

EPA PUBLISHES EXTENSIVE PFAS CHEMICAL REPORTING RULE WITH WIDE-RANGING IMPACTS

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SUMMARY

Quick Take #1: EPA has finalized a rule requiring companies which, since January 1, 2011, manufactured, produced, or imported PFAS chemicals for a commercial purpose, whether as a chemical substance or in a mixture or article, to report an expansive range of data that includes the type(s) of PFAS chemical, volume, uses (commercial, industrial and consumer), disposal information, and information on environmental and health effects.

Quick Take #2: The new rule will impact many companies which do not currently realize that they are impacted, and it will require regulated entities to perform a significant amount of work to collect and submit the information to EPA on the timeline required by the rule.

On September 28, 2023, the United States Environmental Protection Agency (“EPA”) issued a [pre-publication rule](#) for reporting and recordkeeping requirements regarding per- and polyfluoroalkyl substances (“PFAS”) under the Toxic Substances Control Act (“TSCA”). EPA is requiring businesses that manufacture or import PFAS chemicals, or have manufactured or imported PFAS chemicals in the past, to submit a significant amount of information to EPA dating back to **January 1, 2011**.

This rule will become effective thirty (30) days after the rule is published in the Federal Register. According to [EPA](#), “Any entities, including small entities, that have manufactured (including imported) PFAS in any year since 2011 will have 18 months following the effective date of this rule to report PFAS data to EPA.” Companies will then be required to report information from January 1, 2011, through the end of the calendar year that precedes the final effective date (which will likely mean December 31, 2022, if the final rule is published in 2023).

AM I AFFECTED?

The rule, which will be promulgated at 40 C.F.R. Part 705, specifically affects companies which manufacture or have manufactured (including importation) PFAS chemicals for a commercial

purpose. TSCA treats this as a very broad category of activities that includes importation, production, or manufacturing for the purpose of obtaining an immediate or eventual commercial advantage, including commercial distribution, test marketing, use in product R&D, and use as an intermediate.

The rule also requires reporting of PFAS chemicals present in mixtures and articles containing a regulated PFAS chemical. The regulation of articles containing PFAS chemicals is a relatively novel concept given articles are often excluded from certain TSCA-related requirements. Furthermore, the rule also captures PFAS chemicals generated as a byproduct or impurity of the manufacturing or production of other chemical substances.

So, what does all of this mean practically speaking? It means that the reporting obligation applies to:

- Companies that manufacture or import PFAS compounds themselves;
- Companies that manufacture or import mixtures or compounds which include PFAS (e.g., one or more PFAS are ingredients); and
- Companies that manufacture or import articles that contain PFAS (e.g., products which contain PTFE).

The third category is by far the broadest, and the area where compliance will be most challenging because many companies may unknowingly use PFAS chemicals in their products, and they will now need to track and report that use going back over ten years.

HOW IS THE TERM "PFAS" DEFINED UNDER THIS RULE?

For purposes of this rule, EPA has expanded the definition of PFAS from the original proposed rule and estimates that the rule applies to at least 1,462 PFAS chemicals. Of these, two are substances that have been most recognized and regulated to date: perfluorooctane sulfonate ("PFOS") and perfluorooctanoic acid ("PFOA").

In this rule, EPA broadly defines PFAS as any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three sub-structures:

- $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons;
- $R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons; and
- $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons.

WHAT DO I NEED TO REPORT?

The list of information to be submitted is extensive. The [rule](#) states that regulated companies will need to provide the following information (which we have summarized at a high level, but the rule provides more detail) for all manufacture, import, or production dating back to 2011:

- **Company and facility information;**
- **Chemical specific information**, including chemical identity and molecular structure;
- Information on **industrial processing and use** (for the regulated entity – what industries use it and for what purposes);
- Information on **consumer and commercial use** (who uses it downstream and for what purposes);
- **Quantities** manufactured, produced, or imported in each calendar year since January 1, 2011;
- **Description of the byproducts** resulting from the manufacture, processing, use or disposal of PFAS chemicals, including information on releases into the environment;
- “All existing information concerning the **environmental and health effects**” of the relevant PFAS chemical in the company’s possession or control, which is not limited to information published since 2011;
- Information regarding **worker exposure**, including the number of individuals exposed, activities performed by the workers, and exposure scenarios and duration; and
- Information regarding **disposal of PFAS chemicals**, including amounts and disposal methods.

Additionally, EPA is developing a streamlined reporting form for article importers to use, which will vary from the reporting requirements for manufacturers or producers. Importers of articles containing PFAS chemicals will be required to report not only estimated information as to the amounts and types of PFAS chemicals contained in the imported articles (subject to reasonable due diligence), but also information relating to the total volume of articles imported that contain PFAS.

WHAT KIND OF INVESTIGATION DO I HAVE TO DO?

In general, the obligation is for regulated companies to report information already in their possession or control, plus “all information that a reasonable person similarly situated might be expected to possess, control, or know.” EPA has indicated that this reporting standard requires:

“[A]n exercise of due diligence, and the information-gathering activities that may be necessary for manufacturers to achieve this reporting standard may vary from case-to-case. This standard would require that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees).

This standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. Such activities may, though not necessarily, include phone calls or email inquiries to upstream suppliers or downstream users or employees or other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing of the PFAS."

Notwithstanding the foregoing, significant questions remain about the extent of the internal review and data collection that must be completed. How much analysis is required to understand potentially hidden or difficult to ascertain PFAS information, especially in records or products from ten years ago when PFAS concerns were not as prevalent, and PFAS was not as regulated? Is an analysis required for every product (using a PFAS chemical) produced or imported since January 1, 2011? What information about downstream use must be completed? And what does "all information that a reasonable person similarly situated might be expected to possess, control, or know" mean?

Regulated companies need to give significant thought, in partnership with legal counsel, as to their process for complying with this rule, as well as how to document those efforts. For example, regulated companies should consider the nature of their operations and product lines and how they would demonstrate their method of compliance to a third party such as EPA or a private litigant who questions it, perhaps even years after the report is submitted.

ADDITIONAL CONSIDERATIONS

- **Reporting Methodology:** Reporting will be conducted using EPA's CDX database. The submission period will end 18 months after the rule becomes published in the Federal Register.
- **Confidentiality Claims:** Regulated companies should carefully assess what information included in their submittal qualifies for claims of confidential business information ("CBI"), and should follow all current TSCA procedures (including those in the rule) for the assertion of such claims at the time of submittal. Notably, certification requirements may be required for CBI claims.
- **Recordkeeping:** Records relevant to information reported to EPA must be maintained for five years from the last day of the submission period. Please note, however, that other provisions of TSCA (or other laws) may require longer retention period for certain data.
- **Enforcement:** Failure to submit necessary information, or to undertake the requisite investigation, can lead to civil or criminal penalties under TSCA.
- **CERCLA Liability:** EPA is expected to list PFOA and PFOS as hazardous substances under CERCLA in early 2024. Under this new TSCA rule, EPA (and potentially private litigants) will have access to a significant amount of information assembled and reported by industry regarding the manufacturing, use, and disposal of PFAS chemicals which could potentially be

used as evidence in cost recovery or other actions under CERCLA. Refer to BCLP's discussion in a [prior Client Alert](#) for additional information regarding the impending changes to CERCLA.

CONCLUSION

BCLP has a simple recommendation for entities regulated by this complicated rule – get started now. Begin digesting the rule, developing a strategy for compliance, and gathering information to identify gaps and questions that need to be answered. Given the nature of the inquiries this rule requires and a 10+ year look-back period, 18 months will pass very quickly.

For more information on PFAS chemicals, and the regulatory and liability risks that they pose, please visit our [PFAS webpage](#). If you have a question the TSCA reporting requirements, contact Tom Lee, Bryan Keyt, Thor Ketzback, Erin Brooks, John Kindschuh, or any other member of our PFAS team at Bryan Cave Leighton Paisner LLP.

RELATED CAPABILITIES

- PFAS

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