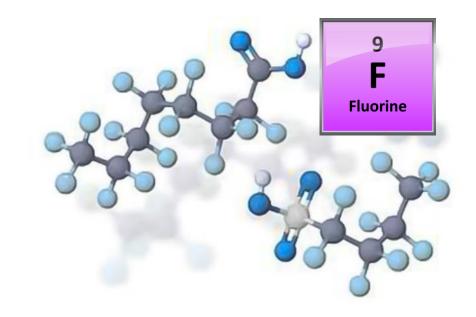
PFAS - What They Are and Related Regulatory Developments

Tim Sheehan Engineering Fellow Raytheon Technologies

NDIA Mission and System Engineering Conference



Nov 3, 2022

Overview

- Per- and polyfluorinated alkyl substances (PFAS) encompass a wide variety of chemicals (several thousand in fact)
 - Many are widely used across the global for multitudes of uses
 - Until recently, PFAS not recognized for environmental and human health impacts
 - Data indicates many have significant toxicity, are accumulating in the environment and are widely distributed in natural media throughout the world (pollution)
 - As a result, increased scrutiny and regulatory activity to control risks
 - At this point, not much is not generally known about their uses as materials and in hardware
- Increasing pace of regulatory activities and legal actions across the globe to address risks to the environment and human health

This presentation is mainly focused on product-related issues impacting the aerospace and defense (AD) industry

What Are PFAS?

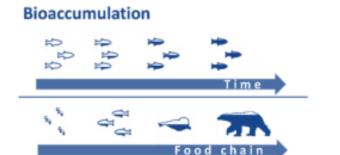
- Per- and Poly-fluoroalkyl Substances (PFAS)
 - Chemistry first developed in 1930s and 1940s

Biomagnification

- Widely used in industrial and consumer applications since the 1950s
- Desirable properties for consumer and industrial products
 - Surfactants
 - Oil and water repellency
 - High and low temperature stability
 - Friction reduction



What's the Problem?.



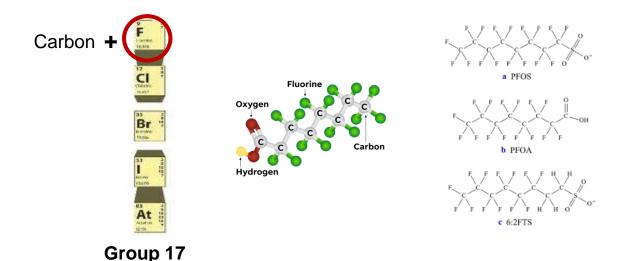
Bioaccumulation

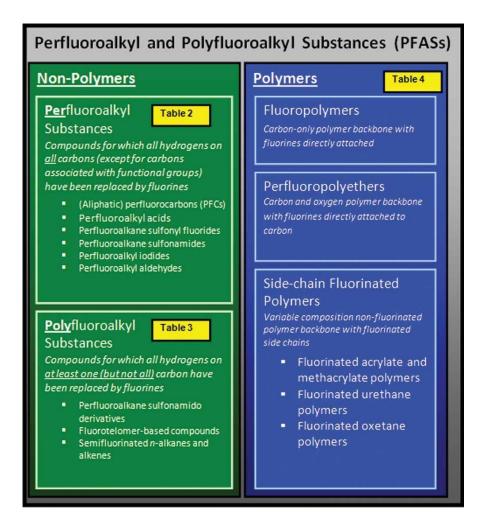
- Gradually accumulating in environment/ humans / animals
- PFAS found in human blood and urine indicating widespread exposures
- Persistent
 - Long half-lives, remain in the environment / body for a long time
- Suspected human health concerns
 - Cancers, liver damage, lowered fertility, chronic kidney disease, thyroid disease, cardiovascular disease, developmental impacts, obesity

PFAS Used Globally in Hundreds of Industrial and Consumer Products and Formulations

PFAS Chemistry

- Synthetic <u>organofluorine</u> (alkyl) <u>c</u>hemical compounds
- Contain fluorine atoms bonded to a carbon chain
- Carbon-fluorine bond is one of the strongest ever created by man
- Not seen in nature VERY STABLE!
- Length of chain can result in different physicochemical properties that influence the substance behavior in the environment and in organisms, and its bioaccumulation and (eco) toxicity





For More Info: OECD Fact Cards of Major Groups of Per- and Polyfluoroalkyl Substances (PFASs)

One (Big) Issue...

Different Definitions of "PFAS"!

Some examples:

$$C_nF_{2n+1}$$
 R_1
 R_2
 R_1
 R_3
 R_1
 R_2

Buck et al., 2011 OECD, 2021 US EPA, 2021

 R_1 , R_2 , R_3 = nonhydrogen atoms

Three definitions of per- and polyfluoroalkyl substances

EU definition includes hydrofluorocarbons (F-gases)!

PFAS Taxonomy and Current Regulatory Focus

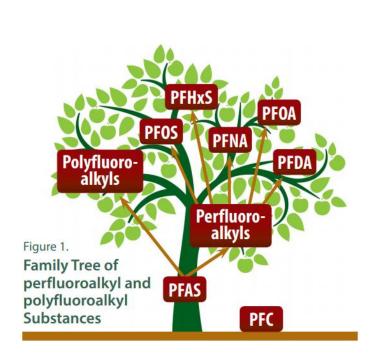
PFAS classifications

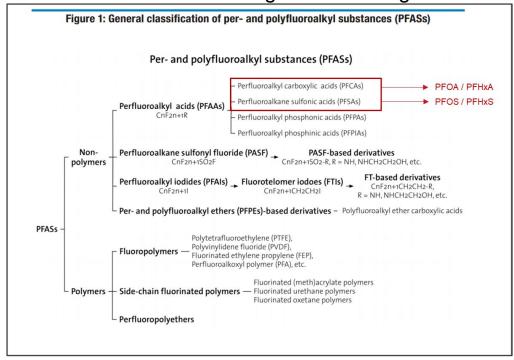
Polymers
Non-Polymers

Numerous Substances

- > 9K manmade chemicals (US EPA)
 > 669 Active on US EPA TSCA Inventory
- Perfluorooctanoic acid (PFOA) and Perfluorooctane sulfonate (PFOS) (non-polymers) Most Widely:

Studied Targeted and Regulated





Each "family" also typically represents numerous substances

Regulatory Developments

Busy and Accelerating!

Regulatory Intent

- Two main thrusts:
 - -Better understand the extent of use and content in products reporting
 - Hardware
 - Materials
 - -Control risks to humans and the environment
 - Response to existing pollution
 - Restriction
 - Replacement

International Developments



- Stockholm Convention on Persistent Organic Pollutants (POPs)
 - International treaty to control risks of high-risk chemicals (POPs)
 - Restrictions on regulated substances have to be ratified by member countries to take effect
- Decisions to amend POPs lists to include PFAS substances:
 - Annex A (Elimination) PFOA, salts and related compounds (existing)
 - ➤ Proposed: Perfluorohexane sulfonic acids (PFHxS), salts and related compounds, long-chained Perfluorocarboxylic acids (LC-PFCA), salts and related compounds
 - Annex B Restriction PFOS, its salts and PFOSF (existing)

Acceptable Pur	rposes and S	Specific	Exemptions ((Examples)	١
----------------	--------------	----------	--------------	------------	---

Decision	Annex		Production	Use
<u>SC-9/12</u>	А	Perfluorocctanoic acid (PFOA), its salts and PFOA-related compounds	Fire-fighting foam: None. For other production, as allowed for the Parties listed in the Register in accordance with the provisions of part X of Annex A	In accordance with the provisions of part X of Annex A
SC-4/17 SC-9/4	В	Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF)		Acceptable purposes include: Aviation hydraulic fluids Etching agent for compound semi-conductors and ceramic filters Fire-fighting foam Specific Exemptions: Coatings and coating additives Rubber and plastics

US Developments

******* ****** ****** ****** ******

- PFAS regulations/requirements are developing in 3 areas:
 - Environmental Protection Agency Broad-based approach and topics (link to EPA PFAS site: CompTox Chemicals Dashboard (epa.gov))
 - Department of Defense Broad-based approach and topics (additions to DoD "Action List")
 - Individual US States Restrictions on "intentional added" of PFAS (e.g., Maine and Washington State)

US Environmental Protection Agency

US TSCA

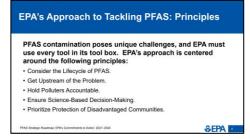
- TSCA Inventory 600+ "Active" PFAS in U.S. commerce
 - New Chemicals Program cleared ~300 PFAS (!!!)
 - ~200 under Section 5(e) Consent Orders / Significant New Use Rules (SNURs)
- July 2020 EPA issued SNUR on certain long-chain PFAS
 - Articles containing certain long-chain PFAS as a surface coating cannot be imported into the US without EPA review
 - · Importers of articles, but not processors of articles are subject to the SNUR.
- PFAS Manufacturing (including import) **Reporting and Recordkeeping** (TSCA Section 8(a)(7))
 - Proposed Rule issued June 2021
 - PFAS listed by CAS#, Accession#, and LVE#; others may be added
 - EPA identified 1,364 PFAS may be potentially covered by this rule as of April 2021, 669 of which are on the active Inventory
 - Final rule anticipated in Jan 2023

EPA Council on PFAS - regulatory development support

- · Established April 27, 2021
- Building on ongoing work better understand & ultimately reduce potential risks caused by PFAS chemicals
- "Whole of EPA approach" chem mgt, water, air, waste, remediation
- "Accelerate scientific work, regulatory action, and voluntary approaches to address PFAS contamination and better protect the health of all Americans"

EPA PFAS Strategic Work Plan

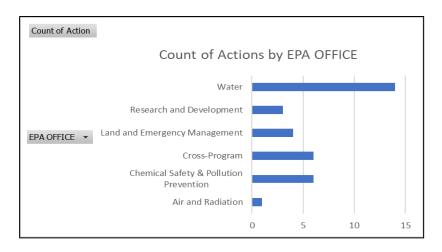
- Issued October 18, 2021
- Focus on 4 central directives: Research, Restrict, Remediate

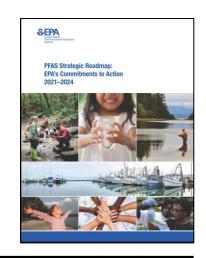


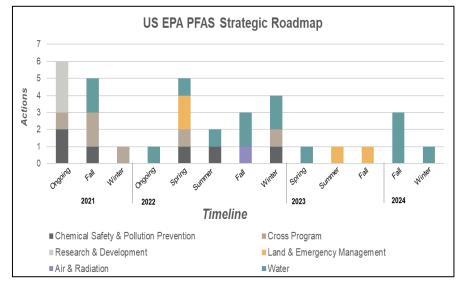
RESEARCH Invest in research, development, and innovation to increase understanding of PFAS exposures and toxicities, human health and ecological effects, and effective interventions that incorporate the best available science. RESTRICT Pursue a comprehsive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment. REMEDIATE Broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems.

US Regulatory Response - EPA Strategic Roadmap (2021 - 2024)

EPA OFFICE	INITIAL ONGOING ACTIONS
Chemical Safety & Pollution Prevention	Ensure a robust review process for new PFAS
	Review previous decisions on PFAS
Research and Development	Develop and validate methods to detect and measure PFAS in the environment
	Advance science to assess human health and environmental risks from PFAS
	Evaluate and develop technologies for reducing PFAS in the environment
Cross-Program	Use enforcement tools to better identify and address PFAS releases at facilities







EPA OFFICE	Action	Year	Quarter
Chem Saf & Poll Prev	Publish national PFAS testing strategy	2021	Fall
Water	Undertake nationwide monitoring for PFAS in drinking water	2021	Fall
Water	Publish the final toxicity assessment for GenX and five additional PFAS	2021	Fall
Cross-Program	Accelerate public health protections by identifying PFAS categories	2021	Winter
Water	Restrict PFAS discharges from industrial sources through multi-faceted Effluent Limitations Guidelines program	2022	Ongoing
Chem Saf & Poll Prev	Enhance PFAS reporting under the Toxics Release Inventory	2022	Spring
Water	Publish health advisories for GenX and PFBS	2022	Spring
Land & Emerg Mgmt	Propose to designate certain PFAS as CERCLA hazardous substances - Proposed Rule	2022	Spring
Cross-Program	Establish a PFAS Voluntary Stewardship Program	2022	Spring
Chem Saf & Poll Prev	Close the door on abandoned PFAS and uses	2022	Summer
Water	Publish multi-laboratory validated analytical method for 40 PFAS	2022	Fall
Water	Establish a national primary drinking water regulation for PFOA and PFOS - Proposed Rule	2022	Fall
Air and Radiation	Build the technical foundation to address PFAS air emissions	2022	Fall
Chem Saf & Poll Prev	Finalize new PFAS reporting under TSCA Section 8	2022	Winter
Water	Leverage NPDES permitting to reduce PFAS discharges to waterways	2022	Winter
Water	Publish final recommended ambient water quality criteria for PFAS - Aquatic Life Criteria	2022	Winter
Land & Emerg Mgmt	Designate certain PFAS as CERCLA hazardous substances - Final Rule	2023	Summer
Land & Emerg Mgmt	Issue updated guidance on destroying and disposing of certain PFAS and PFAS-containing materials	2023	Fall
Water	Establish a national primary drinking water regulation for PFOA and PFOS - Final Rule	2024	Fall
Water	Publish final recommended ambient water quality criteria for PFAS - Human Health Criteria	2024	Fall
Water	Publish updates to PFAS analytical methods to monitor drinking water	2024	Fall

US Reporting/ Restrictions

- 2020, 2021, 2022, 2023 National Defense Authorization Acts (NDAA) have all had PFAS reporting/ restriction language proposed
 - Requirements for reporting and remediation
 - Limited numbers of purchase restrictions included (so far) cookware, fabrics, AFFF
 - Reporting under Toxic Release Inventory added in 2021 and modified in subsequent years
 - Drives need to understand PFAS in materials and hardware

US States

- States are (just) beginning to regulate PFAS
 - Most regulatory restrictions and reporting are for consumer-type uses apparel, food contact materials, furnishings, children's goods
- Recently, several states (e.g., ME, CA, WA) have gone beyond this to propose general restrictions/ reporting on many other uses of PFAS
 - Example: Maine "An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution" (2021)



Maine "An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution" (LD 1503)

- Regulatory touchpoints: All products "manufactured" in the State of Maine that contain "intentionally added" PFAS (IAP)
 - Manufacture includes first distribution of products into the state
- Regulatory requirements:
 - By January 1, 2023 report IAP to the state (or else!) prohibition IPA in carpets, stain-repellents
 - By January 1, 2030 No more IAP in products (waivers possible)
- Very onerous for hardware industries!
 - Usually don't know when they're (intentionally) adding PFAS to their products
 - Don't know they are state-importing PFAS-containing products

EU/UK Regulatory Activities





Current PFAS Listings

EU/ UK REACH SVHC (Candidate List)	REACH Annex XIV (Authorisation List)	Recommended for Authorisation	REACH Annex XVII (Restriction List)
11 "family" entries (many, many unique CAS#'s) 1 family proposed for listing by EU (perfluoroheptanoic acid and its salts)	NONE	NONE	 EU and UK: C9-C14 linear and/or branched perfluorocarboxylic acids (C9-C14 PFCAs), their salts and C9-C14 PFCAs-related substances (Entry 68) EU: Perfluorocarboxylic acid (PFOA, CAS 335-67-1, EC 206-397-9), and any other linear or branched perfluoroheptyl derivative with the formula C7F15-X and any linear or branched perfluorocatyl derivative with the formula C8F17-X (where X=any group, including salts, other than F, Cl, Br), except those derivatives with the formula C8F17-SO2X', C8F17-C(=O)OH or C8F17-CF2-X' (where X'=any group, including salts) shall not be manufactured, used or placed on the market as substances on their own, as constituents of other substances, in a mixture or in articles. EU REACH Annex XVII Restriction Report (01/14/2022): PFAS in Fire Fighting Foams (not UK) Proposed Restriction (paragraph 2.2.5)

EU Registry of restriction intentions until outcome:

ALL PFAS	Current Intention: Dossier Expected 14 Jan 2023	Restriction on manufacture, placing on the market and use of PFAS. "Essential Use Concept" will not be used to develop restriction – what can/ will be exempted *BIGGIE*
PFHxS	Opinion Adopted	Restrict the manufacture, use and placing on the market of PFHxS , its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof.
PFNA; PFDA; PFUnDA; PFDoDA; PFTrDA; PFTDA; including their salts and precursors	Opinions Adopted	Shall not be manufactured, used or placed on the market as substances, as constituents of other substances, in a mixture <u>AND</u> Articles or any parts thereof containing one of the substances shall not be placed on the market.
PFHxA (w/indicative list of substances)	Final Opinions Published	Shall not be manufactured or placed on the market as substances on their own from [date]. Shall not, from [date], be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, in a concentration equal to or above x %.

15

PFAS Risks and Management

Challenges

- Lack of visibility into supply chain use
 - Safety data sheets (SDS) still may omit PFAS in many regions (e.g., the US)
 - Therefore, processors may not know when PFAS are being added to their products
 - Downstream customers cannot effectively manage risk/ report PFAS
 - "Bailing the boat with water still coming in"
- Advocacy Positions (AD)
 - PFAS do not all pose similar risks cost/ benefit should be considered
 - Initial regulation is best at the top of the chemical supply chain (manufacturers/ formulators)
 - Where PFAS are being introduced
 - Phase in regulatory action for lower tiers of the supply chain
 - Exclude articles from reporting articles (hardware)
 - Require the inclusion of PFAS in SDS



Aerospace and Defense PFAS (Known) Uses

General	Aerospace & Defense-Specific
 Fire Fighting Foam (FFF) Processing Aid (e.g., to make Teflon) Surface protection (textiles) 	 Phosphate ester-based brake & hydraulic fluids Flotation fluids in gyroscopes Wire and cable insulation Engine lubrication and elastomeric Seals
 Electronics (heat transfer) Machinery functional fluids & additives Plastics and Rubber production Formulated coatings, paints & varnishes 	 Thermal control / Radiator systems Coatings (various) Plating (various) Electronics (various applications) Metal processing Mold release agent Foam blowing Flame retardant (e.g., in polycarbonate plastics) Fire Fighting Foams (FFF)

Common Uses

- Fluoropolymers (such as PTFE) used extensively in aviation / aerospace & defense mechanical components including:
 - Semiconductors
 - Wiring
 - Tubing
 - Piping
 - Seals
 - Gaskets
 - cables
- Salts of Perfluorosulfonic acids (PFSAs; primarily PFOS) used as additives in hydraulic fluids:
 - content < 0.1%
 - Prevents evaporation, fires & corrosion
- No general reporting requirement for reporting PFAS in hardware
- Many AD uses include qualified materials composition changes can be challenging

What Are the Business Risks to the AD Industry?

- Compliance
 - Regulatory
 - Customer requirements
- Obsolescence/ Business continuity
 - Loss of supply
 - Product reformulation/ discontinuation
 - Significant time needed to develop/ qualify/ industrialize alternatives
- Legal action
- Insurance







AD Industry Activities

- Aerospace Industries Association (AIA)
 - NAS411-1 update will cover all US DoD "Action-List" PFAS species
 - Already in NAS411-1, as prohibited "POPs": perfluorobutane sulfonic acid (PFBS) CAS# 375-73-5, perfluorooctane sulfonic acid (PFOS) 1763-23-1 perfluorooctanoic acid (PFOA) 335-67-1
 - Proposed new line entries as "restricted":

PFBA, Perfluorobutanoic acid	375-22-4
PFHxA, Perfluorohexanoic acid	307-24-4
PFNA, Perfluorononanoic acid	375-95-1
PFDA, Perfluorodecanoic acid	335-76-2
PFHxS, Perfluorohexanesulfonic acid*	355-46-4

- International Aerospace Environmental Group (IAEG®)
 - Include "regulated/ soon-to be regulated" PFAS in scope of Aerospace and Defense Declarable Substances List (AD-DSL) – contains many species of PFAS, more expected
 - Heads-up communications / Alerts issued

* Currently proposed as a POP

Legal Front...

- Class action lawsuits for PFAS increasing
 - False/ inaccurate product claims 'non hazardous"
 - Omission of hazard information

Drivers

- Increasing understanding of the presence of PFAS in products/ environment
- Increasing understanding of health effects
- Increasing listings of PFAS in regulatory lists (e.g., PFOA/ PFOS proposed addition to CERCLA)

Corporate Insurance...

- Increasing market-wide trend by insurance providers to identify PFAS risk & claims portfolio exposure.
 - Comprehensive Insurance Providers (Excess Casualty, General Liability, Environmental Liability, Other related) (e.g., for Industrial Companies)
- Global (not just US)
- Risk thresholds driving exclusions from coverage
 - Could affect premiums
 - Could be used in Peer-evaluation risk assessment
 - May eventually connect to corporate reporting
- "....the next asbestos or PCB type of issue"

Insurance carriers beginning to add **PFAS exclusions** on all new and renewal quotes for properties suspected of using PFAS or might have been exposed to PFAS from neighboring properties.

Summary

Conclusions

- PFAS regulatory and customer restrictions and reporting requirements will continue to increase
 - The (global) debate to regulate individual substances vs. whole "families" will continue
- PFAS is used in AD products, but only limited information is available now
 - Regulatory compliance and other risks are driving the need to better understand/ address
 PFAS dependence
- Removal of PFAS from the materials supply chain will pose availability risks
- Efforts must continue to identify and minimize PFAS use in products and processes.

Thank you!

Additional References

- OECD PFAS Site: https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/
- US EPA PFAS Site: https://www.epa.gov/pfas
- US DoD PFAS site: https://www.acq.osd.mil/eie/eer/ecc/pfas/index.html
- "Per and Polyfluoroalkyl Substances Technical and Regulatory Guidance" (2021) provides minformation (https://pfas-1.itrcweb.org/wp-content/uploads/2022/03/PFAS-Full-PDF-December-2021-Update.pdf)
- Prepared by the Interstate Technical and Regulatory Council (ITRC)
 - Public-Private Coalition
 - Members from all 50 states and District of Columbia