

A Tour of the PFAS Landscape: A Survey of Key Federal and State Regulatory Developments Impacting Products – Part 1

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Gavin advises manufacturers, marketers & trade associations on characterizing chemical exposures to humans from consumer products, food, food processing & packaging, household items, and environmental media. Product investigations include basic & specialty chemicals, pulp & paper, cosmetics, consumer & household products, food ingredient, processing & packaging materials. He conducts comprehensive exposure & safety assessments, consultations with regulatory agencies, and successful submissions for pre-manufacturing and pre-market approvals, including TSCA PMN, SNUN, LVE & BFI submissions, FIFRA registrations, GRAS notifications & FCNs. In support of these projects, Gavin designs, supervises, and interprets field sampling and laboratory analysis of chemical ingredients and contaminants in environmental media, HI&I/consumer products, and food products to characterize potential human health risks.

Overview

Part 1:

- **Introduction to PFAS**
- **State Regulation of PFAS**

Part 2:

- Federal PFAS Regulation
- PFAS Litigation

Introduction to PFAS

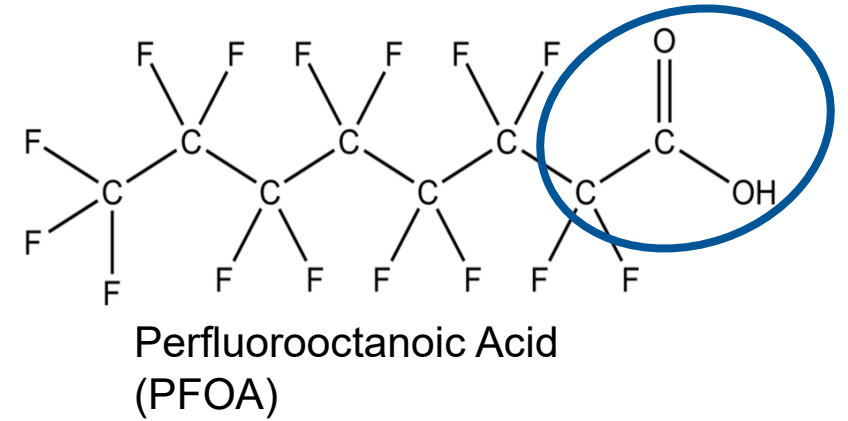
Ashish Deshmukh, PhD



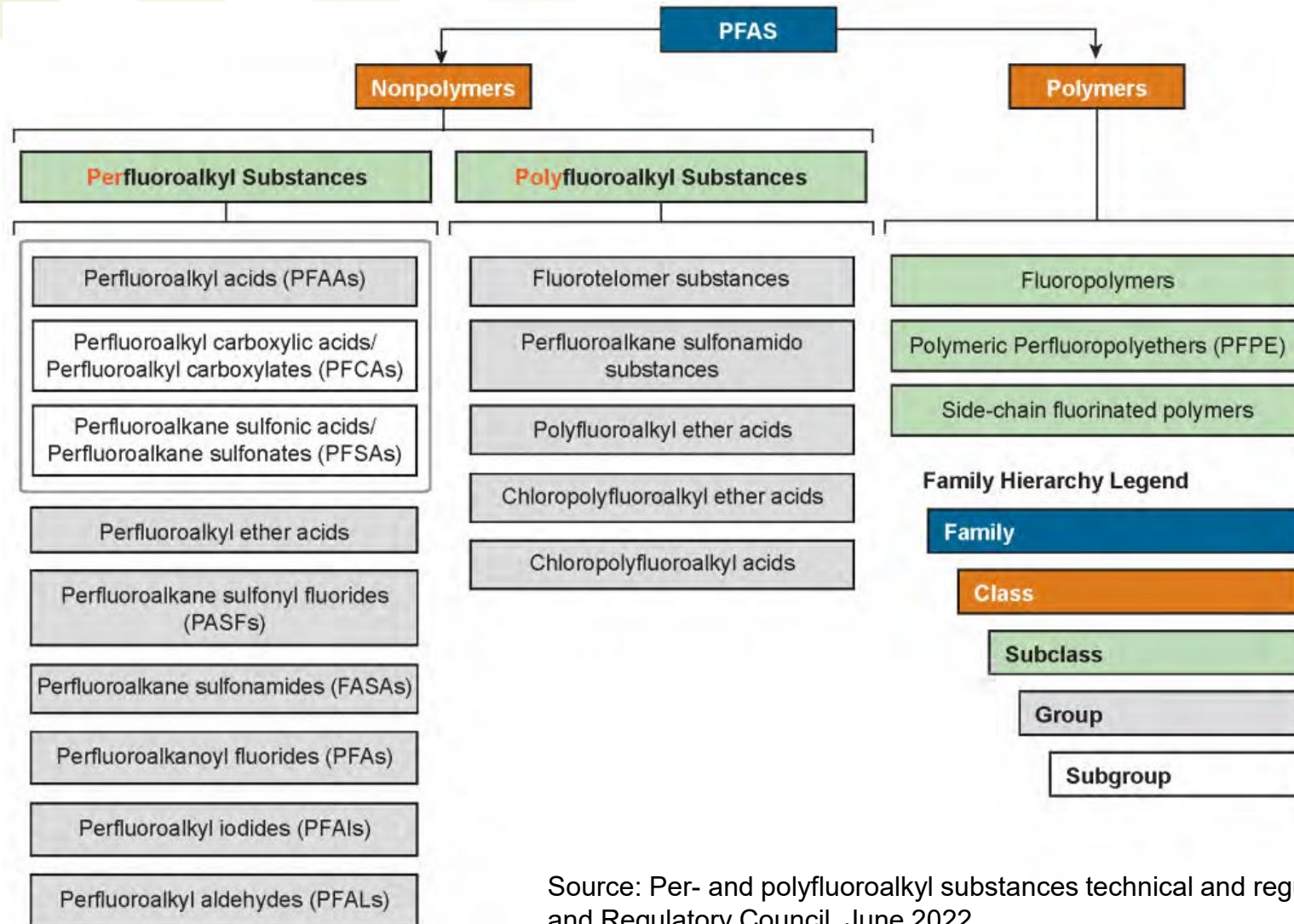
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What is a Per- and Polyfluoroalkyl Substance (PFAS)?

- Per (all)
- Poly (many)
- Fluoroalkyl – carbon chain with fluorine
- NOT a single chemical
 - Large class of diverse chemicals
 - Two major classes: **non-polymers and polymers**
 - Common feature – stability (aka: persistence)
- P – Persistent
- B – Bioaccumulative
- T – Toxic

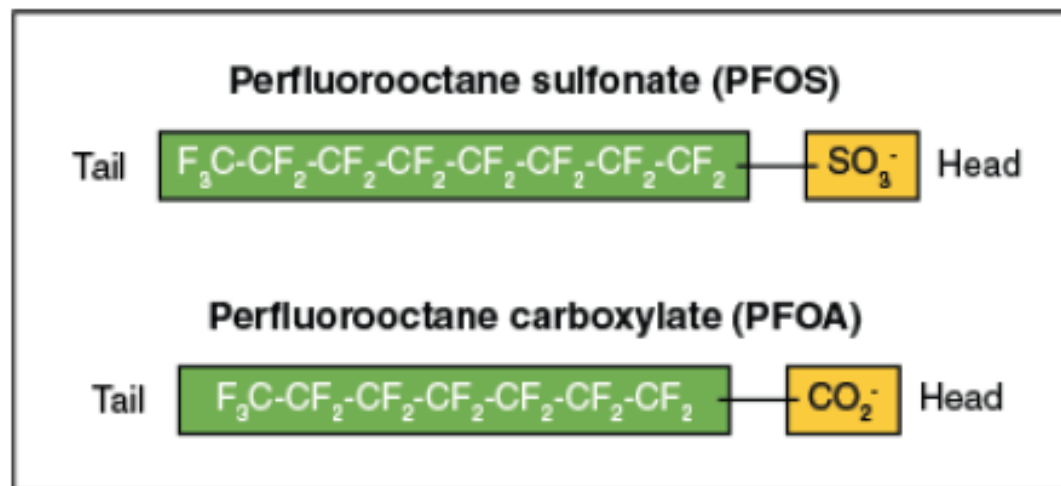


Classification of PFAS



Source: Per- and polyfluoroalkyl substances technical and regulatory guidance, The Interstate Technology and Regulatory Council, June 2022

Perfluoroalkyl Substances

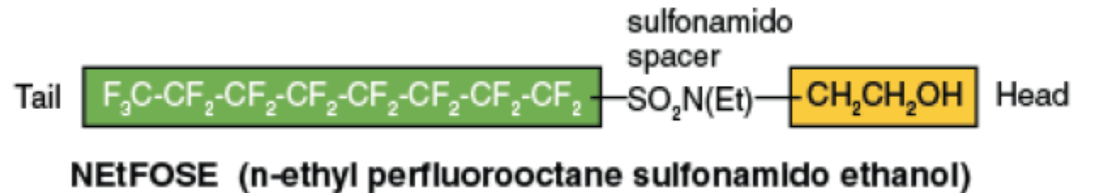
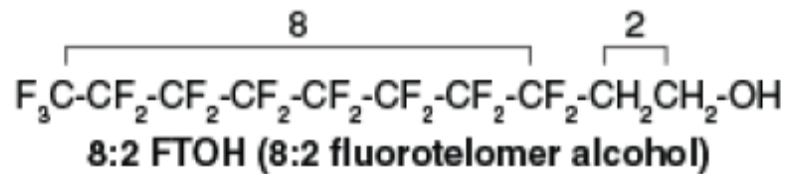


Number of Carbons	4	5	6	7	8	9	10	11	12
PFCAs	Short-chain PFCAs				Long-chain PFCAs				
	PFBA	PFPeA	PFHxA	PFHpA	PFOA	PFNA	PFDA	PFUnA	PFDaA
PFSAs	PFBS	PFPeS	PFHxS	PFHpS	PFOS	PFNS	PFDS	PFUnS	PFDoS
	Short-chain PFSAs		Long-chain PFSAs						

Source: Per- and polyfluoroalkyl substances technical and regulatory guidance, The Interstate Technology and Regulatory Council, June 2022

Polyfluoroalkyl substances

- They have a nonfluorine atom (typically hydrogen or oxygen) attached to at least one carbon atom, while one or more of the remaining carbon atoms in the carbon chain tail are fully fluorinated.
- The carbon-hydrogen (or other nonfluorinated) bond in polyfluoroalkyl molecules creates a “weak” point in the carbon chain that may be susceptible to biotic or abiotic degradation; potential to be transformed into perfluoroalkyl acids.



Advantages of PFAS

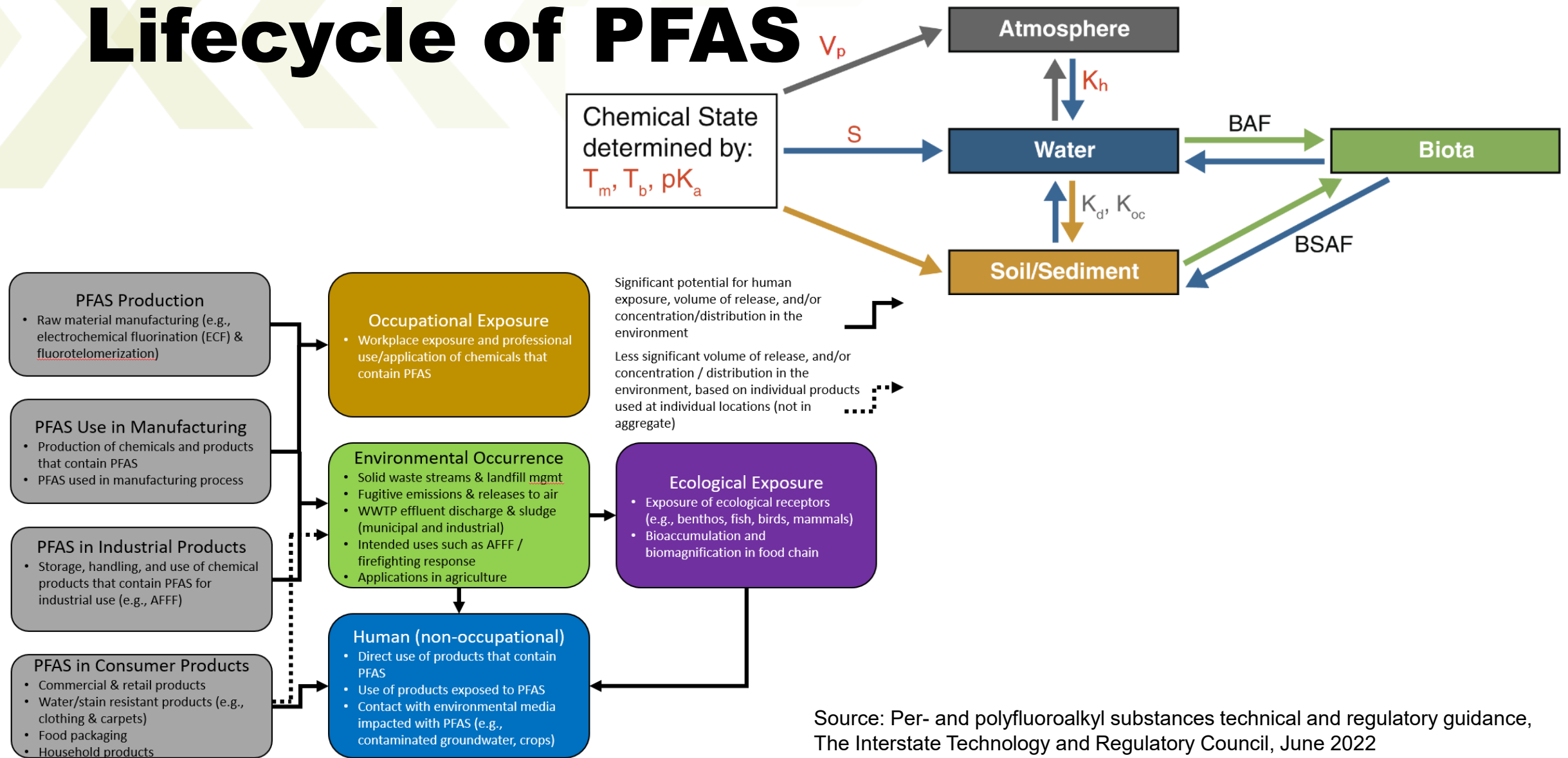
- They exhibit both **water and oil repellency** when adsorbed on substrates such as textiles or paper.
- They **lower the surface tension** of aqueous systems **at very low concentrations (ppm level)**, tend to aggregate into micelles (form a sphere with the hydrophobic portion of the molecules oriented toward the air) above a certain concentration.
- **Stable** to heat, acids, and bases, as well as reducing and oxidizing agents.

History and Use of PFAS

PFAS ¹	Development Time Period							
	1930s	1940s	1950s	1960s	1970s	1980s	1990s	2000s
PTFE	Invented	Non-Stick Coatings			Waterproof Fabrics			
PFOS		Initial Production	Stain & Water Resistant Products	Firefighting foam				U.S. Reduction of PFOS, PFOA, PFNA (and other select PFAS ²)
PFOA		Initial Production	Protective Coatings					
PFNA					Initial Production	Architectural Resins		
Fluoro-telomers					Initial Production	Firefighting Foams		
Dominant Process ³		Electrochemical Fluorination (ECF)						Fluoro-telomerization (shorter chain ECF)
Pre-Invention of Chemistry /			Initial Chemical Synthesis / Production			Commercial Products Introduced and Used		

Source: Per- and polyfluoroalkyl substances technical and regulatory guidance, The Interstate Technology and Regulatory Council, June 2022

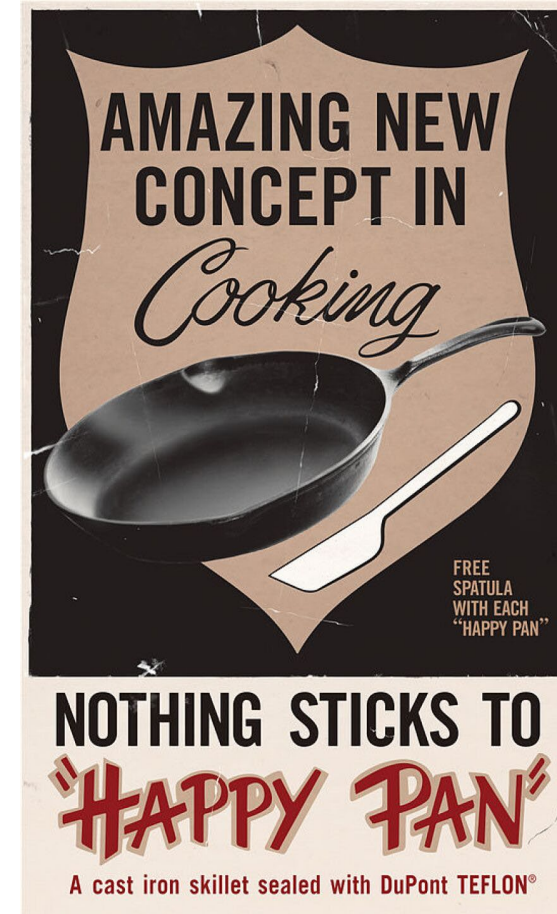
Lifecycle of PFAS



Source: Per- and polyfluoroalkyl substances technical and regulatory guidance, The Interstate Technology and Regulatory Council, June 2022

How are we exposed to PFAS?

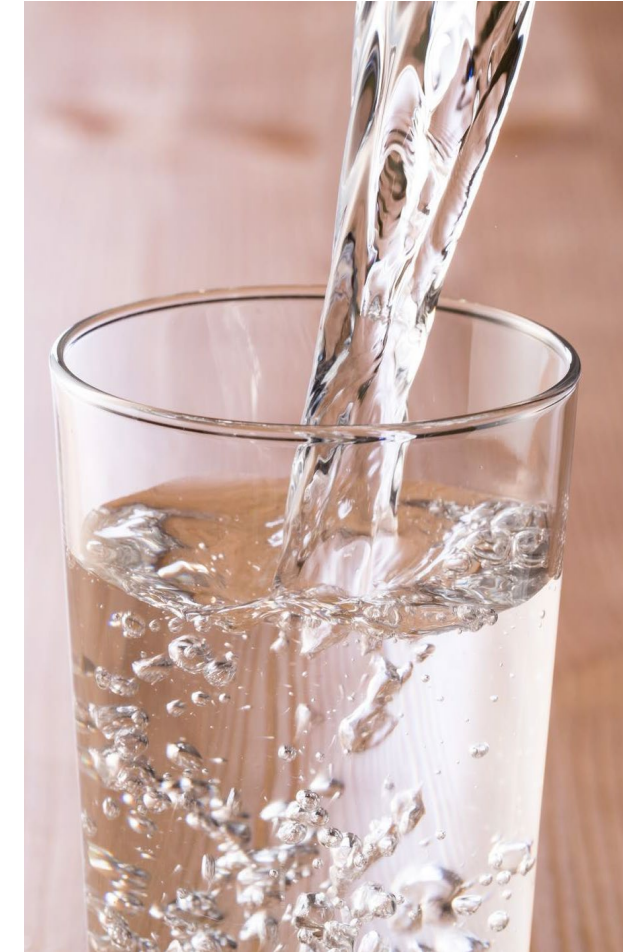
- Manufacturing facility discharges
- Firefighting foam (AFFF)
- Contaminated drinking water
- Food (fish, livestock)
- Food packaging
- Land application of biosolids
- Exposure to consumer goods
- Household products (carpets, upholstery, clothing, paints, varnishes, sealants, cookware)
- Ambient and indoor air and dust



Adverse Effects – Humans and Animals

Animal	Human (possible links)
Liver effects	Liver effects (serum enzymes/bilirubin, cholesterol)
Immunological effects	Immunological effects (decreased vaccination response, asthma)
Developmental effects	Developmental effects (birth weight)
Endocrine effects (thyroid)	Endocrine effects (thyroid disease)
Reproductive effects	Reproductive effects (decreased fertility)
Hematological effects	Cardiovascular effects (pregnancy induced hypertension)
Neurobehavioral effects	
Tumors (liver, testicular*, pancreatic*)	Cancer* (testicular, kidney)

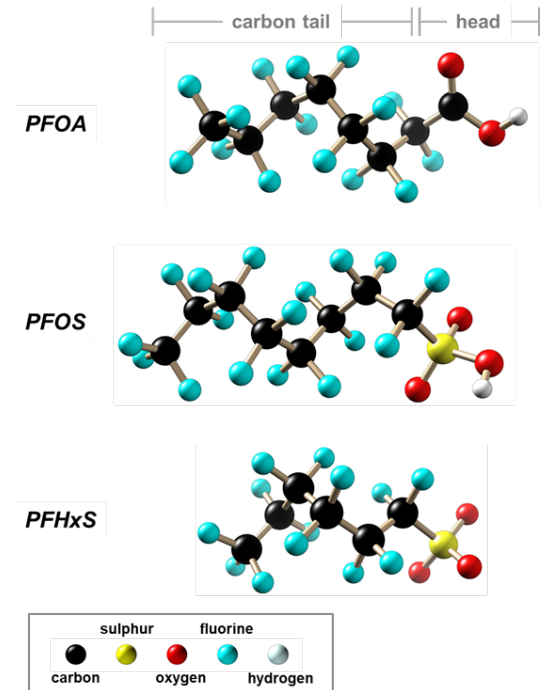
*PFOA only



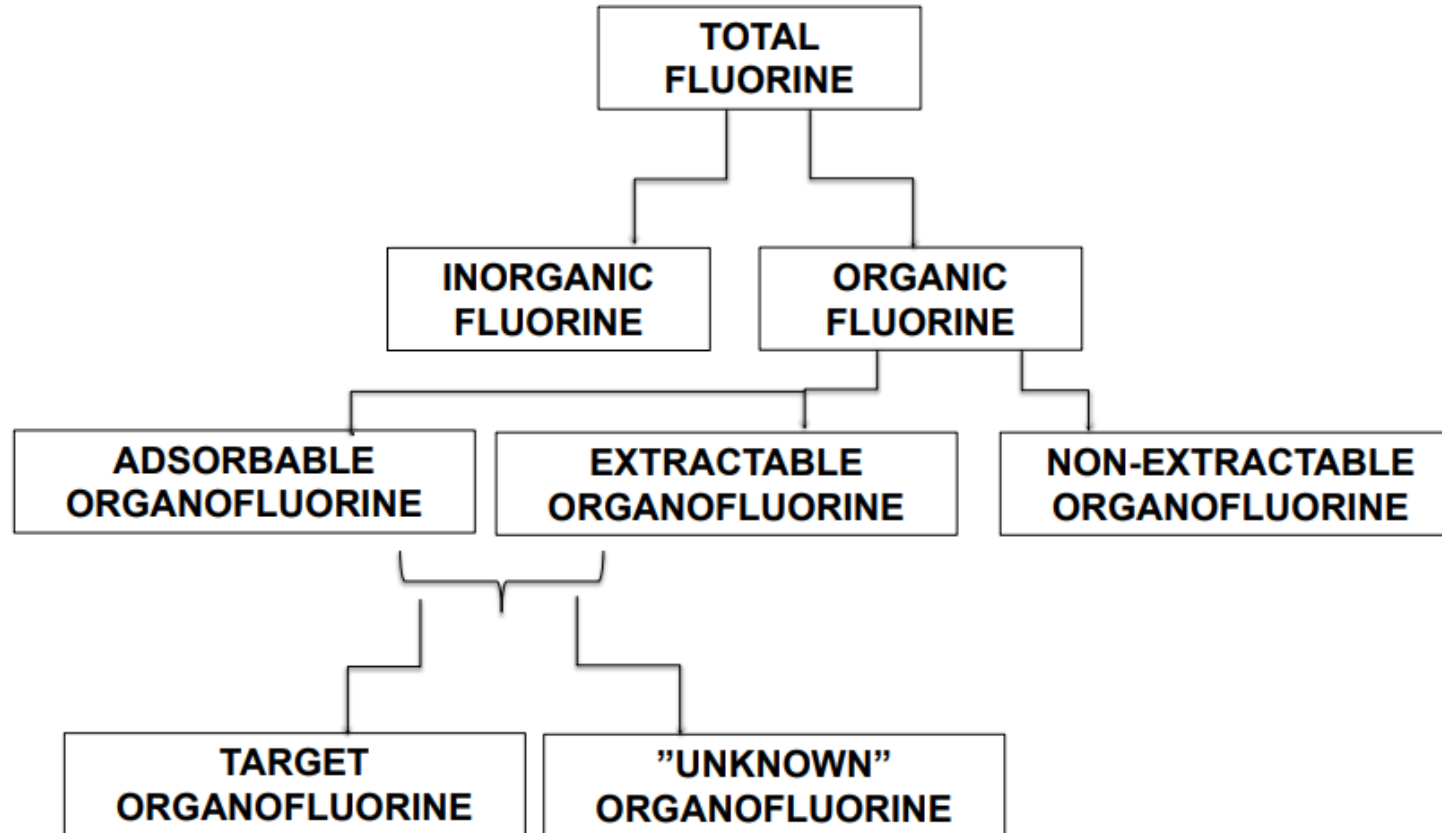
Analysis of PFAS

Challenges for PFAS Analysis

- Statistics as of 2021:
 - >12,000 known PFAS (vs. 209 PCB and 210 PCDD/PDCF congeners)
 - ~9,000 with known chemical structures
 - ~4,700 with assigned CAS numbers
 - ~700 on TSCA Active Inventory (i.e., currently being distributed in US commerce)
- Some regulatory thresholds based on total fluorine, e.g., CA AB 1200 for food packaging (100 ppm)
- Others regulate individual PFAS, e.g., CA Proposition 65 listing for PFOA, PFOS and PFNA (no NSRL or MADL)
- Some regulations have not established *de minimis* thresholds or safe harbor levels, e.g., TSCA Significant New Use Rule for PFAS



Types of PFAS Analysis



Increasing
specificity of
PFAS (-CF₂-)
substances

Sample PFAS Analytical Methods

- FDA Method C-010.02: Determination of 16 PFAS in Processed Food using Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS)
- EU CEN/TS 15968: Determination of Extractable PFOS in Coated and Impregnated Solid Articles, Liquids, and Fire Fighting Foams; can be used for analysis of paper and board food contact materials
- EPA Method 537 modified with cryo-milling preparation: testing of commercial articles
- EPA Methods 533, 537, and 537.1 for drinking water and groundwater that may be used as drinking water
- ASTM D7968 for soil/solids and ASTM D7979 for non-drinking water, groundwater, surface water, wastewater



State Regulation of PFAS



Irene Hantman



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State Laws and Other Activities

- Fire fighting foams
- Drinking water standards
- Hazardous waste
- **Consumer products**
- Litigation

State Regulation of PFAS in Consumer Products

California

November 2017: Prop 65 warning required for PFOA (Nov. 2017)

July 2021: Ban children's products containing intentionally added PFAS (July 2023)

October 2021: Ban on food packaging that contains 1) PFAS that are intentionally added to a product or 2) more than 100 ppm of PFAS (Jan. 2023)

December 2021: Prop 65 warning required for PFNA (Dec. 2022)

April 2022: “Priority Product Notification” required for leather and textile products containing PFAS (April 2022)

August 2022: Ban on cosmetic products containing PFAS (Jan. 2025)

State Regulation of PFAS in Consumer Products – Colorado

June 2022: ban on certain products containing intentionally added PFAS (effective Jan. 2024)

- Carpets & rugs
- Cosmetics
- Fabric treatments
- Upholstered furniture
- Textile furnishings
- Oil & gas products
- Food packaging
- Children's products

State Regulation of PFAS in Consumer Products – Maryland

March 2022:

- Ban on rugs and carpets that contain intentionally added PFAS (effective January 1, 2024)
- Ban on food packaging designed for direct food contact that contains intentionally added PFAS (effective January 1, 2024)

New York

April 2022. Ban on food packaging with intentionally added PFAS (effective December 31, 2022)

May 2022. Ban on apparel with intentionally added PFAS (effective December 31, 2023)

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FDA Regulation of PFAS

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PFAS Authorized by FDA in Food Contact Uses

- **Repeat-use items** such as non-stick cookware.
- **Parts of food processing equipment** (gaskets, O-rings , etc.) incorporate PFAS resin to improve the wear life of the equipment (durability).
- **As processing aids** in the manufacture of food-contact polymers; the PFAS reduces the accumulation of residuals and polymer product on equipment during manufacture of the polymer.
- **Food packaging materials**, in particular, OGR coatings for paper and paperboard, for example, on wrapping paper for quick serve food (fast-food wrappers), liners for microwave popcorn bags, paperboard containers.

Food/Food Packaging Connection

- July 2020 – FDA requested “voluntary withdrawal” of food contact notifications (FCNs) for oil & grease resistant food contact coatings
 - Based on rodent studies showing **biopersistence, NOT safety information**
 - Three manufacturers
 - > 20 short-chain PFAS containing 6:2 fluorotelomer alcohol (6:2 FTOH) withdrawn
 - Substances had previously replaced long chain PFAS after the 2011 withdrawal
 - 3-year phase-out began 2021
- Jan 2022 – FDA seeks new authority to restrict products
 - proposed rule to make FCN withdrawals easier, explicitly for non-safety reasons
- FDA’s inventory of effective FCNs still has several PFAS substances

Fluorinated HDPE – Request for Information

- Surface fluorination of polyethylene containers allows for improved chemical barrier properties (21 CFR 177.1615)
 - Requires a certain manufacturing process
 - EPA discovered PFAS is formed when other processes are used and can migrate
- On July 20, 2022, FDA published a Request for Information (RFI) notice related to use of fluorinated polyethylene in food contact applications
 - Current food contact uses, including conditions of use
 - Details of the fluorination process
 - Analyses of surface chemical functionalities
 - Analyses of substances migrating from surfaces to food
 - Safety studies on substances migrating
 - Safety assessment of PFAS that may migrate from these food use applications
 - Manufacturing processes

EPA Regulation of PFAS

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EPA Regulations

- CERCLA
 - See <https://www.epa.gov/superfund/proposed-designation-perfluorooctanoic-acid-pfoa-and-perfluorooctanesulfonic-acid-pfos>
- EPCRA (TRI)
 - See <https://www.epa.gov/toxics-release-inventory-tri-program/addition-certain-pfas-tri-national-defense-authorization-act>
- **FIFRA**
- SDWA
 - See <https://www.epa.gov/sdwa/drinking-water-health-advisories-has>
- **TSCA**
- PFAS Strategic Roadmap
 - See <https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024>

PFAS Regulation under TSCA

Proposed TSCA PFAS Reporting Rule

TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements (86 FR 33926)

- PFAS subject to rule
 - All PFAS listed as active on the TSCA Inventory
 - PFAS subject to LVE applications -- including PFAS subject to LVE applications that have since been withdrawn
 - 40 CFR § 705.5 lists these substances by CASRN, Accession No., and LVE No.
- For each year since January 1, 2011, report
 - Use
 - Volumes manufactured (including imported) and processed
 - Environmental and health effects
 - Worker exposure
 - Disposal

Proposed TSCA PFAS Reporting Rule Cont'd

Reporting Criteria

- Volume threshold: any amount
- Concentration: any amount
- Exemptions: none
 - Articles containing PFAS are subject to the rule
 - PFAS manufactured and processed in R&D are subject to the rule
 - PFAS present as byproducts are subject to the rule

Proposed TSCA PFAS Reporting Rule Cont'd

Reporting Standard

- Reporting required “to the extent that the information is known to or reasonably ascertainable by the manufacturer”
 - All information in a person’s possession or control
 - All information that a reasonable person similarly situated might be expected to possess, control, or know
- The Reasonably Ascertainable standard requires manufacturers to make inquiries to ...
 - Upstream suppliers
 - Downstream users
 - Employees and agents involved in R&D, import, production, marketing

Proposed TSCA PFAS Reporting Rule Cont'd

Industry Comments on the Rule

- Clarify the Definition of “PFAS”
- Include common TSCA exemptions: articles, R&D, byproducts, impurities
- Include reporting thresholds: volume & concentration
- Require use and exposure data for only the principal reporting year
- Clarify application of the “reasonably ascertainable” standard
- Exclude reporting for PFAS for which EPA has data/data are publicly available
- Exclude substances with low exposure potential or of low concern
- Data should be of practical utility

National PFAS Testing Strategy

Identification of Candidate Per- and Poly- fluoroalkyl Substances for Testing
([Oct. 2021](#))

- 6,504 PFAS
- 70 “terminal” categories
- 56 terminal categories that lack any data about the toxicity of the PFAS in that category
- 24 contained PFAS with an identifiable manufacturer(s) to whom EPA could issue a test order

PFAS Test Order

- June 2022 Section 4 [Test Order](#): 6:2 Fluorotelomer sulfonamide betaine (CASRN: 34455-29-3)
 - Firefighting foam & floor finishes
 - Chemours, DuPont, National Foam, & Johnson Controls
 - Tiered testing process
 - Tier 1: physical-chemical properties & health effects (inhalation route)
 - EPA will then assess whether additional tests are necessary
 - Testing on this substance will inform EPA's understanding of the human health effects of 503 additional PFAS with similar structures

TSCA Section 21 Petition for PFAS Testing

- North Carolina public health and environmental justice organizations.
- Target: 54 “PFAS” manufactured by Chemours
- EPA [response](#)
 - Near-Term testing covers 30 of 54 petition chemicals
 - Subsequent testing may cover nine of 54 petition chemicals
 - Remaining 15 petition chemicals do not fit the definition of PFAS used in developing the National Testing Strategy

PFAS SNURs Forthcoming

- SNURs will limit applications of approx. 150 PFAS
 - Substances that were listed on the TSCA Inventory before the 2016 Lautenberg amendments
- SNURs will affect companies that PMNed the target substances
- SNURs will affect companies processing or using those substances

PFAS SNURs

Long-chain perfluoroalkyl carboxylates (LCPFAC) ([Final Rule 2021 40 CFR § 721.10536](#))

Significant new uses:

- Manufacture (including import) or processing **for any use** after December 31, 2015
 - Any use includes “as part of a surface coating on articles”
 - Import or processing as part of articles, containing chemical substances identified in [paragraph \(b\)\(3\)](#) (PFOA and Examples of Its Salts) of this section shall not be considered as a significant new use
 - Specific uses exempted for specific substances

PFAS LVEs

- Policy Statement: PFAS will no longer be granted LVEs (April 2021)
- Stewardship Program: to encourage voluntary withdrawal of previously granted PFAS LVEs (July 2021)
- Revocation Petition: to revoke all PFAS LVEs (October 2022)

PFAS in HDPE

March [letter](#) regarding fluorinated high-density polyethylene (HDPE)

- PFAS unintentionally form during or following the process of fluorinating polyolefins
- Identified in containers used in storing and transporting pesticides
- Long-chain PFAS subject to significant new use rule at 40 CFR § 721.10536
- Not eligible for the byproducts exemption

TSCA Enforcement – Swix Sports USA

- Swix imported ski waxes containing PFAS not listed on the TSCA Inventory
- EPA found violations for
 - Failure to file Premanufacturing Notices
 - Failure to file Import Certifications
- 2020 Settlement
 - Civil penalty of \$375,625
 - Responsible Waxing Program
 - \$1,000,000 educational program
 - Raise awareness in ski communities about PFAS chemicals in ski waxes,
 - Promote alternatives with lower environmental impact
 - Phase out the use of PFAS containing wax products

(In re Swix Sports USA, Docket No. TSCA-HQ-2020-5005)

TSCA Enforcement – TASR

- TASR imported ski waxes PFAS not listed on the TSCA Inventory
- Voluntarily self-disclosed violations to EPA
- EPA found violations for
 - Failure to file Premanufacturing Notices
 - Failure to file Import Certifications
- 2021 Settlement
 - TSCA Compliance Management Plan to address
 - Compliance with Premanufacture Notification and Import Certification requirements
 - Requirements regarding subsequent distribution in commerce, use, or disposal of chemicals subject to TSCA
 - Civil penalty of \$12,445

(*In re TASR*, Docket No. TSCA-HQ-2021-5001)

PFAS Regulation under FIFRA

Pesticide Inert Ingredients

September 13, 2022 ([Proposed Rule](#))

- Remove 12 PFAS chemicals from list of approved inert ingredients
- No longer used in any registered pesticide product.

PFAS Litigation



Consumer Product Litigation

- Burger King sued over PFAS in Whopper Wrapping (April 2022; voluntarily dismissed August 2022)
- Burt's Bees (class action), L'Oreal (class action), Cover Girl Cosmetics (class action), Shiseido (class action) sued over PFAS in various cosmetic products (2021 & 2022)
- REI sued in class action lawsuit over PFAS in “sustainable gear” including waterproof jackets (April 2022; voluntarily dismissed July 2022)
- Knix sued in class action lawsuit over PFAS in menstrual underwear (April 2022)
- Cava sued in class action lawsuit over PFAS in food packaging (August 2022)

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