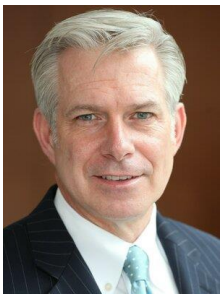
EPA's Final PFAS Rule Greatly Expands Cos.' Reporting Duties

By **Lawrence Culleen and Judah Prero** (October 17, 2023)



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The U.S. Environmental Protection Agency has belatedly released its final regulation requiring extensive one-time reporting by entities that have manufactured or imported products containing any of the chemicals known as per- and polyfluoroalkyl substances.[1]

The regulation — which is little changed from the version proposed in June 2021 — applies to any entity that has manufactured or imported, for commercial purposes, any chemical substance, mixture or manufactured product that contained PFAS at any time from the start of 2011 through the end of 2022.

Congress ordered the EPA to impose such reporting requirements in a provision of the National Defense Authorization Act for fiscal year 2020, and to do so not later than Jan. 1 of this year. The provision — which added Section 8(a)(7) to the Toxic Substances Control Act, or TSCA — directs the agency to promulgate a rule requiring "each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011" to report certain information.[2]

The final rule implementing this mandate will greatly expand compliance obligations for entities subject to the rule, as well as their risks of exposure to EPA enforcement actions — especially for entities that ordinarily might not have an awareness of the TSCA. This comes at a time when multiple states, such as Maine and Minnesota, are gearing up to impose their own reporting obligations on any entity that distributes PFAS-containing products in the U.S.

The final rule imposes reporting obligations on traditional manufacturers and importers of chemical substances and mixtures who are likely to be familiar with the TSCA generally. Importantly, the obligations also apply to U.S. businesses not typically subject to TSCA reporting requirements.

These include businesses that import everything from stain- and water-resistant garments to complex, highly technical products that contain many hundreds of individual component parts — such as certain mobile phones, televisions, automobiles and even aircraft — that may be manufactured using small quantities of PFAS.

Substantial sectors of the U.S. economy will need to develop an awareness of the new rule's requirements, and begin making timely inquiries of their suppliers if they hope to avoid potential violations of the rule. Penalties could exceed $45,000 per day per violation.[3]

Enormous Scope of New Requirements

The scope of PFAS subject to the new reporting rule is significantly broader than for the EPA's periodic TSCA Section 8(a) reporting requirements for chemical manufacturers and importers, known as the Chemical Data Reporting rule.

Unlike the CDR rule, the final PFAS reporting rule establishes no lower limit, or de minimis threshold, on the amount of PFAS that must be present in the material manufactured or

imported during the periods covered for reporting to be required.

CDR reporting exempts many substances — including many polymers, substances present only as impurities, certain byproducts and all research and development chemicals. And chemical substances present in imported manufactured products have never been reported to the EPA pursuant to the CDR rule. This is not so with the final PFAS reporting rule.

The final rule excludes PFAS from reporting only if the PFAS is produced solely for use as a pesticide, or in food, food additive, drug, cosmetic or medical device uses.[4] However, the rule requires reporting on PFAS when manufactured for virtually any other use — including when present as an unintentional impurity or byproduct of manufacturing, and when imported as a component in manufactured articles.

This might include articles such as office machinery and manufacturing equipment containing components that may come to contain PFAS during manufacturing abroad. There is no exemption offered for substances produced only in small quantities — such as certain laboratory reagents and other substances used only for research and development efforts — or for substances unintentionally present in another product or mixture.

The EPA has elected not to exempt small businesses. The agency's only gestures in recognition of the enormity of its new requirements are to provide that importers and manufacturers of PFAS-containing articles and research and development substances in quantities below 10 kilograms per year will have the option to submit more streamlined reporting forms than the longer, standard form, and will have a longer time frame during which to report.

The final PFAS reporting rule also will gather much more information than the EPA obtains in the four-year CDR reports — including previously unreported data on health and environmental studies that pertain to PFAS.

Unknown Number of Substances Covered by Final Rule

Rather than provide a list in the final rule of the specific substances for which reporting is required, the EPA has adopted a structural definition for PFAS intended to define the boundaries of the substances for which reporting is required.[5]

This leaves uncertainty on the number of substances for which reporting will be required. But, as discussed below, this is reasonably likely to be in the thousands.

The agency defends this approach by saying it has "determined that a structural definition was more appropriate for this rule than a discrete list of specifically identified substances," and that "limiting the scope of reporting to a discrete list of chemicals would eliminate reporting on substances of interest to the Agency."

The EPA says that this is because there are:

> various reporting exemptions for both existing chemicals (e.g., certain byproducts and research and development (R&D) substances are exempt from reporting in the Chemical Data Reporting (CDR) rule) and new chemicals (e.g., byproducts and impurities that are not listed on the Inventory), and with minimum reporting thresholds under other rules, EPA may be unaware of some TSCA chemical substances which meet this structural definition of PFAS.

Moreover, the agency cites as precedents other TSCA requirements that have relied on a structural definition, such as the significant new use rule for long-chain perfluoroalkyl carboxylate substances[6] and the polymer exemption rule for new chemical premanufacture notices.[7]

Thus, the PFAS subject to the final requirements include:

> any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three sub-structures:
>
> (1) R-(CF2)-CF(R')R'', where both the CF2 and CF moieties are saturated carbons
>
> (2) R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons
>
> (3) CF3C(CF3)R'R'', where R' and R"" can either be F or saturated carbons.[8]

The structural definition in the final rule reflects edits made to the definition in the June 2021 proposal. These are detailed in the preamble to the final rule.

Some of the changes noted were made to "expand the universe of PFAS to include additional substances of potential concern because they are likely to be persistent." The EPA reports that changes are intended to focus the "definition on those substances most likely to persist in the environment."

For example, the "final definition does not include substances that only have a single fluorinated carbon or unsaturated fluorinated moieties (e.g., fluorinated aromatic rings and olefins)," because "the latter set of substances are more susceptible to chemical transformation than their saturated counterparts, and therefore, are less likely to persist in the environment."

Furthermore, unlike the PFAS definition being employed in some state PFAS reporting requirements, "[the] EPA has determined that, for the purpose of this rule, it is unnecessary to extend reporting requirements to substances that only have a single fluorinated carbon or unsaturated fluorinated moieties," as these substances are "less likely to persist in the environment."

Nevertheless, the EPA made other changes to the definition to be certain to "capture certain fluorinated ethers" which it "believes … are likely to be found in water." One other change was made to ensure the structural definition will "capture a different type of branching for highly fluorinated substances" that would not have the proposed definition "due to their non-adjacent fluorinated carbons."

In spite of numerous public comments received from trade groups and chemical manufacturers recommending otherwise, the EPA has affirmed that "fluoropolymers which meet this rule's definition of PFAS are reportable under this rule; this includes higher molecular weight fluoropolymers."

The agency estimated that the structural definition used in the proposed edition of the rule would have captured as many as 9,400 substances.[9] Both the proposed and final definitions would still be narrower than the structural definition employed by the Organization of Economic Cooperation and Development, which the EPA estimates would capture as many as 23,000 additional substances.[10]

Streamlined Reporting for Imported Articles Containing PFAS

As mentioned, the EPA has declined to exempt the importers of PFAS-containing articles from the PFAS rule. The agency concluded that exempting article importers from the scope of the rule would "perpetuate data gaps in EPA's level of knowledge related to PFAS manufactured for a commercial purpose since 2011" because of the reporting exemptions for articles in other TSCA reporting rules.

The EPA states that after considering comments concerned about requiring reporting on PFAS in products, the agency "is finalizing a reporting option for article importers to provide data to EPA on a streamlined form, if they do not know or cannot reasonably ascertain information requested on the longer standard form."

The EPA explains that while this streamlined form would still request information including chemical identity, processing and use information, and production volume, "[t]he production volume requested is the volume of the imported article, rather than the PFAS."

The rule explains that based on information received during the small business advocacy review process, the agency "believes it is more likely that an article importer is able to determine the total imported production volume of articles rather than the volume related to just the PFAS contained within the article."

Length of Time Permitted for Compliance

The EPA has extended the reporting deadline originally included in the proposed rule, which would have provided a six-month information collection period, followed by a six-month reporting period.

The final rule extends the deadline for reporting forms by at least six months from what was proposed. The final rule provides all entities, including small entities, with 18 months from the effective date of the final rule to gather and submit the requested information.

For small manufacturers — as defined at Title 40 of the Code of Federal Regulations, Section 704.3 — whose reporting obligations under the final rule are exclusively from article imports, the agency has increased the deadline for reporting forms by an additional six months.

Thus, small article importers have 24 months from the effective date of the rule to submit the required information. This provides potential reporters a year and a half following the effective date of the final rule to collect and submit all required information to the EPA.

But given the complex nature of the supply chains for the manufacturers and importers of highly complicated manufactured durable goods — such as certain household appliances, office equipment, transportation equipment and military hardware — even this extended time frame could pose significant hurdles to compliance.

Production and Use Information and Unpublished Data Subject to Reporting

The EPA is requiring reporting for each site of each of the PFAS in a long list of data elements, reportable "to the extent known to or reasonably ascertainable by" the manufacturer. The information elements include:

- Company and plant site information for each site at which a reportable chemical substance is manufactured;
- Chemical name and specific identity;
- Trade or common name;
- Representative molecular structure;
- Physical form of chemical or mixture;
- Industrial processing and use information;
- Consumer and commercial use information;
- Manufactured amounts, including production volumes;
- Whether the substance is imported for use on-site or solely for distribution;
- Whether the uses are site-limited;
- Maximum quantity stored on-site at any time;
- Total volume recycled on-site;
- For byproducts produced during the manufacture, processing, use or disposal of each PFAS, identifying information for the chemical and its releases to the environment, if any;
- Worker exposure at various sites;
- Disposal processes;
- Total volume released and incinerated on-site;
- All existing information related to health and environmental effects, using the Organization of Economic Cooperation and Development harmonized templates;[11] and
- Other data relevant to health and environmental effects. The scope of this final category of information is not limited to studies conducted or published since 2011.

Level of Diligence Required

Under the final rule, manufacturers must report information "to the extent known to or reasonably ascertainable by" the submitter.[12] This includes "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."[13]

This reporting standard is the same as in other TSCA regulations, such as the CDR rule. As the EPA advises,

> This reporting standard requires reporting entities to evaluate their current level of knowledge of their manufactured products (including imports), as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. This standard carries with it an 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.

The agency notes that submitters will need to "conduct a reasonable inquiry within the full scope of their organization." Meeting the reporting standard also may entail inquiries outside the submitter's organization "to fill gaps in the submitter's knowledge."

The EPA notes in the preamble to the final rule that 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."

The agency has created additional compliance guidance related to this reporting standard, including for small entities and for article importers.[14] It therefore anticipates many reporters under this rule are familiar with this reporting standard, and resources are available to support those reporters who may not be familiar with the standard.

However, given that this rule applies to many entities not previously subject to TSCA reporting, and given the fact-dependent nature of the reporting standard, companies will likely confront numerous questions about what constitutes a reasonable inquiry.

The EPA acknowledges in the proposed rule that importers of articles may lack knowledge of importing PFAS, and recommends such importers "document [their] activities to support any claims [they] might need to make related to due diligence."[15]

Because submitters may have reported some information required by this rule due to CDR requirements, the agency has made certain accommodations for reporters to indicate in the reporting tool — i.e., its Central Data Exchange — when they previously provided such information through CDR for certain years. The manufacturer will still need to submit any other information required by the final rule.

Accomodation for Confidential Business Information Claims

Similar to other TSCA reporting rules, the EPA will permit entities submitting a reporting form to claim portions of the form as confidential.[16]

The agency will require the submitter to substantiate its confidential business information claims, and certain information may not be claimed confidential — such as the specific identity of substances that are listed on the public version of the TSCA inventory, as well as most information included in a health and safety study.

Similarly, a submitter may not claim as confidential a response left blank or designated as "not known or reasonably ascertainable."

Required Recordkeeping

The EPA is imposing a five-year recordkeeping period, which begins on the last date of the submission period — i.e., 18 months after the effective date of the final rule. The rule does

not itself require any company to maintain information upon which a decision not to report is based.

Potential Enforcement-Related Implications

The reporting to the EPA of information previously not submitted to the agency raises the opportunity for enforcement personnel to review the new information — and potentially raise concerns about the information, and whether it is consistent with previously reported information, or should have been submitted previously to the agency.

For example, reporting information to the EPA about the manufacture or import of PFAS that are not on the active portion of the TSCA inventory, or are not listed on the inventory at all, could lead to allegations that a violation of the TSCA's Section 8 chemical reactivation requirements, or Section 5 requirements concerning new chemical notification, may have occurred.

Submitters reporting new forms of production, use and release information for PFAS that also have been subject to reporting for purposes of the Toxics Release Inventory rule also could raise enforcement concerns within the EPA.

Importantly, the requirement to provide previously unreported data and information relevant to health and environmental effects could have profound implications for submitters of existing data that heretofore has not been shared with the agency.

A separate provision of the TSCA, Section 8(e), requires the immediate submission to the EPA of information "which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment."

An entity that reports, pursuant to this new requirement, information which the agency determines qualified for immediate reporting previously under TSCA Section 8(e) could face exposure to stiff penalties for violations of a provision of the statute which the EPA vigorously enforces.

Conclusion

The lengthy and complicated PFAS reporting rule will require manufacturers and importers of PFAS to devote considerable time and attention to determining their compliance obligations, and devising a strategy for gathering the necessary information in a timely and accurate way — and to ensuring the information prepared is carefully reviewed in light of the collateral enforcement concerns noted above before submission is made.

The failure to do so could lead to significant consequences if the EPA elects to monitor and vigorously enforce the new rule, and to exploit the information gathered for purposes of cross-checking it against information submitted — or omitted — by the same entity in the context of other TSCA regulations.

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[1] A pre-publication notice for the final rule is available here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping. See also 86 Fed. Reg. 33926 (June 28, 2021) (proposed rule).

[2] 15 U.S.C. § 2607(a)(7), as added by Pub. L. No. 116-92, Section 7351.

[3] See 15 U.S.C. §§ 2614, 2615(a)(1); 40 C.F.R. §19.4.

[4] TSCA section 3(2), 15 U.S.C. § 2602(2).

[5] The EPA is providing a list of substances that meet this definition; this list will be available in the CompTox Chemicals Dashboard at https://comptox.epa.gov/dashboard. The list is expected to contain approximately 1,462 substances meeting the final rule's definition of PFAS — an increase from the 1,364 PFAS identified for purposes of the proposed rule's definition. Nevertheless, the agency warns in the preamble to the final rule, a "substance that is not on this list but still falls under the definition of a 'chemical substance' under TSCA … is subject to this rule if the substance has been manufactured for a commercial purpose since 2011." The EPA-generated lists have been based on PFAS on the TSCA inventory and all PFAS subject to TSCA Section 5 new chemicals submissions that have been previously reviewed by the agency, and permit the substances to be produced subject to certain limitations in the U.S.

[6] 40 C.F.R. § 721.10536.

[7] 40 C.F.R. § 723.250.

[8] 40 C.F.R. § 705.3.

[9] See preamble in Section III.A.1.

[10] See preamble in Section IV.A.2.

[11] The EPA notes it intends "environmental and health effects information" to be interpreted broadly. See preamble at III.E. For example, the EPA identified the following types of information as examples: toxicity information, range-finding studies, medical screening or surveillance and adverse effects reports. Id.

[12] 40 C.F.R. § 705.15.

[13] 40 C.F.R. § 705.3.

[14] EPA, Small Entity Compliance Guidance for the TSCA PFAS Data Call (Sept. 2023).

[15] 86 Fed. Reg. 33926, 33929 (June 28, 2021).

[16] 40 C.F.R. § 705.30.