

# **PFAS Regulation: What's Next? A Global Perspective – U.S. REGULATORY UPDATE**

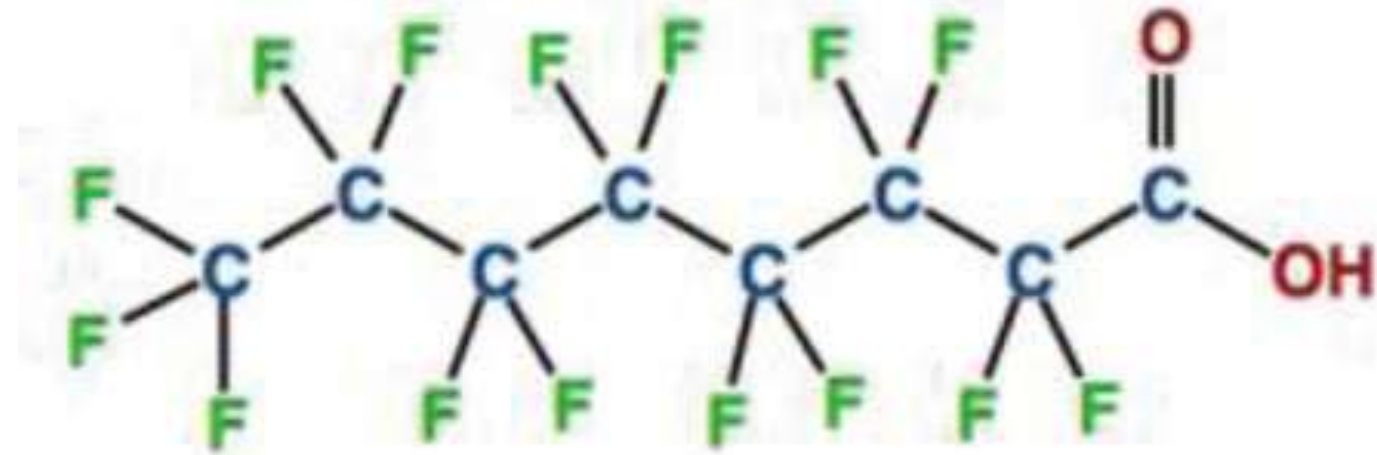
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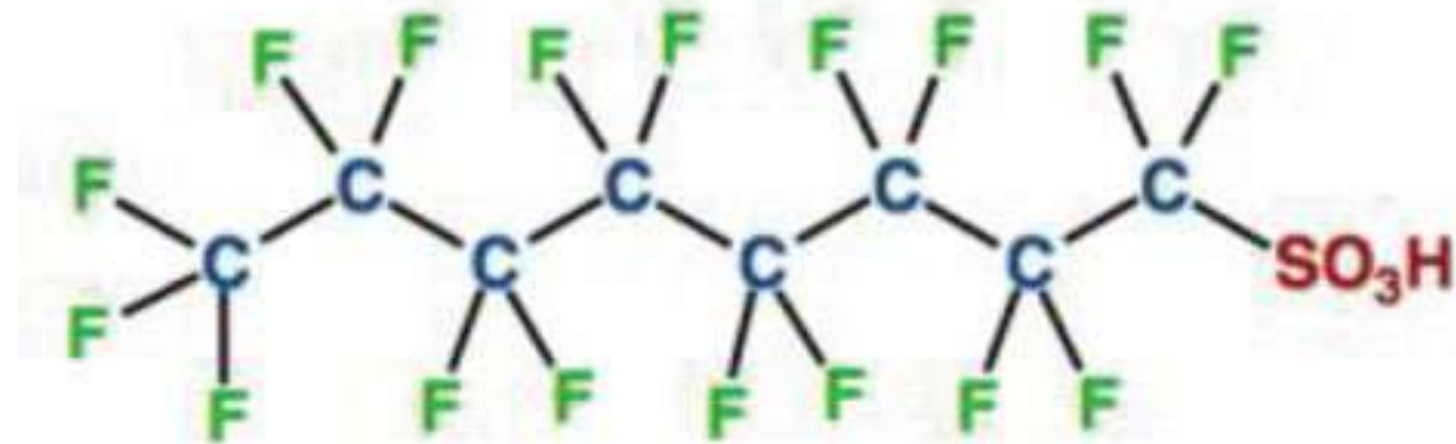
# PFAS In The Value Chain

|                        |                 |                                      |                     |                                |                          |
|------------------------|-----------------|--------------------------------------|---------------------|--------------------------------|--------------------------|
| Adhesives and sealants | Chemicals       | Fertilizers, pesticides and biocides | Machinery           | Packaging                      | Printing                 |
| Aerosol propellants    | Cleaning agents | Firefighting foam                    | Medical Products    | Paper products                 | Optical devices          |
| Aerospace and Aviation | Coating         | Floor polish                         | Mining              | Particle physics               | Soil remediation         |
| Ammunition             | Construction    | Furniture                            | Musical instruments | Personal Care Products         | Sporting Equipment       |
| Automotive             | Cookware        | Glass                                | Nuclear Energy      | Pharmaceuticals                | Textiles                 |
| Biotech                | Electronics     | Leather Products                     | Refrigerants        | Pipes and fittings             | Utilities                |
| Carpets                | Energy          | Lubricants                           | Oil and Gas         | Plastics, resins, and polymers | Water/effluent treatment |

# Long-Chain PFAS



**PFOA** - perfluorooctanoic acid



**PFOS** - perfluorooctanesulfonic acid

# Broadest to Narrowest PFAS Definitions

**Table 1. Chemical Structure-Based Definitions of the PFAS Class\***

|                      | Source  | Definition   |
|----------------------|---|--|
| Broadest Definition  | NDA for FY 2021   | A man-made chemical in which all of the carbon atoms are fully fluorinated carbon atoms, and man-made chemicals containing a mix of fully fluorinated carbon atoms, partially fluorinated carbon atoms, and non-fluorinated carbon atoms.  |
|                      | Organisations for Economic Co-operation and Development 2021 <sup>4</sup> | Fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any hydrogen (H)/chlorine/bromine/iodine atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group (-CF <sub>3</sub> ) or a perfluorinated methylene group (-CF <sub>2</sub> -) is a PFAS. |
| Narrowest Definition | Buck et al. 2011 <sup>5</sup>   | Highly fluorinated aliphatic substances that contain one or more carbon (C) atoms on which all the H substituents (present in the nonfluorinated analogues from which they are notionally derived) have been replaced by fluorine (F) atoms, in such a manner that they contain the perfluoroalkyl moiety C <sub>n</sub> F <sub>2n+1</sub> .                   |
|                      | EPA's Office of Pollution Prevention and Toxics <sup>6</sup>              | A structure that contains the unit R-CF <sub>2</sub> -CF(R')(R''), where R, R', and R'' do not equal H and the carbon-carbon bond is saturated (note: branching, heteroatoms, and cyclic structures are included).   |

<sup>3</sup> <https://www.gao.gov/assets/gao-21-37.pdf>.

<sup>4</sup> <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf>

<sup>5</sup> <https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.258>.

<sup>6</sup> Although EPA does not have a consensus definition of PFAS, some offices, such as EPA's Office of Pollution Prevention and Toxics, have applied certain criteria or definitions to advance program-specific efforts under different statutory authorities. OPPT's definition, for example, has been used for purposes of carrying out certain actions under the Toxic

# State-of-Play Definition-wise

## U.S. EPA – Office of Pollution Prevention and Toxics (OPPT)

Consistently using a PFAS definition that covers chemicals which contain at least one of these three structures: •  $R-(CF_2)-CF(R')R''$ , where both the  $CF_2$  and  $CF$  moieties are saturated carbons; •  $R-CF_2OCF_2-R'$ , where  $R$  and  $R'$  can either be  $F$ ,  $O$ , or saturated carbons; or •  $CF_3C(CF_3)R'R''$ , where  $R'$  and  $R''$  can either be  $F$  or saturated carbons

## U.S. EPA – Other Program Offices

Not yet clear

## Other U.S. Federal Agencies

Not yet clear

## State PFAS Laws

Many recent laws (*e.g.*, California, New York, Maine, Minnesota, Washington) use OECD definition expressed in more simple terms (*e.g.*, NYS 37-0101 “Perfluoroalkyl and polyfluoroalkyl substances’ or ‘PFAS’ shall mean a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.”)

## European Union

ECHA PFAS Restriction Proposal uses OECD definition

## United Kingdom

Has not supported the EU Restriction Proposal due to the breadth of the PFAS definition



# State-of-Play Definition-wise

“EPA believes it has been chemically precise in the proposed structural definition and appreciates that there are differences between the definition of PFAS used for this rule, for other actions in the Agency, and by other Federal agencies. The Agency considered adopting various definitions, including some of those suggested by commenters, but ultimately determined those definitions were not appropriate for this rule because they were not developed to focus on substances most likely to be persistent in the environment while excluding those substances that are “lightly” fluorinated. In reaching this decision, EPA considered that OECD also stipulates that there may be different definitions of “PFAS” for different entities or for different purposes, and that it may be appropriate for there to be different definitions or interpretations depending on the specific scenario. The proposed definition focused on substances with greater potential for exposures to people and/or the environment and by extension more potential to present risks. **Adopting the OECD definition of PFAS for this rule would have included many substances whose only fluorine molecule is in a terminal -CF<sub>3</sub> and that do not share a structure that is likely to result in the substance’s persistence in the environment, or which would degrade to a substance that shares toxicological or physiochemical properties with PFOA, PFOS, or GenX (Ref. 9).”**

*Final Significant New Use Rule for Substances Designated as “Inactive” on TSCA Inventory, 89 Fed. Reg. 1822 (January 11, 2024), available at <https://www.govinfo.gov/content/pkg/FR-2024-01-11/pdf/2024-00412.pdf>*

# Recently Finalized EPA Regulations

## LISTING ADDITIONAL PFAS ON TRI

- *Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory Beginning With Reporting Year 2023*, 88 Fed. Reg. 41035 (Jun. 23, 2023)

## REPORTING FOR “MANUFACTURERS” AND “IMPORTERS” OF PFAS AND PFAS-CONTAINING MIXTURES AND “ARTICLES”

- *Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*, 88 Fed. Reg. 70516 (Oct. 11, 2023)

## ELIMINATING *DE MINIMIS* EXCEPTION FROM TRI REPORTING FOR PFAS

- *Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting*, 88 Fed. Reg. 74360 (Oct. 31, 2023)

## PROHIBITING MANUFACTURE AND IMPORT OF “INACTIVE” PFAS WITHOUT SNUN APPROVAL

- *Final Significant New Use Rule for Substances Designated as “Inactive” on TSCA Inventory*, 89 Fed. Reg. 1822 (January 11, 2024)

# PFAS Reporting Rule

## REPORTING PERIOD

January 1, 2011-November 13, 2023

## REPORTING DEADLINE

May 8, 2025 (except November 10, 2025 for small businesses which import “articles”)

## APPLICABILITY

- Manufacturers and importers of “PFAS” as a separate chemical substance
- Manufacturers and importers of a “mixture” containing one or more “PFAS” as a component
- Manufacturers who produce “PFAS” coincidentally during manufacture, processing and use of another chemical substance
- Importers of an “article” containing one or more “PFAS”

## SCOPE

“Known or reasonably ascertainable by”  
– meaning “all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control or know”



# Significant EPA Regulations On The Horizon

## LISTING CERTAIN PFAS AS CERCLA “HAZARDOUS SUBSTANCES”

- *Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances; Proposed Rule, 87 Fed. Reg. 54415 (Sept. 7, 2022) (final rule expected March 2024)*
- *Addressing PFAS in the Environment; Advanced Notice of Proposed Rulemaking, 88 Fed. Reg. 22399 (Apr. 13, 2023)*

## REGULATING CERTAIN PFAS UNDER SAFE DRINKING WATER ACT

- *PFAS National Primary Drinking Water Regulation Rulemaking; Proposed Rule, 88 Fed. Reg. 18638 (Mar. 29, 2023) (final rule expected September 2024)*

## MAKING PFAS INELIGIBLE FOR TSCA PMN EXEMPTIONS

- *Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA); Proposed Rule, 88 Fed. Reg. 34100 (May 26, 2023) (final rule expected February 2025)*

## LISTING CERTAIN PFAS AS RCRA “HAZARDOUS CONSTITUENTS” AND POTENTIALLY COVERING OTHER PFAS AS STATUTORY “HAZARDOUS WASTE”

- *Listing of Specific PFAS as Hazardous Constituents; Proposed Rule, 89 Fed. Reg. 8686 (Feb. 8, 2024)*
- *Definition of Hazardous Waste Applicable to Corrective Action for Releases From Solid Waste Management Units; Proposed Rule, 89 Fed. Reg. 8598 (Feb. 8, 2024)*

# Just Some Of The Other Notable Initiatives

## NATIONAL ENFORCEMENT AND COMPLIANCE INITIATIVE (NECI) TO ADDRESS PFAS CONTAMINATION

- *Public Comment on EPA's National Enforcement and Compliance Initiatives for Fiscal Years 2024–2027*, 88 Fed. Reg. 2093 (Jan. 12, 2023)

## LONG-CHAIN PFAS SNUR ENFORCEMENT

- *U.S. v. Inhance* (Eastern District of PA)
- *Inhance v. EPA* (5<sup>th</sup> Circuit)

## PROHIBITING “INTENTIONALLY-ADDED PFAS” IN PACKAGING UNDER EPA SAFER CHOICE STANDARD

- EPA, Docket EPA-HQ-OPPT-2023-0520, *Modifications to the Safer Choice Standard and Potential Implementation of a Safer Choice Cleaning Service Certification Program* (Nov. 14, 2023)

## PFAS ANALYTICAL METHOD DEVELOPMENT

- *E.g.*, Method 1633 for 40 PFAS Compounds (published in final January 2024 and developed by EPA Office of Water in partnership with the Department of Defense's (DoD) Strategic Environmental Research and Development Program

## STATE PFAS REPORTING

- *E.g.*, “Intentionally added PFAS” product reporting in Maine beginning January 1, 2025



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Julie (Julia A.) Hatcher is a partner in the Washington, D.C. office of Latham & Watkins, focusing on environmental, health, safety and product defense. Ms. Hatcher possesses deep expertise in federal laws administered by U.S. EPA that control chemicals at every life cycle stage, including the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Resource Conservation and Recovery Act (RCRA), the Superfund laws (CERCLA and EPCRA), the Safe Drinking Water Act, the Clean Water Act and the Clean Air Act as well as laws administered by other agencies pertaining to worker safety and chemicals in products, including in cosmetic, personal care and consumer products. She also deals regularly with the intersection of these laws with litigation liability and with related state laws. Her expertise also extends to consumer products-related requirements for labeling, reporting, “green” and “health” claims and recalls administered by the Consumer Products Safety Commission, the Federal Trade Commission and state counterpart agencies as well as to chemical control regimes outside of the U.S. Ms. Hatcher has worked on Per- and Polyfluoroalkyl Substances (PFAS) matters for over 20 years, and has extensive knowledge regarding PFAS manufacturing technologies, chemistry, functionality, supply chains and many other facets.