

Risk Management for Per- and Polyfluoroalkyl Substances (PFASs) under TSCA

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On May 19, 2016, EPA established health advisories for PFOA and PFOS based on the agency's assessment of the latest peer-reviewed science to provide drinking water system operators, and state, tribal and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents. [Learn more.](#)

[Learn more about EPA efforts on PFASs.](#)

What are PFASs and where are they found?

Many per- and polyfluoroalkyl substances (PFASs), also referred to as perfluorinated chemicals (PFCs), are found world-wide in the environment, wildlife, and humans.

PFASs are substances that have many manufacturing and industrial applications because they impart useful properties, including fire resistance and oil, stain, grease and water repellency. These chemicals are used in a wide range of industrial applications and the manufacture of consumer goods, and may be found in cleaners, textiles, leather, paper and paints, fire-fighting foams, and wire insulation.

Why is EPA concerned about Long-chain PFASs?

**Exhibit
3711**

State of Minnesota v. 3M Co.,
Court File No. 27-CV-10-28862

EPA is particularly concerned about so-called long-chain PFAS chemicals. These are persistent in the environment, bioaccumulative in wildlife and humans, and are toxic to laboratory animals and wildlife, producing reproductive, developmental, and systemic effects in laboratory tests.

These long-chain PFASs comprise two sub-categories:

- long-chain perfluoroalkyl carboxylic acids (PFCAs) with eight or more carbons, including PFOA, and
- perfluoroalkane sulfonates (PFASs) with six or more carbons, including
 - perfluorohexane sulfonic acid (PFHxS) and
 - perfluorooctane sulfonic acid (PFOS).

While persistent in the environment, PFCA chemicals with fewer than eight carbons, such as perfluorohexanoic acid (PFHxA), and PFSA chemicals with fewer than six carbons, such as perfluorobutane sulfonic acid (PFBS), are generally less toxic and less bioaccumulative in wildlife and humans.

What is EPA doing?

EPA has taken a range of regulatory actions to address PFAS substances in manufacturing and consumer products as noted below. In addition, EPA developed and industry implemented a global stewardship program with the goal of eliminating these chemicals from emissions and products by 2015.

- Learn more about [EPA's 2010/2015 PFOA Stewardship Program](#).
- [Read Background information on PFAS](#).
- *Current actions*
 - On January 21, 2015, EPA proposed a [Significant New Use Rule under the Toxic Substances Control Act to require manufacturers \(including importers\) of PFOA and PFOA-related chemicals, including as part of articles, and processors of these chemicals to notify EPA at least 90 days before starting or resuming new uses of these chemicals in any products](#). This notification would allow EPA the opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity.
 - [EPA's New Chemicals program reviews alternatives for PFOA and related chemicals](#) before they enter the marketplace to identify whether the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances may be present in order to ensure that the new chemicals may not present an unreasonable risk to health or the environment.
- *Previous actions*
 - On September 30, 2013, [EPA issued a rule requiring companies to report all new uses of certain PFOA-related chemicals as part of carpets](#), a category of potentially harmful chemicals once used on carpets to impart soil, water, and stain resistance. Companies must now report to EPA their intent to manufacture (including import) these chemical substances intended for use as part of carpets or to treat carpets, as well as import carpets already containing these chemical substances.
 - On October 9, 2007, EPA finalized a SNUR on 183 PFAS chemicals believed to no longer be manufactured (including imported) or used in the United States. [Read more information on the 2007 SNUR for 183 chemicals](#).
 - On March 11, 2002, EPA published a SNUR to require notification to EPA before any future manufacture (including import) of 13 PFAS chemicals specifically included in the

voluntary phase out of PFOS by 3M that took place between 2000 and 2002. This SNUR allowed the continuation of a few specifically limited, highly technical uses of these chemicals for which no alternatives were available, and which were characterized by very low volume, low exposure, and low releases. Any other uses of these chemicals would require prior notice to and review by the Agency. [Read more information on the 2002 SNUR for 13 chemicals](#).

- On December 9, 2002, EPA published a SNUR to require notification to EPA before any future manufacture (including import) of 75 PFAS chemicals specifically included in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002. This SNUR allowed the continuation of a few specifically limited, highly technical uses of these chemicals for which no alternatives were available, and which were characterized by very low volume, low exposure, and low releases. Any other uses of these chemicals would require prior notice to and review by the Agency. [Read more information on the 2002 SNUR for 75 chemicals](#).

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Background

PFASs are synthetic chemical substances with special properties and hundreds of manufacturing and industrial applications. Perfluorooctanoic acid (PFOA) is a long-chain perfluoroalkyl carboxylic acid (PFCA), a subset of per- and polyfluoroalkyl substances (PFASs), that does not occur naturally in the environment.

EPA has investigated PFOA because it:

- Is very persistent in the environment
- Is found at very low levels both in the environment and in the blood of the general U.S. population
- Remains in people for a very long time
- Causes developmental and other adverse effects in laboratory animals.

Uses of PFOA, PFOS, and other PFASs

PFOA was used as an aqueous dispersing agent to make fluoropolymers. PFOA is no longer used in United States to manufacture fluoropolymers but some fluoropolymers containing PFOA are imported as part of articles. Fluoropolymers impart valuable properties, including fire resistance and oil, stain, grease, and water repellency to articles, and are used in many industry segments, including the aerospace, automotive, building/construction, chemical processing, electronics, semiconductors, and textile industries.

PFOA can also be produced by the breakdown of some fluorinated telomers, substances that are used in surface treatment products to impart soil, stain, grease, and water resistance. Some telomers are also used as high performance surfactants in products that must flow evenly, such as paints, coatings, and cleaning products, fire-fighting foams for use on liquid fuel fires, or the engineering coatings used in semiconductor manufacture.

Consumer products made with fluoropolymers and fluorinated telomers, including Teflon® and other trademark products, are not PFOA. Rather, some of them may contain trace amounts of PFOA and other related PFASs as impurities. The information that EPA has available does not indicate that the routine use of consumer products containing PFASs poses a concern.

Use of PFASs in Aqueous Film Forming Foams (AFFF)

AFFF that contain PFASs are typically used to extinguish highly flammable or combustible liquid Class B fires, such as fires involving gas tankers and oil refineries. The biggest users of AFFF are in the U.S. military, petrochemical, and aviation industries.

Releases of AFFF should be minimized because PFASs are persistent in the environment. In using AFFF, care should be taken to minimize its release into the environment. EPA encourages the use of training foams that are available which simulate AFFF without containing PFASs.

EPA's Investigation of Perfluorooctyl Sulfonate (PFOS), PFOA, and Other Long-Chain PFASs

In the late 1990's, EPA received information indicating that perfluorooctyl sulfonate (PFOS) was widespread in the blood of the general population and presented concerns for persistence, bioaccumulation and toxicity. Following discussions between EPA and the 3M, the manufacturer of PFOS, the company terminated production of these chemicals.

Studies have found other related perfluorinated compounds, including perfluoroalkane sulfonates (PFASs), in very small amounts in the blood of the general human population as well as wildlife. Although most of the health and environmental studies have focused primarily on PFOS, analysis of the structure of the compounds indicates that the results of those studies may be applied to a larger category of PFSA chemicals. EPA believes that the chemical similarity between PFOS and PFSA raises the likelihood that health and environmental concerns are similarly present for PFSA compounds. Following the voluntary phaseout of PFOS by the principal worldwide manufacturer, EPA took prompt regulatory actions in 2002 and 2007 under the TSCA to limit any future manufacture or importation of 271 PFSA chemicals, essentially encompassing all PFSA chemicals on the U.S. market.

Findings on PFOS and PFSA led EPA to review similar chemicals to determine whether they might present similar concerns. The agency began investigating PFOA in 1990s and found that it, too, is very persistent in the environment, is found at very low levels both in the environment and in the blood of the general U.S. population, and causes developmental and other adverse effects in laboratory animals.

EPA summarized its concerns and identified data gaps and uncertainties about PFOA in the [April 16, 2003, Federal Register notice](#). Supporting information is available in EPA docket [EPA-HQ-OPPT-2003-0012](#).

Beginning in 2003, EPA negotiated with multiple parties to produce missing information on PFOA through enforceable consent agreements (ECAs), memoranda of understanding (MOUs), and [voluntary commitments](#). All data generated under ECAs is available in EPA dockets [EPA-HQ-OPPT-2003-0071](#) (Fluoropolymer Incineration ECA) and [EPA-HQ-OPPT-2004-0001](#) (Fluorotelomer Incineration ECA). All data generated under MOUs is available in EPA dockets [EPA-HQ-OPPT-2004-0112](#) (3M PFOA MOU) and [EPA-HQ-OPPT-2004-0113](#) (DuPont PFOA MOU).

In 2006, EPA and the eight major companies in the PFASs industry launched the [reviewing substitutes for PFOA, PFOS, and other long-chain PFASs](#) as part of its review process for new chemicals under TSCA [New Chemicals Program](#). Over 300 alternatives of various types have been received and reviewed by EPA. EPA reviews the new substances against the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances, as well as any issues that may be raised by new chemistries. EPA requires testing for PFAS chemicals and polyfluorinated ethers it reviews under its new chemical process. For some of these chemicals, EPA requires degradation testing before the chemical can be commercialized.

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PFOA Stewardship Program

In 2006, [EPA invited](#) eight major leading companies in the per- and polyfluoroalkyl substances (PFASs) industry to join in a global stewardship program with two goals:

- To commit to achieve, no later than 2010, a 95 percent reduction, measured from a year 2000 baseline, in both facility emissions to all media of perfluorooctanoic acid (PFOA), precursor chemicals that can break down to PFOA, and related higher homologue chemicals, and product content levels of these chemicals.
- To commit to working toward the elimination of these chemicals from emissions and products by 2015.

Participating companies included:

- Arkema
- Asahi
- BASF Corporation (successor to Ciba)
- Clariant
- Daikin

- 3M/Dyneon
- DuPont
- Solvay Solexis

All companies have met the PFOA Stewardship Program goals. [Read the final progress reports.](#)

All public documents from the PFOA Stewardship Program are available in [EPA Docket EPA-HQ-OPPT-2006-0621](#).

[Read 2010/2015 PFOA Stewardship Program fact sheet for more information.](#)

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Access PFAS Dockets

All of the "EPA-HQ-OPPT" dockets are available on the Federal Dockets website, www.regulations.gov. Use the "Advanced Search" feature and search on the complete docket number.

Administrative Record AR-226 is not currently available online, but copies can be requested on CD-ROM from the EPA Docket Office by calling 202-566-0280 or sending an email request to: oppt.ncic@epa.gov.

EPA has established the following public dockets for the various activities related to PFAS:

- Significant New Use Rule: Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Docket ID number [EPA-HQ-OPPT-2013-0225](#).
- Significant New Use Rule: Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances Used as Part of Carpets; Docket ID number [EPA-HQ-OPPT-2012-0268](#).
- 2010/2015 PFOA Stewardship Program; Docket ID number [EPA-HQ-OPPT-2006-0621](#).

- Significant New Use Rule: Perfluoroalkyl Sulfonates; Docket ID number [EPA-HQ-OPPT-2005-0015](#).
- DuPont PFOA Site-Related Monitoring and Environmental Assessment at Washington, West Virginia; Docket ID number [EPA-HQ-OPPT-2004-0113](#).
- 3M/Dyneon PFOA Site-Related Monitoring and Environmental Assessment at Decatur, Alabama; Docket ID number [EPA-HQ-OPPT-2004-0112](#).
- Laboratory Scale Incineration Testing of Fluorotelomer-Based Polymers: Final Enforceable Consent Agreement (ECA) and Testing Consent Order; Docket ID number [EPA-HQ-OPPT-2004-0001](#).
- Laboratory Scale Incineration Testing of Fluoropolymers: Final Enforceable Consent Agreement (ECA) and Testing Consent Order; Docket ID number [EPA-HQ-OPPT-2003-0071](#).
- Perfluorooctanoic acid (PFOA), Fluorinated Telomers: Solicitation of Interested Parties for Enforceable Consent Agreement Development; Docket ID number [EPA-HQ-OPPT-2003-0012](#).
- Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers; Docket ID number [EPA-HQ-OPPT-2002-0051](#).
- Significant New Use Rule: Perfluoroalkyl Sulfonates; Docket ID number [EPA-HQ-OPPT-2002-0043](#)

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