CENTER FOR TRUTH IN SCIENCE

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Per-and Polyfluoroalkyl Substances Issue Primer

Overview

Per-and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that includes the two most well-known compounds—PFOA and PFOS—and several thousand other fluorinated substances.

PFAS have been manufactured and used in many industries around the world, including in the United States, since the 1940s. There are thousands of different PFAS compounds that can be found in a wide range of household and industrial products, including stain-resistant carpet, water-resistant clothing, nonstick cookware, firefighting foam, electronics, and food packaging.

The incredibly strong bonds between the carbon and fluorine chemicals in PFAS compounds make them exceptionally durable and able to withstand heat, physical force, and other chemicals. This durability is the reason why PFAS have become essential ingredients in several innovations critical to human progress, including automobile anti-lock braking systems, 5G data networks, implanted medical devices, and aircraft firefighting foam.

This durability also means PFAS compounds break down slowly and persist in the environment for many years. This is particularly true of PFOA and PFOS. Even though PFOA and PFOS were voluntarily discontinued by U.S. manufacturers nearly two decades ago, they remain in the environment. These long-chain PFAS can also remain in the human body for many years.

PFOA and PFOS have been detected near military bases or airports where firefighting foam was used, in landfills where items containing PFAS are discarded and leach into the soil and groundwater, and in wastewater treatment facilities where PFAS are found in the sludge byproduct of the treatment process.

The preferred PFAS chemistries have evolved since the 1940s. The two original PFAS had eight carbon-fluorine bonds. Modern versions of the compounds typically contain only four to six of these bonds. The human half-life (the time it takes to eliminate half of the body burden) of C4 compounds is on the order of weeks, rather than years, and consequently, these compounds are often much less toxicologically potent.

Because of their ubiquity in the environment, low levels of PFAS are commonly found in the blood of people and animals all over the world. Concerns have been raised regarding potential associations between PFAS exposure and a variety of health hazards, and PFOA and PFOS are the most thoroughly studied of the PFAS compounds.

After research indicated PFOA and PFOS were persistent in the environment and detectable in humans, the U.S. manufacturers of these compounds began to voluntarily phase out production in 2000 (PFOS) and 2006 (PFOA and some precursor chemicals).

In 2016, the U.S. Environmental Protection Agency (EPA) adopted a voluntary drinking water guideline of 70 ppt of PFOA and PFOS, individually and in total. To put this in perspective, one part-per-trillion (ppt) is approximately a one drop in an Olympic-sized swimming pool.

PFAS have been named a high priority under the Biden administration, and in January, the EPA announced its intent to readdress PFAS and their potential risks to humans. The agency has begun the process of developing federal national primary drinking water standards for PFOA and PFOS, and has pledged to designate these two PFAS as hazardous materials under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)—otherwise known as the Superfund law. This latter action would reopen some previously remediated and closed sites for investigation and possible additional remedial action.

The epidemiological studies on the human health effects of PFAS exposure levels and potency are inconsistent, and may have substantial methodological limitations that make it difficult to determine whether there are true associations. This is particularly true of the short-chain compounds.

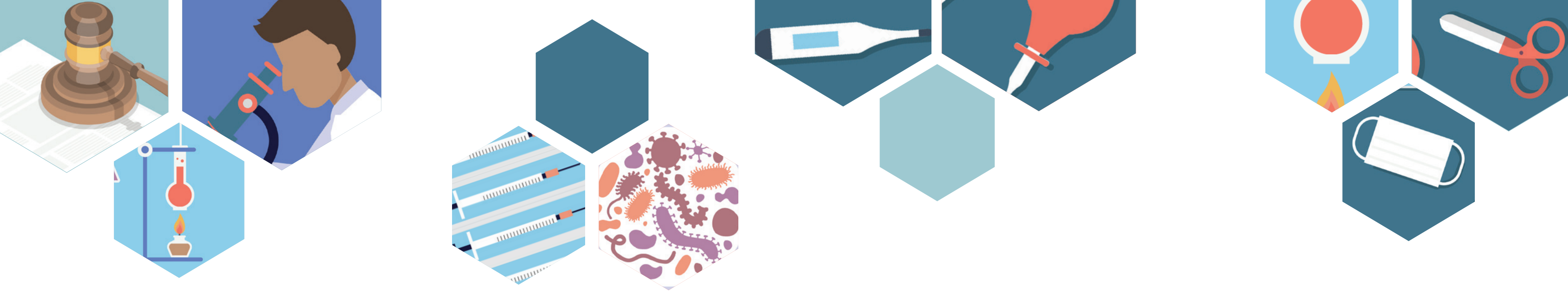
A recent review published in Environmental Research and funded by the Centers for Disease Control and Prevention (CDC) examined 18 of the most comprehensive epidemiologic studies of possible links between PFAS and cancer. They reviewed the evidence to determine what study designs would prove most useful for future researchers to "meaningfully increase knowledge." They found strengths and weaknesses in the design of each study.

According to the authors, "Weaknesses in study design and methods can, in some cases, lead to questionable associations, but in other cases can make it more difficult to detect true associations if they are present."

Moreover, many of the studies on PFAS exposure have been done on animals. According to the CDC, "Humans and animals react differently to PFAS, and not all effects in animals may occur in humans."

Fast facts

- PFAS is an acronym that stands for per-and polyfluoroalkyl substances, which is a group of thousands of man-made chemicals.
- PFAS have been manufactured and used in a variety of industries since the 1940s.
- PFAS are found in a wide range of products, from common household items to sophisticated safety, medical, and data transmission devices.
- Low levels of PFAS are commonly found in the blood of people and animals all over the world and are present at low levels in a variety of products.
- The EPA concluded there is "suggestive" evidence of carcinogenicity of PFOS and PFOA in humans, among other concerns, based largely on findings in high-dose animal studies. This was a hazard-based conclusion, irrespective of dose. The CDC has stated the health effects at low environmental levels of PFAS are "uncertain" and that "more research is needed" to assess the human health effects of exposure to PFAS."
- In 2017, the International Agency for Research on Cancer (IARC), a division of the World Health Organization (WHO), concluded PFOA is "possibly carcinogenic to humans."
- In 2020, the European Food Safety Authority (EFSA) concluded there is "insufficient support for carcinogenicity of PFOS and PFOA in humans."



- The National Toxicology Program (NTP) concluded both PFOS and PFOA should be "presumed to be an immune hazard to humans" based on a high level of evidence that the two compounds suppress the antibody response from animal studies, and a moderate level of evidence from human studies.
- Much of the concern regarding PFAS is based on animal studies with exposure levels typically higher than those of the general population, and animals metabolize PFAS very differently than humans. Therefore, the likelihood of human health effects from low environmental levels of PFAS remains uncertain.

Timeline

1940s-1950s: Scientists develop PFOS and PFOA, two PFAS used in stain- and water-resistant products, protective coatings, and firefighting foams.

1970s: Studies find PFAS in the blood of occupationally exposed workers and fish.

1990s: Researchers from Harvard University report trace quantities of PFAS in the blood of the general human population.

1998: 3M Corporation researchers find PFOS in bald eagles.

2000s: Several studies are published on PFAS detection in polar bears and other Arctic wildlife.

2000: 3M Corporation, the principal worldwide manufacturer and sole U.S. manufacturer of PFOS, announces a voluntary phaseout of PFOS and PFOA.

2006: Other U.S. manufacturers announce a phaseout of PFOA and related precursors.

2008: 3M Corporation completes the phaseout.

2015: Other U.S. manufacturers complete the phaseout.

2016: The EPA publishes voluntary PFOS and PFOA drinking water health advisories of 70 ppt each (separately and combined).

2019: The EPA publishes an action plan on PFOS and PFOA.

2020: Joe Biden pledges on the presidential campaign trail to designate PFAS as "hazardous substances" and to set enforceable limits for PFAS in the Safe Drinking Water Act.

How PFAS is regulated in the U.S.

PFOS and PFOA were in production before the existence of the U.S. Environmental Protection Agency (EPA) and the relevant pieces of legislation under which it derives its authority: the Safe Drinking Water Act of 1974 (SDWA) and the Toxic Substances Control Act of 1976 (TSCA). Under the Biden administration, multiple EPA offices are working to evaluate and regulate PFAS, including the Office of Water and the Office of Pollution Prevention and Toxics.

The SDWA is the primary mechanism to protect public drinking water supplies, as the EPA can set enforceable drinking water standards known as Maximum Contaminant Levels (MCLs) for chemicals, which typically require regular monitoring and reporting to the EPA. There are no MCLs for PFAS, but MCLs are expected for PFOS and PFOA in the next few years. In the interim, the EPA has established voluntary health advisories for PFOS and PFOA (noted above). Some states have enacted enforceable MCLs for PFAS, and numerous others have voluntary drinking water guidance levels that are more stringent than the EPA's health advisories.

Separately, the TSCA, as enacted in 1976, dictated that all existing chemicals (it listed 62,000 of them) were considered to be safe for use and subsequently "grandfathered" into the TSCA Chemical Substance Inventory permitted for use in the United States. The TCSA also gave the EPA authority to investigate the risks posed by a new chemical before going into production or when an existing chemical is being proposed for a new use. New PFAS chemistries and those proposed for new uses are reviewed under the New Chemicals Program.

Under the TSCA, offices within the EPA can regulate any chemicals that pose an "unreasonable" risk to human health or the environment, which can range from specific requirements for warnings to bans on all uses. Until 2016, bans had only been exercised for five compounds—polychlorinated biphenyls, chlorofluorocarbons, dioxin, asbestos, and hexavalent chromium. Additional chemicals have been recently limited or prohibited under amended TSCA, discussed below, and more risk management can be expected.

In 2016, the TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The law mandated offices within the EPA (e.g., Office of Water and Office of Pollution Prevention and Toxics) to evaluate existing chemicals with clear and enforceable deadlines. All prioritized chemicals in the TSCA Chemical Substance Inventory must now be assessed against a risk-based safety standard.

Under the "old" TSCA, the EPA was limited to ordering safety testing and regulation only after evidence presented that a chemical might pose a risk of injury to health or the environment. However, the new TSCA expands the EPA's authority to order tests for risk evaluations on a chemical. Now, testing can be done before the risk evaluation. Since the new authority was granted, the EPA has issued test orders for several (10 as of April 2021) of the chemicals undergoing TSCA review.

In 2019, after concluding there is suggestive evidence of the carcinogenicity of PFOS and PFOA in humans, the EPA published a 72-page Action Plan outlining activities across numerous EPA offices, including:

- Actions the agency has already taken with respect to PFOS and PFOA
- Methods of reducing exposure
- Efforts to identify contaminated regions and water supplies
- The cost effectiveness of different methods for removing PFAS from contaminated areas

On Feb. 26, 2020, the EPA released an update on its action plan, which included:

- A preliminary determination to regulate PFOA and PFOS in drinking water
- A supplemental proposal to ensure new uses of persistent long-chain PFAS in surface coatings cannot be made or imported into the U.S. without notification and review under TSCA
- A new validated method to accurately test for 11 additional PFAS in drinking water
- Recommendations for addressing groundwater contaminated with PFOS and PFOA, providing guidance for federal cleanup programs
- $4.8 million in funding for research on managing PFAS in agriculture

In January 2021, the EPA published more specific guidance on how companies are prohibited from "manufacturing, importing, processing, or using certain long-chain PFAS without prior EPA review and approval" under the agency's July 2020 final Significant New Use Rule.

Most recently, President Biden has requested about $75 million of the fiscal year 2022 budget for PFAS research, MCL determinations, and hazardous substance designations.

The Center's Focus

The Center for Truth in Science seeks to determine if there is conclusive, consistent, scientific evidence that demonstrates a link between exposure to PFAS and the development of cancer or other chronic illnesses at human relevant exposure levels.

The Center also seeks to examine the potential health and economic impacts of limits or bans on the use of PFAS.