chemical substance review and risk management activity established under TSCA. On June 22, 2017, EPA issued a final rule entitled *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* on the procedures for prioritization of chemicals for risk evaluation under TSCA. This Final Rule establishes the process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time. The Final Rule describes the processes for formally initiating the prioritization process on a

chemical, providing opportunities for public comment, screening the chemical against certain criteria, and proposing and finalizing the designation of priority.

[Read the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act](#)

TSCA gives limited direction as to how chemicals will be identified as candidates for prioritization, and therefore the Final Rule indicated that EPA would initiate a public process to discuss how such candidate chemicals should be identified. To initiate a dialogue, EPA requested public comments and on December 11, 2017, EPA held a public meeting to discuss possible approaches for identifying potential candidate chemicals for EPA's prioritization process under TSCA. In September 2018 EPA published *A Working Approach for Identifying Potential Candidate Chemicals for Prioritization*. The document lays out EPA's near-term approach for identifying potential chemicals for prioritization and includes a longer-term risk-based approach for managing the larger TSCA chemical landscape.

[Read A Working Approach for Identifying Potential Candidate Chemicals for Prioritization](#)

TSCA requires that the prioritization process be not less than 9 months and not more than 12 months. On March 20, 2019, EPA initiated prioritization for 40 chemicals – 20 potential Low-Priority candidates and 20 potential High-Priority candidates. This announcement begins a 90-day public comment period. In July EPA expects to publish the proposed priority designation for the 40 chemicals, which is followed by a second 90-day public comment period. This is followed by the final priority designation, so that by December 22, 2019, EPA will have designated 20 substances as Low Priority and initiated risk evaluations on 20 High Priority substances. EPA is on track to meet these milestones.

[Read about the Chemicals Undergoing Prioritization](#)

Resources Necessary for Risk Evaluations

On September 27, 2018, EPA finalized the “Fees for the Administration of the Toxic Substances Control Act” 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. 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. In addition, the rule establishes fees for manufacturer-requested risk evaluations at either 50% or 100% of the actual costs associated with the evaluation, dependent on whether or not the chemical is included in the TSCA Work Plan for Chemical Assessments: 2014 Update.

[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.

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

This report serves as the 2019 annual plan for risk evaluations as required under TSCA Section 26(n). Scope and problem formulation documents have been published for the first ten chemicals undergoing risk evaluation. The draft risk evaluation for PV-29 has been published for public comment and the Agency is continuing its work on developing the draft risk evaluations for the other nine chemicals and is on schedule for completion by the statutory deadline. For review of existing chemicals beyond the first ten, EPA has published the list of the next 40 candidate chemicals to undergo the prioritization process and finalized rules on the process for prioritizing and evaluating chemicals.