Manufacturers Face Daunting Reporting Requirements Under EPA's TSCA PFAS Reporting Rule

By Brian D. Gross

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On October 11, 2023, the US Environmental Protection Agency (EPA) published in the Federal Register a final rule, under the Toxic Substances Control Act (TSCA), that establishes reporting requirements for manufacturers of per- and poly-fluoroalkyl substances (PFAS). PFAS are synthetic chemicals that are used in various consumer products for their thermal and chemical stability, water and stain resistance, and their ability to serve as a surfactant. While the potential health effects of exposure to PFAS are still under review, PFAS have become the subject of national legislation, regulation and litigation.

EPA's October 11 publication of its final PFAS reporting rule set November 13 as the effective date of the rule. The final rule requires any company that manufactures or has manufactured PFAS (including imports), or articles that contain PFAS, in any year since January 1, 2011, to submit within 18 months of the effective date to EPA information regarding PFAS uses, production volumes, byproducts, disposal, exposures and existing information on environmental or health effects. Some small business have an additional six months to meet the reporting requirements under the rule.

Notably, the final rule utilizes a structural classification, as found in 40 CFR 705.3, to define covered PFAS, rather than identifying the particular PFAS substances subject to reporting. That structural definition for PFAS encompasses chemical substances that include at least one of the following structures:

R-(CF2)-CF(R')R'', where both the CF2 and CF moieties are saturated carbons;

R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons; and

CF3C(CF3)R'R'', where R' and R'' can either be F or saturated carbons.

That structural definition of PFAS utilized by EPA is incredibly broad and will likely include approximately 1,462 PFAS. In stark contrast, federal and state legislators and regulators, to date, have largely focused on only a handful of PFAS chemicals. As a result, the broader scope of EPA's reporting requirements will challenge PFAS manufacturers and importers, many of which have never been subject to prior regulation or retained data sought by EPA. EPA is compiling a list of substances that comport with this definition and will make the list of reportable PFAS with Chemical Abstracts Service Registry Numbers (CASRN) available on the CompTox Chemicals Dashboard. Companies must be aware, however, that even if a substance is not included in this list, it may still be reportable if it falls under the definition of a “chemical substance” pursuant to TSCA and has been “manufactured for a commercial purpose since 2011.” EPA defines “manufacture for a commercial purpose” to include the import, production, or manufacturing of a chemical substance or mixture containing a chemical substance with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer. This includes, but is not limited to, the manufacture of chemical substances or mixtures for commercial distribution, including test marketing, or for use by the manufacturer itself as an intermediate or for product research and development (R&D). “Manufacture for commercial purposes” also includes the coincidental manufacture of byproducts and impurities that are produced during the manufacture, processing, use, or disposal of another chemical substance or mixture. EPA clarifies that

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“simply receiving PFAS from domestic suppliers or other domestic sources is not, in itself, considered manufacturing PFAS for commercial purposes. Companies that have only processed, distributed in commerce, used, or disposed of reportable PFAS are not required to report under the final rule unless they also have manufactured PFAS for a commercial purpose. EPA notes that TSCA section 8(a)(7) only refers to manufacturers and that expanding the final rule to processors “would be pursuant to EPA's separate rulemaking authority at TSCA section 8(a)(1), which the agency is not pursuing at this time.” EPA will provide applicability criteria at 40 CFR 705.10 and 705.12 to help companies determine whether they are subject to this reporting rule.

EPA's final reporting rule will ultimately require manufacturers and importers to provide EPA with a list of every product they have manufactured and/or imported since 2011 that contains PFAS. That will provide EPA with a roadmap of companies to target for regulatory enforcement actions, particularly if EPA finalizes its proposed rule to designate certain PFAS as hazardous substances under CERCLA. This rule is particularly problematic following EPA's recent warning that the top priority of its Office of Enforcement and Compliance Assurance (OECA) will be the investigation and prosecution of PFAS manufacturers. As such, companies can expect that EPA will use the information it gleans from the required TSCA reporting to zero in on companies for enforcement actions. Moreover, because the information provided by manufacturers pursuant to the TSCA rule will be publicly available, state environmental agencies and plaintiffs' counsel may also use the information to form the basis for actions against reporting companies.

As a result, and due to the costs associated with compliance—EPA estimates compliance will cost industry between $800 million and $843 million—legal challenges to the final rule are expected. Those challenges will most likely come from those companies that manufacture or import products that incorporate PFAS. That is due to EPA's expansion of the rule to include reporting requirements for manufactured goods that contain PFAS, despite the fact that the 2020 National Defense Authorization Act (NDAA)—the law which prompted EPA to issue the this reporting rule under TSCA—only referred to chemical substances.

The scope of reporting required by this rule is daunting, particularly for those companies that manufacture or import PFAS-containing goods that may not be familiar with TSCA reporting and may not even be aware that PFAS was incorporated into the product. The rule requires companies to report information known to or reasonably ascertainable by the covered entity. This will necessitate inquiries both within and outside the organization. This mandatory exercise may very well take the full 18 months EPA provides, so companies should start these efforts now. It is never too early to begin developing procedures for compliance and reaching outside the organization for information necessary for compliance.

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