PFAS: From Here to Eternity

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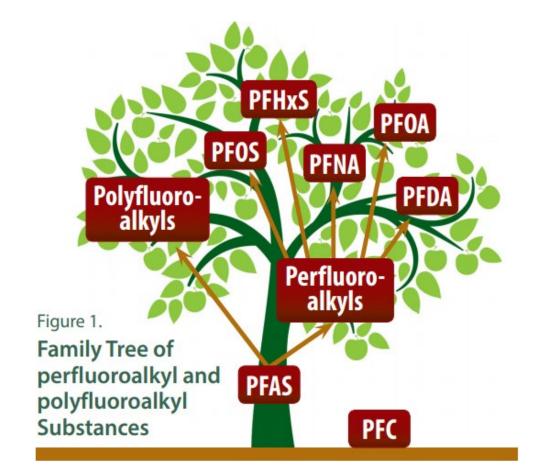
Agenda

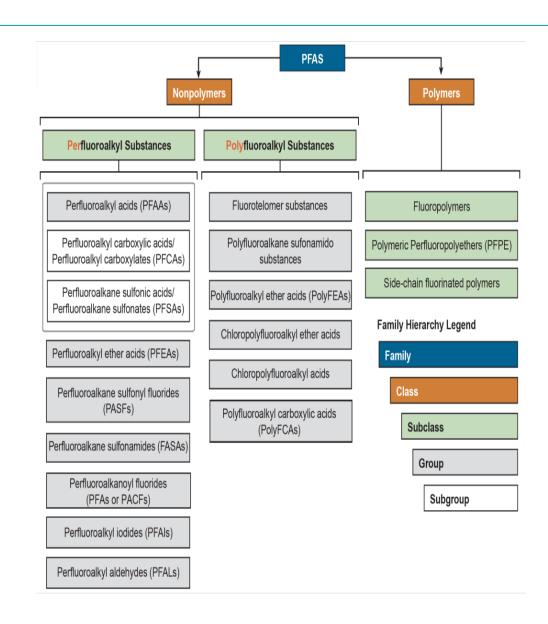
- What is PFAS?
- Why does definition matter?
- Consumer Product Regulations
- PFAS & TSCA\(8(a) \)
- Inhance Technologies L.L.C. v. EPA
- Measuring PFAS
- PFAS & Toxic Inventory Reporting
- PFAS & the Clean Water Act
- PFAS & CERCLA



What is (are) "PFAS"?

 First manufactured in the 1930 and commercialized in the 1940s





PFAS Definition – Overview

SOURCE	DEFINITION	HOW MANY?
Buck et al. (2011)	A subset of fluorinated substances is the highly fluorinated aliphatic substances that contain 1 or more C atoms on which all the H substituents (present in the nonfluorinated analogues from which they are notionally derived) have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety CnF2n+1–. These compounds are hereafter referred to as "perfluoroalkyl and polyfluoroalkyl substances" and denoted by the acronym PFASs.	268 (excludes fluoropolymers)
Buck et al. (2021)	Bottom-up evaluation, using 2011 definition (241 commercially relevant) and adding 15 compounds that did not meet or were excluded from the 2011 definition (but commercially relevant): HFEs, HFOs, refrigerants, or containing an aromatic ring.	256 (commercially relevant)
OECD 2018	Database of compounds that contain a $-CnF2n-(n \ge 3)$ or $-CnF2nOCmF2m-(n and m \ge 1)$ moiety.	4,729
OECD 2021 and ECHA 2023 (proposed)	New Definition: PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/l atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS.	>7 million (PubChem, based on OECD definition)
California AB 1200	a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. NOTE: this is definition, but only "regulated" if intentionally added, or >100 ppm TOF.	MANY
EPA	EPA OPPT Working Definition: a structure that contains the unit R-CF2-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). This definition identifies chemicals with at least two adjacent carbon atoms, where one is fully fluorinated and the other is at least partially fluorinated. Most recently (2023), EPA eliminated its definition, citing that it will look at the definition on a case-by-case basis, depending on the context and regulatory program that is being considered.	Program-dependent (2023)



WHY DOES DEFINITION MATTER?

- Can the definition be specific to a jurisdiction or regulation?
- Will differing definitions result in widely disparate or confused interpretation?
- Without clear definition, will it be difficult to design toxicological studies for PFAS as a Class?
- Without a clear definition, will it be difficult to develop or determine appropriate analytical methods?

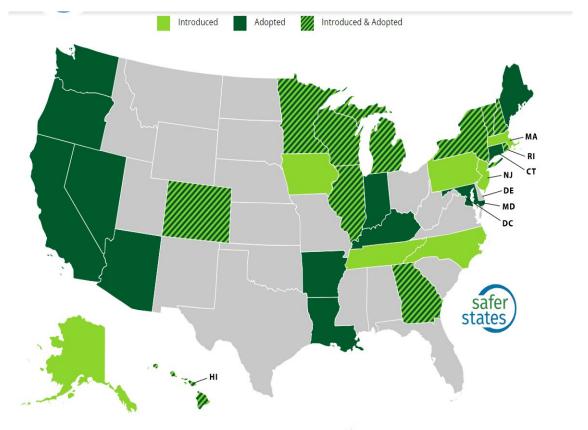




Regulations Governing Consumer Products

In February 2024, ASTM F15.81 – PFAS in Consumer Products Re-balloted its first DRAFT Standard Guidance

	California	Connecticut	Hawaii	lowa	Maine	Maryland	Massachusettes	Minnesota	New York	Oregon	Rhode Island	Vermont	Washington
Cosmetics	Χ					X	Р		Р		Р	Р	Р
Rugs & Carpets	Χ				Χ	Χ	Р		Р		Р		
Fire-Fighting Foam		Χ		Р		Χ							Χ
Food Packaging	Χ	Χ	Р	Р	Χ	Χ	Р	Χ	Χ		Р	Р	Χ
Juvenile Products	Χ						Р		X	X	Р	X	Χ
Fabric/Textiles	Р				X		Р		Р		Р		
Anti-Fogging Sprays									Р				
Ski Wax												χ	





P = Proposed Legislation

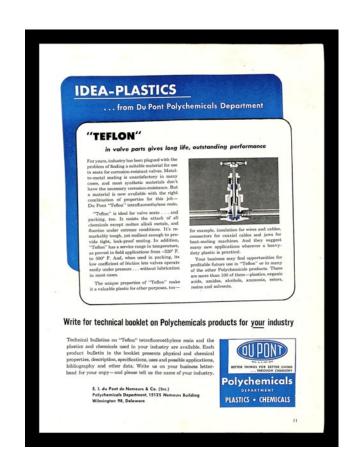


PFAS & TSCA§8(a)(7)

(7)PFASDATA.—Not later than January 1, 2023, the <u>Administrator</u> shall promulgate a rule in accordance with this subsection requiring each person who has manufactured a <u>chemical substance</u> that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011, to submit to the <u>Administrator</u> a report that includes, for each year since January 1, 2011....

(2) ... reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

- (A)The common or trade name, the chemical identity, and the molecular structure of each substance or mixture ... chemical
- (B)The categories or proposed categories of use of each such substance or <u>mixture</u>.
- (C)The total amount of each such substance and <u>mixture</u> manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.
- (D)A description of the byproducts resulting from the <u>manufacture</u>, processing, use, or disposal of each such substance or mixture.
- (E)All existing information concerning the environmental and health effects of such substance or mixture.
- (F)The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.
- (G)In the initial report under paragraph (1) on such substance or <u>mixture</u>, the manner or method of its disposal, and in any subsequent report on such substance or <u>mixture</u>, any change in such manner or method.



Inhance Technologies, L.L.C. v. EPA

- In 2020, certain PFAS were found by PEER in a pesticidal product used for spray application
- Further investigation suggested that the source of the PFAS may have been containers
- Inhance fluorinates pre -molded HDPE containers and fuel tanks and was target of investigation
- In December 2023, EPA issued two orders under § 5 of TSCA (Significant New Use)
 - Prohibition from manufacturing or processing long chain PFAS in their fluorination process
- Inhance challenged orders in the 5th Circuit Court of Appeals
- March 2024 decision
 - Process that had been used for decades before SNUR not a "significant new use"
 - Congress intended existing uses to be subject to § 6 which includes a cost -benefit analysis
 - Fails to provide fair notice before finding of violation
- EPA granted a petition for § 6 rulemaking on July 11, 2024



Detailed Summary - Measuring PFAS

Targeted Analysis

- Identification of individual target PFAS compounds
 - ~ 40 PFAS analytes (some up to 80)
 - Typical limits of quantitation (LOQs) of ng/L (ppt) in aqueous and sub-µg/kg (ppb) in solids
- Dependent on available standards for each target *Note* some laboratories are obtaining reference standards from noncertified sources
- Various speciated LC/MS/MS methods
- Total oxidizable precursor assay (TOPs) This is theoretical, but it is targeted

Non-Targeted Analysis

- Cumulative measurement of both known and unknown PFAS compounds
- Can be used as screening methods in conjunction with LC/MS/MS analysis
- Total fluorine (TF)
- Total adsorbable organic fluorine (TAOF)
- Total extractable organic fluorine (TEOF)
- Total organic fluorine (TOF) mostly



Overview/Timeline of Targeted US EPA PFAS Methods

- US EPA Method 537.0 Drinking Water September 2009 (14 PFAS Compounds)
 - Because UCMR3 (May 2012) included 6 PFAS compounds.
- US EPA Method 537.1

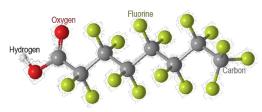
 Revised November 2018 (18 PFAS Compounds)
 - Same as 537.0, but added four more PFAS.
- US EPA SW846 Method 8327 Non-Drinking Water Aqueous Method – (24 PFAS Compounds)
 - June 2019 (draft) Direct injection, screening only and not usable.
 - September 2021 (Rev 0) (and Method 3512).
 - This method is best used for long -term monitoring of GW with 20 - 100 ppt PFAS.
- US EPA Method 533 Drinking Water (35 PFAS Compounds)
 - December 2019 11 more PFAS (shorter chains).
 - Alternate preservation, enhanced SPE and ID quantitation.

- US EPA Method 1633- Non-DW Aqueous, (Literally, everything but DW) – Draft Rev 5 – January 2024 – (40 PFAS Compounds)
 - Posted on the US EPA website, single-laboratory study (still has not undergone draft Rule Making).
 - Inconsistencies and major reporting problems (e.g., no resolution criteria - branched/linear analysis).
 - This is the method to be most concerned with matrix/bias/false positives and negatives for complex matrices.
- US EPA Method 1621

 Adsorbable Organic Fluorine (AOF) (by Ion Chromatography)
 - Posted on the US EPA website, single-laboratory study (still has not undergone draft Rule Making).
 - This method is already being used as a PROXY for total PFAS.

The US Toxic Release Inventory (TRI) reporting includes 196 PFAS compounds

The US TSCA reporting includes 1,462+ PFAS compounds



TF, TAOF and TEOF By Combustion Ion Chromatography

CIC methods are proxies for "Total PFAS"

- Huge assumptions what is PFAS
- Huge differences in detection and quantitation limits
 - Total fluoride MDL by Method 300.0 and by CIC is 10 μ g/L with LOQ ~50 μ g/L
- TAOF and TEOF MDLs by CIC is 0.5-5 μg/L with LOQs 2-10 μg/L depend on concentration (blow-down) factors
- This is NOT *TOF* Does not include fluoropolymers
 - Methanol does not extract fluoropolymers

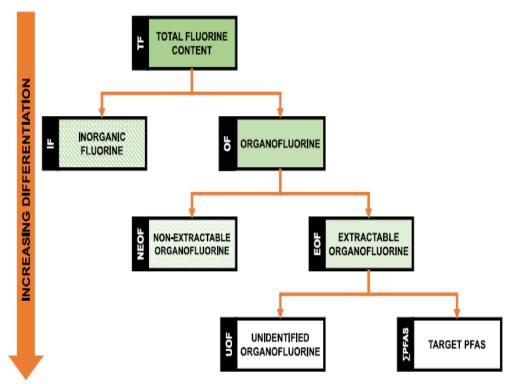


Image from "Combustion ion chromatography for extractable organofluorine analysis." *iScience*, Volume 24, Issue 9, 24 September 2021, 102968

PFAS & TRI

- Oct.31 final rule is effective now July 1 reporting deadline has passed
- 196PFAS on list; new "chems of special concern" auto-added per 2020 NDAA
- These have <u>100 pound</u> threshold for manufacture/process/otherwise use
- Default 25,000 lbs for M/P or 10,000 lbs for OU so lower 100 lb # is a big deal
- Because PFAS often appear in trace concentrations, they could have been deemed exempt (not counted toward threshold) as *de minimis* (<1% or 0.1%)
 - As "chemicals of special concern," these **PFAS** now ineligible for de minimis exemption
 - Rule removes de minimis from Supplier Notification as well upstream and downstream
- Have sympathy for your TRI reporters because this is a significant burden is your company/facility resourced and ready for this new lift?
- If you didn't perfect this by RY2023 reporting deadline, consider an audit and EPA eDisclosure later this year



PFAS & Water

- EPA finalized PFAS Drinking Water Standard on April 10, 2024
 - MCLs at 4.0 ppt for PFOA & PFOS
 - MCLs at 10.0 ppt for PFNA, PFHxS, and GenX
 - Hazard Index of 1 for mixtures of PFNA, PFHxS, PFBS, & Gen X
- Rule has been challenged by water utilities
 - Failure to rely on best available science
 - Underestimated cost of the rule
 - Major questions doctrine?





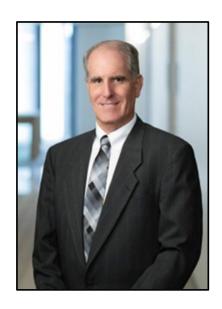
PFAS & CERCLA

- September 2022 EPA proposed listing PFOA and PFOS as "hazardous substances" under CERCLA
- April 2024 EPA finalized the listing
- Rule became effective on July 8, 2024
 - Triggered immediate release reporting
 - EPA issued enforcement policy indicating EPA will not pursue passive receivers
- US Chamber of Commerce challenged rule on June 13, 2024
 - First time chemicals are directly listed as CERCLA hazardous substances
 - Allegation that the rule fails to provide clear standards for when a site would be deemed hazardous under CERCLA





Thank you!



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