

September 22, 2022

Don Brown, Clerk
Illinois Pollution Control Board
60 E. Van Buren, Suite 630
Chicago, IL 60605

Re: Public Comment, R 2022-018, Proposed Amendments to Groundwater Quality Standards,
35 Ill. Adm. Code Part 620

Via email: Don.Brown@illinois.gov
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To The Clerk and Hearing Officer:

Please be advised that I represent Citizens Against Ruining the Environment (“CARE”). CARE requested my assistance to submit public comments to contribute to Illinois Pollution Control Board Docket R 2022-018, Proposed Amendments to Groundwater Quality Standards, 35 Ill. Adm Code Part 620. Specifically, CARE is submitting comments in support of the Illinois EPA’s (“ILEPA”) rulemaking proposal to establish regulatory standards for six chemicals – PFOS, PFOA, PFNA, PFBS, PFHxS and GenX – which I will refer to collectively as PFAS. With the exception of PFOS, as explained below, CARE welcomes the numerical standards proposed by ILEPA for PFAS, which are consistent with the highest quality public health information and align with other states taking seriously the pressing public health issues these toxic chemicals present.

However, CARE, which represents persons residing in Will County who largely depend on groundwater for their drinking water needs, wishes to bring to the Illinois Pollution Control Board’s (“Board”) attention that the ILEPA’s proposed PFOS Class I groundwater quality standard, for this hazardous substance widely found in Illinois’s drinking water, is *385 times higher* than a recent federal interim health advisory reflecting the best available peer-reviewed science.¹ This large discrepancy has significant public health implications for Will County residents. Under the ILEPA’s current proposed groundwater quality standard for PFOS, all Will County residents’ water would be deemed “safe” for drinking. In stark contrast, levels were recorded by the ILEPA in Will County drinking water at six groundwater public water supplies that exceed the recently-announced safe level by between 110 and 365 times.

CARE suggests that the Board set the PFOS Class I groundwater quality standard at the lowest concentration of this hazardous substance that the ILEPA represents can reliably be detected (2 ng/L). The selection of this level as the PFOS groundwater quality standard is consistent with the Illinois Groundwater Protection Act, which requires the Board to consider the feasibility of any standard it selects, and is in line with the Board’s construction of that Act, which expects that ILEPA groundwater quality standards reflect the best available science. In addition, CARE

¹ See Interim Drinking Water Health Advisory: Perfluorooctane Sulfonic Acid (PFOS), U.S. EPA, Office of Water, Doc. No. EPA/822/R-22/004 (June 2022). This PFOS health advisory is included in this Public Comment as **CARE Attachment 1**.

submits that the very framework proposed and employed by the ILEPA in the present rulemaking compels using U.S. EPA's toxicity value in setting the PFOS groundwater quality standard in Illinois.

The increasing realization of the harmful health effects of PFAS is rightly being called a "rapidly developing situation" by the U.S. EPA.² For example, only six years ago the U.S. EPA identified a standard for PFOS that was 3,500 times higher than what it has identified as safe in the recent health advisory.³ ILEPA has stated that the purpose of this rulemaking is to keep Illinois groundwater quality standards "current as scientific data and methods supporting development of groundwater quality standards have evolved."⁴ Both the ubiquity of hazardous PFAS in Illinois' drinking water and other media and the exponentially smaller concentrations that the scientific community is realizing is harmful to human health dictate that the recent federal health advisory numbers be seriously considered in the present rulemaking.

I. Citizens Against Ruining The Environment

CARE is a not-for-profit Will County-based environmental education organization whose members live in several Will County communities that depend on groundwater resources for their drinking water supplies, including Lockport, Joliet and Crest Hill. In some cases, these residents receive their water through a municipal public water supplier. In other cases, like thousands of others in Will County, these residents are using private wells. In both cases, the primary source of drinking water is groundwater, making hundreds of thousands of Will County residents directly or indirectly impacted by groundwater quality.

For more than 30 years, CARE's mission has been to educate Will County residents about environmental issues that affect public health, safety, and welfare. PFAS contamination is now CARE's highest priority. Because of the potential impact of PFAS in Will County, CARE has joined forces with several other organizations to educate Will County residents about this public health issue. CARE has co-hosted several public meetings for Will County residents to educate them about PFAS and efforts in Illinois to address PFAS. As part of its efforts, CARE developed three fact sheets which have been distributed to hundreds of local residents. *See CARE Attachments 2 through 4 to these comments.*

Because of CARE's efforts, the Board may be receiving comments from individuals who live in Will County. The comments I'm submitting today are for CARE as an organization, not for any individual or other organization.

Clear and protective standards are necessary to inform the strategies used by groundwater-dependent Will County public water suppliers and private well users to evaluate and address risks. And this is exactly what the ILEPA delivers with its proposal, with the exception of its proposed PFOS standard. This is especially timely in Will County because many municipal

² Attachment 1 at 1.

³ *Id.* (U.S. EPA recently identified safe level of .02 parts per trillion for PFOS replaces 70 parts per trillion identified by U.S. EPA in 2016 "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.").

⁴ *Proposed Amendments to Groundwater Quality (35 Ill. Admin. Code 620)*, R2022-18, ILEPA, Statement of Reasons, p. 1, 12/07/2021 ("SOR").

water suppliers and their consumers are confronting long-term decisions about switching to Lake Michigan water in light of groundwater depletion and quality concerns. Clear and protective PFAS standards are an essential – and perhaps decisive – factor as part of this decision making. Needless to say, when ILEPA states that PFOS is safe at a level 385 higher than that identified by the U.S. EPA, both these municipality-wide decisions, and safe choices of every person residing in Will County that relies on groundwater, are shrouded in confusion. The Board should rationally employ the Illinois Groundwater Protection Act and rely on the best available science as envisioned by the ILEPA’s welcome proposal now to protect Illinois’ groundwater resource and the health of Illinois residents.

II. PFAS are Widespread in Will County Drinking Water.

Starting in September 2020, the ILEPA began a statewide PFAS investigation, which included community water supply sampling for 6 PFAS (PFOA, PFOS, PFBS, PFHxA, PFHxS, and PFHpA).⁵ Alarmingly, the results of this investigation show not only that 20 different Will County community water supplies contain PFAS, but that recorded levels exceed what the U.S. EPA recently identified as safe for humans by as much as 3,750 times.⁶ *See Appendix* (table showing PFAS recorded in Will County’s drinking water). One Will County community water supply contains levels of PFOA that are 7.5 times higher than the ILEPA’s own proposed PFOA groundwater quality standard (2 ng/L), a standard, it should be pointed out, that was set by reference to the lowest level of PFOA that can be detected, as opposed to the purely health-based level arrived at by ILEPA, which was nearly a quarter of that (0.6 ng/L). *See Section V.B. below.* While PFAS contamination in drinking water is a statewide public health issue,⁷ in this public comment, CARE is focusing on Will County.

What is more, just because no PFAS were detected does not mean that unsafe levels are not present in Will County community water supplies. To illustrate: the lowest level that both PFOA and PFOS can be detected at is 2 ng/L per the ILEPA,⁸ whereas the best available science indicates that anything above 0.004 ng/L for PFOA,⁹ and 0.02 ng/L for PFOS,¹⁰ is harmful to human health. What this means is that, with regards to PFOA, for example, levels that are around 475 times higher than what the best available science indicates is safe for humans may be present, yet undetectable in Will County community water supplies. CARE submits that this is likely the case given that PFOA levels were actually recorded at much higher levels in the County than the lowest detectable concentrations. That safe levels are so far below what can be detected counsels that regular updates should be made as detection capabilities improve.

⁵ ILEPA, *PFAS Statewide Investigation Network: Community Water Supply Sampling*, accessed 9/9/22, <https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-statewide-investigation-network.aspx/>

⁶ ILEPA, *Illinois EPA’s PFAS Sampling Network*, accessed 9/9/22,

<https://illinois-epa.maps.arcgis.com/apps/dashboards/d304b513b53941c4bc1be2c2730e75cf>

⁷ *Proposed Amendments to Groundwater Quality (35 Ill. Admin. Code 620)*, R2022-18, ILEPA, Testimony of Carol L. Hawbaker on Proposed Updated Groundwater Quality Standards, p. 15, 12/07/2021 (“Hawbaker Testimony”)

⁸ ILEPA, Attachment to *Health Advisory for PFOS*, 4/16/21, p. 2 (stating that “U.S. EPA’s Method 537.1 for analyses of PFAS drinking water samples states the PFOS MRL is 2 ng/L . . .”).

⁹ Interim Drinking Water Health Advisory: Perfluorooctanoic Acid (PFOA), U.S. EPA, Office of Water, Doc. No. EPA/822/R-22/003 (June 2022), at p. 10. This PFOA health advisory is included in this Public Comment as **CARE Attachment 5**.

¹⁰ Attachment 1 at 10.

Finally, CARE represents the interests of the many Will County residents who rely on either non-community-based public well systems or on private potable wells for their everyday domestic water supply. Neither of these water sources were included within ILEPA's statewide testing initiative.¹¹ CARE is gravely concerned about the high likelihood of contamination within private potable groundwater supplies throughout Will County if public water supplies already show such alarming levels of contamination.

The prevalence of these hazardous substances throughout Will County's water supplies is a major concern of CARE. Its members are residents of Will County who drink that water, bathe in that water, clean their dishes in that water, water their crops with that water, and otherwise utilize it every day. The issue of contamination in these water supplies is not abstract for CARE. It hits home in every sense of the word. As ardent advocates for safe, clean drinking water and as citizens immensely impacted by the ruling, CARE has a sizable stake in making sure Illinois' PFAS groundwater quality standards protect the health of the people of Will County.

CARE therefore encourages the Board to consider how households with self-supplied domestic water will obtain data about the safety of their water, how it will be brought up to safe standards, and who will be responsible for these activities. The proposed groundwater quality standards in this rulemaking are a welcome first step to address documented hazardous substances in the drinking water of Will County and statewide. However, given that miniscule concentrations of PFAS are harmful to human health, ILEPA must reconsider whether, in light of U.S. EPA's interim health advisories, their proposed standard for PFOS adequately protects residents from the harmful effects associated with consuming PFOS.

III. CARE is Particularly Concerned that Will County Groundwater Would be Deemed Safe if ILEPA's PFOS Standard Were Adopted, Whereas the Best Available Science Indicates Will County Groundwater Contains Astronomically Unsafe Levels.

PFAS are widespread in Will County community water supplies. As just one example, 6 different PFAS were detected in Will County drinking water at the same time. CARE maintains that this widespread confluence, considered in light of the ever-decreasing concentrations of PFAS found safe for humans, makes it imperative that the standards the Board adopts now reflect the best available science. Only then can CARE's constituents make informed health-based decisions regarding their drinking water. While ILEPA's proposal is a welcome first step, its groundwater quality standard for PFOS is problematic in that it would label as "safe" drinking water that contains concentrations of PFOS that are 385 times higher than the recently announced federal interim lifetime health advisory level reflecting the best available science according to the U.S. EPA (iHA level). The ILEPA states that 7.7 ng/L is safe, while the iHA level is 0.02 ng/L.¹²

The discrepancy—if a 385 times difference can be called that—is of pressing concern to CARE, an organization representing residents of largely groundwater-dependent Will County. Below is

¹¹ Hawbaker Testimony at p. 15.

¹² *Compare* Attachment 1 (federal interim health advisory), at 10, identifying .02 ng/L as safe, with groundwater quality standard proposed by the ILEPA (7.7 ng/L), at proposed, revised Section 620.410(b).

a chart¹³ comparing actually-recorded PFOS levels in Will County public water supplies to the recently announced iHA level for PFOS. Strikingly, Will County drinking water contains concentrations of PFOS that are up to 365 times higher than what the U.S. EPA determined is safe for humans. But the ILEPA’s proposed PFOS standard of 7.7 ng/L would deem all of this potentially hazardous Will County water “safe.”

Community Water Supply	Exceedance of U.S. EPA Health Advisory Level (ng/L)
Crest Hill TP 01-WELL 1	PFOS: 2.7 (135 times higher)
Crest Hill TP 03-Well 4	PFOS: 2.1 (105 times higher)
College View Subdivision TP 01-Well 1	PFOS: 2.2 (110 times higher)
Joliet Criswell Ct.	PFOS: 5.6 (280 times higher)
Joliet Ingalls Park Subd.	PFOS: 2.2 (110 times higher)
Rockdale TP 03-Well 3	PFOS: 7.3 (365 times higher)
Channahon TP 06 - COMBO OF FIN WTR WLS 2,3,5	PFOS: 5.1 (255 times higher)
Wilmington TP 03 Surface Water Treatment Plant	PFOS: 2.2 (110 times higher)

IV. No Groundwater Quality Standards Are Currently in Place in Illinois to Regulate PFAS, a Group of Hazardous Compounds Documented to be Extensive in Illinois Drinking Water.

PFAS have been measured in indoor air, outdoor air, dust, food, groundwater, surface water, drinking water, and various consumer products.¹⁴ Current scientific literature indicates that most exposure to the general public is through ingestion of food and water.¹⁵ PFAS chemicals bioaccumulate, or build up, in the blood and organs of humans.¹⁶ USEPA and State-led studies have linked PFAS exposure to numerous adverse health outcomes including: reproductive, developmental, liver, and kidney issues, negative immunological effects, reduced response to vaccines, low infant birth rates, pregnancy-induced hypertension, thyroid hormone disruption, and Kidney and testicular cancers.¹⁷

Certain subpopulations are at an increased risk. Children drink more water relative to their body weights than adults, have higher exposure to contaminated soils and household dusts, and do not eliminate chemicals from the body as easily as adults. As a result, children are more sensitive to

¹³ The recorded occurrences of PFAS in Will County public water supplies is taken from ILEPA, PFAS Statewide Investigation Network: Community Water Supply Sampling, accessed 9/9/22.

<https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-statewide-investigation-network.aspx/>

¹⁴ ILEPA, *Per- and Polyfluoroalkyl Substances (PFAS)* <https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/default.aspx> (last visited Sept. 21, 2022).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

the effects of PFAS at lower quantities and have greater exposure.¹⁸ Pregnant women also face heightened dangers from PFAS. PFAS can be transported through umbilical cord blood and breast milk to the unborn fetus and infant child.¹⁹ Given the bioaccumulative nature of these chemicals, it is important to minimize exposure before, during and after pregnancy.²⁰

Despite all of the known dangers PFAS present, PFAS in groundwater are not currently regulated in Illinois. CARE agrees with the ILEPA that Illinois needs PFAS groundwater standards immediately. PFAS is already a threat to Illinois groundwater.²¹ It is critical to the health and safety of Illinois residents that the Board adopt rules to address PFAS contamination. Research and data on the toxicity of PFAS and PFAS-like compounds will continue to evolve for decades. The alarmingly disparate toxicity values for PFOS relied on by the ILEPA and the U.S. EPA is a quintessential example. CARE agrees with ILEPA and urges the Board to adopt strict rules now, updating them in the future as more information becomes available.²² With regards to PFOS, more current health information is already available and should be incorporated into the rulemaking now, not after another generation has been exposed to water containing what the best sources indicate contain astronomically larger quantities of PFOS than is healthy.²³ Illinois has the authority and duty to set protective groundwater standards for PFAS and it should not wait for the U.S. EPA to offer final guidance.²⁴

V. The PFOS Class I Groundwater Quality Standard Adopted by the Board Should be Changed from the ILEPA-Proposed 7.7 ng/L to 2 ng/L, a Feasible Standard Based on the Best Available Science.

The striking difference between the ILEPA-proposed PFOS groundwater quality standard and the recent health advisory level is unexpected, since both the ILEPA and U.S. EPA seek to identify safe levels that protect all people, including the most vulnerable. As explained below, the difference is in large part the result of the U.S. EPA utilizing a much lower toxicity value than the value used by the ILEPA in arriving at health-based standards. Utilizing the U.S. EPA's toxicity value, rather than the outdated and ill-suited toxicity value ILEPA has chosen, is more consistent with a rational application of the welcome framework proposed and employed by the ILEPA itself in the present rulemaking (Section A below). Reliance on the U.S. EPA's recent toxicity value results in a standard that is below currently detectable limits. Therefore, again

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Proposed Amendments to Groundwater Quality (35 Ill. Admin. Code 620)*, R2022-18, March 9, 2022 Hearing Transcript, p. 27.

²² *Id.* at p. 47.

²³ See Proposed Rule: *Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFAS) as Cercla Hazardous Substances*, at 36-56 of 103, https://www.epa.gov/system/files/documents/2022-08/FRL%207204-02-OLEM%20_%20Designating%20PFOA%20and%20PFOS%20as%20HHS%20_NPRM_20220823.pdf where the proposal designates all the extreme negative health consequences of PFOS (and PFOA) including multiple forms of cancer, reduce birthweight in new born children, immune system problems, and cardiovascular problems. Further, PFOS has a half-life of somewhere in between 3.3 and 27 years, causing these substances to build up in the human body.

²⁴ See 415 ILCS 55/2(b) (policy of Illinois “to restore, protect, and enhance” its groundwater so “waste and degradation of the [groundwater] resources be prevented.”)

utilizing the framework proposed by the ILEPA in this rulemaking, the groundwater quality standard should be set at the lowest level that can reliably be detected according to the ILEPA (Section B below). Lowering the PFOS Class I groundwater quality standard from 7.7 ng/L (ILEPA's present proposal) to 2 ng/L (the lowest detectable concentration per ILEPA) is consistent with the dictates of the Illinois Groundwater Protection Act and the Board's construction thereof, since it is both based on the best available science and is feasible (Section C below).

- A. *The toxicity value used to calculate the U.S. EPA's health advisory level for PFOS should be used to set the PFOS groundwater quality standard in Illinois.*

The startling difference between ILEPA's proposed PFOS groundwater quality standard (7.7 ng/L) and the recently announced interim health advisory level (.02 ng/L) is, for the most part, the result of choosing different toxicity values. ILEPA bases their proposed standard on a toxicological profile last updated in March 2020 and finalized (though not updated) by the Agency for Toxic Substances and Disease Registry ("ATSDR") in June 2021.²⁵ ATSDR, over two years ago, identified an intermediate-duration oral minimal risk level of 0.000002 mg/kg-day ("MRL").²⁶ An intermediate-duration, for purposes of this ATSDR calculation, is exposure for between 15 and 364 days to the substance under discussion.²⁷ ATSDR arrived at this MRL based solely on an analysis of laboratory animal data, which found the critical effect of "delayed eye opening and decreased pup weight in rats" to occur at amounts above the MRL of 0.000002 mg/kg-day over the intermediate-duration period of 15-364 days.²⁸ The study informing ATSDR's derivation of the MRL is nearly 20 years old.²⁹

By contrast, the U.S. EPA, in deriving its interim lifetime health advisory level, identified a reference dose of 0.000000079 mg/kg-day, a level "to protect all Americans, including sensitive populations and life stages, from adverse health effects resulting from exposure *throughout their lives*" to PFOS.³⁰ In arriving at this astronomically lower number, the U.S. EPA employed a "systematic review process [that] has been peer reviewed and is used by EPA's Office of Research and Development's (ORD) Integrated Risk Information System (IRIS) program."³¹ Unlike the ATSDR-identified intermediate MRL, the U.S. EPA based their number on a human study, finding "deficient antibody response to diphtheria vaccine in children" as a result of PFOS exposure during a developmental life stage, which "can result from even brief exposure during a critical period of development."³² The U.S. EPA in 2022 did not rely on solely animal studies,

²⁵ Hawbaker Testimony at pp. 10-11.

²⁶ U.S. Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Perfluoroalkyls*, Released May 2021, Last Updated March 2020, at p. 17.

²⁷ *Id.*

²⁸ *Id.* at 17, 20.

²⁹ *Proposed Amendments to Groundwater Quality (35 Ill. Admin. Code 620)*, R2022-18, Pre-Filed Testimony of Stephen P. Risotto of the American Chemistry Council, p. 12, 09/15/2022 ("The proposed groundwater standard for PFOS is based on ATSDR's analysis of a two-generation study by Luebker et al. (2005).")

³⁰ Attachment 1 at 1, 10 (emphasis added).

³¹ *Id.* at 4-5.

³² *Id.* at 6.

as the ATSDR did in deriving its reference dose in 2020. Rather, the U.S. EPA arrived at the reference dose after review of human studies.³³

The ILEPA, in proposing revisions to Section 620 in the present rulemaking, has rightfully determined that an “acceptable daily exposure” to PFOS and other harmful substances should be determined by reference to amounts “which if ingested daily by a child for 0 to 6 years of age results in no adverse effects.”³⁴ As more fully expressed in Section VII below, CARE wholeheartedly supports this proposed change, especially considering PFAS bioaccumulates in the human body. At first blush, the ILEPA’s approach would seem different than that employed by the U.S. EPA in arriving at a lifetime health advisory level, since the U.S. EPA figure is based on exposure over a lifetime, whereas the ILEPA proposes considering exposure during the first six years of life. However, as the U.S. EPA explained when releasing its PFOS health advisory, “risk assessment guidelines indicate that adverse effects can result from even brief exposure during a critical period of development” and as such the lifetime iHA for PFOS . . . and the draft chronic RfD [toxicity value] from which it is derived . . . are considered applicable to short-term PFOS exposures via drinking water.”³⁵ Similarly, as the ILEPA explains, “adjusting the exposure factors from an adult to a young child protects both children and adults from harmful effects of exposure via ingestion of chemicals in drinking water.”³⁶ The laudable, shared goal of both the ILEPA and U.S. EPA—protecting the most vulnerable and thereby protecting everyone else—is best served by utilizing the U.S. EPA’s toxicity value, as it best aligns with that shared goal. Working within the very framework proposed by the ILEPA in this rulemaking, it makes abundantly more sense to base a toxicity value on adverse reactions in young children than exposure for under a year in rats. This conclusion is buttressed by the systematic review process employed by the U.S. EPA in arriving at its health advisory number.

A feature of the revisions to Section 620 proposed by the ILEPA in this rulemaking is the explicit recognition of the use of the U.S. EPA’s OSWER toxicity hierarchy, which ranks sources of toxicity values.³⁷ The most valued source for toxicity values under the hierarchy proposed by the ILEPA is the U.S. EPA’s Integrated Risk Information System (“IRIS”).³⁸ Recall that the U.S. EPA states that it arrived at its toxicity value for PFOS using IRIS’s systematic review process.³⁹ Compare that to ATSDR toxicity values, upon which the ILEPA’s proposed PFOS standard is based, which is two steps below IRIS per the hierarchy.⁴⁰

³³ *Id.* at 7; *see also* 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, Office of Water, Doc No. EPA 822D21002 (Nov. 2021), at p. 311 (summarizing “updated review” of human epidemiological studies, that formed the basis of the U.S. EPA’s June 2022 PFOS interim health advisory concentration, which “indicates an association between increased serum levels of PFOS and decreased antibody production following routine vaccinations, particularly in children Overall, the Faroe Islands studies observed associations between elevated levels of PFOS and decreased adjusted levels against tetanus and diphtheria in children at birth, 18 months, age 5 years (pre-and post-booster), and at age 7 years, with some being statistically significant.” (internal citations to health studies omitted).

³⁴ Hawbaker Testimony at pp. 6-8.

³⁵ Attachment 1 at 6-7.

³⁶ Hawbaker Testimony at p. 6.

³⁷ *Id.* at p. 7.

³⁸ Hawbecker Testimony at pp. 6-8.

³⁹ Attachment 1 at 4-5.

⁴⁰ Hawbecker Testimony at pp. 6-8.

- B. *Given that safe levels of PFOS are well below detectable levels, the groundwater quality standard should be set at the lowest concentration that can reliably be detected pursuant to the ILEPA's own proposed amendments to Section 620.*

Utilization of the U.S. EPA's toxicity value for PFOS results in a standard that is well below what can be detected. According to the ILEPA, the lowest concentration of PFOS that can be reliably detected is 2 ng/L,⁴¹ whereas the purely health-based standard is 0.02 ng/L.⁴² In other words, the detectable level is 100 times higher than what is safe for all people according to the best available science. CARE suggests that the groundwater quality standard should therefore be set at 2 ng/L.

As detailed below, setting the groundwater quality standard to a detection limit is both envisioned by the revisions proposed by the ILEPA, and was actually done with regards to the setting of the PFOA standard by the ILEPA itself in this rulemaking. CARE submits the same should be done with PFOS—another widely prevalent, hazardous PFAS.

Part 620, Subpart F and Appx. A provide the basis for developing new and revised numerical groundwater quality standards. Ill. Admin. Code. 620.601(c).⁴³ Pursuant to ILEPA's proposed amendments to Section 620, Subpart F, if the guidance level of any substance, calculated pursuant to the formulas in Sec. 620, Appx. A, is less than what can be detected, "the guidance level is the lowest appropriate LLOQ or LCMRL." Part 620.605(b)(1) (Subpart F). The PFOA Class I groundwater quality standard proposed by ILEPA in this rulemaking was set in this fashion—by pegging the standard to the lowest level that can be detected. *See* ILEPA, Pre-Filed Responses to PFAS Regulatory Coalition's Questions, 3/7/22, at 2 ("calculated PFOA HNTAC of 0.0000006 mg/L (0.6 ng/L) is less than the LCMRL for PFOA; therefore, pursuant to Part 620.605(b)(2), the Illinois EPA selected the LCMRL of 0.000002 mg/L (2 ng/L) as the proposed PFOA groundwater quality standard.").

Since utilizing the toxicity value for PFOS identified by the best available science results in a concentration well below what can be detected, the Board should set the Class I groundwater quality standard for PFOS at the lowest level that can be detected determined by the ILEPA (2 ng/L). As demonstrated above, this suggested approach is consistent with the overall framework proposed and actually employed by the ILEPA in arriving at its proposed standards in the present rulemaking.

⁴¹ ILEPA, Attachment to *Health Advisory for PFOS*, 4/16/21, p. 2 (stating that "U.S. EPA's Method 537.1 for analyses of PFAS drinking water samples states the PFOS MRL is 2 ng/L . . .").

⁴² Attachment 1 at 10.

⁴³ *See also* Hawbaker Testimony at pp. 2-3.

- C. *Setting the PFOS groundwater quality standard at the lowest level that can be detected is permissible under the Groundwater Protection Act's requirement that the Board consider the feasibility of standards it adopts, and best furthers the Board's expectation that groundwater quality standards reflect the best available science.*

The Illinois Legislature, via the Illinois Groundwater Protection Act, has chosen to employ a policy that is both remedial and preventative in nature with regards to preserving the groundwater resource. *See* 415 ILCS 55/2(b) (policy of Illinois “to restore, protect, and enhance” its groundwater so “waste and degradation of the [groundwater] resources be prevented.”). In heeding the Legislature’s call, the Board has characterized groundwater standards as “directed toward an early alert to, and staving off of, any increase in contamination in the sensitive groundwater/ potential source situations.”⁴⁴ Exhibiting a rational recognition that our understanding of the harmful effects of various substances is a continually-evolving enterprise, the Board has stated that “it expects from the [ILEPA] regular updates of the groundwater standards.”⁴⁵ Therefore, the ILEPA has proposed multiple rounds of amendments to the comprehensive quality standards throughout the years, including in the present rulemaking, to keep the standards “current as scientific data and methods supporting development of groundwater quality standards have evolved.”⁴⁶

The recent U.S. EPA-identified concentration of 0.02 ng/L is the “concentration level [of PFOS] . . . at or below which exposure for a [lifetime] is not anticipated to lead to adverse human health effects.”⁴⁷ In arriving at this figure, the U.S. EPA systematically reviewed the best available peer-reviewed science.⁴⁸ Indeed, the health advisory figure is purely health-based, and does not take into account “technical feasibility and economic reasonableness of measuring or reducing the particular type of pollution,” as the Illinois Legislature has directed the Board to do when setting groundwater quality standards. 415 ILCS 55/8(b); 415 ILCS 5/27(a).

That is why CARE is not advocating for the groundwater quality standard for PFOS to be 0.02 ng/L—the health advisory level. CARE does not believe it would be feasible to set a standard that cannot be confirmed via current detection techniques and is mindful that the Legislature has directed the Board to take into account “existing methods of detecting and quantifying contaminants with reasonable analytical certainty” when setting groundwater quality standards. 415 ILCS 55/8(b)(6). Rather, CARE suggests the PFOS standard be set at 2 ng/L, itself 100 times higher than the purely health-based level recently identified by the U.S. EPA. CARE suggests 2 ng/L since it is the lowest concentration of PFOS that can be detected according to the ILEPA.

The Groundwater Protection Act further directs the Board to show a “preference for numerical water quality standards where possible, over narrative standards, especially where specific contaminants have been commonly detected in groundwaters or where federal drinking water

⁴⁴ *Groundwater Quality Standards (35 Ill. Adm. Code 620)*, R89-14(B) GQS, slip op. at 16 (“R89-14(B)”).

⁴⁵ *Id.* at 19.

⁴⁶ SOR at p. 1.

⁴⁷ Attachment 1 at 1.

⁴⁸ Attachment 1 at 7.

levels or advisories are available.” 415 ILCS 55/8(b)(3). A federal drinking water advisory is available, PFOS has been commonly detected in drinking water, and 2 ng/L is a numerical standard.

In sum, selecting 2 ng/L as the Class I groundwater quality standard for PFOS is consistent with the approach the Board has taken in prior rulemakings implementing the directives of the Groundwater Protection Act. The Board has viewed groundwater quality standards as “rule[s] of general applicability,”⁴⁹ with economic impacts resulting not from the mere existence of the standards, but rather from their implementation as part of other programs. *See, e.g., Groundwater Quality Standards (35 Ill. Adm. Code 620)*, R08-18, Final Order at 25 (Board explaining that, since groundwater quality standards “do not require any new corrective action program” and “all such programs are part of other regulations already in place or proposed . . . [i]t is accordingly not appropriate to attribute to today’s regulations the cost of corrective actions that are not prompted by today’s regulations.”) (emphasis in original).

CARE acknowledges that the federal health advisory level is provisional. It appears that the ILEPA dismisses it on this ground and prefers to wait for a finalized MCLG from the USEPA.⁵⁰ However, given the striking trend of exponentially decreasing safe concentrations of PFOS identified by evolving scientific understanding, CARE submits that it is highly unlikely that a finalized MCLG, a figure based on the same considerations as the iHA level,⁵¹ would increase 100-fold over the iHA level identified by the USEPA this past summer. It must be remembered that CARE is not advocating that the PFOS standard be set to 0.02 ng/L, which would be unworkable given the lowest concentrations that can be detected are 100 times higher. The Board should set the PFOS Class I groundwater quality standard at 2 ng/L.

VI. With the Exception of PFOS, ILEPA’s Proposed Standards for PFAS Otherwise Align with Current Scientific Knowledge and Methodology.

CARE supports the ILEPA’s use of the latest, peer-reviewed scientific data as a foundation for the proposed Class I groundwater quality standards (“GQS”). With the exception of PFOS, this is what the ILEPA has done.⁵² ILEPA’s proposed GQS are derived from a procedure of 35 Ill. Adm. Code 620, Appx. A, which determines a Human Threshold Toxicant Advisory Concentration.⁵³ This method uses several factors, including: 1) the acceptable daily exposure (ADE), or toxicity value, of a substance which if ingested daily will result in no adverse health effects for humans; 2) the relative contribution drinking water has to the total amount of exposure of a chemical; and 3) a person’s average daily water consumption.⁵⁴ This method is

⁴⁹ R89-14(B) at 25.

⁵⁰ *See Proposed Amendments to Groundwater Quality (35 Ill. Admin. Code 620)*, R2022-18, June 21, 2022 Hearing Transcript, pp. 34-35.

⁵¹ The MCLG is solely health-based, 40 CFR § 141.2, as is the health advisory number, *see* Attachment 1.

⁵² In June 2022, the U.S. EPA issued final lifetime health advisory levels for PFBS and GenX, which align with the concentrations proposed by the ILEPA in the present rulemaking. *See* Technical Fact Sheet: Drinking Water Health Advisories for Four PFAS (PFOA, PFOS, GenX chemicals, and PFBS), U.S. EPA, Office of Water, Doc. No. EPA 822-F-22-002 (June 2022), included as **Attachment 6 to this Public Comment**.

⁵³ *Proposed Amendments to Groundwater Quality (35 Ill. Admin. Code 620)*, R2022-18, ILEPA, Initial Filing Package, p. 4903 of combined PDF, 12/07/2021.

⁵⁴ *Id.*

consistent with the US EPA's methodology for non-carcinogen chemicals while carcinogen chemicals, like PFOA, utilize a similar, but more stringent equation.⁵⁵

The ILEPA's amendments adjust the language of 35 Ill. Adm. Code 620 to allow the use of the U.S. EPA's OSWER toxicity hierarchy.⁵⁶ The toxicity hierarchy ranks various scientific studies and is consistent with the Board's own approach to evaluating the risk to human health posed by environmental conditions, TACO.⁵⁷ CARE supports use of this hierarchy, but maintains that a wooden application of it by the ILEPA with regards to PFOS could lead to results that do not reflect the best available science.

CARE supports treating PFOA as a carcinogen. The International Agency for Research on Cancer (IARC) has classified PFOA as potentially carcinogenic, which meets the definition of a carcinogen in Section 620.110.⁵⁸ As such, ILEPA calculated a non-carcinogenic standard (ATSDR) and a carcinogenic standard based on a recent peer-reviewed study conducted by the California EPA, another highly ranked tier 3 study, and utilized the more stringent standard.⁵⁹ Furthermore, ILEPA utilized another tier 3 study from October, 2021 conducted by the US EPA's Office of Water Toxicology profile for the GQS value for GenX.⁶⁰ CARE supports the use of these recent, reliable values and urges that the same be done with regards to PFOS.

VII. CARE Supports Illinois EPA's Proposal to Utilize Child Exposure Factors

CARE supports the ILEPA's proposal to use child exposure levels in determining toxicity levels for PFAS. Following multiple comments made during community outreach sessions in the early stages of the rulemaking process, the ILEPA amended their proposed GQS for PFAS.⁶¹ These proposed changes adjust the equation used to determine toxicity values for a given chemical compound discussed above. The proposed change adjusts the per capita daily water consumption and average body weight of an average adult to that of an average child (age 0-6).⁶²

This adjustment is consistent with the Board's tiered approach to corrective action objectives (TACO)⁶³ and consistent with U.S. EPA methodology.⁶⁴ The source of the child exposure factor is the U.S. EPA's Office of Solid Waste and Emergency Response (OSWER) directive 9200.1-120.⁶⁵ OSWER's directive offers guidance to U.S. EPA offices in human health evaluation.⁶⁶ Furthermore, the childhood exposure factors are also listed at the U.S. EPA's Regional Screening Levels for Chemical Contaminants at Superfund Sites (RSL).⁶⁷ The RSL database and equations

⁵⁵ *Id.*

⁵⁶ Hawbaker Testimony at p. 7.

⁵⁷ 35 Ill. Adm. Code 742.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 12.

⁶¹ SOR at p. 18.

⁶² Hawbaker Testimony at p. 5.

⁶³ 35 Ill. Adm. Code 742.

⁶⁴ SOR at p. 13.

⁶⁵ Hawbaker Testimony at p. 5.

⁶⁶ *Id.*

⁶⁷ *Id.*

use the most up-to-date methodologies, exposure factors assumptions, chemical-physical properties, and toxicity values within OSWER's toxicity hierarchy.⁶⁸

The ILEPA's change to child exposure factors for toxicity values used to calculate the proposed PFAS GQS is significant. The standards will now be protective of the most vulnerable citizens, including children, the immunocompromised, and pregnant women from harmful effects associated with the ingestion of PFAS contaminated groundwater described earlier.⁶⁹ By protecting groundwater used for drinking, irrigation, and livestock from PFAS contamination at levels protective of the vulnerable the ILEPA and the Board will be ensuring safe, clean groundwater for all of Illinois' citizens.

VIII. CARE Supports Proposed Wellhead Protection Areas

Many Will County residents receive their domestic water from wells rather than public water supplies. Adopting PFAS GQS is the first step toward ensuring that household well users can obtain safe groundwater for drinking. The availability of data on self-supplied domestic water is limited. However, a 2012 report from the Illinois State Water Survey Prairie Research Institute indicates that, as of 2005, 395,000 people in Northeastern Illinois obtained water from household wells.⁷⁰ To better protect well users from PFAS, CARE endorses the ILEPA's proposal to extend wellhead protection areas around community wells.⁷¹ The groundwater in the proposed wellhead protection area is expected to enter the well within five (5) years.⁷² Requiring the water surrounding the wellhead to be free from PFAS provides an additional layer of protection that is essential given the toxicity and documented prevalence of PFAS.

IX. Illinois EPA's Proposed Amendment is One Progressive Piece of an Extensive, Widespread Response to Address the Dangers of PFAS and Aligns with Similar Rulemakings from States, Federal Agencies, and the International Community

The proposed amendment to 35 Ill. Adm. Code 620 includes GQS for six PFAS chemicals: PFOS, PFOA, PFNA, PFBS, PFHxS, and GenX. Identification of these six PFAS for regulation follows several years of evolving understandings of PFAS chemicals, statewide testing, and community outreach. The ILEPA's statewide investigation into the prevalence and occurrence of PFAS in finished drinking water resulted in detections of all six proposed PFAS compounds.⁷³ These are the compounds we know to be in our water and CARE fully supports ILEPA tackling these specific PFAS compounds. The proposed standards generally align with the direction of regulatory requirements, enforcement actions, and other activities of many federal, state, and international entities.

⁶⁸ *Id.* at 6.

⁶⁹ *Id.* at 5

⁷⁰ Illinois State Water Survey, Prairie Research Inst., Northeastern Illinois Water Planning Investigations: Opportunities and Challenges of Meeting Water Demand in Northeastern Illinois, March 2012, p. 5.

⁷¹ *Proposed Amendments to Groundwater Quality (35 Ill. Admin. Code 620)*, R2022-18, ILEPA, Testimony of Lynn Dunaway, Initial Filing Package, p. 4875 of combined PDF, 12/07/2021.

⁷² *Id.* at 4876.

⁷³ Hawbaker Testimony, p. 15.

Illinois standards are in line with other states that are protecting their citizens from these widely found, hazardous chemicals. A study conducted by the Environmental Council of States (ECOS), last updated in April 2021, surveyed thirty state efforts to combat PFAS contamination.⁷⁴ Twenty-two states have implemented regulatory standards or advisory levels for various PFAS compounds with nineteen specifically having guidelines for groundwater.⁷⁵ Of the eight states without PFAS guidelines, six have state laws prohibiting drinking water or groundwater guidelines more stringent than federal levels.⁷⁶ This dissuades states from implementing guidelines that may later be overturned when federal guidelines are enacted. However, ECOS found that many states which have not implemented PFAS guidelines are still taking actions to monitor, investigate, and remediate PFAS.⁷⁷

The ILEPA is not creating the PFAS GQS without precedent. There are many other states which have similarly reviewed the scientific data regarding the necessity to regulate PFAS and have come to similar conclusions. Of the states which have implemented groundwater guidelines, virtually all of them have specifically regulated PFOA and PFOS and around half have implemented levels for PFBS and PFNA.⁷⁸ ILEPA is also not the first to contemplate standards for GenX nor PFBS.⁷⁹ Furthermore, most states have chosen to implement guidelines for individual PFAS compounds, like the ILEPA.⁸⁰

The proposed interim health advisories from the U.S. EPA are not their first efforts in controlling PFAS. The EPA began regulating PFAS as early as 2002, finalizing a number of Toxic Substances Control Act (TSCA) Section 5(a) Significant New Use Rules (SNURs), covering hundreds of existing PFAS.⁸¹ U.S. EPA has issued drinking water health advisories for PFOS and PFOA starting in 2009, releasing more and more stringent values until the most recent interim health advisories in 2022.⁸² Interim Recommendations to Address Groundwater Contaminated with PFOA and PFOS were issued in 2019 which provide a starting point for making site-specific cleanup decisions.⁸³ Other actions by the EPA include requiring notice and EPA review before reuse of phased-out PFAS could begin again, adding 172 PFAS to the Toxics Release Inventory, EPA Science Advisory Board review of independent scientific PFAS studies, and EPA regulatory action under RCRA.⁸⁴

The Federal Government is addressing PFAS through more than just the U.S. EPA. Besides the above-described ATSDR efforts, the Department of Defense (DoD) included PFOS and PFOA

⁷⁴ Sarah Longworth, *Processes & Considerations for Setting State PFAS Standards*, Environmental Council of the States, 8 (updated Apr. 29, 2021), <https://www.ecos.org/wp-content/uploads/2021/04/Updated-Standards-White-Paper-April-2021.pdf>.

⁷⁵ *Id.* at 9-10.

⁷⁶ *Id.* at 8.

⁷⁷ *Id.*

⁷⁸ *Id.* at 33.

⁷⁹ *Id.*

⁸⁰ *Id.* at 10-11.

⁸¹ Proposed Rule: Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFAS) as CERCLA Hazardous Substances, at 58 of 103 https://www.epa.gov/system/files/documents/2022-08/FRL%207204-02-OLEM%20%20Designating%20PFOA%20and%20PFOS%20as%20HSS%20_NPRM_20220823.pdf

⁸² *Id.* at 58-60.

⁸³ *Id.* at 60.

⁸⁴ *Id.* at 60-64.

on its list of emerging chemicals of concern.⁸⁵ The Department of Energy issued a memo that focused on four main points: 1) discontinue use of AFFF except in emergencies, 2) suspend disposal of AFFF pending further guidance, 3) establish reporting requirements for any release or spill of PFAS, and 4) establish a DOE PFAS Coordinating Committee.⁸⁶ And finally, the Food and Drug Administration reached voluntary agreements with manufacturers and suppliers of long chain PFAS subject to Food Contact Notification to no longer sell those substances for use in food contact applications and revoked any remaining exceptions by 2016.⁸⁷

The United States is not the only country taking a protective stance against PFAS. The international community began restricting PFOS products at the 2009 Stockholm Convention, agreeing to limit production and use of PFOS, but included significant exceptions.⁸⁸ PFOS has been classified as a persistent, highly bio-accumulative organic pollutant and is subject to international treaties and individual country regulations pertaining to its production, use, and release to the environment.⁸⁹ The European Union set safety levels for PFOS and PFOA in 2018 and called for the elimination of all non-essential uses in 2019.⁹⁰ A number of countries have issued standards and guidance values for PFOS and PFOA, including Australia, Canada, China, Japan, Denmark, Norway, and New Zealand.⁹¹ These standards include health advisory levels, production or manufacture limits, and bans.⁹²

It is hard to ignore the writing on the wall, given the striking trend of exponentially-decreasing safe levels of PFAS as revealed by the best available science. Michigan, for example, in adopting some of the nation's strongest PFAS regulations on July 22, 2020,⁹³ reviewed both existing and proposed health-based drinking water standards from around the nation and noted the trend of PFAS guidelines throughout the country becoming stricter and stricter over time as a result of evolving science.⁹⁴ The recent safe level of PFOS identified by the U.S. EPA is another example. With the exception of the PFOS GQS, CARE welcomes the ILEPA's proposal, which is in line with leading states all part of a national trend implementing the newest, peer-reviewed scientific studies to derive ever-diminishing safe levels of PFAS. CARE implores the same be done with regards to PFOS so as to protect the health of Will County residents while the Board has the chance.

X. Conclusion

CARE endorses the addition of six new PFAS and PFAS-like chemicals to Illinois groundwater standards. The rapidly evolving understanding of the public health impacts of PFAS is moving

⁸⁵ *Id.* at 65-67

⁸⁶ *Id.* at 67-68

⁸⁷ *Id.* at 68.

⁸⁸ *Id.* at 86-87.

⁸⁹ *Id.* at 86.

⁹⁰ *Id.* at 87.

⁹¹ *Id.* at 88-92.

⁹² *Id.*

⁹³ EGLE Media Office, *Michigan Adopts Strict PFAS in Drinking Water Standards*, Department of Environment Great Lakes and Energy (July 22, 2020), https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-534663--00.html.

⁹⁴ Jamie Dewitt, *Health-Based Drinking Water Value Recommendations*, 26-27 (June 27, 2019), http://www.akleg.gov/basis/get_documents.asp?session=32&docid=25701.

in one direction – that there are no safe levels of PFAS exposure. The U.S. EPA is only beginning its regulatory journey, especially related to safe drinking water standards. CARE is grateful that the ILEPA is at the forefront of developing protective standards for groundwater resources and urges the Board to proceed in the same proactive and protective spirit by adopting the proposed regulations and recognizing the best available science in setting the PFOS standard. CARE believes the proposed standards and methods for determining toxicity levels will better protect Will County residents and their groundwater resources and similarly situated communities in Illinois. CARE strongly endorses the ILEPA’s progressive approach, which, with the exception of the PFOS Class I groundwater quality standard, aligns with the best quality existing and emerging data related to the hazards of PFAS. CARE urges the Board to proceed in the same proactive and protective spirit by adopting the proposed regulations.

Sincerely,

/s/ Keith Harley

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APPENDIX

PFAS Recorded in Will County Public Water Supplies (as of September 9, 2022)

All numerical units expressed in ng/L

Key:

iHA: Interim Health-based concentrations identified by the U.S. EPA in June 2022.⁹⁵

HA: Final Health-based concentrations identified by the U.S. EPA in June 2022.⁹⁶

GQS: The groundwater quality standards proposed by the ILEPA in this rulemaking.⁹⁷

	PFOA iHA: 0.004 GQS: 2	PFOS iHA: 0.02 GQS: 7.7	PFBS HA: 2000 GQS: 1200	PFHxA (no GQS or HA/iHA)	PFHxS GQS: 77 (no HA/ iHA)	PFHpa (no GQS or HA/iHA)
Channahon (TP 06-Wells 2, 3, 5)	5.4	5.1	15.0	13.0	2.0	3.7
College View Subdivision (TP 01-Well 1)		2.2	4.2			
Crest Hill (TP 01-Well 1)	15.0	2.7	34.0	18.0	6.4	16.0
Crest Hill (TP 03-Well 4)	2.5	2.1	2.9	3.5	11	n/a
Crest Hill (TP 05-Well 7)	3.1		9.9	5.1		3.6
Crest Hill (TP 06-Well 8)	2.6		3.9	6.4	4.9	
Crest Hill (TP 07-Wells 9, 12)			4.3			

⁹⁵ See See Technical Fact Sheet: Drinking Water Health Advisories for Four PFAS (PFOA, PFOS, GenX Chemicals and PFBS), U.S. EPA, Office of Water, Doc. No. EPA 822/F-22-002 (June 2022).

⁹⁶ *Id.*

⁹⁷ See ILEPA's proposed amendments to Section 620.410 (Groundwater Quality Standards for Class I: Potable Resource Groundwater).

	PFOA iHA: 0.004 GQS: 2	PFOS iHA: 0.02 GQS: 7.7	PFBS HA: 2000 GQS: 1200	PFHxA (no GQS or HA/iHA)	PFHxS GQS: 77 (no HA/ iHA)	PFHpa (no GQS or HA/iHA)
Crest Hill (TP 08-Well 10)	13.0		37.0	18.0	4.2	14.0
Crisswell Court (TP 02-Well 2)	7.2	5.6	3.4	7.3	2.5	4.6
East Moreland Water Service Assn. (TP 01-Well 1)			5.0			
Garden Street Improvement Assn. (TP 01)			7.2			
Ingalls Park Subdivision (TP 01-Wells 1, 2)		2.2	2.8			
Lockport (TP 12-Well 11)			2.4	2.2	5.4	
Minooka (TP 03-Wells 3, 6, 7)	2.2		2.9			
Rockdale (TP 03-Well 3)	2.0	7.3				
Rockdale (TP 05-Well 7)	3.6		2.4	3.4		3.2
Romeoville (TP 04-Well 5)				7.3		4.2
Romeoville (TP 02-Well 3, 4)				11.0		3.1
Sunnyland Subdivision (TP 01-Well 1)			3.6			
Wilmington (TP 03-Surface Water)		2.2	2.1	6.7		

CARE ATTACHMENT 1



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

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

NOAEL	no-observed-adverse-effect level	SAB	Science Advisory Board
NOM	natural organic matter	SAB PFAS Panel	Science Advisory Board Per- and Polyfluoroalkyl Substances Review Panel
NPDWR	National Primary Drinking Water Regulation		
OGWDW	Office of Ground Water and Drinking Water	SDWA	Safe Drinking Water Act
ORD	Office of Research and Development	SNUR	Significant New Use Rule
OST	Office of Science and Technology	TSCA	Toxic Substances Control Act
OW	Office of Water	UCMR	Unregulated Contaminant Monitoring Rule
PAC	powdered activated carbon		
PBPK	physiologically-based pharmacokinetic	UCMR 3	third Unregulated Contaminant Monitoring Rule
PFAS	per- and polyfluoroalkyl substances	UCMR 5	fifth Unregulated Contaminant Monitoring Rule
PFBS	perfluorobutane sulfonic acid	UF	uncertainty factor
PFOA	perfluorooctanoic acid	UF _A	interspecies uncertainty factor
PFOS	perfluorooctane sulfonic acid	UF _C	composite uncertainty factor
pK _a	acid dissociation constant	UF _D	database uncertainty factor
POD	point of departure	UF _H	intraspecies uncertainty factor
POD _{HED}	point of departure human equivalent dose	UF _L	lowest observed adverse effect level-to-no observed adverse effect level extrapolation
ppq	parts per quadrillion		
ppt	parts per trillion		
PWS	public water system		
QC	quality control	UF _S	subchronic-to-chronic exposure duration extrapolation uncertainty factor
RfD	reference dose		
RfV	reference value		
RO	reverse osmosis		
RPF	relative potency factor	µg/L	microgram per liter
RSC	relative source contribution		

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 noncancer lifetime 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

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 2021⁴ 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

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 506 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

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 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 UCMR5, 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 for 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 based on updated toxicity information 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 life stage, when identified. The Joint Institute for Food Safety and Applied Nutrition's Food Commodity Intake Database (FCID) Consumption Calculator Tool⁸ includes the EPA EFs and

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.

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

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 HA Calculation

The following equation 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.

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

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 HA 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-day)	PFOS Exposure in Critical Study	Critical Effect	Principal and Associated Studies (Study Type)
<i>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]</i> (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-day = milligram per kilogram 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 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 $\sim 10^{-7}$ to 10^{-9} milligrams per kilogram per day (mg/kg-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-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	<i>Exposure Factors Handbook</i> , 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 bodyweight 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 described in the draft PFOS document). 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%. 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:

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

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

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

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

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

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

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

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 (Söregård 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 by-product (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).

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 results 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 methylene blue numbers are most correlated with higher PFOS removal (Söregård et al., 2020). Installing activated carbon as a treatment method may also have ancillary benefits on finished water quality, particularly regarding disinfectant byproduct control, other contaminants, and 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). In conclusion, 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 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 options 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.

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

$$HI = HQ_{PFOA} + HQ_{PFOS} + HQ_{GenX} + HQ_{PFBS} \tag{Eq. 3}$$

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

Where:

HI = hazard index

n = the number of component (i) PFAS

HQ_i = hazard quotient for component (i) PFAS

E_i = human exposure for component (i) PFAS

RfV_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 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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CARE ATTACHMENT 2

August 2022: Drinking water from many sources in Will County contains amounts of harmful chemicals known as PFAS that greatly exceed health-based concentrations recently identified by the federal government.

What are PFAS?

PFAS, known as **forever chemicals**, are a group of virtually indestructible, odorless and tasteless human-made toxic chemicals that build up in the human body and take years to leave. In widespread commercial use since the 1940s for a variety of commercial and household applications, it was only in the last 20 years that forever chemicals' harmful effects on human health—and prevalence in drinking water—received any widespread public attention. The United States EPA (USEPA) and others in the scientific community are increasingly realizing that exposure to very small amounts of several PFAS can cause cancer and other diseases, including testicular and kidney cancer, birth defects, liver damage, impaired fertility, immune system disorders, high cholesterol and obesity. This summer, in what the USEPA is calling an “urgent or rapidly developing situation,” it announced an interim safe level of one PFAS in drinking water that is **17,500 times lower** than the level the USEPA itself identified only 8 years ago.

Summer 2022 Federal Health Advisories

In June 2022, the USEPA, after analyzing a multitude of health studies, determined that safe concentrations of 4 widespread PFAS in drinking water are far lower than it previously advised. The below table summarizes the recent USEPA health advisories. These levels are not legally enforceable, though the USEPA has announced its plans to begin the process of setting nationwide, legally enforceable maximum concentrations in the fall of 2022, which it expects to finalize by the end of 2023. The health-based levels identified below are also subject to change. Whereas the below are concentrations of PFAS in drinking water, at or below which, no adverse health effects are expected for any person, any final level, on the other hand, will factor in concentrations that can be obtained given available filtration and other technology and how much it would cost to do so.

Specific PFAS	2022 Lifetime Health Advisory Level (parts per trillion or ppt)	Minimum Reporting Level (ppt)
PFOA	0.004 (interim)	4
PFOS	0.02 (interim)	4
GenX Chemicals	10 (final)	5
PFBS	2,000 (final)	3

The minimum reporting level specified in the right column of the above table is the lowest level that can be reliably and accurately detected using current approved lab techniques. Therefore, with regards to two PFAS (PFOA and PFOS), **any detectable level is not safe** according to these latest health advisories, and even when no concentration is detected, the level may exceed these health-based concentrations. Parts per trillion is as miniscule of an amount as it sounds. To illustrate, combining a single Olympic-sized swimming pool of PFOS with all the drinking water of every American would exceed the above PFOS health advisory level.

Citizens Against Ruining the Environment

was established in 1995, making it the oldest environmental nonprofit in Will County, Illinois.

CARE is a volunteer, grassroots organization dedicated to preserving, improving, and revitalizing the Will County environment by providing research, education, and assistance to residents facing detrimental environmental issues and impacts.



At several Will County public water sources, the level of toxic PFAS recorded by the Illinois EPA is over **3,000 times** higher than the concentrations recently identified by the USEPA as maximally protective of human health.



Will County's Water Contains Concentrations of PFAS that Greatly Exceed Latest Health-Based Levels

For the last several years, the Illinois EPA has been conducting an extensive statewide investigation into the prevalence and occurrence of 7 PFAS in drinking water, including the 4 PFAS subject to the June 2022 USEPA health advisories summarized on page 1. Below is a chart identifying concentrations of those 4 PFAS, as reported by the Illinois EPA investigation, that exceed the USEPA's recent health advisories in Will County – **and by how much**. While the Illinois EPA announced it would be sampling for GenX chemicals (HFPO-DA), the interactive website reporting results of the Illinois EPA investigation does not report levels for GenX chemicals. No reported result from the Illinois EPA investigation exceeds the USEPA's health advisory for PFBS. All public water supplies identified below source water from **groundwater**, except for Wilmington, which sources from surface water. The results, as compared to the health advisories, are shocking: the reported levels **exceed the USEPA health-based levels by as much as 3,750 times**, and no less than 100 times.

Community Water Supply	Exceedance of USEPA Health Advisory Level (ppt)
College View Subdivision TP 01-WELL 1	PFOS: 2.2 (110 times higher)
Crest Hill TP 08-WELL 10	PFOA: 13 (3,250 times higher than health advisory level)
Crest Hill TP 05-WELL 7	PFOA: 3.1 (775 times higher)
Crest Hill TP 01-WELL 1	PFOA: 15 (3,750 times higher) PFOS: 2.7 (135 times higher)
Joliet Criswell Ct.	PFOA: 7.2 (1,800 times higher) PFOS: 5.6 (280 times higher)
Joliet East Moreland	PFOA: 2.0 (500 times higher)
Joliet Ingalls Park Subd.	PFOS: 2.2 (110 times higher)
Rockdale TP 05-WELL 7	PFOA: 3.6 (900 times higher)
Rockdale TP 03-Well 3	PFOS: 7.3 (365 times higher)
Minooka TP03 BLEND WELLS #6, #7, & #3	PFOA: 2.2 (550 times higher)
Channahon TP 06 - COMBO OF FIN WTR WLS 2,3,5	PFOA: 5.4 (1,350 times higher) PFOS: 5.1 (255 times higher)
Wilmington TP 03 Surface Water Treatment Plant	PFOS: 2.2 (110 times higher)

What you can do now.

1. Certain treatment options for private residences, includes GAC filters and RO filters, can reduce your exposure to harmful PFAS via tap water. More info can be found on USEPA's PFAS website (<https://www.epa.gov/sciencematters/reducing-pfas-drinking-water-treatment-technologies>).

2. You do not have to wait for the federal government to act. The Illinois Pollution Control Board is considering PFAS groundwater quality standards (IPCB Case No. R2022-018) **right now**. Nearly all Will County residents are served by groundwater, and many Will County water sources have documented concentrations of PFAS that greatly exceed the latest health-based levels. Participate by:

- **Filing a Written Public Comment** with the Clerk of the Board. The Board must consider your comments, which become part of the public record. You can submit a comment via email or regular mail:
 - o **Email** comments to Don.Brown@illinois.gov and include the docket number "IPCB R2022-018" in the subject line.
 - o **Mail** comments to the Illinois Pollution Control Board, Clerk's Office, 100 W. Randolph St., Suite 11-500, Chicago, IL, 60601. Be sure to include docket number "IPCB R2022-018."
- **Making public remarks at a Board Meeting.** The public may make remarks not to exceed 5 minutes at Board meeting where the proposed PFAS groundwater quality standards are on the agenda. You will not be cross-examined. The next Board hearing on this topic will be held on December 7, 2022 at 9:00 a.m. in Chicago and Springfield, Illinois.

What to Tell the Board

Tell the Illinois Pollution Control Board about the alarming discrepancies between the USEPA PFAS health advisory levels, that are based on the latest scientific understanding, and levels actually recorded at your groundwater public water supplies in Will County.

CARE ATTACHMENT 3

Illinois' Obligation to Groundwater Protection

The Illinois Ground Water Protection Act makes it state policy to restore, protect, and enhance the state's groundwater resources. The Act requires the Illinois Environmental Protection Agency (IEPA) to propose comprehensive water quality standards to the Illinois Pollution Control Board (Board). These standards address contaminants known, or suspected, to **cause cancer, birth defects, or any other adverse side effect to human health.**

IEPA has submitted a new proposal to the Board which will update Illinois law to include six new PFAS **groundwater quality standards (GQS)**. The proposal is listed by the Board as **Docket Number IPCB R2022-018** and can be found at:

<https://pcb.illinois.gov/Cases/GetCaseDetailsById?caselid=17099>

35 Illinois Administrative Code 620

35 Ill. Adm. Code 620 establishes various aspects of groundwater quality, non-degradation provisions, standards for groundwater quality, and various procedures and protocols for the management and protection of groundwater. The Board has recognized that **to prevent the degradation** of groundwater, it is periodically **necessary to amend and update GQS**. Triggers for these updates include:

- The advent of new data;
- New technical breakthroughs; and
- Changes to federal laws.

35 Ill. Adm. Code 620 classifies groundwater within Illinois into several categories. Class 1 covers potable groundwater, or groundwater used as drinking water. Class 2 covers general groundwater that is used for livestock consumption and irrigation.

IEPA's Reasons to Amend 35 Ill. Adm. Code 620

IEPA's proposed amendments aim to keep GQS current with **evolving scientific data and methodology** for potable and general groundwater. IEPA is proposing to change the methodology in calculating toxicity values by utilizing **child exposure factors** in place of adult exposure factors and to add GQS for **six PFAS chemicals** including:

- PFOS
- PFNA
- PFHxS
- PFOA
- PFBS
- GenX

The new GQS will be used in the **valuation of groundwater quality** for private residential wells in Illinois. Additionally, they will be used to assess what type of **remedial activities** will be necessary for protecting other groundwater of the state. Such activities may include clean up, prohibiting use, on-site restrictions, and others.

The proposed amendments follow several years of evolving understandings of PFAS chemicals and community outreach. Following the release of new **peer-reviewed scientific data** from the Agency for Toxic Substances and Disease Registry (ATSDR) IEPA updated its proposal to **tighten standards and add more** PFAS chemicals.

Additionally, after listening to **comments from community outreach** sessions advocating IEPA consider sensitive populations, IEPA updated its proposal to utilize child exposure factors in place of adult factors. The age adjusted exposure factors come from the **US EPA's regional screening levels.**

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CARE is a volunteer, grassroots organization dedicated to preserving, improving, and revitalizing the Will County environment by providing research, education, and assistance to residents facing detrimental environmental issues and impacts.



500,000

Illinois citizens utilize groundwater from non-community public well systems and **thousands** more utilize private potable wells



IEPA's Proposal are Progressive

IEPA's proposed amendments to 35 Ill. Adm. Code 620 are **far more protective** than current standards. The proposed standards for the six PFAS compounds establish rules in Illinois that are **progressive** and ranks Illinois amongst the **leaders** of statewide PFAS regulation. These standards are some of the most stringent in the US. In addition to covering a wide range of current chemicals, the proposal looks forward to the next generation of PFAS, GenX, ensuring protection against future waves of PFAS compounds.

Furthermore, by adjusting the chemical exposure factors from adult to child offers **increased protection** against the harmful effects caused by ingestion of such chemicals in drinking water. These toxicity values based on childhood exposure risks will protect the most **sensitive and vulnerable** of Illinois' citizens.

IEPA has utilized **new, peer-reviewed scientific data** and community outreach consistent with the methodology used by the **US EPA**. This methodology includes a hierarchy and tier ranking of various scientific data sources. The data sources from this hierarchy IEPA used includes the ASTDR, US EPA's Office of Water, California's EPA, and others.

IEPA's proposed amendment is consistent with CARE's mission to advocate for clean and safe drinking water throughout Will County. CARE believes the public should support IEPA's proposal to the Board and recommends actions be taken to show support.



Actions

Tell the Illinois Pollution Control Board that you **support** the proposed PFAS groundwater quality standards in IPCB R2022-018. There are two ways to make your voice heard:

- **Public Remarks at a Board Meeting.** Members of the public who attend Illinois Pollution Control Board Meetings where the proposed PFAS groundwater quality standards are on the agenda, may make remarks before the Board for up to 5 minutes. You will not be cross-examined. The next Board hearing on this topic will be held on June 21, 2022, at 9:00 a.m. in Springfield, Illinois.
- **File a Written Public Comment** with the Clerk's Office of the Illinois Pollution Control Board. Written comments may be submitted by mail or electronically. The comments will be considered by the Board and become part of the public record on the rulemaking. For questions about filing, contact the Clerk's Office at 312-814-4925 or PCB.Clerks@illinois.gov.
 - Mail comments to the Illinois Pollution Control Board, Clerk's Office, 100 W. Randolph St., Suite 11-500, Chicago, IL, 60601. Be sure to include docket number "IPCB R2022-018."
 - Email comments to Don.Brown@illinois.gov and include the docket number "IPCB R2022-018" in the subject line.

GQS v MCLs

GQS are not the same as Maximum Contaminant Levels (MCLs). GQS apply to the original place of the water and are enforceable numerical standards intended to protect and restore the beneficial use of groundwater resources. MCLs apply at the entry point to a public water supply distribution system. The finished or treated water must meet the MCLs before being distributed to consumers to provide assuredly safe drinking water. IEPA has finished a statewide testing of community water supplies for PFAS contamination and will use the data to develop PFAS MCLs.



What to Tell the Board

Tell the Illinois Pollution Control Board that the proposed GQS are on the right track! We want the most protective standards possible, backed up by the most current scientific data about the risks from PFAS. We do not want to maintain old water standards while new threats have become known. We want to adopt strict standards NOW so that we can begin getting PFAS out of our groundwater.

CARE ATTACHMENT 4

What Are PFAS?

Per- and polyfluoroalkyl substances ("PFAS") are a group of chemicals used to make coatings and products that resist heat, oil, stains, grease, and water in addition to other industrial uses such as aqueous firefighting foam (AFF). Since these chemicals are tightly bonded and do not easily break down, they are commonly known as "**forever chemicals.**" PFAS are used in many industrial and consumer processes to make everyday items non-stick, or water-, oil-, or stain-resistant (see right image).

Because of their widespread use in both industrial and consumer products these chemicals **find their way into the environment** through multiple sources including:

- The disposal of items containing PFAS into waste and treatment facilities;
- Use of agricultural fertilizers with wastewater biosolids;
- Production, manufacturing, and industrial processes;
- Use of firefighting foam.

Health Effects and Exposure

PFAS have been measured in indoor air, outdoor air, dust, food, water, and various consumer products. Potential routes of PFAS exposure include ingestion, dermal, and inhalation. Current scientific literature indicates that most exposure to the general public is through ingestion of food and water.

PFAS chemicals bioaccumulate, or build up, in blood and organs of humans. USEPA and State led studies have linked PFAS exposure to numerous **adverse health outcomes**, including:

- Reproductive, developmental, liver, and kidney issues
- Negative immunological effects
- Low infant birthrates
- Thyroid hormone disruption
- Kidney and testicular cancers.

Regulation of PFAS at the Federal Level

On October 18, 2021, the USEPA announced a roadmap, laying out an agency-wide approach to regulating PFAS. The plan includes actions to be taken by numerous bureaus within the agency through 2024. The effort is driven by three directives:

- (1) **Research:** invest in research, development, and innovation for toxicity levels of individual PFAS, contamination and exposure pathways, and environmental justice impacts related to PFAS;
- (2) **Restrict:** control and prevent contamination and exposure by holding responsible polluters accountable, establishing voluntary programs to minimize release and use, and prevent or minimize discharges; and
- (3) **Remediate:** Broaden and accelerate the cleanup of PFAS contamination by securing funding and performance by responsible parties, provide resources to impacted communities, and accelerate the use of proper technologies.

USEPA's goal is to identify past and ongoing releases of PFAS at facilities where PFAS has been used, manufactured, or released and to address the entire lifecycle of PFAS through research, public outreach, remediation, and regulation.

Citizens Against Ruining the Environment

was established in 1995, making it the oldest environmental nonprofit in Will County, Illinois.

CARE is a volunteer, grassroots organization dedicated to preserving, improving, and revitalizing the Will County environment by providing research, education, and assistance to residents facing detrimental environmental issues and impacts.

Common Items with PFAS



95%

of the US population has PFAS in their body.

Center for Disease Control Analysis

CARE ATTACHMENT 5

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

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CASRN 335-67-1

Prepared by:

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- 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	HECD	Health and Ecological Criteria Division
ANSI	American National Standards Institute	HESD	Health Effects Support Document
AWWA	American Water Works Association	HI	hazard index
BMD	benchmark dose	HQ	hazard quotient
BMDL	benchmark dose lower confidence limit	iHA	interim Health Advisory
Br-DBP	brominated disinfection by- product	i	mixture component chemical
bw or BW	body weight	IRIS	Integrated Risk Information System
CCL	Contaminant Candidate List	L/(m ² ·hr)	liter per square meter per hour
CDC	Centers for Disease Control and Prevention	LC/MS/MS	liquid chromatography/tandem mass spectrometry
CI	confidence interval	LOAEL	lowest-observed- adverse-effect level
CSF	cancer slope factor	MCL	Maximum Contaminant Level
DBP	disinfection by- product	MCLG	Maximum Contaminant Level Goal
DOM	dissolved organic matter	mg/kg-day	milligram per kilogram per day
DQO	data quality objective	mg/L	milligram per liter
DWI	drinking water intake	m/hr	meter per hour
DWI-BW	body weight-adjusted drinking water intake	MPa	megapascal
E	human exposure	MRL	minimum reporting level
EBCT	empty bed contact time	NF	nanofiltration
EF	exposure factor	ng/L	nanogram per liter
EFH	Exposure Factors Handbook	NHANES	National Health and Nutrition Examination Survey
EPA	U.S. Environmental Protection Agency	NOAEL	no-observed-adverse- effect level
FCID	Food Commodity Intake Database	NOM	natural organic matter
GAC	granular activated carbon	NPDWR	National Primary Drinking Water Regulation
HA	Health Advisory		

OGWDW	Office of Ground Water and Drinking Water	SAB PFAS Panel	Science Advisory Board Per- and Polyfluoroalkyl Substances Review Panel
ORD	Office of Research and Development		
OST	Office of Science and Technology	SDWA	Safe Drinking Water Act
OW	Office of Water	SNUR	Significant New Use Rule
PAC	powdered activated carbon	TSCA	Toxic Substances Control Act
PBPK	physiologically-based pharmacokinetic	UCMR	Unregulated Contaminant Monitoring Rule
PFAS	per- and polyfluoroalkyl substances	UCMR 3	third Unregulated Contaminant Monitoring Rule
PFBS	perfluorobutane sulfonic acid		
PFOA	perfluorooctanoic acid	UCMR 5	fifth Unregulated Contaminant Monitoring Rule
PFOS	perfluorooctane sulfonic acid	UF	uncertainty factor
pK _a	acid dissociation constant	UF _A	interspecies uncertainty factor
POD	point of departure	UF _C	composite uncertainty factor
POD _{HED}	point of departure human equivalent dose	UF _D	database uncertainty factor
ppq	parts per quadrillion	UF _H	intraspecies uncertainty factor
ppt	parts per trillion		
PWS	public water system	UF _L	lowest observed adverse effect level-
QC	quality control		to-no observed adverse effect level
RfD	reference dose		extrapolation
RfV	reference value		uncertainty factor
RO	reverse osmosis		
RPF	relative potency factor	UF _S	subchronic-to-chronic exposure duration
RSC	relative source contribution		extrapolation
SAB	Science Advisory Board	μg/L	uncertainty factor microgram 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 (µg/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”(see 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.

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 noncancer lifetime 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) 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 36,972 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 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 <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program>

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 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 µg/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 based on updated toxicity information 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 life stage, when identified. The Joint Institute for Food Safety and Applied Nutrition's Food Commodity Intake Database (FCID) Consumption Calculator Tool⁸ includes the EPA EFs 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

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.

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

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 HA Calculation

The following equation 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.

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

(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.

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

Source	For the Lifetime iHA for PFOA			
	RfD (mg/kg-day)	PFOA Exposure in Critical Study	Critical Effect	Principal and Associated Studies (Study Type)
<i>Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water [Draft]</i> (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)

Note: mg/kg-day = milligram per kilogram 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 per day (mg/kg-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-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 (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 dose lower 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 PFOA is robust (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 community water, consumers-only population, two-day average ^a	<i>Exposure Factors Handbook</i> , 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 bodyweight 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 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 described in the draft PFOA document). 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%. 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:

$$\begin{aligned} \text{Lifetime iHA} &= \left(\frac{\text{RfD}}{\text{DWI-BW}} \right) * \text{RSC} \\ \text{Lifetime iHA} &= \left(\frac{0.0000000015 \frac{\text{mg}}{\text{kg bw-day}}}{0.0701 \frac{\text{L}}{\text{kg bw-day}}} \right) * 0.2 \\ \text{Lifetime iHA} &= 0.000000004 \frac{\text{mg}}{\text{L}} \\ &= 0.000004 \frac{\mu\text{g}}{\text{L}} \\ &= 0.004 \frac{\text{ng}}{\text{L}} \end{aligned} \tag{Eq. 1}$$

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 µg/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 by-product (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

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

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 results 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 (Söregård et al., 2020). Installing activated carbon as a treatment method may also have ancillary benefits on finished water quality, particularly regarding disinfectant byproduct control, other contaminants, and 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). In conclusion, 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 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.

PFOA removal fluxes are generally 20–80 liters per square meter per hour (L/[m²·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.

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

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

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

Where:

HI = hazard index

n = the number of component (i) PFAS

HQ_i = hazard quotient for component (i) PFAS

E_i = human exposure for component (i) PFAS

RfV_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 $\mu\text{g/L}$ or 4 ng/L).

7.0 References

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CARE ATTACHMENT 6

Technical Fact Sheet: Drinking Water Health Advisories for Four PFAS (PFOA, PFOS, GenX chemicals, and PFBS)

Summary

As part of EPA's commitment to safeguard communities from per- and polyfluoroalkyl substances (PFAS), EPA has issued interim updated drinking water health advisories for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), and final health advisories for hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt (together referred to as "GenX chemicals") and perfluorobutane sulfonic acid and its related compound potassium perfluorobutane sulfonate (together referred to as "PFBS"). The interim health advisories for PFOA and PFOS are intended to provide information to states and public water systems until the National Primary Drinking Water regulation for PFAS takes effect. All four of these health advisories provide drinking water system operators, and state, tribal, and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents.

Background

What Are PFAS?

PFAS are synthetic chemicals that have been manufactured and used by a broad range of industries since the 1940s. PFAS are used in many applications because of their unique physical properties such as resistance to high and low temperatures, resistance to degradation, and nonstick characteristics. PFAS have been detected worldwide in the air, soil, and water. Due to their widespread use and persistence in the environment, most people in the United States have been exposed to PFAS. There is evidence that exposure above specific levels to certain PFAS may cause adverse health effects.

What Are Drinking Water Health Advisories?

Drinking water health advisories (HAs) provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. EPA's HAs are non-enforceable and non-regulatory and provide technical information to drinking water system operators, as well as federal, state, tribal, and local officials on health effects, analytical methods, and treatment technologies associated with drinking water contamination.

Why is EPA Issuing These HAs?

In 2016, EPA published HAs for PFOA and PFOS based on the evidence available at that time (U.S. EPA 2016, a,b). The science has evolved since then and EPA is now replacing the 2016 advisories with interim updated lifetime HAs for PFOA and PFOS that are based on new studies and draft toxicity values from EPA's 2021 draft PFOA and PFOS health effects documents. Fulfilling EPA's commitment in its October 2021 PFAS Strategic Roadmap, EPA has issued final lifetime HAs for GenX chemicals and PFBS.

How Does EPA Calculate HAs?

The following equation is used to derive a lifetime noncancer health advisory. A lifetime noncancer health advisory is designed to be protective of noncancer effects over a lifetime of exposure, including sensitive populations and life stages, and is typically based on data from experimental animal toxicity and/or human studies.

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

Where:

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.

DWI-BW = the 90th percentile DWI for the selected population or life stage, adjusted for body weight (BW), 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).

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

What Types of Health Outcomes are Associated with Exposure to These Four PFAS, and How Did EPA Develop the HAs?

PFOA and PFOS

EPA is conducting extensive evaluations of human epidemiological and experimental animal study data to support the Safe Drinking Water Act (SDWA) National Primary Drinking Water Regulation for PFOA and PFOS. In November 2021, EPA released draft documents that summarize the updated health effects analyses for [EPA Science Advisory Board \(SAB\) review](#) (U.S. EPA, 2021a, b). EPA evaluated over 400 studies published since 2016 and used new human health risk assessment approaches, tools, and models. Human studies have found associations between PFOA and/or PFOS exposure and effects on the immune system, the cardiovascular system, development (e.g., decreased birth weight), and cancer. The new published peer-reviewed data and draft EPA analyses (U.S. EPA, 2021a, b) indicate that the levels at which negative health outcomes could occur are much lower than previously understood when the agency issued its 2016 HAs for PFOA and PFOS (70 parts per trillion or ppt). EPA's 2021 draft non-cancer reference doses (RfDs) based on human epidemiology studies for various effects (e.g., developmental/growth, cardiovascular health outcomes, immune health) range from $\sim 10^{-7}$ to 10^{-9} mg/kg/day. These draft RfDs are two to four orders of magnitude lower than EPA's 2016 RfDs of 2×10^{-5} mg/kg/day (U.S. EPA, 2021a, b).

The most sensitive non-cancer effect based on the draft EPA analyses, decreased immunity (i.e., decreased serum antibody concentrations after vaccination) in children in a human epidemiology study, was selected as the basis for the draft RfD (toxicity value) in the PFOA and PFOS health effects draft documents (U.S. EPA, 2021a, b). EPA used the draft RfD to derive the interim updated HAs for PFOA and PFOS. In the critical study, EPA selected the critical effect of decreased serum antibody concentration in children associated with increased serum PFOA and/or PFOS concentrations. EPA expects this critical effect to be protective of all other adverse health effects observed in humans because this adverse effect can reduce the protection afforded by vaccines after exposure to PFOA/PFOS during a sensitive developmental life stage and it yields the lowest point of departure (POD) (U.S. EPA, 2021a, b). For both PFOA and PFOS, an intraspecies uncertainty factor

(UF_H) of 10 was applied to account for variability in the response within the human population (U.S. EPA, 2002). EPA identified children ages 0-5 years as a sensitive life stage, based on the critical study, and selected the corresponding DWI-BW. Based on a literature search of the available information on exposure sources and routes, EPA calculated the interim HAs for PFOA and PFOS using an RSC of 0.20, meaning 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 (U.S. EPA, 2022a, b; U.S. EPA, 2000).

While there is evidence that PFOA is likely to be carcinogenic to humans, EPA has not derived a cancer risk concentration in water for PFOA at this time. For PFOS, there is suggestive evidence of carcinogenic potential in humans. Additional analyses of the cancer study data are ongoing for both PFOA and PFOS.

The underlying science that EPA used to develop the interim health advisories is currently undergoing SAB review, and therefore, these interim health advisories are subject to change. After receiving the SAB's final report, EPA will complete its revisions to address their feedback and recommendations, which could lead the agency to draw different conclusions than are reflected in the draft health effects analyses (U.S. EPA, 2021a, b). As a result, the interim health advisory levels for PFOA and PFOS (U.S. EPA, 2022a, b) could change. EPA may update or remove the interim health advisories for PFOA and PFOS upon finalization of the National Primary Drinking Water Regulation.

GenX Chemicals and PFBS

EPA's final health advisories for GenX chemicals and PFBS are based on animal toxicity studies following oral exposure to these chemicals. Studies of exposure to GenX chemicals have reported health effects in the liver, kidney, immune system, development, as well as cancer. The most sensitive non-cancer effect among the available data was an adverse liver effect (constellation of liver lesions) (U.S. EPA, 2021c). This critical effect was the basis for the final chronic RfD which EPA used to derive the final HA for GenX chemicals. To develop the final chronic RfD for GenX chemicals, EPA applied a composite UF of 3,000 (i.e., 10X for intraspecies variability (UF_H), 3X for interspecies differences (UF_A), 10X for extrapolation from a subchronic to a chronic dosing duration (UF_S), and 10X for database deficiencies (UF_D)) (U.S. EPA, 2021c). EPA identified lactating women as an adult life stage with the greatest potential exposure from drinking water, based on the critical study, and selected the corresponding DWI-BW. EPA calculated the final HA for GenX chemicals using an RSC of 0.20, meaning 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 (U.S. EPA, 2022c). There is suggestive evidence of carcinogenic potential of oral exposure to GenX chemicals in humans and the available data are insufficient to derive a cancer risk concentration in water for GenX chemicals.

For PFBS, animal studies have reported health effects on the thyroid, reproductive system, development, and kidney following oral exposure. The most sensitive non-cancer effect was an adverse effect on the thyroid (i.e., decreased serum total thyroxine) in newborn mice in a study with exposure throughout gestation in the mothers. This critical effect was the basis for the final chronic RfD which EPA used to derive the final HA for PFBS (U.S. EPA, 2021d; U.S. EPA, 2022d). EPA applied a composite UF of 300 (i.e., 10X for intraspecies variability (UF_H), 3X for interspecies differences (UF_A), and 10X for database deficiencies (UF_D)) (U.S. EPA, 2021d). EPA identified women of child-bearing age as a sensitive life stage, based on the critical study, and selected the corresponding DWI-BW. EPA calculated the final HA for PFBS using an RSC of 0.20, meaning 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 (U.S. EPA, 2022d). There were no studies identified that evaluated potential cancer effects after PFBS exposure so the potential for cancer effects after PFBS exposure could not be evaluated.

What are the HAs for the four PFAS?

PFOA Interim Updated Health Advisory – Input Parameters and HA Value			
Parameter	Value	Units	Source
Chronic RfD	1.5E-9	mg/kg/day	U.S. EPA, 2021a. <i>Draft</i> RfD based on developmental immune health outcome (suppression of tetanus vaccine response in 7-year-old children). Human epidemiological studies.
DWI-BW	0.0701	L/kg-day	U.S. EPA, 2019. 90th percentile direct and indirect consumption of community water, consumers-only population, two-day average, for children ages 0 to <5 years based on 2005–2010 National Health and Nutrition Examination Survey (NHANES).
RSC	0.2	N/A	U.S. EPA, 2021a. RSC based on a review of the current scientific literature.

PFOA Interim Updated Lifetime Health Advisory = 4E-09 mg/L or 0.004 ppt (EPA 2022a)

PFOS Interim Updated Health Advisory – Input Parameters and HA Value			
Parameter	Value	Units	Source
Chronic RfD	7.9E-09	mg/kg/day	U.S. EPA, 2021b. <i>Draft</i> RfD based on developmental immune health outcome (suppression of diphtheria vaccine response in 7-year-old children). Human epidemiological studies.
DWI-BW	0.0701	L/kg-day	U.S. EPA, 2019. 90th percentile direct and indirect consumption of community water, consumers-only population, two-day average, for children ages 0 to <5 years based on 2005–2010 NHANES.
RSC	0.2	N/A	U.S. EPA, 2021b. RSC based on a review of the current scientific literature.

PFOS Interim Updated Lifetime Health Advisory = 2E-08 mg/L or 0.02 ppt (EPA 2022b)

GenX Chemicals Final Health Advisory – Input Parameters and HA Value			
Parameter	Value	Units	Source
Chronic RfD	3E-06	mg/kg/day	U.S. EPA, 2021c. Final RfD based on critical liver effects (constellation of liver lesions as defined by the National Toxicology Program Pathology Working Group) in parental female mice exposed to HFPO dimer acid ammonium salt by gavage for 53–64 days.
DWI/bw	0.0469	L/kg-day	U.S. EPA, 2019. 90 th percentile two-day average, consumer only estimate of combined direct and indirect community water ingestion for lactating women (13 to <50 years) based on 2005–2010 NHANES.
RSC	0.2	N/A	U.S. EPA, 2021c. Based on a review of the current scientific literature.

GenX Chemicals Final Lifetime Health Advisory = 0.00001 mg/L or 10 ppt (EPA 2022c)

PFBS Final Health Advisory – Input Parameters and HA Value			
Parameter	Value	Units	Source
Chronic RfD	3E-04	mg/kg/day	U.S. EPA, 2021d: Final RfD based on critical effect of decreased serum total thyroxine (T4) in newborn (postnatal day (PND) 1) mice after gestational exposure to the mother.
DWI-BW	0.0354	L/kg-day	U.S. EPA, 2019. 90 th percentile two-day average, consumer only estimate of combined direct and indirect community water ingestion for women of childbearing age (13 to <50 years) based on 2005–2010 NHANES.
RSC	0.2	N/A	U.S. EPA, 2021d. Based on a review of the current scientific literature.

PFBS Final Lifetime Health Advisory = 0.002 mg/L or 2,000 ppt (EPA 2022d)

Application of Health Advisories to Different Exposure Scenarios

Because the critical effects identified for PFOA, PFOS, and PFBS are developmental effects that can potentially result from short-term exposure to these PFAS during a critical period of development, EPA guidelines support applying the lifetime health advisories for these three PFAS to both short-term and chronic risk assessment scenarios (U.S. EPA, 1991).

The lifetime health advisory for GenX chemicals used a chronic RfD from the final EPA toxicity assessment (U.S. EPA, 2021c) based on the critical effect of adverse liver effects in adults (parental females) from a subchronic study (53–64 day exposure). In the assessment, a 10X UF_s for subchronic to chronic exposure was applied to derive the chronic RfD (U.S. EPA, 2021c). Because the critical effect identified for GenX chemicals is in adults, the HA applies to chronic exposure scenarios. The HA was based on exposure to lactating women, an adult life stage with the greatest drinking water intake rate. Application of the GenX chemicals HA to a shorter-term risk assessment scenario would provide a conservative, health protective approach in the absence of other information.

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)* that is currently undergoing SAB review (U.S. EPA, 2021e). That draft document provides a flexible, data-driven framework that facilitates practical evaluation of two or more PFAS based on current, available EPA chemical mixtures approaches and methods. 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.

The health advisory documents provide an example of how to use the HI approach to assess the potential noncancer risk of a mixture of PFOA, PFOS, GenX chemicals, and PFBS (U.S. EPA, 2022 a-d). A mixture PFAS HI can be calculated when health-based water concentrations (e.g., HAs, MCLGs) for a set of PFAS are available or can be calculated. In the example, hazard quotients (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), as shown in the equation below. Component HQs are then summed across the PFAS mixture to yield the mixture PFAS HI. A mixture PFAS HI greater than 1 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, please see U.S. EPA (2021e).

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

Where:

HI = hazard index;

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

[PFAS_{HA}] = the HA value for a given PFAS

Where can I find more information?

To view the HA documents, go to: <https://www.epa.gov/sdwa/drinking-water-health-advisories-has>

To view the PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, go to: <https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024>

For information on drinking water, go to: www.epa.gov/safewater

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