Maine CDC Scientific Brief: 2023 PFOS Fish Consumption Advisory

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The Maine Center for Disease Control and Prevention (Maine CDC) is responsible for regularly assessing whether any health threats exist for persons consuming freshwater and anadromous fish caught in state waters by noncommercial anglers and issuing a consumption advisory if threats to public health are identified (MRSA 22 § 1696 I). This document discusses recent analyses and recommendations regarding freshwater fish consumption in Maine. Specifically, it describes proposed waterbody-specific advisories based on newly obtained data on elevated levels of PFOS in fish tissue.

I. Approach to Fish Consumption Advisories

Maine CDC derives and uses chemical-specific fish tissue action levels (FTALs) as a guide to determine the need to develop a fish consumption advisory. FTALs are concentrations of a contaminant, in this case perfluorooctane sulfonic acid (PFOS) [1], in fish tissue below which there should be negligible risk of toxicity at a set fish consumption rate. Measured concentrations of PFOS in fish tissue are compared to the FTAL. When fish tissue concentrations exceed an FTAL, the development of a fish consumption advisory is considered. Fish consumption advisories are presented as an allowable fish consumption rate that is not expected to exceed the toxicity value of PFOS, which is a measure of daily dose that results in a minimal risk of any adverse health outcome. In 2022, Maine CDC updated the PFOS FTAL to 3.5 nanograms per gram (ng/g) to reflect the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) 2021 toxicity value, which is 10-fold lower than the U.S. Environmental Protection Agency (EPA) toxicity value upon which Maine CDC had previously relied (*see* Appendix B). Using ATSDR's toxicity value and an 8 oz fish meal size for adults, Maine CDC calculates fish tissue PFOS concentrations that correspond to specified meal frequencies (Table 1).

Table 1. Levels of PFOS in fish and corresponding 8-ounce meal advice categories.

PFOS in fish (ng/g)	Meal advice
3.5	1 meal per week
7.5	2 meals per month
15	1 meal per month
30	6 meals per year
60	3 meals per year
> 60	Do Not Eat

Maine CDC considers issuing a fish consumption advisory if fish cannot be safely consumed at a rate of at least one meal per week. Thresholds for issuing a Do Not Eat (DNE) advisory are evaluated on a contaminant-specific basis. For PFOS, Maine CDC will issue a DNE advisory when fish cannot be safely consumed at a rate of at least three meals per year because at very low consumption rates (and the

[1] For PFAS action levels, Maine CDC follows the PFAS naming convention indicated by ATSDR, which follows the U.S. CDC's PFAS terminology in using the acid form when listing the compounds full name, e.g., perfluorooctane sulfonic acid versus perfluorooctane sulfonate (ATSDR 2021).

associated higher fish tissue levels), the impact on exposure to PFOS of eating just one additional fish meal per year becomes increasingly large. Additionally, there is still emerging science on the health effects from PFOS exposure and lower toxicity values have been adopted (European Food Safety Authority) or proposed (California and EPA). Maine CDC is aware of other states using 12 meals per year (New Jersey), six meals per year (Michigan), and one meal per year (Massachusetts) as the threshold for a DNE advisory for PFOS.

In considering whether to issue an advisory, Maine CDC also evaluates whether the resulting advisory would be more restrictive than any existing advisories[2], such as the statewide mercury fish consumption advisory (Table 2). The FTAL of 3.5 ng/g for PFOS by itself allows for consumption of 8-ounces per week of any sport caught fish of any species for adults. However, a weekly consumption of recreationally caught fish in Maine waters of up to one meal per week is only recommended for landlocked salmon and brook trout and only by a segment of the population due to the presence of mercury in fish tissue and the associated statewide consumption advisory (Table 2). For all other fish species, the statewide mercury consumption advisory is to eat no more than two fish meals per month. For sensitive populations (children less than 8 years of age and women who are or who may become pregnant), the statewide mercury advisory is much more restrictive and recommends no consumption of freshwater fish from Maine's inland waters except for landlocked salmon and brook trout which can be consumed at a rate of one meal per month. Thus, in determining whether a PFOS-specific advisory needs to be issued, Maine CDC will evaluate whether the concentrations of PFOS in fish tissue warrant an advisory that is more restrictive than the current statewide mercury advisory or any other waterbody-specific advisories.

Table 2. Statewide mercury fish consumption advisory.

Sensitive populations (pregnant and nursing women, women of childbearing age, children under age 8)	
Brook trout and landlocked salmon	One meal per month
All other species	Do Not Eat
General population (all other adults and children aged 8 and older)	
Brook trout and landlocked salmon	One meal per week
All other species	Two meals per month

[2] Current fish consumption advisories can be found under Maine CDC's Freshwater Fish Safe Eating Guidelines (https://www.maine.gov/dhhs/mecdc/environmental-health/eohp/fish/2kfca.htm)

II. Recommended Waterbody-Specific Fish Consumption Advisories

Maine CDC is issuing freshwater fish consumption advisories on six waterbodies in Maine. Some of the advisories are for new waterbodies and some represent expansions of advisories issued last year. The new advisories come after testing of fish in these locations found elevated levels of per- and polyfluoroalkyl substances (PFAS) above Maine CDC's recommended levels for regular consumption. The advisories recommend limiting consumption of all fish or certain fish species from these waterbodies.

Elevated levels of PFOS were detected in fish samples from the Limestone Stream below the dam near Route 229 in Limestone, Kennebec River between Hinckley and Fairfield, Number One Pond on Mousam River in Sanford, Halfmoon Stream in Thorndike, Fifteenmile Stream in Albion, and China Lake. The new fish consumption advisories apply to game fish caught in these waterbodies:

Table 3. Recommended waterbody-specific fish consumption advisories.

Area	Waterbody	Consumption Advisory
Albion	Fifteenmile Stream from the Yorktown Brook inlet at the Hussey Road to Route 137/202 in Albion.	Consume no more than 2 meals per month of brook trout.
China	All of China Lake.	Consume no more than 1 meal per month of any fish species.
Fairfield	Kennebec River from the Carrabassett Stream inlet just North of Route 23 to the Lockwood Dam in Waterville.	Consume no more than 9 meals per year of smallmouth bass.
Limestone	All of Durepo Pond and Limestone Stream from Durepo to the Canadian Border.	Consume no more than 4 meals per year of brook trout and do not eat smallmouth bass.
Sanford	All of Number One Pond.	Consume no more than 1 meal per month of largemouth bass.
Thorndike	Halfmoon Stream from the Shikles Road in Thorndike to the Berry Road in Unity near the confluence with Sandy Stream.	Consume no more than 2 meals per month of brook trout.

III. Basis for Waterbody-Specific Fish Consumption Advisories

A. Fifteenmile Stream - Albion

Area: Fifteenmile Stream from the Yorktown Brook inlet at the Hussey Road to Route 137/202 crossing in Albion.

Advisory: For the general population, consume no more than two brook trout meals per month.

Justification: In 2022, a total of five five-fish composite brook trout samples were collected along Fifteenmile Stream in Albion (Appendix Figure A1). Two of those samples were collected near the Robbins Road, two were collected near the South Freedom Road, and the final sample was a composite of fish collected at both locations (labeled "Albion" in Figure 1). The upstream samples collected near the Robbins Road had PFOS concentrations of 2.6 and 3.1 ng/g. The downstream samples collected near the South Freedom Road had PFOS concentrations of 4.1 and 6.6 ng/g (Figure 1). The middle composite sample had a PFOS concentration of 5.9 ng/g. Given the Robbins Road sample had lower PFOS concentrations than the downstream samples, the two downstream samples were combined. The combined downstream samples had a mean PFOS concentration of 5.6 ng/g and an upper confidence limit on the mean of 7.8 ng/g. Given that the upper confidence limit was greater than the maximum measured concentration, the maximum concentration of 6.6 ng/g was used as a conservative estimate of fish tissue concentrations. This corresponds to a consumption rate of no more than two brook trout meals per month.

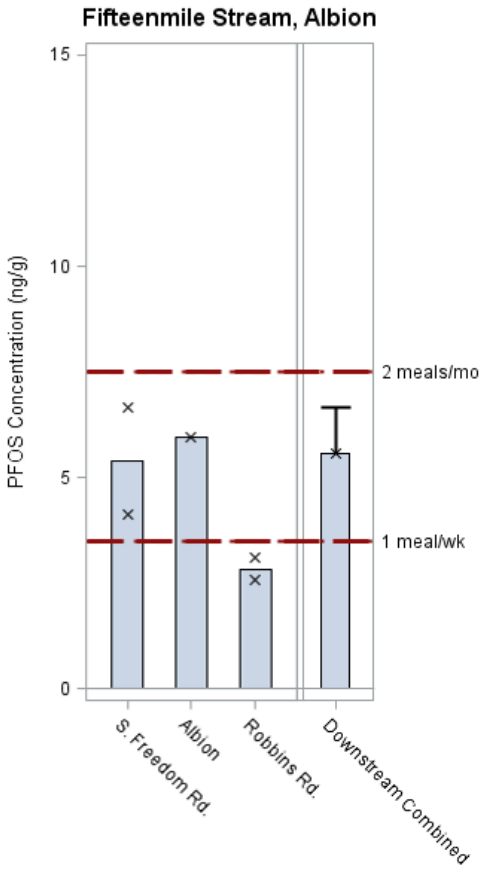


Figure 1. Fish tissue PFOS concentration in Fifteenmile Stream in Albion*. The bars correspond to the mean PFOS tissue concentration for brook trout at each location specified. The Xs correspond to the PFOS concentration in individual composite samples. The cap of the error bar (downstream combined) corresponds to the upper confidence limit on the mean.*

Given that the fish tissue PFOS concentrations at the Robbins Road and upstream were notably lower than the fish collected upstream, no fish advisory is warranted for the upstream locations at this time. The nearest geographic landmark to the Robbins Road is the Yorktown Brook inlet at the Hussey Road, which will serve as the upstream boundary for the advisory. The downstream boundary is Route 137/202, which is the nearest easily recognizable downstream landmark to where fish tissue samples were collected.

B. China Lake - China

Area: All of China Lake.

Advisory: Consume no more than one meal per month of any fish species.

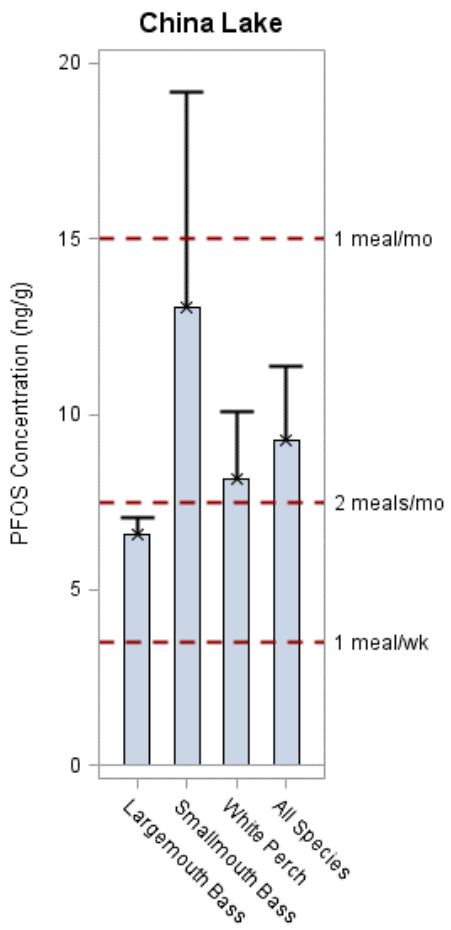


Figure 2. Fish tissue PFOS concentrations in China Lake in China. *Each bar corresponds to the mean PFOS tissue concentration for a fish species (or all species combined). The cap of the error bar corresponds to the upper confidence limit on the mean.*

Justification: Between 2020 and 2022 five five-fish composite largemouth bass, five five-fish composite smallmouth bass, and five five-fish composite white perch samples were collected from China Lake. China Lake is made up of an Eastern and Western basin (Appendix Figure A2). Most of the fish samples were caught in the Western basin. However, the few samples caught from the Eastern basin do not look appreciably different than those caught in the Western basin.

The largemouth bass samples had PFOS concentrations ranging from 5.7 to 7.0 ng/g with a mean concentration of 6.6 ng/g. The smallmouth bass samples had PFOS concentrations ranging from 6.6 to 20.72 ng/g with a mean concentration of 13.1 ng/g. The white perch samples had PFOS concentrations ranging from 5.8 to 10.7 ng/g with a mean concentration of 8.2 ng/g. Given the overlapping concentration ranges between species, all samples were combined for statistical analysis, resulting in a mean PFOS concentration of 9.3 ng/g and an upper confidence limit on the mean of 11.4 ng/g (Figure 2). The 11.4 ng/g upper confidence limit PFOS concentration corresponds to a consumption rate of no more than one meal per month.

Given the similarities in PFOS tissue levels in largemouth bass, smallmouth bass, and white perch, the above advisory applies to all fish caught in China Lake.

C. Kennebec River - Fairfield

Area: Kennebec River from the Carrabassett Stream just North of Route 23 to the Lockwood Dam in Waterville.

Advisory: For the general population, consume no more than nine meals per year of smallmouth bass.

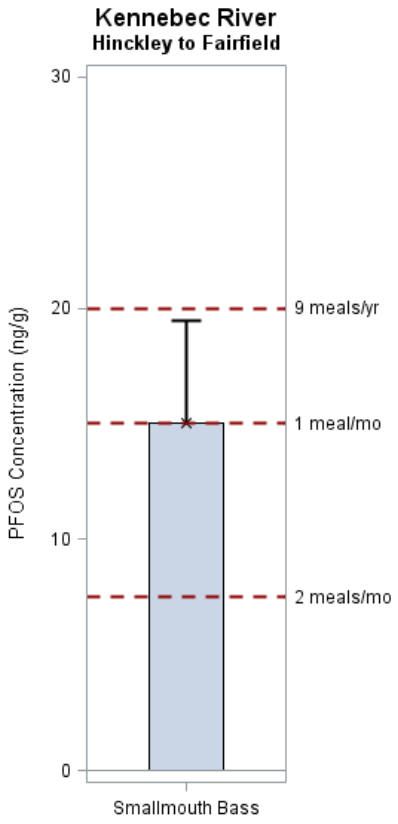


Figure 3. Fish tissue PFOS concentrations in the Kennebec River from Hinckley to Fairfield. *The bar corresponds to the mean PFOS tissue concentration for smallmouth bass, with the cap of the error bar corresponding to the upper confidence limit on the mean.*

Justification: There has been ongoing testing for PFOS in fish tissue in the Kennebec River between Madison and Gardiner since 2015. PFOS levels in fish tissue are low (i.e., <3.5 ng/g) at Skowhegan and upstream. There is a notable spike in fish sampled near Hinckley and Fairfield. At Sidney and Gardiner, PFOS levels in fish are lower, but still elevated relative to the Skowhegan and upstream samples. PFOS levels in fish tissue collected on the segment of the Kennebec River near Hinckley and Fairfield have been quite variable and were therefore sampled again in the summer of 2022. There are now a total of 10 five-fish composite smallmouth bass samples collected from the Kennebec River from Hinckley to below the Shawmut Dam. PFOS concentrations were not notably different for these two sampling locations, ranging from 6.3 to 27.6 ng/g above the dam and 7.2 to 25.5 ng/g below the dam (Appendix Figure A3). These samples were pooled for statistical analyses and the mean PFOS concentration in smallmouth bass for this section of the Kennebec River is 15.0 ng/g with an upper confidence limit on the mean of 19.5 ng/g. The upper confidence limit of 19.5 ng/g corresponds to a consumption rate of no more than nine meals per year (Figure 3). A consumption advisory of nine meals per year for smallmouth bass for the general population is more restrictive than the current advisory of no more than one to two meals per month (12 to 24 meals per year) for this stretch of water due to the historical presence of PCBs and dioxins.

The nearest upriver samples to the Hinckley samples were collected in Skowhegan. In 2019 and 2021, a total of four five-fish composite smallmouth bass samples were collected in Skowhegan below the Weston Dam. The mean PFOS concentration in these samples was 1.9 ng/g with a maximum PFOS concentration of 2.7 ng/g. Downstream of Fairfield, the nearest sample location is in Sidney. In 2019, two five-fish composite smallmouth bass samples were collected from the Kennebec River in Sidney that had PFOS concentrations of 6.2 and 7.3. Given the available data for upstream and downstream sections of the Kennebec River, the boundaries for this fish consumption advisory were deemed to fall somewhere between Skowhegan and Sidney. In the absence of additional fish tissue data along these sections, the Carrabassett Stream inlet and Lockwood Dam were selected as easily recognizable landmarks to serve as Northern and Southern boundaries to this fish consumption advisory.

D. Durepo Pond and Limestone Stream – Limestone

Area: All of Durepo Pond and Limestone Stream to the Canadian border.

Advisory: Consume no more than four meals per year of brook trout and Do Not Eat smallmouth bass.

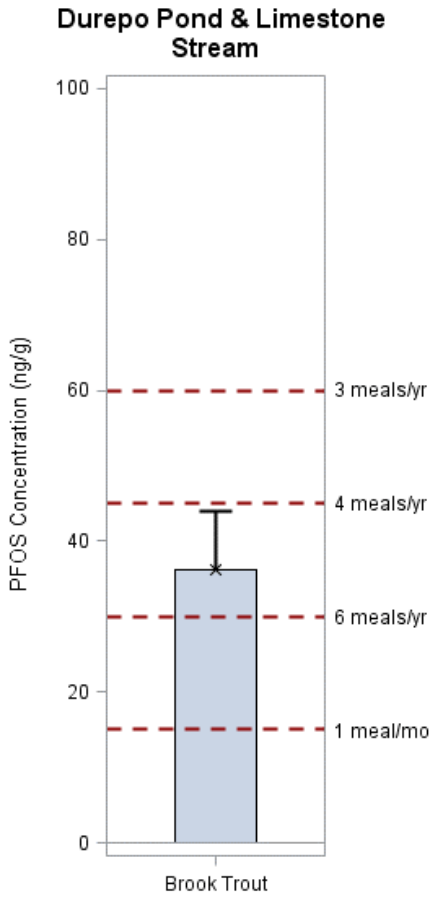


Figure 4. Fish tissue PFOS concentrations in Durepo Pond and Limestone Stream in Limestone. *Each bar corresponds to the mean PFOS tissue concentration for a fish species, with the cap of the error bar corresponding to the upper confidence limit on the mean.*

Justification: In 2022 a fish consumption advisory of no more than three meals per year of brook trout and a do not eat advisory for smallmouth bass was issued for all of Durepo Pond and Limestone Stream from Durepo Pond to the dam near Route 229 in Limestone. The brook trout advisory was based on four three-fish composites, one four-fish composite, and two individual brook trout samples collected from Durepo Pond between 2013 and 2017, as well as two four-fish and one five-fish composite brook trout samples collected from Limestone Stream in 2015 and 2016 (Appendix Figure A4). The PFOS concentrations were not notably different between the brook trout collected from Durepo Pond and Limestone Stream, therefore the two connected waterbodies were combined into one simplified fish consumption advisory.

In 2022, two additional five-fish composites were collected from Limestone Stream below the dam that had served as the downstream boundary for the 2022 fish consumption advisory (Appendix Figure A4). The PFOS concentrations in the two brook trout composite samples were 25.5 and 33.0 ng/g. These two results fall within the range of results from samples collected in Durepo Pond and Limestone Stream above the dam (28.5 to 82.7 ng/g). Therefore, the new additional brook trout samples from below the dam were combined with the prior data from Durepo Pond and Limestone Stream for calculating summary statistics as one waterbody. The mean brook trout concentration for Durepo Pond and all of Limestone Stream, weighted by the number of fish in each composite sample, was 36.1 ng/g with an upper confidence limit on the mean of 44.0 ng/g (Figure 4). Using the upper confidence limit on the mean as a conservative estimate for fish tissue PFOS concentrations results in a corresponding fish consumption advisory of no more than four meals per year. In the absence of any barriers to fish movement further downstream or significant tributaries that could lower surface water levels of PFOS, the advisory is extended to the border with Canada.

E. Number One Pond - Sanford

Area: All of Number One Pond in Sanford.

Advisory: For the general population, consume no more than one meal per month of largemouth bass.

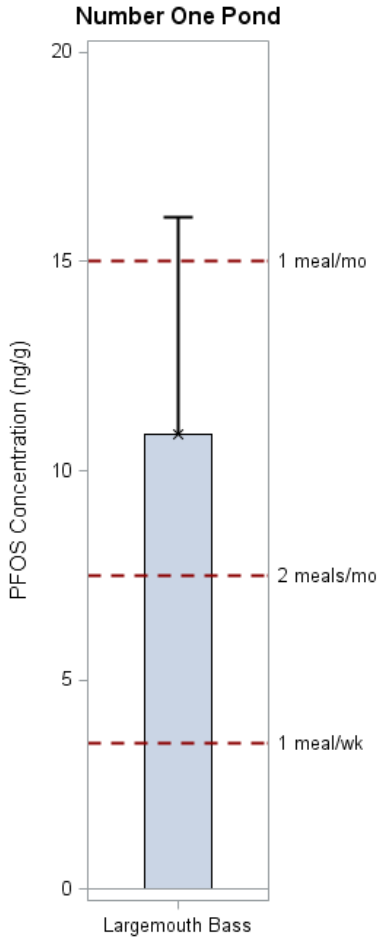


Figure 5. Fish tissue PFOS concentration in Number One Pond in Sanford. *The bar corresponds to the mean PFOS tissue concentration for largemouth bass. The cap of the error bar corresponds to the upper confidence limit on the mean.*

Justification: In 2022, a fish consumption advisory was issued for Mousam River from the Number One Pond Dam in Sanford to the Outlet Dam on Estes Lake, including all of Estes Lake (Appendix Figure A5). Over the summers of 2016, 2020, and 2022 a total of six five-fish composite largemouth bass samples were collected from Number One Pond with PFOS concentrations ranging from 6.1 to 23.5 ng/g with a mean of 10.9 ng/g. The upper confidence limit on the mean is 16.1 ng/g, which is slightly above the one meal per month consumption rate (Figure 5). Given that one of the six five-fish composite samples had a measured PFOS concentration more than two-fold greater than the next highest PFOS concentration, a recommended consumption rate of no more than one meal per month of largemouth bass is likely to be protective for the majority of fish harvested from this waterbody.

In the absence of data on other fish species, and with the understanding that largemouth bass are the primary game fish species present in Number One Pond, the above consumption advisory is specific to largemouth bass. This advisory is limited to Number One Pond and is separate from the more restrictive advisory issued in 2022 for waters of Mousam River below Number One Pond extending to the outlet of Estes Lake. Mean PFOS concentrations in largemouth bass collected from Mousam Lake, which is substantially upstream from Number One Pond, were notably lower at 1.6 ng/g.

F. Halfmoon Stream – Thorndike

Area: Halfmoon Stream from the Shikles Road in Thorndike to the Berry Road in Unity near the confluence with Sandy Stream.

Advisory: For the general population, consume no more than two brook trout meals per month.

Justification: From 2019 to 2022 a total of five five-fish composite brook trout samples were collected from Halfmoon Stream in both Thorndike and Knox (Appendix Figure A6). To date these are the only waters where testing of fish tissue has found elevated levels of PFAS other than PFOS, specifically the presence of PFOA and PFNA, such that the presence of these other PFAS could affect a resulting fish consumption advisory. These two PFAS have ATSDR toxicity values very similar to PFOS (3 ng/kg/day versus 2 ng/kg/day, respectively) and thus would have similar fish tissue action levels if considered separately. Alternatively, these PFAS can be considered in an additive manner weighted by their ATSDR toxicity values relative to PFOS (*see* Appendix B for more detail). In 2019, the toxicity weighted sums of PFOS, PFNA, and PFOA for Thorndike were 10.4 and 10.9 ng/g. In 2020 and 2022 the toxicity weighted sums of PFOS, PFNA, and PFOA ranged from 6.0 to 6.9 ng/g. Taken all together, the toxicity weighted sums of PFOS, PFNA, and PFOA for Thorndike ranged from 6.0 to 10.9 ng/g with a mean concentration of 8.2 ng/g and an upper confidence limit on the mean of 10.4 ng/g (Figure 6). Using the upper confidence limit as a conservative estimate of fish tissue PFAS concentrations corresponds to a consumption rate of fewer than two meals per month. However, the fish tissue concentrations of PFOS, PFNA, and PFOA all look higher in 2019 than in 2020 and 2022. Thus, the recommended fish consumption advisory will round down to two meals per month.

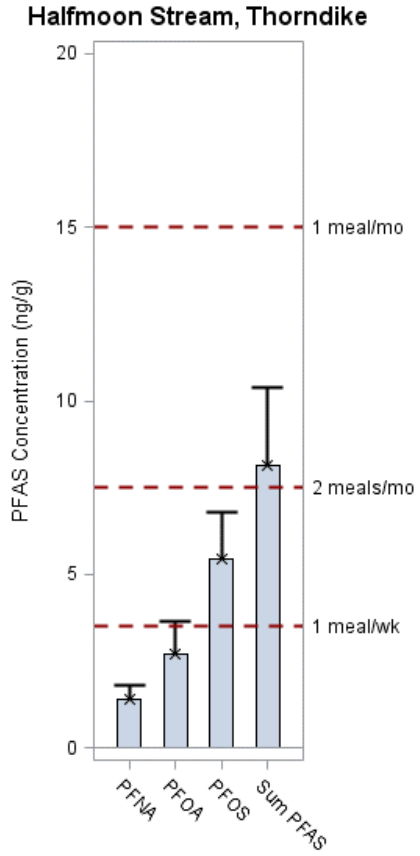


Figure 6. Fish tissue PFOS concentrations Halfmoon Stream in Thorndike and Knox. *Each bar corresponds to the mean PFNA, PFOA, PFOS, or toxicity weighted sum of PFAS fish tissue concentration for a fish species, with the cap of the error bar corresponding to the upper confidence limit on the mean.*

PFOS, PFOA, and PFNA levels in fish collected upstream near Knox Center from the Route 137 crossing up were considerably lower and appear to be trending downward over the 2019 – 2022 sampling period. The nearest upstream road crossing between Knox and Thorndike is the Shikles Road, which will serve as the upstream boundary for the advisory. Sampling of fish for the Thorndike area extended upstream from the Route 220 bridge. PFOS, PFOA, and PFNA were detected in surface water samples collected at the Route 220 bridge. The consumption advisory will be extended downstream to the confluence of Halfmoon Stream with Sandy Stream near the Berry Road crossing.

Appendix A: Locations of Fish Sample Collections

Figure A1. Approximate locations of fish sampling for PFOS from Fifteenmile Stream in Albion annotated with mean and range of PFOS concentrations in brook trout. The middle sampling point consisted of fish collected both upstream and downstream of illustrated point.

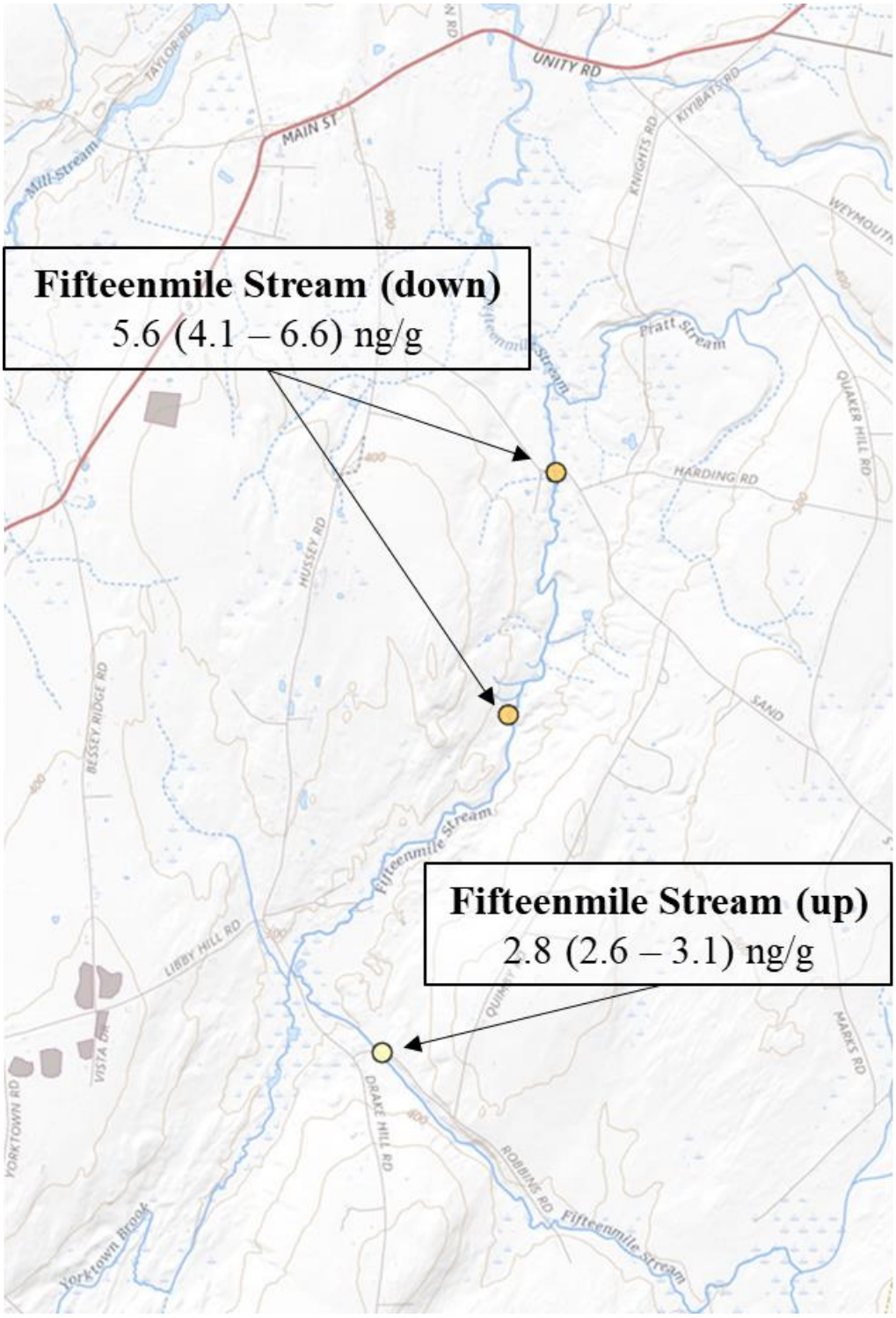


Figure A2. Approximate location of fish sampling for PFOS from China Lake in China annotated with mean and range of PFOS concentrations in each species sampled.

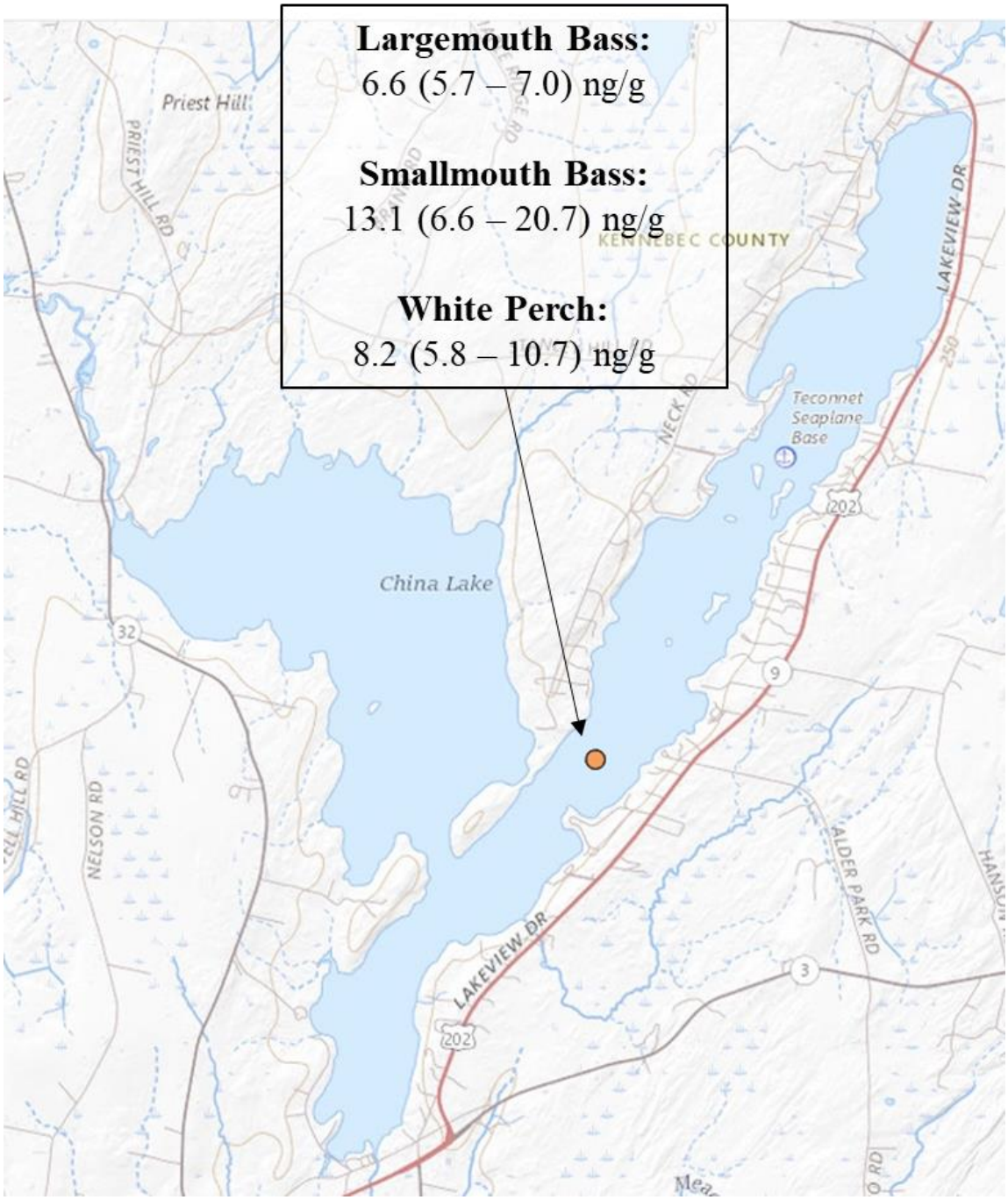


Figure A3. Approximate location of fish sampling for PFOS from the Kennebec River at Hinckley and Fairfield annotated with mean and range of PFOS concentrations in smallmouth bass.

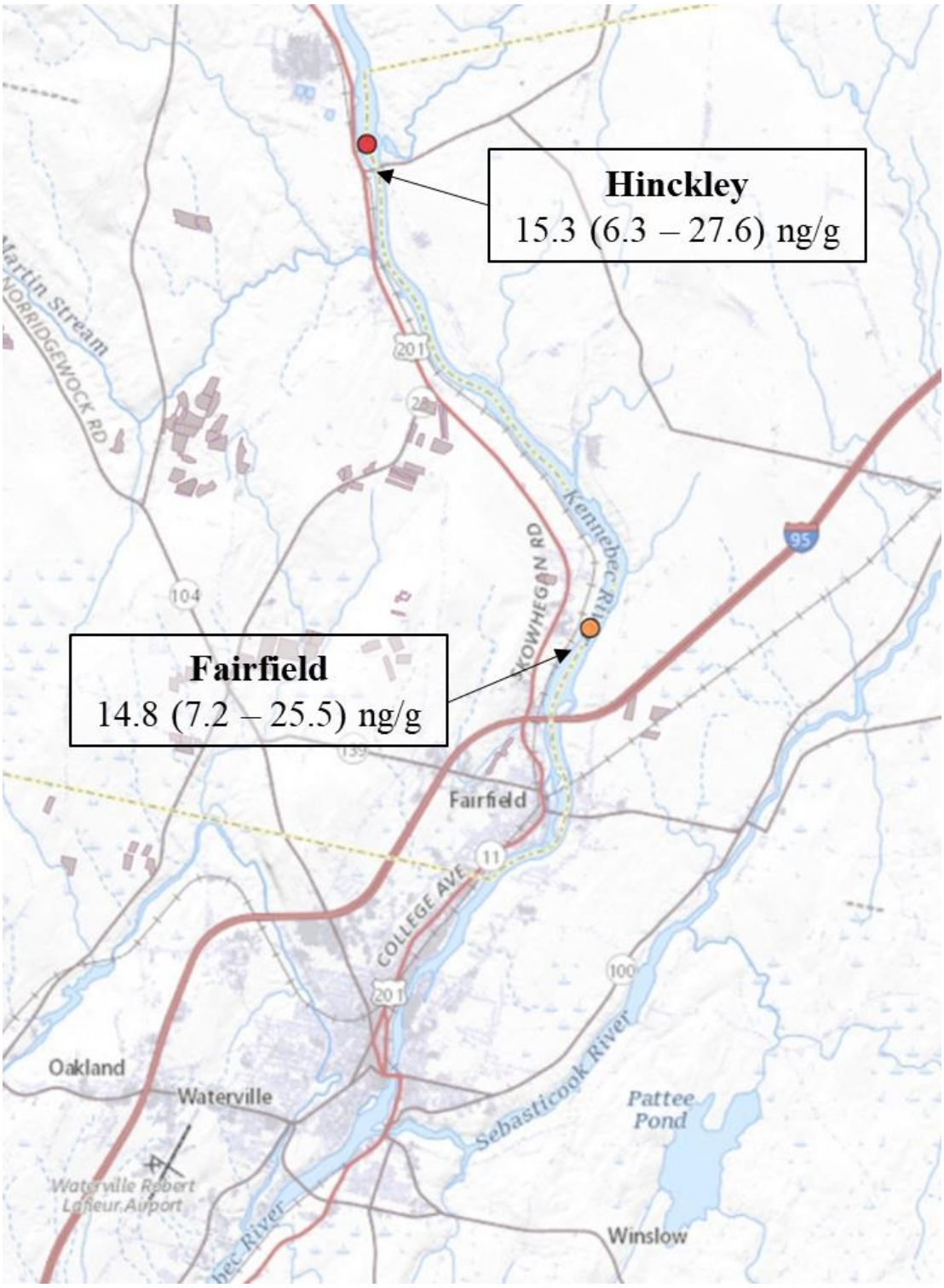


Figure A4. Approximate location of fish sampling for PFOS from Durepo Pond and Limestone Stream annotated with mean and range of PFOS concentrations in brook trout.

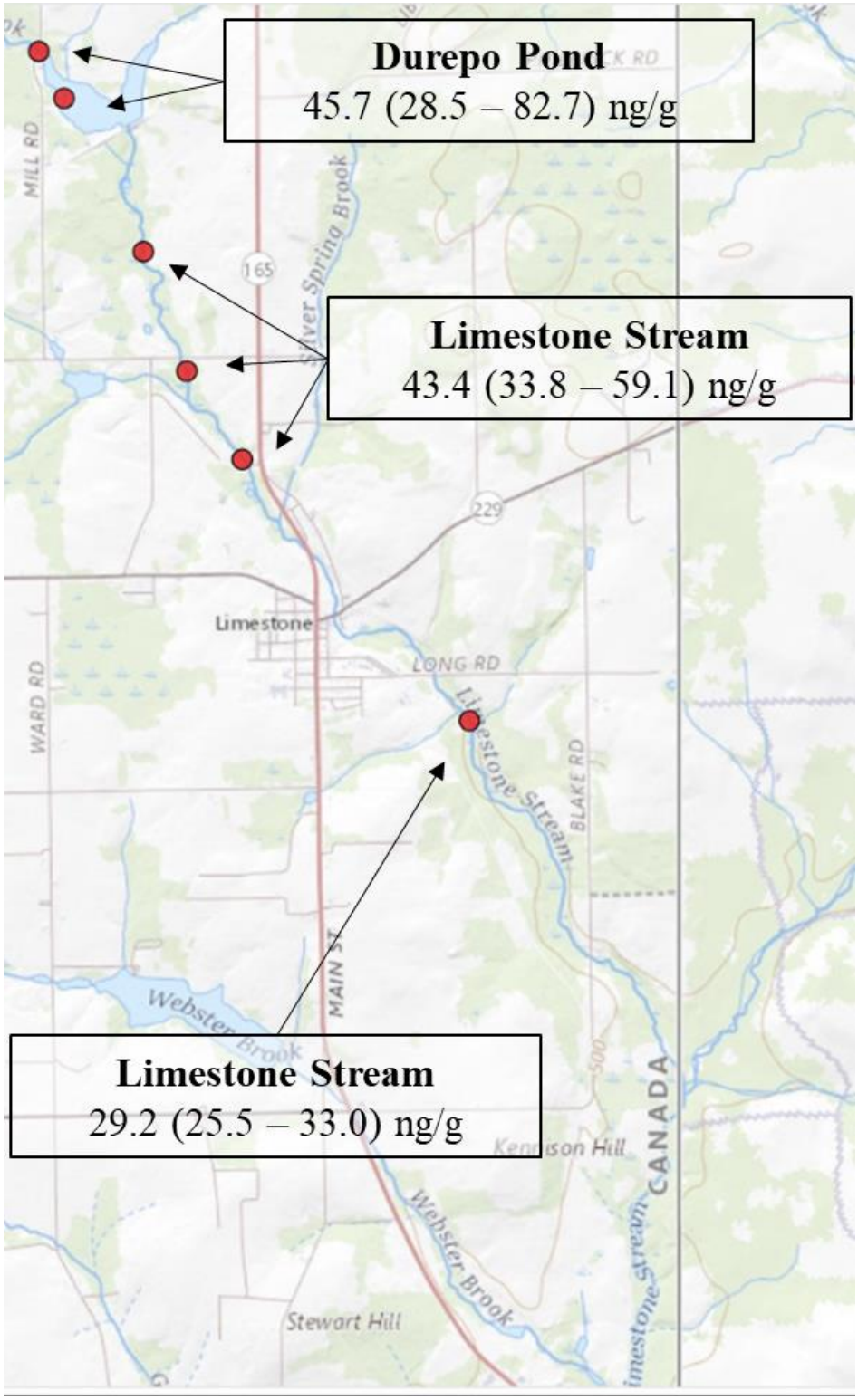


Figure A5. Approximate location of fish sampling for PFOS from Number One Pond, Estes Lake and Mousam River in Sanford annotated with mean and range of PFOS concentrations in largemouth bass.

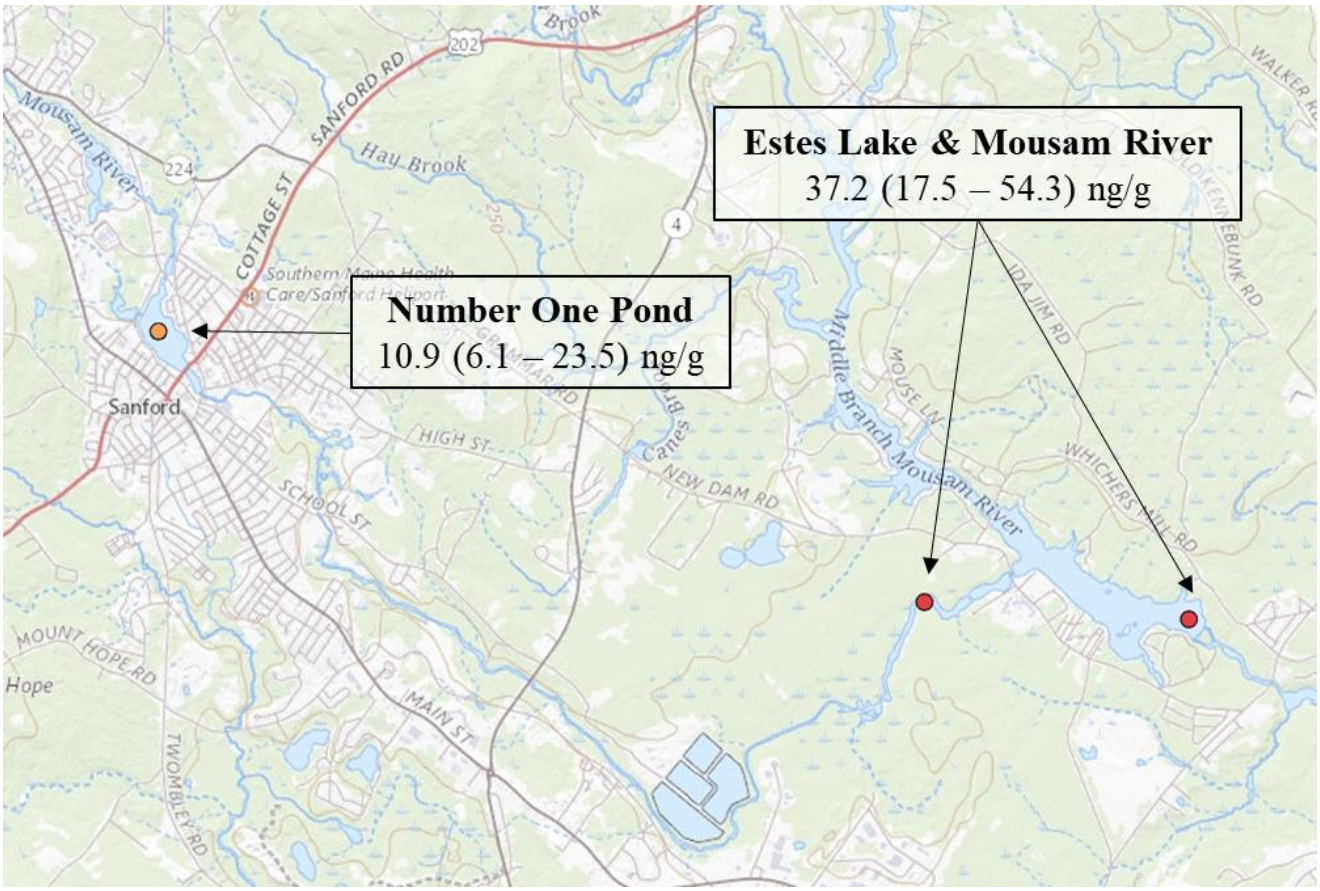
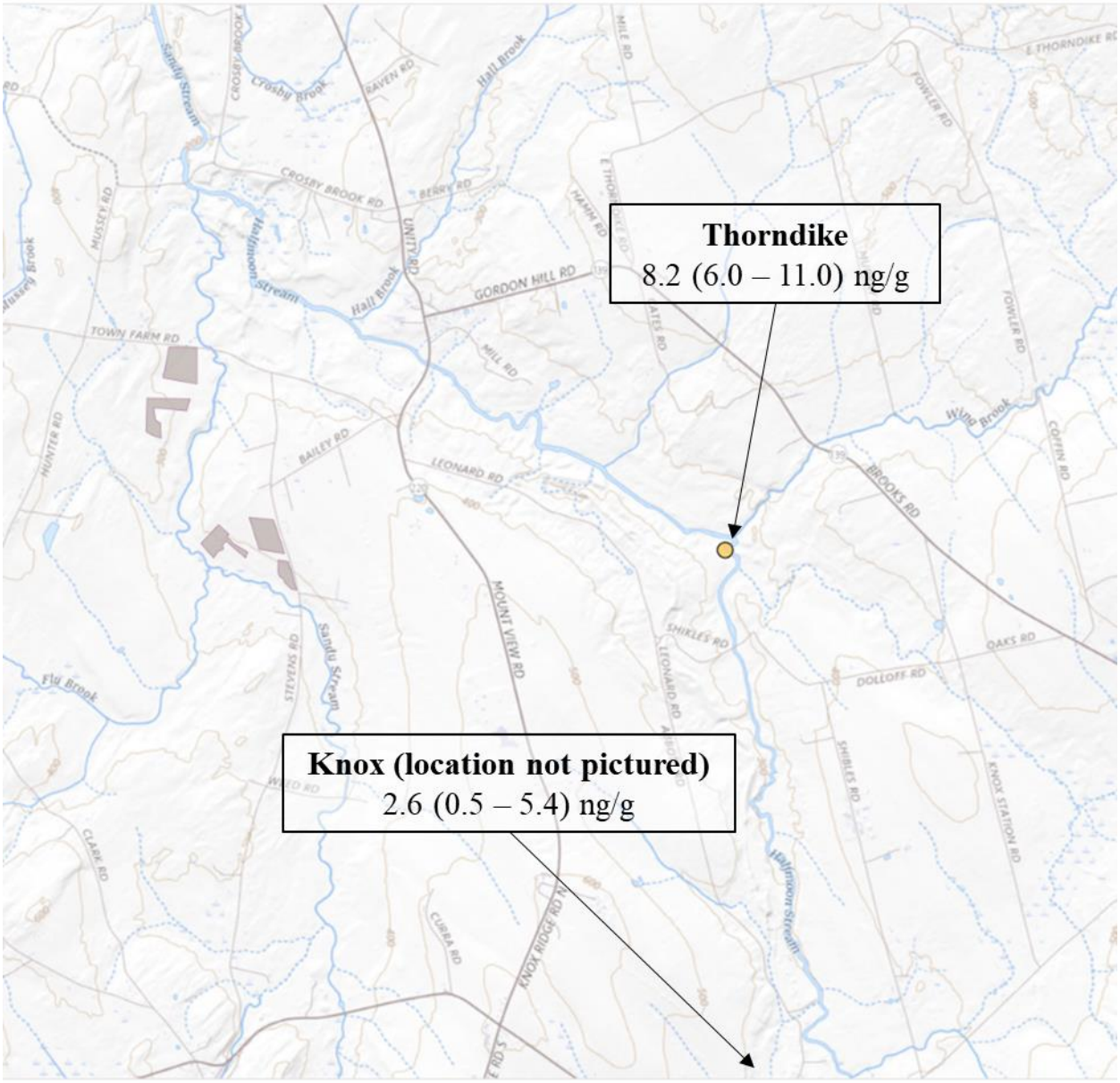


Figure A6. Approximate location of fish sampling for PFAS from Halfmoon Stream in Thorndike and Knox annotated with mean and range of the toxicity weighted sum concentrations of PFOS, PFOA, and PFNA in brook trout.



Appendix B: Derivation of Fish Tissue Action Levels

This Appendix describes the derivation of the updated FTAL for PFOS. If conditions exist in which consumption of fish caught in state waters poses a threat to public health, then Maine CDC will issue a corresponding fish consumption advisory. Maine CDC derives and uses fish tissue action levels (FTALs) as a guide to determine the need to develop a fish consumption advisory. Contaminant-specific FTALs in fish are derived following the U.S. Environmental Protection Agency (EPA) Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories (EPA 1996; EPA 2000a; EPA 2000b). FTALs are concentrations of a contaminant in fish tissue below which there should be negligible risk of toxicity at a set fish consumption rate. Maine CDC typically uses a fish consumption rate of 8-ounces of recreationally caught fish per week. This fish consumption rate is considered protective of most sport fishers. Measured concentrations of contaminants in fish tissue are compared to contaminant specific FTALs. When fish tissue concentrations exceed an FTAL, the development of a fish consumption advisory is considered.

As noted above, Maine CDC has developed an FTAL for PFOS of 3.5 nanograms per gram (ng/g).

Updating Maine's FTAL based on ATSDR's Toxicity Value for PFOS

In 2018, FTALs for PFOS were developed in response to elevated levels of PFOS detected in fish tissue in an area surrounding the former Loring Air Force Base near Limestone, Maine (Maine CDC 2018). The 2018 PFOS FTALs were 34.1 ng/g for the sensitive population defined as pregnant women, women of childbearing age, and children under the age of 8, and 79 ng/g for the general population of all other adults and children 8 years of age and older. The FTAL for the sensitive population was developed using the EPA Office of Water PFOS reference dose (RfD) of 20 nanograms/kilogram/day (ng/kg/day), based on developmental effects in an animal study (EPA 2016). The general population FTAL was developed using a candidate RfD from the EPA Office of Water for changes in liver and kidney function observed in an adult animal study (EPA 2016). Since this time, several states and the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) have derived their own toxicity values for PFOS that range from 1.8 ng/kg/day up to 5 ng/kg/day.

These lower states and ATSDR toxicity values are based on adult animal studies of immune system toxicity as the most sensitive endpoint. The European Food Safety Authority (EFSA) developed a tolerable weekly intake for PFOS and three other PFAS based on human epidemiological studies of reduced vaccine response in 1-year old children that equates to a toxicity value of 0.6 ng/kg/day (EFSA CONTAM Panel 2020). Additionally, in November of 2021 as part of the EPA's process to establish a maximum contaminant level for PFOS in drinking water the EPA proposed a new draft PFOS RfD that is considerably lower than anything previously proposed or adopted. The U.S. Food and Drug Administration (FDA) has reported that it now relies on the ATSDR Minimal Risk Levels (MRLs) for assessments of the safety of exposure to certain PFAS detected in foods (FDA 2021). Based on the growing scientific consensus that PFOS toxicity values lower than the 2016 EPA values are appropriate, and that immune system toxicity is a more sensitive endpoint than developmental toxicity, Maine CDC has updated the PFOS FTAL using the PFOS toxicity value published by ATSDR in May 2021 (ATSDR 2021).

Action Level Derivation

Fish consumption advisories based on noncarcinogenic toxicological endpoints are set at a level believed to represent a minimal risk of a deleterious effect from lifetime exposure even for sensitive subpopulations. It is assumed that noncarcinogenic toxicological endpoints have a threshold response (i.e., there is a dose below which toxic effects will not occur). Fish consumption advisories are set such that total exposure from eating on average 8 ounces per week will result in a daily dose below the threshold.

1. Action level equation

Maine CDC derived the PFOS FTAL using EPA's standard for determining action levels for noncancer toxicological endpoints (EPA 2000a). FTALs are calculated using the following equation:

$$FTAL = \frac{(RfD \times BW)}{FC} X\ RSC \qquad (Eq. 1)$$

Where,

FTAL = Fish Tissue Action Level in nanograms per gram (ng/g)

RfD = Reference Dose in nanograms per kilogram body weight per day (ng/kg/day)

BW = Body Weight in kilograms (kg)

FC = Fish Consumption Rate in grams per day (g/day)

RSC = Relative Source Contribution (unitless)

2. Equation inputs

A. Reference dose

A reference dose (RfD) is defined by the EPA as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure level (mg/kg/day) for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime (EPA 2000a). Reference doses are both chemical and toxicological endpoint specific. The lower the RfD value, the more toxic the substance.

In selecting a RfD, Maine CDC typically relies on toxicity values developed by federal agencies, e.g., the EPA or the ATSDR. In May 2021 ATSDR finalized its toxicity profile for PFAS, which included the derivation of MRLs for PFOS, PFOA, PNFA, and PFHxS. The ATSDR MRLs are 2 ng/kg/day for PFOS, 3 ng/kg/day for PFOA, 3 ng/kg/day for PFNA, and 20 ng/kg/day for PFHxS (ATSDR 2021).

The ATSDR MRL of 2 ng/kg/day for PFOS was derived from the same developmental toxicity study EPA relied on in 2016 to develop its 20 ng/kg/day RfD. To account for immune effects as a potentially

more sensitive endpoint, ATSDR applied a 10-fold modifying factor to the derivation of the MRL based on developmental effects. The addition of the 10-fold modifying factor effectively reduced the developmental endpoint MRL of 20 ng/kg/day to 2 ng/kg/day for the final PFOS MRL. Some states have developed their own toxicity values for PFOS based on the reported immune system toxicity in adult animal studies with values ranging from 1.8 to 3 ng/kg/day, which is consistent with the 2 ng/kg/day MRL developed by ATSDR (NJ 2016; MI 2019; MN 2019; NH 2019). ATSDR did not utilize the immunotoxicity studies directly due to a lack of pharmacokinetic model parameters required to estimate a time-weighted average serum level for the mouse strains used and instead applied the 10-fold modifying factor (ATSDR 2021).

Given Maine CDC's preference for relying on toxicity values developed by federal agencies and the general consensus that a toxicity value in the range of 1.8 to 3 ng/kg/day is protective over immune system effects observed in adult laboratory animals, ATSDR's 2 ng/kg/day PFOS MRL has been selected to derive the FTAL for PFOS. Further, given that the observed immune system effects occurred at lower exposures than the observed developmental effects, the 2 ng/kg/day PFOS MRL is protective of exposure to all populations, thus eliminating the need for population specific PFOS FTALs.

B. Body weight

The estimated body weight (BW) of the exposed individual is required in the action level calculation since the RfD is expressed on a "per kilogram body weight" basis. The most recent edition of the EPA's Exposure Factors Handbook (EPA 2011) recommends use of an average body weight of 80 kg for all adults. As noted in the fish consumption rate section below, use of an 80 kg body weight for adults produces a generally protective fish consumption rate on a body weight basis as compared to other age groups and populations.

C. Fish consumption rate

A fish consumption rate (FCR) of 8 ounces (227 grams) per week is used to derive action levels. This consumption rate corresponds to the standard health-based recommendation for fish consumption for adults (AHA 2021; FDA 2021). An 8-ounce per week consumption rate is equivalent to an average daily FCR of 32.4 grams per day (g/day). This consumption rate is considered protective of fish consumption by most individuals who consume recreationally harvested fish and is supported by the following sources:

- EPA's Guidance for Assessing Chemical Contaminant Data for use in Fish Advisories (EPA 2000a) recommends a default fish consumption rate of 17.5 g/day. The EPA's default fish consumption rate has since been updated to 22 g/day (EPA 2014), which represents the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the US adult population (≥21 years of age) based on National Health and Nutrition Examination Survey (NHANES) data from 2003-2010.

- A survey of Maine sport fishers (Ebert et al. 1993) reported a 95th percentile consumption of 26 g/day for all inland waters (lakes, ponds, rivers, streams, and brooks), assuming equal

consumption of sport caught fish among all household members. If only adults share consumption, the 95th percentile consumption increases to 28 g/day. EPA preferentially recommends the use of local data, the use of data reflecting similar geography or population groups, or the use of data from national surveys over the default consumption rate (EPA 2000a; EPA 2015).

- A recent National survey of high-frequency fish consumers in the U.S. (von Stackelberg et al. 2017) examined rates of overall and self-caught fish consumption among individuals consuming three or more fish meals per week, which corresponds to the 95th percentile of fish consumption as reported in NHANES. Mean self-caught fish consumption among these high-frequency fish consumers was 30 g/day. The survey further reported regional differences in self-caught fish consumption with the East-South Central and New England regions reporting the lowest consumption rates of self-caught fish (12 to 16 g/day).

Based on these data, it is judged that a fish consumption rate of 32.4 g/day is conservatively representative of an upper-level fish ingestion rate for Maine recreational anglers and is consistent with health-based guidance for recommended fish consumption.

In many dietary risk assessments child intake rates are calculated separately from adults as they may have a higher intake on a body weight basis. However, there is limited available survey data on child consumption of recreationally caught sport fish. In lieu of child-specific sport fish intake rates, Maine CDC compared the usual fish consumption rate estimates for freshwater and estuarine fish for children aged 1 to 6 years and adults, adjusted for body weight (EPA 2014; EPA 2011). The usual fish consumption rates compiled by EPA are based on national dietary recall survey data from the U.S. CDC's NHANES. The usual fish consumption rates are only provided on a g/day basis but can be adjusted to estimate rates on a g/kg body weight/day basis using nationally representative body weight estimates from EPA's Exposure Factors Handbook (EFH).

Table B1. Comparison of body weight-adjusted fish consumption rates (NHANES 2003-2010).

Fish consumption age grouping	90th percentile intake (g/day) (EPA 2014)	Age group mean body weight (kg) (EPA 2011)	Estimated 90th percentile intake (g/kg/day)
1 - <3 years	4.7	12.6	0.37
3 - <6 years	5.8	18.6	0.31
>21 years	22	80	0.28

Using Maine CDC's adult fish consumption rate of 32.4 g/day and the adult mean body weight of 80 kg yields a body weight-adjusted consumption rate of 0.405 g/kg/day. This adult rate 0.405 g/kg/day consumption rate is higher than the young child age groups rates of 0.37 g/kg/day for a 1 to 3-year-old and 0.31 g/kg/day for a 3 to 6-year-old. Thus, the consumption rate for an adult will be protective for these younger consumers.

D. Relative source contribution

EPA's Guidance for Assessing Chemical Contaminant Data for use in Fish Advisories (EPA 2000a, b) encourages states to use available information on other non-fish sources of exposure when possible in setting consumption limits. As noted above, the RfD represents a toxicological threshold below which the risk of a deleterious effect is considered negligible. By using the RfD to set an FTAL, there is an inherent assumption that 100% of the daily intake for a chemical comes from fish consumption. In such a case, any additional "background" exposures via consumption of other foods, drinking water, etc. could result in cumulative exposures that exceed the RfD. EPA's fish advisory guidance (EPA 2000b) recommends states use available exposure information to apportion some fraction of the total allowable daily dose (e.g., 10, 20, or 30 percent) to fish consumption. EPA's guidance specifically references a Relative Source Contribution (RSC) approach that was being developed at the time of publication. A method of evaluating an RSC to account for multiple sources of exposure to pollutants has since been published in the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (EPA 2000c; EPA 2015).

It is clear from U.S. CDC biomonitoring programs that exposure to PFOS is ubiquitous, as it is present in the blood of most individuals tested in recent samplings of Americans 12 years and older (USCDC 2021). The presence of PFOS, as well as several other PFAS, in the general U.S. population is the result of exposure from multiple sources, including dietary sources, house dust, drinking water, and indoor and outdoor air (ATSDR 2021; Egeghy and Lorber 2011; Gebbnik et al. 2015; Trudel et al. 2008). PFOS levels measured in blood may also reflect some contribution of exposure to PFOS precursors that have undergone biotransformation to PFOS within the body (Gebbnik et al. 2015; Vestergren et al. 2008). When there is no known exposure source, e.g., contaminated community drinking water, studies estimating daily PFOS exposures from various media suggest that the largest contributor to overall PFOS exposure is likely diet for adults, and diet and house dust for young children (Egeghy and Lorber 2011; Tittlemier et al. 2007; Trudel et al. 2008). However, the magnitude and relative contribution of these external daily exposure estimates from various individual sources, such as diet, indoor dust or drinking water, are uncertain and may not be entirely representative of current exposures for the general U.S. population.

A measured PFOS serum level in an individual represents a comprehensive exposure metric as serum integrates all external exposures and absorption from diet, water, hand-to-mouth activities, inhalation etc. Measured PFAS serum levels from U.S. CDC National Health and Nutrition Examinations Surveys (NHANES) biomonitoring studies, which are designed to be nationally representative of the general U.S. population, reflect exposure to PFAS, including PFOS, from all sources for the general population. Thus, measured PFAS serum levels from NHANES biomonitoring can be viewed as representative of background exposure for the general U.S. population and utilized to estimate an RSC factor.

To derive a PFOS-specific RSC factor using recent NHANES PFOS serum levels, Maine CDC utilized a one-compartment pharmacokinetic model (Equation 2). This is the same pharmacokinetic model EPA and ATSDR applied in their PFOS RfD and minimum risk level (MRL) derivations, respectively, to convert a dose on a serum level basis to an oral intake dose (EPA 2016; ATSDR 2021). The pharmacokinetic model converts a measured serum to an oral equivalent dose, i.e., the ingested dose on a body weight basis that is required to result in the measured serum level.

$$Background\ exposure\ (ng/kg/day) = Cp \times kp \times Vd \quad (Eq. 2)$$

Where,

Cp = PFOS serum concentration in nanograms per milliliter (ng/mL)

kp = first-order elimination rate in per day (1/day or day^{-1})

Vd = volume of distribution in milliliters per kilogram body weight (mL/kg)

For a serum concentration, Maine CDC used the total population geometric mean PFOS serum concentration of 4.25 ng/mL from the 2017-2018 NHANES survey (USCDC 2021), a PFOS elimination rate of 0.00056 day^{-1}, based on a PFOS human half-life of 1241 days (Li et al. 2018), and a volume of distribution of 230 mL/kg-body weight for an adult (Thompson et al. 2010). The calculated background PFOS exposure on a ng/kg/day basis using the geometric mean serum level of 4.25 ng/mL for the total population ages 12 years and older based on the 2017-2018 survey is 0.55 ng/kg/day and is trending downward. The geometric mean was selected to represent the central tendency PFOS serum level, as it is EPA guidance to use central tendencies for RSC intake estimates (EPA 2000c).

Considering this oral equivalent dose to represent average, general background PFOS exposure, the remaining dose which could be allocated to other sources is calculated by subtracting the background exposure from the 2 ng/kg/day PFOS RfD. Here the selected PFOS RfD is the ATSDR PFOS MRL. The RSC is derived by dividing the remaining dose by the PFOS RfD (Equation 3).

$$RSC = \frac{PFOS\ RfD\ (ng/kg/day) - Background\ exposure\ (ng/kg/day)}{PFOS\ RfD\ (ng/kg/day)} \times 100 \quad (Eq. 3)$$

Using the 0.55 ng/kg/day background exposure estimate in comparison to the ATSDR PFOS MRL of 2 ng/kg/day produces an RSC of 73%. The rounded value of 70% is used as the RSC for PFOS.

Given that there is also exposure to other PFAS, such as PFOA, PFNA, and PFHxS where there may be a potential for additive toxicities, RSC values were calculated for PFHxS, PFOA, and PFNA based on ATSDR MRLs and NHANES 2017-2018 geometric mean serum levels. Using a toxicity value-weighted approach, the sum of the average daily exposure to PFOS, PFOA, PFNA, and PFHxS results in an RSC of approximately 60%. The 60% RSC is largely dominated by PFOS and PFOA which have higher background serum levels than PFNA and PFHxS. As levels for these four PFAS have continued to

decrease based on NHANES biomonitoring from 1999-2018, it's expected that current serum levels are lower than 2017-2018 years. Lower background serum levels would result in a calculated RSC of greater than 60%. The use of a 70% RSC for PFOS is therefore considered generally protective of potential additive effects of background exposure to other PFAS for which toxicity values and serum data are available.

3. Action level

Using ATSDR's 2 ng/kg/day MRL, the standard 80 kg adult body weight, a conservative upper estimate of 32.4 g/day of sport fish consumption, and a 70% RSC to account for background exposure to PFOS as inputs to Equation 1, Maine CDC calculated a PFOS FTAL of 3.5 ng/g. This updated PFOS FTAL is applicable to both sensitive and general populations. The ATSDR MRL accounts for both developmental effects in animal studies and immune system effects in adult animal studies which occur at lower doses than the developmental effects. Further, the 32.4 g/day fish consumption rate on a body weight basis for adults is not likely to be exceed for young children when accounting for differences in body weight. Thus, the 3.5 ng/g PFOS FTAL is sufficiently protective of both adult and child populations.

Extension to other PFAS

Although rare, Maine CDC has encountered one waterbody with elevated levels of perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA) in fish tissue at levels that could change a potential fish consumption advisory when combined with detected PFOS levels. To date this has been limited to the co-occurrence of elevated levels of PFOA and PFNA with PFOS still the predominant PFAS present in fish tissue. In this one event where the presence of PFAS other than PFOS in fish tissue were detected at levels that could change a potential fish consumption advisory, Maine CDC used a weighted potency approach to calculate PFOS fish tissue equivalents to compare to the PFOS FTAL. PFOA and PFNA have ATSDR published toxicity factors that are similar in value to PFOS and are based on development endpoints as is PFOS. Maine CDC summed the concentrations of each PFAS weighted by their potency (i.e., toxicity values) relative to PFOS. The total PFOS equivalents ($C_{fish,PFOS\ equivalents}$) were calculated as:

$$C_{fish,PFOS\ equivalents} = C_{fish,PFOS} + C_{fish,PFOA} * \frac{PFOS\ RfD}{PFOA\ RfD} + C_{fish,PFNA} * \frac{PFOS\ RfD}{PFNA\ RfD} \quad (Eq. 4)$$

This approach is being used on an interim basis as needed while MECDC evaluates EPA's recently proposed Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (EPA 2023).

4. Action level implementation

In accordance with MRSA 22 § 1696 I, if fish sampled from Maine freshwater have levels of PFOS that exceed the FTAL of 3.5 ng/g, Maine CDC will consider issuing a fish consumption advisory. Fish consumption advisories are presented as an allowable fish consumption rate that is not expected to

exceed the toxicity value. Using an 8 oz fish meal size for adults, Equation 1 is used to calculate PFOS concentrations in fish that correspond to specified meal frequencies (e.g., 1 meal per week, 2 meals per month, etc.). Table B2 illustrates PFOS fish tissue concentration ranges associated with meal frequencies that can be used in assessing the need for consumption advisories. As a matter of policy, Maine CDC will only consider issuing a fish consumption advisory if fish cannot be safely consumed at a rate of at least one meal per week. Thresholds for issuing a Do Not Eat (DNE) advisory are evaluated on a contaminant-specific basis. For PFOS, Maine CDC will issue a DNE advisory when fish cannot be safely consumed at a rate of at least three meals per year because at very low consumption rates and associated higher fish tissue levels the impact of eating just one additional fish meal per year becomes increasingly large. Additionally, there is still emerging science on the health effects from PFOS exposure and the potential health effects from exposure to multiple PFAS.

Table B2. Levels of PFOS in fish and corresponding 8-ounce meal advice categories.

PFOS in fish (ng/g)	Meal advice
3.5	1 meal per week
7.5	2 meals per month
15	1 meal per month
30	6 meals per year
60	3 meals per year
> 60	Do Not Eat

In consideration of whether to issue an advisory, Maine CDC also evaluates whether the resulting advisory would be more restrictive than any exiting advisories[3], such as the statewide fish consumption advisory for mercury (Table B3). The FTAL of 3.5 ng/g for PFOS by itself allows for consumption of 8-ounces per week of any sport caught fish of any species for adults. However, a weekly consumption of recreationally caught fish in Maine waters of up to one meal per week is only recommended for landlocked salmon and brook trout and only by a segment of the population due to the presence of methylmercury in fish tissue and the associated statewide consumption advisory (Table B3). For all other fish species, the statewide methylmercury consumption advisory is to eat no more than two fish meals per month. For sensitive populations (children less than 8 years of age and women who are or who may become pregnant), the statewide mercury advisory is much more restrictive and recommends no consumption of freshwater fish from Maine's inland waters except for landlocked salmon and brook trout which can be consumed at a rate of one meal per month. Thus, in determining whether a PFOS-specific advisory need to be issued, Maine CDC will evaluate whether the concentrations of PFOS is fish tissue warrant an advisory that is more restrictive than the current statewide methylmercury advisory or any other waterbody-specific advisories.

[3] Current fish consumption advisories can be found under Maine CDC's Freshwater Fish Safe Eating Guidelines (https://www.maine.gov/dhhs/mecdc/environmental-health/eohp/fish/2kfca.htm)

Table B3. Statewide mercury fish consumption advisory.

Sensitive populations (pregnant and nursing women, women of childbearing age, children under age 8)	
Brook trout and landlocked salmon	One meal per month
All other species	Do Not Eat
General population (all other adults and children aged 8 and older)	
Brook trout and landlocked salmon	One meal per week
All other species	Two meals per month

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