**MAY 2025** 

# PFAS

Bans, Restrictions, Reporting, and Minimizing Liability

# What to know now, and what to expect







# Introduction

Perfluoroalkyl and polyfluoroalkyl substances (PFAS) are attracting global legal, regulatory, commercial, and litigation attention as no other "emerging contaminant" has.

Companies producing, processing, distributing, and/or using these substances must be aware of these global legal developments and take steps now to minimize legal, regulatory, and commercial risk.





Bergeson & Campbell, P.C. and The Acta Group have been deeply engaged in the science, law, and policy of PFAS for years.

We outline in this document key regulatory developments that reflect an incessant global demand for information on the manufacture, regulatory classification, testing, processing, distribution, and use of PFAS, and the legal and commercial implications of these developments.

We also identify measures stakeholders could consider to prepare for the new normal -- the relentless global drive to eliminate PFAS except in highly-regulated and explicitly approved applications deemed essential.

### In the United States and globally, the number of bans, restrictions, and reporting requirements for PFAS increases seemingly daily.

The European Union (EU) is currently considering a proposal to restrict more than 10,000 PFAS under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. If adopted, this would be the most extensive regulatory restriction on PFAS to date, in one of the world's largest markets. Other jurisdictions are considering similar measures.

The stakes are high. Companies must stay informed of the latest developments, ascertain which legal requirements apply and how each may impact business operations and risk profiles, take proactive measures as appropriate to ensure compliance with any applicable requirements, and seek to minimize legal liability.

The need to balance commercial imperatives with legal, commercial, and stewardship sensitivities is not easy, and companies need all the help they can get to make sound, informed decisions.

This document offers a high-level outline of considerations, focusing on the most significant bans and restrictions, the most impactful potential legal developments regarding PFAS, and the most important steps chemical product manufacturers should be taking now to identify, diminish, and supplant PFAS in their supply chains.

We would be pleased to provide additional information and assist with PFAS-related scientific, regulatory, or legal questions that you may have.



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# What Are PFAS?

PFAS are a group of widely used man-made organic chemical substances. They contain alkyl groups on which all or many of the hydrogen atoms have been replaced with fluorine. Well known PFAS contain fully fluorinated carbon chains of various chain lengths attached to a functional group, like carboxylic or sulfonic acids. Such groups are called perfluorinated acids and include perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS).

Shorter chain PFAS have been developed more recently to substitute the longer chain ones. In this context, an important distinction is the one between "long chain" and "short chain" PFAS. The PFAS group also includes polymers: e.g., fluoropolymers, perfluoropolyethers, and sidechain fluorinated polymers.

According to the U.S. government, nearly 15,000 chemicals are considered PFAS and are used to make fluoropolymer coatings and products that resist corrosion, grease, water, stains, and heat. The carbon-fluorine bond is the chemical backbone of PFAS and one of the shortest and strongest bonds known to exist. The bond makes PFAS highly resistant to breakdown, hence their nickname "forever chemicals." They are found in consumer and industrial applications, including non-stick coating in cookware, stain-resistant clothing, furniture, food packaging, adhesives, electrical insulation wire, tank linings, and firefighting foams.



## **Is This PFAS?**

A critical issue vexing stakeholders is the uncertainty regarding whether a particular chemical substance is a PFAS.

B&C and Acta chemists, toxicologists, and regulatory specialists live by the maxim "data rules."

Our professionals follow the data and expertly review compositional and manufacturing information to assist clients in determining chemical identity to be absolutely certain a regulatory initiative is jurisdictionally relevant. In 1999, the U.S. Centers for Disease Control and Prevention (CDC) measured at least 12 PFAS in human blood serum, indicating exposure to these chemicals in the U.S. population. PFAS contamination in humans and in the environment is believed to be pervasive.

While the measurable presence of a substance in serum alone tells us nothing about whether that presence causes an adverse effect, it is clear people do not want PFAS to contaminate their bodily fluids, consumer products, or groundwater supplies.



Source: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A52020SC0249



The current regulatory landscape in the United States is primarily focused on PFAS in the soil or drinking water given their potential to facilitate exposure to humans. On October 18, 2021, the U.S. Environmental Protection Agency (EPA) announced its <u>PFAS</u> <u>Strategic Roadmap</u>, laying out a whole-of-agency approach to addressing PFAS.

The Strategic Roadmap is centered on three guiding strategies: increase investments in **research**; leverage authorities to take immediate action to **restrict** PFAS chemicals from being released into the environment; and **remediate** PFAS contamination.



EPA is also focusing on enforcement of measures to restrict PFAS. Many PFAS are subject to Toxic Substances Control Act (TSCA) Significant New Use Rules (SNUR) or Consent Orders that provide specific conditions with which a company must comply for the manufacture, processing, distribution, or disposal of the substance.

EPA has also in the recent past stepped up issuance of information requests and notices of inspection to companies subject to SNURs or Consent Orders for PFAS. Due to EPA's strong focus on controlling and remedying the damage caused by PFAS, EPA can be expected to make use of its extensive TSCA enforcement authorities to penalize non-compliance with SNURs, Consent Orders, or other provisions applicable to PFAS.



States are also moving at a faster pace and are comprehensive enacting regulations that restrict or ban PFAS in a broad range of products. Most frequently, states restrict or ban the use of PFAS in firefighting foams, food contact materials, pesticides, and consumer products. Some of these state bans are now in effect, while others will become effective in the Once upcoming years. effective. the prohibitions apply to companies marketing products within the state. EPA issued the first ever national drinking water standards for certain PFAS on April 26, 2024. Certain states have passed or are proposing maximum contaminant levels (MCL) for certain types of PFAS in groundwater or wastewater.

Several of these state regulations involve reporting requirements for PFAS, and more states will consider reporting schemes in 2025. These regulations are increasing at a rapid pace, and the scope of PFAS reporting and/or bans is extensive. Minnesota, for example, will essentially ban any product containing intentionally added PFAS as of **January 1**, **2032**, with narrow exemptions for uses deemed currently unavoidable uses (CUU). Companies can expect similar bans to be enacted in other states as well.

**Knowing** about these developments is essential. **Preparing to comply** with them is another matter, requiring careful and strategic consideration of legal and commercial factors involving litigation, insurance, and brand-management expertise.

## **More Information:**

- <u>CPSC Requests Information on PFAS in Consumer Products</u> (Sept. 25, 2023)
- EPA Authors Describe Categorization Approach to PFAS to Identify Potential Candidates for Testing and Human Health Assessments (Aug. 21, 2024)
- <u>U.S. Chamber of Commerce Releases Report Examining Impact</u> of Essential Fluorochemistries (Sept. 12, 2024)
- <u>NSF Announces PFAS-Free Certification for Nonfood</u>
  <u>Compounds and Food Equipment Materials</u> (Apr. 7, 2025)
- **EPA Outlines Actions to Address PFAS** (Apr. 29, 2025)



B&C and Acta professionals assist clients with evaluating potential liabilities in chemical product lifecycles and supply chains. Identifying precisely where in the supply chain PFAS may enter will often influence the regulatory status of a PFAS and will certainly influence business operations and commercial options.

Our professionals develop innovative and resilient product stewardship and compliance strategies based on this information to help identify and manage risk and thus minimize potential liability.

## Where Are PFAS?





# Expanding U.S. Requirements

## Federal Reporting Requirements for PFAS Manufactured in the United States

The fiscal year 2020 (FY2020) National Defense Authorization Act (NDAA) amended TSCA to add Section 8(a)(7), mandating that EPA 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.

EPA's October 2023 <u>final rule</u> requires all manufacturers (including importers) of PFAS in any year since 2011 to report information related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal. EPA states that the rule will help it better characterize the sources and quantities of PFAS manufactured in the United States and support its research, monitoring, and regulatory efforts.

This reporting standard requires submitters to conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). This standard also entails inquiries outside the organization to fill gaps in the sub-

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mitter's knowledge. Such activities may include phone calls or e-mail 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."

### Key aspects of the rule include:

- No exemption for small businesses.
- No exemption for PFAS produced as byproducts.
- No exemption for PFAS-containing articles (including articles containing PFAS as part of surface coatings).
- On September 5, 2024, EPA issued a direct final rule postponing the reporting period. The submission period will begin July 11, 2025, and end January 11, 2026. Article importers that are also considered small manufacturers will have until July 11, 2026, to submit reports.
- On May 12, 2025, EPA announced an interim final rule that will postpone the reporting period to April 13, 2026. Submissions are due October 13, 2026. Reports from small manufacturers reporting exclusively as article importers are due April 13, 2027.

On May 2, 2025, a coalition of chemical companies petitioned EPA to amend the reporting rule. Filed under TSCA Section 21 and the February 19, 2025, Executive Order on Ensuring Lawful Governance and Implement the President's "Department of Government Efficiency" Deregulatory Initiative, the petition states that EPA's rule should have included "the typical TSCA 8(a) reporting exemptions (e.g., by-products, impurities, articles, [research and development (R&D)] materials, and a production volume threshold)" that apply in other TSCA Section 8(a) reporting rules. According to petitioners, although EPA maintains that

TSCA Section 8(a)(7) is a standalone subsection to TSCA Section 8(a), it applies the Section 8(a)(2) "known or reasonably ascertainable" due diligence standard and the Section 8(a)(5) bar against duplicative or unnecessary reporting, but not the Section 8(a) (1) exemption for small manufacturers. The petitioners ask that EPA revise the reporting rule to exclude imported articles, R&D materials, impurities, byproducts, non-isolated intermediates, and PFAS manufactured in quantities of less than 2,500 pounds (lb.). Petitioners also request that EPA remove the requirement to submit "all existing information concerning the environmental and health effects' of the chemical substance covered by" the reporting rule and instead allow "robust summaries, similar to the approach adopted by the European Chemicals Agency" (ECHA).

- EPA Releases Final TSCA Section 8(a) (7) Reporting Rule for PFAS (Oct. 3, 2023)
- EPA Holds Webinar on PFAS Reporting <u>Rule Requirements</u> (Jan. 30, 2024) Webinar on Demand -- "<u>Determining</u>
- PFAS Content in Your Supply Chain and Expanding Data Collection Practice" (July 23, 2024)
- EPA Will Postpone Submission Period for TSCA Section 8(a)(7) Reporting on PFAS (Sept. 4, 2024)
- EPA Proposes to Update Proposed SNURs for 17 PFAS, Designating Manufacture (Including Import) as a Significant New Use (Dec. 6, 2024)



## State Reporting Requirements for Products Containing Intentionally Added PFAS

At this time, Minnesota and New Mexico have enacted broad PFAS reporting requirements. With Minnesota's January 1, 2026, reporting deadline fast approaching for reporting on products containing intentionally added PFAS, on April 21, 2025, the Minnesota Pollution Control Agency (MPCA) published a proposed clarify rule intended to the reporting requirements, specify how and what to report, and establish fees. Under Minnesota's 2023 statute, the following information must be reported:

- A brief description of the product, including a universal product code (UPC), stock keeping unit (SKU), or other numeric code assigned to the product;
- (2) The purpose for which PFAS are used in the product, including in any product components;
- (3) The amount of each PFAS, identified by its Chemical Abstracts Service Registry Number® (CAS RN®), in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes;
- (4) The name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer; and
- (5) Any additional information requested by the commissioner as necessary to implement the requirements of this section.

Rather than requiring information regarding the purpose for which PFAS are used in the product, the proposed rule would require that manufacturers provide "the function that each PFAS chemical provides to the product or its components." Under the proposed rule's definition of function ("the explicit purpose or served by PFAS when intentionally role incorporated at any stage in the process of product or preparing а its constituent components for sale, offer for sale, or distribution for sale"), manufacturers would be required to report not only any PFAS intentionally added to the product, but PFAS used during the manufacturing process even if the PFAS are not present in the final product.

New Mexico's law, enacted on April 8, 2025, will require manufacturers of products containing intentionally added PFAS to report similar information on or before **January 1, 2027**. While Minnesota's proposed rule includes limited exemptions from the reporting requirement, New Mexico's statute would exempt more products from both its reporting and prohibition requirements. Most notably, the exemptions include products containing certain fluoropolymers.

## **How Should We Report PFAS?**

B&C and Acta professionals regularly assist clients with recordkeeping and reporting obligations and developing business-sensitive supply chain communication strategies and business documents that reflect critical information elicited in these communications.

Stakeholders are increasingly being asked to report PFAS-related information, and doing so accurately, consistently, and smartly is crucial for compliance purposes and to ensure supply chain and corporate brand integrity.



## EPA Regulation under TSCA Sections 5 and 6

EPA announced on December 1, 2023, that it issued orders to Inhance Technologies, L.L.C. (Inhance) directing it not to produce PFAS, "chemicals that are created in the production of its fluorinated [high-density polyethylene (HDPE)] plastic containers." EPA states that in Inhance December 2022. submitted significant new use notices (SNUN) for nine long-chain PFAS. According to EPA, upon review of the SNUNs and consistent with its Framework for Addressing New PFAS and New Uses of PFAS, it determined that three of the PFAS (PFOA, perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA)) "are highly toxic and present unreasonable risks that cannot be prevented other than manufacture." prohibition through of Therefore, under TSCA Section 5(f), EPA prohibited the continued manufacture of PFOA, PFNA, and PFDA that are produced from the fluorination of HDPE.

EPA notes that it also determined that "the remaining six of the nine PFAS chemicals manufactured by Inhance (PFuDA [perfluoroundecanoic acid], PFDoA [perfluorododecanoic acid], PFTrDA [perfluorotridecanoic acid], PFTeDA [perfluorotetradecanoic acid], PFHxDA [perfluorohexadecanoic acid] and PFODA [perfluoro-n-octadecanoic acid])" may present an unreasonable risk of injury to health or the environment and, under TSCA Section 5(e), is requiring Inhance to cease manufacture of these chemicals and to perform additional testing if it intends to restart production. According to EPA, Inhance's current fluorination process for

plastics produces all nine of the PFAS chemicals subject to these orders simultaneously, however, including PFOA, PFNA, and PFDA. Thus, EPA states, "the production of the other six PFAS could not restart so long as the fluorination process continues to produce PFOA, PFNA and PFDA."

### Court Challenge

Inhance challenged EPA's orders, and on March 21, 2024, the U.S. Court of Appeals for the Fifth Circuit vacated EPA's orders prohibiting Inhance from manufacturing or processing PFAS during its fluorination process. The court notes that in March 2022, EPA "charged for the first time" that Inhance's fluorination process was subject to the 2020 **SNUR** for perfluoroalkyl long-chain carboxylate chemical substances. The court states that it agrees with Inhance that EPA "exceeded its statutory authority by issuing orders under Section 5 instead of Section 6



because Inhance's forty-year-old fluorination process is not a 'significant new use' under TSCA." Inhance maintained that its fluorination process cannot be considered new because it is a "decades-old" process that did not "recently come into existence," while EPA argued that a significant new use is "any use 'not previously known to the EPA." Because Inhance did not identify its fluorination process as an "ongoing use" during the SNUR rulemaking process, EPA argued that the fluorination process qualified as a significant new use.The court "hasten[s] to add that our ruling [prohibiting EPA's December 2023 orders] does not render the EPA powerless to Inhance's fluorination process." regulate According to the court, EPA "can properly proceed, abiding the [Administrative Procedure Act's (APA)] procedural guardrails, under TSCA's Section 6 by conducting inter alia the appropriate cost-benefit analysis required for ongoing uses -- a proposition even Inhance concedes." The court notes that EPA "is just not allowed to skirt the framework set by Congress by arbitrarily deeming Inhance's decades-old fluorination process a 'significant new use.' "



### **TSCA Section 21 Petition**

Almost certainly in response to the Inhance Technologies decision, Earthjustice filed a TSCA Section 21 petition requesting that EPA establish regulations under TSCA Section 6 prohibiting the manufacturing, processing, use, distribution in commerce, and disposal of three PFAS formed during the fluorination of plastic containers. While EPA has historically denied Section 21 petitions, EPA promptly heeded the court's advice, announcing on July 11, 2024, that it granted the petition.

EPA "will promptly commence an appropriate proceeding under TSCA Section 6." On September 30, 2024, EPA requested public comment on the manufacture of certain PFAS, including PFOA, PFNA, and PFDA, during the fluorination of HDPE and other plastic containers to inform regulations as appropriate under TSCA. EPA stated that it is particularly interested in the number, location, and uses of fluorinated containers in the United States; alternatives to the fluorination process that generates PFOA, PFNA, and PFDA; and measures to address risk from PFOA, PFNA, and PFDA formed during the fluorination of plastic containers.

### New Court Challenge

Although EPA granted the Section 21 petition on July 11, 2024, on July 25, 2024, the Center for Environmental Health (CEH) and Public Employees for Environmental Responsibility (PEER) <u>filed suit</u> against EPA in the U.S. District Court for the District of Columbia seeking a rule under TSCA Section 6 to prohibit the production of PFOA during Inhance's fluorination process. CEH and PEER claim that after EPA issued a proposed National Primary Drinking Water Regulation (NPDWR) for PFOA and five PFAS on March 29, 2023, stating that "PFOA ... [is] likely to cause cancer (e.g., kidney and liver cancer) and that there is no dose below which ... [it] is considered safe," EPA had 180 days to perform non-discretionary duties prescribed by TSCA Section 4(f). The petitioners asked the court to "enter an order setting an expeditious deadline for the Agency to propose a rule under TSCA section 6 prohibiting production of PFOA during the Inhance fluorination process." On December 11, 2024, the court dismissed the suit, agreeing with EPA that fulfilled it has anv nondiscretionary duties under TSCA and granting EPA's motion to dismiss.

CEH and PEER filed an appeal in the U.S. Court of Appeals for the District of Columbia on December 27, 2024. *PEER v. Regan* (No. 24-5294). CEH and PEER argue that granting a TSCA Section 21 petition and requesting information for a possible rulemaking are insufficient to satisfy EPA's duty under TSCA Section 4(f) to initiate applicable action under TSCA Section 5, 6, or 7 or determine that the risk is not unreasonable. On January 24, 2025, Inhance filed a motion to intervene, which the court granted on April 22, 2025.

## Toxics Release Inventory (TRI) Reporting for PFAS

TRI data are reported to EPA annually by facilities in certain industry sectors, including federal facilities, that manufacture, process, or otherwise use TRI-listed chemicals above certain quantities. The data include quantities released into the environment or otherwise managed as waste. The FY2020 NDAA



- Appellate Court Vacates EPA's TSCA Section 5 Orders Prohibiting Inhance from Manufacturing or Processing PFAS during Its Fluorination Process (Mar. 25, 2024)
- Appellate Court Affirms Decision That TSCA Section 21 Petition Seeking PFAS Testing Is Not Subject to Review (June 11, 2024)
- EPA Grants TSCA Section 21 Petition Seeking Section 6 Rule Prohibiting Three PFAS Found in Fluorinated Plastic Containers (July 16, 2024)
- CEH and PEER File Suit Seeking TSCA Section 6 Rule Prohibiting Production of PFOA During Fluorination of Plastic Containers (July 30, 2024)
- <u>EPA Seeks Public Comment on</u> <u>Manufacture of Certain PFAS during</u> <u>Fluorination of HDPE and Other Plastic</u> <u>Containers</u> (Oct. 9, 2024)
- <u>NGOs Appeal Dismissal of Suit</u> <u>Seeking TSCA Section 6 Rule</u> <u>Prohibiting Production of PFOA during</u> <u>Fluorination of Plastic Containers</u> (Dec. 31, 2024)

identifies certain regulatory activities that automatically add PFAS or classes of PFAS:

- EPA issuing a final toxicity value; and
- Being subject to a SNUR.

On October 31, 2023, EPA published a final rule eliminating an exemption that allowed facilities to avoid reporting information on PFAS when those chemicals were used in small concentrations. The final rule added PFAS subject to reporting under the Emergency Planning and Community Rightto-Know Act (EPCRA) and the Pollution Prevention Act (PPA) pursuant to the FY2020 NDAA to the list of Lower Thresholds for Chemicals of Special Concern (chemicals of special concern). The addition of these PFAS to the list of chemicals of special concern means such PFAS are subject to the same reporting requirements as other chemicals of special concern (i.e., it eliminates the use of the de minimis exemption and the option to use Form A and limits the use of range reporting for PFAS). The final rule removes the availability of the *de minimis* exemption for purposes of the Supplier Notification Requirements for all chemicals on the list of chemicals of special concern, "help[ing] ensure that purchasers of mixtures and trade name products containing such chemicals are informed of their presence in mixtures and products they purchase to better inform any TRI reporting obligations." The final rule applies for the reporting year beginning January 1, 2024 (reports due July 1, 2025).



EPA proposed on October 8, 2024, to add 16 individual PFAS and 15 PFAS categories representing more than 100 individual PFAS to the TRI list of toxic chemicals subject to reporting under EPCRA and the PPA to comply with the NDAA. The proposed rule also addresses how PFAS categories should be treated. Separately, the proposed rule discusses what events may trigger the automatic addition of a PFAS to the TRI pursuant to the NDAA.

On January 17, 2025, EPA <u>proposed</u> to clarify the timeframe for when companies must first notify a customer that one of its mixtures or trade name products contains a PFAS listed on the TRI list of toxic chemicals. The FY2020 NDAA adds certain PFAS automatically to the TRI beginning January 1 of the year following specific triggering events. According to EPA's January 16, 2025, <u>press release</u>, EPA is proposing the rule in response to questions from industry regarding the effective date of supplier notifications for PFAS added to the TRI pursuant to the NDAA.

Stakeholders questioned whether the supplier notification requirements for such PFAS begin on January 1, when the PFAS are added to the statutory TRI chemical list, or upon EPA completing a rulemaking to include the added PFAS in the Code of Federal Regulations. EPA states that the proposed rule would clarify that the supplier notification requirement for these PFAS starts immediately when they are added to the TRI (January 1) by explicitly defining PFAS added to the TRI by the NDAA as TRI chemicals. EPA

notes that as TRI chemicals, they are immediately covered by the TRI regulation's supplier notification provision, as well as all other TRI reporting requirements. Supplier notifications must begin with the first shipment of the calendar year in which the chemical addition to the TRI is effective.

- EPA Will Add PFAS Subject to TRI Reporting to List of Chemicals of Special Concern (Oct. 24, 2023)
- EPA Issues Final SNUR to Prevent Inactive PFAS from Reentering Commerce (Jan. 12, 2024)
- EPA Proposes to Add 16 PFAS and 15 PFAS Categories to the TRI List of Chemicals (Oct. 17, 2024)
- Pulling the Threads of the 'Complicated Patchwork of Federal and State Law' around PFAS Class Action Lawsuits (Jan. 15, 2025)
- EPA Proposes to Clarify Supplier Notification Requirements for TRI-Listed PFAS (Jan. 22, 2025)
- EPA Extends Comment Period on Draft Sewage Sludge Risk Assessment for PFOA and PFOS (Apr. 28, 2025)

## Designation of PFOA and PFOS as CERCLA Hazardous Substances

On May 8, 2024, EPA designated PFOA and PFOS, "two of the most widely used PFAS," as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The final rule includes the salts and structural isomers of PFOA and PFOS. The rulemaking requires entities to report immediately releases of PFOA and PFOS that meet or exceed the reportable quantity (RQ) of one pound or more in a 24-hour period. When EPA announced its final rule, it also issued a separate PFAS Enforcement Discretion and Settlement Policy Under CERCLA, stating that it will focus enforcement on parties who significantly contributed to the release of PFAS into the environment, including parties that have manufactured PFAS or used PFAS in the manufacturing process, federal facilities, and other industrial parties. In April 2023, EPA issued an advance notice of proposed rulemaking on various PFAS under CERCLA to seek public input on whether to seek similar CERCLA designation of other PFAS.

Entities affected include:

- PFOA and/or PFOS manufacturers (including importers and importers of articles);
- PFOA and/or PFOS processors;
- Manufacturers of products containing PFOA and/or PFOS;
- Downstream product manufacturers and users of PFOA and/or PFOS products; and
- Waste management and wastewater treatment facilities.

Implementation of the final rule is expected to jump-start extraordinary remediation activities resulting in significant CERCLA-related cleanups, demands for cost recovery, reopening of "cleaned-up" sites, and private litigation. The insurance industry is bracing for the impact.

- Webinar on Demand -- <u>Analyzing the</u> <u>EPA's Proposal to List PFAS Chemicals as</u> <u>Hazardous Substances</u> (Jan. 30, 2023)
- EPA Publishes ANPRM Seeking Information to Assist in Consideration of Future CERCLA Regulations Regarding PFAS (Apr. 13, 2023)
- EPA Designates PFOA and PFOS as CERCLA Hazardous Substances, Releases CERCLA Enforcement Discretion Policy (Apr. 23, 2024)
- Lynn L. Bergeson, "<u>EPA Proposes</u> <u>Expanded Chemical Tracking for PFAS</u>, <u>Now What?</u>," *Chemical Processing* (Dec. 6, 2024)
- Senate Subcommittee Holds Hearing on Public Health Impacts of PFAS Exposures (Dec. 11, 2024)





## Proposed Resource Conservation and Recovery Act (RCRA) PFAS-Related Rules

In February 2024, EPA announced two proposed rules that will add to its "comprehensive approach" for addressing PFAS pollution and to the commercial bottom line for hundreds of businesses facing costs for cleanup. The first proposed rule would modify the definition of hazardous waste as it applies to cleanups at permitted hazardous waste facilities. EPA states that this modification "would EPA's assure that clearly reflect FPA's regulations and authorized states' authority to require cleanup of the full range of substances" that RCRA intended, including emerging chemicals of concern, such as PFAS, that may present substantial hazards at permitted facilities.

The second <u>proposed rule</u> would amend the RCRA regulations to add multiple PFAS compounds as hazardous constituents. According to EPA, the following PFAS "would be added to the list of substances identified for consideration in facility assessments and, where necessary, further investigation and cleanup through the corrective action process at hazardous waste treatment, storage and disposal facilities [TSDF]":

- PFOA;
- PFOS;
- Perfluorobutanesulfonic acid (PFBS);
- Hexafluoropropylene oxide-dimer acid (HFPO-DA or GenX);
- PFNA;
- Perfluorohexanesulfonic acid (PFHxS);
- PFDA;
- Perfluorohexanoic acid (PFHxA); and
- Perfluorobutanoic acid (PFBA).

- EPA Announces New Framework Intended to Prevent Unsafe New and New Uses of PFAS from Entering the Market (July 14, 2023)
- EPA Proposes to Modify the Definition of Hazardous Waste and Add Multiple PFAS as Hazardous Constituents (Feb. 5, 2024)
- EPA Issues Fifth Test Order for a PFAS (Nov. 4, 2024)
- EPA Releases Third Annual PFAS Strategic Roadmap Report (Nov. 15, 2024)
- Lynn L. Bergeson, "<u>The Cost of Cleanup:</u> <u>Preparing for PFAS remediation</u> <u>battles</u>," *Corporate Disputes* (Jan.-Mar. 2025)



### **Drinking Water Standards**

In April 2024, EPA issued the first-ever national drinking water standard for six PFAS. The National Primary Drinking Water Regulation (NPDWR) establishes MCLs for six PFAS in drinking water: PFOA, PFOS, PFHxS, PFNA, and HFPO-DA as contaminants with individual MCLs, and PFAS mixtures containing at least two or more of PFHxS, PFNA, HFPO-DA, and PFBS using a Hazard Index MCL to account for the combined and co-occurring levels of these PFAS in drinking water. EPA also issued final health-based, non-enforceable Maximum Contaminant Level Goals (MCLG) for these PFAS.

Under the final rule, public water systems must:

- Conduct initial and ongoing compliance monitoring for the regulated PFAS;
- Implement solutions to reduce regulated PFAS in their drinking water if levels exceed the MCLs; and
- Inform the public of the levels of regulated PFAS measured in their drinking water and if an MCL is exceeded.

- EPA Issues First-Ever Drinking Water Standards for PFAS (May 9, 2024)
- MPCA Recommends Exempting until 2032 Intentionally Added PFAS in Electronic or Other Internal Components within the 11 Product Categories Prohibiting PFAS in 2025 (Feb. 4, 2025)
- States Take Action to Regulate and Limit PFAS in Industrial Effluent Despite Federal Inaction (Mar. 28, 2025)
- <u>Comments on Minnesota's Proposed Rule for</u> <u>Reporting Products Containing Intentionally</u> <u>Added PFAS Are Due May 21, 2025</u> (Apr. 22, 2025)





### State Prohibitions on Products Containing Intentionally Added PFAS

Maine, Minnesota, and New Mexico have enacted broad PFAS statutes that include prohibitions on products containing intentionally added PFAS, first on certain consumer products, and then a ban beginning on January 1, 2032, on all products that contain intentionally added PFAS that do not have a CUU. Maine has already banned intentionally added PFAS in carpets or rugs and fabric treatments, and beginning January 1, 2026, will ban intentionally added PFAS in cleaning products, cookware, cosmetics, dental floss, juvenile products, menstruation products, textile articles (with exception), ski wax, and upholstered furniture.

On January 1, 2025, Minnesota banned intentionally added PFAS in carpets or rugs, cleaning products, cookware, cosmetics, dental floss, fabric treatments, juvenile products, menstruation products, textile furnishings, ski wax, and upholstered furniture. In New Mexico, beginning January 1, 2027, intentionally added PFAS will be banned in cookware, food packaging, dental floss, juvenile products, and firefighting foam. Beginning January 1, 2028, New Mexico will prohibit intentionally added PFAS in carpets or rugs, cleaning products, cosmetics, fabric treatments, feminine hygiene products, textiles, textile furnishings, ski wax, and upholstered furniture.



### State Prohibitions on Products Containing Intentionally Added PFAS



SOURCE: https://www.saferstates.org/resource/2025-analysis-of-state-policy-addressing-toxic-chemicals-and-plastics/phasing-out-pfas-use/

- California Attorney General Issues Enforcement Advisory Letter to Warn Companies of Responsibility to Disclose Presence of PFAS (Oct. 18, 2023)
- Maine Amends Its PFAS Statute, Exempting Certain Product Categories from the Sales Prohibition and Eliminating the General Notification Requirement (May 24, 2024)
- Cookware Association Files Federal Challenge to Minnesota's Ban on PFAS in Cookware (Jan. 14, 2025)
- Maine Board Approves Motion to Adopt Rule on PFAS in Products; CUU Proposals for Products Prohibited as of January 1, 2026, Are Due June 1, 2025 (Apr. 11, 2025)
- New Mexico Will Phase Out Products Containing Intentionally Added PFAS and Require Reporting; Exemptions Include Fluoropolymers (Apr. 11, 2025)

# Canadian, European, and UK Regulation







### **Canada's State of PFAS Report**

On March 15, 2025, Canada announced the availability of its final <u>State of Per- and Polyfluoroalkyl Substances</u> (*PFAS*) <u>Report</u> (State of PFAS Report) and <u>proposed risk</u> <u>management approach</u> for PFAS, excluding fluoropolymers. The State of PFAS Report concludes that the class of PFAS, excluding fluoropolymers, is harmful to human health and the environment. To address these risks, on March 8, 2025, Canada published a <u>proposed</u> <u>order</u> that would add the class of PFAS, excluding fluoropolymers, to Part 2 of Schedule 1 to the Canadian Environmental Protection Act, 1999 (CEPA).

Environment and Climate Change Canada (ECCC) states in its March 5, 2025, press release that it will prioritize the protection of health and the environment while considering factors such as the availability of alternatives. ECCC states that it will publish a final decision on the proposed addition of 131 individual PFAS to the National Pollutant Release Inventory (NPRI) with reporting to take place by **June 2026** for PFAS releases that occurred during the 2025 calendar year.

ECCC states that these data will improve its understanding of how PFAS are used in Canada, help it evaluate possible industrial PFAS contamination, and support efforts to reduce environmental and human exposure to harmful substances. Comments on the proposed risk management approach and the proposed add the class PFAS, order to of excluding fluoropolymers, to CEPA Schedule 1 Part 2 were due May 7, 2025.





ECCC proposes the following new risk management actions through a phased prohibition under CEPA:

- Phase 1: Prohibition of the use of PFAS, excluding fluoropolymers, not currently regulated in firefighting foams, due to high potential for environmental and human exposure.
- Phase 2: Prohibition of the uses of PFAS, excluding fluoropolymers, not needed for the protection of health, safety, or the environment, which includes consumer applications. ECCC states that prioritization of uses for prohibition is based on, and will take into account, costs and benefits, availability of suitable alternatives, and other socio-economic considerations. Proposed uses to be regulated in Phase 2 include:
  - Cosmetics;
  - Natural health products and non-prescription drugs;
  - Food packaging materials, food additives, and nonindustrial food contact products such as paper plates, bowls, and cups;
  - Paint and coating, adhesive and sealant, and other building materials available to consumers;
  - Consumer mixtures such as cleaning products, waxes, and polishes;
  - Textile uses (including in personal protective equipment (PPE) such as firefighting turnout gear); and
  - Ski waxes.

Phase 3: Prohibition of the uses of PFAS, excluding fluoropolymers, requiring further evaluation of the role of PFAS for which currently there may not be feasible alternatives and taking into consideration socio-economic factors, including:

- Fluorinated gas applications;
- Prescription drugs (human and veterinary);
- Medical devices;
- Industrial food contact materials;
- Industrial sectors such as mining and petroleum; and
- Transport and military applications.





ECCC states that at each phase of risk management, it will consider exemptions, when necessary, with attention to feasible alternatives and socio-economic factors.

Canada notes that, based on available information, fluoropolymers may have significantly different exposure and hazard profiles compared with other PFAS. According to Canada, given these differences, additional work on fluoropolymers is warranted, and Canada will consider them in a separate assessment. The ministers will also consider at a future date whether fluoro-polymers are possible candidates to the Watch List under CEPA Section 75.1.

### Canada's Mandatory Survey on 312 PFAS

On July 27, 2024, Canada's Minister of the Environment published a Canada Gazette notice announcing a mandatory survey to obtain information on the manufacture, import, and use of 312 specific PFAS. Canada's "Guidance manual for responding to the: Notice with respect to certain per- and polyfluoroalkyl substances (PFAS)" states that the purpose of the notice is to collect information on certain PFAS substances, either alone, in mixtures, products, or manufactured items in Canadian commerce for the calendar year 2023. Canada will use this information to establish baseline commercial use data and support future activities related to the class of PFAS. The list of specific PFAS "is focused on those substances known, or anticipated to be in Canadian commerce that have not been recently surveyed." Responses were due January 29, 2025.



### **REACH Restriction Proposal**

The EU's Annex XV restriction proposal, which was released for public comment on March 22, 2023, would restrict more than 10,000 PFAS under the REACH regulation. The national authorities of Denmark, Germany, the Netherlands, Norway, and Sweden submitted proposal after finding risks in the the manufacture, placement on the market, and use of PFAS that, in their view, pose risks to human health and the environment that are not adequately controlled and need be to addressed throughout the EU and the European Economic Area (EEA).

The restriction proposal analyzes various risk management options and concludes that a REACH restriction is the preferred risk management option. According to the restriction proposal, the best option to avoid PFAS emissions to the environment during manufacture, production, and use of PFAScontaining articles and at the waste stage is to prohibit the manufacture and use of PFAS to the largest extent possible.

The restriction proposal analyzes the likely impacts of a full ban that would enter into force after a transition period of 18 months and proposes the following use-specific, timelimited restriction options:

A full ban 18 months after the restriction enters into force of manufacture and placement on the market of all PFAS for which alternatives are known and can be available in adequate quantities;

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- A five-year derogation when there is "sufficiently strong evidence" that alternatives are in development but their implementation within the 18-month transition period is not feasible technically or economically;
- A 12-year derogation when there is evidence" "sufficiently strong that technically economically feasible and alternatives will not be available within the five-year derogation window, or may require regulatory approval or certification that cannot be completed within the fiveyear timeframe; and
- Time-unlimited (only for a limited number of specific uses; applies to active ingredients regulated in plant protection products, biocidal products, and medicinal products for human or veterinary use).

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## UK Regulatory Management Options Analysis

While the EU is considering a ban of more than 10,000 PFAS, the United Kingdom's (UK) Health and Safety Executive (HSE) has published a regulatory management options analysis (RMOA) for PFAS. The RMOA is a preliminary step used within the UK REACH framework. Using a modification of the definition of PFAS developed by the Organisation for Economic Co-operation and Development (OECD), a definition that excludes substances with a single, isolated methylene group (*i.e.*,  $-CF_2$ -) from consideration as PFAS, the RMOA "reduces the number of PFAS in scope to hundreds, maintaining focus on substances that are persistent degradation products of PFAS."

Based on scientific evidence, the UK considers that the excluded substances are not transformed to highly persistent substances that pose human health or environmental concerns. The restriction proposal in the EU, however, uses a broader definition that is aligned with OECD's, but more than doubles the number of PFAS substances.



The RMOA states that based on initial considerations of likely effectiveness and efficiency of options -- and considering the Precautionary Principle -- HSE concludes that it would be appropriate to consider initiating risk management measures with regard to certain uses of PFAS, including preparing background dossiers to support UK REACH restrictions of PFAS, such as:

- The use and disposal of fire-fighting foams where non-PFAS alternatives are available;
- Other wide dispersive uses such as the application of coatings or use of cleaning agents; and
- The manufacture and placing on the market of consumer articles from which PFAS are likely to be released into air, water, or soil, or directly transferred to humans. This includes textiles, upholstery, leather, apparel, rugs and carpets, paints, varnishes, waxes and products. polishes. and cleaning Consideration may given to other be consumer articles if other gaps are identified in consultation with other legislative regimes such as food contact materials.

The effects of whatever final approach is adopted by the EU are years away, but U.S. companies take note. The EU's approach will have a profound impact on the global economy and inevitably impact manufacturing practices and standards far beyond the EU. It is the first concrete step taken by one of the world's strongest economies to signal that PFAS as a chemical category will be phased out.



### More Information:

- ECHA Publishes Proposal to Restrict More Than 10,000 PFAS under REACH (Feb. 13, 2023)
- HSE Publishes RMOA for PFAS (Apr. 12, 2023)
- OECD Publishes Draft Report on PFAS and Alternatives in Coatings, Paints, and Varnishes (Jan. 3, 2024)
- Canada Requests Information on 312 PFAS; Responses Due January 29, 2025 (July 29, 2024)
- EC Adopts REACH Restriction for PFHxA and Related Substances (Sept. 19, 2024)
- ECHA and Five National Authorities Issue Progress Update on REACH Restriction (Nov. 20, 2024)
- Canada Releases Final State of PFAS Report and Proposed Risk Management Approach (Mar, 24, 2025)

### **Acta Offices and Global Partners**



# What Are the Global Implications of PFAS?

Acta's U.S., UK, and EU professionals assist clients to manage worldwide supply chain communication and compliance planning. Our scientists, lawyers, and regulatory affairs specialists can ensure a consistent science-based compliance approach that seamlessly reflects jurisdictional variations in PFAS restrictions.

# Expanding Commercial Liability



# Remediation Liability under CERCLA

EPA is widely expected to designate PFOA and PFOS as CERCLA hazardous substances. Under CERCLA, multiple parties may be held jointly and severally liable for cleanup costs at designated sites, even if the release occurred decades ago and contributed only marginally to the PFOA or PFOS contamination, and even if the site was previously remediated for other contaminants.

Companies that own or operate PFOA- and PFOS-contaminated sites, or that have been involved in the manufacture, distribution, or disposal of PFOA- and PFOS-containing products, could face litigation and the associated cost.

## Property/Personal Injury Liability

Thousands of lawsuits have already been filed alleging personal injury and property damage allegedly caused by PFAS. The remediation of sites under CERCLA will almost certainly drive new litigation, implicating a new class of potential defendants. Companies will need to manage the fallout and assess the potential for legal action and prepare accordingly.







The plaintiffs' bar has never wanted for creativity, and those skills are being deployed with vigor in the PFAS litigation area. There are a growing number of consumer product liability cases seeking class action certification alleging the *presence* of PFAS in purchased products and asserting fraud, various breaches of implied or express warranty, negligent misrepresentation, state consumer protection provisions, and unfair competition claims, among other novel theories of liability. Our <u>blog</u> on the class action lawsuit filed against Tom's Wicked Fresh mouthwash that was found to contain measurable concentrations of PFAS is an excellent example of how consumer protection laws can be used as a cudgel to weaponize state laws that are intended to protect against marketing practices. Demonstrating personal injury beyond modest economic injury is not necessary to elicit an adverse ruling, significant transaction costs, and unwanted reputational injury and brand damage.

PFAS litigation is expanding. PFAS manufacturers and the product manufacturers intentionally adding PFAS to their products have been embroiled in litigation for years and likely will bear the greatest burden in terms of cleanup/remediation/medical monitoring/personal injury liability.

Product manufacturers marketing products with intentionally added PFAS are, however, now increasingly at risk, depending on the products' applications. These marketers should be pursuing all the risk minimizing/mitigating strategies, including reformulation, labeling/disclosure, and contractual protections/waivers, as appropriate, to minimize liability.

Product manufacturers marketing products with detectable levels of PFAS that did not intentionally add PFAS, but their products are found to contain PFAS for any number of reasons, are increasingly at risk, particularly in consumer products that resonate with consumers, including cosmetics (<u>Coty</u>), undergarments (<u>Thinx</u>), outer garments (<u>REI</u>), mouthwash (<u>Tom's</u>), and many more.

- Webinar on Demand -- "<u>Preparing a PFAS Game Plan in the U.S.,</u> the UK, and the EU" (July 11, 2023)
- "Expanding PFAS liability in the US," Financier Worldwide (July 2023)
- "Reporting PFAS: reporting burden is the least of businesses" worries," Financier Worldwide (Dec. 2023)
- "PFAS Risk and the Role of the Corporate Fiduciary," Corporate Disputes Magazine (Oct. - Dec. 2024)

# What to Do?

In the current legal, regulatory, and commercial landscape and with the likely outlook over the coming decade, companies must develop a PFAS gameplan. A company must consider all aspects of its supply chain and understand where PFAS might enter it.

Given the ubiquity of these chemicals, PFAS may enter a supply chain in an astonishing number of ways -- intentionally added, unintentionally added (byproduct, contaminant), or manufacturing process water contaminant. The maddening reality is PFAS is literally everywhere, so the potential for liability is correspondingly open-ended.



# A PFAS gameplan must include at least these elements:





# Ascertain where in the supply chain of a product line there might be PFAS:

- Eliminate the source of the PFAS, if possible, and/or reformulate the product.
- If it is not possible, for whatever reason, to reformulate, it is essential to ensure continued market access. Clarify as much as possible what is known about each PFAS species: composition, performance, properties, uses, applicable bans, restrictions, or reporting requirements, and develop a plan to protect market access.

# Ensure your operations are fully informed about PFAS regulations, pending trends and proposed regulations:

- Global bans and restrictions could affect companies, even if they do not have an active presence in the markets in question.
- Develop now detailed justifications for PFAS that are essential and seek protections under domestic and international regulatory frameworks for exemptions and derogations that reflect the essential nature and functionality of PFAS that can and should enjoy extended market-life protections.

# Assess business options, including insurance policies, contractual indemnifications, and related private-party risk mitigation measures:

- Conduct an insurance audit and shore up deficits as much as possible.
- Review supply agreements and related commercial agreements with a view toward seeking indemnifications from suppliers to provide as much contractual protection as possible.
- Revisit your company's product component certification program to ensure the protections your company seeks and the assurances your company is providing are state of the art.
- Assess if your company's procurement policies are "PFAS sensitive." In other words, confirm your supply chain, R&D activities, and product development policies disallow PFAS at every step of the process.



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# How We Can Help

The professionals of B&C and Acta have unparalleled experience in scientific, legal, policy, and regulatory issues related to PFAS. Our robust science team includes seven Ph.D. chemists and toxicologists, including former senior EPA scientists and directors of regulatory compliance at Fortune 500 companies. Our attorneys, scientists, and regulatory specialists have worked on some of the toughest compliance issues of the last three decades, assisting clients in planning, product defense, and business strategy development.

#### Our services include:

Chemical Product Review --

- Assist in the identification of PFAS in chemical products
- Assist with reporting obligations related to PFAS
- Assist with labeling and notice requirements

Recordkeeping and Reporting Assistance

Regular Updates on PFAS Legislative and Regulatory Developments

Marketing and Response to PFAS Awareness

Strategic Business Advice --

- Map consumer/market PFAS developments and legal and industry mandates
- Planning and budgeting

### Visit our PFAS Resource Center:

<u>https://www.lawbc.com/per-and-polyfluoroalkyl-</u> <u>substances-pfas-news-and-information/</u> We would be pleased to provide additional information and assist with PFAS-related scientific, regulatory, or legal questions that you may have.

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# **PFAS RESOURCES**

## **B&C's PFAS News & Information**





## **EPA PFAS Resource Page:**



# **European Chemicals Agency** (ECHA) PFAS Resource Page:



HFPO-DA or GenX Hexafluoropropylene oxide-dimer acid

**PFAS** Perfluoroalkyl and polyfluoroalkyl substances

**PFBA** Perfluorobutanoic acid

**PFBS** Perfluorobutanesulfonic acid

**PFDA** Perfluorodecanoic acid

**PFHxA** Perfluorohexanoic acid

**PFHxS** Perfluorohexanesulfonic acid

**PFNA** Perfluorononanoic acid

**PFOA** Perfluorooctanoic acid

**PFOS** Perfluorooctane sulfonic acid