

EPA's Spring Regulatory Agenda – Upcoming Toxic Substances Control Act (TSCA) Actions

Released June 2022

The Environmental Protection Agency (EPA) recently released its [Spring 2022 Regulatory Agenda](#) detailing its upcoming rulemakings, including TSCA-related rules. EPA's robust agenda covers new chemicals, existing chemical evaluations and regulations, data reporting, confidential business information, and TSCA fees. EPA is also taking actions not listed in the regulatory agenda to revise chemical assessments performed by the Trump administration to reflect the new Biden Administration policies.

EPA's agenda reflects 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 (OSCPP) recently requested that Congress authorize more than double the appropriations and 50 percent more personnel to manage the Agency's workload, including these new regulatory actions, and to reduce delays in carrying out its obligations under TSCA. Whether EPA receives the resources it has requested will have an impact on its proposed timelines for regulatory actions.

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 Fall 2021 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*	Released April 12, 2022	Expected November 2023
2.	Methylene Chloride	Delayed from December 2022 to February 2023	Delayed from July to August 2024
3.	Perchloroethylene (PCE)	Delayed from December 2022 to February 2023	Expected August 2024
4.	Trichloroethylene (TCE)	Delayed from October 2022 to March 2023	Delayed from June to August 2024
5.	Carbon Tetrachloride	Delayed from October 2022 to April 2023	Delayed from June to 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.

	“First Ten” Chemicals	Expected Release Date for Proposed Risk Management Rule	Expected Release Date for Final Risk Management Rule
6.	1-Bromopropane	Delayed from October 2022 to May 2023	Delayed from May to August 2024
7.	N-methylpyrrolidone (NMP)	Delayed from December 2022 to May 2023	Delayed from July to August 2024
8.	Cyclic Aliphatic Bromide Cluster (HBCD)	Delayed from September 2022 to July 2023	Delayed from April to July 2024
9.	C.I. Pigment Violet 29 (PV29)	Delayed from November 2022 to July 2024	Delayed from June to August 2024
10.	1,4-Dioxane	Delayed indefinitely (“TBD”)	Delayed indefinitely (“TBD”)

* Note: EPA expects the risk evaluation for Asbestos Part 2: Legacy Uses and Associated Disposals to be released December 1, 2024.

- [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 is also considering revisions to [risk determinations](#), which are a component of the risk evaluations, for each of the first ten chemicals to align with the Agency’s position on the [“whole chemical approach,”](#) that is, have one risk determination for the “whole chemical” based on the majority of conditions of use evaluated, rather than individual risk determinations for each condition of use. The revised risk determinations will also reflect EPA’s baseline risk scenarios that do not assume workers always appropriately use personal protective equipment (PPE). EPA has not provided a timeline for these actions. As of July 8, 2022, EPA has released draft revised risk determinations for [PV29](#), [NMP](#), [PCE](#), [TCE](#), and [methylene chloride](#), and a final revised risk determination for [HBCD](#). EPA expects to release revised risk determinations for the remaining “first ten” chemicals: asbestos (Part 1 and Part 2 combined), 1,4-dioxane, carbon tetrachloride, and 1-bromopropane.

EPA has stated that it expects to miss its statutory deadlines for the “first ten” chemicals.

- [Proposed Changes to Procedural Rule for Chemical Risk Evaluation](#): EPA plans to propose revisions to its existing regulation on chemical risk evaluations by 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 this rulemaking will incorporate the “whole chemical approach”—although EPA has already issued one final and five proposed revised risk determinations using this approach without amending the risk evaluation regulation that has been in effect since 2017. Interestingly, EPA 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): DecaBDE; PIP (3:1); 2,4,6-TTBP; HCBP; and 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 plans to re-examine the rules “with an eye towards reducing exposure to the extent practicable, environmental justice, scientific integrity, and EPA’s mission of protecting human health and the environment.” EPA plans to issue the revised rules in June 2023 and final rules by September 2024.

Fees

- **Increased TSCA Fees:** EPA plans to issue a supplemental notice of proposed rulemaking by October 2022 in light of public comments received on its January 2021 [proposed rule](#) to revise its fees to administer the TSCA program. The proposed rule is currently [under review](#) at OMB. 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.

Reporting and Recordkeeping

- **Tiered Data Reporting to Inform Prioritization, Risk Evaluations, and Risk Management:** EPA plans to propose by May 2023 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. Because EPA is required to evaluate 20 chemicals at any given time, EPA needs to “maintain a pool of potential candidate chemical substances” to ensure a sufficient number of substances are ready to be prioritized and potentially evaluated. This proposal seeks to ensure that EPA can gather information from companies on chemicals during each stage of the prioritization, risk evaluation, and risk management processes. EPA [announced](#) on July 6, 2022 that it is inviting small businesses to participate in a Small Business Advocacy Review (SBAR) Panel for this proposed rule.
- **Expansive Reporting Rules for Asbestos and PFAS:** This year, EPA plans to finalize two significant reporting rules under TSCA Section 8 for companies to report information on asbestos and PFAS. The proposed asbestos rule, expected to be finalized by November 2022, would require manufacturers (including importers) and processors of asbestos and asbestos-containing articles within the past four years to report exposure-related information to EPA. The proposed PFAS rule, expected to be finalized by December 2022, 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. These proposed rules do not contain exemptions for impurities, byproducts, or trace amounts of chemicals in products. Companies must report information that is “known or reasonably ascertainable by” the company, which includes the duty to conduct a reasonable inquiry within the organization and potentially ask upstream suppliers or downstream users for information. We discuss the implications of the proposed PFAS reporting rule [here](#).

New Chemicals and Significant New Use Rules

- **New Series of SNURs for High Priority Chemicals and PFAS:** EPA unveiled for the first time a proposed series of significant new use rules (SNURs) for new or resumed uses of chemicals EPA has designated as “high priority” in order to manage the potential risks of new or returned uses of the substances while they are undergoing risk evaluation. EPA interestingly does not name the chemicals it plans to issue SNURs for, but they may cover most or all of the 30 chemicals EPA is evaluating under Section 6 of TSCA. Between September and December of 2022, EPA will propose SNURs for conditions of use for “phthalates,” “flame retardants,” “certain solvents,” and “other chemicals undergoing risk evaluation” identified in EPA’s scoping documents as “not currently ongoing.” EPA has also proposed a SNUR for uses of PFAS substances that are on the “inactive” portion of the TSCA Inventory, meaning the substances are not currently manufactured, imported, or processed in U.S. commerce.

Finally, EPA is also finalizing a SNUR on its long-term agenda (with no release date yet) for uses of alkylpyrrolidone products except for the ongoing uses as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives. This SNUR was proposed in November of 2016.

- **SNUR on Hazard Communication:** EPA released its long-awaited rule on July 5, 2022 (ahead of its projected release date of October 2022) amending its SNUR governing hazard communication requirements to align with revisions made to hazard communication standard (HCS) in 2012 by OSHA. (Note that OSHA plans to finalize yet another update to the HCS by [December 2022](#) to align with Revision 7 of the UN Globally Harmonized System of Classification and Labelling of Chemicals or GHS.) The regulation also reflects changes in OSHA’s Respiratory Protection Standard and the NIOSH respirator certification requirements.
- **New Chemical Procedural Regulations:** By February 2023, EPA plans to propose rules aimed at increasing the efficiency of new chemical reviews and aligning them with 2016 Lautenberg amendments. This procedural rule is

part of a broad effort [announced by EPA](#) last month to help improve transparency to companies who submit pre-manufacture notifications (PMNs) and low volume exemptions (LVEs) and help reduce unnecessary delays from having to “rework” cases in the risk assessment process. EPA plans to conduct extensive stakeholder outreach and training to discuss how it evaluates data and common issues that cause delays in the PMN and LVE review process. These efforts are in conjunction with other Agency initiatives, such as creating a streamlined process for new biofuels and increasing coordination with EPA’s Office of Research and Development, to address the backlog of PMNs the Agency continues to struggle to reduce.

Confidential Business Information

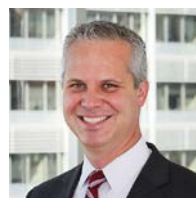
- **Bolstered CBI Requirements:** In May 2022, EPA proposed a rule to consolidate the CBI requirements into one regulation and revise the regulations for CBI claims. The proposal includes several substantive and procedural revisions to CBI requirements, including: requiring electronic submissions of 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 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. EPA expects to finalize this rule by May 2023.

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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