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Legal Insights for Manufacturing: PFAS

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As the regulatory landscape surrounding PFAS continues to develop, in the past year alone, the Environmental Protection Agency (EPA) has taken no fewer than seven new actions to address PFAS, and dozens of states continue to finalize new regulations of their own, often with greater restrictions. The many nuanced—and at times inconsistent—regulations strain the manufacturing industry as it navigates a compliance minefield.

Among the actions taken by the EPA this year, in April 2024, the agency finalized a rule to designate two widely used PFAS (Perflurooctanoic Acid, or PFOA, and Perfluorooctanesulfonic Acid, or PFOS) as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); issued a national, legally enforceable drinking water standard; eliminated the threshold for reporting certain PFAS compounds in Toxic Release Inventory reporting; and announced changes to the General Services Administration's custodial specifications to ensure that cleaning products purchased for federal buildings are free of "toxic PFAS." These new actions add to already burdensome rules imposed on manufacturers while they continue to gather data under the EPA's Toxic Substances Control Act (TSCA) Reporting and Recordkeeping Requirements for PFAS final rule.

The EPA's TSCA Rule went into effect in November 2023 with reporting deadlines extending into 2025. According to the EPA, it finalized this rule "both to fulfill its obligations under TSCA section 8(a)(7)... and to create a more comprehensive database of previously manufactured PFAS to improve the Agency's understanding of PFAS in commerce and to support actions to address PFAS exposure and contamination." Essentially, without an understanding of the extent to which PFAS is used nationwide, the EPA plans

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to use these extensive reporting requirements to gather broad information about PFAS' role in manufacturing, findings which will likely lead to additional regulations.

Initially, all entities that have manufactured or imported PFAS in any year since 2011 had 18 months following the effective date—November 13, 2023—to report the above data to the EPA; however, in September 2024 EPA granted companies an eight-month extension, citing "a budget shortfall that has delayed the agency's ability to develop a fully functioning reporting tool in time for its November start date." This decision moves the start date of the information submission period for most to July 11, 2025, which will end January 11, 2026. This amendment to the final rule also extends the reporting period for article importers that are small manufacturers (as defined by 40 C.F.R. 704.3) until July 11, 2026.

The rule requires that all manufacturers, including importers, determine which products they manufactured or imported for a commercial purpose contain PFAS, including all articles or component parts of said products. The term "manufacture" extends to "substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance," so there is no exemption for impurities. The standard for determining and reporting which products contain PFAS is "information known to or reasonably ascertainable by [the manufacturer]." "This standard carries with it an exercise of due diligence," and requires that reporting entities "conduct a reasonable inquiry within the full scope of their organization," as well as may "entail inquiries outside the organization" such as contacting "upstream suppliers or downstream users or employees or other agents of the manufacturer."

2023 TSCA RULE REPORTING & RECORDKEEPING REQS



Source: U.S. Environmental Protection Agency.

Accordingly, to be in compliance with the rule, the EPA requires any entity that manufactured or imported a product that contained PFAS at any point since 2011 to conduct its due diligence to ascertain which products or articles contained PFAS, even if the product was manufactured after 2011 but is no longer in circulation. To accomplish this, manufacturers and importers are not required to test products, but most likely will need to reach out to their suppliers, who likely will then need to reach out to their suppliers, and so on, to provide documentation indicating whether any article supplied contained PFAS. Under this rule, it will not be sufficient for, say, a chair

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manufacturer to report that no bulk PFAS was contained in the chair. The manufacturer will also need to make an effort to determine if any components of the articles, such as paint, vinyl, fabric, coating, screws, leather, etc., had PFAS in them at all.

The rule encourages entities that are not able to reasonably ascertain whether they manufactured or imported a product, or article, that contained PFAS at any time since 2011 to "document [their] activities to provide evidence of due diligence." The burden to the industry comes at no small cost: the EPA estimates that resultant costs to the industry by undertaking this process would be approximately 11.6 million hours and roughly \$800 million; furthermore, the TSCA final rule is merely one initiative of many that is in play at the federal level.

Along with the TSCA Rule and the EPA's multiplying PFAS regulations, manufacturers also face heavy state-level legislation dictating PFAS use and limitations across multiple product types, including firefighting foam, drinking water, food packaging, textiles, and other consumer products. Although these regulations have different compliance timelines and reporting requirements, they commonly emphasize a ban on "intentionally added PFAS," largely in consumer products. For example, Maryland Senate Bill 273 prohibits—beginning January 2024—"the manufacture, sale, and distribution for sale or use" of products within the state that contain "intentionally added" PFAS, including new rugs or carpets, food packaging, and firefighting foam (with several temporary exceptions). A company that manufactures or sells rugs, carpets, or food packaging in Maryland—if requested by the state—may be required to provide a certificate of compliance to attest that the product is in compliance with the law, which also provides for civil penalties that may increase up to \$1,000 per violation.

Colorado has a similar law, HB22-1345, that provides limitations beginning in January 2024, for carpets, rugs, fabric treatments, food packaging, juvenile products, and oil and gas products. This bill also requires that, if a manufacturer of cookware sells a product that contains intentionally added PFAS chemicals in the state, the product label must list the presence of PFAS chemicals and a statement that directs consumers to a website where they can find information about why PFAS chemicals were intentionally added. Likewise, Maine has a bill, H.P. 1113-L.D. 1503, that became effective in January 2023, which prohibits the sale or distribution by January 2030 of "any product that contains intentionally added PFAS," unless the state has determined that such use was "unavoidable." Like Maryland, Maine's law permits the state to require a certificate of compliance from the manufacturer if it suspects that a product contains intentionally added PFAS in violation of the law.

Navigating the ever-changing PFAS compliance landscape is burdensome, and unfortunately, it does not appear that either the federal or state governments' regulation of this area will let up anytime

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soon. Staying on top of reporting and other regulatory or legislative requirements, while costly, allows companies to avoid further government inquiries and possible civil penalties.

PFAS-RELATED FEDERAL ACTIONS, 2021-2024

2021

- Denial/Withdrawal of TSCA LVEs
- More Stringent Existing & New Chemical Manufacturing, Importation, and End-Use
- TSCA Reviews, Inventory Re-reviews, Rules, and Orders
- · TSCA Section 4 Test Orders
- PFAS Categories Identification
- Final Toxicity Assessment for PFBS & Gen X
- Increased Enforcement/Oversight via RCRA, TSCA, CWA, SDWA, CERCLA
- Total Adsorbable Fluorine (TAD) Method for Wastewater

2022

- National Ambient Water Quality Criteria for Aquatic Life
- Health Advisories for PFBS & GenX
- Voluntary Stewardship Program for Industry
- Hazardous Air Pollutant Designation
- Expanded TRI Reporting/ Chemicals of Special Concern Designation
- Soil Leaching Analytical Method
- Multimidia Test Methods for 40 PFAS
- IRIA Assessments for PFBA, PFHxS, PFHxA, PFNA, PFDA
- Annual Progress Report on PFAS Strategic Roadmap
- Final ELG Plan 15
- · National Fish Tissue Surveys
- Drinking Water Treatment Technologies

2023

- CERCLA Hazardous Substance Designation/Cost Recovery
- TSCA 2011 Retroactive Reporting
- UCMR 5 Implementation
- Additional Health Advisories
- NPDES Permitting
- Update Guidance on Destroying & Disposing PFAS
- Fish Consumption Advisory PFAS List

2024

- National Primary Drinking Water Regulations
- National Ambient Water Quality Criteria for Human Health
- · Additional Health Advisories
- · Effluent Limitation Guidelines
- Drinking Water Methods Updates
- · Biosolids Risk Assessment

Source: Adapted and revised from Trihydro Corporation.