# **EPA's Recent Release of its "Spring 2023" Regulatory Agenda: Upcoming Toxic Substances Control Act (TSCA) Actions**

#### Released June 2023

The US Environmental Protection Agency (EPA) on June 13, 2023, released its "Spring 2023" regulatory agenda detailing its upcoming rulemakings, including TSCA-related rules. Also in June 2023, EPA finalized a rulemaking to bolster confidential business information requirements and released its proposed procedural rule for new chemicals. While EPA has begun to release multiple proposed risk management rules under section 6 of TSCA, multiple planned regulatory actions are still delayed, including the majority of the TSCA risk management rules, likely due to funding and resource challenges.

EPA's agenda continues to reflect the following priorities: advancing risk management regulations, improving transparency, clarifying procedures for new and existing chemical evaluations, data collection from companies for new and existing chemicals and substantially increasing fees from companies regulated under TSCA.

## TSCA Risk Evaluation and Risk Management Rules for Existing Chemicals

EPA continues to have a large workload for evaluating and regulating existing chemicals under section 6 of TSCA. In addition to its work on risk management rules summarized below, EPA is currently working on risk evaluations for 20 high-priority chemicals and three manufacturer-initiated risk evaluations (MREs) and is considering a request for a fourth MRE.

New Risk Management Rules for the "First Ten" Chemicals: Section 6(a) of TSCA mandates that EPA issue risk management rules necessary to mitigate the risks of chemical substances which it determines through risk evaluations present an unreasonable risk of injury to health or the environment. EPA began evaluating these chemicals in December 2016, and has now issued proposed risk management rules for three of the ten chemicals based on risk evaluations completed after the Lautenberg Act was enacted. Falling further behind in meeting its statutory obligations, EPA has further delayed the release dates of the risk management rules for the "first ten" chemicals from the deadlines outlined in the Fall 2022 regulatory agenda:

	"First Ten" Chemicals	Expected Release Date for Proposed Risk Management Rule	Expected Release Date for Final Risk Management Rule
1.	Asbestos Part 1: Chrysotile Asbestos <sup>2</sup>	Released April 2022; supplemental notice released March 2023	January 2024
2.	Methylene chloride	Released May 2023	June 2024
3.	Perchloroethylene (PCE)	Released June 2023	August 2024
4.	Trichloroethylene (TCE)	Delayed from June 2023 to October 2023	October 2024
5.	Carbon tetrachloride	Delayed May 2023 to September 2023; cleared OMB review on June 30	October 2024

<sup>&</sup>lt;sup>1</sup> EPA also promulgated a risk management final rule for methylene chloride in paint and coating removers for consumer use in 2019 that was based on a risk assessment published before the Lautenberg Amendments were enacted. See 40 C.F.R. § 751.101, et seq.

<sup>&</sup>lt;sup>2</sup> Asbestos Part 2: Legacy Uses and Associated Disposals is not in the regulatory agenda.



	"First Ten" Chemicals	Expected Release Date for Proposed Risk Management Rule	Expected Release Date for Final Risk Management Rule
6.	1-Bromopropane	Delayed from September 2023 to November 2023	March 2025
7.	N-methylpyrrolidone (NMP)	Delayed from September 2023 to October 2023	December 2024
8.	Cyclic aliphatic bromide cluster (HBCD)	Delayed from February 2024 to April 2024	Delayed indefinitely ("TBD")
9.	C.I. pigment violet 29 (PV29)	May 2024	Delayed indefinitely ("TBD")
10.	1,4-Dioxane	August 2025	Delayed indefinitely ("TBD")

- Revised Risk Evaluations: While EPA has moved to the risk management phase for the majority of the "first ten" chemicals, it is continuing to conduct additional work on 1,4-dioxane and asbestos. In June 2023, EPA announced that it was seeking external peer reviewers to assist in the Science Advisory Committee on Chemicals (SACC) review of a forthcoming draft supplement to the 1,4-dioxane risk evaluation. EPA is evaluating certain exposure pathways, such as drinking water and ambient air, and conditions of use where the chemical is generated as a byproduct that were not included in the final risk evaluation. While EPA has not stated when the draft risk evaluation supplement will be released, it is expecting to release the proposed 1,4-dioxane risk management rule in August 2025.
  - EPA, also in June 2023, <u>announced</u> that it is seeking peer reviewers to review a forthcoming "2023 White Paper on the Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2." EPA will be seeking input on the quantitative approach for assessing cancer and non-cancer risks for Part 2 of the risk evaluation for asbestos. It has not announced when it will release the risk evaluation for Asbestos Part 2.
- Proposed Changes to Procedural Rule for Chemical Risk Evaluation: EPA is proposing revisions to its existing regulation on chemical risk evaluations. The existing regulation outlines the procedures and information EPA considers in TSCA section 6(b)(4) risk evaluations, including the scoping process, hazard assessment, exposure assessment, risk characterization, peer review and risk determination. While the regulatory agenda does not specify what revisions the agency is considering, EPA has suggested publicly that this rulemaking will codify the "whole chemical approach"—although it has already issued eight final risk determinations using this approach without amending the risk evaluation regulation which has been in effect since 2017. On June 29, 2023, EPA sent the proposed rule to OMB for interagency review. EPA intends to release the proposed rule by September 2023, and finalize the rule by November 2024.
- Revised Risk Management Rules for PBT Chemicals: EPA expects to propose revised risk management rules for the five persistent, bioaccumulative and toxic chemicals (PBTs) subject to TSCA section 6(h): decabromodiphenyl ether (DecaBDE); phenol, isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); hexachlorobutadiene (HCBD) and pentachlorothiophenol (PCTP). EPA is initiating revised rulemakings in response to industry concerns about implementation when the risk management rules were originally released in January 2021, and to broadly consider how Biden Administration executive orders will be addressed in the rules. EPA states in the regulatory agenda that it is considering revisions to all five of the final rules to further reduce exposures, promote environmental justice and better protect human health and the environment. EPA plans to issue the proposed revised rules in October 2023, and is no longer providing an expected completion date for the final rules.

#### **Fees**

• Increased TSCA Fees: In November 2022, EPA took comment on a <u>supplemental notice of proposed rulemaking</u> to revise its fees for administering the TSCA program. TSCA requires that EPA review and adjust fees every three years. EPA has stated publicly that companies should expect to see "significant" increases in TSCA fees due to the agency's budget and personnel shortage. EPA continues to delay the date of when it expects to finalize the fees



### Reporting and Recordkeeping

- Tiered Data Reporting to Inform Prioritization, Risk Evaluation and Risk Management: EPA has delayed its plans to propose a rule under sections 8(a) and 8(d) of TSCA to establish reporting requirements for chemicals undergoing risk evaluation and risk management under section 6 of TSCA and update the reporting requirements under the Chemical Data Reporting (CDR) regulation. EPA is developing this rule to obtain information about potential hazards and pathways for occupational, environmental and consumer exposure related to certain chemicals. EPA intends to use this information to inform prioritization, risk evaluation, and risk management of the substances under TSCA section 6. The Small Business Administration is considering conducting a Small Business Advocacy Review (SBAR) panel for this rulemaking. EPA has delayed the release of the proposed rule to February 2024, and plans to finalize the rule by July 2025.
- Expansive Reporting Rules for Asbestos and PFAS: This year, EPA plans to finalize two significant reporting rules regarding asbestos and PFAS under TSCA section 8. The final asbestos rule, which has yet to be released (it was expected to be finalized by June 2023, although it has cleared OMB review), would require manufacturers and processors of asbestos and asbestos-containing articles within the past four years to report exposure-related information to EPA. The proposed PFAS rule proposes to require companies that have manufactured or imported certain PFAS and PFAS-containing articles since January 1, 2011, to report information on uses, production volumes, disposal, exposures and hazards to EPA. EPA conducted an SBAR panel to evaluate the impacts of the rule on small businesses. The report from the SBAR panel was released for public comment in November 2022. We discuss the implications of the proposed PFAS reporting rule here. EPA is now expecting to finalize this reporting rule in September 2023.

## New Chemicals and Significant New Use Rules (SNURs)

- New Series of SNURs for High Priority Chemicals and PFAS: EPA plans to propose a series of SNURs for certain chemicals, which would require companies to submit significant new use notices (SNUNs) at least 90 days prior to manufacturing (including importing) or processing the chemical for that significant new use. By June 2023, EPA intended to propose SNURs for certain uses of "phthalates," "certain solvents" and chemicals undergoing <u>risk evaluation</u> identified in EPA's scoping documents as "not currently ongoing." However, these proposals have not been released yet. In June 2023, EPA released a proposed SNUR for "flame retardants." Comments on this proposal are due August 7, 2023. In January 2023, EPA proposed a SNUR for uses of PFAS substances that are on the "inactive" portion of the TSCA Inventory, meaning the substances have not been manufactured, imported or processed in US commerce since 2006. EPA intends to finalize this PFAS SNUR in December 2023.
- New Chemical Procedural Regulations: In May 2023, EPA proposed a rule aimed at increasing the efficiency of new chemical reviews and aligning them with the 2016 Lautenberg Amendments. EPA also proposed to codify some existing procedures and to eliminate some exemptions for PFAS and PBT chemicals. Comments on this proposal are due July 25, 2023, and EPA intends to finalize the rule in February 2025.



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