



## 8 Basis of Regulations

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. ITRC also maintains [updated tables of PFAS water values, and PFAS soil values from state, federal, and some international countries](#) posted as an Excel file). This section also includes a brief explanation of examples of various health-based criteria. ITRC also has tables posted as an Excel file of [the basis for PFOA and PFOS values in the United States](#) that is updated periodically.

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### 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. 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 PFOS and PFOA 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. See the tables of the [basis for PFOA and PFOS values in the United States](#) for the specific differences underlying drinking water or groundwater regulations and advisories for PFOA and PFOS.

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 2017a](#)). Additionally, the Organisation for Economic Co-operation and Development ([OECD \(2015a\)](#)) 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 acts, as provided below; however, USEPA has not yet listed 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. To date, USEPA has also not regulated any PFAS under the Safe Drinking Water Act.

### 8.2.2.1 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 2017a](#)). 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 PFCAs and their salts and precursors that were used in carpets or to treat carpets ([USEPA 2015e](#)). 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 2017a](#)). 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. The proposed SNUR does not place a regulatory restriction on the imports of fluoropolymers dispersions and emulsions containing PFOA or its salts ([FluoroCouncil 2018](#)). As a result of changes made to section 5(a) of TSCA when TSCA was amended in June 2016, USEPA is now developing a supplemental proposed SNUR for the import of certain long-chain PFCA and PFSA as part of categories of certain articles ([USEPA 2018i](#)).

USEPA continues to review the new short-chain PFAS chemicals through USEPA's New Chemicals Program before approving commercialization. Since 2006, USEPA has reviewed around 300 Premanufacture Notices for PFAS chemicals and has regulated about 200 of them through a combination of Consent Orders and SNURs ([USEPA 2018j](#)).

### 8.2.2.2 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 Maximum Contaminant Levels (MCLs) for specific chemicals and 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 nor to water not being used for drinking.

USEPA has not established regulations for any PFAS under SDWA; however, the agency recently indicated in its PFAS Action Plan ([USEPA 2019h](#)) that it will be initiating steps to evaluate the need for MCLs for PFOA and PFOS. The SDWA specifies the following three requirements for making a Regulatory Determination regarding MCL development:

- The chemical may have an adverse effect on the health of persons.
- The chemical is known to occur or there is a substantial likelihood that it will occur in PWSs with a frequency and at levels of public health concern.
- In the sole judgment of the EPA administrator, regulating the contaminant presents a meaningful opportunity for health risk reductions for persons served by PWSs.

More information regarding USEPA's PFAS Action Plan is found below in this section.

In May 2016, USEPA established a lifetime health advisory (LHA) of 70 ng/L for PFOA and PFOS in drinking water. This LHA is applicable to PFOA and PFOS individually or in combination if both chemicals are present at concentrations above the reporting limit ([USEPA 2016c, d](#)). The LHA supersedes USEPA's 2009 short-term (week to months) provisional health advisories of 200 ng/L for PFOS and 400 ng/L for PFOA ([USEPA 2009c](#)). The LHA for PFOA and PFOS is advisory in nature; it is

not a legally enforceable federal standard and is subject to change as new information becomes available ([USEPA 2016c, d](#)). USEPA states that the LHAs “provide Americans, including the most sensitive populations, with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water” ([USEPA 2016e pg.2](#)).

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 2017g](#)). USEPA uses the UCMR to collect data for chemicals that are suspected to be present in drinking water but that do not have health-based 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 were 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](#)).

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](#)) are used by the USEPA and some states 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 2017g](#)).

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

Exceed LHA (70 ppt)	Reporting Limit (ppt)	Number of PWSs	PWS (%)
PFOS	40	46	0.9
PFOA	20	13	0.3
∑ PFOA + PFOS <sup>1</sup>		63	1.3
<sup>1</sup> PWSs that exceeded the combined PFOA and PFOS health advisory (USEPA 2016d; 2017o)			

PFOA and PFOS were listed on Contaminant Candidate List 3 (CCL 3) in 2009 and are currently listed on CCL 4 published in late 2016, which indicates that the USEPA Office of Water is considering deriving MCLs for these specific PFAS as indicated above.

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 2009e](#), [2014b](#), [2015a](#)).

USEPA issued a PFAS Action Plan ([USEPA 2019h](#)) in February 2019. In addition to the evaluation of the need for an MCL for PFOA and PFOS, that Action Plan included the following main actions that encompass more than just safe drinking water issues:

- Develop interim groundwater cleanup recommendations to address groundwater contaminated with PFOA and PFOS
- Finalize draft toxicity assessments for Gen X chemicals and PFBS
- Develop additional toxicity values for PFBS, PFHxA, PFHxS, PFNA, and PFDA
- Conduct chemical safety reviews as new PFAS are developed and enter the market and issue proposed supplemental SNURs
- Incorporate the latest research results for additional PFAS into USEPA’s online drinking water treatment database

- Evaluate listing of PFOA and PFOS as hazardous substances
- Evaluate performance and identify costs associated with treatment and remediation approaches to address PFAS in the environment
- Support communities that have PFAS releases by using federal enforcement authorities where relevant and appropriate
- Develop an interactive map providing the public with available information on sources and occurrence of PFAS
- Develop coordinated messaging on PFAS across the federal government
- Develop a risk communications toolbox for PFAS to be used for the public
- Evaluate the listing of PFAS chemicals to the Toxics Release Inventory
- Determine if available data for PFAS are sufficient to establish ambient water quality criteria for human health
- Explore identifying industrial sources that may warrant regulation through national Effluent Limitation Guidelines and Standards (ELGs) and the setting of minimum levels of control needed for National Pollutant Discharge Elimination System (NPDES) permits
- Develop toxicity information for a larger group of PFAS and potentially address groups of PFAS
- Add PFAS monitoring to UCMR5, using newer analytical methods for a wider suite of PFAS, while achieving lower minimum reporting levels than earlier UCMRs
- Develop an inventory of PFAS data for media other than drinking water
- Assess ecological risk from PFAS exposure
- Evaluate air transport of PFAS.

### **8.2.2.3 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)—“Superfund”**

PFAS, including PFOA and PFOS, are not listed as CERCLA hazardous substances but may be addressed as CERCLA pollutants or contaminants, for example, as defined by section 101 (33) of CERCLA (40 CFR 300.5). As listed above in [Section 8.2.2.2](#), under its PFAS Action Plan ([USEPA 2019h](#)), USEPA is evaluating listing PFOA and PFOS as hazardous substances. The action plan also includes a priority action to develop interim cleanup recommendations for groundwater contaminated with PFOA and PFOS. The USEPA released a draft recommendation for public comment in spring 2019, which includes using a screening level of 40 ppt for each (individually) of PFOA and PFOS (hazard index of 0.1), and using 70 ppt combined as a preliminary remediation goal. CERCLA investigations are beginning to include PFAS when supported by the CSMs (for example, ([USEPA 2017d](#))). PFAS are often included in a remediation site’s 5-year review, when supported by site-specific information. According to USEPA, as of April 2018, there were active PFAS investigations occurring at 32 federal facility National Priorities List (NPL) sites and 17 non-federal sites, and these numbers are expected to continue to increase as PFAS are included in more remediation programs (Peter Gravatt, Director of USEPA’s Office of Ground Water and Drinking Water, ITRC PFAS team presentation April 24, 2018). [Section 9](#) provides a discussion and recommendations for how to consider PFAS during a site-specific risk assessment.

*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 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 1997a](#)). The ARAR process can be complex and can result in impacts on scope, budget, and public acceptance components of a project ([USEPA 2019k](#)).

The tables of [PFAS water values, and PFAS soil values from state, federal, and some international countries](#) posted as an Excel file include current state regulatory and guidance values for PFAS. 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 2017l](#)) and the RSL online calculator([USEPA 2017k](#)) 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 2003a](#)). Currently, PFBS and the potassium salt of PFBS are the only PFAS listed in the RSL generic tables. For PFBS and its salt, the generic tables provide a noncancer reference dose (RfD), screening levels for soil and tap water, and soil screening levels for the protection of groundwater. As stated in its PFAS Action Plan, USEPA is in the process of developing toxicity values for PFBS and GenX chemicals. Draft toxicity assessments were posted on November 14, 2018, for public review ([USEPA 2018d, e](#)). When finalized, these toxicity values may be incorporated into the RSL table for these PFAS, as well. The online RSL calculator currently supports site-specific calculations for PFBS, PFOA, and PFOS in tap water and soil. The noncancer RfDs derived by the USEPA Office of Water are provided as Tier 3 toxicity values for PFOA and PFOS. The USEPA 2016 cancer ingestion slope factor is also provided for PFOA, but screening levels are based on the noncancer endpoint. 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 2016b](#)).

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 2016g](#)) 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. To date no U.S. regulatory agency has established ecological criteria for PFAS. Another example of a risk-based 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 [4.1](#) and [5.1](#)), site-specific values will need to be derived.

#### **8.2.2.4 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 2015c](#)). 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.

#### **8.2.2.5 Clean Air Act (CAA)**

Under the CAA, USEPA is required to regulate toxic air pollutants from large industrial facilities. USEPA may develop standards for controlling certain air toxic 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.

According to the [USEPA \(2018j\)](#) website on PFAS Laws and Regulations, the CAA applies to discharges of PFAS to air under National Emission Standards for Hazardous Air Pollutants; however, 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.

### 8.2.2.6 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 federal water quality standards for any PFAS at this time. However, USEPA released the Final 2016 Effluent Guidelines Program Plan in May 2018, which listed PFAS as a topic for future investigation ([USEPA 2018f](#)). The USEPA plans to review PFAS surface water discharges from industrial categories for both long-chain and short-chain PFAS. The regulation of PFAS in discharge effluents is discussed below in [Section 8.2.3](#).

### 8.2.2.7 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, which required submission of chemical, toxicological, and environmental information on the FCS itself and on any potential impurities.

Currently, the FDA has 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. Side-chain acrylate and methacrylate fluoropolymers are currently approved and used within the United States for FCS. As of September 2019, there were approximately 60 specific FCS with PFAS that are listed on FDA's inventory of effective FCS notifications (recognizing its approval for specific uses, designated in the application).

### 8.2.2.8 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. Since 1999, the NHANES program has been providing an assessment of the exposure of the U.S. population to a small subgroup of PFAAs. This information is useful to scientists and regulatory agencies to understand "background" (that is, likely nonsite-related) human exposure levels and trends over time. CDC has recently expanded their NHANES analysis to include evaluation of PFAAs 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 full description of ATSDR's actions regarding PFAS is on their web page ([ATSDR, 2018a](#)). On June 20, 2018, ATSDR issued a revised draft *Toxicological Profile for Perfluoroalkyls* for public comment ([ATSDR 2018e](#)). 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 stated that these provisional MRLs are intended to serve as "screening levels" for identifying contaminants and potential health effects that may be of concern at hazardous waste sites and are not intended to be used for regulatory action, including to define cleanup or action levels.

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 50 states have different priorities, resources, and processes. Several 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 8.2.3.4](#). The information below is meant to provide examples only; the ITRC tables of [PFAS water values, and PFAS soil values from state, federal, and some international countries](#) posted as an Excel file should be consulted for more current and detailed information.

The ITRC PFAS team and the Environmental Council of States (ECOS) jointly issued a survey to state agencies to identify the various ways in which each state may be addressing PFAS, as discussed in [Section 8.2.3.6](#).

The following subsections provide several different categories of state-adopted laws and regulations along with examples of each.

#### **8.2.3.1 Product Labeling and Consumer Protection Laws**

Several states have programs regulating PFAS in consumer products, including product labeling. Note that due to the state legislative review and finalization process, only bills that have been finalized into law are discussed below.

In November 2017, PFOS and PFOA were listed as potential developmental toxicants under California's Proposition 65 (California Office of Environmental Health Hazard Assessment [CA OEHHA] ([2018](#))). The listing includes labeling requirements for manufacturers, distributors, and retailers, and will prohibit companies from discharging PFOA or PFOS (or their related salts) to sources of drinking water if the discharges would result in exposures that exceed a health-based "safe harbor" level, which has not yet been defined as of September 2019 by the state. The California Department of Toxic Substances Control Safer Consumer Products program is also addressing PFAS. This program has labeled the entire family of PFAS as "Candidate Chemicals" and is drafting "Priority Product" work plans to evaluate the use of these chemicals on "converted textiles or leathers such as carpet, upholstery, clothing, and shoes" ([CA DTSC 2019a](#)) and food packaging ([CA DTSC 2019b](#)).

Washington State has required the reporting of PFOS in children's products since 2012 ([Washington State Legislature 2008](#)). The 2017 Children's Safe Products Act update added reporting of PFOA in children's products starting in January 2019. Washington also tests products for chemicals to ensure manufacturers are reporting accurate information. In 2018, Washington enacted two laws addressing PFAS in specific products: AFFF ([Washington State Legislature 2018a](#)) and food contact materials ([Washington State Legislature 2018b](#)). After July 2018, PFAS-containing AFFF is not allowed to be used for training. After July 2020, PFAS-containing AFFF will not be allowed for sale or distribution. The AFFF sale ban does not apply to the U.S. Department of Defense, FAA, oil and gas terminals, or chemical plants. The AFFF restrictions do not apply to the use of AFFF in response to fire emergencies. After 2022, PFAS will be banned in food packaging materials if results of the Department of Ecology's alternatives assessment identify safer alternatives.

#### **8.2.3.2 State of Washington Chemical Action Plans**

Chemical action plans (CAPs) identify, characterize, and evaluate uses and releases of specific persistent, bioaccumulative, and toxic (PBT) chemicals or metals. Washington State prepares CAPs under an administrative rule ([Washington State Legislature 2006](#)). Washington has prepared an interim PFAS CAP and is planning to release recommendations to address PFAS contamination in 2019. The CAP, as developed so far, recommends setting state drinking water levels or advisory levels for PFAS, expanding water testing near potential sources of contamination, developing cleanup levels for PFAS, and evaluating and producing best practices for cleaning up soils, surface water, and groundwater. The CAP also recommends investigating other sources of PFAS by requiring manufacturers of products containing PFAS to provide information regarding safety of their products and performing assessment of alternatives to PFAS in AFFF, food contact paper, and textiles. More information on the Washington CAP process for PFAS is available from their web page ([Washington State Department of Ecology 2018](#)).

### 8.2.3.3 Designation of Hazardous Waste or Hazardous Substance

Regulations that target select PFAAs as hazardous wastes or hazardous substances have not been promulgated in most states. Formal PFAA regulations as hazardous substances have been promulgated in Vermont, New York, New Jersey, Colorado, and Alaska (ITRC State Survey 2018, unpublished), and are under development in several other states. Vermont regulates PFOA and PFOS as hazardous wastes when present in a liquid at a concentration  $\geq 20$  ppt, but allows exemptions for 1) consumer products that were treated with PFOA and are not specialty products; 2) remediation wastes managed under an approved CAP or disposal plan; and 3) sludge from wastewater treatment facilities, residuals from drinking water supplies, or leachate from landfills when managed under an approved plan ([VT DEC 2016b, a](#)).

In 2017, the New York State Department of Environmental Conservation (NYDEC) finalized regulations that identify PFOA (the acid) and its salt, ammonium perfluorooctanoate and PFOS (the acid) and its salt, perfluorooctane sulfonate, as hazardous substances that may be found in Class B firefighting foams ([NY DEC 2017a](#)). The regulations specify storage and registration requirements for Class B foams that contain at least 1% by volume of one or more of these four PFAS, and prohibit the release of 1 pound or more of each into the environment during use. If a release exceeds the 1-pound threshold, it is considered a hazardous waste spill and must be reported; cleanup may be required under the state's Superfund or brownfields programs ([NY DEC 2017a](#)).

### 8.2.3.4 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 [ITRC tables of PFAS water values, and PFAS soil values from state, federal, and some international countries](#) posted as an Excel file). Many states have either adopted the USEPA LHAs for PFOA and PFOS or selected the same health-based values, choosing to use the concentrations as advisory, nonregulated levels to guide the interpretation of PFOA and PFOS detections. As with any contaminant of potential concern at a remediation site, available toxicity values that meet USEPA policy requirements ([USEPA 1993](#), [2003a](#), [2013e](#)) can be used to derive screening levels for groundwater and soil. As of May 2018, the USEPA has not adopted the PFOA and PFOS toxicity values as "Tier 3" to officially derive an RSL; however, the necessary information is available within the online USEPA RSL calculator and screening levels for PFOA, PFOS, and PFBS are readily available ([USEPA 2017k](#)). [Section 9](#) provides more information on site-specific risk assessment for PFAS.

In addition to the process using the USEPA RSL calculator discussed above, some states have developed screening levels for PFOA and PFOS in soils assuming direct contact and/or ingestion. See [ITRC tables of PFAS water and soil values](#) and [USEPA \(2017l\)](#). At least a couple of states (for example, Alaska, Connecticut) have developed values for protection of groundwater (ITRC State Survey 2018, unpublished).

Some states, such as California and Minnesota, have "antidegradation" policies aimed at protecting the quality of groundwater and (in California) high quality (or Tier 2) surface waters. Those policies can be used in decisions on cleanup and discharge under permits. As an example, in California, the State Water Resources Control Board adopted Resolution 68-16 as its antidegradation policy. When evaluating the discharge or cleanup of chemicals, the Regional Water Quality Control Boards are required to initially set the effluent limitation or cleanup standard at the background concentration of each chemical. This is done regardless of whether there is a drinking water standard or other health-based value available. Final discharge or cleanup values consider potential health impacts, designated beneficial uses of the water body, and technical and economic feasibility in their development.

### 8.2.3.5 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 would be established in the same manner as other pollutants. Michigan is currently the only state with a PFAS discharge standard. The Michigan Department of Environmental Quality Rule 57 Water Quality Values can be found on their web page ([MI EGLE 2019](#)).

### 8.2.3.6 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. In the ITRC 2018 State Survey on PFAS, no state indicated that they had regulations on PFAS in biosolids application to land. However, Alaska, Delaware, Illinois, Michigan, Montana, New York, Vermont, and Wisconsin were in the process of considering and/or developing such regulations. In March 2019, Maine began requiring land applicators of biosolids to test for PFOA, PFOS, and PFBS before application, and prohibited application of biosolids if those PFAAs exceed specific levels (2.5 ppb for PFOA, 5.2 ppb for PFOS, and 1900 ppb for PFBS) ([ME DEP 2019](#)).



New Hampshire has an ambient air limit for ammonium perfluorooctanoate of 0.05 ug/m<sup>3</sup> (24-hour) ([NH DES 2016](#)).

On March 6, 2019 California's Water Resources Control Board held a public meeting where it unveiled its PFAS Investigation Plan ([CA Water Boards 2019](#)). That plan has been reassessed and there is now only a second phase with no timeline. One part of the reassessed plan has been completed which was issuing informational orders to plating shops. The next set of orders will be issued to wastewater treatment plants (to be completed spring 2020). After those orders are completed, informational orders will be issued for biosolids application areas and potentially bulk fuel/chemical facilities with AFFF capabilities. Sampling of domestic water supply wells in the vicinity of these sites is also planned. Results will be available on the [CA Water Boards \(2020\)](#) web page.

Finally, some states have issued state regulations or programs related to AFFF. For example, New York, Vermont, and Massachusetts have established AFFF take-back programs in an attempt to reduce the potential discharge of PFAS associated with AFFF into the environment. Other states (for example, New Hampshire) are in the process of developing an AFFF take-back programs. See [Section 3](#) for a more detailed discussion on AFFF and related regulations and guidance.

### 8.3 Differences in the Available Regulations, Advisories, and Guidance Regulatory

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, primarily nonpolymer long-chain PFAAs. There are a number of draft toxicity evaluations available for different PFAS. This is an area of active research. Additional information is presented in [Section 7.1](#) and [17.2](#).

As of September 2019, regulatory human health-based guidance values and/or standards have been derived for 16 PFAAs, two polyfluoroalkyl precursors, and one fluorinated ether carboxylate (FECA) by state and/or federal agencies in the United States. The values for these nonpolymeric PFAS 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, also differs. PFOA and PFOS have the vast majority of regulatory guidance and/or standards available, and the key differences in regulatory decisions within the United States for those chemicals can be seen in the ITRC tables posted as an Excel file of [the basis for PFOA and PFOS values](#). These same key decision points also underlie the differences that exist in the other perfluoroalkyl substance regulatory values, but are not documented in the tables. Some examples that describe differences in these toxicity values for PFAAs, including some of the bases of these values, their commonalities are the focus of the remainder of this section.

[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	<p>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. (<a href="#">ATSDR 2018d</a>)</p> <p>Importantly, the MRL is a daily dose, applicable for any oral exposure; it is not a threshold concentration in water or other environmental media.</p>	<p><a href="https://www.atsdr.cdc.gov/mrls/index.asp">https://www.atsdr.cdc.gov/mrls/index.asp</a></p>

Term	Acronym	Agency	Definition	Link
Regional Screening Level	RSL	USEPA Regions	<p>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 2019i)</p>	<p><a href="https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide#intro">https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide#intro</a></p>

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 2019b)	<a href="https://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information">https://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information</a>
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 2018h)	<a href="https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations">https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations</a>

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 PFAAs, and there are differences in the interpretation of relevant toxicological data for individual PFAAs.

Toxicological data from animal species are used as the basis for all of the U.S. PFAS human health toxicity factors and related standards or guidance. However, the European Food Safety Authority's PFOA and PFOS tolerable weekly inputs are based on human 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 (such as RfDs) from animal toxicology data. For PFOA and PFOS, different scientific and regulatory policy conclusions have been made for nearly each decision point by different agencies. Examples of some of the key differences will be discussed below. Agency support documents should always be consulted for more specific details. The ITRC tables of [PFAS water values, and PFAS soil values from state, federal, and some international countries](#) posted as an Excel file). and ITRC tables posted as an Excel file of [the basis for PFOA and PFOS values in the United States](#) should be reviewed for more current and detailed information.

### 8.3.1 Determination of Key Study and Critical Effect

To date, PFAAs and FECA regulations, standards, and guidance have largely been based on potential noncancer effects. RfDs are used by most U.S. agencies 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 2019d).

However, the USEPA, New Jersey Drinking Water Quality Institute (NJDWQI), and California OEHHA also considered potential cancer endpoints for PFOA and PFOS, and concluded that PFOA and PFOS are “suggestive” carcinogens and developed cancer toxicity values (cancer slope factor, CSF) for PFOA, while only OEHHA developed a CSF for PFOS. The threshold levels derived from RfDs by USEPA and NJDWQI are lower, that is, more protective, than those based on CSFs; thus, regulating or screening based on chronic noncancer risks was deemed to be protective of potential cancer risk by those entities. The methodology for deriving a 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, specific to PFOA and PFOS, below.

The first step in deriving a human health-based toxicity value (that is, RfD) 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 rodent bioassays. Older assessments relied upon primate studies due to concerns that rodent studies were not relevant to human health because of rodent-specific modes of action and toxicokinetics ([USEPA 2009c](#)), ([NCDENR 2012](#)) ([MDH 2008](#)). The more recent derivations of PFOA and PFOS toxicity values are based on rodent studies with lower effect levels (compared to primate studies), citing potential modes of action that are relevant to humans and improved toxicokinetic models to extrapolate between species. Some agencies, such as the USEPA and NJDWQI, selected only key studies with serum measurements of PFOA or PFOS, which enable the use of the more advanced toxicokinetic modeling in serum levels; rodent bioassays without serum measurements were used as supporting studies in weight-of-evidence evaluation and decision-making. In general, all U.S. agencies with RfDs for PFOA and PFOS agree that liver effects, developmental effects, and/or immune effects are the most sensitive and relevant endpoints. However, methodologies for selection of the key studies and critical effects, and quantification of the RfD itself, vary widely. Some examples are discussed below; however, the ITRC tables posted as an Excel file of [the basis for PFOA and PFOS values in the United States](#) should be consulted for more current and detailed information.

### 8.3.1.1 PFOA

USEPA identified a subset of animal studies for their PFOA toxicity value derivation based on sensitivity and human relevancy of the endpoint, exposure durations of greater than 7 weeks, multiple dose groups, use of a concurrent control, and studies that provided serum data amenable for modeling. Although this last requirement, studies with measured serum levels, excluded some studies, USEPA noted that the remaining studies encompassed the range of doses evaluated and the LOAELs observed in studies that lacked serum data. The resulting candidate studies included endpoints such as immune effects ([Dewitt et al. 2008](#)), developmental effects ([Lau et al. 2006](#)), increased liver weight and necrosis ([Perkins et al. 2004](#)), reduced pup weight ([Wolf et al. 2007](#)), reduced relative body weight (BW), and increased relative kidney weight ([Butenhoff et al. 2004](#)). The [Lau et al. \(2006\)](#) developmental study (LOAEL for reduced ossification in proximal phalanges and accelerated puberty in male mice) ultimately yielded the lowest RfD based on USEPA’s kinetic extrapolation, and was deemed to be protective of the other endpoints ([USEPA 2016h](#)). [USEPA \(2016h\)](#) reviewed the studies of mammary gland development in mice, but chose not to consider this endpoint as a potential critical effect due to unknown mode of action and unclear functional significance. Minnesota Department of Health [MDH \(2018b\)](#) selected [Lau et al. \(2006\)](#) for their key study and critical effect, but also identified other health effects (liver effects, immune system effects, kidney weight changes, and other development effects) as effects of concern.

Conversely, [NJDWQI \(2018a\)](#) determined that the developmental effects noted in [Lau et al. \(2006\)](#) were not permanent structural changes and had unknown long-term consequences and unclear functional significance. Additionally, they noted that there was not a typical dose-response relationship in these effects with increasing dose (the greatest effects for delayed ossification and accelerated puberty occurred at the lowest dose, with less of an effect at higher doses) ([NJDWQI 2017a](#)). NJDWQI selected increased liver weight in mice ([Loveless et al. 2006](#)) as their critical effect for PFOA’s RfD. Additionally, they applied an uncertainty factor to account for delayed mammary gland development, persistent liver toxicity, and other potential developmental effects that they concluded could occur at lower exposure levels ([NJDWQI 2017a](#)). NJDWQI determined that the delayed mammary gland developmental effect ([Macon et al. 2011](#)) was a more sensitive critical effect that was scientifically valid; however, its use as the basis for chemical risk assessment was unprecedented and therefore, ultimately not chosen. Texas Commission for Environmental Quality (TCEQ) selected the mammary gland developmental effects in mice ([Macon et al. 2011](#)) as their critical effect, stating that it was the most health protective ([TCEQ 2016](#)). TCEQ did not have a requirement that serum PFOA levels be measured in the key study and used administered dose as the dose metric.

Rather than selecting just one key study, Maine's CDC selected six PFOA animal bioassays across multiple species (rats and mice) with increased liver weight and hepatocyte enlargement ([Lau et al. 2006](#); [Perkins et al. 2004](#) (three studies with varying conditions; [Sibinski 1987](#); [Butenhoff, Kennedy, Frame, et al. 2004](#)). MDEP used the geometric mean of the benchmark dose limits from these six studies as their final point of departure ([Maine CDC 2014](#)).

### 8.3.1.2 PFOS

Similarly as for PFOA, USEPA identified a subset of animal studies for their PFOS toxicity value derivation based on sensitivity and human relevancy of the endpoint, exposure duration considerations, multiple dose groups, use of a concurrent control, and studies that provided serum data amenable for modeling. Using toxicokinetic models and dose-response modeling (both described below) of the selected studies and endpoints, USEPA concluded that the internal dose levels associated with developmental and liver endpoints were similar; endpoints considered as critical effects included offspring growth and survival, liver weight changes, liver histopathology, and changes in serum biochemistry indicative of systemic effects.

USEPA did not consider the monkey study from [Seacat et al. \(2002\)](#) appropriate because of the premature deaths of two of the six male monkeys at the LOAEL. However, this was the key study and critical effect from USEPA's provisional health advisory derived in ([USEPA 2009c](#)) and is the key study (critical effect of increased thyroid-stimulating hormone, reduced total T3, and reduced high-density lipoproteins) utilized by Maine Department of Environmental Protection (ME DEP) for their PFOS RfD and development of their Remedial Action Guideline ([ME DEP 2016](#)). In 2017, MDH selected the same key study and critical effect for PFOS as the USEPA but added a database uncertainty factor to the USEPA RfD for potentially more sensitive immune effects ([MDH 2017a](#)). In 2019, MDH selected a different key study in mice with immunotoxicity as the critical effect ([MDH 2019a](#)).

Regarding immune effects, USEPA concluded that there is a concern for PFOS-mediated immune effects, but determined that the available studies (including [Dong et al. \(2009\)](#)) were not amenable to use in RfD derivation. They state that both human dosing information and low-dose confirmation of immune effects in animals is lacking ([USEPA 2016g](#)). The USEPA derived an RfD for PFOS based on decreased neonatal rat BW from the two-generation study by [Luebker, York, et al. \(2005\)](#) because this key study and critical effect combination yielded the lowest RfD of the remaining studies ([USEPA 2016g](#)).

New Jersey derived their PFOS RfD based on the NOAEL for plaque-forming cell response in mice, an indication of immunosuppression ([Dong et al. 2009](#)), as the critical effect to determine their RfD. NJDWQI stated that this endpoint is more sensitive than the decreased neonatal BW from [Luebker, Case, et al. \(2005\)](#); [Luebker, York, et al. \(2005\)](#) and this immune effect is supported by other studies in mice and humans ([NJDWQI 2018b](#)). [NJDWQI \(2018a\)](#) discussed some concerns and issues related to USEPA's rationale and selection of the to [Luebker, York, et al. \(2005\)](#) endpoint.

Texas selected a study with hippocampus synapse structure effects ([Zeng et al. 2011](#)) as the critical effect to determine their RfD for PFOS. [TCEQ \(2016\)](#) stated that based on their calculations and examination of potential RfDs, use of [Seacat et al. \(2002\)](#) and protection against thyroid effects may not adequately protect against potential neurological developmental effects. Thus, [TCEQ \(2016\)](#) used [Zeng et al. \(2011\)](#), based on their toxicokinetic extrapolation methods (discussed below), for a lower and more health-protective RfD. [NJDWQI \(2018a\)](#) concluded that [Zeng et al. \(2011\)](#) provided only "mechanistic information" and did not include this study in their evaluation. USEPA discussed the results from [Zeng et al. \(2011\)](#) in their PFOS Health Effects Support Document; however, it is not clear why this study was not moved forward as a potential candidate for the PFOS RfD ([USEPA 2016g](#)).

### 8.3.2 Approaches Used for Animal-to-Human Extrapolation

Given that animal laboratory studies serve as the basis for human health risk assessments (HHRAs), derivation of human health toxicity values requires conversion of the dose administered to the test species to an appropriate human equivalent dose. In lieu of robust chemical-specific toxicokinetic and toxicodynamic information, the accepted default method to derive the human equivalent dose is by body-weight scaling to the 3/4 power (that is,  $BW^{3/4}$ ), which relies upon the known relationship between BW and the various metabolic and physiological functions of humans compared to rodents ([USEPA 2011b](#)). The use of  $BW^{3/4}$  scaling for deriving an RfD is recommended when the observed effects are associated with the parent compound or a stable metabolite in the absence of available chemical-specific toxicokinetic models ([USEPA 2011b](#)). When the necessary information is available, the preferred approach is to use chemical-specific physiologically based toxicokinetic modeling to convert toxicologically equivalent doses of orally administered agents from laboratory animals to humans. Another approach may include using chemical-specific toxicokinetic and toxicodynamic information to derive chemical-specific adjustments. For chemicals such as long-chain PFAAs that exhibit species-specific pharmacokinetic properties, chemical-specific adjustment using specific information about the species differences is most appropriate. The

type of chemical-specific pharmacokinetic information that is available dictates the complexity of the human equivalent dose extrapolation method, which may range from (1) using ratios of rodent to human clearance factors, to (2) using complex physiologically based pharmacokinetic models to extrapolate from administered (oral) dose to internal dose in the rodent, to internal dose in the human, and then to administered (oral) dose in the human.

Nonpolymeric long-chain perfluoroalkyl substances such as PFOA and PFOS exhibit marked differences in species-specific pharmacokinetics, mainly due to differences in elimination rates (because of higher renal reabsorption and serum protein binding in humans relative to rodents). To date, a wide range of technical approaches are employed to address these species-specific differences for PFOA and PFOS. Examples of some approaches are described here; however, the ITRC tables posted as an Excel file of [the basis for PFOA and PFOS values in the United States](#) should be consulted more current and detailed description of agency approaches.

The USEPA chose to rely on animal bioassays that collected internal serum measurements for PFOA and PFOS, then employ a pharmacokinetic model to estimate the animal's average serum concentrations for each study-specific exposure duration ([USEPA 2016c, d](#)). USEPA used the serum concentration at the NOAEL or LOAEL in the animal studies, rather than administered dose, for animal-to-human dose comparison. USEPA then used a first-order kinetic model for chemical clearance, using previously published single point estimates for elimination half-lives and volumes of distribution, to convert the serum concentration at the PFOA or PFOS NOAEL or LOAEL in the animal study to an external administered human (oral) dose that would result in the same serum concentration in humans.

NJDWQI's recommended MCL for PFOA and PFOS also relied upon studies that included serum measurements taken close to the end of the dosing period; NJDWQI conducted dose-response modeling and applied uncertainty factors to the internal serum levels measured at the end of the dosing period from the animal bioassays to derive a target human serum level. NJDWQI then calculated the RfD by applying the same PFOA clearance factors used by USEPA to convert the target human serum level to an administered dose in ug/kg-day.

Other agencies within the United States used different approaches for PFOA and/or PFOS. For example, Maine Department of Environmental Protection used all available animal studies (they did not limit their pool to only those studies with internal serum measurements) and used the ratio of clearance for the animal species over human clearance to convert the animal administered dose to a human equivalent dose. Agencies such as TCEQ used the ratio of elimination half-lives to convert the rodent administered dose directly to the human equivalent administered dose.

There are only a few toxicity values derived for short-chain PFAAs, and the methods to extrapolate from animal to human dose also vary and include either the use of BW scaling (allometric scaling of  $BW_{\text{animal}}^{1/4}$  divided by  $BW_{\text{human}}^{1/4}$ ) or the ratios of elimination half-lives. The [USEPA \(2014c\)](#) derived a subchronic and chronic toxicity value for PFBS, based on a subchronic rat study, and used body-weight scaling to derive the human equivalent dose. They stated that based on information available at the time of their derivation, including a lack of definitive information regarding pharmacokinetic differences between species, the use of BW scaling was most appropriate. [USEPA \(2018e\)](#) has a draft human health toxicity values report for PFBS.

More recently, the French National Agency for Food Safety, Environment, and Labor (ANSES) also used this same BW scaling approach when deriving their toxicity values for short-chain PFAAs such as PFBS, PFBA, and PFHxA ([ANSES 2017](#)). Use of the allometric BW scaling approach to calculate a human equivalent dose is the default approach for chemicals that do not exhibit species-specific adsorption, distribution, metabolism, or elimination processes, and absent chemical-specific information.

Chemical-specific support for the use of BW scaling to derive the human equivalent dose for some short-chain PFAAs has been demonstrated in recent studies. For example, [Russell, Nilsson, and Buck \(2013\)](#) and [Luz et al. 2019](#) found that elimination rates of PFHxA scale by BW, given that there are no known species-specific elimination mechanisms that dramatically alter elimination kinetics between species. Citing these reasons, the PFHxA toxicity value and related proposed drinking water standard derived by Michigan uses the allometric BW scaling due to this chemical-specific information. In contrast, the Minnesota Department of Health used the ratio of human to rodent half-lives to adjust the rodent-administered dose to a human equivalent dose for their derivation of PFBA and PFBS noncancer health risk limits ([MDH 2018a, 2017c](#)). MI also used the ratio of half-lives for PFBS to calculate the human equivalent dose for toxicity value derivation ([MI SAW 2019](#); [MI DHHS 2019](#)).

The estimation of an RfD includes two additional components that are shown in the ITRC tables posted as an Excel file of [the](#)

[basis for PFOA and PFOS values in the United States](#) and includes 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, as detailed in the tables. Uncertainty factors used include the standard risk assessment extrapolations as detailed in the tables, and also vary by agency.

### 8.3.3 Exposure Assumptions

For each of the exposure factors discussed in this section, See the ITRC tables posted as an Excel file of [the basis for PFOA and PFOS values in the United States](#) for the most current information and details.

#### 8.3.3.1 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-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 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) 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). 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.

USEPA combined their toxicity values with exposure parameters specific for lactating women. According to USEPA, this addressed the potential increased susceptibility during pregnancy and lactation. USEPA used the rate of 54 mL/kg-day based on the “consumers only” estimate of combined direct and indirect water ingestion at the 90th percentile for lactating women from their Exposure Factors Handbook (see table 3-81 in [USEPA \(2011a\)](#)).

Vermont used USEPA Office of Water toxicity values for PFOA and PFOS, but combined those toxicity values with exposure parameters specific for infants (0–1 year of age), assuming a drinking water intake rate of 0.175 L/kgBW-day ([Vermont DOH 2016](#)). Texas chose to combine their state-derived toxicity values with exposure parameters for children (ages 0–6 years); [TCEQ \(2016\)](#) used the default child BW of 15 kg and ingestion of 0.64 L-day, equivalent to 0.043 L/kg-day of water.

Minnesota is thus far unique in using specific exposure parameters based on exposure to breast-fed and formula-fed infants for the derivation of the PFOA and PFOS health-based guidance values. They selected the 95th percentile water intake rates or upper percentile breast milk intake rates ([USEPA 2011a](#)) and calculated breast milk concentrations by multiplying the maternal serum concentration by a calculated breast milk transfer factor of 5.2% for PFOA and 1.3% for PFOS ([MDH 2018b, 2019a](#)).

#### 8.3.3.2 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 most common route of exposure for the general public is via the diet, including water, and followed by indoor dust, especially for children. 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. 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. 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 the other pathways. Following USEPA’s exposure decision tree ([USEPA 2000c](#)), USEPA determined that significant potential sources other than drinking water ingestion exist; however, they concluded that information is not available to quantitatively characterize exposure from all of the different sources. Therefore, USEPA adopted a default RSC of 20% (0.20) for PFOA and PFOS drinking water health advisories.



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.

Some state agencies have incorporated RSC when deriving their state guidance/standards for long-chain PFAAs. For example, New Jersey Department of Environmental Protection adopted a 50% RSC for PFNA ([NJDWQI 2015](#)) and a 20% RSC for PFOA and PFOS ([NJDWQI 2017a](#), [2018a](#)), which they state also “implicitly accounts for greater exposures to breast-fed and formula-fed infants than older individuals.” Minnesota used an RSC of 50% based on their analysis of biomonitoring serum concentrations from local and national general populations ([MDH 2017b, a](#)).

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