



PFAS SUMMARY & TALKING POINTS

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History/Overview of PFAS/PFOA

PFAS are a family of thousands of chemicals that vary widely in their chemical and physical properties, as well as their potential risks to human health and the environment. The unique physical and chemical properties of PFAS impart oil, water, stain, and soil repellency, chemical and thermal stability, and friction reduction to a range of products. These products have application in many industries, including the aerospace, semiconductor, medical, automotive, construction, electronics, and aviation industries, as well as in consumer products (such as carpets, clothing, furniture, outdoor equipment, food packaging), and firefighting applications.

PFAS chemistry was discovered in the late 1930s. Since the 1950s, many products commonly used by consumers and industry have been manufactured with or from PFAS. Two major processes, electrochemical fluorination (ECF) and fluorotelomerization, have been (and are) used to manufacture PFAS substances that contain perfluoroalkyl chains: sidechain fluorinated polymers, perfluoroalkyl acids and polyfluoroalkyl surfactants (USEPA 2003 Ref#858; Benskin, DeSilva, and Martin 2010; KEMI 2015 Ref#658; OECD 2018). Table 1 summarizes types of perfluoroalkyl acids (PFAAs) produced by these processes. More than 600 intermediate processes have also been used to further produce certain PFAS and the associated final products.

An industry survey, reported in Buck et al. (2021), noted that only 256 of the 4,700 PFAS with CAS Registry Numbers are commercially relevant, with others of lesser environmental significance but potentially still occurring in the environment. See history below:

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		Predominant form of firefighting foam
Dominant Process ³		Electrochemical Fluorination (ECF)						Fluoro-telomerization (shorter chain ECF)
Pre-Invention of Chemistry /			Initial Chemical Synthesis / Production			Commercial Products Introduced and Used		
Notes:								
1. This table includes fluoropolymers, PFAAs, and fluorotelomers. PTFE (polytetrafluoroethylene) is a fluoropolymer. PFOS, PFOA, and PFNA (perfluorononanoic acid) are PFAAs.								
2. Refer to Section 3.4.								
3. The dominant manufacturing process is shown in the table; note, however, that ECF and fluorotelomerization have both been, and continue to be, used for the production of select PFAS.								
Sources: Prevedouros et al. 2006; Concawe 2016; Chemours 2017; Gore-Tex 2017; US Naval Research Academy 2017								

EU Status:

The European Union had originally put forth a regulation [i], REACH regulation (EC) No. 1907/2006 requiring a limitation of no more than 25 parts per billion (grams per thousand tons) of PFOA in PTFE micro-powder to take effect on July 4, 2020. To conform to this new REACH regulation, PTFE micro-powders need to be tested and, if necessary, treated to ensure PFOA content is less than 25 parts per billion (ppb).

On April 8, 2020, this regulation was amended and superseded by POP Regulation (EU) 2019/1021 (as amended by Commission Delegated Regulation (EU) 2020/784), which allows for the use of PTFE micro-powders with PFOA up to 1000 ppb, until July 4, 2022, after which, it is expected to revert to the originally proposed 25ppb limit.

US Status:

State:

Coalition of Northeastern Governors (CONEG): The 2021 update to the CONEG legislation added perfluoroalkyl and polyfluoroalkyl substances (PFAS) to its list of prohibited chemicals in packaging. This prohibition applies to the “intentional introduction” 2 of this substance into packaging and packaging components.

California Proposition 65: In 2017 PFOA was listed under “developmental” toxicity in Prop 65 list. In March 2021 the California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment (OEHHA) published a notice of its intent to list *perfluorooctanoic acid (PFOA)* (CAS RN 335-67-1) as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65[1])

Federal:

EPA: Safe Drinking Water Act (SDWA) – Considering PFAS regulation under the Safe Drinking Water Act (SDWA)

EPA: CERCLA Hazardous Substance Designation – Considering designation of PFOA and PFOS as Comprehensive Environmental Response, Liability and Cleanup Act – 1980 hazardous Substances.

EPA: Toxic Substances Control Act (TSCA) – In June of 2021 EPA issue a proposed rule on reporting requirements for PFAS products that are manufactured or imported in the United States.

EPA: New Chemicals Program – EPA is reviewing substitutes for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS) and other long-chain per- and polyfluoroalkyl substances (PFASs) for new chemicals under EPA's New Chemicals Program (NCP).

Food and Drug Administration (FDA): No formal regulatory action.

Testing for PFOA

PFAS Testing Status:

As of this time, there is no globally accepted standard test method for measuring PFAS content in PTFE micro-powders, nor is there any indication as to how the regulation will be enforced. Shamrock has pro-actively adopted a method similar to 3M's Standard Test Method (Edition 1.0, Nov 2016), based on extraction of PTFE powders with methanol and the use of Liquid chromatography-mass spectrometry (LC-MS) to determine the concentration of PFOA. Shamrock's internal Test Method, QSOP-202E^[ii], has correlated well with test data (of the same powder samples) from external test centers to validate accuracy and precision. Scientists generally agree that an accepted test method is calibration with known standards whereby the results of the same samples in different labs are within experimental error.

Talking Points on EPA Actions ⁽¹⁾

The Federal Government Should Implement a Consistent Approach for Assessing and Regulating Specific PFAS With Clear Timelines. The appropriate interagency processes should be used to coordinate regulatory actions among all interested agencies so that government regulations, actions, and communications are consistent and coordinated for maximum effectiveness. Clear timelines will ensure that policy decisions and regulatory outcomes are harmonized and implemented in a timely fashion.

Regulations Should Be Based on the Best Available Science. Any regulatory action addressing different PFAS chemicals should be based on sound, peer-reviewed science and a transparent and well-informed record. Agencies should identify sources of uncertainty and the research needed to reduce those uncertainties. Likewise, regulations should also remain flexible to accommodate emerging science.

Specific PFAS Should Be Regulated Based on Risk to Protect Human Health and the Environment. A quantitative, risk-based approach considers both hazard and levels of exposure. Risk-based approaches are necessary for forming a basis for directing limited societal resources for risk mitigation only to those chemicals and use patterns that pose risks of concern. This rational, quantitative approach is superior to decisions made of the basis on exposure alone (e.g. the mere presence or persistence of a substance). Chemicals of low concern should be treated accordingly.

Regulatory Outcomes Should Not Be Predetermined. Regulatory decisions should be made using existing regulatory frameworks, which have been developed carefully based on sound science and guided by the notice and comment procedures within the Administrative Procedure Act to ensure that all relevant public policy goals are considered.

PFAS Chemistries Should Be Regulated Independently, or Appropriate Sub-Categories, not as a Single Group. Risk estimates require consideration of both hazard and exposure. PFAS chemicals have a wide variety of different properties and uses. Due to this variation, it is inappropriate to regulate all PFAS chemicals as a single group, and broadly restrict different PFAS chemistries through wide-reaching bans. Rather, each

individual chemistry or “well defined” specific small groups of chemicals should be regulated based on the specific risks posed, not simply on structural or physical / chemical similarities. Risks associated with one member of the PFAS class should not be attributed to other members of the PFAS class without clear scientific justification. Any grouping of PFAS for risk assessment should also be scientifically justified. Suitable substitutes for critical-use applications should be identified prior to instituting regulatory restrictions. Additionally, wherever possible, the federal government should strive to minimize patchwork regulations and instead develop nationwide standards that limit regulatory uncertainty, reduce confusion, provide clarity, and improve cleanup outcomes for stakeholders and the public.

Agencies Should Provide Meaningful Risk Communication and Regulatory Transparency. Agencies should ensure that the public can easily understand the magnitude of the risks associated with specific PFAS chemicals and exposures. This includes candid discussions regarding the processes associated with evaluating those chemicals as well as any scientific uncertainties in those analyses.

EPA and Other Federal Agencies Should Establish Regular Consultation with Stakeholders. Since PFAS regulation affects many parties, EPA should consult with local government, state officials, tribal governments, federal agencies, and other stakeholders, including the business community prior to regulatory decisions.

Congress Should Provide Regulatory Agencies with the Proper Oversight and Funding Necessary to Evaluate and Address Specific Priority PFAS. Congress should provide oversight to ensure a coordinated and timely government response and must appropriate the funding necessary to invest in peer-reviewed scientific research and the management, mitigation, and ongoing monitoring of specific PFAS.

⁽¹⁾ Chamber of Commerce Coalition August 29, 2022 Request for Information on Identifying Critical Data Gaps and Needs to Inform Federal Strategy Plan for PFAS Research and Development, White House Office of Science & Technology Policy (OSTP); Document Number 2022-14862, 87 FR 41749

Talking Points on Potential CERCLA Designation

National issue. EPA should demonstrate that releases of the specific substance of concern are occurring in many parts of the country and in multiple states.

Addressing environmental levels that pose risk of concern that require immediate cleanup or removal.

Theoretical or potential exposure or risk can be addressed through other statutes and programs. Cleanup or removal activities will mitigate risks of concern that have been identified via sound science and robust risk assessment frameworks.

Ensuring that CERCLA’s unique tools are necessary before listing individual PFAS as hazardous substances.

CERCLA is a statute of last resort and can have significant unintended consequences for a broad range of stakeholders including public entities and local governments. EPA should demonstrate that existing state and federal programs are not available to address the identified sites as CERCLA may not be the best tool.

Utilizing best available science. Available hazard and exposure evidence should meet EPA’s highest standards for scientific integrity and transparency. EPA’s hazard and risk assessments should undergo a public, independent scientific peer review.

Ensuring no delay on current cleanups. EPA should demonstrate that designating new hazardous substances will not delay cleanup activity for existing CERCLA sites (including five-year reviews) due to limited funding and/or EPA resources.

State PFAS/PFOA Legislative Activity

See Legislative Summary Paper.