

Critical Review

US and international per- and polyfluoroalkyl substances surface water quality criteria: A review of the status, challenges, and implications for use in chemical management and risk assessment

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Abstract

Regulation of per- and polyfluorinated substances (PFAS) in surface water is a work-in-progress with relatively few criteria promulgated in the United States and internationally. Surface water quality criteria (SWQC) or screening values derived for perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) by Australia, Canada, the European Union (EU), and four US states (Florida, Michigan, Minnesota, and Wisconsin), and the San Francisco Bay Regional Water Quality Control Board (SFB RWQCB; California) were compared. Across these eight jurisdictions, promulgated numeric criteria for the same compound and receptor span over five orders of magnitude as a result of different approaches and data interpretations. Human health criteria for PFOS range from 0.0047 to 600 ng/L depending on route of exposure (e.g., fish consumption or drinking water) and are lower than most ecological criteria for protection of aquatic and wildlife receptors. Data gaps and uncertainty in chronic toxicity and bioaccumulation of PFOS and PFOA, as well as the use of conservative assumptions regarding intake and exposure, have resulted in some criteria falling at or below ambient background concentrations and current analytical detection limits (around 1 ng/L for commercial laboratories). Some jurisdictions (e.g., Australia, Canada) have deemed uncertainty in quantifying water-fish bioaccumulation too great and set fish tissue action levels in lieu of water criteria. Current dynamics associated with the emerging and evolving science of PFAS toxicity, exposure, and environmental fate (i.e., data gaps and uncertainty), as well as the continuous release of scientific updates, pose a challenge to setting regulatory limits. *Integr Environ Assess Manag* 2024;20:36–58. © 2023 AECOM Technical Services, Inc and The Authors. *Integrated Environmental Assessment and Management* published by Wiley Periodicals LLC on behalf of Society of Environmental Toxicology & Chemistry (SETAC).

KEYWORDS: Criteria development; Per- and polyfluoroalkyl substances; Risk management; Surface water quality criteria

INTRODUCTION

Per- and polyfluoroalkyl substances (PFAS) are found throughout the environment due to a variety of factors, including broad historical uses and environmental fate characteristics (Glüge et al., 2020; Jarvis et al., 2021; Kurwadkar et al., 2022; Muir & Diaz, 2021; Vedagiri et al., 2018). Although much of the regulatory focus has

been on drinking water, other environmental exposure media are increasingly being targeted, such as soil, bio-solids, surface water, fish, and food. This article focuses on surface water regulatory limits set for PFAS in the United States and internationally. Regulation of PFAS in surface water is an evolving area with limited promulgated criteria. The USEPA has identified the national criteria as a priority action in the USEPA's PFAS Strategic Roadmap (USEPA, 2021b). Although the USEPA has not yet set national recommended ambient water quality criteria (NRWQC) for any PFAS, in April 2022 the agency released Draft Recommended Aquatic Life Ambient Water Criteria for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS; <https://www.govinfo.gov/content/pkg/FR-2022-05-03/pdf/2022-09441.pdf>). In the absence of national criteria, some states have derived their own criteria

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or are doing so (ECOS, 2022; ITRC, 2022). Outside the United States, several countries have developed standards and guidelines for PFAS in surface water, including Australia and Canada. In Europe, environmental quality standards (EQS) established by the European Union (EU) for several media including surface water have been adopted by member states. Criteria development has focused mostly on PFOS, with some jurisdictions also deriving criteria for PFOA and other PFAS.

The published surface water quality criteria (SWQC) vary widely, spanning several orders of magnitude (more than five), reflecting differences in the protection goal, target population, assumptions about PFAS toxicity and exposure, derivation methodology, and regulatory policy. In some cases, criteria are below ambient levels and analytical detection limits. This article explores the basis of the SWQC that have been published by several US states and countries. Approaches and assumptions are compared to understand the basis for the broad range of published criteria and to provide insight on derivation challenges. Although not intended to be exhaustive, this review provides a cross-section of current international approaches and associated issues and uncertainties and discusses implications for risk management of PFAS in surface water.

METHODS

The authoritative jurisdictions included in this review have published SWQC or screening values for PFOS and PFOA in surface water, and include four US states (Florida, Michigan, Minnesota, and Wisconsin), Australia, Canada, and the EU. Additionally, the aquatic habitat environmental screening levels (ESL) derived for PFOS and PFOA by the San Francisco Bay Regional Water Quality Control Board (SFB RWQCB) in California are also included, because a similar derivation methodology was used. It is important to note that the aquatic habitat ESLs are screening values for evaluating groundwater that discharges to surface water and their use is not mandatory; rather, exceedances suggest that further evaluation is required to better understand risk and inform the need for further action (SFB RWQCB, 2019, 2020).

Legislative frameworks for protection of surface waters

In the United States, the establishment of NRWQC to protect aquatic life and human health falls under the Clean Water Act (CWA; US Code of Federal Regulations 40 CFR 131, 1983). Section 304(a) of the CWA sets out recommended national criteria that provide the numerical concentrations of pollutants that, if not exceeded, generally ensure adequate water quality for protection of a designated use (e.g., recreation, fish propagation, drinking water; USEPA, 2014a). States can adopt the recommended national criteria or calculate state-specific criteria that must be approved by USEPA. Many states rely on USEPA to set criteria because of the complexity and high cost of the process. The methodology for deriving NRWQC under Section 304(a) is laid out in guidance (Stephen et al., 1985 [aquatic life]; USEPA, 2000 [human health]). The agency

released draft national recommended aquatic life criteria for PFOA and PFOS in April 2022 (USEPA, 2022a, 2022b) and has the objective of issuing human health criteria in 2024 (USEPA, 2021b). The USEPA also indicated publishing benchmarks for other PFAS where data are sufficient to define a recommended aquatic life criteria value.

In Australia, the Heads of Environment Protection Authorities (HEPA) published the PFAS National Environmental Management Plan Version 2.0 (PFAS NEMP), which provides nationally agreed-on and consistent guidance on the environmental regulation and management of PFAS (HEPA, 2020). The PFAS NEMP provides SWQC for the protection of human health and ecological receptors for PFOS, PFOA, and perfluorohexanesulfonic acid (PFHxS). As the PFAS NEMP is not enforceable, each Australian state and territory government promulgates jurisdiction-specific legislation to enforce compliance.

In Canada, the Canadian Council of Ministers of the Environment (CCME) establishes Federal Environmental Quality Guidelines (FEQGs), which are promulgated at the province and/or territory level. A surface water FEQG has been derived for PFOS to protect ecological receptors (ECCC, 2018; direct toxicity). The CCME has not derived surface water FEQGs based on wildlife or human consumption of fish because of uncertainty in the surface water–biota bioaccumulation relationship (Longpre et al., 2020).

In Europe, environmental legislation for water quality falls under the directive of the European Commission (EC) of the EU, which is an economic and political union of 27 countries. European Union laws and regulations are applicable to all member states. Perfluorooctane sulfonic acid and its derivatives are included as a priority hazardous substance under the EU's Water Framework Directive (EU, 2013). The dossier for PFOS specifies EQS for protection of human and ecological receptors for inland and marine waters (EU, 2011) which have been adopted by member states. The UK exited the EU in 2020 but currently continues to participate in several EU programs including the Water Framework Directive (EC, 2000).

Across these regulatory frameworks, the acceptable concentration of a contaminant in surface water is based on the target receptors and intended uses (e.g., drinking water, recreation, fish propagation, fish consumption), assumptions about toxicity and exposure and regulatory policy. A common thread is the use of a risk-based methodology to derive the numeric criteria. The term criteria or SWQC refers here to the risk-based concentrations derived to be protective of human and ecological exposures to PFAS in surface water. In some cases, the criteria are enforceable, such as the EU's EQS and Michigan's water quality standards, whereas some are screening levels (e.g., SFB RWQCB, Florida), used to indicate whether further study or action is needed.

Overview of SWQC derivation

The development of SWQC for contaminants with bioaccumulative potential, such as PFAS, typically considers

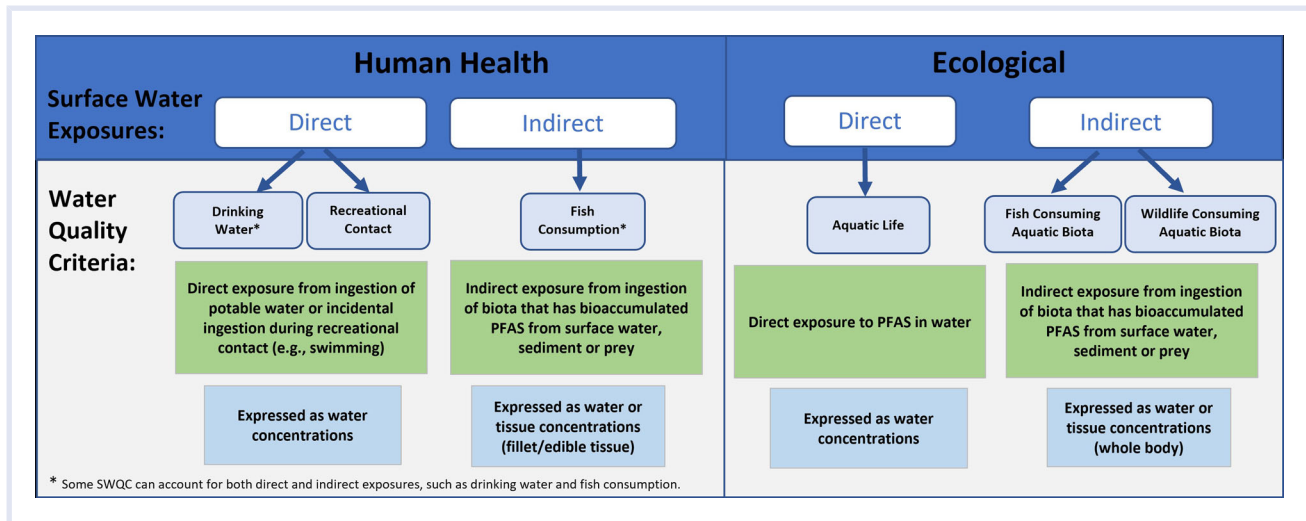


FIGURE 1 Generalized framework for derivation of surface water quality criteria for per- and polyfluorinated substances (PFAS)

both direct (e.g., ingestion) and indirect exposure (e.g., consumption of biota or prey). Figure 1 presents an overview of the general framework for SWQC derivation. Criteria for protection of human health may be based on consumption of water for potable purposes or recreational exposures (e.g., swimming), consumption of fish (bioaccumulation-based), or both drinking water and fish consumption. Table 1 presents the human health SWQC that have been derived for PFOS and PFOA by the eight jurisdictions covered in this article. For PFOS, all but Australia and Canada have derived human health criteria based on fish consumption or drinking water and fish consumption. Australia and Canada deem uncertainty in quantifying PFAS bioaccumulation too great and have not derived water-based criteria protective of fish consumption. Australia and the state of Wisconsin (PFOA only) are the only jurisdictions with criteria based on recreational (nondrinking water) exposure. Supporting Information: Tables S-3 and S-4 provide additional details on the derivation of human health SWQC.

Criteria for protection of ecological receptors may also consider direct and indirect exposures (Figure 1). Aquatic life criteria represent the surface water concentration of a contaminant that, if not exceeded, is expected to protect fish, invertebrates, and other aquatic life from adverse effects associated with direct chemical exposure (Stephen et al., 1985). Both acute and chronic aquatic life values are typically derived; the more stringent chronic criteria are the focus of this review. Surface water quality criteria protective of wildlife (also referred to as secondary poisoning criteria) are similar to human health criteria in that they are based on bioaccumulation into prey items that might be consumed by wildlife. Wildlife criteria can be water-based or tissue (prey)-based values. Tables 2 and 3 present the aquatic life and wildlife SWQC, respectively, that have been derived for PFOS and PFOA. Supporting Information: Tables S-5 and S-6 provide additional details on the derivation of these SWQC.

All jurisdictions reviewed, except for the state of Wisconsin, have published freshwater aquatic life criteria for PFOS, and all but Canada and the EU have also derived criteria for PFOA (Table 2). There are fewer marine aquatic life criteria, and Australia's freshwater-based criteria are also applicable to marine waters. Surface water quality criteria for protection of wildlife are limited. Only the SFB RWQCB, Michigan, and the EU have derived bioaccumulation-based wildlife criteria for PFOS in freshwater, and only the EU and SFB RWQCB for PFOS in marine waters (Table 3). As previously noted, USEPA released draft national recommended aquatic life criteria for PFOS and PFOA in April 2022 (USEPA, 2022a, 2022b; Table 2). USEPA (2022a, 2022b) also derived tissue-based criteria that protect invertebrates and fish. The new water quality and tissue-based criteria for PFOS and PFOA are intended to be independently applicable and neither criterion is considered more suitable than the other (USEPA, 2022a, 2022b).

DISCUSSION

Internationally, SWQC for PFOS and PFOA span several orders of magnitude (more than five), reflecting differences in inputs and approaches, as well as time frames. Similar to US state drinking water guidelines (Post, 2021), SWQC derived more recently are generally more stringent than older criteria. Human health criteria based on fish consumption are lower than current drinking water standards and are also lower than most ecological criteria for protection of aquatic and wildlife receptors. A notable exception is Australia's PFOS SWQC for 99% species protection (spp.) of 0.23 ng/L, which is the lowest of the ecological criteria. In some cases, criteria are below ambient background concentrations and current analytical detection limits (Figure 2 for human health criteria and Figure 3 for ecological criteria). There are practical implications of setting criteria below analytical detection limits, including increased uncertainty in the reliability of

TABLE 1 Human health SWQC for PFOS and PFOA

Exposure scenario	California San Francisco Bay RWQCB		Florida		Michigan		Minnesota	
	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA
Surface water as drinking water and fish consumption (ng/L)	Not derived	Not derived	Not derived	Not derived	11	420	0.05	In progress
Fish consumption only (ng/L)	0.0047	0.022	10	500	12	12,000	0.05	
Drinking water only (ng/L)	1 (PHG) 2 (HPC)	0.007 (PHG) 3 (HPC)	70	70	16	8	15	35
Recreational use	–	–	–	–	–	–	–	–
Status of SWQC	Interim final ESL (groundwater discharging to surface water)		Screening levels		Final		Final (site-specific)	
Source(s)	San Francisco Bay RWQCB (2020)		FDEP (2020); Stuchal and Roberts (2020)		Michigan EGLE (2020)		MPCA (2020a)	
Exposure scenario	Wisconsin		Australia		Canada		European Union	
	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA
Surface water as drinking water and fish consumption (ng/L)	Not derived	Not derived	Not derived—Evaluate fish consumption using seafood trigger levels	Not derived	Not derived	Not derived	Not derived	Not derived
Fish consumption only (ng/L)	8	Not derived			Evaluate on site-specific basis		0.65 (fresh) 0.13 (salt)	48 (Dutch)
Drinking water only (ng/L)	20 (Enforcement standard) 2 (Preventive action limit)		70	560	600	200	500 (total)	100 (sum of 20 PFAS)
Recreational use	–	95	2000	10,000	–	–	–	–
Status of SWQC	Proposed		Final		–		Final	
Source(s)	WDNR (2021)		NHMRC (2019)		–		EQS dossier (EU, 2011) RIVM (2017)	

Note: See Supporting Information: Table S-3 for basis and status of drinking water criteria and fish tissue screening levels and Supporting Information: Table S-4 for additional details on human health SWQC derivation and references.
 Abbreviations: EGLE, Michigan Department of Environment, Great Lakes, and Energy; EQS, Environmental Quality Standard; ESL, Environmental Screening Level; EU, European Union; FDEP, Florida Department of Environmental Protection; HPC, Health Protective Concentration; MPCA, Minnesota Pollution Control Agency; ng/L, nanograms per liter; NHMRC, National Health and Medical Research Council; PFAS, perfluoroalkyl substances; PFOA, perfluorooctanoic acid; PFOS, perfluorooctane sulfonate; PHG, Public Health Goal; RIVM, National Institute for Public Health and the Environment; RWQCB, Regional Water Quality Control Board; SWQC, Surface Water Quality Criteria; WDNR, Wisconsin Department of Natural Resources.

TABLE 2 Chronic aquatic life SWOC for PFOS and PFOA

	USEPA		California San Francisco Bay RWQCB		Florida		Michigan		Minnesota		
	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	
Chronic criteria type and value (ng/L)	CCC 8400	CCC 94 000	Direct exposure ESL 540 000 freshwater 2600 marine	Direct exposure ESL 540 000 freshwater; also used for marine	Tier 2 CC 13 000	Tier 2 CC 37 000	Tier 2 CC 1 300 000	Tier 2 FCV 140 000	Tier 2 FCV 880 000	Tier 2 CC 19 000	Tier 2 CC 1 705 000
Applicable waterbodies	Freshwater	Freshwater	Freshwater and marine	Freshwater and marine	Freshwater	Freshwater	Marine	Freshwater	Freshwater	Freshwater	Freshwater
Status of SWOC	Draft	Draft	Interim final	Interim final	Screening levels	Screening levels	Screening levels	Final	Final	Draft	Draft
Source(s)	USEPA (2022a, 2022b)	San Francisco Bay RWQCB (2020)	FDEP (2020); Stuchal and Roberts (2019)	FDEP (2020); Stuchal and Roberts (2019)	EGLE (2020)	MPCA (2007a)	MPCA (2007b)	MPCA (2007a)	MPCA (2007b)	MPCA (2007a)	MPCA (2007b)
Derivation guidance/approach	USEPA methodology for the derivation of ambient water quality criteria for the protection of aquatic life (Stephen et al., 1985)	Overall ESL approach presented in SFB RWQCB (2019); values are 1% hazardous concentrations (HC; protective of 99% of species) from SSDs presented by Conder et al. (2020)	USEPA methodology for the derivation of ambient water quality criteria for the protection of aquatic life (Stephen et al., 1985)	USEPA methodology for the derivation of ambient water quality criteria for the protection of aquatic life (Stephen et al., 1985); USEPA, 1995)	USEPA methodology for the derivation of ambient water quality criteria for the protection of aquatic life (Stephen et al., 1985); USEPA, 1995)	USEPA methodology for the derivation of ambient water quality criteria for the protection of aquatic life (Stephen et al., 1985); USEPA, 1995)	USEPA methodology for the derivation of ambient water quality criteria for the protection of aquatic life (Stephen et al., 1985); USEPA, 1995)	Michigan Rule 57 (R 323.1057[3]) of the Part 4 Rules, water quality standards	Michigan Rule 57 (R 323.1057[3]) of the Part 4 Rules, water quality standards	Minnesota Rules, Chapter 7050.0218 Methods for protection of surface waters from toxic pollutants for which numerical standards not promulgated	Minnesota Rules, Chapter 7050.0218 Methods for protection of surface waters from toxic pollutants for which numerical standards not promulgated

(Continued)

	Australia		Canada		European Union		Netherlands	
	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS
Chronic criteria type and value (ng/L)	Direct exposure, growth, and reproduction endpoints 99% spp: 19 000 95% spp: 220 000 90% spp: 632 000 80% spp: 1 824 000	Direct exposure, growth, and reproduction endpoints FWQG = 6800 (5th percentile of SSD)	Direct exposure, growth and reproduction endpoints	Direct exposure, growth and reproduction endpoints	-	AA-EQS based on NOEC for emergence of invertebrates	See EU	AA-EQS based on NOEC for fathead minnow
Status of SWOC	Draft	Draft	Final	Final	-	Final	-	see EU Proposed
Source(s)	DoEE (2016c)	DoEE (2016c)	ECCC (2018)	EU (2011)	-	EU (2011)	-	RIVM (2017)

Table 2 (Continued)

	PFOA	PFOA	PFOA	PFOA	PFOA	PFOA	PFOA	PFOA	PFOA
Derivation guidance/approach	Draft WQC originally published in DoEE (2016c) and recommended by HEPA (2020) and ANZG (2018) for use in site assessments	Draft WQC originally published in DoEE (2016c) and recommended by HEPA (2020) and ANZG (2018) for use in site assessments	Published in ECCC (2018) and cited in Longpre et al. (2020)	-	-	-	-	-	Derivation performed in accordance with methodology of the EU WFD
Applicable waterbodies	Freshwater and marine	Freshwater and marine	Freshwater	-	-	-	-	-	Freshwater and marine

Note: See Supplemental Table S-5 for additional details on criteria derivation and references. AA-EQS, Annual Average Environmental Quality Guideline; ANZG, Australia and New Zealand Governments; CC, Chronic criterion; CCC, Chronic continuous criterion; DoEE, Department of Environment and Energy; EC, European Commission; ECCC, Environment and Climate Change Canada; EGLE, Michigan Environment, Great Lakes, and Energy; ESL, Environmental screening level; EU, European Union; FCV, final chronic value; FDEP, Florida Department of Environmental Protection; FWQC, Federal Water Quality Guideline; HC, hazardous concentration; HEPA, Heads of Environment Protection Authority; MPCA, Minnesota Pollution Control Agency; ng/L, nanograms per liter (parts per trillion); NOEC, no observed effect concentration; PFOA, perfluorooctanoic acid; PFOS, perfluorooctane sulfonate; RWQCB, Regional Water Quality Control Board; spp., species protection; SSD, species sensitivity distribution; SWQB, State Water Resources Control Board; WQC, Water Quality Criteria; WFD, Water Framework Directive.

the results and challenges in demonstrating compliance (Gust et al., 2021).

The human health criteria that account for fish consumption span more than three orders of magnitude for PFOS and five orders of magnitude for PFOA (Figure 2). The broad range is driven in part by the seafood ingestion ESLs derived by the California SFB RWQCB (0.0047 ng/L for PFOS and 0.022 ng/L for PFOA). The PFOS ESL is an order of magnitude lower than the next lowest fish consumption-based criterion of 0.05 ng/L derived by Minnesota for use in specific water bodies where PFAS is of concern (Minnesota Pollution Control Agency [MPCA], 2020a).

The aquatic life criteria span more than five orders of magnitude, due in part to the Australian 99% spp. criterion (Figure 3). However, excluding this lowest criterion, aquatic life criteria still range over three orders of magnitude, from 130 ng/L (Australia's 95% spp.) to 140 000 ng/L (Michigan). The few published wildlife criteria are lower than most aquatic life values and span a smaller range (2–75 ng/L for PFOS in freshwater and 0.47–75 ng/L in marine waters).

The five orders of magnitude variation in PFOS and PFOA SWQC observed across the jurisdictions evaluated here reflect differences in agency decisions about the available data on toxicity, bioaccumulation, and exposure, as well as differences in derivation methodology, treatment of uncertainty, and regulatory policy. Although some of the factors that contribute to observed variability in the derived criteria are not unique to PFAS (e.g., human exposure parameters), the generation of new and sometimes confounding studies, as well as extant data gaps, has likely amplified this variability in PFAS SWQC compared with other contaminants whose corpus of literature is more mature. Key considerations and challenges are discussed below, first for human health followed by ecological criteria development. Implications for implementation of criteria, including current analytical capabilities for measuring PFAS, and ambient levels in the environment, are also discussed.

Considerations and challenges in human criteria development

Four parameters contribute most to the differences in the human health criteria evaluated for this review: toxicity factor, fish consumption rate, bioaccumulation factor, and relative source contribution (RSC). The assumptions and approaches used for each parameter are discussed below.

Toxicity factors. The human toxicity factors used to derive human health SWQC are based on noncancer effects, except for the SFB RWQCB, which bases its seafood ingestion ESLs on cancer risk. Reference doses (RfD) or tolerable daily intakes (TDI) are used to assess noncancer effects, with the latter dose metric typically used in the EU, Australia, and Canada. Both represent the amount of a substance in water, soil, or food that can be consumed daily over a lifetime without resulting in adverse health effects and are expressed in units of milligram of chemical per kilogram of body weight per day (mg/kg-day or mg/kg-bw/day). The

TABLE 3 Wildlife-based SWQC for PFOS and PFOA

Parameter	Michigan		California—San Francisco Bay RWQCB		European Union		The Netherlands	
	PFOS Avian wildlife value	PFOS Mammalian wildlife value	PFOS Secondary poisoning ecotoxicity ESL	PFOA Secondary poisoning Ecotoxicity ESL	PFOS Secondary poisoning AA-EQS	Secondary poisoning AA-EQS	PFOA Secondary poisoning EQS	
Wildlife SWQC								
Wildlife value (ng/L)	35	84	75	4400	2 (freshwater)		990 (freshwater)	
Status of SWQC	Draft screening values (not listed on table of Rule 57 Surface water quality values [EGLE, 2020])		Interim final		Final		Proposed	
Source(s)	MDCH (2015)		San Francisco Bay RWQCB (2020)		EU (2011)		RIVM (2017)	
Derivation guidance/ approach	Michigan Rule 57 (R 323.1057(3)) of the Part 4 Rules, water quality standards		Overall ESL approach presented in SFB RWQCB (2019); wildlife-based surface water screening levels derived by Divine et al. (2020)		Working Group E of the Common Implementation Strategy for the Water Framework Directive		EU Water Framework Directive	

Note: See Supporting Information: Table S-6 for additional details on criteria derivation and references.

Abbreviations: AA-EQS, Annual Average Environmental Quality Guideline; EGLE, Michigan Environment, Great Lakes, and Energy; ESL, Environmental Screening Level; EU, European Union; MDCH, Michigan Department of Community Health; ng/L, nanograms per liter (parts per trillion); PFOA, perfluorooctanoic acid; PFOS, perfluorooctane sulfonate; RIVM, National Institute for Public Health and the Environment; RWQCB, Regional Water Quality Control Board; SWQC, Surface Water Quality Criteria.

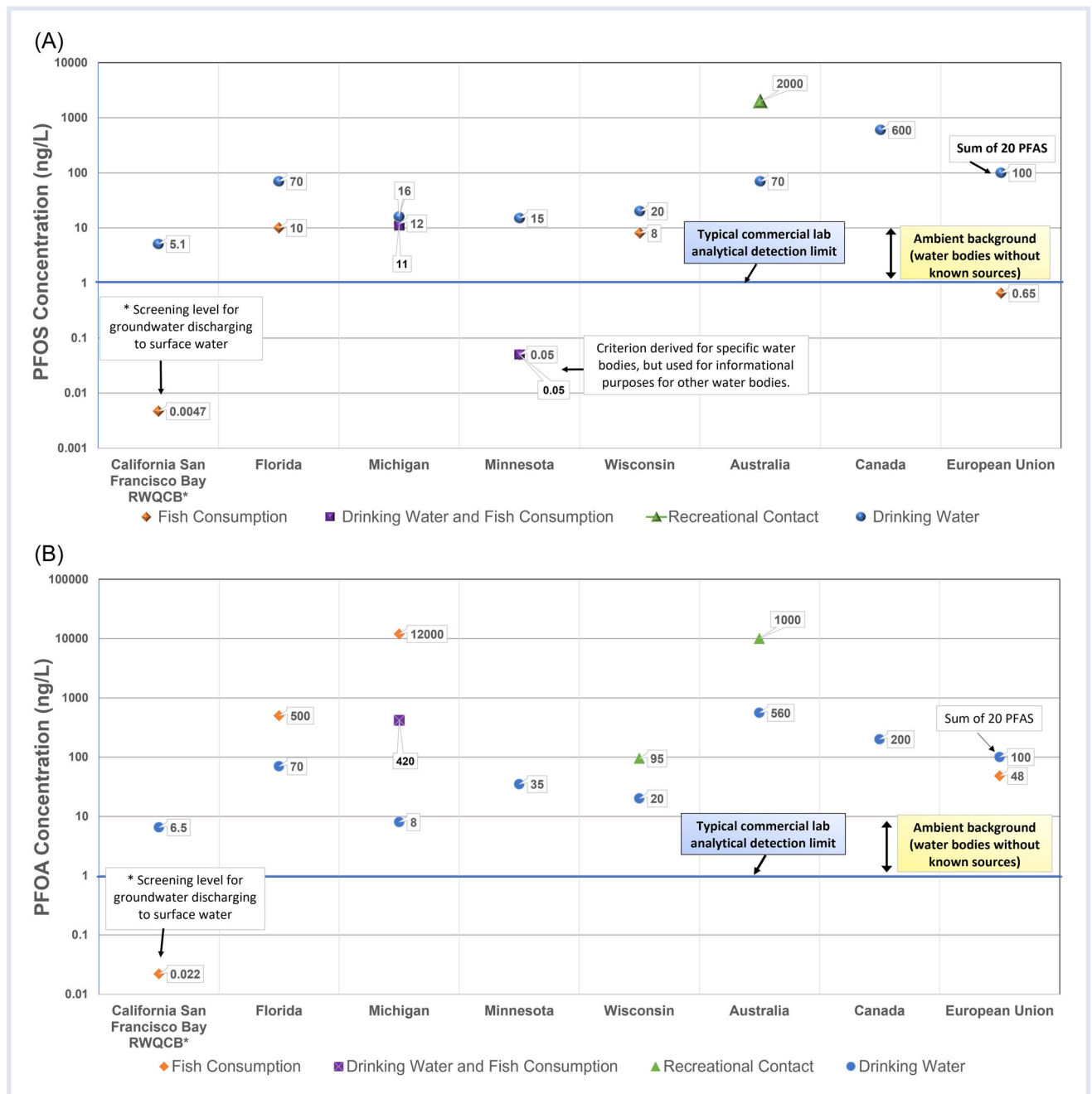


FIGURE 2 Surface water quality criteria for the protection of human health. (A) Perfluorooctane sulfonic acid (PFOS). (B) Perfluorooctanoic acid (PFOA). RWQCB, Regional Water Quality Control Board

specific toxicity values used in SWQC derivation, and their basis are provided in Supporting Information: Table S-1

Data gaps in understanding the relative significance of the various toxicity endpoints, different application of uncertainty factors (UF), and toxicokinetic modeling approaches, as well as the choice of primary study and data have resulted in a broad range of toxicity factors. The RfDs and TDIs span more than two orders of magnitude (Figure 4). In the United States, the PFOS RfDs derived by several states are 7–30-fold more stringent than the RfD used by USEPA to derive the 2016 drinking water advisory

level (e.g., New Jersey and New Hampshire in 2019, Minnesota in 2020, and California in 2021 update). A similar trend is apparent for PFOA.

Selection of the target endpoint or critical effect(s) is a key difference among the RfDs and TDIs used in human health criteria derivation. The selected endpoints span several systems, including developmental, reproductive, liver, kidney, immune, thyroid, cardiovascular, and endocrine system effects. Combined UF ranging from 30 to 3000 were used to account for toxicological uncertainties including animal-to-human extrapolation (UFs from 2.5 to 10),

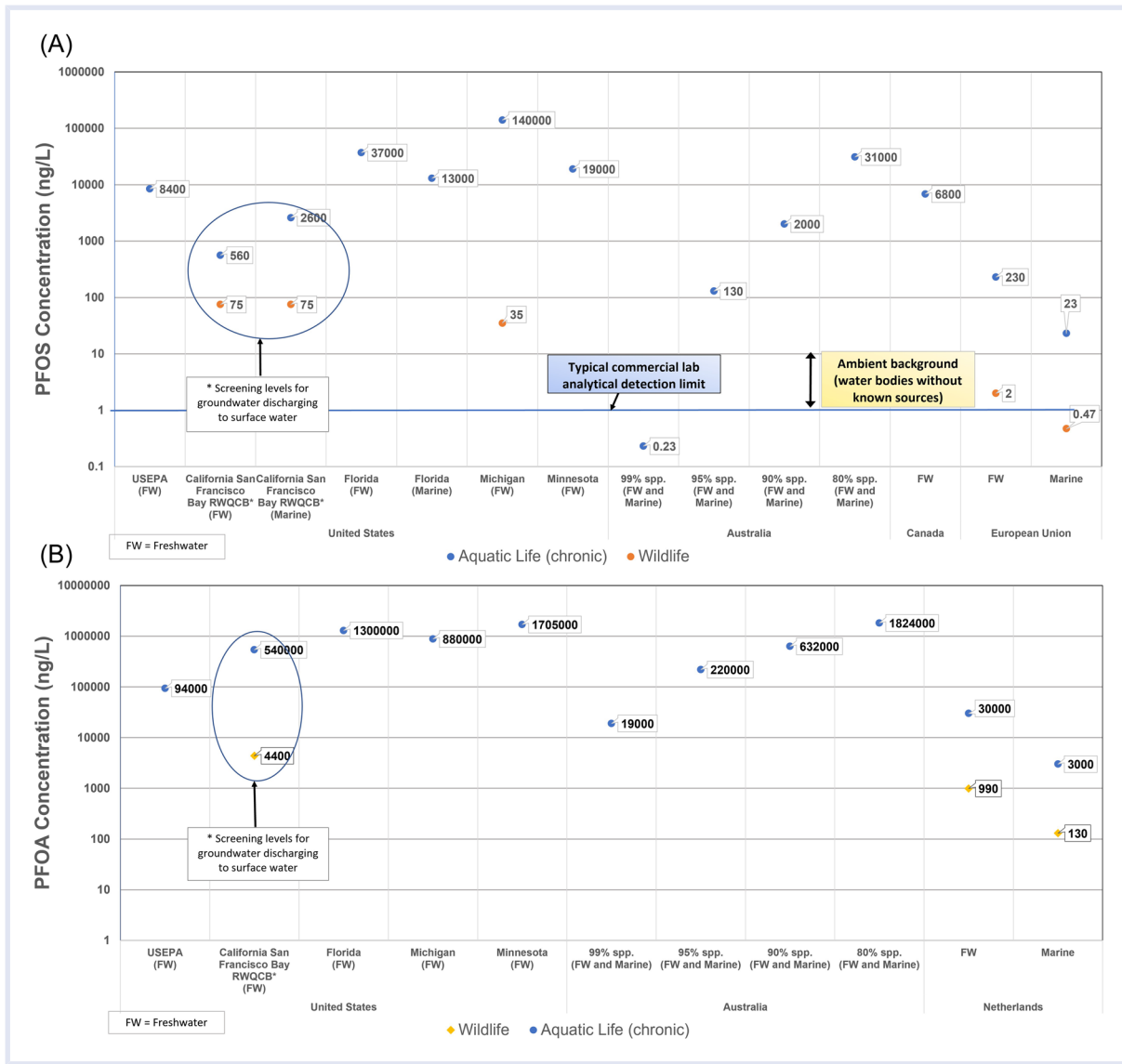


FIGURE 3 Surface water quality criteria for the protection of ecological receptors. (A) Perfluorooctane sulfonic acid (PFOS). (B) Perfluorooctanoic acid (PFOA). RWQCB, Regional Water Quality Control Board

interhuman variability (UFs from 3 to 10), extrapolation of lowest observed adverse effects level (LOAEL) to no observed adverse effects level (NOAEL; UFs from 3 to 10), use of a subchronic study (UF of 10), and database uncertainty (UFs from 2 to 10). In some cases, jurisdictions have applied different UFs to the same study, resulting in different RfDs. For example, USEPA (2016b), Minnesota (MDH, 2020a), and Australia (FSANZ, 2017) have developed RfDs and/or TDIs for PFOA based on developmental effects from a mouse study (Lau et al., 2006). The USEPA and Minnesota each applied a UF of 300 for intra/interspecies differences and use of a LOAEL, whereas FSANZ applied a UF of 30 for intra/interspecies differences, resulting in the USEPA and Michigan RfDs being 10-fold lower than the Australian value. Similarly, USEPA (2016a), Wisconsin (WDHS, 2019) and Australia (FSANZ, 2017) selected developmental effects based on a rat study (Luebker et al., 2005) as the basis of their PFOS values. The USEPA and Australia applied UFs of

30 whereas Wisconsin selected 300; all three included UFs for intra/interspecies differences, but Wisconsin included an additional factor based on the concern that immunotoxicity may be the more sensitive endpoint.

To date, animal studies are the principal basis for deriving human health SWQC for PFOS and PFOA (see Supporting Information: Table S-1). However, epidemiological data are increasing. In Europe, a tolerable weekly intake (TWI) released in 2020 by the European Food Safety Authority (EFSA) relies on human epidemiological data to derive a TWI of 4.4 ng/kg-bw/week (which equates to a TDI of 6.3E-07 mg/kg-bw/day; EFSA [EFSA Panel on Contaminants in the Food Chain], 2020).

In Australia, the authority responsible for oversight of food safety concluded the epidemiological data for PFAS are inconclusive and derived PFOS and PFOA TDIs from animal studies (FSANZ, 2017). A recent study of three Australian communities with PFAS contamination commissioned

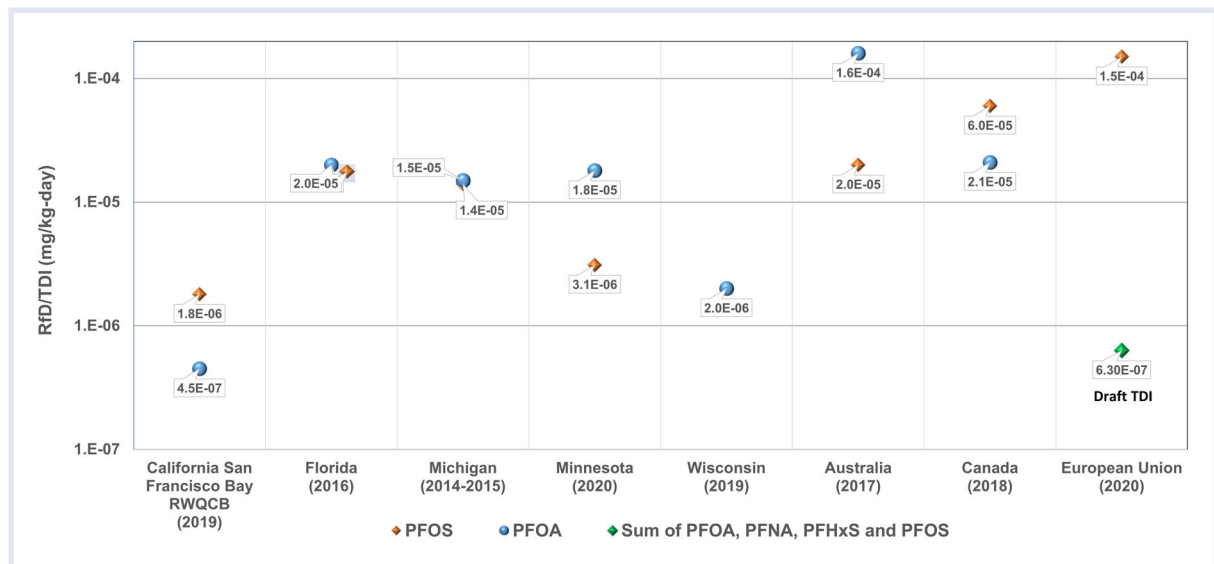


FIGURE 4 Noncancer toxicity factors used in human health surface water quality criteria derivation. mg/kg-day, milligrams per kilogram per day; PFHxS, perfluorohexane sulfonic acid; PFNA, perfluorononanoic acid; PFOA, perfluorooctanoic acid; PFOS, perfluorooctane sulfonic acid; RfD, reference dose; TDI, tolerable daily intake

by the Australian Government Department of Health (PFAS Health Study) found an association between higher contaminant levels and elevated cholesterol levels but found limited evidence of other adverse health outcomes (ANU, 2021). As the body of epidemiological data expands and the concordance between animal and human study outcomes is reported, reliance on epidemiological data as the basis for criteria development may increase (ATSDR, 2021; EFSA, 2020; Fenton et al., 2021; OEHHA, 2021b; Steenland et al., 2020). The USEPA recently published draft RfDs for PFOS and PFOA of $7.9\text{E}-09$ and $1.5\text{E}-09$ mg/kg-day, respectively, based on epidemiological data citing support from animal studies that also indicate general immune effects (USEPA, 2022c, 2022d).

Toxicity values are continually being updated so criteria are susceptible to change. For example, the TDI used by the EU to derive the 2011 PFOS EQS was updated by the European Chemicals Agency and EFSA in 2018 and again in 2020 to incorporate new data; the 2020 TDI is more than 200-fold more stringent. If this updated TDI were used along with the exposure and bioconcentration factor (BCF) and biomagnification factor (BMF) assumptions used in the 2011 PFOS dossier, the EU's current human health fish consumption EQS of 0.65 ng/L would decrease to a single digit picogram per liter concentration, which is well below current analytical detection limits for aqueous samples (typically ranging between 0.1 and 100 ng/L). As another example, in July 2021, California published updated toxicity values for PFOS and PFOA, which replace the 2019 values, based on new data and toxicokinetic approaches (OEHHA, 2021b).

Based on detection in biota and human serum, other PFAS besides PFOS and PFOA are targeted for criteria development, including perfluorobutane sulfonic acid (PFBS), perfluorononanoic acid (PFNA), and PFHxS. The USEPA and

some states, including Minnesota and California, recently derived RfDs for PFBS (MDH, 2020b; OEHHA, 2021a; USEPA, 2021a). Further, there is growing interest in a compound class approach to PFAS regulation that considers properties such as bioaccumulation potential, persistence, mode of action, and structural similarity (Cousins et al., 2020; EU, 2020; Kwiatkowski et al., 2020; Patlewicz et al., 2019; Sha et al., 2019). Canada plans to move forward with a class-based approach to “address situations where exposure occurs to multiple PFAS at the same time” (Canada Gazette, 2021). Some jurisdictions have adopted dose additivity based on presumed similarity in toxicity and/or environmental characteristics. The EU's new TDI applies to the combined exposure to four PFAS: PFOS, PFOA, PFNA, and PFHxS, which are considered to have several similar effects in animals, toxicokinetics, and observed levels in human blood (EFSA, 2020). In 2022, the EC's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) published their opinion on updated EQS for PFAS, which includes a proposed drinking water standard of 4.4 ng/L for 24 PFAS based on the new TDI and relative potency factors (RPF) for PFOA (SCHEER, 2022). The Netherlands (RIVM) has derived RPFs for 19 perfluoroalkyl acids (PFAAs) using PFOA as the index chemical and liver toxicity as the target endpoint (Zeilmaker et al., 2018). However, data gaps in the understanding of mixture toxicity and differences in mode of action and toxicity endpoint across PFAAs pose challenges to a grouping strategy consisting of broad-based additivity or relative potency approach (Deepika et al., 2022; Goodrum et al., 2021).

Fish consumption rate. Consumption of fish is a primary route of PFAS exposure for humans as well as wildlife (Augustsson et al., 2021; De Silva et al., 2021; EFSA, 2020; Sunderland et al., 2019). For bioaccumulative contaminants

such as PFAS, the derivation of human health criteria typically accounts for exposure from fish consumption. Fish consumption rates (FCR) used in the derivation of SWQCs for PFOS and PFOA range from 15 g/day (Michigan) to 115 g/day (EU; Table 4). The nearly 10-fold range in consumption rates reflects differences in the selected study, regulatory policy, and target population (e.g., general population, sport anglers, or specific subpopulation). To set NRWQC, the USEPA uses an FCR of 22 g/day, which is based on the 90th percentile consumption of fish and shellfish from fresh and estuarine waters for US adults (USEPA, 2014b, 2015), and is considered protective of the general population and sport anglers. For the three Great Lakes states included in this review, FCRs are comparable with the national rate. Michigan, Wisconsin, and Minnesota use rates of 15, 20, and 30 g/day to derive their respective statewide human health criteria (Michigan EGLE, 2020; MPCA, 2020a; Wisconsin Statutes, 2010). These FCRs are derived to be protective of sport anglers who consume their catch at average (Michigan) or upper-bound (Minnesota) rates.

For the site-specific PFOS criterion (applicable to Lake Elmo and connected waterbodies, Bde Maka Ska, and Pool 2 of the Mississippi River), Minnesota determined their statewide FCR of 30 g/day was not sufficiently protective of women of child-bearing age (WCBA) who may eat large amounts of self-caught fish (MPCA, 2020a, 2020b). Instead, MPCA used an upper percentile rate of 66 g/day derived from a Minnesota Department of Health (MDH) survey that focused on WCBA living in the North Shore of Minnesota, and included Native American women (MDH, 2017; MPCA, 2020a, 2020b). Minnesota Pollution Control Agency's upper-bound FCR of 66 g/day is considered "an interim rate used in WQC for pollutants characterized as developmental toxicants to ensure reasonable maximum protection from adverse health effects for babies whose mothers eat fish and shellfish as part of a healthy and balanced diet" (MPCA, 2020b).

To derive their seafood ingestion ESLs, California's SFB RWQCB used an adult FCR of 80 g/day, which is the 95th percentile rate for recent (within prior four weeks) consumers of San Francisco Bay fish (SFEI, 2000). This rate is well above the 95th percentile rate (32 g/day) calculated in the same study for all consumers of San Francisco Bay fish (not just recent consumers), as well as the 95th percentile rate of fish and shellfish consumption from fresh and estuarine waters (34.9 g/day) for the general population in the Pacific coastal area of the United States (USEPA, 2014b). The 95th percentile FCR of 32 g/day (one meal per week) was used to derive the statewide mercury fish consumption advisory and the site-specific sportfishing mercury water quality objective for San Francisco Bay and the Sacramento-San Joaquin Delta (CalEPA, 2017). The SFB RWQCB's use of an FCR two and half times higher than the statewide 95th percentile rate for sport anglers suggests the water quality objective for PFOS and PFOA may be based on subsistence consumption.

Florida is the only jurisdiction to use a probabilistic approach to derive criteria for PFOA and PFOS (FDEP, 2020; Stuchal & Roberts, 2020). The FCR was defined as a set of lognormal distributions representing consumption of trophic levels 2, 3, and 4 freshwater and estuarine finfish and shellfish weighted by population for the Southern, Gulf of Mexico, and Atlantic regions of Florida, using "usual" fish consumption rate data published by USEPA (2014b). The distribution mean and 95th percentile are approximately 11 and 45 g/day, respectively.

The EU FCR of 115 g/day was based on the highest yearly consumption observed for a member state in a 1992 survey (RIVM, 2016b). In 2018, EU revisited the FCR and determined that 115 g/day was still a representative 95th percentile based on data from 16 countries reporting on consumption of fishery products (EU, 2018). Nonetheless, this is the highest FCR used compared with the FCRs used by other jurisdictions in this review.

The nearly eightfold range in FCRs observed in this review reflects differences in the target population and the fish consumption study selected. Some states have selected FCRs that reflect high-end consumption by the general population and average consumption by sport anglers (e.g., Michigan, Wisconsin). Florida's use of a probabilistic approach explicitly includes high-end as well as average consumers and allows for selection from a distribution of water quality criteria associated with various levels of protectiveness. The PFOS and PFOA criteria selected by Florida correspond to the 10th percentile on the distribution of criteria (i.e., protective of 90% of the population). The jurisdictions with the most stringent human health criteria, including Minnesota, California's SFB RWQCB, and the EU, used FCRs ranging from 66 to 115 g/day. These rates are more than three to five times the 90th percentile of 22 g/day for the general US population used by the USEPA to set NRWQC (USEPA, 2017). The EU's FCR of 115 g/day exceeds the 99th percentile of usual fish consumption by the general US population (USEPA, 2014b) and is equivalent to eating a half-pound of freshwater fish and shellfish every other day of the year.

The FCRs used to derive SWQC should represent long-term (usual) consumption patterns of a population (USEPA, 2014b, 2015). The degree to which survey design and data analysis methods were considered when selecting an FCR for human health criteria derivation is uncertain. Due to the episodic nature of fish consumption, use of consumption data from short-term surveys (especially those conducted during peak fish consumption periods) without proper statistical adjustment can lead to FCRs that do not represent long-term consumption or the target population (USEPA, 2014b, 2016c).

Bioaccumulation factors. Bioaccumulation of PFAS in aquatic organisms has been extensively documented (Buck et al., 2011; Burkhard, 2021; Giesy & Kannan, 2001; Houde et al., 2006; Martin et al., 2004). Bioaccumulation factors (BAFs) reflect contaminant uptake via all exposure routes and media (e.

TABLE 4 Key exposure parameters for human health SWQC for PFOS and PFOA

Parameter	California San Francisco Bay RWQCB	Florida	Michigan	Minnesota	Wisconsin	Australia	Canada	European Union
<i>Fish consumption rate (FCR)</i>								
FCR (g/day-ww)	80	Mean = ~11	15 (total) 3.6 (TL3)	66	20	8 g/day (crustaceans) 73 g/day (finfish)	Evaluate on site-specific basis	115
		95th percentile = ~45	11.4 (TL4)			5 g/day (fish liver)		
<i>Bioaccumulation factors (BAF)</i>								
PFOS BAF (L/kg)	13 229 dw	937 ww (TL2) 2959 ww (TL3)	2329 (TL3)	7210	Derived using statistical regression of paired surface water and fish tissue data	No SWQC based on fish consumption; evaluate using seafood trigger levels	–	BCF = 2796 (based on bluegill sunfish) BMF = 5
PFOA BAF (L/kg)	894 dw	35 ww (TL2) 71 ww (TL3)	5047 (TL4)	–				–
	224 ww	161 ww (TL4)						
<i>Relative source contribution (RSC)</i>								
RSC	Not used	0.6 (fish only)	0.8 (water and fish)	0.2 (water and fish)	0.8 (water and fish)	0.1 (fish)	0.2 (water only)	0.1 (water) 0.1 (fish)

Note: See Supporting Information: Table S-4 for exposure parameter details and references. Abbreviations: BAF, bioaccumulation factor; BCF, bioconcentration factor; BMF, biomagnification factor; dw, dry weight; FCR, fish consumption rate; L/kg, liters per kilogram; PFOA, perfluorooctanoic acid; PFOS, perfluorooctane sulfonate; RSC, relative source contribution; RWQCB, Regional Water Quality Control Board; TL, trophic level; ww, wet weight.

g., water, food, sediment) and are typically based on field studies, whereas BCFs reflect uptake through water exposure only and are laboratory-derived (Burkhard, 2021; USEPA, 2003). The implicit assumption is that an acceptable concentration of the contaminant in the fish tissue is achieved when the SWQC is met such that adverse effects are not observed.

Apart from the EU, which used a BCF coupled with a BMF to derive its PFOS EQS based on fish consumption, BAFs have been used to derive PFOS and PFOA criteria. The BAFs range more than an order of magnitude reflecting differences in the studies used, the species and/or trophic level selected, tissue type, and degree of conservatism (e.g., use of upper-bound statistic vs. geometric mean; Table 4 and Figure 5). The USEPA (2000) specifies that the edible portion of fish (fillet) should be used to calculate BAFs for human health criteria; however, some BAFs are based on the entire fish or parts of fish such as the liver where PFAS preferentially accumulate. Bioaccumulation factors need to be expressed on the same basis as FCRs (both wet weight [ww] or both dry weight [dw]) to correctly calculate SWQC. Fish consumption rates are typically expressed on a ww (raw) basis.

Available data suggest that PFOA is not as bioaccumulative as PFOS, which is reflected in the lower BAFs (Table 4). The highest BAF (13 229 L/kg-dw for PFOS) is the geometric mean of 23 field-measured BAFs (ranging from 720 to 126 302 L/kg-dw, standard deviation of 33 421 L/kg-dw, 95th percentile 98 409 L/kg-dw) for a variety of fish species (Divine et al., 2020). The Divine et al. (2020) BAFs were developed

to evaluate ecological risk, include whole body data, and are presented on a dw basis. The SFB RWQCB used a dw BAF in conjunction with a ww FCR to derive its ESLs, leading to the human health seafood ingestion ESLs being artificially low. Had the BAF been converted to a ww basis (using a 75% moisture content [USEPA, 1993]), the resulting BAFs of 3307 kg/L-ww (PFOS) and 224 kg/L-ww (PFOA) would be more in line with the BAFs used by other states (Table 4 and Figure 5).

The PFOS BAFs used by the other US states in human criteria development range from 937 L/kg-ww (Florida, trophic level 2) to 7210 L/kg-ww (trophic levels 3 and 4, Minnesota). Michigan and Florida's BAFs represent geometric means based on fillet tissue for multiple species. Minnesota derived a PFOS BAF from paired surface water and fillet tissue data for trophic levels 3 and 4 fish species historically revealing higher PFOS levels (MPCA, 2020a). To account for WCBA who may regularly consume species with higher PFOS levels, Minnesota determined that an additional measure of conservatism was needed and used the 90th percentile of the geometric means (7210 L/kg-ww) instead of the geometric mean (4289 L/kg-ww; MPCA, 2020a). Instead of using a numeric BAF, Wisconsin applied a regression approach using paired surface water and fish tissue data to identify the PFOS surface water concentration (8 ng/L, referred to as the level of public health significance) that is expected to meet the one meal per week threshold of 50 ng/g used by the state for setting a fish consumption advisory (WDNR, 2021).

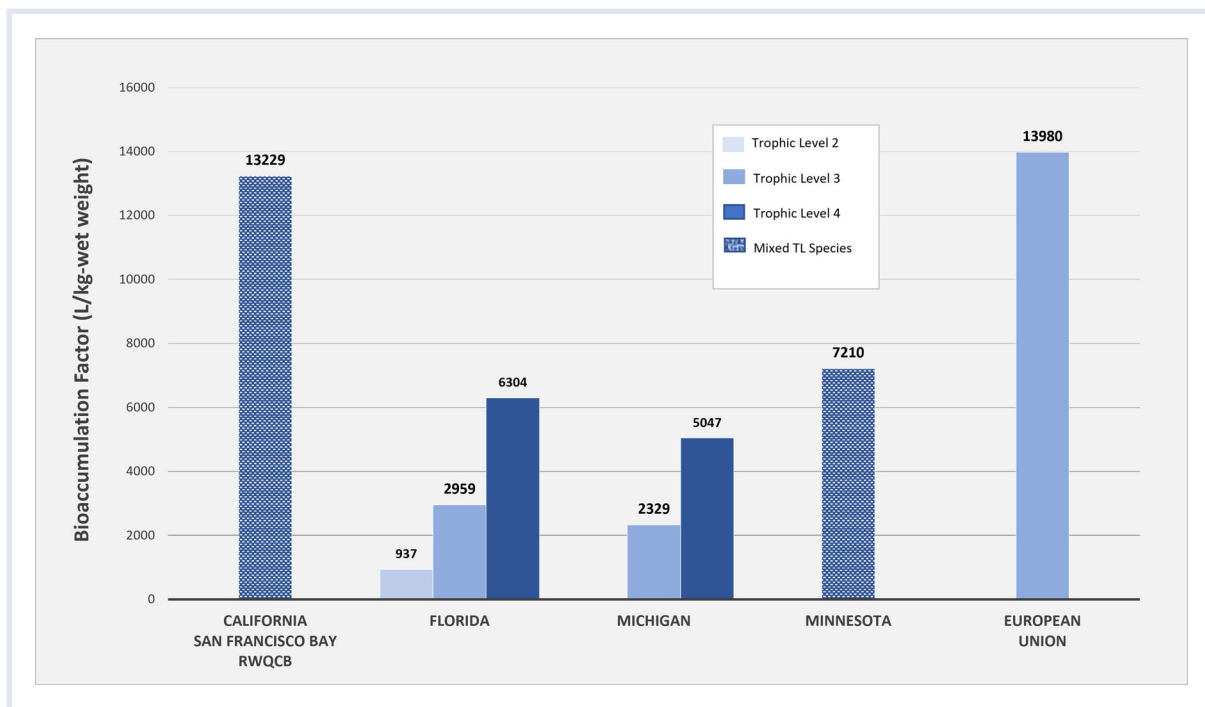


FIGURE 5 Bioaccumulation factors for perfluorooctane sulfonic acid used in human health surface water quality criteria derivation. The bioaccumulation factor shown for the California San Francisco Bay RWQCB of 13 229 L/kg is a dry weight value (SFB RWQCB, 2020); however, it was used in screening level derivation as if a wet weight value. The bioaccumulation factor shown for the European Union is the product of a bioconcentration factor of 2796 L/kg (whole body bluegill sunfish) and a biomagnification factor of 5 (EU, 2011). BAF, bioaccumulation factor; L/kg, liters per kilogram; RWQCB, Regional Water Quality Control Board; TL, trophic level

To derive the PFOS EQS for human fish consumption, the EU used a BCF of 2796 L/kg based on a study of bluegill sunfish (whole fish) and a BMF of 5 kg consumer/kg diet-ww (EU, 2011). The BMF is the average of multiple values (range of 0.77–6) published in a review by the Dutch National Institute for Public Health and the Environment (RIVM, 2010). There is uncertainty in the BMF although RIVM has continued to use a BMF of 5 for PFOS in more recent evaluations (RIVM, 2016a, 2020). Conder et al. (2020) recommend a diet to fish tissue BMF of 0.32 for PFOS. Divine et al. (2020) note that biomagnification of PFOS between trophic levels is not fully understood, and there is a large variation in BMFs reported for PFAS constituents, geographical locations, and food web complexity. Biotransformation into other, more stable, PFAS is also a complicating factor in determining BMFs (Divine et al., 2020).

Data gaps in understanding the influencing factors on organism uptake, metabolism, and depuration of PFAS are considerable (Ankley et al., 2021; Burkhard, 2021). Study design, sampling methods, species, and environmental variables also influence bioaccumulation factors (Barnhart et al., 2021). As previously noted, Australia and Canada have deemed uncertainty in quantifying the surface-water-fish bioaccumulation relationship too great and elected not to derive SWQC for human or wildlife receptors based on fish consumption. Instead, Australia uses risk-based seafood “trigger levels” to evaluate fish consumption risk if PFAS are a contaminant of concern (FSANZ, 2017). Canada takes a site-specific approach if PFAS are present and fish consumption is a pathway of concern (Longpre et al., 2020).

Relative source contribution. Humans may be exposed to PFAS through multiple media, including diet, drinking water, contact with consumer products, indoor air, and dust. The derivation of SWQC based on noncancer effects includes an RSC factor that represents the amount of the RfD or TDI allocated to water and fish consumption. The RSCs used in SWQC derivation range from a low of 10% for fish consumption and 10% for drinking water (EU) to 80% for the combination of fish consumption and drinking water (Michigan; Table 4). The eightfold range in RSCs used by various jurisdictions reflects regulatory policy, consideration of the RSC used for drinking water, and uncertainty in the degree to which fish and other sources of exposure contribute to total daily intake of various PFAS.

The USEPA's default RSC for surface water criteria derivation is 20%; however, alternative RSCs up to 80% may be used depending on exposure data (USEPA, 2000). Florida used an RSC of 60% in their derivation of criteria for PFOS and PFOA based on fish consumption. The Florida Department of Environmental Protection (FDEP) contracted the University of Florida to review the available data and derive chemical-specific RSCs for PFOS and PFOA (Roberts & Stuchal, 2020). Using the “percentage” method (USEPA, 2000), the acceptable daily intake afforded by the RfD used by Florida (2E–05 mg/kg-day) was apportioned to various exposures, including 20% to drinking water (already

incorporated in the state's guidelines), 1% to diet other than fish, and 20% to other sources (41% total). Based on the analysis, it was determined that the remainder (approximately 60%) could be allocated to fish consumption (Roberts & Stuchal, 2020). The RSC analysis performed to support Florida's human health criteria development could be adapted to other jurisdictions and exposure data.

Several studies have used human serum concentrations to quantify exposures via various pathways (Poothong et al., 2020; Sunderland et al., 2019). Sunderland et al. (2019) compiled exposure estimates from eight studies and identified diet as the largest contributor for both PFOS and PFOA (see Supporting Information: Figure S-1). A study in Norway estimated that 91% (median) of exposure to PFAAs comes from diet and drinks and 5% from indoor air and dust (Poothong et al., 2020). Based on dietary exposure survey and analytical data of more than 10 000 food samples, EFSA identified consumption of fish and seafood as the largest contributor to dietary PFOS exposure (average of approximately 60%; EFSA, 2018). For both PFOS and PFOA, the available data support an RSC higher than a default of 20%. Increasing the RSC will result in a corresponding increase in the SWQC.

Considerations and challenges in ecological criteria development

The five orders of magnitude variation observed in aquatic life criteria reflect differences in agency choices regarding data adequacy (e.g., toxicity data selection and treatment of uncertainty), derivation methodology (e.g., species sensitivity distribution [SSD]), and bioaccumulation factors. Wildlife criteria are fewer and less variable than aquatic life criteria; however, the same issues of data adequacy (e.g., limited quality data and variability in derivation assumptions), as well as uncertainty in quantifying bioaccumulation, challenge the development of these criteria. Considerations and challenges associated with ecological criteria development are discussed below.

Data adequacy. The data requirements for derivation of aquatic life criteria are significant. For example, as described by Stephen et al. (1985), USEPA requires toxicity testing data for at least one species of freshwater animal in at least eight different families and requires that studies be excluded when certain criteria are not met, including when taxa are not ecologically relevant, when chemical exposure involves more than a single chemical, and when exposure concentration or dose rates are not included. Similar toxicity data requirements are applied by other jurisdictions in their derivation of aquatic life criteria (e.g., Australia, Canada). As indicated in USEPA's publication of draft federal aquatic life criteria in April 2022, acceptable data are available to satisfy most of the minimum data requirements in freshwater for PFOS and PFOA (USEPA 2022a, 2022b); however, other PFAS currently do not have sufficient data for aquatic life criteria development. The lack of available toxicity values and the cost to conduct toxicity studies and evaluate the

data are cited by states as reasons for deferring criteria development and waiting for national efforts to fill data gaps and/or calculate criteria (ECOS, 2022; New Hampshire Department of Environmental Services [NHDES], 2019; VT ANR, 2019).

Although acute toxicity data are far more available than chronic toxicity data, derivation of SWQC requires the latter. An acute-to-chronic ratio (ACR) can be calculated using acute and chronic toxicity data (preferably from the same study) and used to estimate chronic toxicity for similar species when only acute toxicity data are available. Species mean ACRs can be calculated and included in the derivation of SWQC to estimate chronic data for related species that have only acute data (Stephen et al., 1985; USEPA, 1995, 2010). This approach was used by Conder et al. (2020) to estimate PFOS and PFOA aquatic chronic toxicity for use in the SSDs used to derive chronic criteria adopted by SFB RWQCB. An ACR of 8.3 was used for PFOS and an ACR of 18 was used for PFOA with the same ACR applied across species (e.g., fish, amphibian, invertebrate) and test endpoints (e.g., survival, growth, reproduction). For the state of Florida, Stuchal and Roberts (2019) derived geometric mean ACRs of 15.3 for PFOA in freshwater, 14.5 for PFOS in freshwater, and 15.6 for PFOS in marine water to develop screening levels for aquatic health in surface water. The use of ACRs to fill chronic toxicity data gaps introduces uncertainty because of the large variation in responses across species, endpoints, chemical mode of action, and test conditions that are not captured using a fixed ACR (Raimondo et al., 2007).

Much of the existing aquatic toxicity and bioaccumulation research on PFAS has focused on PFOA and PFOS with far less data available for other PFAS. Of the PFAS exposure studies conducted with aquatic animals, more data are available for aquatic invertebrates (e.g., daphnids, insect larvae) than for fish or amphibians. Ankley et al. (2021) indicated that more than 90% of the fish toxicity data in USEPA's ECOTOX Knowledgebase focuses on PFCAs and PFASs with the remainder focusing mostly on fluorotelomers. Perfluorooctane sulfonic acid and PFOA represent more than 60% of the available fish data with twice as many data for PFOS than PFOA. Most toxicity and bioaccumulation testing have been conducted using freshwater species. The ECCC (2018) indicated there were not enough marine chronic data for PFOS to derive a marine water quality guideline, so the criterion applies only to freshwater systems. Similarly, bioaccumulation data for marine species are more limited than for freshwater species. According to Burkhard (2021), further research is needed to determine whether BAFs for freshwater and marine species should be the same or different.

Although not developed as regulatory criteria, recommended water quality risk-based screening levels (RBSLs) protective of aquatic life were developed recently through the US Strategic Environmental Research and Development Program (SERDP) for 23 PFAS (Divine et al., 2020; Zodrow et al., 2021) based on published literature reviews and

peer-reviewed aquatic toxicity studies, and Great Lakes Initiative (GLI) methodology (USEPA, 2012). This methodology requires toxicity data for eight species groups to derive a Tier I value and provides an approach to deriving Tier II values using UF when the data requirements for eight species groups are not met.

Only PFOS and PFOA had sufficient data available to derive Tier I values, and UF were used to derive Tier II values for the remaining PFAS. This approach may result in Tier II values that are lower than Tier I values because of the application of conservative UF intended to account for fewer taxa being represented in the datasets. Although PFOS had sufficient data to derive a Tier I chronic aquatic life RBSL of 3900 ng/L (Zodrow et al., 2021), several Tier II values for fluorotelomer carboxylic acids (FTCAs) were lower. Given the smaller datasets for the FTCAs, the Tier II values reflect the use of UF, and these PFAS are unlikely to be more toxic than PFOS. The difference between Tier I and Tier II values is an example of how the lack of sufficient toxicity data can influence the derivation of SWQC and the interpretation of potential exceedances. The use of UF to derive Tier II values when the requirements for a Tier I value are not met is likely to result in overly conservative criteria.

As previously noted, SWQC for wildlife are limited (Michigan, California SFB RWQCB, and the EU; Table 3). To derive SWQC protective of wildlife, chronic PFAS toxicity studies with avian and mammalian test species are needed. To date, most wildlife toxicity research has been conducted with PFOS and small mammals such as mice, rats, and rabbits (Divine et al., 2020). Endpoints such as survival, growth, and reproduction are most relevant to the derivation of wildlife SWQC, and the inclusion of other types of endpoints (e.g., histopathology, liver function) may not be relevant to the overall health of the wildlife community to be protected. The available PFAS toxicity data for birds are far less than for mammals; only nine avian toxicity values were used by Divine et al. (2020) to derive avian RBSLs for PFOS whereas more than 50 toxicity values were used for mammals.

The ongoing publication of new studies poses a challenge to jurisdictions attempting to derive regulatory criteria because the state-of-the-science continually evolves. Minnesota developed draft aquatic life SWQC for PFOA and PFOS in 2007 (MPCA, 2007a, 2007b), and Michigan developed values in 2010 and 2014 (Michigan EGLE, 2020). Additional toxicity data have been developed since these early values were published. For PFOS alone, Zodrow et al. (2021) identified 187 aquatic toxicity endpoints from 60 papers with approximately 60% of the papers published after 2007. It should be noted that, as new studies and data are generated, emphasis should be placed on the evaluation of study design, QA/QC, and analytical methodologies to ensure only well-founded studies are used for criteria development (Moore et al., 2022).

Species sensitivity distributions. Species sensitivity distributions serve as the basis for aquatic life SWQC derived by the three jurisdictions reviewed: California SFB RWQCB,

Australia, and Canada. According to Fox et al. (2020), the SSD is a statistical approach used to estimate either the concentration of a chemical that is hazardous to no more than $x\%$ of all species (the HC x) or the proportion of species potentially affected by a given concentration of a chemical. Although the method is widely used for criteria derivation, the approach to selecting toxicity data (e.g., acute, chronic, no effect, effect) and distribution models are not standardized and vary by regulatory entity. Consequently, the resulting SWQC are sensitive to the range and distribution of values used in the SSD.

For example, the aquatic toxicity ESLs for PFOS and PFOA derived by the California SFB RWQCB were based on SSDs that considered no observed effect concentration (NOEC) acute and chronic results for a variety of algae, macrophytes, aquatic invertebrates, and fish, with aquatic invertebrate data making up most of the datasets for both chemicals (Conder et al., 2020). Acute-to-chronic ratios from Giesy et al. (2010) were used to convert acute values to chronic values for use in the SSDs, rather than using only chronic study results. Conder et al. (2020) noted that, although some may opt to include only chronic studies to derive PFAS SWQC, the use of ACRs may be appropriate to allow a wider inclusion of species when deriving chronic criteria. For both PFOS and PFOA, the HC1 and HC5 values identified by the SSD (protective of 99% and 95% of species, respectively; Table 2 and Supporting Information: Table S-5) are below the lowest of the toxicity values considered in the distribution. USEPA (2022a, 2022b) identified sufficient acute and chronic aquatic toxicity data that ACRs were not necessary to derive the draft national recommended aquatic life chronic criteria for PFOA and PFOS (i.e., acute toxicity data were used to derive the acute criteria, and chronic toxicity data were used to derive the chronic criteria).

Australia (DoEE, 2016a, 2016b) also used SSDs to derive draft PFOS and PFOA SWQC. The level of species protection for a site is chosen according to the degree of protection afforded to a water body based on its ecosystem condition. As shown in Table 2, values were derived for the protection of 99%, 95%, 90%, and 80% of species. A major source of uncertainty in the PFOS SWQC is that the SSD statistically extrapolated the test results to concentrations that are well below the concentrations that correspond to effects measured in the toxicity studies. There is greater uncertainty for estimating a 99% spp. than a 95% spp. value from an SSD due to lower confidence in the model fit at extremes of the distribution (Batley et al., 2018). The most sensitive species to PFOS exposure was the zebrafish (*Danio rerio*; Keiter et al., 2012), which is primarily responsible for the PFOS 99% spp. SWQC of 0.23 ng/L. A recent review identified several limitations to this study, which has been replicated with a more robust experimental design, including a greater number of exposure concentrations, more replicates, and improved analytical capabilities, to “increase statistical rigor and ensure technically defensible results” (Moore et al., 2020). Preliminary results found no significant effects on survival or reproduction of zebrafish at the highest

tested PFOS concentration of 100 000 ng/L. Reduced growth was observed at the highest PFOS exposure concentration of 100 000 ng/L (Gust et al., 2021; Moore et al., 2022), but the growth reduction reported by Keiter et al. (2012) at 600 ng/L was not reproducible. The USEPA (2022b) discussed Keiter et al. (2012) but did not include the study results in the quantitative derivation of the draft national recommended aquatic life criteria for PFOS due to the “...poor concentration-response relationship with the endpoints evaluated...” and test design complications.

In Canada, the PFOS Federal Water Quality Guideline (FWQG) of 6800 ng/L represents the 5th percentile calculated from an SSD developed using long-term (chronic) toxicity data for two amphibians, five fish, five invertebrates, and eight plant species (ECCC, 2018). This value is expected to be associated with no, or only a very low, likelihood of adverse effects. The SSD approach considered several cumulative distribution functions and the best model (log-normal) was selected based on goodness-of-fit (ECCC, 2018). The 5th percentile selected as the FWQG was only slightly below the lowest toxicity data point considered in the SSD.

Conder et al. (2020) noted that for PFOS, SSDs derived by multiple authors indicate that adverse effects to the majority (95%) of aquatic species are not expected in freshwater systems below approximately 5000 ng/L (ECCC, 2018; Giesy et al., 2010; Qi et al., 2011), or below 220 000 ng/L for PFOA (DoEE 2016a; Giesy et al., 2010). Similarly, SSDs based on marine species suggest that adverse effects for the majority (95%) of aquatic species are not expected below 8000 ng/L for PFOS or below 9000 ng/L for PFOA (Conder et al., 2020; CRC CARE, 2017).

Differences in SSD modeling software may influence the SWQC, and the selected software and model are not always identified (Conder et al., 2020; ECCC, 2018). Fox et al. (2020) identified nine different software tools for fitting SSDs using a variety of methods with varying limitations (e.g., the ability to handle censored data). The selection of the distributional form and fit of the SSD model is important because it influences the left-tail (sensitive) region and the resulting HC5 or HC1, particularly for small datasets. The strengths and weaknesses of the software program selected for SSD development should be understood and communicated as part of the derivation of the associated SWQC.

Bioaccumulation factors. A few jurisdictions (California SFB RWQCB, Michigan, and EU) have developed SWQC that are protective of wildlife that consume aquatic prey items such as fish (Table 3). The derivation of these criteria requires BAFs that account for the accumulation of PFAS from surface water into the prey items consumed by wildlife.

Bioaccumulation factors used to derive wildlife SWQC should be based on whole body tissue concentrations because wildlife often consume the entire prey item. Bioaccumulation studies for PFAS have focused primarily on PFOS and PFOA and have generally prioritized fish tissue over other tissue types that could also be consumed by

wildlife (e.g., shellfish). Burkhard (2021) identified whole body fish and fillet BAFs for several perfluorocarboxylic acids (PFCAs; e.g., PFOA, PFBA, PFHxA) and perfluorosulfonic acids (PFSAs; e.g., PFOS, PFHxS), but few for phosphonic acids and fluorotelomers. For classical nonionic organic chemicals (e.g., PCBs, dieldrin), lipid normalizing can result in equivalent BAFs for whole body and fillet; thus the same BAF can be used to develop SWQC for human health and wildlife (Burkhard, 2021). However, because PFAS may also bind to serum proteins and accumulate in protein-rich tissues such as blood and liver (Barnhart et al., 2021; Jones et al., 2003) in addition to lipids, lipid normalization may not be appropriate, and separate whole body and fillet BAFs may be needed to derive SWQC for wildlife and humans, respectively.

The SFB RWQCB (2020) used the lowest wildlife RBSLs derived by Divine et al. (2020) as secondary poisoning ESLs to be protective of higher trophic level receptors (e.g., birds and mammals) consuming aquatic species. The wildlife RBSL for PFOS was derived using the same BAF (13 229 L/kg-dw; see Supporting Information: Table S-6) used in the derivation of the human seafood ingestion ESL; however, because Divine et al. (2020) expressed the food ingestion rates for wildlife on a dw basis, no ww conversions were needed. The PFOA secondary poisoning ESL was based on the RBSL for a bat so the selected BAF (379 L/kg-dw; see Supporting Information: Table S-6) represents the geometric mean of six field-measured BAFs for benthic invertebrates (e.g., bivalves and gastropods) used to represent aerial insects in the bat diet.

Michigan (MDCH 2015) derived provisional avian wildlife values for PFOS using a trophic level 3 BAF of 2367 L/kg-ww based on whole fish data for yellow perch, golden shiner, bluegill sunfish, and white bass (see Supporting Information: Table S-6). Trophic level 4 BAFs for whole fish were not available, so the ratio of the trophic level 4 fillet BAF to the trophic level 3 fillet BAF was used to estimate a whole fish trophic level 4 BAF of (5129 L/kg-ww). Using the ratio of fillet BAFs to estimate a whole fish BAF (which would include protein rich tissues where more PFAS would be expected to accumulate) results in some uncertainty in the trophic level 4 BAF.

Although Canada does not have PFAS SWQC for wildlife consuming aquatic prey, ECCC (2018) has derived tissue-based Federal Wildlife Dietary Guidelines for PFOS for the protection of wildlife (8200 ng/kg-ww—avian; 4600 ng/kg-ww—mammalian). Canada has also derived a tissue-based Federal Fish Tissue Guideline (FFTG) for PFOS for protection of fish health (see Supporting Information: Table S-5). The PFOS FFTG of 9.4 mg/kg-ww tissue was derived from the aquatic life criterion using a whole body BAF of 1378 L/kg-ww, which is based on the geometric mean of data for blue gill sunfish and carp (ECCC, 2018).

The USEPA (2022a, 2022b) used BAFs identified by Burkhard (2021) to translate the chronic aquatic life criteria for PFOS and PFOA into tissue-based criteria protective of invertebrates (whole body) and fish (whole body and muscle).

The USEPA selected the 20th percentile of the distribution of BAFs as a relatively conservative BAF estimate to protect species across taxa and across water bodies with variable bioaccumulation conditions. According to USEPA (2022a, 2022b), the use of the 20th percentile BAF protects species and conditions where bioaccumulation of PFOS or PFOA and resultant tissue-based exposures are relatively low, as well as those conditions where the bioaccumulation potential is relatively high. For PFOS, the 20th percentile BAF for whole fish is 803.9 L/kg-ww (USEPA, 2022b), which is below the BAFs discussed above for Canada and Michigan and derived by Divine et al. (2020; the BAF of 13 229 L/kg-dw is equivalent to 3307 L/kg-ww using a 75% moisture content [USEPA, 1993]).

In many Australian ecological risk assessments, local bioaccumulation effects are explicitly and quantitatively assessed (e.g., via tissue sampling and/or food web modeling) thus not requiring adoption of a higher species protection SWQC. It is unknown whether BAFs will be incorporated into updated SWQCs; however, this is considered unlikely given the NEMP position that PFAS BAFs are not sufficiently reliable (HEPA, 2020). Burkhard (2021) observed that the ranges of BAFs for several PFAS are not that different from some legacy pollutants, such as PCBs, for which BAFs are regularly used in criteria development and risk assessment.

The EU has derived secondary poisoning EQS of 2 ng/L (freshwater) and 0.47 ng/L (marine) for PFOS, and the Netherlands has derived secondary poisoning EQS for PFOA of 990 ng/L (freshwater) and 130 ng/L (marine; EU, 2011; RIVM, 2017). The EU EQS are at least an order of magnitude lower than those derived in the United States. For PFOS, this is partly a consequence of the use of a BCF and BMF that is equivalent to a whole body BAF of 13 980 L/kg-ww, which is significantly higher than the PFOS BAFs used by others and discussed above.

The wide range of PFOS BAFs (Figure 5) may be attributed to variability across species and/or trophic level, water concentration (e.g., higher BAFs observed at lower concentrations), tissue type (fillet vs. whole body), study type, and conservatism. Bioaccumulation data are limited for many PFAS and models for estimating uptake are uncertain. Because PFAS bioaccumulation may be affected by both lipid and nonlipid mediated mechanisms (Droge, 2019), field-measured BAFs should be used (vs. laboratory-measured; USEPA, 2000, 2015). Several factors contribute to variability in BAFs, including fish sex, reproductive status, and life-stage or age, as well as the degree of spatial and temporal pairing of water and fish data (Arnot & Gobas, 2006; Barnhart et al., 2021; Burkhard, 2021). Surface water quality criteria derived for the protection of wildlife should consider a wider array of tissues and species (e.g., whole body fish of different trophic levels, crustaceans, emerging insects). Understanding the basis of the BAF is important for proper application; however, relevant details are often not reported or considered in study design (Barnhart et al., 2021). Other challenges include the presence of some PFAS as both parent substance and transformation and/or

metabolism by-products and current analytical limitations measuring low (sub ng/L) concentrations (Ankley et al., 2021; Barnhart et al., 2021; Burkhard, 2021). Additionally, as a wider range of wildlife species is considered for SWQC derivation and ecological risk assessments, BAFs based on relevant prey items will be needed to avoid use of proxy species with different physiology, habitat, and diet. The limited and variable bioaccumulation data remain a major data gap and area of uncertainty for development of SWQC based on fish consumption and is a research priority (USEPA, 2020).

Analytical and background considerations

A practical limitation of current analytical methods is that detection limits are not adequate to quantify PFOS and PFOA in water at very low (sub-ng/L) criteria. Typical PFOS and PFOA reporting limits for commercial laboratories using LC/MS/MS are in the range of 1–5 ng/L for the water matrix. The USEPA's draft 1633 method released in 2021 and supporting single laboratory validation study indicate nominal detection limits of 1–2 ng/L at the lowest (USEPA, 2021c; Willey et al., 2022). As detection limits decrease below 1 ng/L, the risk of false positives caused by carryover, cross-contamination, and laboratory background may increase. Although method development continues and compound lists expand, analytical sensitivity is not expected to be sufficient to detect PFAS at the pg/L levels of some SWQCs. The lack of current or imminent analytical capability to reliably detect PFAS levels in surface water at concentrations below 1 ng/L poses a practical limitation on the application of criteria in the sub-ng/L (ppt) range.

The prevalence of PFAS in the environment poses another challenge to implementation of sub-ng/L criteria. In many locations, ambient surface water concentrations are well above the SWQC. Based on a review of data from hundreds of studies of US water bodies, Jarvis et al. (2021) reported a range of eight orders of magnitude for PFOS in US surface waters, with a geometric mean of 5.5 ng/L and median of 3.6 ng/L. The authors classify surface water bodies with concentrations less than 30 ng/L as “very low” (Jarvis et al., 2021). Vedagiri et al. (2018) reported a two to three order of magnitude range in background levels of PFOA and PFOS, with median concentrations higher than 10 ng/L in multiple North American water bodies. In several studies of rivers and lakes in the northeastern United States, median concentrations of PFOS and PFOA ranged from less than 1 to 6.3 and 1 to 8.8 ng/L, respectively, with lower concentrations in rural versus urban areas (New Jersey Department of Environmental Protection, 2018; Savoie & Argue, 2022; Zhang et al., 2016). Detection of PFAS in less developed regions of the world suggests consumer products as potential sources as well as long-range atmospheric transport (Kurwadkar et al., 2022).

In Australia, surface waters at 55 sites in Queensland were monitored bimonthly for a year (2019–2020); biota sampling was also performed at select sites (Baddiley et al., 2020). Per- and polyfluorinated substances concentrations close to

the reporting limits of 0.1–1.0 ng/L were observed at locations near conservation, agriculture, and forestry and/or grazing land. The highest surface water PFAS concentrations were reported at urban and industrial locations in southeast Queensland, with up to 17 ng/L PFOS in urban areas. This finding is consistent with other Australian monitoring programs conducted in Victoria (Allinson et al., 2019; Sardiña et al., 2019), New South Wales (Thompson et al., 2011), and South Australia (Gaylard, 2017).

Between 2014 and 2019 in the UK, the Environment Agency (EA) sampled groundwater and surface water (fresh, estuarine, and coastal waters) as well as fish for a range of 16 PFCAs and PFSA. The monitoring program included approximately 470 freshwater sites, predominantly rivers, throughout the UK. Mean concentrations of PFOS and PFOA in fresh surface waters were reported to range up to 610 and 73 ng/L, respectively (EA, 2021). The highest concentrations were observed near urban and industrialized areas; in more rural areas, mean concentrations up to 5 ng/L were observed. Sampling near approximately 600 wastewater treatment works in the UK found mean upstream and downstream PFOS levels to be 4.7 and 5.2 ng/L, respectively, and 3.7 and 4.0 ng/L for PFOA, indicating a prevalence across English waters (EA, 2021).

Surface water sampling for PFAS has also been undertaken in several EU countries. In the Netherlands, concentrations of PFOS and PFOA were reported for 46 surface water sampling locations, and concentrations above the detection limit were reported for 25 (54%) of the samples. The average and maximum detected concentration of PFOS were 3.2 and 40 ng/L, respectively. For PFOA, the average and maximum detected concentrations were 18 and 100 ng/L, respectively (Expertisecentrum PFAS, 2018).

In summary, PFAS concentrations in fresh and estuarine surface waters range over several orders of magnitude, with higher concentrations near urban and industrialized areas and known point sources (Jarvis et al., 2021; Zhang et al., 2016). Based on the studies summarized here, ambient concentrations of PFOS and PFOA in surface waters without known point sources range from less than 1 to 10 ng/L (or higher), with concentrations generally increasing as location characteristics change from rural to urban (see Supporting Information: Table S-7 for additional details on the cited surface water studies).

SUMMARY AND CONCLUSIONS

Efforts to regulate PFAS in surface water continue because of their environmental prevalence, identified ecological and mammalian hazard profile, and their bioaccumulation potential in aquatic and terrestrial organisms. However, data gaps and uncertainty in PFAS toxicity, exposure, and environmental fate, as well as the continuous publication of new studies and scientific updates, pose significant challenges to agencies striving to establish policy and regulatory limits. These data gaps have led to a diverse array of criteria and approaches, leading to continued uncertainty and lack of consensus within the regulatory and

scientific communities. Across the eight jurisdictions included in this review, criteria promulgated for the same compound and target receptor span more than five orders of magnitude as a result of the use of different mechanistic and empirical approaches, and data interpretations. Some of the reviewed criteria are below analytical detection limits and ambient background levels.

The broad range of reported associations in humans and the variability in sensitivity by gender, age, and health status pose challenges to establishing confident human health protection levels for PFAS in surface water. Concerns regarding the potential for adverse outcomes during sensitive life stages as well as uncertainty in PFAS exposures have led to conservative assumptions regarding toxicity, intake rates, bioaccumulation, and exposure source. The lack of acute and chronic aquatic toxicity data for a variety of test organisms, small and often highly variable toxicity and bioaccumulation datasets available for many PFAS, and reliance on limited ACR data to address chronic toxicity data gaps increases uncertainty in ecological SWQC for PFAS.

Understanding of PFAS toxicity and exposure continues to evolve. Knowledge gaps in mode of action, critical endpoint, organism exposure, and environmental fate present opportunities for application of new approach methodologies, standardization of protocols, and additional studies to refine data gaps and associated assumptions used in criteria derivation. There is a need for validation using empirical data and improved models that accurately characterize bioaccumulation and exposures depending on PFAS. Application of *in silico* approaches to advance understanding of PFAS behavior and toxicity has potential implications for focusing criteria development on specific types of PFAS (e.g., compounds with higher bioaccumulation potential). Computational tools such as quantitative structure activity relationships and SSDs provide robust methods for integrating disparate and limited datasets (Dalgarno, 2021; Fox et al., 2020). Probabilistic risk assessment remains an underutilized tool for explicitly incorporating variability and uncertainty in criteria development and providing more complete information for risk management decision-making (Barnhart et al., 2021; Tatum et al., 2015).

Key knowledge gaps where the authors believe additional information would most readily reduce uncertainty and improve PFAS SWQC development include: (1) improved understanding of the fate of PFAS in aquatic ecosystems, including partitioning to biotic and abiotic matrixes and differences across chain length and functional groups, to improve estimates of bioaccumulation-based criteria; (2) improved understanding of the relative importance of human exposure routes for key PFAS, including the contribution from fish relative to other sources to inform the choice of RSC factor; (3) expanded datasets of chronic duration aquatic life studies across multiple species and PFAS to increase the aquatic toxicity knowledge base; (4) improved understanding of PFAS toxicity to wildlife including birds, amphibians, and reptiles to allow for the development

of criteria protective of higher trophic level vertebrates; and (5) expanded knowledge bases on ambient levels of PFAS in surface waters to provide context for SWQC.

AUTHOR CONTRIBUTION

Betsy Ruffle: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; supervision; visualization; writing—original draft; writing—review and editing. **Christine Archer:** Data curation; formal analysis; investigation; methodology; resources; visualization; writing—original draft; writing—review and editing. **Kelly Vosnakis:** Data curation; formal analysis; investigation; methodology; resources; visualization; writing—original draft; writing—review and editing. **Josh D. Butler:** Data curation; resources; writing—review and editing. **Craig W. Davis:** Data curation; resources; writing—review and editing. **Belinda Goldsworthy:** Data curation; formal analysis; investigation; writing—original draft; writing—review and editing. **Rick Parkman:** Data curation; formal analysis; investigation; writing—original draft. **Trent A. Key:** Conceptualization; data curation; funding acquisition; project administration; resources; writing—review and editing.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data supporting the findings of this study are available within the article and the Supporting Information. Any questions on data may be directed to the corresponding author Betsy Ruffle at betsy.ruffle@aecom.com.

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SUPPORTING INFORMATION

Tables and figures provide additional details on the inputs and assumptions used by each jurisdiction included in the review, as well as additional information on the studies cited for estimating ambient levels of PFAS in surface water. PFAS SWQC_Manuscript_SupplInfo_v1_04122023.

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