8 Basis of Regulations

The PFAS team developed a Risk Assessment and Regulations training video with content related to this section.

This section describes various federal and state regulatory programs that apply to PFAS. Because state regulations for PFAS in environmental media are changing rapidly, only a few state regulations are summarized in this section, as examples. A PFAS Regulatory Programs Summary Excel file has been developed and is available as an Excel file. ITRC also maintains updated the PFAS Environmental Media Values Table Excel file that includes information on state, federal, and some international countries. This section includes a brief explanation of examples of various health effects and how they are used in the development of regulations and advisories.

Section Number	Topic
8.1	Introduction
8.2	Regulatory Programs
8.3	Differences in the Available Regulations, Advisories, and Guidance

8.1 Introduction

PFAS became contaminants of emerging concern in the early 2000s. In recent years federal, state, and international authorities have established a number of health-based regulatory values and evaluation criteria. As with the case for most emerging contaminants, the regulatory process dealing with PFAS is in various stages of development, and the values and criteria being established vary between individual states, the U.S. government, and international agencies. This section describes examples of various federal and state regulatory programs and includes links to tables that provide established PFAS health-based criteria.

The terms “regulatory” or “regulation” are used in this document to refer to requirements that have gone through a formal process to be promulgated and legally enforceable as identified under local, state, federal, or international programs. The terms “guidance” and “advisory” apply to all other policies and numerical values.

8.2 Regulatory Programs

8.2.1 Background to Regulation of PFAS

The scientific community is rapidly recognizing and evolving its understanding of PFAS in the environment, causing an increased pace of development of guidance values and regulations. the PFAS Environmental Media Values Table Excel file has been developed and is available as an Excel file. Human health protection is the primary focus of the PFAS regulations, guidance, and advisories developed to date. Regulations and guidance have focused on the PFAAs, precursor compounds, and FECAs. Like many other emerging contaminants, the regulatory and guidance values for PFAS can vary across programs, with differences due to the selection and interpretation of different key toxicity studies, choice of uncertainty factors, and approaches used for animal-to-human extrapolation. The choice of exposure assumptions, including the life stage and the percentage of exposure assumed to come from non-drinking water sources, may also differ. Thus, both differences in scientific conclusions and public health policy choices affect the myriad of regulatory and guidance initiatives for PFAS. More information is included in Section 8.3.

In addition to values that specify health-based concentration limits, agencies have used various strategies to limit the use and release of PFAS. For example, the USEPA worked with the eight primary U.S. PFAS manufacturers and processors to eliminate PFOA and many PFOA precursors and higher homologues by 2015 (USEPA 2017). Additionally, the Organisation for Economic Co-operation and Development OECD (2015) has described various international policies, voluntary initiatives, biomonitoring, and environmental monitoring programs to control PFAS. More information regarding the history of these

developments is in Section 2.4.

Authority for regulating PFAS in the United States is derived from a number of federal and state statutes, regulations, and policy initiatives. This section provides a brief overview of the major federal statutes and regulatory programs that govern PFAS.

8.2.2 Federal PFAS Regulations

Within the United States, currently both the USEPA and the FDA have regulatory or guidance initiatives for PFAS. The USEPA has the authority to regulate PFAS under several different statutes as outlined below. To date, USEPA has not yet finalized listing PFAS as hazardous wastes or substances under its available statutory authorities, including the Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Emergency Planning and Community Right-to-Know Act, or the Clean Air Act. USEPA has also not yet finalized regulations for any PFAS under the Safe Drinking Water Act. However, USEPA has now proposed listing PFOS and PFOA as CERCLA hazardous substances (Section 8.2.2.6) and has proposed draft primary drinking water regulations for a number of PFAS (Section 8.2.2.4). The Key Actions to Address PFAS website includes more detailed information about the actions of some of these programs (USEPA 2023). Key Actions to Address PFAS website includes more detailed information about the actions of some of these programs.

Through the Office of Regulatory Affairs, the Office of Management and Budget maintains a list of regulatory actions which have been initiated by the USEPA and certain other federal agencies. That list is updated periodically to give the status of the regulations and is available at https://www.reginfo.gov/public/Forward?SearchTarget=RegReview&textfield=PFAS.

8.2.2.1 National Defense Authorization Act (NDAA)

Through the NDAA, which is enacted early each year, Congress mandates many actions that the Department of Defense (DOD) must comply with, some of them concerning PFAS. At times, separate PFAS-related requirements for the USEPA or other federal entities are also made. Although these activities are not regulatory or guidance in nature, they are important in advancing human health exposure studies of PFAS, remediation of PFAS-contaminated water, development of new technologies to reduce PFAS exposure, interagency collaboration on PFAS, and other PFAS-related actions at the federal level.

The Regulatory Programs Summary Excel file lists by responsible agency the PFAS actions enacted through each NDAA. The NDAA for 2018 was the first one to have a PFAS requirement mandating the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to study PFAS exposure and health implications in communities near current or former military bases and known to have had PFAS in their drinking water, groundwater, or other sources of water. Subsequent NDAAs have had increasing numbers of PFAS-related requirements, as listed on the PFAS Regulatory Programs Summary Excel file.

8.2.2.2 USEPA PFAS Action Plan

USEPA issued a PFAS Action Plan (USEPA 2019) in February 2019 and an update a year later (USEPA 2020). The plan included a discussion about the process for moving forward to establish PFOA and PFOS MCLs for drinking water, and it included a number of main actions that encompassed more than just safe drinking water issues. More information about USEPA's previous actions to address PFAS is available on their website (USEPA 2021). The USEPA (2021) document was superseded by the strategic roadmap described below.

8.2.2.3 USEPA Strategic Roadmap

In October 2021, the USEPA published the *PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024* (USEPA 2021). The USEPA's stated goals for addressing PFAS are focusing on research, restriction, and remediation. The strategic roadmap includes actions across the different divisions of USEPA. More information about USEPA's actions to address PFAS under this roadmap is available on their website (https://www.epa.gov/pfas), and in a November 2022 progress report (USEPA 2022).

8.2.2.4 Safe Drinking Water Act (SDWA)

The SDWA is the federal law that protects public drinking water supplies throughout the nation (USEPA 1974). Under the SDWA, the USEPA has authority to set enforceable National Primary Drinking Water Regulations, such as MCLs, for specific chemicals and to require testing of public water supplies. The SDWA applies to all public water systems (PWSs) in the United

States but does not apply to private domestic drinking water wells or to water not being used for drinking.

Much of the current occurrence data available regarding PFAS in public drinking water was generated by USEPA under the SDWA Unregulated Contaminant Monitoring Rule (UCMR) program (USEPA 2017). USEPA uses the UCMR to collect data for chemicals that are suspected to be present in drinking water but that do not have standards set under the SDWA. The third round of this monitoring effort, or UCMR3, included six PFAAs:

- perfluorooctanesulfonic acid (PFOS)
- perfluorooctanoic acid (PFOA)
- perfluorononanoic acid (PFNA)
- perfluorohexanesulfonic acid (PFHxS)
- perfluoroheptanoic acid (PFHpA)
- perfluorobutanesulfonic acid (PFBS).

Samples were collected during a consecutive 12-month monitoring period between 2013 and 2015 from large PWSs serving more than 10,000 people, and a limited number of smaller systems determined by USEPA to be nationally representative. Based on USEPA's UCMR3 reported limits of between 10 and 90 ng/L, depending on the specific PFAAs, at least one of the six PFAAs listed above was detected in 194 out of 4,920 PWSs tested (~4%), which serve about 16.5 million people in 36 states and territories (Hu et al. 2016).

The USEPA and some states use occurrence data produced by the UCMR program, not only for PFOA and PFOS, but also for other PFAS as well (Table 8-1 and Table 17-3), to help determine which substances to consider for future regulatory action. All of the data from the UCMR program are published in the National Contaminant Occurrence Database (NCOD) and available for download from USEPA's website (USEPA 2017).

Table 8-1. UCMR3 occurrence data for PFOA and PFOS

Chemical	Analytical reporting limit (ppt)	Number of PWSs[1]	PWS (%)[1]
PFOS	40	46	0.9
PFOA	20	13	0.3
∑ PFOA + PFOS		63	1.3

[1] Number and percent of public water systems (PWS) that exceeded the 2016 health advisory by chemical.

The Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) was published in December 2021. UCMR5 requires sample collection for 30 chemical contaminants between 2023 and 2025. This includes a list of 29 PFAS with minimum reporting limits ranging from 2 to 20 ppt (USEPA 2021). Individual PWS data has been reported online (USEPA 2024). UCMR5 will include all US public water systems serving 3,300 or more people, which is a change from previous UCMRs that included systems serving 10,000 or more people.

The USEPA has established final regulations for PFAS under the SDWA. USEPA published a rule on April 26, 2024 that includes National Primary Drinking Water Regulations (NPDWRs) for six PFAS (USEPA 2024). In this rulemaking, USEPA has classified PFOA and PFOS as likely human carcinogens and proposes health-based MCLGs for PFOA and PFOS of zero, consistent with USEPA's approach for likely human carcinogens in general. The individual MCLs for PFOA and PFOS are at 4 ng/L, which is the analytical reporting level and practical quantitation level. This rulemaking includes MCLGs and MCLs for PFNA, PFHxS, and GenX individually at 10 ng/L provided they are not in a mixture as well as mixtures of PFHxS, Gen-X, PFNA, and PFBS at a total hazard index of 1 (unitless). All six of these PFAS are included in the UCMR5 analyte list.

For PFAS and other unregulated drinking water contaminants with limited occurrence data, the USEPA begins the process of making regulatory decisions under the SDWA by evaluating the nationwide extent of drinking water contamination and potential health effects that may result from exposure to contaminants via drinking water. This evaluation begins with considering contaminants for inclusion on the Contaminant Candidate List (CCL), which is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations but are known or anticipated to occur in public water systems. USEPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection, including occurrence data collection under UCMR. On November 14, 2022, USEPA

published the final CCL5, which includes PFAS as a chemical class (USEPA 2022).

In addition, when the USEPA determines there may be an "imminent and substantial endangerment" from a contaminant that is present in or likely to enter a PWS, under Section 1431 of the SDWA, it may issue emergency administrative orders (EAOs) to take any action necessary to protect human health if state and local authorities have not acted (42 U.S.C. §300i). USEPA has issued several such EAOs to protect public and private water supply wells contaminated with PFOA or PFOS (USEPA 2009, 2014, 2015, 2022).

8.2.2.5 Toxic Substances Control Act (TSCA)

TSCA authorizes the USEPA to require reporting, record keeping, testing, and restrictions of chemicals and chemical mixtures that may pose a risk to human health or the environment. Section 5 of TSCA authorizes the USEPA to issue Significant New Use Rules (SNURs) to limit the use of a chemical when it is newly identified, or when a significant new use of an existing chemical is identified, before it is allowed into the marketplace (USEPA 2017). From 2002 to 2013, USEPA issued four final SNURs covering 271 PFAS, including PFOS and PFOA. The first three SNURs covered PFAS included in the 3M Corporation's voluntary phaseout of PFOS. The 2013 SNUR required notification to USEPA prior to manufacture or import of seven PFAS that had been reviewed by USEPA under the TSCA New Chemicals Program but had yet to be commercially manufactured or imported into the United States. This SNUR also included long-chain perfluoroalkyl carboxylic acids (PFCAs) and their salts and precursors that were used in carpets or to treat carpets (USEPA 2015). Collectively, these SNURs placed notification requirements on the manufacture (including import) of specific PFAS for new use. The SNURs allowed for continued, low-volume use of some PFAS in photographic/imaging, semiconductor, etching, metal plating, and aviation industries (USEPA 2017). In January 2015, USEPA proposed another SNUR to require notification to USEPA before any future manufacture (including import) of PFOA and PFOA-related chemicals, including as part of articles, and processing of these chemicals. As a result of changes made to section 5(a) of TSCA when TSCA was amended in June 2016, USEPA undertook developing a supplemental SNUR for the import of certain long-chain PFCA and PFSAs as part of categories of certain articles (USEPA 2018).

As required by the NDAA, the USEPA finalized the supplemental SNUR in June 2020 and published the final notice in the Federal Register in July 2020 (https://www.govinfo.gov/content/pkg/FR-2020-07-27/pdf/2020-13738.pdf). The 2020 SNUR designates as a significant new use the manufacture, import, or processing of a specific subset of long-chain perfluoroalkyl carboxylate (LCPFAC) substances for any use that was not ongoing as of December 15, 2015, and for all other LCPFAC chemical substances for which there were no ongoing uses as of January 21, 2015. The SNUR also prohibits the import of certain LCPFAC as part of a surface coating on articles, and the import of carpet containing perfluoroalkyl sulfonate chemical substances, without USEPA review.

Finally, USEPA recently proposed a new SNUR for those PFAS that have not been manufactured (including imported) or processed for many years and are consequently designated as inactive on the TSCA Chemical Substance Inventory (USEPA 2023). Persons or companies subject to the SNUR would be required to notify USEPA at least 90 days before commencing any manufacture (including import) or processing of the chemical substance for a significant new use.

The USEPA continues to review new PFAS through USEPA's New Chemicals Program before approving commercialization. In October 2021, USEPA published the National PFAS Testing Strategy to "help EPA identify and select PFAS for which the Agency will require testing using TSCA authorities" (USEPA 2021). In 2023, USEPA released a new framework for addressing new PFAS and new uses of PFAS which is intended to require more extensive toxicity and fate data for PFAS with potential exposures or releases (USEPA 2023).

8.2.2.6 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)—"Superfund"

PFAS, other than PFOA and PFOS, are not currently listed as CERCLA hazardous substances but may be addressed as CERCLA pollutants or contaminants as defined by section 101 (33) of CERCLA (40 CFR 300.5). USEPA finalized a rule in April 2024 to designate PFOA and PFOS as hazardous substances (USEPA 2024). This rulemaking requires entities to immediately report releases of PFOA and PFOS that meet or exceed the reportable quantity to the National Response Center, state or Tribal emergency response commission, and the local or Tribal emergency planning committee (local emergency responders). Entities would not be required to report past releases of PFOA or PFOS as they were not yet listed as hazardous substances. In addition to the final rule, EPA is issuing a separate CERCLA enforcement discretion policy (USEPA 2024) that makes clear that EPA will focus enforcement on parties who significantly contributed to the release of PFAS chemicals into the environment, including parties that have manufactured PFAS or used PFAS in the manufacturing process, federal

facilities, and other industrial parties.

CERCLA Protection of Human Health. CERCLA requires, among other things, that Superfund response actions ensure protectiveness of human health and the environment, and compliance with laws and regulations that constitute "applicable or relevant and appropriate requirements" (ARARs); the statute also provides possible ARAR waivers in limited circumstances. The lead agency (as defined in 40 CFR 300.5) identifies potential ARARs and to-be-considered values (TBCs), based in part on the timely identification of potential ARARs by states. Risk-based cleanup goals may be calculated and used to determine cleanup levels when chemical-specific ARARs are not available or are determined not to be sufficiently protective (USEPA 1997). The ARAR process can be complex and can result in impacts on scope, budget, and public acceptance components of a project (USEPA 2019).

The Environmental Media Values Table Excel file includes information from state, federal, and some international agencies. These values are not necessarily automatically recognized as ARARs and must be evaluated by the lead agency to determine their ARAR status. In the Superfund program, USEPA regions evaluate potential ARARs, including state standards, on a site-specific basis to determine whether a specific standard or requirement is an ARAR for response decision and implementation purposes. Determining if a state requirement is promulgated, substantive, and enforceable are some of the factors in evaluating whether a specific standard may constitute an ARAR or TBC (40 CFR 300.5 2001; 40 CFR 300.400 2019, (g); USEPA 1988, 1991).

As mentioned above, risk-based cleanup goals may be calculated when chemical-specific ARARs are not available or are determined not to be protective (USEPA 1997). The USEPA's Regional Screening Levels (RSLs) Generic Tables (USEPA 2023) and the RSL online calculator (USEPA 2017) are used by risk assessors to identify screening levels and preliminary remedial goals for contaminants of potential concern at a site. These goals are typically based on toxicity values that have been selected in accordance with the USEPA's published hierarchy (USEPA 2003). In May 2022, USEPA added five PFAS (PFOA, PFOS, PFNA, PFHxS, and GenX) to the RSL table (USEPA 2023). PFBS had previously been listed in the RSL generic tables. For these six PFAS, the generic tables provide noncancer reference doses (RfDs), screening levels for soil and tap water, and soil screening levels for the protection of groundwater. USEPA issued a final toxicity value for PFBS in April 2021 (USEPA 2021). In October 2021, USEPA issued a final toxicity assessment for GenX chemicals (USEPA 2021). The online RSL calculator currently supports site-specific calculations for the same six PFAS. The USEPA also provides tables and a calculator for removal management levels (RMLs). In general, RMLs are not final cleanup levels, but can provide a reference when considering the need for a removal action (for example, drinking water treatment or replacement) (USEPA 2016).

Because RSLs and RMLs are periodically updated, they should be reviewed for revisions and additions before using them. RSLs and RMLs are not ARARs, but they may be evaluated as TBCs. The USEPA has emphasized that RSLs and RMLs are not cleanup standards (USEPA 2023) and suggests that final remedial goals be informed by a baseline risk assessment so that site-specific information can be incorporated. Section 9 provides more information on site-specific risk assessment for PFAS.

CERCLA Protection of the Environment. CERCLA requires that remedies also be protective of the environment. Risk-based cleanup goals that are protective of the environment are site-specific and depend in part on the identification of the ecological receptors to be protected. Another example of a risk-based cleanup goal is a cleanup standard for a chemical in soil that is protective of groundwater quality and is developed on a site-specific basis. Given the challenge associated with deriving accurate physical and chemical properties for PFAS (Sections 4.1and 5.1), site-specific values will need to be derived.

8.2.2.7 Resource Conservation and Recovery Act (RCRA)

RCRA provides USEPA with the authority to regulate hazardous waste management, nonhazardous solid waste facilities and practices, and underground storage tanks holding petroleum or certain hazardous substances. No PFAS have been formally listed as RCRA hazardous waste for regulation under this program. However, there are at least a couple of examples where action on PFAS was taken under the auspices of RCRA. For example, in 2004 USEPA pursued violations of RCRA and TSCA at an E.I. DuPont de Nemours and Company (DuPont) facility in West Virginia due to environmental release of the hazardous constituent PFOA (USEPA 2015). In the case of DuPont, the facility already had a RCRA permit for hazardous waste disposal and was under a Corrective Action Permit. Some states, Texas, for example, are regulating certain PFAS under their RCRA permits and requiring investigation and cleanup.

In February 2017, a U.S. District Court denied motions to dismiss RCRA "imminent and substantial endangerment" claims relating to PFAS (*Tennessee Riverkeeper, Inc. v. 3M Co.*, No. 5:16-cv-01029-AKK, 2017 WL 784991 (N.D. Ala. Feb. 10, 2017)). This case involved the alleged continuing contamination of the Tennessee River and associated public drinking water

supplies with PFAS that the plaintiff claims originated from a local manufacturing facility and two local landfills. There were several arguments that the claims should be dismissed. One argument by the landfill owners was that the claims were an attack on existing, valid permits that included a solid waste permit authorizing disposal in the landfill of PFAS-bearing materials. The court denied the motion to dismiss, stating that the permits only authorize disposal of nonhazardous waste, and there is a dispute over whether the PFAS-containing material is a hazardous waste. Additionally, there are a continually growing number of citizen lawsuits filed under RCRA in state courts throughout the United States. Thus, the applicability of RCRA regulations and statutes to PFAS does not appear to be settled and can be complicated.

On June 23, 2021, New Mexico Governor Michelle Lujan Grisham petitioned USEPA Administrator Michael Regan to designate PFAS as "hazardous waste" under the Resource Conservation and Recovery Act, citing imminent and substantial endangerment. On October 26, 2021, EPA administrator Regan responded to the governor's petition (USEPA 2021). In February of 2024 USEPA proposed to add nine PFAS (PFOA, PFOS, PFBS, GenX, PFNA, PFHxS, PFDA, PFHxA, and PFBA) as RCRA Hazardous Constituents in Title 40 of the Code of Federal Regulations Part 261 Appendix VIII (USEPA 2024). In addition, USEPA has proposed a rulemaking to clarify that RCRA has the authority to require the cleanup of solid wastes that meet the statutory definition of hazardous waste. This will mean that "emerging contaminants such as PFAS can be cleaned up through the RCRA corrective action process." (USEPA 2024).

8.2.2.8 Clean Air Act (CAA)

Under the CAA, USEPA is required to regulate emissions of hazardous air pollutants from industrial facilities. USEPA may develop standards for controlling certain hazardous air emissions from sources in a specific industry group. Within 8 years of establishing emission standards, USEPA must determine whether the standards are sufficiently protective of human health and protect against adverse environmental effects. This determination also considers improvements in air pollution controls and evaluates effective and feasible alternatives. There are no air emission standards for PFAS at this time. There is no indication how far along USEPA is in this process for regulating PFAS under the CAA.

8.2.2.9 Clean Water Act (CWA)

Since 1972, the CWA has given the USEPA authority to control water pollution by regulating discharges into the nation's surface water by setting wastewater standards for industry. There are no nationally recommended water quality criteria for any PFAS at this time. However, USEPA published draft aquatic life criteria for PFOA and PFOS in summer 2022 (USEPA 2022, 2022). USEPA released the Final 2016 Effluent Guidelines Program Plan in May 2018, which listed PFAS as a topic for future investigation (USEPA 2018). More recently, USEPA finalized Effluent Guidelines Plan 15 in January 2023 (USEPA 2023) (see Section 16.6).

In December 2022, USEPA released a memorandum relating to NPDES permitting for PFAS discharges which supersedes the April 2022 USEPA memo (USEPA 2022, 2022). More information about these USEPA documents can be found in Section 16.1. The regulation of PFAS in discharge effluents by states is discussed below in Section 8.2.3, and in Section 16.6.

8.2.2.10 Toxics Release Inventory (TRI) Program

The Toxics Release Inventory (TRI) program requires the annual reporting of environmental releases of approximately 800 chemicals which the USEPA has concluded cause:

- Cancer or other chronic human health effects
- Significant adverse acute human health effects
- Significant adverse environmental effects

For chemicals regulated under the TRI, facilities that manufacture, process or use these chemicals in amounts above established levels must submit annual reporting forms for each chemical.

As stipulated by the NDAA, the USEPA finalized a rule requiring 180 PFAS be added to the list of chemicals that must be reported under the TRI program for Reporting Year 2022 (USEPA 2023). An additional nine PFAS were added to the list for Reporting Year 2023 (USEPA 2023) and an additional seven PFAS were added for Reporting Year 2024 (USEPA 2024). The PFAS subject to TRI reporting requirements under the original NDAA included all PFAS listed as an active chemical substances under TSCA's Section 8(b)(1) inventory. Each of these PFAS will have a 100-pound reporting threshold. In the 2022 changes to reporting requirements (USEPA 2022), these PFAS were added to the List of Lower Thresholds for Chemicals of Special Concern (chemicals of special concern), which eliminates the use of the *de minimis* exemption, which is expected to increase the reporting of PFAS found in mixtures or products in low concentrations (USEPA 2023). Reporting for each calendar year is due in July of the following calendar year; these data–as with all TRI data–will be publicly-available

approximately 1 year after they were reported (USEPA 2020).

8.2.2.11 U.S. Food and Drug Administration (FDA)

One of the responsibilities of the FDA is regulation of "food contact substances" (FCSs), chemicals added to or components of "food contact materials" (FCMs), such as food wrappers and packaging. The FDA currently regulates certain PFAS used as grease-proofing agents for food packaging via a Food Contact Notification Program within the Center for Food Safety and Applied Nutrition's Office of Food Additive Safety. The PFAS used in FCMs and their known degradants and impurities have all undergone review for human health and environmental safety concerns through the food contact notification process and food additive petition process, which requires submission of chemical, toxicological, and environmental information on the FCS itself and on any potential impurities. Perfluorinated ion exchange membranes are also regulated under these processes.

In 2016 the FDA banned three perfluoroalkyl ethyl compounds from use in food packaging material (81 FRN 5, Jan. 4, 2016, Indirect Food Additives: Paper and Paperboard Components): diethanolamine salts of mono- and bis (1 H, 1H, 2H, 2H perfluoroalkyl) phosphates with even-numbered alkyl groups in the range of C8–C18; pentanoic acid, 4,4-bis [(*gamma–omega*-perfluoro-C8-20-alkyl)thio]; and perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[([gamma],[omega]-perfluoro C4–C20 alkylthio) methyl]-1,3-propanediol, polyphosphoric acid, and ammonium hydroxide.

In July 2020, the FDA announced that three manufacturers had agreed to a voluntary phase out of FCS that contain 6:2 fluorotelomer alcohol (6:2 FTOH). A fourth manufacturer had previously stopped sales of 6:2-FTOH-containing products in the US. The phase-out began in January 2021; the FDA predicted that it may take up to 18 months after that time to exhaust existing supplies of food contact papers that contain 6:2 FTOH (USFDA 2020).

As of February 2022, there were some FCS with PFAS listed on FDA's inventory of effective FCS notifications. The FDA (2023) inventory of FCS notifications is an online database. PFAS that are authorized for use in contact with food generally fall into four application categories:

- Nonstick cookware: PFAS may be used as a coating to make cookware non-stick.
- Gaskets, O-rings, and other parts used in food-processing equipment: PFAS may be used as a resin in forming certain parts used in food-processing equipment that require chemical and physical durability.
- Processing aids: PFAS may be used as processing aids for manufacturing other food contact polymers to reduce build-up on manufacturing equipment.
- Paper/paperboard food packaging: PFAS may be used as grease-proofing agents in fast-food wrappers, microwave popcorn bags, take-out paperboard containers, and pet food bags to prevent oil and grease from foods from leaking through the packaging (FDA 2019). However, the side-chain PFAS polymers used in grease-proofing are the subject of a voluntary phaseout agreement.

8.2.2.12 Other Federal Agency Actions

Other U.S. federal agencies and programs are actively involved in PFAS-related matters; however, their work largely focuses on data generation and analysis to help inform regulations/restrictions/regulatory action. These federal programs often provide valuable information, guidance, and resources for state regulatory and public health agencies. For example, the U.S. Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES) program provides valuable information about human exposure to chemicals (CDC 2023). Since 1999, the NHANES program has been providing an assessment of the exposure of the U.S. population to a small subgroup of PFAS. This information (PFAS concentrations in blood, serum, urine samples) is useful to scientists and regulatory agencies to understand "background" (that is, likely nonsite-related) human exposure levels and trends over time. In 2013-2014 CDC expanded their NHANES analysis to include evaluation of PFAS in serum and urine (Kato et al. 2018).

Under the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*] amendment to CERCLA (or Superfund) [42 U.S.C. 9601 *et seq.*], the U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR) was established to assess the potential public health risk from exposure to hazardous substances commonly found at National Priorities List facilities. CERCLA provides ATSDR with the authority to develop toxicological profiles that describe the health effects of these hazardous substances and to support site-specific response actions with health consultations and/or exposure investigations. A description of ATSDR's actions regarding PFAS is on their web page (ATSDR 2018). In May 2021, ATSDR released a final *Toxicological Profile for Perfluoroalkyls* (ATSDR 2021). In this revision, the agency discussed potential human health risks related to 14 specific PFAS and derived "provisional

intermediate Minimal Risk Levels" (MRLs) for PFOA, PFNA, PFOS, and PFHxS.

ATSDR (2023) has posted an online calculator that the general public can use to estimate the increase in their blood serum levels from exposure to PFOA, PFOS, PFNA, or PFHxS in drinking water.

The U.S. Geological Survey (USGS) has had an emerging contaminants program for over a decade within which they measure emerging contaminants, including PFAAs, in various environmental media and ecological receptors. The objective of their work is to characterize environmental occurrence, sources, and source pathways that may contribute to environmental exposure. This has been a useful source of information for scientists and regulatory agencies on occurrence, fate, and transport of PFAS. Information on the USGS program can be found on their web page (USGS 2017).

The U.S. Department of Defense SERDP and ESTCP are jointly managed with USEPA and the U.S. Department of Energy to develop the latest science and technology to improve DOD's environmental footprint and mission capabilities. Beginning in fiscal year 2011, SERDP and ESTCP have funded a significant number of projects related to developing a better understanding of PFAS occurrence, fate and transport, ecotoxicity, and remediation treatments, as well as investigating the next generation of fluorine-free firefighting foams. More information on SERDP and ESTCP funding projects and statements of need can be found on their website (SERDP-ESTCP 2019).

8.2.3 State PFAS Regulations and Guidance

State regulatory agencies often have the delegated authority to regulate and enforce environmental and public health requirements, although the states and US territories have different priorities, resources, and processes. Many states have been actively involved with addressing PFAS contamination across multiple regulatory programs. Examples of key state programs for water, soil, remediation, hazardous substances, and consumer products are described below, and information about regulatory, advisory, and guidance values is discussed in Section 8.3. The information below is meant to provide examples only; the Environmental Media Values Table Excel file should be consulted for more current and detailed information.

The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) has a PFAS resources website that includes links to PFAS information for states and territories (https://pfas.astswmo.org). The Environmental Council of the States (ECOS) published their updated white paper, Processes and Considerations for Setting State PFAS Standards, in April 2024 (ECOS 2024).

ITRC has developed the PFAS Regulatory Programs Summary Excel file that summarizes the regulations and programs in each state that target PFAS. The focus of the table is on PFAS regulations that have been enacted by any of the states or territories of the United States. The table also includes state programs that may not be mandated by a specific regulation, but which state agencies are pursuing on a discretionary basis. This table does not include any numeric criteria, but instead includes a description of the type of regulation or program, and a link to the applicable website. For specific regulatory values, the Environmental Media Values Table Excel file should be consulted.

The following subsections describe several different categories of state-adopted laws and regulations along with a brief explanation of each; please refer to the PFAS Regulatory Programs Summary Excel file for the most up-to-date information. Note that due to the state legislative review and finalization process, only bills that have been finalized into law are included in the PFAS Regulatory Programs Summary Excel file.

8.2.3.1 Product Labeling and Consumer Protection Laws

Several states have programs regulating PFAS in consumer products, including product labeling. Some of these regulations include PFAS in food packaging, children's products, firefighting gear, and other products. More specific information is available in the PFAS Regulatory Programs Summary Excel file with details available at the links provided.

8.2.3.2 Designation of Hazardous Waste or Hazardous Substance

Regulations that target select PFAS as hazardous wastes or hazardous substances have not been promulgated in most states. Formal PFAS regulations as hazardous substances have been promulgated in a number of states, and are under development in several other states. Please refer to the PFAS Regulatory Programs Summary Excel file for detailed information.

8.2.3.3 Drinking Water, Groundwater, Soil, and Remediation Programs

Several states have developed standards and guidance values for PFAS in drinking water, groundwater, and soil (see the Environmental Media Values Table Excel file). Some states adopted (by default) the USEPA LHAs published in either 2016 or 2022, while others adopted values developed via a risk assessment process, regulatory process, or legislative action. Some others use the LHA concentrations as advisory, nonregulated levels to guide the interpretation of PFAS detections. The May 2022 RSL table lists screening values for soil and tap water for six PFAS. Section 9 provides more information on site-specific risk assessment for PFAS.

In addition to the process using the USEPA RSL table mentioned above, some states have developed screening levels for various PFAS in soils assuming direct contact and/or ingestion. See the Environmental Media Values Table Excel file and USEPA (2021) Certain states have also developed values for the protection of groundwater (see the Environmental Media Values Table Excel file).

Some states have “antidegradation” policies aimed at protecting the quality of groundwater and high quality (or Tier 2) surface waters. Those polices can be used in decisions on cleanup and discharge under permits. Please see the PFAS Regulatory Programs Summary Excel file as well as the Environmental Media Values Table Excel file for more information.

8.2.3.4 Surface Water Discharge and Permitting

National Pollutant Discharge Elimination System (NPDES) permits use a standard process for developing effluent limits for pollutants. Effluent and receiving water limitations for PFAS would be established in the same manner as other pollutants. A number of states have established surface water quality standards for PFAS. More information on surface water effects can be found in Section 16.

8.2.3.5 Other State Regulations or Programs

Another concern for PFAS is in the application of biosolids from municipal wastewater treatment plants to land for disposal or reuse. A number of states are currently in the process of considering and/or developing such regulations (ECOS 2023). An example of this type of regulation may include a law to prohibit the land application of sludge as well as the sale and distribution of products containing sludge and septage. Other potential regulations may focus on reducing PFAS inputs into wastewater treatment plants while further assessing the impacts associated with land application of biosolids containing PFAS. See Section 3 for a more detailed discussion of PFAS in biosolids.

Some states have developed an ambient air limit for PFAS. See the PFAS Environmental Media Values Table and the PFAS Regulatory Programs Summary Excel file for more information.

Finally, some states have issued state regulations or programs related to AFFF. For example, some states have established AFFF take-back programs to reduce the potential discharge of PFAS associated with AFFF into the environment. Other states are in the process of developing an AFFF take-back program. See Section 3 for a more detailed discussion on AFFF and related regulations and guidance. A number of states have banned the manufacture, sale, and use of PFAS-containing AFFF in most applications (see PFAS Regulatory Programs Summary Excel file).

8.3 Differences in the Available Regulations, Advisories, and Guidance

Human health protection is the primary focus of the PFAS regulations, guidance, and advisories developed to date. Internationally, including in the United States, the nonpolymer PFAS have been the regulatory focus. Several toxicity evaluations are available for certain PFAS. This is an area of active research and regulatory activity. Additional information is presented in Sections 7.1 and 17.2.

Human health–based guidance values and/or regulatory standards have thus far been derived for a number of PFAS, including PFAAs, polyfluoroalkyl precursors, and fluorinated ether carboxylates (FECA) by state and/or federal agencies in the United States. The health-based values for these nonpolymeric PFAS vary across programs, with differences due to the selection and interpretation of different key toxicity studies, use of human or animal data as the basis, use of a noncancer reference dose or a cancer slope factor, choice of uncertainty factors when a reference dose is used, and approaches used for animal-to-human extrapolation. The choice of exposure assumptions, including the life stage and the percentage of the reference dose assumed to come from non-drinking water sources, also differs. Most available guidance values and/or regulatory standards are for PFOA and PFOS, and the key differences in regulatory and guidance decisions within the United

States for those chemicals can be seen in the ECOS white paper (ECOS 2024).

Table 8-2 provides the underlying definition and context for the various federal regulations, standards, and guidance values that may apply to PFAS in the United States.

Table 8-2. Definition of terms associated with drinking water and/or groundwater standards or guidance

Term	Acronym	Agency	Definition	Link
Minimum Risk Level	MRL	CDC ATSDR	An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure. MRLs are intended to serve as screening levels to identify contaminants and potential health effects that may be of concern. MRLs are not intended to define cleanup or action levels for ATSDR or other agencies. (ATSDR 2018) Importantly, the MRL is a daily dose, applicable for any oral exposure; it is not a threshold concentration in water or other environmental media.	https://www.atsdr.cdc.gov/mrls/index.asp

Term	Acronym	Agency	Definition	Link
Regional Screening Level	RSL	USEPA Regions	Default screening level tables including chemical-specific concentrations for individual contaminants in air, drinking water, and soil that may warrant further investigation or site cleanup. Generic screening levels (SLs) are based on default exposure parameters and factors that represent reasonable maximum exposure conditions for long-term/chronic exposures and are based on the methods outlined in EPA's Risk Assessment Guidance for Superfund, Part B Manual (1991) and Soil Screening Guidance documents (1996 and 2002). It should be emphasized that SLs are not cleanup standards. (USEPA 2019)	https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide#intro

Term	Acronym	Agency	Definition	Link
Health Advisory	HA	USEPA Office of Water	Health advisories provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. EPA's HAs are nonenforceable and provide technical guidance to state agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. (USEPA 2019)	https://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information
Maximum Contaminant Level Goa	MCLG	USEPA Office of Water	The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. MCLGs are nonenforceable public health goals. MCLGs consider only public health and not the limits of detection and treatment technology effectiveness. (USEPA 2018).For contaminants classified as known or likely human carcinogens, it is USEPA policy to set the MCLG at zero (0). (USEPA 2023)	https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations

Term	Acronym	Agency	Definition	Link
Maximum Contaminant Level	MCL	USEPA Office of Water	The highest level of a contaminant that is allowed in drinking water. MCLs are set as close to MCL goals as feasible using the best available treatment technology and taking cost into consideration. MCLs are enforceable standards. (USEPA 2018)	https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations

8.3.1 Toxicity Values

As stated above, available PFAS regulations, guidance, and advisories are generally based on human health protection. However, the available values that are deemed protective of human health vary across international and U.S. jurisdictions. In general, there are similarities and differences in the understood toxicological effects, potencies, and modes of action for various PFAS, and there are differences in the interpretation of relevant toxicological data for individual PFAS.

Toxicological data from both animal and human epidemiology studies are used as the basis for U.S. state and federal PFAS human health toxicity factors and related standards or guidance. The European Food Safety Authority's tolerable weekly intake for the total of PFOA, PFOS, PFNA, and PFHxS is based on human data (EFSA 2020). More recently, California EPA and USEPA have developed draft reference doses for PFOA and PFOS (CA OEHHA 2023; USEPA 2023), as well as for PFHxS (USEPA 2023) and PFDA (USEPA 2023), and a draft cancer slope factor for PFOA (USEPA 2023; CA OEHHA 2023) based on human general population data that are far below current values based on animal data. See Section 7 for a review of the toxicology data for PFAS. Many scientific considerations and decision points are involved in developing human health toxicity factors (RfDs and cancer slope factors) from animal toxicology data or human epidemiology data. For PFOA and PFOS, different scientific and regulatory policy conclusions have been made for nearly every decision point by different agencies. Some of the key topics that account for toxicity value differences are discussed below. More specific information on these differences can be found in the Environmental Media Values Table Excel file; as well as the PFAS Regulatory Programs Summary Excel file and the ECOS white paper (ECOS 2024).

Although previous PFAS regulations, standards, and guidance have largely been based on potential noncancer effects, several recent draft or proposed values are based on cancer risk. RfDs have been used by most U.S. states to describe the estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (USEPA 2019).

The New Jersey Drinking Water Quality Institute (NJDWQI) and California Office of Environmental Health Hazard Assessment (OEHHA) also considered potential cancer endpoints for PFOA and PFOS. In its recent proposed PFAS MCL rule, USEPA (2023) classified both PFOA and PFOS as likely human carcinogens and developed cancer slope factors for both. NJDWQI (2023) concurred with USEPA (2023) that PFOA is a likely human carcinogen. However, at the time of New Jersey's recent analysis, the NJDWQI (2023) was unaware of the information identified by USEPA (2023) that is the basis for its conclusion that PFOS is also a likely human carcinogen. The methodology for deriving chemical-specific toxicity values is generally applicable to both cancer and noncancer endpoints where dose-response relationships and weight-of-evidence analyses of available data sets are evaluated, and is described in detail.

The first step in deriving a human health-based toxicity value (RfD or CSF) is the review of applicable data to identify potential human health hazards (toxicity endpoints) based on sensitive effects that are consistently seen across several studies, are deemed related to an adverse health outcome or its known precursor, and are relevant to humans based on mode of action considerations. Not all agencies have utilized the same candidate studies and health endpoints for PFOA and PFOS due to differences in selection criteria and differences in opinion on the relevancy to human health and on adversity of effects seen in recent studies.

The estimation of an RfD includes two additional components: the selection of the dose-response method and uncertainty

factors. For dose-response evaluation, either the benchmark dose or the study NOAEL or LOAEL is utilized as the point of departure. Uncertainty factors used include the standard risk assessment extrapolations, and the choice of uncertainty factors also varies by agency.

8.3.2 Exposure Assumptions

General exposure factors that are used in derivation of PFAS regulations and guidance values are discussed below.

8.3.2.1 Body Weights, Drinking Water Ingestion, and Exposure Durations

Once a human health toxicity value is derived in units of ug/kg-day (or ng/kg-day or mg/kg-day), the toxicity value is combined with exposure parameters to result in the ultimate threshold concentration in drinking water (guidance or standard). The choice of exposure parameters used can be a flexible science- and/or policy-based decision based on default assumptions or chemical-specific data, or may be set based on regulatory framework. The exposure parameters used under the U.S. CERCLA program (for example, USEPA regional screening levels) include default exposure parameters and factors that represent conditions for long-term/chronic exposures, including an exposure frequency of 350 days per year, exposure duration of 6 years for a 15-kg child who drinks 0.78 L water per day, or 26 years for an 80-kg adult who drinks 2.5 L of water a day. In contrast to CERCLA, drinking water guidance values and standards (MCLs and MCLGs) developed by USEPA or states are generally based on lifetime exposure using default adult parameters, and they do not usually include a duration of exposure parameter. For PFOA and PFOS, USEPA and state agencies have not always relied upon these default exposure parameters. Some have decided to utilize exposure parameters that are specific for more sensitive subpopulations (infants, children, or lactating/pregnant women) and/or a toxicokinetic model that considers exposures to the developing fetus and the higher exposures to the breast-fed infant. For example, MDH developed a toxicokinetic model to estimate the total exposure to breast-fed and formula-fed infants (Goeden, Greene, and Jacobus 2019), and this model was used to derive standards in Minnesota, New Hampshire, and Michigan.

8.3.2.2 Relative Source Contribution

Humans can be exposed to nonpolymeric PFAS, including precursor chemicals, via multiple sources, including air, food, and consumer and industrial products. The relative source contribution (RSC) term is used in health-based guidance and standards developed by the USEPA under the federal SDWA and related state programs to account for potential non-drinking water exposures to chemicals. In general, the concept ensures that when a criterion based on an RfD for noncancer effects is established for a single exposure pathway, such as drinking water, potential exposures that occur from other pathways are accounted for so that total exposure does not exceed the RfD (USEPA 2000). The default RSC of 20% means that the drinking water pathway is assumed to contribute only 20% of the RfD, and all other exposure pathways contribute the remaining 80%. In practice, therefore, the drinking water concentration based on RfD and drinking water consumption assumptions is multiplied by the RSC (for example, 20%) to account for exposure via the other pathways.

The RSC term generally does not exist in CERCLA/RCRA-based remediation programs because baseline risk assessments specifically investigate and quantify risks associated with all potential site-specific exposure routes (not just drinking water), and then consider a receptor's cumulative risk. Therefore, there is no downward adjustment to a residential groundwater (termed "tap water" by USEPA) drinking water screening level, for example, to account for potential other exposures—all site-specific exposures are quantified. See Section 9 for more information on site-specific risk assessments for PFAS.

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