PLEASE NOTE: EPA is committed to advancing science to protect public health from the risks of exposure to certain PFAS, and to provide essential health protective information to regulators and the public. That is why EPA published interim Health Advisories for PFOA and PFOS in June 2022, based on a robust assessment of the best available science at that time. On March 14, 2023, EPA released a proposed national primary drinking water regulation (NPDWR) for PFOA and PFOS, as well as for four additional PFAS and their mixtures. This rule has considered additional updates to the science and is responsive to peer review feedback provided by EPA's Science Advisory Board.

In the proposed rule, EPA presents updated noncancer toxicity values based on evaluating additional scientific information. These updated values are different from those used to calculate the 2022 interim HAs, which EPA based on the best available science at that time. EPA is accepting public comments on its proposed NPDWR, including on the proposed maximum contaminant level goals (MCLGs), other supporting information, and the draft 2023 toxicity values for PFOA and PFOS which are based on the best available science. Note that the MCLGs in the proposed rule are zero.

The 2022 interim Health Advisories for PFOA and PFOS will continue to remain available as EPA finalizes a national primary drinking water regulation for those contaminants.

United States
Environmental Protection
Agency

Office of Water
OST
EPA
PUBLICATION #
EPA/822/R-22/004

INTERIM
Drinking Water Health Advisory: Perfluorooctane Sulfonic Acid (PFOS)
CASRN 1763-23-1

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Prepared by:

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EPA Document Number: EPA/822/R-22/004

June 2022

Acknowledgments

This document was prepared by the Health and Ecological Criteria Division (HECD), Office of Science and Technology (OST), Office of Water (OW) of the U.S. Environmental Protection Agency (EPA).

The OW scientists and managers who provided valuable contributions and direction in the development of this health assessment are, from OST: Carlye Austin, PhD (lead); Czarina Cooper, MPH; Susan Euling, PhD; Colleen Flaherty, MS; Brittany Jacobs, PhD; Casey Lindberg, PhD; and from the Office of Ground Water and Drinking Water (OGWDW): Ryan Albert, PhD; Stanley Gorzelnik, PE; Ashley Greene, MS; and Daniel P. Hautman.

The document underwent a technical edit by the contractor Tetra Tech (contract number 68HERC20D0016).

This Health Advisory document was provided for review by staff in the following EPA program Offices:

- Office of Water
- Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics
- Office of Land and Emergency Management
- Office of Policy
- Office of Children's Health Protection
- Office of Research and Development

Contents

Abbreviations and Acronyms iii

1.0 Introduction: Background and Scope of Interim Health Advisory 1
- 1.1 PFOS General Information and Uses 2
- 1.2 Occurrence in Water and Exposure to Humans 3
  - 1.2.1 Occurrence in Water 3
  - 1.2.2 Exposure in Humans 4
- 1.3 Source of Toxicity Information for Interim Health Advisory Development 4
- 1.4 Exposure Factor Information 5
- 1.5 Approach for Lifetime Health Advisory Calculation 6

2.0 Interim Health Advisory Derivation: PFOS 6
- 2.1 Toxicity 7
- 2.2 Exposure Factors 9
- 2.3 Relative Source Contribution 10
- 2.4 Derivation of Health Advisory Value: Interim Lifetime Noncancer HA 11

3.0 Analytical Methods 11

4.0 Treatment Technologies 12
- 4.1 Sorption Technologies 13
  - 4.1.1 Activated Carbon 14
  - 4.1.2 Ion Exchange 15
- 4.2 High-Pressure Membranes 16
- 4.3 Point-of-Use Devices for Individual Household PFOS Removal 17
- 4.4 Treatment Technologies Summary 17

5.0 Consideration of Noncancer Health Risks from PFAS Mixtures 17

6.0 Interim Health Advisory Characterization 19

7.0 References 20

Tables

Table 1. Draft Chronic RfD, Critical Effect, and Critical Study Used to Develop the Lifetime iHA for PFOS 8

Table 2. EPA Exposure Factors for Drinking Water Intake for Candidate Sensitive Populations Based on the Critical Effect and Study. 10

Abbreviations and Acronyms

AIX	anion exchange
ANSI	American National Standards Institute
AWWA	American Water Works Association
BMD	benchmark dose
BMDL	benchmark dose lower confidence limit
Br-DBP	brominated disinfection byproduct
bw or BW	body weight
CASRN	Chemical Abstracts Service Registry Number
CCL	Contaminant Candidate List
CDC	Centers for Disease Control and Prevention
CDR	Chemical Data Reporting
CI	confidence interval
CSF	cancer slope factor
DBP	disinfection byproduct
DOM	dissolved organic matter
DQO	data quality objective
DWI	drinking water intake
DWI-BW	body weight-adjusted drinking water intake
E	human exposure
EBCT	empty bed contact time
EF	exposure factor
EFH	Exposure Factors Handbook
EPA	U.S. Environmental Protection Agency
Eq.	equation
FCID	Food Commodity Intake Database
GAC	granular activated carbon
HA	Health Advisory
HECD	Health and Ecological Criteria Division
HESD	Health Effects Support Document
HI	hazard index
HQ	hazard quotient
iHA	interim Health Advisory
i	mixture component chemical
IRIS	Integrated Risk Information System
$L/(m^2 \cdot hr)$	liters per square meter per hour
lbs	pounds
LC/MS/MS	liquid chromatography/ tandem mass spectrometry
LOAEL	lowest-observed-adverse-effect level
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg/kg bw-day	milligrams per kilogram body weight per day
mg/L	milligrams per liter
m/hr	meters per hour
MPa	megapascal
MRL	minimum reporting level
NF	nanofiltration

ng/L	nanograms per liter
NHANES	National Health and Nutrition Examination Survey
NOAEL	no-observed-adverse-effect level
NOM	natural organic matter
NPDWR	National Primary Drinking Water Regulation
OGWDW	Office of Ground Water and Drinking Water
ORD	Office of Research and Development
OST	Office of Science and Technology
OW	Office of Water
PAC	powdered activated carbon
PBPK	physiologically-based pharmacokinetic
PFAS	per- and polyfluoroalkyl substances
PFBS	perfluorobutane sulfonic acid
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonic acid
pK_a	acid dissociation constant
POD	point of departure
POD_{HED}	point of departure human equivalent dose
ppq	parts per quadrillion
ppt	parts per trillion
PWS	public water system
QC	quality control

RfD	reference dose
RfV	reference value
RO	reverse osmosis
RPF	relative potency factor
RSC	relative source contribution
SAB	Science Advisory Board
SAB PFAS Panel	Science Advisory Board Per- and Polyfluoroalkyl Substances Review Panel
SDWA	Safe Drinking Water Act
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act
UCMR	Unregulated Contaminant Monitoring Rule
UF	uncertainty factor
UF_A	interspecies uncertainty factor
UF_C	composite uncertainty factor
UF_D	database uncertainty factor
UF_H	intraspecies uncertainty factor
UF_L	lowest-observed-adverse-effect level-to-no-observed-adverse-effect level extrapolation uncertainty factor
UF_S	subchronic-to-chronic exposure duration extrapolation uncertainty factor
µg/L	micrograms per liter

1.0 Introduction: Background and Scope of Interim Health Advisory

The Safe Drinking Water Act (SDWA) (42 U.S.C. § § 300f - 300j-27) authorizes the U.S. Environmental Protection Agency (EPA) to develop drinking water Health Advisories (HAs).[1] HAs are national non-enforceable, non-regulatory drinking water concentration levels of a specific contaminant at or below which exposure for a specific duration is not anticipated to lead to adverse human health effects.[2] HAs are intended to provide information that tribal, state, and local government officials and managers of public water systems (PWSs) can use to determine whether actions are needed to address the presence of a contaminant in drinking water. HA documents reflect the best available science and include HA values as well as information on health effects, analytical methodologies for measuring contaminant levels, and treatment technologies for removing contaminants from drinking water. EPA's lifetime HAs identify levels to protect all Americans, including sensitive populations and life stages, from adverse health effects resulting from exposure throughout their lives to contaminants in drinking water.

Interim or provisional HA values can be developed to provide information in response to an urgent or rapidly developing situation. EPA has developed an interim lifetime noncancer HA (iHA) for perfluorooctane sulfonic acid (PFOS) to replace the 2016 lifetime HA of 0.07 micrograms per liter (µg/L) (70 parts per trillion [ppt]) because analyses of more recent health effects studies show that PFOS can impact human health at exposure levels much lower than reflected by the 2016 PFOS lifetime HA. EPA has developed an interim rather than a final HA for PFOS because the input values used to derive the iHA are currently draft values and EPA has identified a pressing need to provide information to public health officials prior to their finalization.

In 2009, EPA developed a provisional HA for PFOS (U.S. EPA, 2009a) based on the best information available at that time. Also, PFOS was included on the third and fourth drinking water Contaminant Candidate Lists (CCLs)[3] (U.S. EPA, 2009b, 2016a). After PFOS was listed on the third CCL in 2009, EPA initiated development of a Health Effects Support Document (HESD) for PFOS to assist officials and PWS managers in protecting public health when PFOS is present in drinking water. The HESD was published in 2016 after peer review (U.S. EPA, 2016b). EPA developed a final HA for PFOS (U.S. EPA, 2016c) based on data and analyses in the 2016 HESD and agency guidance on exposure and risk assessment.

In March 2021, EPA published a final determination to regulate PFOS with a National Primary Drinking Water Regulation (NPDWR) under SDWA (U.S. EPA, 2021a). NPDWRs include legally-enforceable Maximum Contaminant Levels (MCLs) and/or treatment technique requirements that apply to PWSs. To support the development of the NPDWR, EPA developed

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[1] SDWA § 1412(b)(1)(F) authorizes EPA to "publish health advisories (which are not regulations) or take other appropriate actions for contaminants not subject to any national primary drinking water regulation." www.epa.gov/sites/default/files/2020-05/documents/safe_drinking_water_act-title_xiv_of_public_health_service_act.pdf

[2] This document is not a regulation and does not impose legally binding requirements on EPA, states, tribes, or the regulated community. This document is not enforceable against any person and does not have the force and effect of law. No part of this document, nor the document as a whole, constitutes final agency action that affects the rights and obligations of any person. EPA may change any aspects of this document in the future.

[3] The CCL is a list (published every five years) of contaminants that are not currently subject to any National Primary Drinking Water Regulation (NPDWR) but are known or anticipated to occur in PWSs and may require future regulation under SDWA.

the *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water* (U.S. EPA, 2021b) (hereafter referred to as "draft PFOS document") which includes an updated health effects assessment of the peer-reviewed literature, draft chronic reference dose (RfD), and draft relative source contribution (RSC) value. The development of the draft noncancer chronic RfD for PFOS was performed by a cross-agency per- and polyfluoroalkyl substances (PFAS) Science Working Group to support the PFAS NPDWR. In November 2021, EPA announced the Science Advisory Board (SAB) PFAS Review Panel's (SAB PFAS Panel's) review (U.S. EPA, 2021c) of the draft PFOS document along with three other draft documents supporting the NPDWR (U.S. EPA, 2022a).

The 2021 data and analyses described in the draft PFOS document indicate that PFOS exposure levels at which adverse health effects have been observed are much lower than previously understood when EPA issued an HA for PFOS in 2016. As a result, EPA announced in 2021[4] that it would move quickly to update the 2016 HA for PFOS to reflect the latest, best available science as well as input from the SAB PFAS Panel. An updated PFOS HA is consistent with EPA's commitments for action on PFAS described in EPA's PFAS Strategic Roadmap (U.S. EPA, 2021d).

In April 2022, the SAB PFAS Panel made public a draft report of its review of the draft PFOS document (U.S. EPA, 2022a), which indicated general support for the draft conclusions but recommended additional analyses be performed prior to finalizing the RfD and RSC. Because the RfD in the draft PFOS document is much lower than the RfD used to derive the 2016 HA, there is a pressing need to provide updated information on the current best available science to public health officials prior to finalization of the health effects assessment. Therefore, EPA has decided to issue an iHA using the draft chronic RfD and RSC values. An updated 10^{-6} cancer risk concentration was not derived in this iHA document because the draft PFOS document concluded that, based on EPA guidelines (U.S. EPA, 2005a), the available human and animal studies provide *suggestive evidence of carcinogenic potential* (U.S. EPA, 2021b). Given the identified uncertainties in the available evidence (see Section 2.0 for further information), the draft PFOS document concluded that these data did not support a quantitative characterization of cancer risk associated with PFOS exposure.

After receiving SAB's final report, EPA will fully address SAB feedback and recommendations, which could lead EPA to draw different conclusions than are reflected in the draft PFOS document and this iHA document. EPA anticipates proposing a NPDWR in fall 2022 and finalizing the NPDWR in fall 2023. EPA may update or remove the iHA for PFOS upon finalization of the NPDWR.

1.1 PFOS General Information and Uses

PFOS is a synthetic fluorinated organic chemical that has been manufactured and used in a variety of industries since the 1940s (U.S. EPA, 2018). It repels water and oil, is chemically and thermally stable, and exhibits surfactant properties. Based on these properties, it has been used in the manufacture of many materials, including cosmetics, paints, polishes, and nonstick coatings on fabrics, paper, and cookware. It is very persistent in the human body and the environment (Calafat

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[4] *EPA Advances Science to Protect the Public from PFOA and PFOS in Drinking Water* [Press release], Nov 16, 2021: https://www.epa.gov/newsreleases/epa-advances-science-protect-public-pfoa-and-pfos-drinking-water

et al., 2007, 2019). More information about PFOS's uses and properties can be found in the 2016 HA document for PFOS (U.S. EPA, 2016c) and the draft PFOS document (U.S. EPA, 2021b).

In 2000, the principal manufacturer of PFOS agreed to a voluntary phase-out of PFOS production and use. This phase-out was completed in 2002 (U.S. EPA, 2007). PFOS is included in EPA's Toxic Substances Control Act (TSCA) Significant New Use Rule (SNUR) issued in December 2002, which ensures that EPA will have an opportunity to review any efforts to reintroduce PFOS into the marketplace and take action, as necessary, to address potential concerns (U.S. EPA, 2002a). Limited existing uses of PFOS-related chemicals, including as an anti-erosion additive in fire-resistant aviation hydraulic fluids and as a component of anti-reflective coating in the production of semiconductors, were excluded from the regulation (U.S. EPA, 2013). PFOS was not reported as manufactured (or imported) in the United States as part of the 2006, 2012, or 2016 TSCA Chemical Data Reporting (CDR) effort, which requires reporting if a certain production volume threshold is met at any single site (the threshold for PFOS was 25,000 pounds [lbs] in 2006 and 2012, and 2,500 lbs in 2016).[5] PFOS manufacture or importation has not been reported to EPA as part of this collection effort since 2002.

1.2 Occurrence in Water and Exposure to Humans

1.2.1 Occurrence in Water

EPA requires sampling at drinking water systems under the Unregulated Contaminant Monitoring Rule (UCMR) to collect data for contaminants that are known or suspected to be found in drinking water and do not have health-based standards under SDWA. A new UCMR is issued every five years. The first four UCMRs required monitoring of all large public drinking water systems (> 10,000 people) and a subset of smaller systems serving < 10,000 people. The third UCMR (UCMR 3), conducted from 2013–2015, is currently the best available source of national occurrence data for PFOS in drinking water (U.S. EPA, 2017a, 2021a,b,e). A total of 292 samples from 95 PWSs (out of 36,972 total samples from 4,920 PWSs) had detections of PFOS (i.e., greater than or equal to the minimum reporting level [MRL][6] of 0.04 µg/L). PFOS concentrations for these detections ranged from 0.04 µg/L (the MRL) to 7 µg/L (median concentration of 0.06 µg/L; 90th percentile concentration of 0.25 µg/L).

In 2016, EPA recommended that when PFOS and perfluorooctanoic acid (PFOA) co-occur at the same time and location in drinking water sources, a conservative and health-protective approach is to consider the sum of the concentrations. An analysis of the UCMR 3 data showed that 508 samples from 162 PWSs (out of 36,971 samples from 4,920 PWSs) had detections of PFOA and/or PFOS (i.e., at or above the MRL of 0.02 µg/L for PFOA or 0.04 µg/L for PFOS). The sum of reported PFOA and/or PFOS concentrations ranged from 0.02 to 7.22 µg/L. Although it is not possible to determine the full extent of PFOS and/or PFOA occurrence based on UCMR 3 detections, sites where elevated levels of PFOS and/or PFOA were detected during UCMR 3 monitoring may have taken steps to mitigate exposure including installing treatment systems

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[5] The TSCA CDR requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals if they meet certain production volume thresholds. For more information, see www.epa.gov/chemical-data-reporting.

[6] The MRL refers to the quantitation level selected by EPA to ensure reliable and consistent results. It is the minimum quantitation level that can be achieved with 95 percent confidence by capable analysts at 75 percent or more of the laboratories using a specified analytical method (U.S. EPA, 2021f).

and/or blending water from multiple sources, or remediating known sources of contamination (U.S. EPA, 2021a).

The fifth UCMR (UCMR 5) will require monitoring for 29 PFAS, including PFOS, using EPA methods 533 (U.S. EPA, 2019a) and 537.1 (U.S. EPA, 2020). UCMR 5 monitoring will take place from 2023–2025 and will include all large public drinking water systems serving > 10,000 people, all systems serving 3,300–10,000 people (subject to the availability of appropriations), and a subset of smaller systems serving < 3,300 people (U.S. EPA, 2021f). EPA established an MRL for PFOS of 0.004 µg/L under UCMR 5, which is 10-fold lower than the MRL used in UCMR 3.

Some states have conducted monitoring for PFOS in drinking water (by selecting sampling locations randomly, and/or sampling from targeted locations). PFOS has been detected in the finished drinking water of at least 19 states (ADEM, 2021; AZDEQ, 2021; CADDW, 2021; CDPHE, 2020; GAEPD, 2021; ILEPA, 2021; KYDEP, 2019; MAEEA, 2021; MDE, 2021; MEDEP, 2020; MI EGLE, 2021; NCDEQ, 2021; NHDES, 2021; NJDEP, 2021; OHDOH, 2020; PADEP, 2021; RIDOH, 2020; SCDHEC, 2020; VTDEC, 2021).

1.2.2 Exposure in Humans

As noted in the draft PFOS document (U.S. EPA, 2021b), the Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES) has measured blood serum concentrations of several PFAS in the general U.S. population since 1999. PFOS has been detected in up to 98% of serum samples collected in biomonitoring studies that are representative of the U.S. general population; however, blood levels of PFOS declined by more than 80% between 1999 and 2014, presumably due to restrictions on PFOS commercial usage in the United States (CDC, 2017). NHANES biomonitoring data from 1999–2000 reveal a mean serum PFOS concentration of 30.4 µg/L (95% confidence interval [CI] of 27.1–33.9 µg/L) and a 90th percentile serum PFOS concentration of 57 µg/L (95% CI 50.2–71.7 µg/L) across 1,562 samples representative of the U.S. population. For 2013–2014, mean and 90th percentile serum PFOS concentrations were 4.99 µg/L (95% CI 4.5–5.52 µg/L) and 13.9 µg/L (95% CI 11.9–15.5 µg/L), respectively (2,165 samples) (CDC, 2021). In 2017–2018, the mean serum PFOS concentration was 4.25 µg/L (95% CI 3.90–4.62 µg/L) and the 90th percentile serum PFOS concentration was 11.5 µg/L (95% CI 10.0–13.1 µg/L) across 1,929 samples (CDC, 2021). For additional information about PFOS exposure in humans, see sections 3.3 and 5.0 of U.S. EPA (2021b).

1.3 Source of Toxicity Information for Interim Health Advisory Development

The lifetime noncancer iHA for PFOS is derived from draft values (i.e., chronic RfD and RSC) and relies on the best available science as derived in the draft PFOS document (U.S. EPA, 2021b), which is currently undergoing peer review by the SAB PFAS Panel. To develop the updated toxicity information in the draft PFOS document, a systematic review and evidence-mapping approach was utilized to identify, screen, and evaluate health effects data for PFOS. A literature search was performed to identify studies on the health effects of PFOS exposure in animals and humans published since the 2016 HESD and HA for PFOS. The search results were screened for relevancy, and literature identified as relevant underwent study quality evaluation and data extraction (please see U.S. EPA [2021b] for more details). Evidence for each health outcome was analyzed and synthesized, and overall judgments about the strength of the evidence were developed. The best available health effects information identified and analyzed using systematic review was then used in the derivation of the chronic RfD. This systematic review process has been peer reviewed and is used by EPA's Office of Research and Development (ORD) Integrated Risk Information System (IRIS) program, as summarized in the draft PFOS document (U.S. EPA, 2021b). Similarly, a systematic review approach was used to identify, screen, and evaluate exposure information to develop the RSC based on the best available science.

1.4 Exposure Factor Information

An exposure factor (EF), such as body weight-adjusted drinking water intake (DWI-BW), is one of the input values for deriving a drinking water HA. EFs are factors related to human activity patterns, behavior, and characteristics that help determine an individual's exposure to a contaminant. EPA's *Exposure Factors Handbook* (EFH)[7] is a resource for conducting exposure assessments and provides EFs based on information from publicly available, peer-reviewed studies. Chapter 3 of the EFH presents EFs in the form of drinking water intake values (DWIs) and DWI-BWs for various populations or life stages within the general population (U.S. EPA, 2019b). The use of EFs in HA calculations is intended to protect sensitive populations within the general population from adverse effects resulting from exposure to a contaminant.

When developing HAs, the goal is to protect all ages of the general population including potentially sensitive populations such as children. The approach to select the EF for drinking water HA derivation includes a step to identify potentially sensitive population(s) or life stage(s) (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) by considering the available data for the contaminant. Although data gaps can prevent identification of the most sensitive population (e.g., not all windows of exposure or health outcomes have been assessed for PFOS), the critical effect and point-of-departure (e.g., human equivalent benchmark dose [BMD]) that form the basis for the RfD can provide some information about potentially sensitive populations because the critical effect is typically observed at the lowest tested dose among the available data. Evaluation of the critical study, including the exposure interval, may identify a particularly sensitive population or life stage (e.g., pregnant women, formula-fed infants, lactating women). In such cases, EPA can select the corresponding EFs for that sensitive population or life stage from the EFH (U.S. EPA, 2019b) for use in HA derivation. When multiple potentially sensitive populations or life stages are identified based on the critical effect or other health effects data (from animal or human studies), EPA selects the population or life stage with the greatest DWI-BW because it is the most health protective. For deriving lifetime HA values, the RSC corresponding to the selected sensitive life stage is also determined when data are available (see Section 2.2). In the absence of information indicating a potentially sensitive population or life stage, the EF corresponding to all ages of the general population may be selected.

To derive a chronic HA, EPA typically uses a DWI normalized to body weight (i.e., DWI-BW in L of water consumed/kg bw-day) for all ages of the general population or for a sensitive population or life stage, when identified. The Joint Institute for Food Safety and Applied

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[7] Available at https://www.epa.gov/expobox/about-exposure-factors-handbook. The latest edition of the EFH was released in 2011, but since October 2017, EPA has begun to release chapter updates individually.

Nutrition's Food Commodity Intake Database (FCID) Consumption Calculator Tool[8] includes the EFs from EPA's EFH and can also be used to estimate DWIs and DWI-BWs for specific populations, life stages, or age ranges. EPA uses the 90th percentile DWI-BW to ensure that the HA is protective of the general population as well as sensitive populations or life stages (U.S. EPA, 2000a, 2016c). In 2019, EPA updated its EFs for DWI and DWI-BW based on newly available science (U.S. EPA, 2019b).

1.5 Approach for Lifetime Health Advisory Calculation

The following equation (Eq. 1) is used to derive an interim or final lifetime noncancer HA. A lifetime noncancer HA is designed to be protective of noncancer effects over a lifetime of exposure and is typically based on a chronic *in vivo* experimental animal toxicity study and/or human epidemiological data.

$$\textbf{Lifetime HA} = \left(\frac{\text{RfD}}{\text{DWI-BW}}\right) * \text{RSC} \qquad \text{(Eq. 1)}$$

Where:

DWI-BW = the 90th percentile DWI for the selected population, adjusted for body weight, in units of L/kg bw-day. The DWI-BW considers both direct and indirect consumption of tap water (indirect water consumption encompasses water added in the preparation of foods or beverages, such as tea or coffee).

RfD = chronic reference dose—an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime.

RSC = relative source contribution—the percentage of the total oral exposure attributed to drinking water sources where the remainder of the exposure is allocated to all other routes or sources (U.S. EPA, 2000a).

2.0 Interim Health Advisory Derivation: PFOS

A lifetime noncancer iHA was derived for PFOS. The DWI-BW selected to derive the iHA is for 0- to < 5-year-old children because PFOS exposure was measured in 5-year-old children in the critical study, and it is reasonable to expect that PFOS exposure levels were similar from birth through age 5 (see Section 2.2). Since a DWI-BW for 0- to < 5-year-old children was used, the iHA for PFOS is expected to be protective of children and adults of all ages in the general population; however, available data on the most sensitive population or life stage are limited.

Short-term iHAs (e.g., one- or ten-day iHAs) were not derived for PFOS because the draft PFOS document did not derive an RfD for short-term exposure. Additionally, EPA considers the lifetime iHA for PFOS to be applicable to short-term as well as lifetime risk assessment scenarios because the critical health effect on which the draft chronic RfD used to calculate the

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[8] Joint Institute for Food Safety and Applied Nutrition's FCID Commodity Consumption Calculator is available at https://fcid.foodrisk.org/percentiles

iHA is based (i.e., deficient antibody response to diphtheria vaccine in children) resulted from PFOS exposure during a developmental life stage. EPA's risk assessment guidelines indicate that adverse effects can result from even brief exposure during a critical period of development (U.S. EPA, 1991). Therefore, the lifetime iHA for PFOS (calculated in Section 2.4) and the draft chronic RfD from which it is derived (see Table 1) are considered applicable to short-term PFOS exposures via drinking water.

As noted in the draft PFOS document (U.S. EPA, 2021b), there is *suggestive evidence of carcinogenic potential* of PFOS based on EPA's *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a). Epidemiological study results suggest a potential association between PFOS exposure and bladder or prostate cancers as discussed in the 2016 HESD for PFOS (U.S. EPA, 2016b). More recent epidemiological studies examining the association between PFOS and breast cancer show mixed results, and study characteristics (e.g., small sample sizes, narrow exposure levels) limit the ability to draw stronger conclusions about PFOS and breast cancer. The single available chronic duration cancer bioassay in animals reported increased incidences of liver, thyroid, and mammary gland tumors in rats, but a dose-response pattern was not observed. As noted in the draft PFOS document (U.S. EPA, 2021b), a draft cancer slope factor (CSF) was not derived for PFOS. This is consistent with EPA's *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a) which state that when the available evidence is suggestive for carcinogenicity, a quantitative risk estimate is generally not derived unless there exists a well-conducted study that could facilitate an understanding of the magnitude and uncertainty of potential risks, ranking potential hazards, or setting research priorities. In the draft PFOS document, EPA concluded that the available human and animal studies for PFOS are not sufficient to establish a reasonable understanding of the magnitude and uncertainty of potential risks for PFOS exposure and tumor incidence, and therefore do not justify a quantitative cancer assessment (U.S. EPA, 2021b). Since a draft CSF was not developed for PFOS, an interim 10^{-6} cancer risk concentration was not derived.

2.1 Toxicity

Table 1 reports the draft chronic RfD derived in the draft PFOS document (U.S. EPA, 2021b) that was used to develop the lifetime iHA for PFOS.

Table 1. Draft Chronic RfD, Critical Effect, and Critical Study Used to Develop the Lifetime iHA for PFOS.

Source	For the Lifetime iHA for PFOS			
	RfD (mg/kg bw-day)	PFOS Exposure in Critical Study	Critical Effect	Principal and Associated Studies (Study Type)
Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water [Draft] (U.S. EPA, 2021b)	7.9×10^{-9}	PFOS measured in serum of 5-year-old children	Developmental immune health outcome (suppression of diphtheria vaccine response in 7-year-old children)	Grandjean et al., 2012; Budtz-Jorgensen and Grandjean, 2018 (epidemiological study)

Note: mg/kg bw-day = milligrams per kilogram body weight per day.

Decreased serum anti-diphtheria antibody concentration in children, which was associated with increased serum PFOS concentrations (Budtz-Jorgensen and Grandjean, 2018; Grandjean et al., 2012), was selected as the critical effect for draft chronic RfD derivation. As noted in the draft PFOS document (U.S. EPA, 2021b), selection of this draft critical effect is expected to be protective of all other adverse health effects in humans because this adverse effect of decreased immune response to vaccination was observed after exposure during a sensitive developmental life stage, and it yields the lowest point of departure (POD) human equivalent dose (POD_{HED}) among the candidate $PODs_{HED}$. Other candidate RfDs were derived based on other health effects (e.g., development/growth) observed in epidemiology studies; all of the candidate RfDs are associated with low daily oral exposure doses, ranging from $\sim 10^{-7}$ to 10^{-9} milligrams per kilogram body weight per day (mg/kg bw-day) (U.S. EPA, 2021b; Table 23).

The selected draft POD_{HED} for this critical effect was derived by performing BMD modeling (see Appendix B.1 of U.S. EPA, 2021b) on measured PFOS serum concentrations at age five reported in the critical study, which yielded an internal serum concentration POD in milligrams per liter (mg/L). This internal serum concentration POD was then converted to an external dose (POD_{HED}) in mg/kg bw-day using the updated physiologically-based pharmacokinetic (PBPK) model developed by Verner et al. (described in section 4.1.3.2 of U.S. EPA, 2021b). Specifically, the POD_{HED} was calculated as the external dose (*in utero* through age five) that results in the internal serum concentration measured at five years of age in the critical study. (Note that the model predicted slightly different values for male and female children; the lower POD_{HED} was selected to be more health protective). An intraspecies uncertainty factor (UF_H) of 10 was applied to the selected draft POD_{HED} to account for variability in the response within the human population in accordance with methods described in EPA's *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002b). EPA applied a value of 1 for the remaining four uncertainty factors (UFs): interspecies UF (UF_A), because the critical effect was observed in humans and there is no need to account for uncertainty associated with animal-to-human extrapolation; lowest-observed-adverse-effect level (LOAEL)-to-no-observed-adverse-effect level (NOAEL) extrapolation UF (UF_L), because a benchmark lower dose confidence limit (BMDL) instead of a LOAEL was used as the basis for POD_HED derivation; subchronic-to-chronic exposure duration extrapolation UF (UF_S), because the critical effect on the developing immune system in children was observed after exposure during gestation and/or early childhood, a sensitive period that can lead to severe effects without lifetime exposure; and a database UF (UF_D), because the database of animal and human studies on the effects of PFOS is comprehensive (see the draft PFOS document [U.S. EPA, 2021b] for further details). Thus, the total or composite UF (UF_C) used to derive the PFOS RfD was 10.

2.2 Exposure Factors

To identify potentially sensitive populations, EPA considered the sensitive life stage of exposure associated with the critical effect on which the draft chronic RfD was based. The critical study that was selected for draft chronic RfD derivation (see Table 1) established an association in children between PFOS serum concentration (measured at age five, after three of four diphtheria vaccinations) and decreased anti-diphtheria antibody concentration (measured at age seven, approximately two years after all four diphtheria vaccinations) (Budtz-Jorgensen and Grandjean, 2018). Based on limited available data to inform the critical PFOS exposure window for this critical developmental immune effect, the serum PFOS concentrations measured in 5-year-old children in this study are assumed to represent PFOS exposure from birth to the time of measurement. EPA acknowledges that the DWI-BW varies between ages 0 and 5 years (U.S. EPA, 2019b); however, the available data do not permit a more precise identification of the most sensitive or critical PFOS exposure window for the developmental immune outcome because studies with different exposure intervals have not been performed.

EPA calculated and considered DWI-BWs for other potentially sensitive age ranges indicated by the critical study data (e.g., 0 to < 7 years, 1 to < 5 years, 1 to < 7 years; Table 2). The DWI-BW for children aged 0 to < 5 years was selected among the DWI-BWs (see Table 2) because it is the greatest value and therefore the most health-protective. EPA also considered the use of a DWI-BW for formula-fed infants (i.e., infants fed primarily or solely with water-reconstituted infant formula) because their DWI-BW is higher (U.S. EPA, 2019b) and the infant life stage occurs within the 0- to < 5-year age range. However, a greater RSC would be used for formula-fed infants than for 0- to < 5-year-olds, which would result in a less health-protective iHA value (see Section 2.3). Therefore, EPA selected the DWI-BW for 0- to < 5-year-olds.

Table 2. EPA Exposure Factors for Drinking Water Intake for Candidate Sensitive Populations Based on the Critical Effect and Study.

Population	DWI-BW (L/kg bw-day)	Description of Exposure Metric	Source
Children aged 0 to < 5 yrs	**0.0701**	90th percentile direct and indirect consumption of community water, consumers-only population, two-day average[a]	*Exposure Factors Handbook*, Chapter 3 (U.S. EPA, 2019b), NHANES 2005–2010[b]
Children aged 0 to < 7 yrs	0.0553		
Children aged 1 to < 5 yrs	0.0447		
Children aged 1 to < 7 yrs	0.0426		

Notes: yrs = years; L/kg bw-day = liters of water consumed per kilogram body weight per day. The DWI-BW used to calculate the iHA is in bold.

[a] Community water = water from PWSs; consumers only population = quantity of water consumed per person in a population composed only of individuals who consumed water during a specified period.

[b] DWI-BWs are based on NHANES 2005−2010 data which is also reported in the EFH. DWI-BWs for the age ranges in this table were calculated using the FCID Commodity Consumption Calculator (available at https://fcid.foodrisk.org/percentiles).

2.3 Relative Source Contribution

When calculating HA values, EPA applies an RSC which represents the proportion of an individual's total exposure to a contaminant that is attributed to drinking water ingestion (directly or indirectly in beverages like coffee or tea, as well as from transfer to dietary items prepared with the local drinking water) relative to other exposure pathways. The remainder of the exposure equal to the RfD is allocated to other potential exposure sources (U.S. EPA, 2000a); for PFOS, other potential exposure sources include food and food contact materials, consumer products (e.g., personal care products), ambient and indoor air, and indoor dust. The purpose of the RSC is to ensure that the level of a contaminant (e.g., the HA value), when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD (U.S. EPA, 2000a).

To determine the RSC, EPA follows the Exposure Decision Tree for Defining Proposed RfD (or POD/UF) Apportionment in EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (U.S. EPA, 2000a). EPA conducted a broad literature search in 2019 to identify and evaluate information on sources of human PFAS (including PFOS) exposure to inform RSC determination, and subsequently updated the search through March 2021 (see U.S. EPA [2021b] for more details on the literature search methodologies and results). This literature search focused on real-world occurrences (measured concentrations) primarily in media commonly related to human exposure (outdoor and indoor air, indoor dust, drinking water, food, food packaging, articles and products, and soil). The initial search identified 3,622 peer-reviewed papers that matched search criteria (U.S. EPA, 2021b). Despite the U.S. phase-out of production, EPA has found widespread PFOS contamination in water, sediments, and soils. Exposure to PFOS can occur through food (including fish and shellfish), water, house dust, and contact with consumer products. The search did not identify adequate exposure information across potential exposure sources and specific to children aged 0 to < 5 years that could be used to quantify exposure and inform RSC derivation. The findings indicate that many other sources of PFOS exposure beyond drinking water ingestion exist (e.g., food, indoor dust), but that data are insufficient to allow for quantitative characterization of the different exposure sources.

EPA's Exposure Decision Tree approach states that when there is insufficient environmental and/or exposure data to permit quantitative derivation of the RSC, the recommended RSC for the general population is 20% (U.S. EPA, 2000a). This means that 20% of the exposure equal to the RfD is allocated to drinking water, and the remaining 80% is attributed to all other potential exposure sources.

2.4 Derivation of Health Advisory Value: Interim Lifetime Noncancer HA

The lifetime iHA for PFOS is calculated as follows:

$$\textbf{Lifetime iHA} = \left(\frac{\text{RfD}}{\text{DWI-BW}}\right) * \text{RSC}$$

(Eq. 1)

$$\textbf{Lifetime iHA} = \left(\frac{0.0000000079\ \frac{\text{mg}}{\text{kg bw-day}}}{0.0701\ \frac{\text{L}}{\text{kg bw-day}}}\right) * 0.2$$

$$\textbf{Lifetime iHA} = 0.00000002\ \frac{\text{mg}}{\text{L}}$$

$$= 0.00002\ \frac{\mu\text{g}}{\text{L}}$$

$$= 0.02\ \frac{\text{ng}}{\text{L}}$$

Based on EPA's *Guidelines for Developmental Toxicity Risk Assessment*, the lifetime iHA can be applied to short-term scenarios because the critical effect identified for PFOS is a developmental effect that can potentially result from short-term PFOS exposure during a critical period of development (U.S. EPA, 1991). EPA concludes that the lifetime iHA of 0.02 nanograms per liter (ng/L) (or 20 parts per quadrillion [ppq]) for PFOS can be applied to both short-term and chronic risk assessment scenarios.

3.0 Analytical Methods

EPA developed the following liquid chromatography/tandem mass spectrometry (LC/MS/MS) analytical methods to quantitatively monitor drinking water for targeted PFAS that include PFOS: EPA Method 533 (U.S. EPA, 2019a) and EPA Method 537.1, Version 2.0 (U.S. EPA, 2020).

EPA Method 533 monitors for 25 select PFAS with published measurement accuracy and precision data for PFOS in reagent water, finished ground water, and finished surface water. For further details about the procedures for this analytical method, please see *Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry* (U.S. EPA, 2019a).

EPA Method 537.1 (an update to EPA Method 537 [U.S. EPA, 2009c]) monitors for 18 select PFAS with published measurement accuracy and precision data for PFOS in reagent water, finished ground water, and finished surface water. For further details about the procedures for this analytical method, please see *Method 537.1, Version 2.0, Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)* (U.S. EPA, 2020).

Drinking water analytical laboratories have different performance capabilities dependent upon their instrumentation (manufacturer, age, usage, routine maintenance, operating configuration, etc.) and analyst experience. Some laboratories will effectively generate accurate, precise, quantifiable results at lower concentrations than others. Organizations leading efforts that include the collection of data need to establish data quality objectives (DQOs) to meet the needs of their program. These DQOs should consider establishing reasonable quantitation limits that laboratories can routinely meet, without recurring quality control (QC) failures that will necessitate repeating sample analyses, increase costs, and potentially reduce laboratory capacity. Establishing a quantitation limit that is too high may result in important lower-concentration results being overlooked.

EPA's approach to establishing DQOs within the UCMR program serves as an example. EPA established MRLs for UCMR 5,[9] and requires laboratories approved to analyze UCMR samples to demonstrate that they can make quality measurements at or below the established MRLs. EPA calculated the UCMR 5 MRLs using quantitation-limit data from multiple laboratories participating in an MRL-setting study. The laboratories' quantitation limits represent their lowest concentration for which future recovery is expected, with 99% confidence, to be between 50 and 150%.

The UCMR 5-derived and promulgated MRL for PFOS is 0.004 µg/L (4 ng/L).

4.0 Treatment Technologies

This section summarizes the available drinking water treatment technologies that have been demonstrated to remove PFOS from drinking water, but it is not meant to provide specific operational guidance or design criteria. In terms of treatment efficacy, PFOS generally shares many characteristics with PFOA but in most circumstances will be removed more easily using the same technologies (Sörengård et al., 2020). Sorption-based treatment processes such as granular activated carbon (GAC), powdered activated carbon (PAC), and anion exchange (AIX), as well as high-pressure membrane processes such as nanofiltration (NF) and reverse osmosis (RO), have been shown to successfully remove PFOS from drinking water to below the 0.004 µg/L MRL for UCMR 5 (Hölzer et al., 2009). These treatment processes may have additional benefits on finished water quality by removing other contaminants and disinfection byproduct (DBP) precursors. Care should be taken when introducing one of these processes into a well-functioning treatment train, as there can be interactions with other treatment processes. Care should also be taken for system operators unfamiliar with proper operation and potential hazards. General information and published PFAS treatment data for these processes may be found in EPA's Drinking Water Treatability Database (U.S. EPA, 2022b).

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[9] Information about UCMR 5 is available at https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule

Non-treatment PFOS management practices such as changing source waters, source water protection, or consolidation are also viable PFOS drinking water reduction options. One resource for protecting source water from PFAS, including PFOS, is the *PFAS − Source Water Protection Guide and Toolkit* (ASDWA, 2020), which shares effective strategies for addressing PFAS contamination risk in source waters. Source water protection is particularly important since PFOS can withstand biotic and abiotic degradation mechanisms except in unique situations that cannot be controlled *in situ* or result in complete defluorination (Huang and Jaffe, 2019; Rahman et al., 2014), indicating that PFOS is persistent and thus, natural attenuation is not a valid PFOS management strategy.

4.1 Sorption Technologies

Sorption technologies remove substances present in liquids by accumulation onto a solid phase (Crittenden et al., 2012). The two main sorption technologies that have been successfully used for full-scale PFOS removal are activated carbon and AIX. Activated carbon has been successfully applied in contactors as GAC or in powdered as well as slurry forms (PAC). Key considerations in choosing sorption technologies include influent water quality and desired effluent quality. Influent water quality can greatly impact the ability of sorption technologies to treat drinking water. Desired water quality can drive both operational and capital expenditures. When using a technology requiring a contactor, sizing the contactor is an important consideration that should include a pilot study. Pilot scale testing is highly recommended to ensure the treatment performance will be maximized for given source waters. EPA's *ICR Manual for Bench- and Pilot-Scale Treatment Studies* (U.S. EPA, 1996) contains guidance on conducting pilot studies for contactors which are used for GAC and AIX. Contactor efficacy can be compromised by particulate, organic, and inorganic constituents.

Both GAC and AIX can typically be regenerated when treatment performance reaches an unacceptable level. The choice between regeneration and replacement is a key planning decision. Regeneration can be on- or off-site. On-site regeneration typically requires a higher spatial footprint and capital outlay. Given water quality and other considerations, regenerated media can become totally exhausted or "poisoned" with other contaminants not removed during the regeneration process and must be replaced. However, most AIX resins in current use for PFOS technologies are single-use resins and not designed to be regenerated.

Two common interferences with sorption technologies relevant to PFAS are preloading (when a non-targeted compound is removed ahead of the targeted contaminant and prevents the targeted contaminant from accessing the sorption site) and competitive sorption (when one compound inhibits the removal of another by direct competition). The interferences can result in slowed sorption kinetics and reduced sorption capacities. It is also important to note that sorption technologies are largely reversible. PFAS in general, and PFOS specifically, can detach from sorbents and re-enter drinking water under certain conditions. In addition, direct competition with stronger sorbing constituents can lead to effluent PFOS concentrations temporarily exceeding influent concentration (known as chromatographic peaking). This has been documented in full-scale treatment plants (Appleman et al., 2013; Eschauzier et al., 2012; McCleaf et al., 2017; Takagi et al., 2011). Common PFOS competitors for binding sites on sorptive media include natural or dissolved organic matter (NOM/DOM) which lowers treatment efficacy (McNamara et al., 2018; Park et al., 2020; Pramanik et al., 2015; Yu et al., 2012). Preloading may be controlled in the design phase through pretreatment processes. For more information about managing preloading, see AWWA (2018a). Competitive sorption may be controlled by changing or regeneration of the sorptive media at appropriate intervals.

4.1.1 Activated Carbon

Activated carbon is a highly porous media with high internal surface areas (U.S. EPA, 2017b). Activated carbon can be made from a variety of materials. Designs that work with carbon made from one source material activated in a specific way may not be optimized for other carbon types. There is some indication that of the common trace capacity tests, higher rose bengal numbers are most correlated with higher PFOS removal (Sörengård et al., 2020). Installing activated carbon as a treatment method may also have ancillary benefits on finished water quality, particularly regarding DBP control, other contaminants, as well as taste-and-odor compounds.

Activated carbon tends to remove non-polar, larger compounds more easily from water than smaller, more polar compounds. Adsorption of acids and bases on activated carbon is pH-dependent. Adsorption of neutral forms, as opposed to anionic forms, is generally stronger, so lowering the pH increases PFOS sorption. However, the calculated acid dissociation constant (pKa) of PFOS is about 3 (Larsen and Giovalle, 2015) and lowering the pH may not be practical operationally.

Before the addition of activated carbon to an existing treatment train, there are issues which should be considered. For instance, activated carbon may change system pH or release leachable metals (particularly arsenic and antimony) especially when new carbon media is first used without acid washing. These effects are typically mitigated through an acid wash or forward flushing. Activated carbon may also impact disinfection efficacy depending on process placement and requires consideration to mitigate its effects; for more information, please see the American Water Works Association (AWWA) GAC standard (American National Standards Institute (ANSI)/AWWA B604-18; AWWA, 2018a) or the AWWA published standard for PAC (ANSI/AWWA B600-16; AWWA, 2016). Activated carbon can also shift the bromide-to-total organic carbon ratio and increase brominated (Br)-DBP concentrations (Krasner et al., 2016); however, despite increased Br-DBP, studies have indicated a decreased overall DBP concentration and risk (Wang et al., 2019). DBPs may be mitigated through NOM (DBP precursor) removal; please see Zhang et al. (2015) for additional information.

4.1.1.1 Granular Activated Carbon

PFOS can be effectively removed from water by using GAC; contactors are normally placed as a post-filter step. Key design criteria include empty bed contact time (EBCT), superficial velocity, and carbon type. Typical EBCTs for PFOS removal are 10–20 minutes and superficial linear velocities are normally 5–15 meters per hour (m/hr). Normal height-to-diameter ratios are around 1.5 to 2.0; lower ratios can cause problems with too-shallow beds and require more space, and higher ratios can induce greater head drops. AWWA has published a GAC standard (ANSI/AWWA B604-18; AWWA, 2018a) and a standard for GAC reactivation (ANSI/AWWA B605-18; AWWA, 2018b).

4.1.1.2 Powdered Activated Carbon

PAC is the same material as GAC, but it has a smaller particle size and is applied differently. PAC is typically dosed intermittently although it can be employed continuously if there are spatial constraints restricting contactor use. PAC dosage and type, along with dosing location, contact time, and water quality, often influence process cost as well as treatment efficiency (Heidari et al., 2021). For more information on employing PAC, please see the Drinking Water Treatability Database (U.S. EPA, 2022b).

While relatively unstudied in PFAS, increasing PAC dose with other contaminants increases removal to a point, after which it starts to decrease. Jar testing is typically used to empirically determine the optimal PAC dosage; doses between 45 and 100 mg/L are generally suitable for PFOS (Dudley, 2012; Hopkins et al., 2018; Sun et al., 2016). Standardized jar testing procedures have been published (ASTM International, 2019; AWWA, 2011). The AWWA published standard for PAC is ANSI/AWWA B600-16 (AWWA, 2016).

PAC can pose additional safety considerations including depleting oxygen in confined or partially enclosed areas, fire hazards including spontaneous combustion when stored with hydrocarbons or oxidants, and inhalation hazards and must be managed accordingly. PAC is also a good electrical conductor and can create dangerous conditions when it accumulates (AWWA, 2016). These dangers can be effectively mitigated through various occupational safety programs such as confined space or fire safety programs. See AWWA (2016) for more information.

4.1.2 Ion Exchange

Ion exchange involves the exchange of an aqueous ion (e.g., contaminant) for an ion on an exchange resin. Once the resin has exchanged all its ions for contaminants, it can either be replaced (single use) or regenerated (i.e., restoring its ions for further use).

Different resin types preferentially bind certain ions over others; therefore, resin selection is an important consideration. As PFOS will predominantly exist in an anionic form in water and is a strong acid (U.S. EPA, 2021g), strongly basic AIX resins will be the most relevant for PFOS. Regenerating PFOS-saturated resins has been accomplished effectively with a brine of > 20% sodium chloride and ammonium chloride. Sodium hydroxide may be added to the sodium chloride solution to combat organic fouling; this is referred to as ‘brine squeeze’ and helps in solubilizing NOM and unplugging pores (Dixit et al., 2021). Regenerated media can be “poisoned,” meaning that a non-target ion not removed by the in-place regeneration procedures eventually crowds out available active sites. When this happens or if media is not regenerated, it must be disposed of appropriately. Once PFAS-contaminated spent brine is recovered, it must be treated or disposed of. Resin regeneration may not be practical for water utilities from safety and/or cost perspectives (Liu and Sun, 2021).

In some situations, AIX may outperform activated carbon for removing PFOS from drinking water (Liu and Sun, 2021). Key design parameters for GAC also apply to AIX, and they can be operated similarly. AIX typically uses 2-to-5-minute EBCTs, allowing for lower capital costs and a smaller footprint; compared to GAC, smaller height-to-diameter ratios are typically used in exchange columns. However, AIX resin is typically more costly compared to GAC which may increase overall operational costs. Columns used in pilot studies are scaled directly to full-scale if loading rates and EBCTs are kept constant (Crittenden et al., 2012).

Before the addition of AIX to an existing treatment train, there are effects which must be considered. For instance, AIX can increase water corrosivity and/or release amines and will increase concentrations of the counter-ion used (typically chloride). These effects may usually be mitigated through prior planning which may include corrosion control adjustments; for more information about corrosion control, see U.S. EPA (2016d). Additionally, PFOS-saturated resin regeneration creates an additional PFOS waste stream which will require appropriate handling. For more information about AIX, please see Crittenden et al. (2012), Dixit et al. (2021), Tanaka (2015), Tarleton (2014), and the EPA Drinking Water Treatability Database (U.S. EPA, 2022b).

4.2 High-Pressure Membranes

NF and RO are high-pressure processes where water is forced across a membrane. The water that transverses the membrane is known as permeate or produce, and has few solutes left in it; the remaining water is known as concentrate, brine, retentate, or reject water and forms a waste stream with concentrated solutes. NF has a less dense active layer than RO, which enables lower operating pressures but also makes it less effective at removing contaminants. Higher operating pressures and initial flux generally enhance removal. Temperature and pH are also significant parameters affecting performance. In general, organic NF membranes have lower operating costs and easier processing than inorganic membranes while maintaining appropriate robustness for PFOS treatment (Jin et al., 2021). NF and RO tend to take up less space than sorptive separation technologies; however, both NF and RO also tend to have higher operating expenses, use a significant amount of energy, and generate concentrate waste streams which require disposal. Generally, NF and RO require pre- and post-treatment processes. Higher expenses typically associated with NF and RO are only rarely competitive from an economic perspective for removing a specific contaminant; however, for waters requiring significant treatment and where concentrate disposal options are reasonably available, NF and RO may be the best option.

PFOS removal fluxes are generally 20–80 liters per square meter per hour (L/[$m^2 \cdot$hr]) at 0.2–1.2 megapascal (MPa) operating pressure (Mastropietro et al., 2021) with removal from 90% to > 99% (Jin et al., 2021). Temperature can dramatically impact flux; it is common to normalize flux to a specific reference temperature for operational purposes (U.S. EPA, 2005b). It is also common to normalize flux to pressure ratios to identify productivity changes attributable to fouling (U.S. EPA, 2005b). It is important to note that water may traverse the membranes from outside-in or inside-out; different system configurations operating at the same flux produce differing quantities of finished water. This means that membrane systems with differing configurations cannot be directly compared based on flux. Total flow per module and cost per module are more important decision support indicators for capital planning. Unlike low-pressure membranes, NF and RO systems are not manufactured as proprietary equipment and membranes from one manufacturer are typically interchangeable with those from others (U.S. EPA, 2005b).

High-pressure membranes may have effects when added onto a well-functioning treatment train. For instance, high-pressure membranes may remove beneficial minerals and increase corrosivity. Increased water corrosivity may need to be addressed through corrosion control treatment modifications and water may require remineralization. For more information, see AWWA (2007) or U.S. EPA (2016d).

4.3 Point-of-Use Devices for Individual Household PFOS Removal

Although the focus of this treatment technologies section is the different available options for removal of PFOS at drinking water treatment plants, centralized treatment technologies can also often be used in a decentralized fashion as point-of-entry (where the distribution system meets a service connection) or point-of-use (at a specific tap or application) treatment in cases where centralized treatment is impractical or individual consumers wish to further reduce their individual household risks. Many home drinking water treatment units are certified by independent third-party accreditation organizations using ANSI standards to verify contaminant removal claims. NSF International has developed protocols for NSF/ANSI Standards 53 (sorption) and 58 (RO) that establish minimum requirements for materials, design, and construction, and performance of point-of-use systems. Previously, NSF P473 was designed to certify PFOS reduction technologies below EPA's 2016 HA of 70 ppt for PFOS; in 2019, these standards were retired and folded into NSF/ANSI 53 and 58. PFOS removal by faucet filters has reportedly averaged 99%, whereas pitcher filters had an average of 71% removal, refrigerator filters 61%, single-stage under-sink filters > 99%, two-stage filters 99%, and RO filters 100%. Some filters can remove PFOS to below the 0.004 µg/L UCMR 5 reporting limit (Herkert et al., 2020). Boiling water is not an effective point-of-use PFOS treatment, as it will concentrate PFOS.

4.4 Treatment Technologies Summary

Non-treatment PFOS management options, such as changing source waters, source water protection, or consolidation are viable strategies for reducing PFOS concentrations in finished drinking water. Should treatment be necessary, GAC, PAC, AIX, NF, and RO are the best means for removing PFOS from drinking water and can be used in central treatment plants or in point-of-use applications. These treatment processes are separation technologies and produce waste streams with PFOS, and all processes may have unintended effects on the existing treatment trains. Some treatment processes have been shown to increase PFOS concentrations, most likely through precursor oxidation. PFOS treatment technologies often require pre- as well as post-treatment and may help remove other unwanted contaminants and DBP precursors. Boiling water will concentrate PFOS and should not be considered as an emergency action.

5.0 Consideration of Noncancer Health Risks from PFAS Mixtures

EPA recently released a *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (U.S. EPA, 2021h) that is currently undergoing SAB PFAS Panel review. That draft document describes a flexible, data-driven framework that facilitates practical component-based mixtures evaluation of two or more PFAS based on current, available EPA chemical mixtures approaches and methods (U.S. EPA, 2000b). Examples are presented for three approaches—Hazard Index (HI), Relative Potency Factor (RPF), and Mixture BMD—to demonstrate application to PFAS mixtures. To use these approaches, specific input values and information for each PFAS are needed or can be developed. These approaches may help to inform PFAS evaluation(s) by federal, state, and tribal partners, as well as public health experts, drinking water utility personnel, and other stakeholders interested in assessing the potential noncancer human health hazards and risks associated with PFAS mixtures.

The HI approach, for example, could be used to assess the potential noncancer risk of a mixture of four component PFAS for which HAs, either final or interim, are available from EPA (PFOA, PFOS, GenX chemicals [hexafluoropropylene oxide dimer acid and its ammonium salt], and perfluorobutane sulfonic acid [PFBS]). In the HI approach described in the draft framework (U.S. EPA, 2021h), a hazard quotient (HQ) is calculated as the ratio of human exposure (E) to a human health-based toxicity value (e.g., reference value [RfV]) for each mixture component chemical (i) (U.S. EPA, 1986). The HI is dimensionless, so in the HI formula, E and the RfV must be in the same units (Eq. 2). In the context of PFAS in drinking water, a mixture PFAS HI can be calculated when health-based water concentrations (e.g., HAs, Maximum Contaminant Level Goals [MCLGs]) for a set of PFAS are available or can be calculated. In this example, HQs are calculated by dividing the measured component PFAS concentration in water (e.g., expressed as ng/L) by the relevant HA (e.g., expressed as ng/L) (Eqs. 3, 4). The component chemical HQs are then summed across the PFAS mixture to yield the mixture PFAS HIs based on interim and final HAs.

$$\mathrm{HI} = \sum_{i=1}^{n} \mathrm{HQ_i} = \sum_{i=1}^{n} \frac{\mathrm{E_i}}{\mathrm{RfV_i}}$$

(Eq. 2)

$$\mathrm{HI} = \mathrm{HQ_{PFOA}} + \mathrm{HQ_{PFOS}} + \mathrm{HQ_{GenX}} + \mathrm{HQ_{PFBS}}$$

(Eq. 3)

$$\mathrm{HI} = \left(\frac{[\mathrm{PFOA_{water}}]}{[\mathrm{PFOA_{iHA}}]}\right) + \left(\frac{[\mathrm{PFOS_{water}}]}{[\mathrm{PFOS_{iHA}}]}\right) + \left(\frac{[\mathrm{GenX_{water}}]}{[\mathrm{GenX_{HA}}]}\right) + \left(\frac{[\mathrm{PFBS_{water}}]}{[\mathrm{PFBS_{HA}}]}\right)$$

(Eq. 4)

Where:
HI = hazard index
n = the number of component (i) PFAS
$\mathbf{HQ_i}$ = hazard quotient for component (i) PFAS
$\mathbf{E_i}$ = human exposure for component (i) PFAS
$\mathbf{RfV_i}$ = human health-based toxicity value for component (i) PFAS
$\mathbf{HQ_{PFAS}}$ = hazard quotient for a given PFAS
$\mathbf{[PFAS_{water}]}$ = concentration for a given PFAS in water
$\mathbf{[PFAS_{HA}]}$ = HA value, interim or final, for a given PFAS

In cases when the mixture PFAS HI is greater than 1, this indicates an exceedance of the health protective level and indicates potential human health risk for noncancer effects from the PFAS mixture in water. When component health-based water concentrations (in this case, HAs) are below the analytical method detection limit, as is the case for PFOA and PFOS, such individual component HQs exceed 1, meaning that any detectable level of those component PFAS will result in an HI greater than 1 for the whole mixture. Further analysis could provide a refined assessment of the potential for health effects associated with the individual PFAS and their contributions to the potential joint toxicity associated with the mixture. For more details of the approach and illustrative examples of the RPF approach and Mixture BMD approaches, please see U.S. EPA (2021h).

6.0 Interim Health Advisory Characterization

The purpose of developing the lifetime iHA for PFOS is to reflect the best available scientific information which indicates that PFOS can lead to adverse noncancer health effects at exposure levels that are much lower than previously understood (U.S. EPA, 2016c). The PFOS iHA of 0.02 ng/L is considered applicable to both short-term and chronic risk assessment scenarios because the critical effect identified for PFOS can result from developmental exposure and leads to long-term adverse health effects. Therefore, short-term PFOS exposure during a critical period of development may lead to adverse health effects across life stages.

In 2019, EPA initiated an updated literature search and analysis of health effects information for PFOS to better characterize the health hazards and risks of exposure using information published since EPA developed the 2016 HA for PFOS (draft PFOS document; U.S. EPA, 2021b). The draft PFOS document includes an updated draft chronic RfD and draft RSC. The draft PFOS document is currently undergoing review by the SAB PFAS Panel as part of EPA's process for developing a NPDWR for PFOS under SDWA. The draft report of the SAB PFAS Panel's review (U.S. EPA, 2022a) is supportive of the draft conclusions; however, the SAB PFAS Panel is recommending analyses that may impact the final RfD and RSC. Because the iHA is based on draft values, it is subject to change.

EPA expects to propose an MCLG and NPDWR for PFOS in the fall of 2022 and to promulgate a final MCLG and NPDWR by the fall of 2023 after considering public comment. EPA will complete its revisions to address the final SAB report's comments in the proposed PFOS MCLG and NPDWR. EPA may update or remove the iHA for PFOS at that time. Based, however, on the updated systematic review of the best available science on PFOS exposure and health effects and taking into consideration the work EPA is doing now to address SAB comments, the health-based drinking water values for PFOS (HA and MCLG) are anticipated to remain below the current UCMR 5 analytical MRL (0.004 µg/L or 4 ng/L).

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