2018 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

1. 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

EPA was required to initiate ten risk evaluations in 2016, and at least 20 more within 3 years after enactment of the Lautenberg Act, or by December 2019. The law required that the initial ten chemicals be drawn from the 2014 Update of the TSCA Work Plan for Chemical Assessments and that EPA publish the list of the initial 10 chemicals within 180 days of enactment. 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
1-Bromopropane
Asbestos
Carbon Tetrachloride
Cyclic Aliphatic Bromide Cluster (HBCD)
Methylene Chloride
N-Methylpyrrolidone
Pigment Violet 29
Trichloroethylene
Tetrachloroethylene

Scope Documents for the first 10 Chemicals Undergoing Risk Evaluation

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.

Read the scope documents for each of the ten chemicals.

Read the Federal Register notice announcing the scope documents.

Problem Formulation Documents for the first 10 Chemicals Undergoing Risk Evaluation

Because of time constraints in issuing 10 scope documents in 6 months under a new statute, EPA is taking 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 anticipates publishing and taking comments for 45-days on problem formulation documents in early calendar year 2018. Comments on the problem formulation documents will inform the draft risk evaluations.

A federal register notice will announce the release of the problem formulation documents. Problem formulation documents will also be made available on each of the ten chemical webpages.

Find the webpages for each of the ten chemicals.

2. Chemical Risk Prioritization

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 is silent 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 entitled *Approaches for Identifying Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA* to discuss possible approaches for identifying potential candidate chemicals for EPA's prioritization process under TSCA.

Read about the December 11, 2017 public meeting.

TSCA requires that the prioritization process be not less than 9 months and not more than 12 months. EPA therefore expects to initiate prioritization for 40 chemicals – at least 20 Low-Priority and 20 High-Priority candidates – by the end of calendar year 2018, so that by December 22, 2019, EPA will have designated 20 substances as Low-Priority and initiated risk evaluations on 20 High-Priority substances. To meet this schedule, in 2018 EPA expects to have determined how it will identify candidates for prioritization.

Resources Necessary for Risk Evaluations

On January 18, 2017, EPA submitted an initial report to Congress, as required under Section 26(m)(1) of TSCA. The report included the best estimates available at that time of the resources necessary to conduct risk evaluations. This report to Congress was required 6 months after enactment of the Lautenberg amendments and every 5 years thereafter.

Read the Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

TSCA provides EPA the authority to establish fees for certain activities under Sections 4, 5 and 6 of TSCA to defray 25 percent of the costs of administering these Sections and Section 14. EPA expects to propose a draft TSCA Fees Rule in early-mid Fiscal Year 2018 and anticipates a final TSCA Fees Rule in late Fiscal Year 2018. The TSCA Fees Rule proposal is currently undergoing interagency review. When published, the proposal will provide estimates of the resources required to undertake risk evaluations.

Conclusion

This report serves as the 2018 annual plan for risk evaluations as required under TSCA Section 26(n). Scope documents have been published for the first ten risk evaluations. Problem formulation documents are anticipated to be released in early calendar year 2018. The Agency is continuing its work on the initial ten risk evaluations and is on schedule for completion by the statutory deadline. For chemicals beyond the first ten, EPA has finalized rules on the process for prioritizing and evaluating chemicals, and is continuing to engage stakeholders on possible approaches for identifying potential candidate chemicals for EPA's prioritization process. The

TSCA Fees Rule Proposal is expected to be published in early-mid FY 2018 and will provide updated estimates of the resources necessary to undertake risk evaluations.