# Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS)

## 1 Introduction

Per- and polyfluoroalkyl substances (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. The terms 'regulatory' or 'regulation' are used in this fact sheet 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 'advisories' apply to all other values.

ITRC has developed a series of six fact sheets to summarize the latest science and emerging technologies regarding PFAS. The purpose of this fact sheet is to:

- describe the primary state and U.S. federal programs that are being used to regulate PFAS
- summarize current regulatory and guidance values for PFAS in groundwater, drinking water, surface water/effluent, and soil (Tables 4-1 and 4-2)
- provide information (summarized in Tables 5-1 and 5-2) regarding the basis for differences between various drinking water criteria for perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS)

## 2 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. A recent analysis of data acquired under the USEPA's Unregulated Contaminant Monitoring Rule (UCMR) program found that approximately six million residents of the United States had drinking water with concentrations of perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS), or both, above the USEPA's Lifetime Health Advisory (LHA) of 70 nanograms per liter (ng/L, equivalent to parts per trillion [ppt]) (Hu et al. 2016). Many of the public water systems with detections of PFOA or PFOS above the USEPA LHA have taken action to reduce these levels. However, most public water systems that supply fewer than 10,000 customers and private wells were not included in the third round of monitoring, or UCMR3 program, and remain untested.

Human health protection is the primary focus of the PFAS regulations, guidance, and advisories developed to date. The 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 (see Table 5-1).

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 3M to achieve the company's voluntary phase-out and elimination of PFOS (USEPA 2000), and with the eight primary U.S. PFOA manufacturers to eliminate or reduce PFOA and many PFOA precursors by 2015 (USEPA 2017a). Buck et al. (2011) define precursors as PFAS polymers or other functional derivatives that contain a perfluoroalkyl group and "degrade in the environment to form PFOS, PFOA, and similar substances." Additionally, the Organisation for Economic Cooperation and Development OECD (2015a) has described various international policies, voluntary initiatives, biomonitoring, and environmental monitoring programs to control PFAS. More information is in the *History and Use Fact Sheet*.

## 3 Regulatory Programs

Authority for regulating PFAS 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, along with examples of representative state regulatory programs.

### 3.1 Federal PFAS Regulations

#### 3.1.1 Toxic Substances Control Act (TSCA)

The TSCA authorizes the USEPA to require reporting, record-keeping, and testing of chemicals and chemical mixtures that may pose a risk to human health or the environment. Section 5 of TSCA allows the USEPA to issue Significant New Use Rules (SNURs) to limit the use of a chemical when it is newly identified, or a significant new use of an existing chemical is identified, before it is allowed into the marketplace (USEPA 2017a). The USEPA has applied a SNUR to PFOS in four separate actions and to 277 chemically-related PFAS (USEPA 2017i). Collectively, these SNURs placed significant restrictions on the use and import of PFAS, allowing only limited uses in select industries and for certain applications. In

addition, one of the rules required companies to report all new uses in the manufacture, import, or processing of certain PFOA-related chemicals for use in carpets or for aftermarket treatment. A recently proposed SNUR (USEPA 2015c) would designate the manufacture, import, and processing of certain PFOA and PFOA-related chemicals (long-chain perfluoroalkyl carboxylates [PFCAs]) as a significant new use. The significant new use would apply to any use that is not ongoing after December 31, 2015, and for all other long-chain PFCAs for which there is currently no ongoing use (USEPA 2015a).

### 3.1.2 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 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 MCLs for any PFAS. However, in May 2016, USEPA established an LHA for PFOA and PFOS in drinking water of 70 ng/L. This LHA is applicable to PFOA and PFOS individually, or in combination, if both chemicals are present at concentrations above the reporting limit (USEPA 2016b, c). 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), which were intended for use as interim guidelines while USEPA developed the LHA. 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 2016b, c).

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

- 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 public water systems (PWS) serving more than 10,000 people, and a limited number of smaller systems determined by USEPA to be nationally representative. Some of the six PFAS mentioned above were detected in 194 out of 4,920 PWS tested (~4%), which serve about 16.5 million people in 36 states and territories (Hu et al. 2016). However, Hu et al. (2016) note that the UCMR3 data may under-report the actual presence of low-level PFAS due to the relatively high reporting limits for EPA method 537. Under-reporting is not expected to have affected the number of exceedances of the USEPA LHA, which are shown in Table 3-1.

**Table 3-1. UCMR3 occurrence data**

| Exceed LHA (70 ppt) | Number of PWS | Percent of PWS |
|---|---|---|
| **PFOS** | 46 | 0.9 % |
| **PFOA** | 13 | 0.3 % |
| **∑ PFOA + PFOS**[1] | 63 | 1.3 % |
| Note 1: PWS that exceeded the combined PFOA and PFOS health advisory (USEPA 2016d; 2017o) | | |

Many of the public water systems where PFOA or PFOS were detected in UCMR3 above the USEPA LHA have taken action to reduce these levels. Occurrence data produced by the UCMR program are used by the USEPA, as well as some states, to help determine which substances to consider for regulation. 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 2017f).

When the USEPA determines there may be an imminent and substantial endangerment from a contaminant that is present in or likely to enter a public water supply, under Section 1431 of the SDWA USEPA 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 at least three such EAOs to protect public and private water supply wells contaminated with PFAS (USEPA 2009d; 2014b; 2015a).

### 3.1.3 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

PFAS, including PFOA and PFOS, are not listed as CERCLA hazardous substances but may be addressed as CERCLA pollutants or contaminants (40 CFR 300.5). CERCLA investigations are beginning to include PFAS when supported by the conceptual site models (for example, USEPA 2017c). PFAS have been reported for 14 CERCLA sites during 5-year reviews (USEPA 2014a).

CERCLA does not contain any chemical-specific cleanup standards. However, the CERCLA statute requires, among other things, that Superfund response actions ensure protectiveness of human health and the environment, and comply with federal 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 1997).

#### *3.1.3.1 CERCLA Protection of Human Health*

The tables in Section 4 include current state regulatory and guidance values for PFAS. These values are not automatically recognized as ARARs. 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 (40 CFR 300.5; 40 CFR 300.400(g); USEPA 1988; USEPA, 1991).

Risk-based cleanup goals are calculated when chemical-specific ARARs are not available or are determined not to be protective (USEPA 1997). The USEPA's Regional Screening Level (RSLs) Generic Tables (USEPA 2017m) and the RSL online calculator (USEPA 2017l) provide screening levels and preliminary remedial goals. These goals are based on toxicity value calculations that have been selected in accordance with the USEPA's published hierarchy (USEPA 2003a). Currently, PFBS is the only PFAS listed in the RSL generic tables. For PFBS, the generic tables provide a non-cancer reference dose, screening levels for soil and tap water, and soil screening levels for the protection of groundwater. The RSL calculator supports site-specific calculations for PFBS, PFOA, and PFOS in tap water and soil. Non-cancer reference doses are provided for PFOA and PFOS. A cancer ingestion slope factor is also provided for PFOA, but screening levels are based on the non-cancer endpoint. Although less frequently used, 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 2016a).

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 are not cleanup standards (USEPA 2016g) and suggests that final remedial goals be derived using the RSL calculator so that site-specific information can be incorporated.

#### *3.1.3.2 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 on the identification of the protected ecological receptors.

### 3.1.4 Other Federal Programs

PFAS are not currently regulated under the Resource Conservation and Recovery Act (RCRA), the Clean Water Act (CWA), nor the Clean Air Act (CAA).

## 3.2 State PFAS Regulations

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 are discussed in Section 4 and presented in Tables 4-1 and 4-2. At the present time, no state requires monitoring of public water supplies for PFAS. The Texas Risk Reduction Program (TRRP) has derived risk-based inhalation exposure limits (RBELs) for select PFAS. These RBELs are applicable to PFAS that may volatilize from soil to air at remediation sites managed under the TRRP rule (Texas Commission on Environmental Quality [TCEQ], 2017).

### 3.2.1 Product Labeling and Consumer Products Laws

PFOS, PFOA, and their salts are under consideration for 'Listing' as potential Developmental Toxicants under California's Proposition 65 (Office of Environmental Health Hazard Assessment [CA OEHHA] 2016). If finalized, the listing will include labeling requirements for manufacturers, distributors, and retailers, and will prohibit companies from discharging these PFAS to sources of drinking water. Washington has required the reporting of PFOS in children's products since 2011 (Washington State 2008). Proposed rules would require reporting of PFOA in children's products starting in January 2019. Washington also tests products for chemicals to ensure manufacturers are reporting accurate information.

### 3.2.2 Chemical Action Plans

Washington prepares chemical action plans (CAPs) under an administrative rule that addresses persistent, bioaccumulative, and toxic (PBT) chemicals (Washington State 2006). These CAPs are used to identify, characterize, and evaluate uses and releases of specific PBTs or metals. Washington is currently preparing a PFAS CAP that is expected to be completed in 2018.

### 3.2.3 Designation as Hazardous Waste or Hazardous Substance

Regulations that target select PFAS as hazardous wastes or hazardous substances have been promulgated in Vermont and New York, and are under development in several other states. Vermont regulates PFOA and PFOS as hazardous wastes when present in a liquid at a concentration > 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 (VTDEC 2016).

In 2017, the New York State Department of Environmental Conservation (NYDEC) finalized regulations that identify PFOA, ammonium perfluorooctanoate, PFOS (the acid) and its salt, perfluorooctane sulfonate, as hazardous substances that may be found in Class B firefighting foams (NYDEC 2017). 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 one pound or more of each into the environment during use. If a release exceeds the one-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 (NYDEC 2017).

### 3.2.4 Drinking Water, Groundwater, Surface Water, Soil, and Remediation Programs

Several states have developed standards and guidance values for PFAS in drinking water and groundwater (see Section 4 tables). 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, non-regulated levels to guide the interpretation of PFOA and PFOS detections. Other states, such as Vermont, Minnesota, and New Jersey, have developed health-based values based on their own analysis of the scientific data. Michigan is currently the only state that regulates certain PFAS in surface water, although Minnesota has established enforceable discharge limits for specific waterbodies. New Jersey has adopted an Interim Ground Water Quality Standard for PFNA, and its drinking water advisory body has recommended proposed MCLs for PFOA and PFNA. While several states have adopted enforceable groundwater standards for PFOA and PFOS, no state other than New Jersey currently has MCLs (or proposed MCLs) for PFAS.

In California, when evaluating the discharge or cleanup of chemicals, the Regional Water Quality Control Boards (RWQCBs) 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. For anthropogenic chemicals such as PFAS, the initial value is the analytical detection limit in water. Technical, economic, and health-based criteria are also considered (for example, CA RWQCB 2016).

Various states address the remediation of PFAS in groundwater and soil; guidance and advisory values may be used by state remediation programs to determine site-specific cleanup requirements (see Section 4 tables). Texas has developed toxicity criteria for 16 PFAS under the TRRP (TCEQ, 2017). These criteria are used to calculate risk-based soil and groundwater values and can also be used for other media such as sediment and fish tissue.

## 4 Available Regulations, Advisories, and Guidance

Regulatory, advisory, and guidance values have been established for PFOS, PFOA, and several other PFAS in environmental media as well as various terrestrial biota, fish, and finished products. Tables 4-1 and 4-2, provided as a separate Excel file, are intended to identify currently available U.S. and international standards and guidelines for groundwater, drinking water, surface water, and effluent or wastewater (Table 4-1), and soil (Table 4-2). The available standards list is changing rapidly. These tables are published separately so they can be updated periodically by ITRC. The fact sheet user should visit the ITRC web site (www.itrcweb.org) to access current versions of the tables.

Table 4-1 presents the available PFAS water values established by the USEPA, each pertinent state, or country (Australia, Canada and Western European countries). The specific agency or department is listed with the year it was published, the media type (groundwater, drinking water, surface water, or effluent), and whether it was published as guidance or as a promulgated rule.

Table 4-2 presents the available PFAS soil values established by the USEPA, each pertinent state, or country (Australia, Canada and Western European countries). Soil screening levels for both groundwater protection and human health are presented. The specific agency or department is listed with the year the value was published.

## 5 Basis of Standards and Guidance

Drinking contaminated water is a potential source of human exposure (see reviews in Lindstrom et al. 2011; NJ DWQI 2017a). As noted above, UCMR3 sampling detected PFOA or PFOS concentrations above the EPA Lifetime HA of 70 ng/L in the source water for municipal systems that supply approximately 6 million U.S. residents (Hu et al 2016). Although there are other potential sources that may lead to PFAS exposures (for example, consumer products), protection of the potable water supply is the primary driver behind most of the available state and federal regulations and guidance, due to the potential for exposure and the known or presumed toxicity of these compounds.

While numerous animal and human studies have evaluated both non-cancer and cancer health effects related to exposure to a limited number of PFAS, including PFOA and PFOS, little to no health-effects data are available for many PFAS. As a result, many of the available standards and guidance are for PFOA and PFOS. In animal studies, PFOA exposure has been associated with adverse effects on the developmental, reproductive, and immune systems and the liver (see summary of original research in USEPA 2016f). There is also evidence of both PFOA and PFOS affecting immune systems, including reduced disease resistance (National Toxicology Program [NTP] 2016) and tumors in rats (USEPA 2016e, f). These and other effects have also been found in human epidemiological studies (ATSDR 2016; C8SP 2017; USEPA 2016e, f; NTP 2016). The International Agency for Research on Cancer (IARC) concluded that PFOA is "possibly carcinogenic to humans (Group 2B)" (IARC 2016), and USEPA concluded that there is suggestive evidence of carcinogenic potential for both PFOA and PFOS in humans (USEPA 2016e, f).

Tables 5-1 and 5-2, provided as a separate Excel file, summarize the differences in the PFOA (Table 5-1) and PFOS (Table 5-2) values for drinking water in the United States, demonstrating that they are attributable to differences in the selection and interpretation of key toxicity data, choice of uncertainty factors, and the approach used for animal-to-human extrapolation. Differences in values are also due to the choice of exposure assumptions, including the life stage used, and the percentage of exposure assumed to come from non-drinking water sources. Only those agencies that have used science or policy decisions that are different from those of the USEPA LHAs are shown. The available information is increasing rapidly and these tables will be updated periodically by ITRC. The fact sheet user should visit the ITRC web site (www.itrcweb.org) to access the current version of the tables.

Some states have not yet developed values or adopted the USEPA LHA. It may be appropriate to consult with the lead regulatory authority (local or federal) to determine the appropriate values to use for site evaluation.

## 6 References and Acronyms

The references cited in this fact sheet, and the other ITRC PFAS fact sheets, are included in one combined list that is available on the ITRC web site. The combined acronyms list is also available on the ITRC web site.

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