wiley

ALERT

EPA Eliminates *De Minimis* Exemption for PFAS Under TRI Reporting, Proposes Changes to Chemical Risk Evaluations Under TSCA

October 26, 2023

This alert was originally published on October 26, 2023, and last updated on October 31, 2023.

The U.S. Environmental Protection Agency (EPA or Agency) has issued two notable regulatory actions that may affect your business. The first one, a final rule, will increase the amount of information that companies must provide on Per- and Polyfluoroalkyl Substances (PFAS) in their 2025 Toxic Release Inventory (TRI) reports. The second one, a proposed rule, would realign the risk evaluation procedures for existing chemicals under the Toxic Substances Control Act (TSCA) to reflect current Administration principles (e.g., a "whole chemical approach") for how Congress intended Section 6 to be implemented and thereby ensure that all future Agency actions will be undertaken consistent with those principles. Comments on the risk evaluation proposed rule are due by December 14, 2023, 45 days after publication of the proposal in the Federal Register.

On October 31, 2023, EPA published a final rule that applies to PFAS subject to reporting under Section 313 of the Emergency Planning and Community Right-to Know Act (EPCRA). In practice, this means that for Toxic Release Inventory (TRI) reporting of PFAS, EPA has eliminated the following options for companies:

- The use of the *de minimis* exemption from supplier notification requirements, that allowed facilities to avoid reporting information on PFAS when those chemicals were used in small concentrations;

Authors

Martha E. Marrapese
Partner
202.719.7156
mmarrapese@wiley.law

Tracy Heinzman
Partner
202.719.7106
theinzman@wiley.law

Sara Beth Watson
Of Counsel
202.719.7071
swatson@wiley.law

Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

- The option for companies to use the simplified Form A (Alternate Threshold Certification Statement) reporting form. Companies will have to use Form R for PFAS reporting; and
- The option to use ranges for reporting PFAS releases and off-site transfers for further waste management.

This final rule will become effective November 30, 2023, and will apply for the reporting year beginning January 1, 2024 (reports due **July 1, 2025**). EPA estimates that this amendment will result in an additional 623 to 2,015 Form R reports being filed annually. EPA estimates that the costs of this action will be approximately $3,318,492 and $10,733,149 in the first year of reporting and approximately $1,580,214 and $5,111,044 in the subsequent years.

By way of background, EPCRA Section 313 requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above the applicable reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually, by July 1. The 2020 National Defense Authorization Act (NDAA) requires that certain regulatory activities automatically result in the addition of PFAS substances to the TRI list, such as EPA issuing a final toxicity value or if the substance is subject to a TSCA Significant New Use Rule (SNUR). Therefore, the list of TRI-reportable PFAS is growing as EPA continues to establish final toxicity values and issue SNURs for PFAS.

On October 30, 2023, EPA published a proposed rule to amend the procedural framework rule for conducting risk evaluations under TSCA. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. EPA is proposing to align these procedures with the Administration's view and experience as to how the risk evaluation program should be implemented.

EPA is proposing that the changes to the procedures as part of this rulemaking would be applied to all risk evaluations initiated on or after the date of the final rule. For risk evaluations in process as of the date of the final rule, EPA would expect to apply the proposed changes to those risk evaluations only to the extent practicable, taking into consideration the statutory requirements and deadlines. Proposed amendments include:

- Definitions
  - Although the rule's procedural requirements generally refer to "chemicals" or "chemical substances," EPA is proposing to clarify that those references also apply to categories of chemical substances.
  - EPA is proposing to eliminate the codified definitions for "best available science" and "weight of scientific evidence." Instead, EPA intends to ensure that its risk evaluations are consistent with EPA's guidance and methodologies in applying these terms. EPA is proposing to amend the regulatory definition of "potentially exposed or susceptible subpopulations" to add "overburdened

communities" – communities that may be disproportionately exposed or impacted by environmental harms – to the list of example subpopulations.

- Scope of TSCA Risk Evaluations

  - EPA is proposing changes in the rule to ensure that risk evaluations include all relevant exposure pathways. Specifically, EPA is proposing to explicitly require that each risk evaluation assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other federal statutes.

- Risk Determinations
  - EPA is proposing that risk evaluations will always culminate in a single risk determination on the "chemical substance" instead of individual risk determinations on individual conditions of use.
  - Regarding "unreasonable risk," the proposed rule clarifies that EPA would consider the risk to potentially exposed or susceptible subpopulations as part of its determination of whether or not the chemical presents unreasonable risk.
- Risk Evaluation Considerations
  - EPA is proposing to eliminate consideration, as part of the unreasonable risk determination, of exposure reduction based on assumed use of personal protective equipment (PPE) by workers, as EPA assumed during the first ten TSCA chemical risk evaluations.
  - EPA is seeking comment on how the Agency could incorporate provisions for cumulative risk assessment into risk evaluations that would include consideration of categories of chemicals.
- Science Policy and Scientific Standards
  - This proposed rule states that EPA will continue to use existing Agency guidance and methodology documents in the development of TSCA risk evaluations, and EPA may develop and use additional guidance as needed using a transparent process.
  - Rather than peer reviewing an entire risk evaluation, EPA proposes that it may be appropriate to conduct peer review only on portions or sections that constitute unreviewed influential information.
  - EPA is clarifying that a TSCA risk evaluation may use peer reviewed products (e.g., risk assessments, hazard assessments, models), or portions thereof, conducted by another EPA office or other authoritative body (e.g., state, national, or international programs), for which both the best available science and weight of scientific evidence standards were adhered to.
  - Consistent with the 2017 proposed and final rules, EPA will not seek peer review of any determination as to whether the risk is "unreasonable," which is an Agency policy determination.
- Process for EPA Revisions to Scope or Risk Evaluation Documents
  - EPA is proposing some new procedures and criteria for whether and how EPA would endeavor to revise or supplement final scope documents and draft or final risk evaluations.

- Process and Requirements for Manufacturer-Requested Risk Evaluations
  - In cases where multiple manufacturers jointly submit a MRRE (i.e., a consortium), EPA expects to treat a consortium as a single entity for purposes of any regulatory determinations with regard to the requests, fee payments, and other general communication regarding the MRRE request and/or the risk evaluation.
  - EPA is proposing that manufacturers only be permitted to make requests for comprehensive evaluations of chemical substances – not individual conditions of use or subsets of conditions of use.
  - EPA is proposing changes that would require more fulsome information as part of the request, based on information that is known to or reasonably ascertainable by the requesting manufacturer. More specifically, EPA is proposing to require that manufacturers include a listing of the chemical's conditions of use and all information known to or reasonably ascertainable by the requesting manufacturer that supports the identification of those circumstances.
  - Where the requesting manufacturer believes that they can neither collect nor develop the identified information, they may request that EPA obtain the information using its authorities under TSCA sections 4, 8, or 11. As part of such a request, the manufacturer must provide a rationale as to why the information is not reasonably ascertainable to them.
  - EPA is proposing changes to the steps the Agency will take upon receipt of a MRRE, including additional measures for transparency and public engagement.

There are many far-reaching implications in the proposed rule, and Wiley's TSCA practitioners would be happy to discuss them with you. The 2016 TSCA amendments required that EPA establish a procedural framework rule on the process for conducting chemical risk evaluations. EPA finalized a risk evaluation framework rule in 2017 that was quickly challenged in court. The United States Court of Appeals for the Ninth Circuit in *Safer Chemicals v. EPA* determined that risk evaluations for existing chemicals must include legacy uses and associated disposals. The 9th Circuit decision left open for future consideration several of the areas that EPA is proposing for change.

Companies, especially ones that foresee being affected by any of the proposed amendments, are encouraged to submit comments on this proposal. These risk evaluations are proving to be an unprecedented resource and time-intensive task for EPA. Input from companies can provide useful information and ensure that the rule that is eventually adopted will improve the clarity and efficiency of this process.