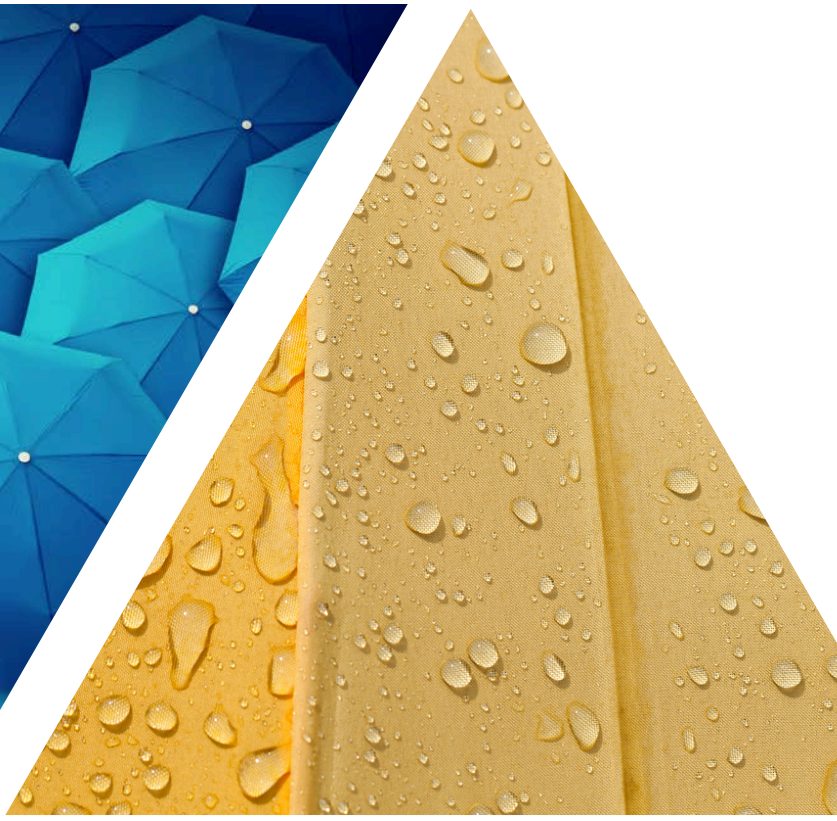
JULY 2024

PFAS

Bans, Restrictions, Reporting, and Minimizing Liability

What to know now, and what to expect



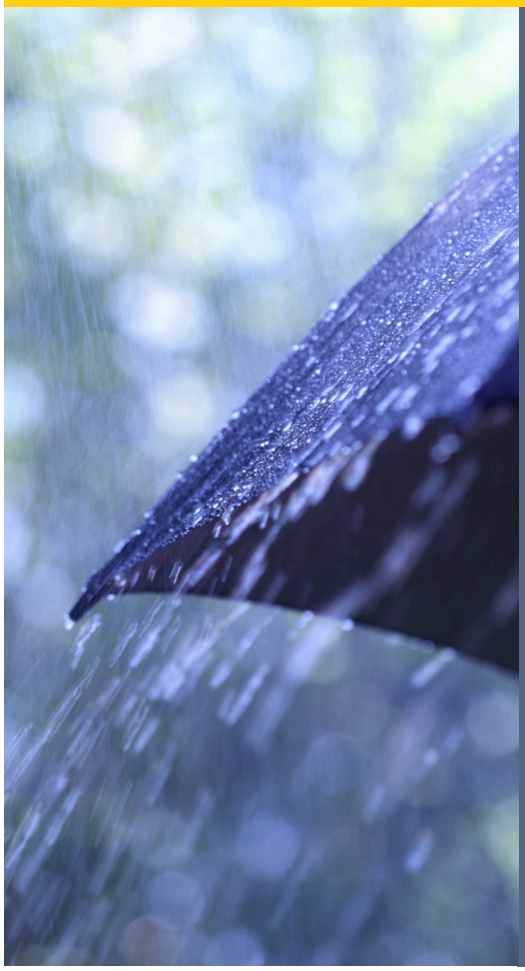
ACTA® ASIA EUROPE THE AMERICAS

BERGESON & CAMPBELL PC

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.

Bergeson & Campbell, P.C. (B&C®)
+1 (202) 557-3800
www.lawbc.com

The Acta Group (Acta®)
+1 (202) 266-5020 (U.S.)
+44 (0) 161 240 3840 (UK)
+32 2 588 48 85 (EU)
www.actagroup.com

CONTENTS:

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 side-chain 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?

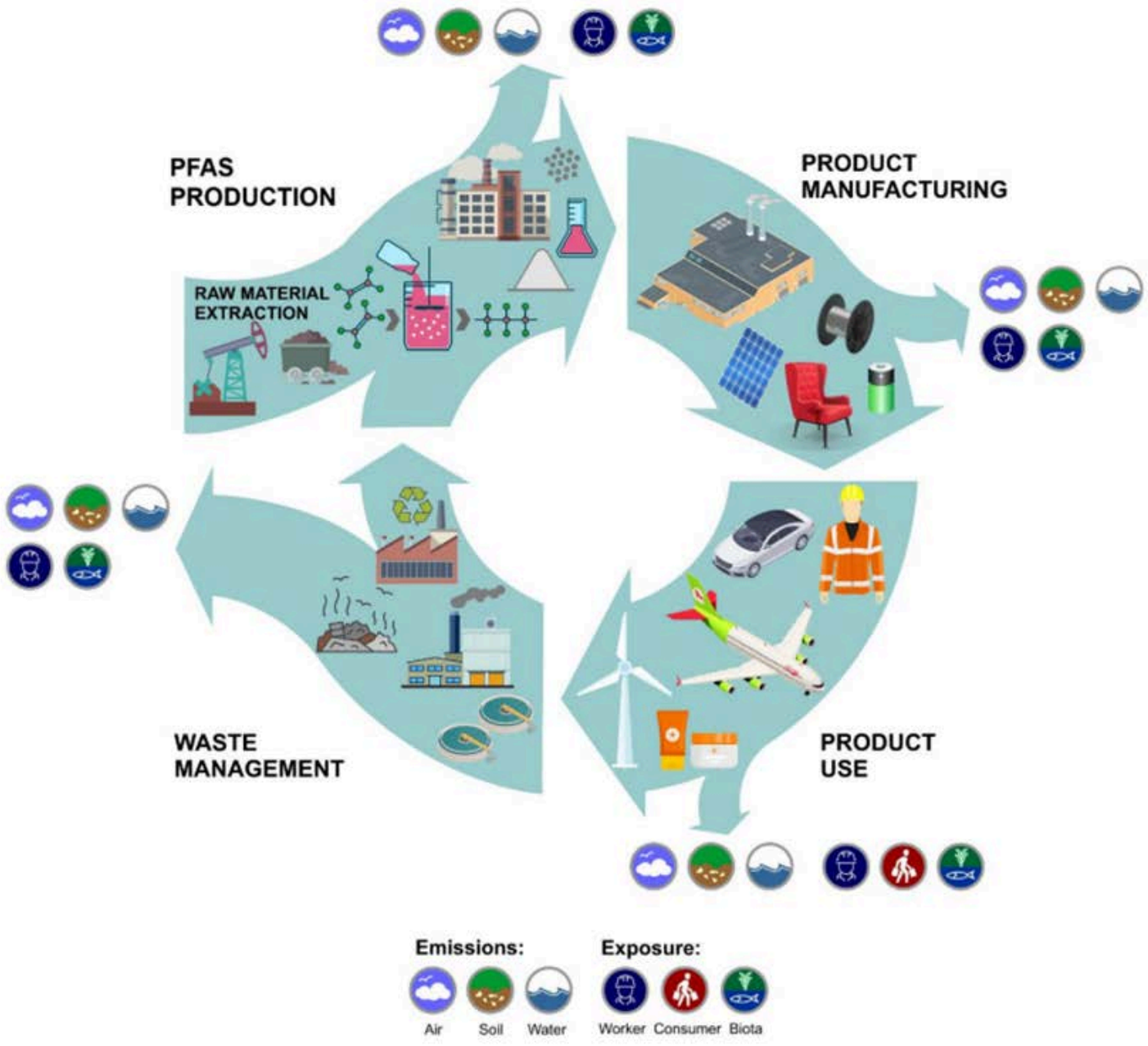
A critical issue vexing stakeholders is the uncertainty regarding whether a particular chemical substance is a PFAS.

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.

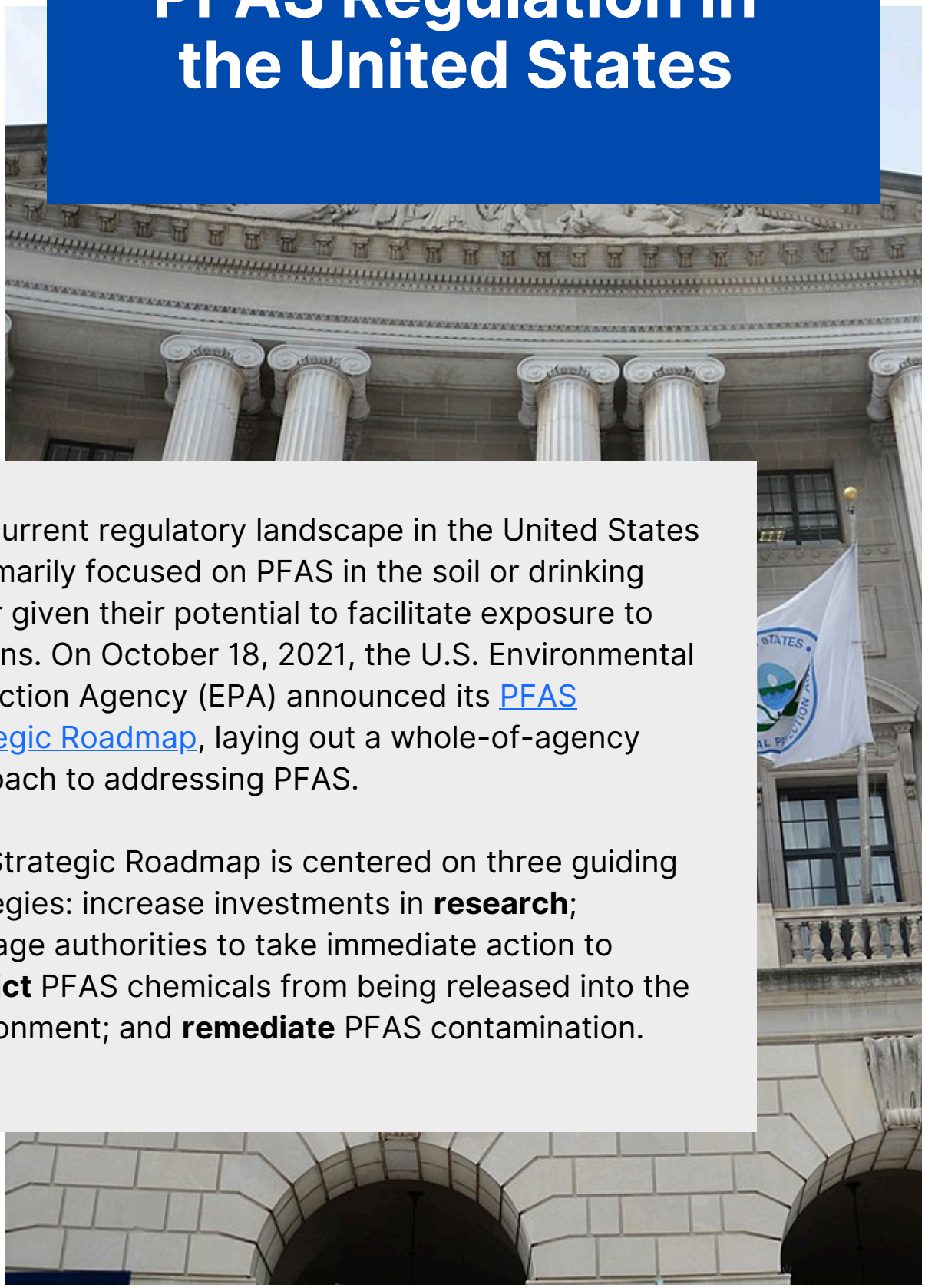
In 1999, the U.S. Centers for Disease Control and Prevention (CDC) measured at least 12 PFAS in human blood serum, indicating exposure to these chemicals in the U.S. population. PFAS contamination in humans and in the environment is believed to be pervasive.

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

PFAS Regulation in the United States



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 PFAS Strategic Roadmap, 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 enacting comprehensive 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 upcoming years. 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.

Most of these state regulations involve reporting requirements for PFAS and apply to companies marketing products in a state. These regulations are increasing at a rapid pace, and the scope of PFAS reporting and/or bans is extensive. Maine and 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:

- Biden Administration Announces Multi-Agency Plan to Confront PFAS Pollution; EPA Releases Strategic Roadmap (Oct. 19, 2021)
- Maine Proposes Rule to Clarify Reporting Requirements for PFAS in Products (Feb. 17, 2023)
- GAO Recommends Actions to Improve DOD's Ability to Prevent the Procurement of Items Containing PFAS (May 3, 2023)
- Minnesota Will Require Manufacturers to Report Intentionally Added PFAS and Will Ban Intentionally Added PFAS in Certain Product Categories Beginning January 1, 2025 (June 14, 2023)
- Maine Amends Its PFAS Statute, Exempting Certain Product Categories from the Sales Prohibition and Eliminating the General Notification Requirement (May 24, 2024)

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

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 final rule 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-

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).
- The submission period will begin **November 12, 2024**, and end **May 8, 2025**. Article importers that are also considered small manufacturerswill have until **November 10, 2025**, to submit reports.

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.

More Information:

- Podcast -- New PFAS: Is Anything NOT Reportable? -- A Conversation with Richard E. Engler, Ph.D., All Things Chemical® podcast, *also available as a transcript*, released July 8, 2021
- CPSC Requests Information on PFAS in Consumer Products (Sept. 25, 2023)
- EPA Releases Final TSCA Section 8(a)(7) Reporting Rule for PFAS (Oct. 3, 2023)
- EPA Holds Webinar on PFAS Reporting Rule Requirements (Jan. 30, 2024)
- Bicameral Legislation Would Ban Non-Essential PFAS Uses within Ten Years (May 13, 2024)

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 December 2022, Inhance 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 through prohibition of manufacture." 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 long-chain perfluoroalkyl 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 regulate Inhance's fluorination process." 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." According to EPA's announcement, EPA intends to request information, including 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.

More Information:

- Appellate Court Vacates EPA's TSCA Section 5 Orders Prohibiting Inhance from Manufacturing or Processing PFAS during Its Fluorination Process (Mar. 25, 2024)
- EPA Holds Webinar on "Reducing PFAS in Products: Progress and Challenges" (May 17, 2024)
- Appellate Court Affirms Decision That TSCA Section 21 Petition Seeking PFAS Testing Is Not Subject to Review (June 11, 2024)
- TSCA Reform -- Eight Years Later: B&C, ELI, and GWU Conclude Best Available Conference (July 9, 2024)
- EPA Grants TSCA Section 21 Petition Seeking Section 6 Rule Prohibiting Three PFAS Found in Fluorinated Plastic Containers (July 16, 2024)

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 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 Right-to-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**).

More Information:

- EPA Implements Statutory Addition of Certain PFAS to TRI Beginning with Reporting Year 2023 (June 26, 2023)
- 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 Announces Automatic Addition of Seven Additional PFAS to TRI List of Chemicals (Jan. 18, 2024)
- EPA Issues Final Rule Requiring TRI Reporting for Seven Additional PFAS (May 22, 2024)

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, re-opening of "cleaned-up" sites, and private litigation. The insurance industry is bracing for the impact.

More Information:

- Lynn L. Bergeson, "EPA Targets PFAS Cleanup," *Chemical Processing* (Sept. 23, 2022)
- Webinar on Demand -- Analyzing the EPA's Proposal to List PFAS Chemicals as Hazardous Substances (Jan. 30, 2023)
- EPA Holds CERCLA PFAS Enforcement Listening Session (Mar. 17, 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)

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 assure that EPA's regulations clearly reflect EPA's 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 proposed rule 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).

More Information:

- EPA Will Act upon Petition by Initiating Two RCRA Rulemakings to Address PFAS (Oct.29, 2021)
- EPA Announces New Framework Intended to Prevent Unsafe New and New Uses of PFAS from Entering the Market (July 14, 2023)
- EPA Issues Third TSCA Test Order for PFAS (Aug. 29, 2023)
- California Attorney General Issues Enforcement Advisory Letter to Warn Companies of Responsibility to Disclose Presence of PFAS (Oct. 18, 2023)
- EPA Proposes to Modify the Definition of Hazardous Waste and Add Multiple PFAS as Hazardous Constituents (Feb. 5, 2024)

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.

More Information:

- President Biden's FY 2024 Budget Includes Additional Funding for TSCA and Funding to Address PFAS Pollution (Mar. 14, 2023)
- Senate Committee Hearing on EPA's Proposed FY 2024 Budget Addresses TSCA, PFAS (Mar. 23, 2023)
- EPA Releases Initial Nationwide Monitoring Data on 29 PFAS and Lithium (Aug. 21, 2023)
- Uhlmann Confirms EPA Will Not Pursue PFAS Enforcement Actions against Farmers, Public Airports, and Municipal Wastewater Facilities (Oct. 13, 2023)
- EPA Issues First-Ever Drinking Water Standards for PFAS (May 9, 2024)

Canadian, European, and UK Regulation

Canada's Updated Draft State of PFAS Report

On July 13, 2024, Canada published a *Canada Gazette* notice announcing the availability of its *Updated Draft State of Per- and Polyfluoroalkyl Substances (PFAS) Report* (Updated Draft Report). Canada proposes to conclude that the class of PFAS, excluding fluoropolymers, meets one or more criteria set out in Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA). According to the notice, the Minister of the Environment and the Minister of Health (the ministers) propose to recommend that the class of PFAS, excluding fluoropolymers, be added to Part 2 of Schedule 1 of CEPA. The Updated Draft Report provides a qualitative assessment of the fate, sources, occurrence, and potential impacts of PFAS on the environment and human health to inform decision-making on PFAS in Canada. The ministers have released a Revised Risk Management Scope for PFAS to initiate discussions with stakeholders on the development of risk management options. Comments on the Updated Draft Report and Revised Risk Management Scope are due September 11, 2024.

As part of the Revised Risk Management Scope, Canada proposes activities to reduce environmental and human exposure to PFAS through a phased approach, including:

- As a first step, a regulation under CEPA to restrict PFAS not currently regulated in firefighting foams;
- Additional instruments under CEPA to prohibit PFAS in other uses or sectors; and
- Possible voluntary risk-management actions to achieve early results to reduce releases of the class of PFAS.

Canada notes that, based on available information, fluoropolymers may have 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 fluoropolymers are possible candidates to the Watch List under CEPA Section 75.1.

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 the proposal after finding risks in 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 to be 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 PFAS-containing 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, time-limited 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;

- 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 "sufficiently strong evidence" that technically and economically feasible alternatives will not be available within the five-year derogation window, or may require regulatory approval or certification that cannot be completed within the five-year 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).

More Information:

- ECHA Publishes Proposal to Restrict More Than 10,000 PFAS under REACH (Feb. 13, 2023)
- ECHA Convenes Online Information Session Regarding the Proposal to Restrict More than 10,000 PFAS under REACH (Apr. 7, 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)
- ECHA Clarifies Next Steps for PFAS Restriction Proposal (Mar. 18, 2024)
- Comments on Canada's Updated Draft State of PFAS Report and Revised Risk Management Scope Are Due September 11, 2024 (July 12, 2024)

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.

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 polishes, and cleaning products. Consideration may be given to other 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.

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.

Product Liability

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 blog 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 (Coty), undergarments (Thinx), outer garments (REI), mouthwash (Tom's), and many more.

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, research and development (R&D) activities, and product development policies disallow PFAS at every step of the process.

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:

https://www.lawbc.com/per-and-polyfluoroalkyl-substances-pfas-news-and-information/

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

Contact us:

Lynn L. Bergeson
Managing Partner, B&C
President, Acta
lbergeson@lawbc.com
(202) 557-3801

Richard E. Engler, Ph.D.
Director of Chemistry
rengler@lawbc.com
(202) 557-3808

Karin F. Baron, MSPH
Director of Hazard Communication and International Registration Strategy
kbaron@actagroup.com
(202) 266-5022

Bergeson & Campbell, P.C.
The Acta Group

United States
2200 Pennsylvania Avenue, NW
Suite 100W
Washington, D.C. 20037

United Kingdom
26 Cross Street
First Floor
Manchester M2 7AQ
United Kingdom

European Union
Place du Luxembourg 2
1050 Brussels
Belgium

PFAS RESOURCES

B&C's PFAS News & Information Site:

EPA PFAS Resources, Data, and Tools Page:

Acta and EPPA Webinar "Preparing a PFAS Game Plan in the U.S., the UK, and the EU":

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