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.



Office of Water OST EPA PUBLICATION # EPA/822/R-22/003

INTERIM Drinking Water Health Advisory: Perfluorooctanoic Acid (PFOA) CASRN 335-67-1

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EPA Document Number: EPA/822/R-22/003

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

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Abbreviations and Acronyms

AIX	anion exchange	GAC	granular activated
ANSI	American National		carbon
	Standards Institute	HA	Health Advisory
AWWA	American Water Works Association	HECD	Health and Ecological Criteria Division
BMD	benchmark dose	HESD	Health Effects
BMDL	benchmark dose		Support Document
	lower confidence	HI	hazard index
	limit	HQ	hazard quotient
Br-DBP	brominated	iHA	interim Health
	disinfection		Advisory
1 DW	byproduct	i	mixture component
bw or BW	body weight		chemical
CASRN	Chemical Abstracts	IRIS	Integrated Risk
	Service Registry	- // 2.4	Information System
CCI	Contominant	$L/(m^2 \cdot hr)$	liters per square meter
CCL	Containnain Candidate List		per hour
CDC	Centers for Disease	LC/MS/MS	liquid
CDC	Control and		tandem mass
	Prevention		spectrometry
CI	confidence interval	LOAEL	lowest-observed-
CSF	cancer slope factor	Lonie	adverse-effect level
DBP	disinfection	MCL	Maximum
	byproduct		Contaminant Level
DOM	dissolved organic	MCLG	Maximum
	matter		Contaminant Level
DQO	data quality objective		Goal
DWI	drinking water intake	mg/kg bw-day	milligrams per
DWI-BW	body weight-adjusted		kilogram body weight
	drinking water intake	1 7	per day
E	human exposure	mg/L	milligrams per liter
EBCT	empty bed contact	m/hr	meters per hour
	time	MPa	megapascal
EF	exposure factor	MRL	minimum reporting
EFH	Exposure Factors		level
	Handbook	NF	nanofiltration
EPA	U.S. Environmental	ng/L	nanograms per liter
_	Protection Agency	NHANES	National Health and
Eq.	equation		Nutrition
FCID	Food Commodity Intake Database		Examination Survey

NOAEL	no-observed-adverse-	RO	reverse osmosis
	effect level	RPF	relative potency factor
NOM	natural organic matter	RSC	relative source
NPDWR	National Primary		contribution
	Drinking Water	SAB	Science Advisory
	Regulation		Board
OGWDW	Office of Ground	SAB PFAS Panel	Science Advisory
	Water and Drinking		Board Per- and
0.0.0	Water		Polyfluoroalkyl
ORD	Office of Research		Substances Review
OGT		CDUUA	
OST	Office of Science and	SDWA	Safe Drinking Water
OW			
Uw DA C	Office of water	SNUK	Significant New Use
PAC	powdered activated		Toxic Substances
DDDV	physicle gizelly based	ISCA	Control Act
FDFK	physiologically-based	UCMR	Unregulated
DEVE	per_ and	OCIVIK	Contaminant
ITAS	polyfluoroalkyl		Monitoring Rule
	substances	UF	uncertainty factor
PFBS	perfluorobutane	UFA	interspecies
	sulfonic acid		uncertainty factor
PFOA	perfluorooctanoic	UFc	composite uncertainty
	acid		factor
PFOS	perfluorooctane	UFD	database uncertainty
	sulfonic acid		factor
pKa	acid dissociation	UFH	intraspecies
	constant		uncertainty factor
POD	point of departure	UF_L	lowest-observed-
PODHED	point of departure		adverse-effect level-
	human equivalent		to-no-observed-
	dose		adverse-effect level
ppq	parts per quadrillion		uncertainty factor
ppt	parts per trillion	LIFe	subchronic-to-chronic
PWS	public water system	013	exposure duration
QC	quality control		extrapolation
RfD	reference dose		uncertainty factor
RfV	reference value	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 perfluorooctanoic acid (PFOA) to replace the 2016 lifetime HA of 0.07 micrograms per liter (μ g/L) (70 parts per trillion [ppt]) because analyses of more recent health effects studies show that PFOA can impact human health at exposure levels much lower than reflected by the 2016 PFOA lifetime HA. EPA has developed an interim rather than a final HA for PFOA 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 PFOA (U.S. EPA, 2009a) based on the best information available at that time. Also, PFOA was included on the third and fourth drinking water Contaminant Candidate Lists (CCLs)³ (U.S. EPA, 2009b, 2016a). After PFOA was listed on the third CCL in 2009, EPA initiated development of a Health Effects Support Document (HESD) for PFOA to assist officials and PWS managers in protecting public health when PFOA is present in drinking water. The HESD was published in 2016 after peer review (U.S. EPA, 2016b). EPA developed a final HA for PFOA (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 PFOA 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 the *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for*

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." <u>www.epa.gov/sites/default/files/2020-05/documents/safe_drinking_water_act-title_xiv_of_public_health_service_act.pdf</u>

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.

Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water (U.S. EPA, 2021b) (hereafter referred to as "draft PFOA document") which includes an updated health effects assessment of the peer-reviewed literature, cancer classification, draft chronic reference dose (RfD), and draft relative source contribution (RSC) value. The development of the draft noncancer chronic RfD for PFOA 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 PFOA document along with three other draft documents supporting the NPDWR (U.S. EPA, 2022a).

The 2021 data and analyses described in the draft PFOA document indicate that PFOA exposure levels at which adverse health effects have been observed are much lower than previously understood when EPA issued an HA for PFOA in 2016. As a result, EPA announced in 2021⁴ that it would move quickly to update the 2016 HA for PFOA to reflect the latest, best available science as well as input from the SAB PFAS Panel. An updated PFOA 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 PFOA 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 PFOA 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. Additionally, EPA derived multiple candidate cancer slope factors (CSFs) in the draft PFOA document but did not yet select one overall draft CSF; therefore, EPA has not derived an updated interim 10⁻⁶ cancer risk concentration for PFOA in this iHA document. As noted in the draft PFOA document, the candidate CSFs derived from the more recent human and animal studies indicate that PFOA is a more potent carcinogen than was described in the 2016 HA document. An initial evaluation of the multiple candidate CSFs indicates that resulting 10⁻⁶ cancer risk concentrations are either comparable to or greater than the lifetime noncancer iHA value for PFOA. EPA is currently reviewing and evaluating the available information to derive a CSF for PFOA as part of the NPDWR.

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 PFOA 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 PFOA upon finalization of the NPDWR.

1.1 PFOA General Information and Uses

PFOA 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

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

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

In 2006, EPA invited eight major companies to commit to working toward the elimination of their production and use of PFOA (and chemicals that degrade to PFOA) and elimination of these chemicals from emissions and products by the end of 2015.⁵ All eight companies have since phased out manufacturing PFOA. PFOA is included in EPA's Toxic Substances Control Act (TSCA) Significant New Use Rule (SNUR) issued in January 2015, which ensures that EPA will have an opportunity to review any efforts to reintroduce the chemical into the marketplace and take action, as necessary, to address potential concerns (U.S. EPA, 2015). Limited existing uses of PFOA-related chemicals, including as a component of anti-reflective coatings in the production of semiconductors, were excluded from the regulations (U.S. EPA, 2021e).

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 PFOA in drinking water (U.S. EPA, 2017a, 2021a,b,f). A total of 379 samples from 117 PWSs (out of 36,972 total samples from 4,920 PWSs) had detections of PFOA (i.e., greater than or equal to the minimum reporting level [MRL]⁶ of 0.02 µg/L). PFOA concentrations for these detections ranged from 0.02 µg/L (the MRL) to 0.349 µg/L (median concentration of 0.03 µg/L; 90th percentile concentration of 0.07 µg/L).

In 2016, EPA recommended that when PFOA and perfluorooctane sulfonic acid (PFOS) cooccur at the same time and location in drinking water sources, a conservative and healthprotective 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 36,972 samples from 4,920 PWSs) had detections of PFOA and/or PFOS (i.e., at or above the MRL of 0.02 μ g/L for PFOA or 0.04 μ g/L for PFOS). The sum of reported PFOA and/or PFOS concentrations ranged from 0.02 to 7.22 μ g/L. Although it is not possible to determine the full extent of PFOA and/or PFOS occurrence based on UCMR 3 detections, sites where elevated levels of PFOA and/or PFOS were detected during UCMR 3 monitoring may have taken steps to mitigate exposure including installing treatment systems and/or blending water from multiple sources, or remediating known sources of contamination (U.S. EPA, 2021a).

⁵ Fact Sheet: 2010/2015 PFOA Stewardship Program available at <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program</u>

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, 2021g).

The fifth UCMR (UCMR 5) will require monitoring for 29 PFAS, including PFOA, 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 PWSs 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, 2021g). EPA established an MRL for PFOA of 0.004 μ g/L under UCMR 5, which is 5-fold lower than the MRL used in UCMR 3.

Some states have conducted monitoring for PFOA in drinking water (by selecting sampling locations randomly, and/or sampling from targeted locations). PFOA has been detected in the finished drinking water of at least 20 states (ADEM, 2021; AZDEQ, 2021; CADDW, 2021; CDPHE, 2020; DE ODW, 2021; 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 PFOA 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. PFOA 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 PFOA declined by more than 60% between 1999 and 2014, presumably due to restrictions on PFOA commercial usage in the United States. (CDC, 2017). NHANES biomonitoring data from 1999-2000 reveal a mean serum PFOA concentration of 5.21 µg/L (95% confidence interval [CI]) of 4.72–5.74 µg/L) and a 90th percentile serum PFOA concentration of 9.4 µg/L (95% CI 8.2–11.1 µg/L) across 1,562 samples representative of the U.S. population. For 2013–2014, mean and 90th percentile serum PFOA concentrations were 1.94 µg/L (95% CI 1.76-2.14 µg/L) and 4.27 µg/L (95% CI 3.57-5.17 µg/L), respectively (2,165 samples) (CDC, 2021). In 2017–2018, the mean serum PFOA concentration was 1.42 µg/L (95% CI 1.33–1.52 µg/L) and the 90th percentile serum PFOA concentration was 2.97 µg/L (95% CI 2.77–3.37 µg/L) across 1,929 samples (CDC, 2021). For additional information about PFOA 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 PFOA is derived from draft values (i.e., chronic RfD and RSC) and relies on the best available science as derived in the draft PFOA 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 PFOA document, a systematic review and evidence-mapping approach was utilized to identify, screen, and evaluate health effects data for PFOA. A literature search was performed to identify studies on the health effects of PFOA exposure in animals and humans published since the 2016 HESD and HA for PFOA. 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 PFOA 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 PFOA), 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 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 Nutrition's Food Commodity Intake Database (FCID) Consumption Calculator Tool⁸ 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

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

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

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.

Lifetime HA =
$$\left(\frac{\text{RfD}}{\text{DWI-BW}}\right) * \text{RSC}$$
 (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: PFOA

A lifetime noncancer iHA was derived for PFOA. The DWI-BW selected to derive the iHA is for 0- to < 5-year-old children because PFOA exposure was measured in 5-year-old children in the critical study, and it is reasonable to expect that PFOA 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 PFOA 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 PFOA because the draft PFOA document did not derive an RfD for short-term exposure. Additionally, EPA considers the lifetime iHA for PFOA 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 iHA is based (i.e., deficient antibody response to tetanus vaccine in children) resulted from PFOA 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 PFOA (calculated in Section 2.4) and the draft chronic RfD from which it is derived (see Table 1) are considered applicable to short-term PFOA exposures via drinking water. In accordance with EPA's *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a), the draft PFOA document (U.S. EPA, 2021b) classified PFOA as *likely to be carcinogenic to humans* based on evidence of kidney and testicular cancer in humans and Leydig cell tumors, pancreatic acinar cell tumors, and hepatocellular adenomas in rats. The draft report of the SAB Panel's review of the draft PFOA document (U.S. EPA, 2022a) indicated general agreement with this classification, but an interim 10⁻⁶ cancer risk concentration for PFOA was not derived because the selection of a CSF is ongoing. Candidate draft CSFs from human and animal studies were identified in the draft PFOA document, but one was not selected as the preferred draft CSF for derivation of a 10⁻⁶ cancer risk concentration (U.S. EPA, 2021b). An initial evaluation of the candidate CSFs shows that they would result in 10⁻⁶ cancer risk concentrations that are either comparable to or greater (i.e., less health-protective) than the iHA value for PFOA.

2.1 Toxicity

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

	For the Lifetime iHA for PFOA			
Source	RfD (mg/kg bw- day)	PFOA 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 Perfluorooctanoic Acid (PFOA) (CASRN 335- 67-1) in Drinking Water [Draft] (U.S. EPA, 2021b)	1.5 × 10 ⁻⁹	PFOA measured in serum of 5-year-old children	Developmental immune health outcome (suppression of tetanus vaccine response in 7-year- old children)	Grandjean et al., 2012; Budtz- Jorgensen and Grandjean, 2018 (epidemiological study)

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

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

Decreased serum anti-tetanus antibody concentration in children, which was associated with increased serum PFOA 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 PFOA 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 POD_{SHED}. 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 $\sim 10^{-6}$ 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 the critical effect was derived by performing BMD modeling (see Appendix B1 of U.S. EPA, 2021b) on the measured PFOA 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, 2002). EPA applied a value of 1 for the remaining four uncertainty factors (UFs): interspecies UF (UFA), because the critical effect was observed in humans and there is no need to account for uncertainty associated with animalto-human extrapolation; lowest-observed-adverse-effect level (LOAEL)-to-no-observed-adverseeffect level (NOAEL) extrapolation UF (UFL), because a benchmark dose lower confidence limit (BMDL) instead of a LOAEL was used as the basis for POD_{HED} derivation; subchronic-tochronic exposure duration extrapolation UF (UFs), 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 PFOA is comprehensive (see the draft PFOA document [U.S. EPA, 2021b] for further details). Thus, the total or composite UF (UF_c) used to derive the PFOA 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 PFOA serum concentration (measured at age five, after three of four tetanus vaccinations) and decreased anti-tetanus antibody concentration (measured at age seven, approximately two years after all four tetanus vaccinations) (Budtz-Jorgensen and Grandjean, 2018). Based on limited available data to inform the critical PFOA exposure window for this critical developmental immune effect, the serum PFOA concentrations measured in 5-year-old children in this study are assumed to represent PFOA 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 PFOA 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	Exposure Factors Handbook Chapter 3
Children aged 0 to < 7 yrs	0.0553	community water, consumers-only population, two-day average ^a	(U.S. EPA, 2019b), NHANES 2005–2010 ^b
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 <u>https://fcid.foodrisk.org/percentiles</u>).

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 PFOA, 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 PFOA) 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 PFOA contamination in water, sediments, and soils. Exposure to PFOA 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 PFOA 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 PFOA is calculated as follows:

Lifetime iHA =
$$\left(\frac{RfD}{DWI-BW}\right) * RSC$$
 (Eq. 1)
Lifetime iHA = $\left(\frac{0.000000015 \frac{mg}{kg bw-day}}{0.0701 \frac{L}{kg bw-day}}\right) * 0.2$
Lifetime iHA = $0.00000004 \frac{mg}{L}$
= $0.00004 \frac{\mu g}{L}$
= $0.004 \frac{ng}{L}$

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 PFOA is a developmental effect that can potentially result from short-term PFOA exposure during a critical period of development (U.S. EPA, 1991). EPA concludes that the lifetime iHA of 0.004 nanograms per liter (ng/L) (or 4 parts per quadrillion [ppq]) for PFOA 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 PFOA: 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 PFOA 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 PFOA 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 PFOA is 0.004 μ g/L (4 ng/L).

4.0 Treatment Technologies

This section summarizes the available drinking water treatment technologies that have been demonstrated to remove PFOA from drinking water, but it is not meant to provide specific operational guidance or design criteria. 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 PFOA from drinking water to below the 0.004 µg/L MRL for UCMR 5 (Bartell et al., 2010; 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

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

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).

Non-treatment PFOA management practices such as changing source waters, source water protection, or consolidation are also viable PFOA drinking water reduction options. One resource for protecting source water from PFAS, including PFOA, 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 PFOA 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 PFOA is persistent and thus, natural attenuation is not a valid PFOA 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 PFOA 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 PFOA 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 PFOA 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 PFOA 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 PFOA 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 methylene blue numbers are most correlated with higher PFOA 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 PFOA sorption. However, the acid dissociation constant (pKa) of PFOA is about 3.8 (Burns et al., 2008) 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

PFOA 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 PFOA 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 PFOA (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 occupational safety programs such as confined space or fire safety programs. Please 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 PFOA will predominantly exist in an anionic form in water and is a strong acid (U.S. EPA, 2021h), strongly basic AIX resins will be the most relevant for PFOA. Regenerating PFOA-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 PFOA 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, PFOA-saturated resin regeneration creates an additional PFOA 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 PFOA 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 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.

PFOA 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) and U.S. EPA (2016d).

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

Although the focus of this treatment technologies section is the different available options for removal of PFOA 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, construction, and performance of point-of-use systems. Previously, NSF P473 was designed to certify PFOA reduction technologies below EPA's 2016 HA of 70 ppt for PFOA; in 2019, these standards were retired and folded into NSF/ANSI 53 and 58. PFOA removal by faucet filters has reportedly averaged 84%, whereas pitcher filters had an average of 67% removal, refrigerator filters 71%, single-stage under-sink filters 56%, two-stage filters > 99%, and RO filters > 92%. Some filters can remove PFOA to below the 0.004 µg/L UCMR 5 reporting limit (Herkert et al., 2020). Boiling water is not an effective point-of-use PFOA treatment, as it will concentrate PFOA.

4.4 Treatment Technologies Summary

Non-treatment PFOA management options, such as changing source waters, source water protection, or consolidation are viable strategies for reducing PFOA concentrations in finished drinking water. Should treatment be necessary, GAC, PAC, AIX, NF, and RO are the best means for removing PFOA 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 PFOA, and all processes may have unintended effects on the existing treatment trains. PFOA treatment technologies often require pre- as well as post-treatment and may help remove other unwanted contaminants and DBP precursors. Boiling water will concentrate PFOA 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, 2021i) 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, 2021i), 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.

$$HI = \sum_{i=1}^{n} HQ_i = \sum_{i=1}^{n} \frac{E_i}{RfV_i}$$
(Eq. 2)

$$HI = HQ_{PFOA} + HQ_{PFOS} + HQ_{GenX} + HQ_{PFBS}$$
(Eq. 3)

$$HI = \left(\frac{[PFOA_{water}]}{[PFOA_{iHA}]}\right) + \left(\frac{[PFOS_{water}]}{[PFOS_{iHA}]}\right) + \left(\frac{[GenX_{water}]}{[GenX_{HA}]}\right) + \left(\frac{[PFBS_{water}]}{[PFBS_{HA}]}\right)$$
(Eq. 4)

Where:

HI = hazard index

 \mathbf{n} = the number of component (i) PFAS

 $HQ_i =$ hazard quotient for component (i) PFAS

 E_i = human exposure for component (i) PFAS

 $\mathbf{R}\mathbf{f}\mathbf{V}_{i}$ = human health-based toxicity value for component (i) PFAS

 $HQ_{PFAS} =$ hazard quotient for a given PFAS

[PFAS_{water}] = concentration for a given PFAS in water

 $[PFAS_{HA}] =$ 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 PFOA or PFOS 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 (2021i).

6.0 Interim Health Advisory Characterization

The purpose of developing the lifetime iHA for PFOA is to reflect the best available scientific information which indicates that PFOA can lead to adverse noncancer health effects at exposure levels that are much lower than previously understood (U.S. EPA, 2016c). The PFOA iHA of 0.004 ng/L is considered applicable to both short-term and chronic risk assessment scenarios because the critical effect identified for PFOA can result from developmental exposure and leads to long-term adverse health effects. Therefore, short-term PFOA 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 PFOA to better characterize the health hazards and risks of exposure using information published since EPA developed the 2016 HA for PFOA (draft PFOA document; U.S. EPA, 2021b). The draft PFOA document includes an updated cancer classification, draft chronic RfD, and draft RSC. The draft PFOA document is currently undergoing review by the SAB PFAS Panel as part of EPA's process for developing a NPDWR for PFOA 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, CSF, and RSC. Because the iHA is based on draft values, it is subject to change. Additionally, the candidate draft CSFs calculated in the draft PFOA document indicate that PFOA is a more potent carcinogen than described in the 2016 HA for PFOA. However, because the draft PFOA document presented multiple candidate CSFs from the available human and animal studies and did not select one draft CSF, EPA did not derive an updated 10⁻⁶ cancer risk concentration for PFOA for this iHA document. Furthermore, an initial evaluation of the multiple candidate CSFs indicates that the resulting 10^{-6} cancer risk concentrations are either greater than or in the same range as the iHA value.

EPA expects to propose an MCLG and NPDWR for PFOA 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 PFOA MCLG and NPDWR. EPA may update or remove the iHA for PFOA at that time. Based, however, on the updated systematic review of the best available science on PFOA 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 PFOA (HA and MCLG) are anticipated to remain below the current UCMR 5 analytical MRL ($0.004 \mu g/L$ or 4 ng/L).

7.0 References

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