United States Environmental Protection Agency
Office of Water 4304T
EPA-822-R-24-011 September 2024

EPA Response to Public Comments on the 2022 Draft Recommended Aquatic Life Criteria for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

September 2024

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1 INTRODUCTION

The U.S. Environmental Protective Agency (EPA) Office of Water (OW) is charged with protecting ecological integrity and human health under the purview of the Clean Water Act (CWA). In support of this mission, the EPA has developed two separate Final criteria/benchmark documents:

- *Final Recommended Freshwater Aquatic Life Ambient Water Quality Criteria and Acute Saltwater Aquatic Life Benchmarks for Perfluorooctanoic Acid (PFOA)*
- *Final Recommended Freshwater Aquatic Life Ambient Water Quality Criteria and Acute Saltwater Aquatic Life Benchmarks for Perfluorooctane Sulfonate (PFOS)*

These documents include Final 304(a) Ambient Water Quality Criteria (AWQC) to protect aquatic life from Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS) in freshwater (U.S. EPA 2024a, b). PFOA and PFOS toxicity data were limited for estuarine/marine species. However, the available data allowed for the development of protective acute estuarine/marine benchmarks for PFOA and PFOS. The EPA derived acute PFOA and PFOS aquatic life benchmark values for saltwater environments under 304(a)(2) of the CWA using the best available data on the effects of these PFAS to provide information that states and Tribes may consider in their water quality protection programs.

Consistent with the EPA's development process for AWQC for aquatic life, these PFOA and PFOS Aquatic Life Criteria and Benchmark documents (U.S. EPA 2022a, b) have previously undergone a contractor-led independent, external peer review. The separate external peer review reports for PFOA (U.S. EPA 2021a; https://www.epa.gov/system/files/documents/2022-04/pfoa-peer-review-report-2022.pdf) and PFOS (U.S. EPA 2021b; https://www.epa.gov/system/files/documents/2022-04/pfos-peer-review-report-2022.pdf) are publicly available. The EPA responded to the external peer review comments in publicly available External Peer Review Response to Comments documents for PFOA (U.S. EPA 2022c; https://www.epa.gov/system/files/documents/2022-04/pfoa-peer-review-response-2022.pdf) and PFOS (U.S. EPA 2022d; https://www.epa.gov/system/files/documents/2022-04/pfos-peer-review-response-2022.pdf).

Following revisions to the PFOA and PFOS Aquatic Life Criteria documents based on comments from the external peer review, both Draft criteria were released for public comment on April 22, 2022. The initial public comment period was set for 30-days, which was then

extended for an additional 30-days, resulting in a public comment period from May 3, 2022 through July 5, 2022. The EPA received 32 comments in the PFOA Aquatic Life AWQC public docket (https://www.regulations.gov/docket/EPA-HQ-OW-2022-0365/comments) and 27 comments in the PFOS Aquatic Life AWQC public docket (https://www.regulations.gov/docket/EPA-HQ-OW-2022-0366/comments). Comments were submitted from a wide range of stakeholders, including representatives from industry, state and local governments, international governmental agencies, academia, and non-governmental organizations. Overall, the public comments submitted to the EPA were generally supportive of the 2022 raft PFOA and PFOS Aquatic Life Criteria, though commenters were rarely unanimous on any particular subject. Comments focused on the toxicity data and technical approaches used to derive the criteria. The majority of comments submitted to the EPA were applicable to both the Draft PFOA and PFOS Aquatic Life Criteria documents but were only submitted into one docket. Therefore, the present document provides the EPA's responses to public comments received for both the Draft PFOA and PFOS criteria documents. These public comments were considered in developing the Final 2024 PFOA and PFOS Aquatic Life Criteria and Benchmark documents. Section 2 of this report presents the summaries of the public comments and the EPA's responses organized by similar topics on the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents.

1.1 Development of the Draft and Final Documents

Toxicity studies used to derive the 2022 Draft and the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmarks were carefully evaluated and thoroughly reviewed by EPA scientists to ensure studies were of sufficient data quality to use in criteria derivation. Scientists from the EPA conducted an extensive review of the PFOA and PFOS toxicity studies, primarily based on studies in the EPA's ECOTOXicology database (ECOTOX; https://cfpub.epa.gov/ecotox/). The Draft criteria and benchmarks relied on toxicity data published through September 2021. Following the public comment period, the criteria/benchmark documents were updated to include toxicity data through March 2024. In developing the Draft and Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents, the EPA obtained concentration-response (C-R) data to the greatest extent possible. C-R data allowed the EPA to independently model statistically sound acute LC_{50} and chronic EC_{10} values to derive the criteria. In addition to contacting study authors for C-R data (when not

reported in the open literature), the EPA also consulted primary authors to clarify the methodologies used, to ensure that the studies utilized to derive criteria were of high quality.

Estuarine/marine toxicity data limitations did not allow for the direct derivation of acute or chronic estuarine/marine criteria for PFOA or PFOS. Therefore, to develop information that states and Tribes could use in adopting protective values for estuarine/marine waters, the EPA developed protective acute PFOA and PFOS benchmarks using a New Approach Methodology (detailed in Appendix L of the PFOA criteria document and Appendix L of the PFOS criteria document).

Addressing data limitations to derive robust criteria/benchmarks, extensively reviewing studies, and calculating point estimates meant that the PFOA and PFOS Aquatic Life Criteria were developed via a comprehensive and rigorous process that included collaborations across EPA scientists in OW and ORD. Beyond detailed discussions between OW and ORD, the PFOA and PFOS drafts also underwent several reviews by additional scientists from both OW and ORD, and by a group of internal EPA reviewers that included representatives from the OW, ORD, other EPA Program Offices, and the EPA Regions. The Draft PFOA and PFOS Aquatic Life Criteria also underwent contractor-led independent, external peer review and subsequent revision, as noted above, followed by further EPA scientific and management review prior to the release of the Draft criteria documents for scientific views during the public comment period.

2 SUMMARY OF PUBLIC COMMENTS AND EPA RESPONSES ORGANIZED BY TOPIC

2.1 General Comments on the Problem Formulation and Scope of the Draft PFOA and PFOS Aquatic Life Criteria

2.1.1 Summary of Public Comments:

The public comments related to background information of PFOA and/or PFOS presented in the Problem Formulation sections of the Draft Aquatic Life Criteria documents encompassed numerous topics, which are summarized below. These topics included comments recommending the incorporation of precursor compounds and Per- and Polyfluorinated Substances (PFAS) mixtures and the inclusion of occurrence data for PFOA, PFOS, and precursor compounds. Specifically, commenters recommended that mixtures of PFAS, including mixtures of PFOA and PFOS, be addressed as these compounds are commonly detected together

in various monitoring data, or that the EPA should consider releasing criteria for PFAS as a class, rather than as individual criteria. Other public comments included the recommendation that aquatic life criteria for individual PFAS should go beyond PFOA and PFOS.

Another comment noted that additional occurrence data are available from several regions, including the Ohio River and waterbodies in Massachusetts and Michigan, and the EPA may consider adding these occurrence data in the Problem Formulation sections of the PFOA and PFOS Aquatic Life Criteria documents. Commenters also suggested that available monitoring data, such as those presented in Section 2.4 and Appendix N of the Draft PFOA and PFOS Aquatic Life Criteria documents, should specify whether the samples were collected in freshwater or saltwater/estuarine environments and should specify concentration averages and sample numbers.

2.1.2 EPA Response to Public Comments:

Regarding the first general comment topic relating to the incorporation of PFAS precursors and mixtures, most of the research regarding toxicity of PFAS has focused on single-chemical PFOA or PFOS exposures, with sparse toxicity data on other PFAS or mixtures in comparison. Therefore, there are currently only sufficient data to derive national freshwater recommended aquatic life criteria for these individual compounds. This approach is consistent with other AWQC to protect aquatic life by the EPA, states and/or Tribes, and other countries (such as Environment and Climate Change Canada and the European Union). With regard to precursors, the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents discuss the transformation and degradation of other PFAS into PFOA and/or PFOS as a final end product when noting the potential sources of PFOA and PFOS into an aquatic system (see Section 2.3 of each document). These criteria are intended to protect aquatic life from the exposures of PFOA and PFOS regardless of the source to the aquatic system. The EPA recognizes that organisms may be exposed to multiple chemicals – including mixtures of PFAS and other pollutants – in the environment, and notes that a critical step in protecting the environment is determining and understanding the toxicity of individual chemicals and establishing protective values that can be adopted by states and Tribes. At this time, data limitations for aquatic species preclude development of PFAS criteria as a broad class. In the meantime, the EPA is using New Approach Methods (NAMs) to develop protective benchmarks for data-limited PFAS, as described the

EPA's PFAS Strategic Roadmap (https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf).

The EPA thanks public commenters for recommending additional occurrence information for the problem formulation sections of the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents. However, these additional data were not included in the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents, as they already contained a significant amount of PFOA and PFOS occurrence data, and the primary focus of the criteria is on the toxicological data to determine protective concentrations. The EPA received requests to provide greater detail pertaining to the occurrence data in the problem formulation sections. However, the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents do indicate whether the occurrence data were collected in freshwater or saltwater environments. In general, a majority of the occurrence data for PFOA and PFOS in U.S. surface waters to date were collected from freshwater environments. Additionally, Section 2.4.1 and Appendix N of the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents report the summary statistics (i.e., ranges, arithmetic mean, and median concentrations) and sample sizes for the publicly available occurrence data for PFOA and PFOS in U.S. ambient surface waters.

2.2 Science Used in the PFOA and PFOS Aquatic Life Criteria Derivation

2.2.1 General Comments Related to the Science Used in the Criteria Derivation

2.2.1.1 Summary of Public Comments:

The EPA received a broad set of comments from the public regarding the science used to derive the Draft PFOA and PFOS Aquatic Life Criteria. Many of the comments fit into specific topic groups addressed below (i.e., underlying science for the freshwater acute or chronic water column criteria or the freshwater tissue criteria). However, several topics did not fit into common topics and therefore, are summarized here under general comments related to the science used in the criteria derivation. These comments focused on: (1) the potential inclusion of environmental factors on the derivation of the criteria, (2) the need for additional details presented in the criteria documents related to the toxicity studies reviewed and/or used in the derivation of the criteria, (3) comments regarding the proposed need to further justify deviations from the EPA's *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (hereafter "Aquatic Life Criteria Guidelines" (U.S. EPA 1985), (4)

additional data that may be considered in the derivation of the criteria, and (5) concerns with the differences between the EPA's Draft PFOA and PFOS Aquatic Life Criteria and those derived by other jurisdictions. Comments related to all of these topics are summarized in more detail below.

Several public commenters requested the EPA integrate the influence of environmental variables on the toxicity of PFOA and PFOS, as was recently done with the 2018 aluminum criteria (U.S. EPA 2018) and 2013 ammonia criteria (U.S. EPA 2013), or better describe current limitations and potential opportunities for including these types of influencing variables.

Second, commenters questioned the EPA's qualitative use classifications when the EPA cited the following reasons: (1) omission of husbandry information, (2) use of field-collected organisms, (3) the use of improper test duration, and (4) discrepancies in study use when known, but low levels, of impurities were quantified in the test substance as compared to tests that did not report chemical purity.

Additional comments indicated that all study summaries should note if tissues were tested for organic fluorine, PFOA, or PFOS in the control population and should reference any protocols suggesting control organisms have not been previously exposed to PFAS. The commenter noted that study summaries should also include detailed methods, whether data below detection limits were used, and how data points below detection were addressed. Additional commenters noted that the EPA should provide the quality assurances and data quality indicators (accuracy, sensitivity, repeatability, bias) for data extrapolated from data plots and graphs.

As for additional data that may be considered in the derivation of the criteria, several commenters provided or noted data that they believed should be considered in the revisions of the Draft PFOA and PFOS Aquatic Life Criteria. These data include occurrence and toxicity data. The occurrence data are summarized in Section 2.1.1 above as these data pertain to the Problem Formulation of the Draft PFOA and PFOS Aquatic Life Criteria. As for the toxicity data, the commenters noted that many of the studies are awaiting publication. Additionally, comments from Environment and Climate Change Canada (ECCC) noted that they obtained additional information from the authors of Boudreau (2002) and Ji et al. (2008).

Lastly, several commenters noted differences between the EPA's PFOA and PFOS magnitudes presented in the Draft Aquatic Life Criteria documents compared to other

jurisdictions. Commenters expressed their belief that the EPA should incorporate evidence and reasoning followed by other states and countries in developing PFOA and PFOS criteria.

2.2.1.2 EPA Response to Public Comments:

The EPA appreciates these comments. The EPA reviewed all of the comments and made edits, as appropriate. The potential influence of water chemistry on PFOA and PFOS toxicity and bioaccumulation is discussed in Sections 2.2 and 2.5, respectively, in the criteria documents. However, water chemistry was not addressed in the derivation of the PFOA and PFOS Aquatic Life Criteria for two reasons. First, the data surrounding the potential influence of physiochemical parameters on PFOA and PFOS toxicity and bioaccumulation in the aquatic environment are relatively limited and do not indicate that incorporating such properties into the calculation of the criteria is warranted. Second, the approach used to derive the PFOA and PFOS Aquatic Life Criteria was consistent with other assessments of organic compounds by the EPA and other jurisdictions.

The EPA carefully evaluated all studies in the 2022 Draft and 2024 Final PFOA and PFOA Aquatic Life Criteria and Benchmark documents. The EPA ensured that all toxicity study summaries included relevant information to help readers easily understand why a particular test was used quantitatively or qualitatively, or not used to derive the PFOA and PFOS Aquatic Life Criteria. This included an evaluation of the overall study use classifications (i.e., quantitatively acceptable for use, qualitatively acceptable for use, or unusable) to ensure they were consistent across studies. In most cases, study use classifications have remained unchanged and greater details were provided to enhance justification for the use classification. In certain cases, the reevaluation of study use classifications following public comments resulted in the reclassification of individual tests. For example, many tests presented in 3M Company (2000) reported approximately 95% test purity with known presence of other PFAS (i.e., C5, C6, and C7, etc.). Certain individual tests by 3M Company (2000) that were previously considered for qualitative use because the test chemical was reported to be approximately 95% pure with known presence of C5, C6, and C7 are now considered for quantitative use if all other test quality guidelines were met. Further, other tests by 3M Company (2000) that were previously considered for quantitative use, but reported an unknown test purity, were changed to qualitative use since other tests in the same publication reported low purity of the test substance (i.e., the 48-hour cladoceran PFOS test with an author-reported EC_{50} of 27 mg/L was changed from

quantitative use to qualitative use since the purity of PFOS was reported to be unknown and another test from the same publication reported a low level of PFOS purity (i.e., 24.5%) in the test compound.

Section 4.2 of the 2022 Draft PFOS Aquatic Life Criteria document provides and summarizes any potential influence of studies considered for qualitative use on the PFOS Aquatic Life Criteria. These qualitatively-acceptable studies include those identified as either not meeting the EPA's data quality guidelines for inclusion in the criteria derivation or not having data available to support the independent calculation of a toxicity value (e.g., LC_{50} and/or EC_{10}). This addresses a public comment that recommended that the EPA present the effect of the qualitative studies on the Draft PFOS Aquatic Life Criteria in lieu of the missing acute, aquatic insect data in the Draft document. A similar analysis was not conducted for PFOA, as no qualitatively-acceptable studies were identified that contained sensitive endpoints that would significantly alter the Draft PFOA Aquatic Life Criteria. As all Minimum Data Requirements (MDRs) are now met in the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents, due to the inclusion of new data, the acute portion of Section 4.2 of the Draft PFOS Aquatic Life Criteria document, describing additional analyses of the acute PFOS criterion with the use of qualitative data, was removed. Lastly, both the 2022 Draft and 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents include summaries of qualitatively acceptable studies focused on the most sensitive species (those used to derive the acute and chronic Aquatic Life Criteria) and those within a factor of two of the Final acute and chronic values. Therefore, these summaries compare relatively sensitive qualitatively acceptable toxicity data to the quantitatively acceptable toxicity data and corresponding criteria magnitudes.

The EPA thanks the commenters who provided or noted additional toxicity data that may be considered in deriving the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents. The 2022 Draft PFOA and PFOS Aquatic Life Criteria documents released for public comment contained toxicity data from the EPA's ECOTOXicology knowledgebase (ECOTOX) through September 2021. Following the closure of the public comment period, the PFOA and PFOS Aquatic Life Criteria documents were updated to include recently published toxicity data, including all PFOA and PFOS toxicity data reported in ECOTOX as of March 2024.

Lastly, the EPA thanks the commenters noting differences between the EPA's 2022 Draft PFOA and PFOS Aquatic Life Criteria magnitudes as compared to protective values from other jurisdictions. In most cases, observed differences were the result of the available toxicity data when a particular protective value/criterion was derived and/or different methodologies to derive protective thresholds. For example, Minnesota developed protective PFOA and PFOS values (as numerical expressions of narrative criteria) through the use of safety factors to account for significant data limitations at the time. The EPA was able to fulfill all MDRs to derive the Final aquatic life AWQC per the Aquatic Life Criteria Guidelines and did not use safety factors. The 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents reflect the latest science, are fundamentally consistent with approaches used for deriving national AWQC in the past, and are directly informed by the latest, high quality toxicity data.

2.2.2 Underlying Science of the Freshwater Acute Water Column Criterion (CMC)

2.2.2.1 Summary of Public Comments:

The public comments related to the underlying science of the freshwater acute water column criteria (criterion maximum concentration, CMC) presented in the Draft PFOA and PFOS Aquatic Life Criteria documents focused on three topic areas: (1) missing MDRs, (2) the EPA's justification for proceeding with the derivation of the acute PFOA and PFOS Aquatic Life Criteria without data for aquatic insects, and (3) toxicity values and the approach used to derive the CMC. Specially, some commenters stated that the recommended criteria should not be finalized until all MDRs are met following the requirements of the Aquatic Life Criteria Guidelines. Alternatively, some commenters noted the criteria values could be released as benchmark values to provide states with greater flexibility.

As for the public comments relating to the EPA's justification to proceed with the derivation of acute PFOA and PFOS Aquatic Life Criteria without filling the aquatic insect MDR, commenters supposed that many states will not adopt the recommended PFOA and PFOS Aquatic Life Criteria until all MDRs are met. Commenters further speculated that the Draft acute PFOA and PFOS criteria may be under protective without the inclusion of quantitatively acceptable mayfly or dragonfly data that were described by the EPA during outreach webinars. Additionally, some commenters stated that while the EPA used web-ICE to support the conclusion that insects may not be the most acutely sensitive taxon to PFOA and PFOS, the taxonomic distance of the final models was at the shared phylum or kingdom level, and therefore

commenters questioned whether aquatic insect species will be protected under the Draft recommended acute criterion presented in the Draft PFOA and PFOS Aquatic Life Criteria documents.

As for comments related to the toxicity data and approach used to derive the CMC in the Draft PFOA and PFOS Aquatic Life Criteria documents, commenters stated that the EPA should justify the inclusion of NOEC and LOEC values in their acute calculations, as they were included with no explanation. Additionally, commenters noted that the EPA should revise Draft PFOA and PFOS Aquatic Life Criteria to follow the Species Sensitivity (SSD) approach, used in Canada and Australia. Further, the commenters noted that three external peer reviewers recommended that the SSD approach be taken.

2.2.2.2 EPA Response to Public Comments:

The 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents now contain recently published data, which fulfills the freshwater acute and chronic eight minimum data requirements (MDRs) for both PFOA and PFOS Aquatic Life Criteria. These new data include mayfly toxicity data referenced in the public comments. Commenters incorrectly stated the EPA verbally communicated that dragonflies are likely sensitive to PFAS. The EPA had only described the predicted sensitivity of mayflies based on range-finding tests during public outreach webinars and did not describe dragonfly toxicity testing. Inclusion of the new insect data, which has been published in peer-reviewed literature (and other new data reviewed since the 2022 release of the Draft PFOA and PFOS Aquatic Life Criteria documents), reflects an updated toxicological database, so the PFOA and PFOS Aquatic Life Criteria and Benchmarks are based on the latest information.

As for comments related to the toxicity data and approach used to derive the freshwater CMC, the commenter was in error in their statement on the EPA's use of NOEC or LOEC data. The EPA did not rely on NOEC or LOEC values to derive the acute PFOA or PFOS Aquatic Life Criteria. The 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmarks documents have been revised to be clearer that NOECs and LOECs were not used in acute criteria development. In certain cases, non-definitive LC_{50} values can be used to derive acute criteria, but this is reserved for "greater than (>) LC_{50} values" for test organisms that are relatively tolerant, as they provide relative information on the lack of sensitivity of a species but do not have a significant effect on the Final criteria magnitudes. The EPA has used the same approach in

previous Aquatic Life AWQC documents (U.S. EPA 2013; also see the EPA's response to a similar comment related to the chronic 2022 Draft PFOA and PFOS Aquatic Life Criteria document in Section: 2.2.3.2 below).

The 2022 Draft acute and chronic PFOA and PFOS Aquatic Life Criteria for freshwater were derived using a genus sensitivity distribution (GSD) rather than an SSD. As stated in the Aquatic Life Criteria Guidelines, the EPA used a GSD because it reduces the effect of overly tested species on the Final criteria; the EPA has continued to use this long-standing Aquatic Life Criteria Guidelines (U.S. EPA 1985) process for criteria derivation for all criteria since that document was released. The EPA has initiated an effort to update the Aquatic Life Criteria Guidelines (See Section 2.5.2 below for more details). When a draft revision is completed, it will be externally peer reviewed and then made available for public comment.

2.2.3 Underlying Science of the Freshwater Chronic Water Column Criterion (CCC)

2.2.3.1 Summary of Public Comments:

The public comments related to the underlying science of the PFOA and PFOS chronic water column criteria (criterion continuous concentration, CCC) presented in the Draft PFOA and PFOS Aquatic Life Criteria documents focused on three topic areas: (1) toxicity values and the approach used, (2) use of the EC_{10}, and (3) use of static and renewal tests to derive the CCC. For comments specifically related to the toxicity values, and the approach used to derive the chronic criterion, commenters stated that before applying the acute to chronic ratio (ACR) approach to derive chronic criterion, the EPA should demonstrate that the physiological mechanisms for toxicological effects are the same in acute and chronic exposures. Some commenters expressed concern that this is not the case for PFOA and PFOS. Additionally, reviewers commented that they appreciated the EPA's detailed summaries of the toxicity tests used in the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents but requested that more information on the EPA-fitted C-R curves be provided in the summaries. Lastly, some commenters stated that the decision to include "greater than" chronic toxicity values was inappropriate and added to the level of uncertainty in the PFOA and PFOS criteria calculations.

Further, several commenters questioned the use of EC_{10} instead of EC_{20} values to derive the CCC presented in the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents. Some commenters reiterated comments from a peer reviewer related to the use of the EC_{10}s and questioned the appropriateness of using EC_{10}s instead of EC_{20}s. Other public commenters noted

that the EPA justified the use of EC_{10} values to derive the 2016 Selenium Aquatic Life Criterion (U.S. EPA 2016c) because of the steepness of the dose-response curves and pointed out that the EPA did not provide a similar justification for use of EC_{10} values in the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents. Also, several commenters felt the bioaccumulative nature of PFOA and PFOS was not a strong enough rationale to justify the increased conservativism (at the expense of increasing statistical uncertainty) associated with using EC_{10}s instead of EC_{20}s to derive the 2022 Draft PFOA and PFOS Aquatic Life Criteria. Lastly, commenters stated that the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents did not provide sufficient justification for using data from partial life-cycle tests and recommended that only data from life-cycle toxicity tests be included. Public commenters recommended that the EPA provide better justification for this deviation from the Aquatic Life Criteria Guidelines if data from partial-life cycle tests are retained in the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents.

2.2.3.2 EPA Response to Public Comments:

Contrary to statements written by several commenters, the EPA did not apply ACRs to derive chronic criteria for PFOA or PFOS. The Draft freshwater PFOA and PFOS Aquatic Life Criteria were derived based on chronic genus sensitivity distributions, not through acute to chronic ratios. The EPA thanks commenters for supporting the detailed descriptions of individual toxicity tests and calculations of chronic values. Additionally, Appendices A.2 and C.2 in both the Draft and Final PFOA and PFOS Aquatic Life Criteria documents show the EPA-calculated concentration-response (C-R) models for all quantitatively acceptable tests that were among the four most sensitive acute and chronic genera (when underlying C-R data were available). These appendices show individual C-R model figures, fitted model type, and corresponding LC_{50} or EC_{10} estimates with 95% confidence intervals (CIs). Moreover, Appendix K in each of the PFOA and PFOS Aquatic Life Criteria documents provides a detailed synopsis of the EPA's curve-fitting methodology, including parameters for selecting the most robust model fit and model diagnostics for evaluating the acceptability of individual models for use in criteria derivation; commenters with interest in seeing this information can review these existing, publicly-available appendices. Finally, the EPA disagrees with the commenters regarding the usefulness of greater than chronic toxicity values. The use of greater than chronic toxicity values are appropriate in certain scenarios. These scenarios are important for understanding the relative sensitives of

species and do not have significant numerical effects on the Final criteria magnitudes. For example, the 2022 Draft PFOA Aquatic Life Criteria document stated:

> *"A decision rule was also applied to the PFOA toxicity data when an author-reported NOEC or LOEC was used, in conformity with the 2013 Ammonia Freshwater Aquatic Life Criteria (U.S. EPA 2013), such that "greater than" values for concentrations of a relatively low magnitude compared to the other available toxicity data, and "less than" values for concentrations of relatively high magnitude were considered to add little significant information to the analyses and were not used quantitatively. Conversely, if data from studies with relatively low "less than" values indicated a significant effect or studies with relatively high "greater than" values only found an incomplete response for a chronic endpoint (indicating low toxicity of the test material), those data significantly enhanced the understanding of PFOA toxicity. Thus, the decision rule was applied as follows: "greater than" (>) high toxicity values and "less than" (<) low toxicity values were used quantitatively to derive the chronic water column-based PFOA criterion."*

The EPA recognizes instances where partial life cycle tests were used to derive the PFOA and PFOS Aquatic Life Criteria and provides justification for this deviation from the Aquatic Life Criteria Guidelines in Section 2.10.2 of the PFOA and PFOS Aquatic Life Criteria documents. Specifically, the PFOA and PFOS CCC were based on endpoints and durations of exposure that were appropriate for the test species. Thus, both life and partial-life cycle tests were utilized, and all chronic tests used in the derivation of the CCC followed taxa specific exposure duration requirements from various test guidelines, such as the Aquatic Life Criteria Guidelines, The Office of Water's Open Literature Standard Operating Procedure (SOP) and Data Evaluation Records (DERs) for Ecological Toxicity Data (https://www.epa.gov/wqc/aquatic-life-criteria-and-methods-toxics) and Office of Chemical Safety and Pollution Prevention's Ecological Effects Test Guidelines (U.S.EPA 2016a). When taxa-specific exposure duration requirements were not available for a particular test organism, both life- and partial-life cycle tests were considered as both provide relevant toxicity data, since

without inclusion of these tests there would be insufficient data to derive freshwater PFOA and PFOS Aquatic Life Criteria.

The EPA retained the use of chronic EC_{10} values to derive the Final chronic PFOA and PFOS Aquatic Life Criteria magnitudes. Although the chronic C-R models were not as steep as those observed in the 2016 Selenium Aquatic Life Criterion (U.S. EPA 2016c), use of EC_{10} values was retained because PFOA and PFOS are not naturally occurring molecules, and unlike selenium and cadmium, organisms contain no natural detoxification mechanisms specific to these persistent and bioaccumulative chemicals. Use of a 10% effect concentration for deriving chronic criteria magnitudes is also consistent with the harmonized guidelines from OECD (2019) and is the generally preferred effect level for countries such as Canada, Australia, and New Zealand (CCME 2007; Warne et al. 2018). Additionally, use of protective EC_{10} values for PFOA and PFOS are justified for these "forever chemicals," which are anticipated not to degrade significantly in the environment. In fact, numerous other PFAS have been found to ultimately degrade into PFOA and PFOS, leading to perhaps increased environmental concentrations and risk from these chemicals. Thus, allowing greater chronic effects to occur in aquatic taxa for these stable, bioaccumulating chemicals is not defensible or concordant with the goals of protective aquatic life designated uses. For similar reasons, the majority of expert peer-reviewers provided support for the use of EC_{10} values to derive the PFOA and PFOS Aquatic Life Criteria.

2.2.4 Underlying Science of the Freshwater Tissue-Based Criteria

2.2.4.1 Summary of Public Comments:

The EPA received several comments related to the science used in the derivation of the freshwater tissue-based values presented in the Draft PFOA and PFOS Aquatic Life Criteria documents. The comments generally fit into five topics: (1) recommendations that the tissue criteria be removed or made benchmarks, (2) statements that the bioaccumulation factors (BAFs) have a high degree of uncertainty, (3) suggestions that the details around the data for the BAFs be elaborated, (4) requests for additional justification for the use of the 20th centile BAFs in the derivation of the tissue-based criteria, and (5) concerns that the tissue-based criteria are not sufficiently protective of aquatic life. The summaries below provide greater details from the comments for these individual topics.

Some commenters stated that the tissue-based values presented in the Draft PFOA and PFOS Aquatic Life Criteria documents were unnecessary because water column values are

included in the criteria structure and fall above the detection limits for PFOA and PFOS. Further, numerous commenters noted that some state data suggest PFOA may not be bioaccumulative enough to require tissue-based criteria. Other public commenters stated that the tissue-based criteria should not be finalized until there are sufficient data to derive the tissue-based criteria following the Aquatic Life Criteria Guidelines. Alternatively, some commenters suggested that tissue-based criteria be released as benchmarks.

Many of the public commenters who were critical of the tissue-based values presented in the Draft PFOA and PFOS Aquatic Life Criteria documents believed that the tissue-based criteria have a high degree of uncertainty. Areas of uncertainty as stated in the public comments include: differences between the species used to calculate BAFs and those used to derive the Draft PFOA and PFOS water column criteria, variable experimental designs in the field studies used to generate the BAFs, differences between the translated tissue-based criteria and empirical tissue data from toxicity studies, insufficient explanation of environmental factors that might affect BAFs (e.g., organism size, gender, benthic vs. pelagic), the lack of evidence supporting a connection between tissue concentrations and toxic effects, and the spatial and temporal distance between collected water and tissue samples used to calculate the PFOA and PFOS BAFs. Also, some commenters suggested that only BAFs that were considered high quality be used to derive the tissue-based criteria as opposed to the use of high and medium quality BAFs. Commenters also noted that the PFOA and PFOS chronic tissue-based criteria were derived for separate fish and invertebrate tissues and requested that the water-column threshold used as the toxicological basis of tissue criteria be derived for similarly grouped taxa as opposed to a mixture of vertebrate and invertebrate species.

Lastly, another topic that public commenters asked the EPA to elaborate on was the use of the 20th centile for the PFOA and PFOS BAFs. Public commenters were concerned the approach is inconsistent with the level of protection afforded to aquatic life in ambient water criteria, which are derived to protect 95% of aquatic genera. Commenters also recommended that the EPA provide additional justification regarding the statement that tissue-based criteria translated from 20th centile BAFs protect species, regardless of whether exposures are low or high. Specifically, several public commenters thought the 20th centile BAF was not sufficiently protective for various reasons, including that: the 20th centile was too high compared to the 5th centile on which the water column criteria were based, scenarios where field-collected fish tissue

concentrations could be higher than the Draft fish tissue-based criteria even when water column concentrations at the same site are not exceeding the Draft PFOA and PFOS chronic water column criteria, and the Draft tissue-based criteria may not protect amphibians. One commenter noted that the EPA should use 10th centile BAFs to be consistent with the centile used in Minnesota's site-specific datasets. Conversely, another commenter believed that the 20th centile BAF was highly conservative, and that the use of a 20th centile BAF to translate the chronic water column criteria based on EC_{10} values would result in overly conservative tissue-based criteria.

2.2.4.2 EPA Response to Public Comments:

The EPA acknowledges the public comments requesting that the tissue-based criteria presented in the Draft PFOA and PFOS Aquatic Life Criteria documents be removed or changed to benchmarks. However, PFOA and PFOS are classified as "forever chemicals," that are not only stable in aquatic environments (and not expected to degrade), but are also bioaccumulative, with PFOS being more bioaccumulative. Thus, the EPA determined that the removal of the tissue-based criteria presented in the PFOA and PFOS Aquatic Life Criteria was not defensible or compatible with the goals of the Clean Water Act to protect aquatic life. Additionally, the EPA is aware of extensive tissue monitoring efforts that are ongoing for PFOA and PFOS across numerous states. Retaining the tissue-based criteria allows states and Tribes to better understand ecological risk associated with PFOA and PFOS concentrations measured in their tissue monitoring programs. Lastly, while the Aquatic Life Criteria Guidelines do not provide details on the derivation of tissue-based criteria, the derivation of PFOA and PFOS tissue-based values is supported by the "good science" clause described in the Aquatic Life Criteria Guidelines, which allows the EPA to evaluate the toxicological data as a whole to determine the most defensible criteria to ensure the protection of aquatic life. The PFOA and PFOS tissue-based criteria derivation methods are similar to those used in other jurisdictions, including Environment and Climate Change Canada, which developed PFOS guidelines/protective values that include various tissue-based criteria to protect aquatic life and aquatic-dependent wildlife (ECCC 2018). Therefore, the EPA retained the PFOA and PFOS tissue-based criteria. The criteria structure presented in the Draft PFOA and PFOS Aquatic Life Criteria documents has remained unchanged, such that the water column and tissue-based criteria are still independently applicable and no one criterion takes primacy over another. As such, the PFOA and PFOS tissue-

based criteria, as with all AWQC recommendations developed pursuant to CWA Section 304(a), are intended to be recommendations to states and Tribes in their water quality programs.

As for the public comments stating that the BAFs used in the derivation of the PFOA and PFOS tissue-based values were highly uncertain, the EPA recognizes the inherent uncertainties that are present with the use of BAFs to calculate tissue-based criteria. As mentioned by several public commenters, these uncertainties include differences in the analytical methods used, the specific species and habitats with paired tissue and water column measurements that were sampled, environmental factors that may impact the BAFs, and the experimental designs that were utilized. For these reasons, the EPA only utilized BAF literature with field-based experimental designs (as opposed to laboratory tests) as these types of tests inherently incorporate the environmental factors that may influence BAFs in a way that laboratory tests cannot.

Additionally, the EPA screened the BAF literature in a manner consistent with the evaluation criteria outlined in Burkhard (2021), which considered epistemic uncertainties in the BAF dataset used. In response to public comment, the EPA conducted an analysis to evaluate the influence of using medium and high quality BAFs as opposed to high quality BAFs only, which was recommended by a public commentor. The 20th centile PFOS BAFs based on high quality data only were 2.3 (i.e., PFOS fish muscle BAF) to 3.4 (i.e., PFOS invertebrate BAF) times greater than corresponding PFOS BAFs based on medium and high quality. The 20th centile PFOA BAFs based on high quality data were 1.3 (i.e., PFOA fish muscle BAF) times lower or 9.5 (i.e., PFOA fish whole body BAF) times greater than corresponding PFOA BAFs based on medium and high quality. Use of high quality BAFs only consistently increased 20th centile PFOS BAFs and had no consistent impact on 20th centile PFOA BAFs. The taxa and sites represented, as well as the overall "n" in the underlying BAF datasets were greatly reduced when using only high quality BAFs, increasing uncertainty. Therefore, the EPA used high and medium quality BAFs to derive tissue-based PFOA and PFOS Aquatic Life Criteria as this resulted in the most robust and scientifically-defensible dataset of BAFs. Burkhard (2021) represents the most extensive PFOA and PFOS BAF compilation available to date. As for the use of PFOA and PFOS BAFs from other jurisdictions, the EPA did not summarize BAFs from other jurisdictions since there is only one tissue-based value for the protection of aquatic life, which was derived by

ECCC (2018) with the use of two BCF/BAF values for bluegill (Drottar et al. 2001) and common carp (Inoue et al. 2012) in whole-body.

Further, some public commenters noted that there were increased uncertainties in the BAFs because there were differences between the species used to calculate the BAFs and those used to derive chronic water column criteria that were ultimately used to derive the tissue-based criteria. The species used to derive both the water column criteria and the BAFs are surrogates for all aquatic life. Additionally, use of invertebrate-specific and fish-specific distributions as the toxicological basis of their respective tissue criteria would have resulted in invertebrate-specific and fish-specific sensitivity distributions based on limited toxicity data, with the 5th centile of those distributions being overly influenced by "n" in those distributions. In contradiction to one public comment that stated there was a lacking connection between the tissue values and toxicity, Sections 4.5 and 4.7 of the Draft PFOA and PFOS Aquatic Life Criteria documents, respectively, evaluate tissue-based toxicity data relative to the tissue-based criteria values. These evaluations found no instances of tissue-based toxicity data suggesting the tissue-based criteria were under protective.

In response to public comments requesting that the EPA add details relating to the data used to calculate the BAFs, the EPA notes BAF locational data were included in the Draft 2022 PFOA and PFOS Aquatic Life Criteria documents that were released for public comment as well as citations for the source material for each individual BAF. Additionally, greater details can be found in the supplemental information of Burkhard (2021), which provides a publicly available BAF database used by the EPA to derive summary and 20th centile PFOA and PFOS BAFs. Beyond use of high and medium quality BAFs, the BAF database was not parsed out further by additional details (e.g., benthic vs pelagic, gender, etc.) since Burkhard (2021) did not clearly demonstrate an influence of these additional factors on the BAFs. Therefore, further limiting BAFs by these variables would greatly reduce the resultant BAFs dataset and taxonomic representation that were used to calculate protective tissue-based criteria.

Comments related to the use of the 20th centile BAF to derive the tissue-based criteria were not unanimous with some commenters noting this value was too protective and others noting it was not protective enough. Use of the 20th centile BAF protects aquatic life species in conditions where the bioaccumulation of PFOA or PFOS is relatively low as well as those conditions with relatively high bioaccumulation potential. To clarify further, use of an 80th

centile BAF (as opposed to a 20th centile BAF) results in higher tissue-based criteria and would not be protective of conditions where tissue-based effects may still occur despite the bioaccumulation potential being relatively low. Using the 20th percentile BAF based on the distribution of the lowest species-level BAF reported at a site to derive the tissue-based criteria is fundamentally consistent with the nationally representative enrichment factors (EFs) used in the national selenium aquatic life criteria, which is the only other tissue based aquatic life criteria derived by the EPA to date (U.S.EPA 2016c).

2.2.5 Underlying Science of the Estuarine/Marine Acute Benchmark

2.2.5.1 Summary of Public Comments:

The EPA received public comments regarding the underlying science used in the derivation of the estuarine/marine acute benchmark relating to two general topics: (1) uncertainties associated with Web-based Interspecies Correlation Estimation (Web-ICE) and (2) concerns with adopting a benchmark value instead of a criterion. The summaries below provide greater details from the public comments related to the acute estuarine/marine benchmark for PFOA and PFOS.

Commenters noted several areas of uncertainty regarding Web-ICE models, including wide confidence intervals, small number of data points in final models, values based on extrapolations beyond the data range of the Web-ICE models, the absence of PFOS or PFOA data from the underlying Web-ICE database, and the use of freshwater surrogates to fill estuarine/marine MDRs. Regarding the use of extrapolated data, it was suggested that the EPA wait until the associated document discussing this issue be released before including extrapolated data. Concerning the use of freshwater surrogates, public commenters noted that the EPA stated that estuarine/marine taxa were generally more sensitive, and the use of freshwater surrogates resulted in uncertainty regarding the protectiveness of the benchmark value. Some commenters stated that uncertainty could be addressed by a deeper discussion of the Web-ICE methodology, as well as a comparison of alternate approaches.

As to concerns with adopting a benchmark value, several commenters suggested it would be more appropriate to include a discussion of the estuarine/marine benchmark in a separate document, or to remove the benchmarks from the PFOA and PFOS Aquatic Life Criteria documents, because of the perceived uncertainties associated with Web-ICE summarized from the public comments above. Other public comments recommended that the EPA wait until there

are sufficient empirical data to derive estuarine/marine criteria following the Aquatic Life Criteria Guidelines. Conversely, some commenters suggested other NAMs (e.g., Ecological Structural Activity Relationships, ECOSAR; Quantitative Structure-Activity Relationship, QSAR) be used to develop PFOA and PFOS chronic estuarine/marine benchmarks. Multiple commenters requested additional clarification of the uncertainties associated with adopting a benchmark value as opposed to a criterion value. Specifically, commenters reiterated benchmarks are not CWA Section 304(a) criteria, and stated that it is not clear how they should be used.

2.2.5.2 EPA Response to Public Comments:

Aquatic life benchmarks, developed under 304(a)(2) of the CWA, are informational values that the EPA generates when there are limited high quality toxicity data available and data gaps exist for several aquatic organism families. The EPA develops aquatic life benchmarks to provide information that states and Tribes may consider in their water quality protection programs. In developing aquatic life benchmarks, data gaps may be filled using new approach methods (NAMs), such as computer-based toxicity estimation tools (e.g., EPA's Web-ICE; Version 3.3; https://www.epa.gov/webice/),other new approach methods intended to reduce reliance on additional animal testing (https://www.epa.gov/chemical-research/epa-new-approach-methods-work-plan-reducing-use-vertebrate-animals-chemical), including the use of read-across estimates based on other chemicals with similar structures, or other information. The EPA's aquatic life benchmark values are not regulatory, nor do they automatically become part of a state's water quality standards.

The peer-reviewed, publicly available tool selected by the EPA to develop the PFOA and PFOS acute estuarine/marine benchmarks was Web-ICE. Without application of Web-ICE models to estimate acute PFOA and PFOS values for estuarine/marine species, the EPA would not have been able to develop and provide informational values that are intended to protect aquatic life species from acute PFOA and PFOS exposures in estuarine/marine waters for states and Tribes to consider. States and Tribes may adopt the acute estuarine/marine PFOA and PFOS benchmarks as state/Tribal water quality standards. If states or Tribes choose not to adopt the acute estuarine/marine benchmarks into their water quality standards, they may still consider the estuarine/marine benchmarks to inform permit limits and for use in monitoring programs where

the benchmarks can serve as threshold values to understand if monitoring data indicate that there may be a concern for aquatic life in specific estuarine/marine waters.

The EPA recognizes the relative uncertainty in the acute estuarine benchmarks. For more information, please see Appendix L.5.1 of the Draft PFOA Aquatic Life Criteria document and Appendix L.2.5 of the Draft PFOS Aquatic Life Criteria document. These appendices specifically evaluate the influence of the epistemic uncertainty noted by commenters and address the use of freshwater surrogate species to predict estuarine/marine species.

Nevertheless, the most sensitive GMAVs used to derive the PFOA and PFOS estuarine/marine benchmarks were based on empirical tests, meaning the benchmark magnitudes themselves were primarily influenced by empirical laboratory-based toxicity tests rather than estimated data. Finally, Appendices L.5.1 and L.2.5 of the PFOA and PFOS Draft Aquatic Life Criteria documents, respectively, also evaluated the benchmark values relative to qualitatively acceptable data. Overall, results of quantitatively- and qualitatively-acceptable empirical toxicity studies with estuarine/marine organisms support the understanding that the aquatic estuarine/marine community would be protected at acute estuarine/marine PFOA or PFOS benchmark magnitudes.

2.2.6 Underlying Science of the Frequency and Duration Components

2.2.6.1 Summary of Public Comments:

The public comments related to the underlying science of the frequency and duration components of PFOA and PFOS Aquatic Life Criteria mainly focused on the frequency of the tissue-based criteria. Generally, commenters were split on the appropriateness of the frequency of the tissue-based criteria of "not to be exceeded more than once in ten years on average", with some commenters stating that this frequency was too conservative, and others requested that the EPA provide additional justifications for the frequency component of the Draft tissue-based criteria. Specifically, some commenters stated that the 10-year exceedance frequency associated with the chronic tissue-based criteria is excessive and is considerably longer than for other chemicals known to bioaccumulate and biomagnify (e.g., selenium, polychlorinated biphenyls, mercury). Several of these commenters also pointed to some external expert peer reviewers who shared this opinion. These public commenters also considered the 10-year exceedance frequency particularly problematic given their perceived uncertainties associated with the derivation of the tissue-based criteria. These commenters stated that the EPA should provide additional rationale

regarding the exceedance frequency beyond the general references to "documented recovery times of pollutants with similar chemical attributes" and more explicitly document the need for longer recovery times for PFOA and PFOS compared to metals. Commenters also requested that the EPA provide data from field collected organisms showing potential recovery times and describe any flexibility states and Tribes may have to deviate from recommended frequency, in order to account for situation-specific ecological recovery. Conversely, some public commenters stated that the EPA should also clarify why the tissue-based exceedance frequency differs from the 2016 "not to be exceeded" frequency for selenium.

2.2.6.2 EPA Response to Public Comments:

While expert peer reviewers did not unanimously agree, most commented favorably on the tissue-based criteria exceedance frequencies presented in the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents. Considering the relative uncertainty in ecological recovery rates following PFOA or PFOS contamination (as noted by expert peer reviewers and public commenters), the EPA revised the frequency component of the PFOA and PFOS tissue-based criteria from "once in 10 years, on average," to "not to be exceeded" to ensure the criteria are protective. The revision was also done so the tissue-based criteria were more consistent with existing tissue-based criteria (i.e., selenium; U.S.EPA 2016c). Further, there are no documented cases of PFOA or PFOS disturbances and resultant recovery times to directly inform an appropriate exceedance frequency for these chemicals. Selenium is persistent and bioaccumulative, as are PFOA and PFOS. Consequently, recovery times from selenium-contaminated sites were considered as surrogate case studies of ecological recovery following PFOA and PFOS contamination. Considering documented cases of ecological recovery rates, the U.S. EPA (2016c) stated:

> *"a protracted period of time (in excess of 10 years) would be necessary for fish communities to recover once a selenium in fish tissue reached concentrations associated with reproductive impacts. Thus, the typical "once-in-three years on average" criteria return frequency is not appropriate for selenium, as this could lead to sustained ecological impacts."*

Additionally, unlike selenium and some other metals, PFOA and PFOS are not essential elements, serve no biological function, and cause adverse effects.

Beyond selenium, a recent review of ecological recovery times (Mebane 2022) determined recovery rates from chronic disturbances (e.g., long-term disturbances) based on water column exposures are longer than acute (short-term) water column disturbances, with recovery from chronic disturbances occurring within 10 years in 75% of cases. Long-term chronic disturbances are likely to provide the time required for PFOA and PFOS to accumulate in tissues and source reservoirs. Thus, exceedances of tissue-based PFOA and PFOS criteria represent chronic disturbances, with relatively long recovery times, as opposed to acute disturbances with fast increases of PFOA or PFOS in the water column followed by rapid dissipation.

Specifying a time interval associated with ecological recovery from PFOA or PFOS tissue criteria exceedances is highly uncertain given the lack of PFOA- or PFOS-specific examples of ecological recovery and the many situational-specific factors influencing recovery (Mebane 2022). For example, the lack of PFOA and PFOS degradation in the environment, and degradation of other PFAS in the environment into PFOA or PFOS, could act as ongoing PFOA and PFOS sources that further delay recovery. Taking all of this information into account, and in response to public commenters who indicated that a return frequency of 10 years may not be sufficiently protective of aquatic life, the EPA is recommending in the 2024 Final PFOA and PFOS criteria documents that PFOA and PFOS tissue-based criteria frequencies are "not to be exceeded." Setting the criteria frequency to "not to be exceeded" would provide greater protection of aquatic life populations from these "forever" chemicals, if the criteria are adopted by states. Moreover, if tissue-based criteria are exceeded, then PFOA/PFOS has likely built up through the food web and PFOA and/or PFOS source reservoirs are likely to exist, representing a broad level of ongoing PFOA/PFOS contamination throughout the aquatic ecosystem.

Finally, the frequency components of water column criteria have remained set at "once in three years, on average," as recent reviews of ecological recovery continue to suggest a once in three-year exceedance frequency for water column-based criteria is appropriate (Gergs et al. 2016; Mebane 2022).

2.2.7 Use of Non-North American Species

2.2.7.1 Summary of Public Comments:

Several public commenters expressed concern with the use of non-North American species in the Draft PFOA and PFOS Aquatic Life Criteria. In particular, some commenters

asserted that the practice of including non-North American species is inconsistent with the goal of the CWA to provide for the protection and propagation of fish, shellfish and wildlife through the restoration and maintenance of the chemical, physical, and biological integrity of the Nation's waters. Other commenters asserted that the use of non-North American species is inconsistent with the Aquatic Life Criteria Guidelines or may preclude some states from adopting the criteria, as they have policies and laws stating they cannot adopt criteria using non-resident or non-North American species. Other commenters suggested that the EPA allow states and Tribes the flexibility to decide whether to adopt aquatic life criteria concentrations based on all taxa or only North American taxa.

Conversely, other public commenters noted that the EPA performed an analysis showing that the inclusion of non-North American taxa generally had a minor effect on the aquatic life criteria for PFOA and PFOS. In general, commenters appreciated this analysis. Several public commenters agreed it was appropriate to include non-North American species in aquatic life criteria at times, but only when their inclusion would result in more protective criteria. Lastly, commenters also noted that the inclusion decisions for using non-North American species seemed inconsistently applied, with specific commenters pointing to the EPA's use of the non-North American species such as the Japanese swamp shrimp (*Neocaridina denticulata*), a planarian (*Dugesia japonica*), and a cladoceran (*Daphnia carinata*), while excluding data for the yellow fever mosquito, based on the commenters interpretation that the yellow fever mosquito is a non-North American species and is invasive.

2.2.7.2 EPA Response to Public Comments:

The EPA disagrees with commenters who assert that inclusion of toxicity data for non-North American species is inconsistent with the CWA objective of the restoring and maintaining the chemical, physical, and biological integrity of the Nation's waters, with the interim goal of providing for the protection and propagation of fish, shellfish and wildlife. The EPA has retained these data in the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents. North American and non-North American species were used to derive the criteria to ensure that the fullest, high-quality dataset available was used to represent the thousands of untested aquatic taxa present in U.S. ecosystems to ensure CWA goals may be met. In many cases, non-North American species used to derive the Draft and Final PFOA and PFOS Aquatic Life Criteria were from the same genus as North American species, indicating their expected genetic and

phenotypic similarity, which is expected to reflect greater similarities in toxicological response. Additionally, non-North American species have been previously used to derive other recent National Ambient Water Quality Criteria for aquatic life under Section 304(a) of the CWA (e.g., aluminum; U.S.EPA 2018). This approach of including North American and non-North American species in the derivation of the Final PFOA and PFOS criteria magnitudes is consistent with the CWA and the "good science clause" in the Aquatic Life Criteria Guidelines. In this case, the inclusion of non-North American species did not have a meaningful impact on the Final criteria magnitudes for PFOA or PFOS, as discussed in the criteria documents (see Section 4.1 and 4.2 in the Final 2024 PFOA and PFOS Aquatic Life Criteria Documents, respectively).

Expert peer reviewers provided minimal comments regarding the EPA's inclusion of Non-North American species in the criteria derivation process; however, one reviewer provided the following comment:

> *"EPA was correct to consider non-North American resident species in developing the criteria. While I can understand why some scientists feel strongly about focusing on native species, I also cannot think of a clear example of widely different chemical tolerances among species from different countries."*

Lastly, as for the comments asserting that EPA was somehow inconsistent in its inclusion of specific non-North American species, the EPA disagrees. For the specific example that the public commenters referenced, the test for yellow fever mosquito was not excluded from the PFOS criteria derivation for the test organism being a non-North American species alone as the public comment implies. Section 4.2.1 of the 2022 Draft PFOS Aquatic Life Criteria document summarizes the acute yellow fever mosquito test and all the reasons this test was not used in the derivation of the criteria. As such this section stated:

"EPA concluded that the inclusion of a qualitative LC50 for A. aegypti in the agency's acute criterion dataset is unwarranted given that: 1) A. aegypti is an invasive pest species; 2) the study was missing important exposure details; and 3) the author-reported LC50 and concentration-response curve could not be assessed by EPA on a statistical basis since model parameters were not provided, and there were insufficient treatment level data to independently calculate toxicity values."

Therefore, the EPA continues to consider the yellow-fever mosquito data from Olson (2017) as acceptable for qualitative use only. Further, these data were not included in the

derivation of the acute freshwater criterion for PFOS but was used as supporting information. As such, the summary of Olson (2017) in the PFOS criteria document includes these reasons for why the data was not acceptable for quantitative use. Lastly, Section 3.1.1.1.6 is not included in the 2024 Final PFOS Aquatic Life Criteria and Benchmark document as the aquatic insect MDR is no longer missing with the addition of quantitative studies published following the release of the 2022 Draft PFOS Aquatic Life Criteria document.

2.2.8 Use of Unmeasured Test Concentrations

2.2.8.1 Summary of Public Comments:

The EPA received a range of comments related to the use of unmeasured tests to derive the PFOA and PFOS Aquatic Life Criteria. These comments generally focused on three topics: (1) that unmeasured test concentrations should not be used and that only tests that meet the Aquatic Life Criteria Guidelines should be utilized to derive aquatic life criteria, (2) requests that particular test details, such as whether test concentrations were measured, be provided, and (3) that supporting information describing the possible range of the criteria with and without unmeasured data should be included. Specific comments are summarized below based on these topic areas.

First, commenters stated that criteria should only be developed using results from measured tests and that the development of the PFOA and PFOS Aquatic Life Criteria should be postponed until sufficient measured test data are available. Further, some commenters stated that only flow-through test data (or renewal for daphnids) should be used to derive chronic criteria. Other commenters stated that the EPA should provide better justification for using data from non-flow through tests to derive the PFOA and PFOS Aquatic Life Criteria. Specifically, several commenters acknowledged that data from measured tests were limited, but concluded that the justifications for using unmeasured test data were not sufficient since both Draft documents demonstrated some differences between measured and nominal concentrations. Additionally commenters noted that the OECD (2019) guidance document states that only measured tests should be used, especially when nominal concentrations deviate from measured by ± 20%, and that the EPA's evaluation of the differences between measured and nominal toxicity tests demonstrated that some measured concentrations differed from nominal by more than 20%. Also, commenters noted that the use of unmeasured test data is problematic since data from unmeasured tests were among the four lowest species mean acute (SMAVs) and species mean

chronic values (SMCVs) as presented in the Draft PFOA and PFOS Aquatic Life Criteria documents.

As for comments related to requests to include test details in the summaries presented in the Draft PFOA and PFOS Aquatic Life Criteria documents, the commenters stated that both Draft criteria documents present an evaluation showing that some experimental conditions (i.e., the test vessel material, presence of solvents, and presence of substrate) affected test concentrations in measured tests. Commenters indicated the EPA's comparison of nominal and measured concentrations and information summarizing the experimental conditions of the toxicity tests (including whether a test was measured or unmeasured, the test vessel material, and the presence or absence of substrate) should be more explicitly described within the main text and tables of the criteria documents.

Commenters also stated that the EPA should perform a quantitative analysis showing possible ranges of the Final PFOA and PFOS Aquatic Life Criteria with both measured and unmeasured tests compared to criteria values derived using measured tests only.

2.2.8.2 EPA Response to Public Comments:

The EPA's inclusion of unmeasured, and/or non-flow-through tests in the derivation of the PFOA and PFOS Aquatic Life Criteria is supported by the extensive analyses presented in the Draft PFOA (Appendix M) and PFOS (Appendix O) Aquatic Life Criteria documents. In summary, the EPA's 2022 Draft criteria documents and a separate, peer-reviewed publication, Jarvis et al. (2023), evaluated how measured PFOA and PFOS concentrations in toxicity tests compared to corresponding nominal concentrations across water types (i.e., freshwater and saltwater) and experimental conditions (i.e., test duration, whether test organisms were fed or unfed, the material of the test vessel, the presence of substrate). Overall, nominal concentrations were very similar to measured concentrations, with the linear correlation analyses showing a high level of correlation (≥ 0.9567) between measured and nominal concentrations across various experimental conditions in the April 2022 Draft PFOA and PFOS Aquatic Life Criteria (e.g., exposure durations, test vessel material, and the presence or absence of a substrate or solvent). This level of correlation suggests a high probability that nominal concentrations from unmeasured tests reflect actual test concentrations for toxicity studies otherwise meeting the EPA's test quality guidelines (U.S.EPA 2016a) and that PFOA and PFOS concentrations in toxicity tests remain stable over time.

Based on the result of the extensive analyses conducted, the EPA disagrees with the public comments suggesting that tests in some experimental conditions showed differences between measured and nominal concentrations and/or that any differences stemming from test conditions were not accounted for in the Draft PFOA and PFOS AWQC documents. The public comments specifically call out test conditions with substrates, plastic test vessels, and in saltwater. While the EPA recognizes some observed differences between measured and nominal concentrations in PFOA and PFOS tests with substrates and PFOS saltwater tests, the EPA disagrees that differences were observed in PFOA and PFOS tests with plastic test vessels as the linear correlation analysis in the Draft PFOA and PFOS AWQC documents showed a high level of correlation (≥ 0.9567) and a relatively low proportion ($< 33\%$) of observed pairs of nominal and measured concentrations differing by ±20%. Further, the EPA notes that the tests in the Draft 2022 PFOA and PFOS AWQC documents with substrate and/or in saltwater were limited (26 and 49 observed pairs with substrate, and 12 and 171 observed pairs in saltwater tests for PFOA and PFOS, respectively). Therefore, it is difficult to discern potential differences between nominal and measured concentrations. However, some differences were observed in tests with these two experimental conditions. The specific findings were discussed in more detail in Appendices M and O of the 2022 Draft PFOA and PFOS Aquatic Life Criteria documents, respectively. In summary, the analysis indicated that measured concentrations from PFOS saltwater tests were lower than nominal, meaning effect concentrations derived from unmeasured saltwater tests may underestimate PFOS toxicity. This analysis could not be conducted for PFOA as there were too few PFOA studies (resulting in at most one pair per experimental condition) in saltwater. Further, for tests with substrate, the PFOA tests (e.g., McCarthy et al. 2021; Oakes et al. 2004), with measured PFOA concentrations were systematically lower than corresponding nominal concentrations indicating added PFOA may have sorbed to the substrate, reducing PFOA in the water column. Oddly, disparities between measured and nominal PFOS concentrations in tests with substrate were not consistent with those predicted based on potential sorption, as the measured concentrations tended to be higher than the nominal concentrations as opposed to lower. Thus, the presence of a substrate in a PFOA or PFOS toxicity test could be considered a sink or source of PFOA and PFOS in toxicity tests depending on the source and physicochemical characteristics of the substrate. Thus, the EPA concluded that while measured PFOA and PFOS toxicity tests are generally preferred, unmeasured PFOA and PFOS tests may

be acceptable in setting protective values. The EPA notes, importantly, that unmeasured tests with substrate were not used to derive the April 2022 Draft PFOA Aquatic Life Criteria.

Further, the EPA's retention of measured and unmeasured tests that otherwise meet the EPA's test quality guidelines (U.S.EPA 2016a) in the derivation of the PFOA and PFOS Aquatic Life Criteria is consistent with other jurisdictions. In particular, unmeasured test concentrations were also used in ECCC's PFOS aquatic life guideline (ECCC 2018). Similarly, the EPA received support from three out of the five external peer reviewers for the use of unmeasured tests in the derivation of the PFOA and PFOS Aquatic Life Criteria considering the stability of these chemicals. As for comments requesting additional study details and analyses, the EPA summarized toxicity test details, including the experimental conditions, particularly whether an individual test was measured or unmeasured. These details are presented in two places throughout the Draft 2022 PFOA (Appendices A through H and M) and PFOS (Appendices A through H and O) Aquatic Life Criteria documents that underwent public comment. The full experimental design details were not presented in the main body of the document as requested in the public comments, as presenting these details earlier in the document would decrease the clarity and readability of the PFOA and PFOS Aquatic Life Criteria. Lastly, the EPA did not include analysis showing possible ranges of the Final PFOA and PFOS Aquatic Life Criteria with both measured and unmeasured tests compared to criteria values derived using measured tests only. The EPA determined that the findings from the analyses comparing nominal and measured concentrations to demonstrate the stability of PFOA and PFOS concentrations over time and across experimental conditions was sufficient to justify the use of unmeasured tests in the derivation of the aquatic life criteria. The 2024 Final PFOA and PFOS criteria and benchmark documents do not contain appendices that compared nominal and measured test concentrations, as the 2022 Draft criteria document did. Instead, the Final 2024 PFOA and PFOS criteria and benchmark documents now reference a recent publication (Jarvis et al. 2023) that demonstrated the use of unmeasured tests are generally acceptable for PFOA and PFOS.

Other recent national recommended aquatic life criteria (e.g., aluminum [U.S. EPA 2018], cadmium [U.S. EPA 2016b], ammonia [U.S. EPA 2013]) have also included non-flow-through/unmeasured tests for particular taxa when preferred flow-through tests with measured concentrations were unavailable. This approach is consistent with the EPA's past practices and with the Aquatic Life Criteria Guidelines, which states:

"For some highly volatile, hydrolyzable, or degradable materials it is probably appropriate to use only results of flow-through tests in which the concentrations of test material in the test solutions were measured often enough using acceptable analytical methods."

Given the high stability and low volatility of PFOA and PFOS, use of static, unmeasured tests is of lower concern than it would be for volatile or unstable chemicals. Jarvis et al. (2023) found that nominal and measured concentrations in the PFOA and PFOS aquatic toxicity literature generally displayed a high degree of linear correlation and relatively low median percent differences between nominal and corresponding measured concentrations. Correlations between measured and nominal concentrations were >0.95 for PFOA and PFOS in freshwater tests. While measured PFOA and PFOS toxicity tests are generally preferred, Jarvis et al. (2023) demonstrated that experimental conditions generally had little influence on observed discrepancies between nominal and measured concentrations.

2.3 Considerations for Aquatic-Dependent Wildlife Criteria

2.3.1 Summary of Public Comments:

Commenters noted that given the persistence and bioaccumulation of PFOA and PFOS in the aquatic food web, higher trophic level mammals and birds may also be exposed to these chemicals. One commenter explicitly inquired if the EPA anticipates developing aquatic-dependent wildlife criteria for PFOS or PFOA in the future.

2.3.2 EPA Response to Public Comments:

The EPA notes that, by design, aquatic life criteria recommendations are not intended to address terrestrial species, as this is outside the scope of these recommended water quality criteria, which are derived to be protective of aquatic life. The EPA does intend, however, to develop independent PFOA and PFOS aquatic-dependent wildlife criteria recommendations if and when there are sufficient data.

2.4 Implementation of the PFOA and PFOS Criteria

2.4.1 Summary of Public Comments

The EPA received several general comments related to the implementation of the PFOA and PFOS Aquatic Life Criteria as well as specific comments relating to the water column- and tissue-based criteria.

General implementation-related comments focused on requests for implementation guidance. Specifically, commenters stated that the EPA should work with states and Tribes to develop implementation guidance documents before the recommended PFOA and PFOS Aquatic Life Criteria are finalized. Also, commenters requested that the guidance include information on treatment options for PFOA and PFOS that are currently available. Further, commenters expressed concern that releasing criteria before any implementation guidance is provided may lead to overly restrictive permit limits for utilities with little to no control over PFAS entering their treatment facilities, particularly in regions where dilution allowances are limited or not permitted. Other commenters stated that the EPA should not finalize the PFOA and PFOS Aquatic Life Criteria until approved analytical methods for detecting and quantifying PFOA and PFOS are available. Commenters also requested that the EPA explain how proposed frequency and duration translate to NPDES permitting and low flows (e.g., 7Q10, etc.) in the implementation materials.

The EPA received comments related to the implementation of the water column values presented in the Draft PFOA and PFOS Aquatic Life Criteria documents. Three themes were identified in the comments related to implementation of the water column criteria; (1) importance of sediment sorption, (2) the layers of surface water that should be evaluated, and (3) the attainability of the PFOA and PFOS water column criteria.

The EPA also received public comments related to the implementation of the tissue-based values presented in the Draft PFOA and PFOS Aquatic Life Criteria documents. These comments focused on suggestions that the criteria documents provide additional guidance regarding implementation of the PFOA and PFOS tissue-based criteria for aquatic life; such as (1) specifying the manner in which fish composites should be sampled (whole-body or fillet), (2) whether tissue concentrations will be based on average concentrations, (3) if there will be recommended target species, and (4) whether states and Tribes will be able to use site-specific

BAFs to supplement the BAFs presented in the PFOA and PFOS Aquatic Life Criteria documents.

2.4.2 EPA Response to Public Comments:

The EPA intends to develop separate implementation materials in the future to provide additional information related to the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents.

2.5 Criteria Derivation Process

2.5.1 Time Extension Request

2.5.1.1 Summary of Public Comments:

There were eleven comments from nine commenters requesting additional time for the public comment. Public commenters also stated if new insect data are added, a 30-day public comment period should be allowed to review any new data before the criteria are finalized.

2.5.1.2 EPA Response to Public Comments:

An additional 30 days were added onto the initial 30-day review period (resulting in a total of 60 days). The EPA considers 60-days a sufficient amount of time for the public comment period. Inclusion of new insect data, that has been published in peer-reviewed literature along with other new data reviewed since the April release of the Draft PFOA and PFOS Aquatic Life Criteria documents, simply reflects an update to the toxicological database. The April 2022 Draft PFOA Aquatic Life Criteria document acknowledged that "insect toxicity testing is an active and ongoing area of research within the ecotoxicological scientific community that will likely provide information to fully evaluate on the sensitivity of insects" to PFOA and PFOS. Additionally, there were no significant changes to the criteria derivation methodology, and all newly-incorporated data were subject to the same rigorous data quality screen as the data reported in the April 2022 Draft PFOA and PFOS Aquatic Life Criteria documents. Therefore, no further public review is warranted at this time.

2.5.2 Revisions to the Aquatic Life Criteria Guidelines

2.5.2.1 Summary of Public Comments:

The EPA received several comments that broadly related to the EPA's Aquatic Life Criteria Guidelines. Comments focused on the Aquatic Life Criteria Guidelines fell into two general categories: (1) the EPA did not provide sufficient justifications in the PFOA and PFOS Aquatic Life Criteria documents to support the deviations from the Aquatic Life Criteria

Guidelines when the 2022 Draft PFOA and PFOS Aquatic Life Criteria were derived, despite a missing minimum data requirement (MDR), and (2) the Aquatic Life Criteria Guidelines themselves need to be revised to reflect the latest scientific knowledge. The Center for Biological Diversity's comment letter also contained several criticisms of the Aquatic Life Criteria Guidelines related to protection of species listed as endangered or threatened under Section 4 of the Endangered Species Act (ESA).

Some commenters stated that the EPA did not provide sufficient justification to support any deviations from the Aquatic Life Criteria Guidelines. While other commenters noted that if the Guidelines are not updated, then the EPA should adhere to the Aquatic Life Criteria Guidelines. These commenters noted that referring to previous criteria documents is not sufficient to justify these deviations.

2.5.2.2 EPA Response to Public Comments:

Public comments requesting specific revisions or a general update to the Aquatic Life Criteria Guidelines were not relevant to the request for comments on the PFOA and PFOS Aquatic Life Criteria documents; therefore, these comments were considered out of scope. The EPA responded to comments specifically related to the PFOA and PFOS Aquatic Life Criteria documents.

As for comments asserting that the PFOA and PFOS Aquatic Life Criteria deviate from the Aquatic Life Criteria Guidelines, the EPA disagrees that its approach was inconsistent with the Guidelines. The Draft and Final criteria for PFOA and PFOS followed the Guidelines approach, including rigorous review of data quality, the use of a genus-level sensitivity distribution for both the acute and chronic criteria for both PFOA and PFOS, and application of the Aquatic Life Criteria Guidelines method for criteria value calculation. In a few instances in the 2022 Draft criteria documents, available data were insufficient to precisely follow recommended approaches (i.e., meet all eight minimum data requirements) according to the Aquatic Life Criteria Guidelines; however, the Aquatic Life Criteria Guidelines are not prescriptive and instead allow for flexibility and best professional judgement when deriving the 2022 Draft PFOA and PFOS Aquatic Life Criteria. For example, the Aquatic Life Criteria Guidelines recognize that such scientific judgments and modifications may be required, stating:

> *"The amount of guidance in these National Guidelines has been increased, but much of the guidance is necessarily qualitative rather than quantitative; much*

judgment will usually be required to derive a water quality criterion for aquatic organisms and their uses. In addition, although this version of the National Guidelines attempts to cover all major questions that have arisen during use of previous versions and drafts, it undoubtedly does not cover all situations that might occur in the future. All necessary decisions should be based on a thorough knowledge of aquatic toxicology and an understanding of these Guidelines and should be consistent with the spirit of these Guidelines, i.e., to make best use of the available data to derive the most appropriate criteria. These National Guidelines should be modified whenever sound scientific evidence indicates that a national criterion produced using these Guidelines would probably be substantially overprotective or under protective of the aquatic organisms and their uses on a national basis. Derivation of numerical national water quality criteria for aquatic organisms and their uses is a complex process and requires knowledge in many areas of aquatic toxicology; any deviation from these Guidelines should be carefully considered to ensure that it is consistent with other parts of these Guidelines."

Following the public comment period, the EPA met all eight MDRs to develop the 2024 Final Aquatic Life Criteria and these Final criteria were derived following the Aquatic Life Criteria Guidelines.

In summary, the 2022 Draft PFOA and PFOS Aquatic Life Criteria had a few instances where available data were insufficient to meet all eight MDRs in the Aquatic Life Criteria Guidelines. In the Drafts, the EPA relied on the flexibility afforded in the Aquatic Life Criteria Guidelines to use modeled toxicity data (through interspecies correlation estimates; ICE) in combination with qualitatively acceptable data to address the missing MDR through multiple lines of evidence. Since the release of the 2022 Draft PFOA and PFOS Aquatic Life Criteria, the EPA was able to fill all MDRs using laboratory test data from quantitatively acceptable studies, due to the availability of new data, which allowed for the 2024 Final PFOA and PFOS Aquatic Life Criteria to be derived following the precise methodology in the Aquatic Life Criteria Guidelines. Finally, modifications to the EPA's Aquatic Life Criteria Guidelines supported by best professional judgement and technical justification have occurred in the derivation of past Aquatic Life Criteria. The EPA's 2016 Final Selenium Aquatic Life Criterion (U.S. EPA 2016)

were derived with a modified methodology to account for bioaccumulation and focus on the most sensitive taxa (i.e., egg laying invertebrates). EPA's Aquatic Life Criteria are recommendations for states and Tribes, who often adopt water quality standards that have been modified to reflect site-specific conditions or water quality standards based on other scientifically defensible methods, including modifications to methods in the Aquatic Life Criteria Guidelines.

The EPA disagrees with the Center for Biological Diversity's criticisms regarding the Aquatic Life Guidelines and the protection of ESA-listed species. The comment letter characterizes the Guidelines as "out-of-date," "under-protective of listed species," and "out of step with the scientific community." The comment letter further asserted that the Guidelines are "not grounded in the 'latest scientific knowledge'" and therefore inconsistent with the CWA. As noted above, the EPA's Guidelines are not the subject of this administrative process. Regardless, the EPA disagrees that the Guidelines are scientifically invalid, inadequately protective of listed species, or inconsistent with the requirements of the CWA. The EPA further disagrees with the comment letter's assertion that the EPA "has tacitly recognized" that the Aquatic Life Criteria Guidelines do not represent the latest scientific knowledge. Please see the EPA's responses in Sections 2.2 above where the EPA addresses specific comments related to the methodology used to derive the EPA's recommended criteria for PFOA and PFOS.

The EPA's recommended PFOA and PFAS Aquatic Life Criteria were derived following methods described in the EPA's peer-reviewed, longstanding agency Aquatic Life Criteria Guidelines. These Aquatic Life Criteria Guidelines reflect general methods that are used worldwide in the development of criteria to protect aquatic life, including the need to consider a range of taxa, to develop a sensitivity distribution to capture the relative sensitivity of species, and to develop values protective of an estimated 95% of taxa assessed. The Center for Biological Diversity's comment alleged that EPA's Aquatic Life Criteria Guidelines have been "excoriated by the scientific community." This is a misleading statement that largely relies on a mischaracterization of a publication by Buchwalter et al. (2017). Citing Buchwalter et al. (2017) as evidence that the Aquatic Life Criteria Guidelines have been "excoriated by the scientific community," grossly overstates the conclusions of a single paper, which included a discussion of the pros and cons of using lab data, mesocosm data, and field data to develop aquatic life criteria. While recognizing some of the challenges and limitations with the approaches in the Aquatic

Life Guidelines, Buchwalter et al. (2017) also recognizes the validity and utility of the methodology outlined in the Guidelines. Specifically:

- Buchwalter et al. (2017) provides a discussion of how lab, mesocosm, and field-based data could all be used through multiple lines of evidence to develop aquatic life criteria. Buchwalter et al. (2017) includes a discussion of the pros and cons of lab data, mesocosm data, and field data.
- Buchwalter et al. (2017) notes that the lab-based toxicity data typically used as the basis of aquatic life criteria "lack ecological realism" but provide the "greatest control and replication" and "strong evidence of causation." The control associated with lab-based toxicity testing helps ensure results can be reproduced, which is a key principle of defensible science.
- Conversely, Buchwalter et al. (2017) notes field data provide a "direct connection to endpoints of concern" but use of field data makes it "very difficult to show direct causation and to identify safe concentrations."
- In fact, Buchwalter et al. (2017) recognizes the validity and utility of lab-based toxicity tests that are the basis of the Guidelines and the EPA's aquatic life criteria and specifically states, "There will always be a place for single-species laboratory toxicity tests to support development of WQC [water quality criteria]."

Additionally, the claim that the EPA's Aquatic Life Criteria Guidelines are out of step with scientific practice is overstated based on limited references provided by the Center for Biological Diversity and belied by the fact that similar guidelines are used throughout the world to set regulatory values for the protection aquatic life. Countries such as Canada (CCME 2007), Australia, and New Zealand (Warne et al. 2018) review data quality and develop distributions of organism sensitivities to chemicals (commonly referred to as species sensitivity distributions, or SSDs) to develop protective aquatic life values in a manner very similar to the EPA's Aquatic Life Criteria Guidelines approach. Fox et al. (2021) provides a robust review of how SSDs have been widely used in the field of ecotoxicology, specifically stating:

> *"Following its introduction in the 1980s (Stephan et al. 1985* [cited as U.S. EPA 1985 here]*; Kooijman (1987);van Straalen and Denneman (1989)), the SSD has remained the most widely used method for deriving water quality benchmarks (guide-lines, criteria, or standards, depending on the jurisdiction) to characterize*

effects of chemical contaminants on water quality and/or for ecological risk assessment purposes."

As discussed earlier in this response, the Aquatic Life Criteria Guidelines also allow for the modification of methods to reflect new scientific knowledge and data and provide a robust basis for the development of Ambient Water Quality Criteria under CWA Section 304(a). The EPA has continuously incorporated updated science into criteria derivation methods since the development of the Aquatic Life Criteria Guidelines. For example, the EPA's PFOA and PFOS Aquatic Life Criteria incorporated cutting-edge science including the development of chronic tissue-based criteria to protect aquatic life from bioaccumulation and the use of New Approach Methodologies to develop acute estuarine/marine benchmarks (PFOA, PFOS).

The Center for Biological Diversity's comment also criticizes the EPA's Aquatic Life Criteria Guidelines "for emphasizing reductionist, single-species toxicity testing that maximizes experimental control and replicability" and imply that the EPA should use "field observations that more closely represent nature but are inherently more variable." As Buchwalter et al. (2017) pointed out; however, field studies make it "very difficult to show direct causation and to identify safe concentrations." Additionally, cause-and-effect data for PFOA or PFOS from field observations were not available to provide a primary or secondary line of evidence in developing the EPA's PFOA and PFOS Aquatic Life Criteria. However, the EPA did use field-based bioaccumulation factors (BAFs; Burkhard et al. 2021) to develop tissue-based criteria to protect aquatic fish and invertebrates from non-aqueous exposures and bioaccumulation of PFOA and PFOS in freshwater. These tissue-based criteria specifically show how the EPA can use the scientific flexibilities described in the Aquatic Life Criteria Guidelines to consider field-based data and novel science to develop criteria that protect species from bioaccumulation and non-aqueous exposures.

While the EPA does not share the Center for Biological Diversity's concerns that the Aquatic Life Criteria Guidelines are inadequately protective of listed species or are otherwise outmoded or unable to incorporate current scientific knowledge, the EPA nonetheless anticipates updating its longstanding Aquatic Life Criteria Guidelines on aquatic life criteria development in the foreseeable future. As noted above, the EPA expects to solicit public comment during that process and encourages interested parties to send comments at that time and as part of that process. This update is not in response to any concern or evidence that the EPA's current

Aquatic Life Criteria Guidelines do not adequately protect listed species. Rather, the EPA desires to update its Aquatic Life Criteria Guidelines in order to develop aquatic life criteria recommendations more expeditiously. In particular, the EPA is interested in leveraging new approaches and methods to develop recommended aquatic life criteria for emerging contaminants in order to publish recommendations even when there tends to be less data and/or data that do not meet the minimum data requirements as described in the Agency's current Aquatic Life Criteria Guidelines.

2.5.3 Endangered Species Act Consultation

2.5.3.1 Summary of Public Comments:

One comment letter, from the Center for Biological Diversity, stated that the EPA must conduct an Endangered Species Act ("ESA") Section 7 consultation with the Fish and Wildlife Service or National Marine Fisheries Service (collectively "the Services") on the PFOA and PFOS Aquatic Life Criteria before publishing any 304(a) aquatic life criteria. A few of the public commenters indicated that the EPA's 304(a) criteria for PFOA and PFOS are not sufficiently protective of species listed as endangered or threatened under Section 4 of the ESA. The Center for Biological Diversity's comment letter also identified particular listed species that, in its view, may be affected by the EPA's 304(a) criteria for PFOA and PFOS, including higher trophic level aquatic-dependent species, as well as terrestrial species.

2.5.3.2 EPA Response to Public Comments:

The EPA disagrees that it is required to consult with the Services under ESA Section 7 before publishing recommended 304(a) criteria, including the Final 2024 PFOA and PFOS Aquatic Life Criteria. Under ESA Section 7(a)(2), federal agencies must "insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction of adverse modification of habitat[.]" 16 U.S.C. 1536(a)(2). The terms "action," "authorized," "funded" and "carried out" are not further defined by the ESA, although the Services' implementing regulations define "action." *See* 50 C.F.R. 402.02.

The Center for Biological Diversity's comment letter appears to assert that the EPA's publication of 304(a) criteria for PFOA and PFOS is an "agency action" as that term is defined by the ESA because publication of 304(a) recommended criteria "authorize[s]" conduct within

the meaning of ESA Section 7.[1] The letter contends that "[a]lmost by definition, an agency authorization covers those situations where a federal agency has a role whereby the consequences of the agency action are somewhat causally remote from the actual harm to listed species. Indeed, this is why the Services' joint regulations specifically contemplate consultations applying to the promulgation of regulations." The letter also maintains that "[t]he act of establishing these criteria under Section 304(a)(1) is therefore an "action" because such criteria set the ceiling for establishment of water quality standards."

The publication of non-binding water quality criteria recommendations and supporting technical information is not an "agency action" that could trigger ESA Section 7's consultation requirement. The position of the United States is that mere publication of technical guidance and scientific information, like the EPA's 304(a) recommended criteria, is not an "agency action" within the meaning of Section 7. For elaboration of that position, please see the United States' briefing in *Center for Biological Diversity v. U.S. EPA et al.*, 9th Cir. No. 23-2946 (pending).[2] More specifically, the EPA disagrees that its 304(a) criteria "authorize" anything, and also disagrees that the 304(a) criteria set the ceiling for water quality standards.

To provide context, Section 303 of the CWA requires states to establish water quality standards for each waterbody (or segment of a waterbody) within their jurisdiction. 33 U.S.C. 1313; 40 C.F.R. Part 131. Water quality standards consist of three components: (1) the designated uses of the water body, which can include use for public water supplies, propagation of fish and wildlife, recreational uses, agricultural uses, industrial uses, and other uses; (2) water quality criteria identifying concentrations or levels of pollutants that will protect the designated uses; and (3) an antidegradation policy that protects existing uses and provides a mechanism for

[1] CBD also appears to assert that EPA's publication of 304(a) recommended criteria is a programmatic action, a term appearing in the ESA regulations. But for the reasons stated, publication of 304(a) recommended criteria is not an action at all. It also does not fit within the definition of programmatic action in the ESA regulations. See 50 CFR 402.02. Specifically, the publication of 304(a) aquatic life criteria provides states with technical, non-binding recommendations and does not involve "multiple similar, frequently occurring, or routine actions expected to be implemented in particular geographic areas" or a "proposed program, plan policy or regulation providing a framework for future proposed actions."

[2] The district court in *Center for Biological Diversity v. U.S. EPA, et al*. (D. Ariz, Aug. 18, 2023) held that EPA must comply with Section 7 because EPA's publication of Section 304(a) recommendations is an "agency action" that "may affect" listed species or designated critical habitat. That lawsuit, which was brought by the Center for Biological Diversity, concerns whether EPA was required to consult under ESA Section 7 on the EPA's publication of 304(a) aquatic life criteria for cadmium. The EPA has appealed the district court's adverse decision. EPA incorporates the government's arguments in that briefing into the record for this water quality criteria recommendation.

maintaining high water quality. See *PUD No. 1 of Jefferson Cty. v. Washington Dep't of Ecology*, 511 U.S. 700, 705 (1994); 40 C.F.R. 130.3, 131.3. Section 303(c) also requires states to submit new and revised water quality standards to the EPA for review. 33 USC 1313(c)(2)-(3). Once a state submits proposed water quality criteria, the EPA determines whether the state's adopted criteria are "based on sound scientific rationale" and "contain sufficient parameters or constituents to protect the designated use" 40 CFR 131.11(a); 40 CFR 131.5(2). If the EPA approves the state's standard, the standard, including the criteria, becomes the CWA applicable water quality standard for that state 33 USC 1313(c)(3); 40 CFR 131.21(c). The applicable water quality standard is then used in other state programs to control pollution.

Section 304 of the CWA, titled [i]nformation and guidelines," is designed to help states fulfill their Section 303 obligations. Section 304(a)(1) of the CWA, directs the EPA to assist states with their CWA responsibilities by developing and publishing "criteria for water quality accurately reflecting the latest scientific knowledge" about the effects of particular pollutants on the health and welfare of both humans and aquatic communities. 33 U.S.C. 1314(a). The EPA's 304(a) criteria—including the recommended aquatic life criteria for PFOA and PFOS—therefore provide information for states and Tribes to consider as they develop their own water quality standards to protect their water bodies.

The EPA's publication of 304(a) criteria does not authorize states to adopt the EPA's recommended criteria as the applicable water quality standard for their state. For the EPA's recommendations to have any legal effect, states must choose to adopt them—and those adoptions must *also* be approved by the EPA pursuant to a separate process; the EPA's approval is subject to compliance with ESA Section 7.

Further, states do not have to adopt the EPA's recommendations. States are free to rely on any scientifically defensible criteria when adopting water quality criteria. 40 C.F.R. 131.11(b)(1). In fact, states do not always adopt the EPA's 304(a) criteria and the 304(a) criteria are not a safe harbor and are not presumed to be appropriate when the EPA reviews a state's adopted criteria for consistency with the CWA.[3] Put differently, the publication by the EPA of

[3] Prior to 1980, the EPA included a presumption in favor of either the 304(a) criteria or more stringent criteria in reviewing state water quality criteria pursuant to CWA Section 303(c). The EPA formally rescinded that policy in 1980. 47 Fed. Reg. 49234, 49249-50 (Oct. 29, 1982). Since recission, the EPA has consistently affirmed that the 304(a) criteria "are not presumed to be applicable," and in fact the state bears the burden of demonstrating that new or revised WQSs meet the requirements of the Clean Water Act. *Id.*; *see also* 48 Fed. Reg. 51411 (Nov. 8, 1983)

304(a) recommended criteria does not create binding standards for states nor does it set a floor or ceiling on state choices.[4] In sum, the publication of non-binding 304(a) recommended criteria does not authorize states to adopt those criteria, does not authorize the EPA to approve those criteria if states choose to adopt them, and does not authorize any private party to discharge any pollutant. 16 U.S.C. 1536(a)(2).

Further, even if the publication of non-binding information is an "agency action," within the meaning of ESA Section 7, consultation is required only when the federal agency determines the proposed action "may affect listed species or designated critical habitat." *See* 50 C.F.R. 402.14(a). The Center for Biological Diversity's comment letter devotes considerable space to arguing that the EPA's 304(a) criteria for PFOA and PFOS "may affect" species. As explained, the EPA's publication of 304(a) recommended criteria is not an "agency action" that implicates Section 7 of the ESA, and therefore a "may effect" determination is not required. But even if the EPA were engaged in "agency action" when it publishes its 304(a) criteria for PFOA and PFOS, the EPA also disagrees that mere publication of 304(a) recommended criteria for PFOA and PFOS has any "effect" on ESA-listed species or critical habitat within the meaning of the ESA.

As an initial matter, the comment letter does not identify the "may affect" standard or otherwise explain why the EPA's putative action "may affect" the identified species. ESA regulations establish that consultation is required only when a federal agency determines that a proposed action "may affect listed species or critical habitat." 50 C.F.R. 402.14(a). Per 50 CFR 402.02, "effects of the action" are defined as all consequences to listed species or critical habitat that are caused by the proposed action and a "consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur." Additionally, the Solicitor of the Department of the Interior has provided guidance elaborating on the "may

("Some commenters apparently believe that the Agency continues to have a policy of 'presumptive applicability' applied to the [304(a) recommendations] or that the proposed Regulation recreated that policy. That policy existed from July 10, 1978 to Nov. 28, 1980, when it was rescinded. No such policy now exists nor is intended in the final rule [the Part 131 regulations in force in 2016]. *While States are free to draw on EPA's 304(a) criteria as support for State criteria, they are equally free to use*
any other criteria for which they have sound scientific support." (emphasis added)).

[4] In order to improve transparency, EPA's regulation at 40 CFR 131.20(a) requires states to provide an explanation during its triennial review if it chooses to "not adopt new or revised criteria for parameters for which EPA has published new or updated CWA Section 304(a) criteria recommendations." This regulation does not require a state to adopt new or revised water quality standards or impose any conditions on a state's adoption of standards; EPA does not approve or disapprove this explanation. See 80 Fed. Reg. 51020, 51029 (Aug. 21, 2015). Thus, this regulation does not convert the publication of EPA's Section 304(a) recommendations into "action authorized, funded, or carried out" by EPA.

affect" standard. *See* Guidance on the Applicability of the Endangered Species Act's Consultation Requirements to Proposed Actions Involving the Emissions of Greenhouse Gases, M-37017 (Oct. 3, 2008), 2008 WL 9836336 at *1-*4. Under the terms of this guidance, an agency's "action" "may affect" species if that "action" has direct or indirect effects in the action area. Direct effects are those immediately caused by the action. Indirect effects are those that would not occur but-for the action and that are "reasonably certain to occur."[5] As explained below, there are no direct or indirect effects from EPA's publication of 304(a) criteria that are "reasonably certain to occur."

The EPA's publication of 304(a) recommended criteria for PFOA and PFOS has no direct effects on listed species or critical habitat, including the species identified in the Center for Biological Diversity's letter. The only immediate effect of the EPA's purported action is publication in the Federal Register, which makes scientific information available to states, Tribes, and the public. See Section 2.3 and Appendix A for a more detailed response to the Center for Biological Diversity's comments regarding effects on particular species.

Nor does the EPA's purported action indirectly affect listed species or critical habitat, because there are no effects from that publication that are "reasonably certain to occur." It is not reasonably certain to occur that *any* state will adopt the EPA's PFOA or PFOS recommended criteria or that that state's chosen criteria will be approved by the EPA after any ESA consultation with the Services on those state-level approvals. As explained above and as explicitly stated in the 304(a) criteria documents for PFOA and PFOS, states do not have to adopt the EPA's recommended 304(a) criteria and "have discretion to adopt criteria that modify the EPA's recommended criteria to reflect site-specific conditions, such as the local water chemistry or ecological conditions, or to develop criteria based on other scientifically defensible methods that are protective of designated uses" (U.S. EPA 2024a, b).

Additionally, the CWA requires states to adopt water quality criteria after the EPA publication of relevant 304(a) criteria only for toxic or priority pollutants, where those pollutants could reasonably be expected to interfere with a state's designated uses. 33 USC 1313(c)(2)(B).

[5] While the regulatory definition of "effects of the action" has been updated since this guidance was issued, the current definition is intended to capture the same "effects" and there fore the same "direct effects" and "indirect effects" of the action. See 84 Fed Reg. 44976, 44977 (Aug. 27, 2019); 89 Fed. Reg. 67, 24270 (Apr. 5, 2024) ("We reassert our position that the retained changes in the 2019 rule and the revisions adopted from the 2024 proposed rule maintain the pre-2019 scope of the effects analysis.").

PFOA and PFOS are not defined as toxic or priority pollutants so the EPA's publication of 304(a) criteria for PFOA and PFOS will not trigger this statutory requirement for states to adopt PFOA and PFOS criteria. Historically, states have not systematically adopted Section 304(a) recommended criteria for pollutants that are not defined as toxic or priority pollutants. For instance, although in 2018 the EPA published 304(a) criteria for aluminum, a pollutant that is not defined aa priority pollutant, as of September 2024, only four states and Tribes have adopted the EPA's 304(a) criteria for aluminum. Whether any states will adopt the EPA's PFOA or PFOS 304(a) criteria is uncertain, and states may opt not to adopt the EPA's recommended criteria for PFOA and PFOS for a variety of reasons, including resource limitations. Because at the time of publication the EPA does not know which—if any—states will adopt the EPA's 304(a) criteria for PFOA and PFOS, the EPA does not know which waterbodies would be affected, whether any listed species or critical habitat are present in those waterbodies, or whether discharge permits ultimately will be affected, undermining the purpose of consultation.[6]

Moreover, while the EPA appreciates the Center for Biological Diversity's perspective that consultation with the Services would support further consideration of the protection of listed species, the EPA does not agree that consultation prior to publication of the 304(a) recommended criteria for PFOA and PFOS is necessary to protect listed species. The EPA's 304(a) recommended criteria for PFOA and PFOS, if adopted and implemented, are expected to generally protect aquatic ecosystems as a whole, including listed species, from the effects of PFOA and PFOS in ambient freshwater.

Overall, listed species are not expected to be more uniquely sensitive to PFOA and PFOS than non-listed species, including those used to derive the PFOA and PFOS Aquatic Life Criteria. For example, the National Research Council's 2013 report Assessing Risks to Endangered and Threatened Species from Pesticides (NRC 2013) states that "[l]isted species are not inherently more sensitive to chemicals than species that are not listed"), citing publications from Sappington et al. (2001), Dwyer et al. (2005), and Besser et al. (2005).

Additionally, existing data confirm the general proposition that the EPA's PFOA and PFOS recommended criteria are generally expected to be protective of listed species. The EPA reviewed the quality of all studies to identify those studies that were unacceptable for deriving

[6] For at least this reason, the EPA does not agree that it needs to consult on the individual species listed in the comment letter at the time of publication of 304(a) recommended criteria.

water quality criteria and those studies that were qualitatively and quantitatively acceptable for deriving criteria, including studies for listed species (e.g., listed salmonids). See Section 2.2.1.2 for more information on EPA's evaluation of studies. Overall, direct toxicity data with listed species were relatively limited, given the logistical challenges associated with conducting toxicity tests on listed species. However, data with listed rainbow trout (PFOA and PFOS) and Atlantic salmon (PFOS only) were available to inform the sensitivity of these listed species.

The quantitatively acceptable toxicity data for listed species indicate the PFOA and PFOS 304(a) criteria are highly protective of these species. As described below, the available data indicate that listed species are not the most sensitive species to either acute or chronic exposures to PFOA and PFOS, and that the Final recommended values for PFOA and PFOS are set at levels lower – by orders of magnitude - than the levels at which adverse acute or chronic effects were observed in these listed species. For PFOA, the one species representative of threatened or endangered salmonids (*Oncorhynchus*) was the 19th most sensitive genus to acute exposures and the 10th most sensitive genus to chronic exposures out of 19 and 12 genera, respectively. The available data indicate that the *Oncorhynchus* genus-level acute toxicity value is more than 400 times higher than the Final recommended acute water column criteria for PFOA and 1,290 times higher than the Final PFOA recommended chronic water column criteria. For PFOS acute exposures, the one species listed as threatened or endangered was the 4th (*Oncorhynchus)* most sensitive genus out of 20 genera. For PFOS chronic exposures, the one species listed as threatened or endangered was the 7th (*Salmo)* most sensitive genus out of 17 genera. The PFOS water column concentration at which *Oncorhynchus* experience adverse acute effects is more than 100 times higher than the Final PFOS acute water column criterion. The PFOS water column concentration at which *Salmo* experienced chronic adverse effects is more than 400 times higher than the Final PFOS chronic water column criterion.

As noted above, listed species are generally not expected to be more sensitive to PFOA and PFOS than non-listed species, including those used to derive the PFOA and PFOS Aquatic Life Criteria. Overall, the PFOA and PFOS recommended 304(a) criteria are generally expected to be protective of threatened and endangered aquatic species based on the high-quality data that were available for threatened and endangered species at the time the criteria were finalized. Please see Section 4.6 of the Final PFOA and Section 4.7 of the Final PFOS Acute Aquatic Life Criteria and Benchmarks documents for more information about the listed species data.

Finally, the EPA believes it is inappropriate to compare the EPA's national recommended aquatic life criteria to drinking water health advisories issued pursuant to the Safe Drinking Water Act, 42 U.S.C. 300g-1(b)(1)(F). While both the drinking water health advisory and the 304(a) recommended criteria are non-regulatory actions that provide scientific information to states and Tribes, aquatic life criteria and drinking water health advisories address different species, endpoints, and exposure pathways/routes, and would thus be expected to yield different protective values. Both set protective levels based on exposure-response information, but it is biologically and toxicologically incorrect to imply the aquatic life criteria are not protective of aquatic life because the aquatic life criteria are greater than the interim human health drinking water advisories for PFOA and PFOS,[7] which are based on an entirely different dataset and are intended to protect people, not fish and other aquatic organisms.

2.5.4 General Comments Related to State, Tribal, and Co-Regulator Engagement in Criteria Derivation

2.5.4.1 Summary of Public Comments:

A state commenter noted that the EPA should continue to monitor emerging PFOA and PFOS toxicity data and commit to revising these criteria in five years to account for emerging toxicity data. The EPA also received comments requesting that the EPA allow co-regulators a review period for all subsequent water quality criteria that includes states, Tribes, and the Association of Clean Water Administrator's (ACWA) prior to the release of recommended criteria for public review. States, Tribes, and co-regulators also requested greater involvement in the development of future aquatic life criteria. A commenter noted that the EPA should have sought greater input from states and Tribes earlier in the criteria derivation process, as the commenter felt that this would have improved communication and fostered a more cooperative spirit. Further, a commenter requested that the EPA focus on comments provided by states and Tribes and make any changes needed to ensure the PFOA and PFOS Aquatic Life Criteria are as useful as possible to stakeholders.

[7] Note, the interim human health drinking water advisories for PFOA and PFOS were replaced by the PFAS National Primary Drinking Water Regulation in April 2024. This occurred after the PFOA and PFOS Aquatic Life Criteria public comment closed in July 2022. For more information on the PFAS National Primary Drinking Water Regulation see: https://www.federalregister.gov/documents/2024/04/26/2024-07773/pfas-national-primary-drinking-water-regulation.

2.5.4.2 EPA Response to Public Comments:

The EPA agrees that aquatic toxicity of PFAS is an active area of research. That said, the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents are up-to-date and take into account newly published toxicity data (through March 2024) and information submitted to the Agency during the public comment period. Importantly, these Final criteria include newly available toxicity data for sensitive aquatic invertebrates (insects, specifically), the taxonomic group generally most sensitive to PFOA and PFOS as compared to other tested species. As a result, the Final criteria for PFOA and PFOS are based on a complete data set (all eight minimum data requirements were met), consistent with the Aquatic Life Criteria Guidelines. As with other published aquatic life criteria, the EPA will consider new toxicity information as it becomes available and prioritize criteria updates accordingly.

The EPA appreciates the interest and comments from states and Tribes. With regard to EPA's outreach to co-regulators prior to release of the Draft criteria, the agency notes that there were several opportunities for states and Tribes to engage with EPA during development of the Draft criteria. For example, the EPA hosted multiple problem formulation development meetings with the Association of Clean Water Act Administrators (ACWA) in the Summer and Fall of 2019. Additionally, the EPA provided states and Tribal representative organizations with presentations describing the Draft PFOA and PFOS Aquatic Life Criteria prior to their release for public comment and more detailed presentations following the release of the draft criteria for public comment. The EPA also granted a 30-day extension to the public comment period so commenters, including states and co-regulators, could have additional time to provide comments on the EPA's Draft PFOA and PFOS Aquatic Life Criteria documents. Following the release of the 2024 Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents, the EPA intends to develop implementation guidance for the PFOA and PFOS Aquatic Life Criteria. The development and completion of implementation guidance will include opportunities for state and Tribal collaboration and input.

2.6 PFOA Specific Comments

2.6.1 Underlying Science for the Freshwater Water Column Criteria

2.6.1.1 Summary of Public Comments:

A few comments related specifically to the underlying science used in the derivation of the PFOA freshwater water column criteria. In these comments, public commenters stated that

data from Li (2009) using *D. magna* were included in the criteria dataset despite the test being conducted at a temperature (25°C) greater than what is recommended in the U.S. EPA published method (OSCPP 850.1010) for acute Daphnia tests. Environment and Climate Change Canada (ECCC) commented that they concurred with the EPA's conclusion that a reliable EC_{10} could not be calculated using the data provided in Logeshwaran et al. (2021), but an EC_{10} similar to the EPA-calculated EC_{10} using C-R data from Colombo et al. (2008) and Zhang et al. (2013) could be calculated using the EPA's Toxicity Response Analysis Program (TRAP).

2.6.1.2 EPA Response to Public Comments:

All studies used to derive the acute and chronic PFOA Aquatic Life Criteria have undergone extensive data quality review. Despite slightly elevated temperatures in test conditions, acute *D. magna* data from Li (2009) were retained for quantitative use, and therefore were used in the derivation of the acute PFOA criterion for freshwater. These results were retained because the acute data from Li (2009; *D. magna* LC_{50} range = 157.9 – 220.8 mg/L; n = 3) aligned with the remaining quantitatively acceptable *D. magna* acute data (remaining *D. magna* LC_{50} range = 114.6 – 542.5 mg/L; n = 8; *D. magna* SMAV = 220.0 mg/L) from the 2022 Draft PFOA Aquatic Life Criteria, suggesting the slightly elevated temperature did not impact final conclusions.

The EPA thanks ECCC for offering to share additional data and for concurring with the EPA's ability to fit robust concentration-response models to certain datasets (i.e., Colombo et al. 2008; Zhang et al. 2013) and not others (i.e, Logeshwaran et al. 2021).

2.7 PFOS Specific Comments

2.7.1 Underlying Science for the Freshwater Water Column Criteria

2.7.1.1 Summary of Public Comments:

Comments related to the underlying science for the PFOS freshwater water column criteria were focused on specific studies and toxicity data used in the derivation of the PFOS Aquatic Life Criteria. One commenter summarized the methods and results of a recently completed zebrafish study conducted by the U.S. Army Corps of Engineers (U.S. ACE) Engineering Research and Development Center (ERDC). The resultant poster presentation from this study was presented at 2022 SETAC Europe and was provided in the public comment as an attachment (https://www.regulations.gov/comment/EPA-HQ-OW-2022-0366-0023). The

commenter stated that results of this study are consistent with the current zebrafish SMCV and that the ERDC study is expected to be published by the end of 2022.

Additionally, other commenters noted specific errors in the Draft PFOS Aquatic Life Criteria for two studies. In particular, Dasgupta et al. (2020) evaluated a study of PFOSA, but it was included in the EPA's review of PFOS studies, and Jantzen et al. (2016) was incorrectly listed as Jantzen et al. (2017) in the Draft PFOS Aquatic Life Criteria document. In addition, the values the EPA used were incorrectly converted from micromolar to mg/L.

2.7.1.2 EPA Response to Public Comments

The EPA reviewed the technical poster from for the U.S. Army Corps of Engineers (U.S. ACE) study with zebrafish and some of the data presented in the poster were incorporated into the 2024 Final PFOS Aquatic Life Criteria and Benchmark document; however, some of these data were not incorporated. The data from the previously mentioned ERDC poster appear to have been published in three separate publications (Gust et al. 2024, Krupa et al. 2022 and Mylroie et al. 2021). The zebrafish data from Krupa et al. (2022) was incorporated in the 2024 Final PFOS Aquatic Life Criteria and Benchmark document as it was added in ECOTOX prior to March 2024. However, Gust et al. (2024) and Mylroie et al. (2021) were not incorporated. Gust et al. (2024) was not included in the 2024 Final PFOS Aquatic Life Criteria and Benchmark document since the study was not added to the ECOTOX database prior to the finalization of the criteria. Mylroie et al. (2021) was not incorporated into the Final since the publication mainly focused on the influence the chorion has on PFOS toxicity. Nevertheless, as the commenter stated, the chronic PFOS Aquatic Life Criteria would likely remain the same since the zebrafish SMCV was consistent with the results reported in the most recent study, and the results of these publications are higher than the two most sensitive species (both aquatic insects) in the PFOS dataset.

Additionally, specific to the studies with potential errors in the PFOS Aquatic Life Criteria document, the EPA reviewed the details of these studies again and made the necessary edits to clarify details in all study summaries and tables in the PFOS Aquatic Life Criteria document as needed.

2.7.2 Underlying Science for the Freshwater Tissue-Based Criteria

2.7.2.1 Summary of Public Comments:

All public comments related to the underlying science used in the derivation of the PFOS freshwater tissue-based criteria were applied to both PFOA and PFOS and as such are

summarized in Section 2.2.4 above. However, there was one comment specific to the PFOS freshwater tissue-based criteria. This comment was based on the EPA statement:

> *"Overall, these results suggest that sorption to sediments should be an important mechanism for PFOS entry into an aquatic ecosystem, but that subsequent dietary uptake from benthic feeding organisms will be more important for PFOS than PFOA,"*

The commenter also indicated that the EPA should clarify if the PFOS tissue criteria are more important than the water column criteria. The commenter suggested that this distinction may warrant the tissue criteria to outweigh the water column criteria rather than exist as "independently applicable" criteria.

2.7.2.2 EPA Response to Public Comments:

The statement mentioned in the public comment from the Draft PFOS Aquatic Life Criteria is part of a broader discussion of PFOS movement and bioaccumulation in aquatic systems. It was intended to provide background information that PFOS has the potential to sorb to sediments and this can be a pathway for exposure in aquatic systems that is largely dependent on a number of factors, such as the physiochemical characteristics of the environment and the chemistry of the individual PFAS. Further, the quoted statement compares the importance of this pathway in PFOS to PFOA. There were insufficient data to derive chronic tissue criteria using a sensitivity distribution approach from empirical tissue data based on dietary exposures. The majority of available data were for water column exposures to PFOA and PFOA, and the EPA used the best available science in criteria derivation. The EPA retained the same criteria structure in the Final PFOS Aquatic Life Criteria and Benchmark document as was presented in the Draft released for public comment. Notably this structure retained the independent applicability of the water column and tissue-based criteria for PFOS so that no one criterion takes primacy over another. This criteria structure allows states and Tribes to adopt the recommended criteria in the manner most consistent with their aquatic systems and the individual needs of their water quality standard programs.

2.8 Other Comments

2.8.1 General Comments

2.8.1.1 Summary of Public Comments:

The EPA received a number of general comments related to the PFOA and PFOS Aquatic Life Criteria documents that did not fit into specific topic groups (i.e., the science used in the PFOA and PFOS Aquatic Life Criteria Derivation or the Criteria Derivation Process). Therefore, these general comments are summarized here under Other Comments. These comments encompass a broad set of topic areas including: (1) appreciation for the opportunity to review the Draft PFOA and PFOS Aquatic Life Criteria documents and to provide comments, (2) recommendations that the aquatic life criteria be part of a holistic approach to ensure PFOA and PFOS are removed from aquatic environments, (3) requests that the federal government invest more in PFAS research, (4) recommendations that the Draft PFOA and PFOS Aquatic Life Criteria be listed differently on the national aquatic life criteria table, and (5) concerns that input from external peer reviewers were not sufficiently addressed in the Draft PFOA and PFOS Aquatic Life Criteria. Comments related to all of these topics are summarized in more detail below.

Specifically, multiple commenters expressed appreciation to the EPA for drafting the recommended PFOA and PFOS Aquatic Life Criteria documents and for the opportunity to comment on the Draft documents. Also, commenters recommended that the proposed criteria be treated as part of a holistic approach that involves coordination with other Federal agencies to assess, address, and remove PFAS from entering the environment, including drinking water sources. Commenters stated that this approach should also include the use of regulatory authority to ensure the responsibility and cost of removing PFAS are not passed on from PFAS manufacturers and users to the receivers of PFAS such as drinking water and wastewater utilities. Lastly, as a response to PFAS contamination, commenters further noted that the federal government needs to invest more heavily in PFAS surface water toxicity research and management. Commenters requested the Draft PFOA and PFOS acute and chronic aquatic life criteria not be listed on the EPA's webpage in the Nationally Recommended Water Quality Criteria Table (https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table), stating that presenting these Draft values in this way may cause confusion about the status of these values.

Lastly, a comment from one of the external peer reviewers noted that they thought several of their and other peer reviewer's original comments were not completely or satisfactorily addressed, either via the EPA's responses to the comments or in the technically supported revisions to the criteria documents released for public comment in April 2022.

2.8.1.2 EPA Response to Public Comments:

The EPA thanks commenters for expressing their appreciation for the opportunity to comment on the Draft PFOA and PFOS Aquatic Life Criteria documents.

For additional information on the EPA's holistic approach to addressing PFAS contamination and effects on the environment and human health, please see the EPA's Strategic PFAS Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024). The Final PFOA and PFOS Aquatic Life Criteria and Benchmark documents, as well as other Agency-wide approaches to addressing PFAS, are based on the best available data from existing research. The PFOA and PFOS Aquatic Life Criteria are protective values derived from established toxicity research on fish and other aquatic life. The Draft PFOA and PFOS Aquatic Life Criteria values were erroneously uploaded to the EPA's Nationally Recommended Water Quality Criteria Table webpage, concurrently with the release of the Draft PFOA and PFOS Aquatic Life Criteria documents in April 2022. These values were removed from the EPA's webpage in the Nationally Recommended Water Quality Criteria Table shortly after their inclusion. The EPA apologizes for any confusion that may have resulted.

The EPA strongly disagrees that the agency dismissed some scientific concerns raised by its peer reviewers without sufficient justification. In many cases, public commenters cited individual comments and the EPA's responses from a single peer reviewer to make the assertion that the EPA did not adequately address peer review comments. In many cases, the five expert peer reviewers did not agree on specific points. For example, expert peer review commenters provided mixed reviews on the use of chronic EC_{10} values for PFOA and PFOS. In advocating for EC_{20} values, a peer reviewer noted the differences between PFAS and selenium C-R curve slopes, as well as increased uncertainty in using EC_{10}s, while another peer reviewer stated, "*using the EC_{10} makes sense for PFAS chronic criteria.*" The EPA considered the overall tendency of comments from all expert peer reviews, as a whole, to inform refinements to the Draft PFOA and PFOS Aquatic Life Criteria documents. The EPA provided technical rationale

when disagreeing with a particular peer review comment. The EPA also developed extensive response to expert peer review comments documents.

2.8.2 Human Health and Drinking Water

2.8.2.1 Summary of Public Comments:

While the Draft PFOA and PFOS Aquatic Life Criteria are the focus of the response to public comments document, the EPA received a number of comments related to human health and drinking water.

2.8.2.2 EPA Response to Public Comments:

Public comments related to human health and drinking water are not relevant to the request for comments on the PFOA and PFOS Aquatic Life Criteria documents. Therefore, these comments were considered out of scope, and the EPA did not respond to comments related to human health and drinking water.

2.8.3 Grammatical and Typographical Errors

2.8.3.1 Summary of Public Comments:

Several commenters identified grammatical and typographical errors throughout the Draft PFOA and PFOS Aquatic Life Criteria documents. These grammatical and typographical error related comments included suggestions intended to improve the document, but this information does not change the overall criteria document, and therefore, are not listed here.

2.8.3.2 EPA Response to Public Comments:

The EPA appreciates these comments. These typographical errors and any inconsistencies between the PFOA and PFOS Aquatic Life Criteria documents have been corrected per recommendations from public comments.

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Appendix A EPA Detailed Responses to Endangered Species Act (ESA)-Related Public Comments on the 2024 Recommended Aquatic Life Criteria for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

September 2024

U.S. Environmental Protection Agency, Office of Water,
Office of Science and Technology, Health and Ecological Criteria Division,
Ecological Risk Assessment Branch,
Washington, D.C.

Comment Number (Organization)	Center for Biological Diversity Comment on Endangered Species Act (ESA) Bin: *The following excerpts were taken from throughout CBD's comment letter. They are grouped together here to allow consistent EPA responses.*	EPA Response	Revision location in Final PFOA and/or PFOA Aquatic Life Criteria Document
EPA-HQ-OW-2022-0365-0024 (Center for Biological Diversity; CBD)	Please accept the following comments from the Center for Biological Diversity ("Center") on the Environmental Protection Agency's ("EPA") recommended aquatic life ambient water quality criteria for Perfluorooctanoic acid ("PFOA") and Perfluorooctane Sulfonic Acid ("PFOS"). The lack of long-overdue water quality criteria for these widespread, persistent, and dangerous novel chemicals has been a massive oversight of behalf the EPA.	Thank you for your comment. The release of the Final 304(a) PFOA and PFOS Aquatic Life Criteria represents an important step in the release of scientific information that states and Tribes can consider when adopting water quality standards to protect aquatic life from elevated concentrations of PFOA and PFOS.	No edits.
EPA-HQ-OW-2022-0365-0024 (CBD)	• The EPA has a firmly established duty to complete consultation prior to finalizing any water quality criteria under the Clean Water Act ("CWA"), as the action of establishing these criteria has both direct and indirect effects on listed species. The establishment of these criteria are responsible for modifications to water quality standards and ultimately water quality itself, as states often choose to simply adopt the EPA's recommendations. • Completing the consultation on the criterion also gives the EPA a better understanding of the effect PFOS and PFOA have on listed species, helping to facilitate the overall protection of the aquatic ecosystem. The odds of the EPA ever revising these criteria are quite low, so it is critical that it get these thresholds right the first time so that imperiled species are not put at risk by inadequate half-measures.	Thank you for your comments. Please see responses to these comments in Section 2.5.3.2.	No edits.

Comment Number (Organization)	Center for Biological Diversity Comment on Endangered Species Act (ESA) Bin: *The following excerpts were taken from throughout CBD's comment letter. They are grouped together here to allow consistent EPA responses.*	EPA Response	Revision location in Final PFOA and/or PFOA Aquatic Life Criteria Document
	• The direct consequences of EPA's promulgation of new water quality criteria likely cross the "may effect" threshold for hundreds of listed species of every taxon that rely on clean water, including the Pallid Sturgeon, Kemp's Ridley Sea turtle, and Polar bear. Therefore, the EPA must initiate consultation with U.S. Fish and Wildlife Service ("USFWS") and National Marine Fisheries Service ("NMFS") before finalizing any water quality criteria related to PFOA and PFOS. • Congress always understood that the ESA's consultation process should apply broadly to federal agency actions. The law requires that each agency "insure that any action authorized, funded, or carried out by such agency" not jeopardize listed species or their critical habitats. Almost by definition, an agency authorization covers those situations where a federal agency has a role whereby the consequences of the agency action are somewhat casually remote from the actual harms to listed species. Indeed, this is why the Services' joint regulations specifically contemplate consultations applying to the promulgation of regulations. • The ESA's broad application to programmatic action with the potential for harm is precisely why the EPA must initiate consultation before finalizing any water quality criteria to ensure that these standards are fully protective of listed species.		

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	• The EPA asserts that new water quality criteria in Section 304(a)(1) of the CWA are "not regulations and do not constitute legally binding requirements." However, EPA also correctly notes that the "draft recommended criteria are the maximum concentrations of PFOA and PFOS that will support protection of aquatic life from acute and chronic effects in freshwater" and that the "recommended criteria provide guidance to states and authorized tribes in adopting water quality standards that ultimately provide a basis for controlling discharges of pollutants." The act of establishing these criteria under Section 304(a)(1) is therefore an "action" because such criteria set the ceiling for establishment of water quality standards. The EPA also exercises discretion at each step of the criteria setting process and in determining how these criteria should be expressed. Even if water quality criteria are not regulatory per se, consequences still flow from the establishment of criteria, as states frequently adopt the EPA's guidance given the time, resources, and expertise that has gone into developing them. Especially in this case where federal standards for PFOA and PFOS have not been published and states have been promulgating different threshold levels, the impacts flowing from the EPA's publication of water quality criteria could be substantial as states update recommendations to meet new federal guidance. Many water quality standards also require the		

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	protection of all existing uses of a waterbody, and such "uses" often include supporting species that are listed as threatened or endangered. The EPA's decisions to consider or exclude listed species in establishing water quality criteria – a component of water quality standards – have real consequences for how states may proceed in establishing water quality standards sufficient to protect these listed species. Consultation on the overarching framework established by the EPA's PFOS and PFOA criteria is therefore necessary to ensure the protection of threatened and endangered species. • The EPA also has an independent obligation under Section 7(a)(1), to "carrying out [its] programs for the conservation of endangered species and threatened species." By consulting on national criteria and coordinating with the Services, EPA can move toward meeting its Section 7(a)(1) obligations. • The line of causation between EPA's actions and the impacts to water quality are clear, and while there may be additional factors that influence water quality and state adoption of water quality standards, the purpose of the consultation process is to both avoid jeopardy and for the action agency to minimize and mitigate the take that it is legally responsible for. The EPA cannot take an action that could jeopardize listed species while not even attempting to account for its fair share of		

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	responsibility. Thus, failing to consult would represent a clear violation of the ESA. • Since the establishment of water quality criteria will effectively set the practical ceiling for the maximum concentration of these chemicals and result in modifications to water quality standards and water quality itself, the EPA's actions clearly lead to a "may affect" determination for the hundreds of species including but not limited to the Pallid sturgeon, Mohave tui chub, Atlantic sturgeon, Green sturgeon, Gulf sturgeon, Smalltooth sawfish, Shortnose sturgeon. Heavy pigtoe, Southern combshell, Southern clubshell, Ovate clubshell, Orange-nacre mucket, Alabama moccasinshell, Reticulated flatwoods salamander, Eastern Hellbenders, Hawksbill sea turtle, Green sea turtle, Leatherback sea turtle, Loggerhead sea turtle, and Kemp's ridleys sea turtle, Kral's water plantain, Hine's emerald dragonfly, Northern long eared bat, Red cockaded woodpecker, Roseate tern, California least tern, and the Polar bear. For these reasons, the EPA must consult with the Services as required by Section 7 of the ESA. • Given the real-world consequences for listed species that flow from the approval of aquatic life water quality criteria, the EPA must consult with the Services as required by Section 7 of the ESA.		

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	• This is not an exhaustive list of fish species that will be adversely affected by the EPA's promulgation of water quality criteria. In fact, given the ability of PFAS to bioaccumulate in the environment, and given the long-lived nature of many benthic fish species, the EPA's actions will cross the "may affect" threshold for the following listed species: Atlantic sturgeon, Green sturgeon, Gulf sturgeon, Smalltooth sawfish, and Shortnose sturgeon. Even while acknowledging that these guidelines are in desperate need of revision, the EPA still has failed to consult with the USFWS or NMFS (collectively "the Services") to ensure that criteria derived from these guidelines are protective of listed species.		
EPA-HQ-OW-2022-0365-0024 (CBD)	• However, the EPA's failure to initiate consultation as required by Section 7 of the Endangered Species Act ("ESA") and reliance on outdated methodologies has led to draft criteria that are inadequate to protect listed species, do not reflect the latest scientific knowledge… • To ensure that the final water quality criteria are both legally defensible and protective of all listed species, the EPA must take this opportunity to modernize its methodologies and finish consultation before finalizing any water quality criteria related to PFOA and PFAS.	Thank you for your comments. Please see responses to these comments in Section 2.5.2.2.	No edits.

Comment Number (Organization)	Center for Biological Diversity Comment on Endangered Species Act (ESA) Bin: *The following excerpts were taken from throughout CBD's comment letter. They are grouped together here to allow consistent EPA responses.*	EPA Response	Revision location in Final PFOA and/or PFOA Aquatic Life Criteria Document
	• We are also concerned that the EPA's reliance on out-of-date methodologies to derive water quality criteria have allowed the agency to justify higher thresholds for these toxic chemicals that do not reflect the latest scientific knowledge and are under-protective of listed species. The EPA continues to rely on Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses ("1985 Guidelines") to derive water quality criteria, even though these guidelines from the have been excoriated by the scientific community, are based on several arbitrary concepts and policy choices, and do not include the precautionary approach of the ESA…For water quality criteria to truly reflect the latest scientific knowledge as required by law, the 1985 Guidelines must be updated. • Since water quality criteria are foundational to many programs of the CWA, any criteria that are not grounded in the "latest scientific knowledge" as required by law undermine the CWA and its remedial purpose. The 1985 Guidelines outline the process the EPA must take in deriving aquatic life water quality criteria. While these guidelines may have been considered cutting-edge thirty-seven years ago, the 1985 Guidelines no longer reflect the latest scientific knowledge. In fact, they are based on several arbitrary concepts and policy choices.		

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	• The 1985 Guidelines also do not meaningfully consider interspecies relationships, non-aqueous exposure to the identified chemical, indirect toxic effects and toxicity from physical stressors, and pollutant mixtures. Long-term exposure to the identified chemicals is not required to derive water quality criteria, only relatively short-term exposures. This is particularly problematic for the many long-lived, benthic fish species that are sensitive to bioaccumulated chemicals. Finally, the 1985 Guidelines do not adopt the ESA's precautionary principle to ensure that listed species are not jeopardized by inadequate water quality criteria, despite ensuring that these "methodological guidelines take into account the need to protect Federally-listed species." • Despite these serious flaws, the EPA continues to base its analysis almost entirely on these out-of-date guidelines. While the EPA has committed to updating its guidance, it continues to rely heavily on guidance that does not reflect the latest scientific knowledge in the interim. Any criteria for water quality cannot accurately reflect the latest scientific knowledge if they continue to be derived from outdated guidance. • In initiating a new revision campaign, the EPA has tacitly recognized that while thirty-seven years ago the 1985 Guidelines may have been cutting-edge, they no longer represent the latest scientific knowledge as required by law. This is not a novel		

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	realization, as the EPA in fact lags behind other counties that have updated their guidance multiple times to reflect scientific advancements. Australia and New Zealand initially adopted equivalent guidelines in 1992, updating them in 2000 and in 2018 to reflect scientific advancements. In Europe, guidelines promulgated in 2000 were updated in 2008 and undergo a periodic evaluation to ensure policy effectiveness, coherence, and relevance. In Canada, guidelines were initially adopted in 1987, and were updated in 1991 and 2007. Even while criteria may be applied differently in other countries, the science is still the same across the globe, and the 1985 Guidelines are lacking in incorporating the latest scientific knowledge. • The EPA has been given an opportunity to implement effective measures to protect listed species, people, and the environment from serious harm, but to do so, it must work at the front-end so that these criteria are not just another inadequate half-measures. • To make sure these criteria reflect the latest scientific knowledge as required by law, the EPA must update it's 1985 Guidelines to ensure that sensitive listed species and biodiversity are sufficiently protected. • The EPA also cannot assume that the effects and impacts on one species from exposure to a pollutant will have the same impact on other		

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	species. Indeed, the consequence of an assumption like this is that EPA will invariably set underprotective criteria for water quality. • The 1985 Guidelines do not accurately characterize "the effects of pollutants on biological community diversity, productivity, and stability" as they rely on single-species toxicity tests that do not represent the vast biodiversity of aquatic life. • The 1985 Guidelines rely on the responses of an extremely limited number of species, many of questionable environmental relevance, to represent the vast range of sensitivity to pollutants observed among all biodiversity of aquatic life in the United States. For example, the 1985 Guidelines only require one aquatic insect in larval stage for criteria development, despite that fact that there are nearly 9000 species of aquatic insects in North America that disproportionately support aquatic food webs. These single-species exposures also underrepresent the complexity of pollutant fate and effects in nature. In the real world, pollutants in aquatic environments interact in synergistic ways, and impact wildlife and plants that are already compromised through their exposure to other pollutants. • The scientific community has criticized the guidelines for emphasizing reductionist, single-species toxicity testing that maximizes experimental control and replicability rather than environmentally realistic experiments and field		

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	observations that more closely represent nature but are inherently more variable. While the EPA itself has recognized that these guidelines need revision and may not reflect the latest science, it still continues to use the 1985 Guidelines to establish water quality criteria that are not sufficiently protective of all aquatic species, including listed species		
EPA-HQ-OW-2022-0365-0024 (CBD)	• While we appreciate the EPA's renewed efforts to update the 1985 Guidelines, it must be noted that previous efforts to make changes have been stymied by industry pressure. The EPA previously initiated a broad criteria modernization effort and made substantial progress towards issuing new guidelines, stacking its Scientific Advisory Board ("SAB") with scientific experts on water quality to review a new document that would inform the scientific basis of future EPA criteria development policies. Two years later, the EPA would shift SAB membership from prominent academic scientists to industry representatives, and ultimately disband the committee tasked with identifying the latest science of criteria development. By 2019, the EPA had abandoned the modernization effort without any public explanation.	The comment is incorrect in stating that the EPA has abandoned its work to update the 1985 Guidelines, and the comment is likewise incorrect that the EPA's work to update the Guidelines has "been stymied by industry pressure." As noted above, the EPA's work to update the 1985 Guidelines is ongoing. The EPA welcomes CBD's comments on potential modifications to the Guidelines in an appropriate forum.	No edits.
EPA-HQ-OW-2022-0365-0024 (CBD)	• …and are [*the 2022 draft PFOA and PFOS Aquatic Life Criteria magnitudes*] overwhelmingly less protective than recent health advisories	The EPA believes it is inappropriate to compare the EPA's national recommended aquatic life criteria to drinking water health advisories issued pursuant to the Safe Drinking Water Act, 42 U.S.C. 300g-1(b)(1)(F).	No edits.

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	implemented earlier this year for the same chemicals. • While it is fortunate that the EPA has initiated an effort to update its 1985 Guidelines, it is unfortunate that these guidelines are still used in the interim to rationalize maximum concentrations, especially when it recently lowered the acceptable level of PFOA and PFOS in drinking water to a "near zero" level. • The EPA's reliance on this outdate methodology may explain why the recommended aquatic life criteria are at much higher levels than the recently implemented health advisories for PFOA and PFOS in drinking water. Earlier this year, the EPA issued interim updated drinking water health advisories for PFOA and PFOS that are based on "new science" and consider lifetime exposure. Given the dangers of PFOA and PFOS, the EPA determined that negative health effects may occur a "near zero" levels of 4 parts per quadrillion and 20 parts per quadrillion respectively, which are below the EPA's ability to detect at this time. Converting the EPA's threshold values from milligrams per liter to parts per million, the EPA's recommended aquatic life water quality criteria are 49 parts per million for PFOA and 3 parts per million for PFOS at acute levels and 0.094 parts per million for PFOA and 0.0084 part per million for PFOS at chronic levels. Since these metrics are expressed in parts per million, they are	While both the drinking water health advisory and the 304(a) recommended criteria are non-regulatory actions that provide scientific information to states and Tribes, aquatic life criteria and drinking water health advisories address different species, endpoints, and exposure pathways/routes, and would thus be expected to yield different protective values. Both set protective levels based on exposure-response information, but it is biologically and toxicologically incorrect to imply the aquatic life criteria are not protective of aquatic life because the aquatic life criteria are greater than the interim human health drinking water advisories for PFOA and PFOS, which are based on an entirely different dataset and are intended to protect people, not fish and other aquatic organisms.	

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	overwhelmingly higher than what the EPA is currently considering safe, based on the latest science, for the protection of public health. The serious discrepancy between these two safety margins emphasizes the need for the EPA to update its 1985 Guidelines immediately to ensure that listed species are not jeopardized by water quality criteria that are not sufficiently protective. • PFOA and PFOS are some of the most common and well-studied Poly- and perfluroalkyl substances ("PFAS"), chemicals that that the EPA has classified as emerging contaminants of concern due to a host of associated health impacts such as increased risk of cancer, decreased fertility, developmental effects in children, and reduced immune system response. These chemicals are so widespread that surveys conducted by the Center for Disease Control show that most people in the United States have been exposed to PFAS in some way.		
EPA-HQ-OW-2022-0365-0024 (CBD)	• PFOA and PFOS are toxic, carcinogenic, emerging contaminants that are widespread, persistent, bioaccumulate in the environment, and are identified by the Department of Defense as presenting a host of risks to threatened and endangered species. • The danger of widespread PFAS contamination is only compounded by the fact that these chemicals persist in the environment	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and has determined that, in any event, there is "no effect" on any listed species or critical habitat. Further, prior to approving any state's 303(c) water quality standards, the EPA will consult with the Services about the effects of that approval on all listed species	No edits.

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	for decades and slowly accumulate in people, animals, and the environment over time. • The tendency for these chemicals to bioaccumulate and persist in the environment also puts terrestrial species like the Northern long-eared bat, Roseate Tern, Red cockaded woodpecker, and Polar bear at risk of harm. • The accumulation of PFAS in the aquatic food web may result in exposures of higher trophic level mammals and birds, and these animals may also be exposed to PFAS in sediment and surface water when the animals forage for plants or invertebrates. Thus, the EPA must consult on a wide range of terrestrial species that may be exposed to PFOA and PFAS through food sources. Studies have pointed out that imperiled insectivores like the Northern long-eared bat and Red cockaded woodpecker are much more sensitive to elevated concentrations of environmental PFAS for these exact reasons. Both these species can be found near military bases with known contamination of PFOA and PFOS, with bats found at Arnold Air Force Base in Tennessee and birds found at Eglin Air Force Base in Florida. The EPA's establishment of new water quality criteria will impact water quality and bioaccumulated contamination, crossing the "may affect" threshold for the Northern long-eared bat and Red cockaded woodpecker.	(which may include aquatic-dependent species), to the extent that the EPA determines that such approval may affect listed species. The goal of recommended 304(a) criteria is to set exposure limits that, if adopted and implemented by states, would be protective of aquatic life from effects of PFOA and PFOS *in the* ambient *water*. The 304(a) recommended criteria for PFOA and PFOS were derived to recommend protective criteria magnitudes that address the effects of potential exposure to these persistent chemicals (i.e., PFOA and PFOS). The Final PFOA and PFOS Aquatic Life Criteria include chronic tissue-based criteria for fish muscle, fish whole-body, and invertebrate tissues that were derived to protect aquatic life from bioaccumulation-based exposures that result in toxicological effects. The EPA notes that, by design, aquatic life and aquatic-dependent wildlife criteria recommendations are not intended to address terrestrial species, as this is outside the scope of these recommended water quality criteria which are derived to be protective of aquatic life. The EPA does intend, however, to develop independent PFOA and PFOS aquatic-dependent wildlife criteria recommendations if and when there are sufficient data.	

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	Insectivores are not only at risk, as PFOA and PFAS readily accumulate in fish, meaning that any piscivorous bird species will also be at risk from exposure. Thus, the EPA's actions will cross the "may affect" threshold for the endangered Roseate tern and California least tern. Since PFOA and PFOS are so widespread and persistent in the environment that they have even been found in the livers of threatened Polar bears living near a PFAS contaminated airport in Utqiagvik Alaska. Studies have shown that these chemicals might possess endocrine disrupting properties for Polar bears. Given the present contamination and level of harm, any impacts to water quality from EPA's actions would cross the "may affect" threshold for the Polar bear.		
EPA-HQ-OW-2022-0365-0024 (CBD)	While these chemicals are **directly toxic** to endangered fish like the Pallid Sturgeon and Mohave tui chub PFOA and PFOS pose a serious risk to other imperiled aquatic species, including the endangered Heavy pigtoe mussel, Eastern hellbender salamander, and even the Kemp's ridley sea turtle. (emphasis added by the EPA)	The toxicity of PFOA and PFOS to endangered fish like the pallid sturgeon and Mohave tui chub is dependent on their sensitivity and the concentrations of PFOA and PFOS to which they might be exposed. It is unclear what data the commenter relies on to make the assertion that PFOA and PFOS are directly toxic to pallid sturgeon and Mohave tui chub or poses serious threats to the heavy pigtoe mussel, or Eastern hellbender. In a footnote, the comments referenced Keller et al. (2012) and Sinclair et al. (2020); however, neither of the publications referenced mentioned the Mohave tui chub, pallid sturgeon, heavy pigtoe mussel, or Eastern hellbender sensitivity to PFOA or PFOS exposure. Absent data, one	No edits.

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		cannot reasonably conclude PFOA and PFOS are directly toxic to endangered fish species at the concentrations recommended in the EPA's PFOA and PFOS Aquatic Life Criteria. The EPA's recommended Aquatic Life Criteria considered the best available ecotoxicity studies to quantify the effects of these chemicals on aquatic life, which included evaluations of available data on PFOA and PFAS effects on mussel and amphibian species. At this time, it is difficult to determine the dose/exposure regimen for PFOA and PFOS that would be toxic to the Kemp's ridley sea turtle in estuarine/marine waters because of a lack of sufficient high-quality data. Overall, listed species are not expected to be more uniquely sensitive to PFOA and PFOS than non-listed species, including those used to derive the PFOA and PFOS Aquatic Life Criteria. For example, the National Research Council's 2013 report, Assessing Risks to Endangered and Threatened Species from Pesticides (NRC 2013), states that "Listed species are not inherently more sensitive to chemicals than species that are not listed" (pg. 129), citing publications from Sappington et al. (2001), Dwyer et al. (2005), and Besser et al. (2005).	

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EPA-HQ-OW-2022-0365-0024 (CBD)	Consultations on water quality criteria are no more or less complicated than other programmatic consultations that potentially apply over large portions of the country. For example, in 2011, the Services completed consultations on the nationwide wildland firefighting program's potential impact on listed species, especially aquatic species that are harmed by the chemicals in fire-retardants dropped from aircraft. No one would ever claim that the Forest Service can predict the place that any specific wildfire would occur in the future, or if during the course of any particular wildfire that the use of fire-retardant would be needed, or that the retardant chemical would be applied over or near a specific body of water. Nonetheless, because there existed a potential for harm — even indirect and causally distant harm — a consultation was completed. Similarly, the EPA has completed several biological opinions on other aspects of its water program, including a consultation for its 316(b) regulations, a consultation on the NPDES general permit for stormwater, and consultations on the use of organophosphate pesticides. For each of these actions, the EPA could not predict exactly when or where a third party will choose to apply a pesticide, or the choice by a third party of technology at any specific facility to address thermal impacts or the amount of pollution from a third party will seek in a general permit for stormwater (not to mention predicting when or how much it will rain). Nonetheless, the EPA's authorizations provided the necessary legal approval for such activities to	The EPA disagrees that publication of 304(a) criteria is a "programmatic action" within the meaning of the Services' ESA regulations. See 50 CFR 402.02.	No edits.

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	eventually occur, influenced and shaped the actions of numerous third parties, and ultimately impacted the conservation status of numerous endangered species.		
EPA-HQ-OW-2022-0365-0024 (CBD)	The EPA's duty to consult on water quality criteria is firmly established by the text of the ESA and a Memorandum of Agreement that clarifies the required procedures for ESA compliance in actions under the CWA. The latter document states that*: EPA and the Services will conduct a section 7 consultation on the aquatic life criteria to assess the effect of the criteria on listed species and designated critical habitat. EPA and the Services will also conduct a conference regarding species proposed for listing and proposed designated critical habitat. EPA will consider the results of this consultation as it implements and refines its criteria program, including decisions regarding the relative priorities of revising existing criteria and developing new criteria.* Since this is also new criteria for novel chemicals, the EPA is wasting a huge opportunity to maximize efficiency and consult at the front end rather than waiting to consult on a state-by-state basis	The EPA disagrees that the text of the ESA requires consultation on the publication of nonbinding recommendations and information. See comment above. The EPA also disagrees that the referenced Memorandum of Agreement "clarifies the required procedures for ESA compliance." In 2001, the Services and the EPA entered into a Memorandum of Agreement (MOA) designed to enhance coordination for ESA Section 7 consultations involving water quality standards. The EPA does not agree that consultation on the PFOA and PFOS recommended criteria would maximize efficiency. The EPA entered the 2001 MOA as a voluntary measure in anticipation that doing so would lead to efficiency gains on state-level consultations. The MOA anticipated that the EPA and the Services would voluntarily consult on the 304(a) criteria for cyanide. After many years of efforts by both the EPA and the Services, those benefits did not materialize, in part because of the exceptionally high level of information that would be necessary to complete a robust consultation on all species present in the waters of all states. The EPA and the Services subsequently agreed to withdraw from the MOA.	No edits.

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		The MOA does not undercut the EPA's longstanding legal position that the publication of 304(a) criteria is not an "agency action" subject to Section 7. The MOA nowhere states that the publication of 304(a) criteria is an "agency action" or that the publication of 304(a) criteria is "authorized, funded, or carried out" by the EPA. Nor does the MOA indicate that 304(a) criteria may affect species. Accordingly, the existence of the MOA has no bearing on EPA's obligations under ESA Section 7.	
EPA-HQ-OW-2022-0365-0024 (CBD)	The Department of Defense has previously found that PFOA and PFOS present a whole host of threats to listed species, specifically noting direct toxic effects to aquatic species and the risk that aquatic-dependent wildlife face from exposure. It also noted that aquatic environments located downgradient of military bases contaminated by PFOA and PFAS from firefighting foam, meaning that most aquatic species near military bases will be "particularly at risk" of harm.	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and has determined that, in any event, there is "no effect" on any listed species or critical habitat. The Department of Defense's conclusion about the "effects" of its "agency action" has no bearing on whether the EPA's conduct is an "agency action" that "may affect" species. The PFOA and PFOS exposures near contaminated military bases are typically orders of magnitude greater than the Final PFOA and PFOS Aquatic Life Criteria. CBD referenced the "Guidance for Assessing the Ecological Risks of PFASs to Threatened and Endangered Species at Aqueous Film Forming Foam-Impacted Sites" (SERDP Project ER18-1614) (SERDP 2020) funded under the Strategic Environmental Research and Development Program as the primary example when describing the risk that PFOA and PFOS	No edits.

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		pose to listed species near U.S. military sites. EPA notes the protective Aquatic Life Criteria are lower (i.e., more protective) than those values described in this report by SERDP (2020), which calculated protective 5% hazard concentrations (HC5) that were intended to be protective of threatened and endangered species using the same fundamental methods the EPA used to derive the Final PFOA and PFOS criteria. For example, SERDP (2020) states, "only NOEC and EC_{10} values were considered to reflect the level of protection required for T&E species," and the EPA preferentially used chronic EC_{10} values to build the chronic PFOA and PFOS genus sensitivity distributions to derive the Aquatic Life Criteria. Once the toxicity data were compiled, SERDP (2020) generally followed sensitivity distribution approaches described by the EPA's 1985 Guidelines (U.S. EPA 1985) to calculate HC5 values reported in Appendix D. SERDP (2020) states, "where toxicological info for PFOS or PFOA is not available for a specific T&E species or surrogate species, a NOEC-based SSD has been developed for PFOS and PFOA to calculate T&E species protective values." The chronic PFOA freshwater HC5 reported in Table 6 of SERDP (2020) is 1.112 mg/L, which is more than an order of magnitude greater than the EPA's Final chronic water column-based PFOA Aquatic Life Criterion of 0.10 mg/L. The chronic PFOS freshwater HC5 reported in Table 6 of SERDP (2020) is 0.00585 mg/L, which is more than 23 times greater than the EPA's Final chronic water column-based PFOS Aquatic Life Criterion of 0.00025 mg/L. The substantial differences can be largely attributed to the inclusion of	

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		more recently published toxicity data in the EPA's 304(a) Final PFOA and PFOS Aquatic Life Criteria, but it also demonstrates that the EPA's criteria are expected to be generally protective of listed species and are based on the latest scientific information.	
EPA-HQ-OW-2022-0365-0024 (CBD)	The risk of harm is especially stark for the Mohave tui chub, a small, endangered fish that requires its habitat be free of toxic substances or the threat of toxic substances. One of the last remaining populations of this fish is at Naval Air Weapons Station China Lake in California, the second most contaminated military PFAS site in the United States.	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and has determined that, in any event, there is "no effect" on any listed species or critical habitat. Further the extent to which particular species are exposed to elevated levels of PFOA/PFOS in particular water bodies or areas would be addressed by EPA in state-level consultations, at the point at which states adopt (and EPA approves) criteria for PFOA/PFOS. Mohave tui chub may be currently exposed to elevated PFOA and PFOS near the Naval Air Weapons Station, China Lake (California) based on the comment's supporting source material found here: https://www.ewg.org/sites/default/files/u352/Top%20100%20PFAS.pdf. The source material notes the sum of the highest PFOA and PFOS concentrations measured was 8,000,000 parts per trillion (ppt). 8,000,000 ppt is equivalent to 8,000 mg/L. This measurement was taken from groundwater; no surface water measurements were reported in the literature provided by CBD comments in	No edits.

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		this instance, so any potential dilution in ambient waters was not considered • The sum of the Final acute PFOA criterion (i.e., 3.1 mg/L) and the Final PFOS acute criterion (i.e., 0.071 mg/L) is 3.171 mg/L, or a combined concentration that is more than 2,500 times lower than the combined PFOA and PFOS exposure occurring in groundwater at the Naval Air Weapons Station China Lake. • The sum of the Final chronic water column-based PFOA criterion (i.e., 0.10 mg/L) and the Final chronic water column-based PFOS criterion (i.e., 0.00025 mg/L) is 0.10025 mg/L, or a combined concentration that is nearly 80,000 times lower than the combined PFOA and PFOS exposure occurring at the Naval Air Weapons Station China Lake.	
EPA-HQ-OW-2022-0365-0024 (CBD)	PFOA and PFOS present a similar problem to the Pallid Sturgeon, an endangered fish whose survival is threatened in part by water pollution. Research suggests a link between environmental contaminants and potential reproductive problems in sturgeon species. Contaminants like PFOA and PFOS tend to bioaccumulate in Pallid sturgeon at greater quantities, as they are long-lived, piscivorous, and have a longer reproductive cycle. Despite ongoing conservation efforts to protect their species, their numbers remain low, and any additional stressors could be highly detrimental to the survival of the species. While these imperiled fish are seriously threatened by	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and has determined that, in any event, there is "no effect" on any listed species or critical habitat. Regardless, the comment cites U.S. FWS (2014) to suggest pallid sturgeon may be experiencing adverse effects resulting from exposure to PFOA and PFOS. This assertion is made without any respect to the dose or concentration of PFOA and PFOS. The reference source material does indicate different pollutant classes that may be impacting pallid sturgeon; however, the source material contains no mention of PFOA or PFOS.	No edits.

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	environmental contamination, they are still spotted in Louisiana's Red River, which runs right by the now defunct England Air Force Base, which is one of the worst spots for PFAS contamination in the country. At 20.7 million parts per trillion of these chemicals found in the drinking water, the site overwhelmingly above any permissible limits. Efforts to modify water quality criteria will clearly affect the management of this watershed and given the risk that these chemicals pose and the proximity of this site to sturgeon habitat, this action clearly crosses the "may affect" threshold for the Pallid sturgeon.	Furthermore, there are no toxicity data to evaluate the sensitivity of pallid sturgeon relative to species included in the PFOA and PFOS criteria documents. Thus, to presuppose this species would be affected without any toxicity data, by assuming that it is more sensitive than any currently tested species, while also presenting no data on ambient water concentrations, is speculative. The EPA's Final PFOA and PFOS Aquatic Life Criteria provide information that states and Tribes can consider as they adopt as water quality standards to protect pallid sturgeon and other listed and non-listed aquatic species from adverse PFOA and PFOS exposures. For example, the 2014 Pallid Sturgeon Recovery Plan referenced by CBD (USFWS 2014) specifically states the beneficial impact of Clean Water Act programs: • *All States whose waters are occupied by Pallid Sturgeon have enacted legislation intended to preserve water quality. Generally these State regulations parallel comparable Federal legislation; in some cases, State statutes may impose requirements that are more stringent than the Federal law. In all cases, Clean Water Act requirements must be adhered to and are enforced in conjunction with State statutes and regulations implemented by the State administrative agencies.* • *The Clean Water Act (33 U.S.C. §§1251 et seq.) regulates pollutant discharges into the nation's waters. This is accomplished through defining,*	

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		monitoring, and regulating water quality standards for all surface waters, establishing industry wastewater standards, and protecting aquatic life and habitats through permitting. • *The Clean Water Act affords substantial protections to the Pallid Sturgeon, its habitat, and life history requirements through establishing water quality standards and reducing the effects from the discharge of harmful pollutants, contaminants, and discharge of dredge or fill material.* • *However, residual effects from historical practices and a lack of species specific information on the sensitivity of the Pallid Sturgeon to common industrial and municipal pollutants may be limiting the full conservation potential of the Clean Water Act as it relates to pollutant discharge and water quality standards.* The 2014 Pallid Sturgeon Recovery Plan (USFWS 2014) clearly describes the beneficial effects of water quality standards and Clean Water Act programs in the recovery of pallid sturgeon populations. The recovery program duly notes that additional work is needed to unlock the "full conservation protentional" of the Clean Water Act. The finalization of the EPA's PFOA and PFOS Aquatic Life Criteria represents an important step in the release of scientific information that states and Tribes can consider when adopting water quality standards to protect aquatic life from elevated concentrations of PFOA and PFOS.	

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EPA-HQ-OW-2022-0365-0024 (CBD)	The EPA must focus on not just listed fish when consulting on water quality criteria, but any other species that depend on or are impacted by freshwater quality, including insects, freshwater mussels, and terrestrial species that depend on healthy freshwater ecosystems for food and survival. The CWA mandates that water quality standards protect not only fish, but all aquatic organism and other wildlife that depend on a healthy aquatic environment. For water quality criteria to be protective of listed species, consultation should consider all listed species that depend on the freshwater aquatic ecosystem.	EPA's Aquatic Life Criteria do not just focus on fish but consider data from at least eight different aquatic taxa that represent a typical aquatic community. Freshwater mussel and insect data were used to derive the PFOA and PFOS Aquatic Life Criteria. Moreover, the EPA will consult with the Services about a proposed approval of state or tribal water quality standards for PFOA or PFOS under Clean Water Act Section 303(c), to the extent that it determines that such approval may affect listed species, which may include aquatic-dependent species based on exposure potential.	No edits.
EPA-HQ-OW-2022-0365-0024 (CBD)	Freshwater mussels are among the most imperiled taxonomic groups worldwide, and they are often among the most sensitive species to aquatic contaminants. Studies have suggested that exposure to PFOS and PFOA can cause reproductive issues in freshwater mussels. Six listed mussels are found in a river adjacent to the Columbus Air Force Base in Mississippi, which is heavily contaminated with PFOS and PFOA. These are the endangered Heavy pigtoe, Southern combshell, Southern clubshell, Ovate clubshell, and the threatened Orange-nacre mucket and Alabama moccasinshell. Given mussel's extreme sensitivity and the pollution in the area, it is apparent that any water quality criteria update will influence that water quality in the area and cross the "may affect" threshold for these six species, and likely many more mussels across the county.	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and because, in any event, there is "no effect" on any listed species or critical habitat. The Final PFOA and PFOS Aquatic Life Criteria considered all relevant acute and chronic mussel toxicity data, including the Hazelton et al. (2012) study referenced in the comment. Overall, freshwater mussels were not uniquely sensitive to PFOA and PFOS at the criteria magnitudes, based on the latest available toxicity data. The sensitivity of mussels was outside the most sensitive species (with mussels ranking between the 5th and 6th most sensitive species for acute and chronic exposure to PFOA and PFOS), with the exception of chronic PFOS exposures to fatmucket, *Lampsilis*	No edits.

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		siliquoidea, which was ranked as the third most sensitive species based on available data during the derivation of the chronic Final PFOS Aquatic Life Criterion. The values at which the most sensitive mussel experienced adverse effects for PFOA (an acute test of 161 mg/L) and PFOS (a chronic tests of 0.01768 mg/L), are at least 52 times higher than the corresponding criterion. The EPA will further evaluate the sensitivity of listed mussel species during future ESA Section 7(a)(2) consultations associated with the approval of state or Tribe water quality criteria for PFOA and PFOS, if the EPA determines that the state or Tribe's criteria may affect ESA-listed mussels or designated critical habitat.	
EPA-HQ-OW-2022-0365-0024 (CBD)	The EPA must also consult on listed amphibians. Studies have shown that exposure to PFAS can negatively affect the body condition, development, and thyroid of amphibians even at very low concentrations. Moreover, salamanders and frogs are generally more susceptible to the harmful effects of PFAS than hardier toads. Many listed amphibians already live in areas highly contaminated by PFAS, like the endangered Reticulated flatwoods salamander that can be found in Florida's contaminated Eglin Air Force Base. Other listed salamanders such as the Eastern Hellbender are also highly sensitive to PFAS and at risk from degraded water quality. The EPA's actions to affect water quality by promulgating a water quality criterion will clearly impact the habitat of these species, crossing the "may affect" threshold for the	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and has determined that, in any event, there is "no effect" on any listed species or critical habitat. The EPA will consult with the Services about a proposed approval of state or tribal water quality standards for PFOA or PFOS under Clean Water Act Section 303(c), to the extent that it determines that such approval may affect listed species, which may include amphibians. Regardless, the recommended PFOA and PFOS Aquatic Life Criteria considered all relevant acute and chronic amphibian toxicity data, including the Flynn et al. (2022) study referenced in the comment (note, footnote 45 of	No edits.

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	Reticulated flatwoods salamander, Eastern Hellbender and many other listed amphibians.	CBD's comments lists this publication as being published in 2021 instead of 2022). Amphibians were not among the four most sensitive genera to acute PFOS exposures (most sensitive amphibian to acute exposures of PFOS was the 7th most sensitive genera) and were systematically tolerant to acute PFOA and chronic PFOS exposures (ranking between the 8th and 13th most sensitive genera). For PFOA, an amphibian genus (*Lithobates*) was the second most sensitive genus to chronic exposures; however, the PFOA value at which *Lithobates* experiences adverse chronic effects (i.e., 0.288 mg/L) is almost three times higher than the Final PFOA chronic water column criterion (i.e., 0.10 mg/L). In a footnote, CBD's comment referenced Keller et al. (2012) and Sinclair et al. (2020) to support the assertion that the Eastern hellbender is sensitive to PFAS exposures; however, neither of the publications referenced discussed Eastern hellbender sensitivity to PFOA or PFOS exposure.	
EPA-HQ-OW-2022-0365-0024 (CBD)	The EPA must also consult on nearly all listed sea turtles, given the significantly levels of PFAS contamination found in their bloodstream and effects any new water quality criteria would have on their habitat. Imperiled sea turtles across the country have been found with PFAS in their blood plasma, including the endangered Hawksbill sea turtle, Green sea turtle, Leatherback sea turtle, Loggerhead sea turtle, and Kemp's ridleys sea turtle. These studies suggest that some turtles are already exposed to	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and has determined that, in any event, there is "no effect" on any listed species or critical habitat. The EPA will evaluate the sensitivity of listed sea turtle species, to the greatest extent the available data allow, during future ESA Section 7(a)(2) consultations	No edits.

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	contamination levels that have the potential to cause health effects. PFOS levels found on unhatched Hawksbill sea turtle eggs were even near those which have caused developmental toxicity in birds. The EPA's actions in affecting freshwater quality ultimately impact the estuarine and marine habitat of these listed turtles, crossing the "may affect" threshold and requiring consultation under Section 7 of the ESA.	associated with the approval of state water quality criteria for PFOA and PFOS in estuarine/marine waters if the EPA determines that the state or Tribe's criteria may affect ESA-listed sea turtle species or designated critical habitat. Additionally, the EPA did not derive recommended PFOA and PFOS Aquatic Life Criteria for estuarine/marine waters (e.g., sea turtle habitats), but only developed acute estuarine benchmarks. No direct toxicity data on survival, growth or reproduction, the basis of 304(a) criteria recommendations, were available for estuarine/marine turtle species at the time the EPA developed acute /estuarine/marine benchmarks. A state or Tribe could adopt estuarine/marine water quality standards that are based on the acute PFOA and PFOS estuarine/marine benchmarks discussed in the Final PFOA and PFOS Aquatic Life Criteria documents or could develop criteria based on other protective and scientifically-defensible values.	
EPA-HQ-OW-2022-0365-0024 (CBD)	The EPA must also consult on the many listed wetland plants and emergent insects that are sensitive to PFAS concentrations in water. For example, wetland plants like the threatened Kral's water plantain and endangered insects like the Hine's emerald dragonfly are directly threatened by water pollution and habitat contamination, meaning this action likely crosses the "may affect" threshold for these and hundreds of other species.	To the extent the comment is making a point that the EPA's 304(a) recommended criteria for PFOA/PFOS "may affect" species, the argument is irrelevant here, because the EPA is not engaged in "agency action" and has determined that, in any event, there is "no effect" on any listed species or critical habitat. To the extent that states adopt EPA's recommended 304(a) criteria, the EPA will further evaluate the	No edits.

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		sensitivity of listed plant and emergent insect species during future ESA Section 7(a)(2) consultations associated with the approval of state or Tribe water quality criteria for PFOA and PFOS, if the EPA determines that the state or Tribe's criteria may affect these ESA-listed species or designated critical habitat. Regardless, the EPA considered the best available ecotoxicity studies to quantify the effects of PFOA and PFOS on aquatic life, which included aquatic plants and emergent insects. The high-quality PFOA and PFOS plant toxicity data indicated plants were less sensitive to PFOA and PFOS than aquatic animals. Therefore, the EPA's 304(a) criteria are considered to be protective of aquatic freshwater plants, including wetland plants.	
EPA-HQ-OW-2022-0365-0024 (CBD)	• The EPA also cannot assume that the effects and impacts on one species from exposure to a pollutant will have the same impact on other species. Indeed, the consequence of an assumption like this is that EPA will invariably set underprotective criteria for water quality. • The 1985 Guidelines do not accurately characterize "the effects of pollutants on biological community diversity, productivity, and stability" as they rely on single-species toxicity tests that do not represent the vast biodiversity of aquatic life.	The EPA considers all available toxicity data on the array of aquatic species tested in developing its recommendations. The EPA inherently considers impacts on many species when deriving Section 304(a) criteria recommendations, if such data is available, because the EPA typically gathers and applies data from the eight minimum data requirements from a broad range of aquatic taxa, representing wide and diverse aquatic communities. Additionally, the scientifically well supported concept (Raimondo et al. 2010; Willming et al. 2016) that taxonomically-related species respond to chemical exposures in similar ways is commonly applied to ESA effect assessments and Biological Evaluations. For example, the EPA has commonly used toxicity data	No edits.

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		from one tested species as surrogate data for a taxonomically-related, but untested, ESA-listed species in recent ESA Section 7(a)(2) consultations on the approval of state or tribal water quality standards. Further, using taxonomic surrogacy to predict the effects of chemicals on other species is a cornerstone of modern toxicological science.	