

EPA’s Recent Release of its “Fall 2022” Regulatory Agenda – Upcoming Toxic Substances Control Act (TSCA) Actions

Released January 2023

The US Environmental Protection Agency (EPA) on January 4, 2023, released its [“Fall 2022” regulatory agenda](#) detailing its upcoming rulemakings, including TSCA-related rules. EPA’s robust agenda primarily delays the release of upcoming regulatory actions, including already long-awaited TSCA risk management rules and data collection requirements.

EPA’s agenda continues to reflect an effort by the agency to gather significantly more information from companies about new and existing chemicals, improve transparency, clarify its procedures for new and existing chemical evaluations, require more from companies who seek to protect confidential information, and substantially increase fees for companies regulated under TSCA.

EPA’s Office of Chemical Safety and Pollution Prevention (OSCP) FY23 budget provides \$19.72 million more than FY22 funding, far short of \$64.66 million the White House had requested. The timelines in the new “Fall 2022” regulatory agenda are likely a reflection of the continued funding and resource challenges the agency faces in meeting its obligations under the Lautenberg Amendments to 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 that it determines through risk evaluations present an unreasonable risk to human health and the environment. EPA began evaluating these chemicals in December 2016 and has issued a proposed risk management rule for only one of the ten chemicals based on a risk evaluation completed after the Lautenberg Act was enacted: chrysotile asbestos (Part 1).¹ EPA has further delayed the release dates for the risk management rules for the “first ten” chemicals from their deadlines outlined in the Spring 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 ²	Released April 12, 2022	October 2023
2.	Methylene Chloride	February 2023 (at OMB)	August 2024
3.	Perchloroethylene (PCE)	Delayed from February 2023 to April 2023	August 2024
4.	Trichloroethylene (TCE)	Delayed from March 2023 to June 2023	September 2024
5.	Carbon Tetrachloride	Delayed from April 2023 to May 2023	August 2024

¹ EPA released a risk management rule in 2019 that was based on a risk assessment published before the Lautenberg Amendments were enacted: methylene chloride in paint and coating removers for consumer use. 40 C.F.R. § 751.101.

² EPA has removed “Asbestos Part 2: Legacy Uses and Associated Disposals” from its 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 May 2023 to September 2023	August 2024
7.	N-methylpyrrolidone (NMP)	Delayed from December 2022 to September 2023	August 2024
8.	Cyclic Aliphatic Bromide Cluster (HBCD)	Delayed from July 2023 to February 2024	Delayed from July 2024 to February 2025
9.	C.I. Pigment Violet 29 (PV29)	Delayed from July 2023 to May 2024	Delayed from August 2024 to May 2025
10.	1,4-Dioxane	Delayed indefinitely (“TBD”)	Delayed indefinitely (“TBD”)

- [Revised Risk Evaluations and Risk Determinations for the “First Ten” Chemicals to Conform with Biden Administration Policies:](#)** While not listed on the regulatory agenda, EPA is also evaluating certain exposure pathways, like 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 evaluations published for some of the “first ten” chemicals. EPA’s projected timing for the 1,4-dioxane risk management rule is “TBD” because EPA is reconsidering the risk evaluation to consider these previously excluded exposures. EPA is also taking a screening approach to consider air and water exposure pathways for TCE, PCE, NMP, and methylene chloride and may decide to revise their risk evaluations in the future.

EPA has finalized revisions to [risk determinations](#), which are components of the risk evaluations, for eight of the first ten chemicals to align with the agency’s [“whole chemical approach”](#) of having one risk determination for the “whole chemical” based on the majority of conditions of use evaluated. This approach differs significantly from EPA’s previous practice of making a separate risk determination for each condition of use for a given chemical. The revised risk determinations reflect EPA’s baseline assumption that workers use personal protective equipment (PPE) inappropriately or not at all. With the 1,4-dioxane risk management rule delayed indefinitely, any changes to 1,4-dioxane’s risk determination are unlikely to occur until the planned risk evaluation revisions are completed.

- [Proposed Changes to Procedural Rule for Chemical Risk Evaluation:](#)** EPA plans to propose revisions to its existing regulation on chemical risk evaluations by May 2023 (which is delayed from September 2022). The current 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 incorporate the “whole chemical approach”—although EPA has already issued eight final risk determinations using this approach without amending the risk evaluation regulation that has been in effect since 2017. Interestingly, EPA still does not provide an expected timeline for finalizing this important framework rule.
- [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 November 2023 (rather than June 2023) and final rules by September 2024.

Fees

- **Increased TSCA Fees:** In November 2022, EPA took comment on a [supplemental notice of proposed rulemaking](#) 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 expects to finalize the fees rule in September 2023.

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 from May 2023 to January 2024 and plans to finalize the rule by May 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 [proposed asbestos rule](#), expected to be finalized by May 2023, 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 March 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 manufacture or processing the chemical for that significant new use. By April 2023, EPA intends to propose SNURs for certain uses of “[phthalates](#),” “[flame retardants](#),” “[certain solvents](#),” and [chemicals undergoing risk evaluation](#) identified in EPA’s scoping documents as “not currently ongoing.” 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:** EPA plans to propose rules aimed at increasing the efficiency of new chemical reviews and aligning them with the 2016 Lautenberg amendments. EPA delayed the release of this proposed rule from February 2023 to July 2023, with plans to finalize it by November 2024.

Confidential Business Information (CBI)

- **Bolstered CBI Requirements:** EPA expects to finalize by February 2023 its proposal to consolidate TSCA’s CBI requirements and revise regulations governing CBI claims. EPA’s May 2022 proposal includes several substantive and procedural revisions to CBI requirements, including: requiring electronic submissions of CBI claims and substantiations; requiring companies to keep contact information up to date so that EPA can communicate with them electronically (through CDX); revising the CBI substantiation questions; codifying the guidance for generating a generic name for confidential chemical substances; clarifying what information can be redacted from data submitted to EPA; and applying the CBI requirements not only to TSCA submissions but also to other submissions that EPA uses for TSCA purposes. Failure to comply with the CBI requirements can result in denial of claims and loss of CBI protections.

Hunton Andrews Kurth LLP's environmental team has the legal knowledge and scientific background required to address [chemical](#) regulatory and compliance challenges. Our natural resource and chemical attorneys work together with our firm's in-house scientist and policy advisors to create comprehensive strategies for our clients nationwide.

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