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June 29, 2022

Jim Justice and Amanda Jarvis Health and Ecological Criteria Division United States Environmental Protection Agency *Via Electronic Docket*

RE: EPA-HQ-OW-2022-0365, EPA-HQ-OW-2022-0366, Draft Recommended Aquatic Life Ambient Water Quality Criteria for PFOA and PFOS

The Association of Clean Water Administrators (ACWA) is the independent, nonpartisan, national organization of state, territorial and interstate ("states") water program directors responsible for the daily implementation of the Clean Water Act's (CWA) water quality programs. We appreciate the difficulty of the task facing the U.S. Environmental Protection Agency (EPA) developing CWA Section 304(a) Recommended Ambient Water Quality Criteria for two of the most-studied per- and polyfluorinated substances (PFAS): Perfluorooctanoic Acid ("PFOA") and Perfluorooctane Sulfonate ("PFOS"), the "draft criteria". Despite their recent scientific scrutiny, the universe of occurrence and toxicity data on PFOA and PFOS is clearly small, and ACWA applauds EPA for expeditiously working with available knowledge to issue draft criteria, as well as marine/estuarine benchmarks. The draft criteria, when finalized, will provide states with a necessary tool to further implement monitoring, source control, and standards for PFOA and PFOS in ambient waters.

To achieve this important milestone, EPA employed approaches that will be problematic for some states interested in adopting the recommended criteria. On this and other bases, ACWA is providing seven high-level comments. An appendix specifies states' feedback on the science and approach of the criteria and benchmark derivations.

 EPA should re-release the criteria as draft, with a public comment period, if changes are made. Changes may include greater conformity with the <u>1985 Guidelines For Deriving Numerical</u> <u>National Water Quality Criteria For The Protection Of Aquatic</u> <u>Organisms And Their Uses</u> ("1985 Guidelines"), such as meeting Minimum Data Requirements ("MDRs"), or incorporation of new or pending data. Only once all MDRs are met will the majority of states be able to consider adopting the criteria. <u>EPA should not release the</u> <u>documents as Final if the criteria values or derivation inputs have</u> <u>changed in any way; the documents should be released again as draft</u> <u>for co-regulators and stakeholders to review</u>. This includes if all MDRs are met, whether the criteria values change or not. Insects are the missing MDR. EPA has stated that the draft criteria will be updated before finalization using pending insect data, and qualitatively expects that the values will not markedly change. Yet EPA has verbally communicated that Mayflies and Dragonflies are likely much more sensitive to PFAS than some fish species, and EPA states, "additional toxicity data on aquatic insects are needed to fully understand the potential acute effects of PFOS on aquatic insects, especially considering the comparison between qualitative data for midge and mosquito, which indicated very different sensitivities among insects for which data are available¹". Insects being one of the more sensitive species would likely materially change the criteria values.

- 2. EPA should work with states and Tribes in updating the **1985 Guidelines For Deriving** Numerical National Water Quality Criteria For The Protection Of Aquatic Organisms And Their Uses. VEPA notes in both "EPA Response to the External Peer Review" documents^{2 3} that, "EPA has initiated an effort to update the 1985 Guidelines. When a draft revision is completed, it will be peer reviewed and made available for public comment." EPA should discuss this matter with states, Tribes and ACWA before proceeding, because of (1) EPA and state/Tribal programs' amassed knowledge and ability with respect to approaches to deriving risk-based benchmarks and criteria; and (2) the technical and policy ramifications, and centrality to state use of 304(a) criteria, of any changes to the 1985 Guidelines. The mention of this update in the EPA Response to External Peer Review documents is the first mention of any potential 1985 Guidelines update to ACWA. Any update should occur via the Federal Register Notice process. These draft criteria bring to bear many areas where the 1985 Guidelines may warrant review and updating - some examples include the use of bioaccumulation factors (BAFs), modeling, benchmarks, and innovative procedures; time between paired data; conformity with the Endangered Species Act; and, the interrelation between the 1985 Guidelines and Recalculation Procedure.
- 3. **EPA needs to develop communication planning.** In June 2022, EPA released updated PFOA and PFOS' Safe Drinking Water Act Health Advisory Levels as interim values that are 4E-09 mg/L and 2E-08 mg/L, respectively (0.004 PPT and 0.02 PPT), below analytical method detection limits. Meanwhile, the draft chronic water column ambient water quality criteria (AWQC) to protect aquatic life in freshwater from PFOS and PFOA are .0084mg/l and .094mg/l respectively, and future Human Health Criteria (HHC) are expected to be far more stringent. States and EPA need to be able to address and communicate the gulf between these and other emerging values (and derivation components like Bioaccumulation Factors), and what the draft criteria values mean in the context of source water protection and fish consumption. This is especially critical for states that combine aquatic life and aquatic organism consumption uses. Those states apply the more stringent of the two uses (typically, consumption), leaving them awaiting applicable recommended criteria. EPA should specifically assist states in this position, which ACWA can facilitate.

¹ EPA 2022. "Response to the External Peer Review of U.S. EPA's 'Draft Aquatic Life Ambient Water Quality Criteria for Perfluorooctane Sulfonate (PFOS)," 53. EPA-842-D-22-003.

² EPA 2022. "Response to the External Peer Review of U.S. EPA's 'Draft Aquatic Life Ambient Water Quality Criteria for Perfluorooctane Sulfonate (PFOS)," 109. EPA-842-D-22-003.

³ EPA 2022. "Response to the External Peer Review of U.S. EPA's 'Draft Aquatic Life Ambient Water Quality Criteria for Perfluorooctanoic Acid (PFOA)," 79. EPA-842-D-22-004.

4. The federal government needs to invest in surface water PFAS toxicity research and management, including monitoring and source control. The paucity of available data relevant to these draft criteria, and the resource gap states will face in attempting to adopt the criteria, reflect the federal government's heavy investment in managing PFAS in drinking water but under-investing in managing PFAS in surface and source waters.

Given PFAS' priority, it is unclear why more toxicity studies were not conducted domestically in the last several years. The draft criteria relied heavily on foreign studies. Since federal and state environmental labs have the capability of performing toxicity tests which may satisfy various requirements in the1985 Guidelines, EPA or other federal support for such testing would have helped the draft criteria conform with the 1985 Guidelines in a timely manner. Further, EPA should be more explicit about resource needs to implement these criteria. And, especially given PFAS laboratory analysis delays experienced around the country, it will be essential that states receive targeted support for potential adoption and implementation of the finalized criteria, such as monitoring and assessment. For example, as EPA states in its response to scientific peer review comments, "Absent of continuous monitoring data, EPA agrees that it may be difficult to assess PFAS concentrations in water bodies with enough temporal resolution to continually assess average acute concentrations over the course of a one-hour duration or average chronic concentrations over the course of four days."

- 5. States appreciate the Marine/Estuarine Benchmarks but ask that (1) EPA release them in separate documentation, and (2) provide greater clarity about what "benchmarks" are in the CWA context. EPA took on significant work and exposure in developing a benchmark using novel approaches, and publishing draft benchmark values that may be updated in the near-term as data becomes available. This is appreciated. At the same time, since benchmarks are not 304(a) criteria recommendations, states feel the benchmarks should be released distinct from the 304(a) PFOA and PFOS recommended criteria. More clarity should be provided about the nature of "recommended benchmarks." What differentiates the benchmarks and ecological screening values EPA releases; are they to be used analogously or differently? What is EPA's vision for state water quality protection programs' use of benchmarks, and are there limits to their use by states? This is especially critical if benchmarks will continue to be used in the future when EPA seeks to develop 304(a) criteria for data-poor emerging compounds or compounds that otherwise cannot meet sufficient 1985 Guidelines provisions.
- 6. The criteria should address precursors to PFOA and PFOS as well as parameters influencing toxicity and bioavailability. Increasing knowledge about the properties of PFAS and analyte-specific precursors has demonstrated that PFAS precursors in the environment are not static. To manage PFOA and PFOS in aquatic systems, it is necessary to manage not only PFOA and PFOS discharges, but also precursor compounds that transform into PFOA and PFOS once discharged or deposited. Furthermore, while EPA mentions that salinity may affect PFOA/PFOS toxicity (but does not elaborate on whether this is incorporated in the criteria derivation), PFOA and PFOS toxicity and bioavailability may be more broadly influenced by other physicochemical parameters. EPA addresses this in the introduction of both criteria documents but does not articulate whether or how this

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addressed in the criteria derivation. EPA should more fully discuss other parameters' influence on PFOA/PFOS; or, if EPA feels this does not warrant addressing, EPA should explain why.

7. ACWA wishes to thank EPA for extending the draft criteria comment period to 60 days. This additional time, while potentially delaying the finalization of the draft criteria, was invaluable to states' review of a draft criteria intended for state use. However, the need for a comment period extension speaks to the need for greater co-regulator awareness of, and conversation about, potential draft 304(a) criteria. ACWA continues to recommend that EPA build on existing processes to share more about criteria under development with state co-regulators between a criterion's Problem Formulation phase and release of the corresponding draft criteria. ACWA stands ready to appropriately facilitate such dialogues.

While ACWA's process to develop comments is comprehensive and intended to capture the diverse perspectives of the states that implement these programs, EPA must consider the recommendations that come directly from individual states, interstates, and territories. ACWA will be keenly interested in how EPA addresses these comments and those of states, interstates, and territories.

Thank you again for the opportunity to provide recommendations, and for EPA's efforts to reach this important milestone. ACWA looks forward to working with EPA as it completes these and other PFAS criteria and associated implementation materials. Please contact ACWA's Executive Director Julia Anastasio at janastasio@acwa-us.org or (202) 756-0600 with any questions regarding ACWA's comments.

Sincerely,

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Andrew Gavin Deputy Director, Susquehanna River Basin Commission President, Association of Clean Water Administrators

cc: Deborah Nagle, EPA Office of Science and Technology Betsy Behl, EPA Human and Ecological Criteria Division

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Appendix: Detailed Feedback

Summary of Detailed Feedback: In general, the derived values appear consistent with the aquatic toxicity data provided, and states appreciate EPA detailing its approach. States generally expect ambient waters, with exceptions for rare "hot spots," not to exceed the criteria. States' primary concerns with the derivation include varying alignment with the *1985 Guidelines for Deriving Numerical National Water Quality Criteria for The Protection of Aquatic Organisms and Their Uses*, publishing draft criteria when missing MDRs are expected to be fulfilled in the near-term, the protectiveness of selected BAFs, and lack of clarity about the Marine/Estuarine Benchmarks in the context of the CWA.

Communications and Outreach

 The draft values are uploaded to EPA's "<u>National Recommended Water Quality Criteria -</u> <u>Aquatic Life Criteria Table</u>" – this assumed an error and should be removed until values are finalized. Additionally, marine/estuarine benchmarks should not be listed in the table. However, it would be helpful to note the availability of these benchmarks and link to them on the Aquatic Life Criteria Table webpage.

Consistency of Studies' Quantitative Inclusion or Exclusion

EPA should provide a list of all met criteria that resulted in studies being retained qualitatively rather than quantitatively used, so readers can understand the universe of selection criteria that were employed throughout the data selection process. This is especially important given the use of nominal rather than measured concentrations of PFOA/PFOS in many studies underpinning the draft criteria. Generally, EPA should provide specific and justified rationales for studies' inclusion or exclusion, be consistent with these rationales, and review study selection for consistency.

- 1. States are concerned at studies' omission due to husbandry information and/or field-collected populations. Some studies are retained qualitatively because of lack of husbandry information or possible population exposure to PFAS (i.e., in one study, specimens are collected from a public fountain later, EPA claims that study's derived EC50 was likely sensitive due to PFAS exposure, despite lacking water column or tissue concentration data from the fountain or specimens). In several instances, this means important observed effects are not included in the derivation. For example,
 - a. The Flynn et al. (2021) frog population (NOEC of .066 mg/l) was less developed relative to the control population after both Day 5 and study termination⁴. EPA classified the observations as a delayed lifestage effect but excluded this study due to the presence of algae and zooplankton and did not account for the growth/lifestage effect in the derivation calculation. Either diminished adult size or slower progression through lifestages should absolutely be considered effects the criteria should protect against. If EPA invests in conducting studies to satisfy MDRs, EPA is encouraged to support a quantitatively acceptable replicate of this study.

⁴ EPA 2022. "Response to the External Peer Review of U.S. EPA's 'Draft Aquatic Life Ambient Water Quality Criteria for Perfluorooctanoic Acid (PFOA)," 113. EPA-842-D-22-004.

b. States echo on scientific peer reviewer' comment, "the EC10 of 0.076 mg/L for resting egg production observed by Zhang et al. (2014b) is potentially a big deal. EPA appears justified in not using this because it was only one replicate, etc. but these data clearly point to a potentially relevant effect at a relatively low concentration."⁵

Therefore, ACWA recommends:

- a. In study summaries, EPA should note any instance that the control population was tissue-tested for total organic fluorine or PFOA/PFOS; given PFAS' ubiquity and difficulty to treat or detect to low levels until recently, contamination of control populations is possible and even likely in laboratory settings.
- b. EPA should reference any protocols that suggest studied populations in selected studies have not been exposed to PFAS. It is possible study populations have been exposed to some level of PFAS, given the difficulty of treating and/or preventing instrument contamination with PFAS.
- c. While reducing scientific defensibility, study populations gathered from a public setting are still helpful, as they reflect environmental conditions and inform Best Professional Judgment. EPA should provide example derived criteria values for multiple scenarios, including quantitative use of qualitatively retained studies.
- d. EPA could group all studies excluded due to duration misalignment (i.e., chronic studies in the 66-hour range rather than 96-hour) and provide examples of how the criteria would change with their quantitative inclusion.
- 2. As a result of EPA's study selection criteria, oftentimes a single study drives a value (i.e., FAVs, etc.) rather than all the relevant studies. That is, in some instances, multiple studies on a genus or species are reduced to a single study, potentially unnecessarily. In other instances, all studies are quantitatively retained despite not meeting selection criteria. It is clear why EPA leans on certain studies/values, but stronger justifications would help would-be state implementers. This is another reason it would be helpful for EPA to provide example derived criteria/benchmark values for multiple scenarios, including quantitative use of qualitatively retained studies.
- It is recommended individual study methods be consistent with EPA-approved toxicity test methods. For example, the elevated temperatures (25°C) reported for Li (2009) in the PFOA document is inconsistent with USEPA's published method for acute Daphnid tests, "OSCPP 850.1010: Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids" (2016)⁶.
- 4. It is concerning that the 3M (2000) studies were excluded due to the PFOA/PFOS being 95% pure but containing 1-3% C6 C8 etc., while other included studies used PFOA/PFOS with 95% purity but no reporting on the remaining contents of the mixture. Furthermore, while these criteria attempt to derive acceptable values for each analyte, due to atmospheric deposition it is nearly impossible that aquatic exposure to a single PFAS analyte in isolation can occur. EPA should be consistent in considering studies with relatively pure PFOA/PFOS.

⁵ EPA 2022. "Response to the External Peer Review of U.S. EPA's 'Draft Aquatic Life Ambient Water Quality Criteria for Perfluorooctanoic Acid (PFOA),'" 50. EPA-842-D-22-004.

⁶ EPA 2016. "Ecological Effects Test Guidelines OCSPP 850.1010: Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids." EPA-712-C-16-013

Draft Criteria's Conformity with 1985 Guidelines

- When EPA diverges from the 1985 Guidelines in the draft criteria, it often references divergent approaches employed in recent criteria documents (i.e., Selenium 2016, Aluminum 2018). Noting where the draft criteria have parallels is useful and should be retained, however EPA should not build "case law" from past criteria's alternative approaches. It should instead reference the 1985 Guidelines, or strongly justify any excursion from it. For example, BAFs are not a part of the 1985 Guidelines, so stronger rationale and narrative on BAFs in the draft criteria would build its defensibility.
- 2. Non-North American species appear to be included or excluded inconsistently. Besides Zebrafish, which are regularly used in toxicity and risk assessments, EPA uses non-North American Species (example: *Daphnia carinata*) to meet MDRs. <u>This is not consistent with the 1985 Guidelines, and some states' laws and policies preclude them from adopting 304(a) criteria derived using non-resident or non-North American species.</u> Conversely, EPA has *yellow fever mosquito* data (50% Lethal Concentration (LC50)=1.18mg/l), the most sensitive species in the insect dataset available, but omitted these data because the species is invasive/non-North American. This is inconsistent with using non-North American species' data elsewhere in the criteria derivation. If there is any data on the rate of consumption of yellow fever mosquitos by fish/aquatic life, these should absolutely be quantitatively considered.

EPA discussed the influence of using non-resident species. Removing non-North American resident species resulted in 46 mg/L rather than 49 mg/L (acute), and 0.048 mg/L rather than 0.094 mg/L (chronic) for PFOA; and 2.8 mg/L rather than 3.0 mg/L (acute), and 0.004001 mg/L rather than 0.0084 mg/L (chronic) for PFOS. EPA did so, "in order to have the largest, high quality dataset to serve as surrogate species⁷", **but clearly, use of surrogate/non-North American species affects the criteria values – in this case, yielding a potentially less-protective value. EPA should be consistent in its use of North American species in deriving criteria values.**

3. All MDRs should use native species widely distributed in North America, to at least the taxon of family. The 1985 Guidelines specify family as the taxon from which all MDRs must comply. However, in criteria recommendations published since 2013's Revised Deletion Process for the Site-Specific Recalculation Procedure for Aquatic Life Criteria (called Recalculation Procedure), there has been an increase in test organisms belonging to taxonomic families not widely distributed in North America. The updated Recalculation Procedure relies solely on taxonomy as a rationale for the acceptance of surrogates belonging to the taxa of order, class, and phylum. The Integrated Taxonomic Information System (ITIS) is the standard database used for identifying taxonomy.

For example, criteria recommendation documents for ammonia (2013), cadmium (2016), and PFOA and PFOS include in their sensitivity distributions *Xenopus laevis*, which is a harmful invasive species to North America. *X. laevis* belongs to Family Pipidae, for which all genera are naturally distributed in sub-Saharan Africa and the Amazon River Basin. Because genera within Family Pipidae are not naturally distributed in North America, *X. laevis* is an invalid surrogate. A strict following of the Recalculation Procedure would require retention of *X. laevis* if there is a native resident belonging to Order Anura (tailless, short-bodied frogs) and

⁷ EPA 2022. "DRAFT AQUATIC LIFE AMBIENT WATER QUALITY CRITERIA FOR PERFLUOROOCTANE SULFONATE (PFOS)," 131. EPA-842-D-22-002. 1634 EYE Street, NW, Ste. # 750, Washington, DC 20006 TEL: 202-756-0605

no other test organisms for its MDR. If toxicity tests results for all frogs belonging to Order Anura are similar, this recommendation could have some validity, yet for PFOA the acute values for species within Order Anura are: *X. laevis* (377.0 mg/L), *Hyla versicolor* (646.2 mg/L), *Anaxyrus americanus* (793.9 mg/L) and *Lithobates* spp. (951.5 mg/L); the difference between the most and least sensitive tested species in Order Anura for PFOA is greater than a factor of 2.5. For PFOS the acute values for species within Order Anura are: *X. laevis* (15.99 mg/L), *Hyla versicolor* (19.88 mg/L), *Anaxyrus americanus* (56.49 mg/L) and *Lithobates* spp. (109.2 mg/L); the difference between the most and least sensitive tested species in Order Anura for PFOS is greater than a factor of 6.8.

Two other problematic test organisms appearing in criteria recommendation documents that are not naturally distributed in North America and without surrogates within the taxon of family are Neocaridina denticulata (Japanese swamp shrimp) and Oryzias latipes (medaka). For the crustacean, N. denticulate belongs to Family Atyidae which is composed of small shrimp with a distribution concentrated between the tropical latitudes. A strict following of the Recalculation Procedure would require its retention if there is a native resident belonging to Order Decapoda (shrimp, crawfish, lobsters, and crabs) and no other test organisms for its MDR; this taxonomic order is very generic and composed of a wide variety of crustaceans, most likely with all having differing sensitivities to toxic substances due to their unique ecological traits. For the fish, O. latipes belongs to Family Adrianichthyidae which is composed of small fish with a distribution concentrated in southeast Asia. A strict following of the Recalculation Procedure would require its retention if there is a native resident belonging to Order Beloniformes and no other test organisms for its MDR. For some states, some species of Order Beloniformes are found in estuarine/marine waters; however, O. *latipes* is listed in freshwater sensitivity distributions. Thus, its use as a surrogate would be invalid at this taxonomic level. Additionally for fish, the taxonomic level of order is used to describe the general morphology of fish and in no way conveys shared ecological traits or similar toxicity results.

- 4. In these draft criteria, the extent of deviation from the 1985 Guidelines could be construed as a policy change. Nonetheless, deviations of any variety and extent result in more difficult and prolonged stakeholder engagements when states consider adopting 304(a) criteria, and make state criteria/standards less defensible.
 - a. No Observed Effect Concentrations (NOECs) and Low Observed Effect Concentrations (LOECs) are typically reserved for chronic evaluations, but are used in EPA's acute calculations without explanation. EPA should explain its thinking.
 - b. EPA included nominal test concentration data in criteria calculation. Typically measured test concentrations are required for a test to be included in criterion development. EPA details why it chose to use measured and nominal concentrations data, but should also detail how future criteria values may change as future research yields more measured concentrations for use in the derivation. And in the PFOS document, given the importance of the toxicity test concentrations to the final criteria magnitudes, the test details (nominal, measured, substrate, etc.) should be presented in Section 3 and included in Tables 3-2, 3-3, 3-6, and 3-7.
 - c. EPA considered all static, renewal, and flow-through tests for PFOS and PFOA acute and chronic criteria. Typically flow-through tests are preferred for chronic tests

especially according to the 1985 Guidelines (with a notable exception for named species/genus' that do not tolerate flow-through tests).

- d. EPA used both life- and partial life-cycle tests for invertebrates in the derivation of the chronic criterion for PFOS and PFOA. The 1985 Guidelines specify the use of life-cycle test for invertebrates to capture chronic effects.
- 5. Interestingly, where EPA followed the 1985 Guidelines sometimes reflects the 1985 Guidelines' shortcomings. For example, the draft criteria appear to be Endangered Species Act (ESA)-incompatible for some states because the criteria values are less stringent than LOECs for some studied species. Protecting 95% of species 99% of the time, as the draft criteria intends, conflicts with the ESA. ESA-listed species are often in the 5% of species not protected by AWQC. Thus, ESA consultations will generally not approve a state AWQC that is above any available species-specific LOEC, much less the 10% Effect Concentration (EC10) goal EPA is using in the draft criteria (similar to Selenium 2016).

Bioaccumulation Factors (BAFs)

- 1. EPA published tables listing state and international criteria or benchmarks for PFOA and PFOS in ambient waters relative to EPA's draft values. It would be helpful for EPA to do the same for BAFs.
- 2. Organisms used to determine chronic values have no overlap with organisms used in determining BAFs. EPA needs to justify and explain any ramifications here.
- 3. EPA claims the 20th centile BAF protects species whether exposure is low or high, but does not provide a scientific rationale. EPA needs to explain in detail why the 20th centile BAF was selected; given PFAS variability at a single site, let alone multiple sites, as well as the order of magnitude difference between employed BAFs, how can EPA be sure its selected BAFs provides 95% species protection 99% of the time?
- 4. EPA took liberties including employing more stringent model constraints than typical in derivations, such as an EC10 rather than 20% Effect Concentration (EC20) or 10-year chronic frequency rather than 3-year. Why was a more stringent BAF (i.e., 10th percentile) not used?
- 5. The time between paired data is much longer than paired data used in past criteria documents. What uncertainty does EPA calculate the paired data's resolution will yield?
- 6. Due to the variability of the pollutant and aquatic systems, would EPA recommend using the draft criteria to establish site-specific BAFs (as was recommended with the Selenium 2016 304(a) criteria))?
- 7. In fish, speed and extent of observed effects and tissue accumulation after a PFAS chemical disturbance is notably worse in males than females, sometimes by a factor of 10. Is this reflected in the criteria derivation approach?
- 8. Burkhard (2021), the source of BAFs considered by EPA, did not discern a difference between freshwater/marine factors, noting that more research is needed. For this reason, EPA should note the statistical uncertainty of both the marine/estuarine Benchmark and selected BAFs in their first appearance (i.e., executive summary criteria tables and BAF distribution crosstab, respectively).

General

- 1. In the draft criteria, PFOA and PFOS are regularly compared with selenium, specifically the 10-year recovery timeframe in the draft criteria's exceedance frequency. It is noted that selenium is akin to PFOA/PFOS with respect to ecological restoration timelines and the criteria's chronic duration, and that the draft criteria take the reverse approach to the 2016 Selenium criteria (i.e., translating tissue criteria to water column). However, Polychlorinated biphenyls (PCBs) and Tributyltin (TBT) are more similar to PFOA/PFOS in that low or no detection in a water column does *not* mean there will be low/no detection in fish tissue. TBT, like PFAS, is organic, and EPA has derived a water column criterion for it in the past (note that the PFOA/PFOS tissue criteria are BAF-translations of the water column criteria). Therefore,
 - a. EPA should be investing in research to independently characterize the ecological recovery time of PFAS classes and highest-priority analytes. As EPA states, ecological recovery time from chemical disturbances is often situation-specific.
 - b. EPA explains its rationale for using a 10-year chronic frequency, based on PFAS' known persistence and bioaccumulation. However, other persistent compounds have frequencies less than 10 years (PCBs, mercury, selenium) in criteria recommendations. While a long frequency like 10 years is helpful, EPA should review further information and reinforce the justification for using ten years.
- 6. EPA provided some of its web-based function and model approaches (i.e., the R.drc package that is publicly available at <u>https://cran.r-project.org/web/packages/drc/drc.pdf</u>). This is appreciated by state reviewers.

State and Tribe Implementation

- 1. ACWA strongly recommends EPA work with states and ACWA prior to the draft criteria's finalization to scope and develop implementation Technical Support Documents.
- 2. What would sampling need to consist of? The criteria document should suggest the pathways EPA envisions states may follow during implementation. For example:
 - Could states and Tribes sample representative species?
 - Is tissue concentration an average or a different distribution?
 - Could tissue composites be assessed, or would single whole fish/fillets be required?
- 3. EPA pragmatically notes that the selected frequency and duration chiefly account for the non-zero probability of accidental PFOA/PFOS chemical release at a NPDES-permitted facility, and aquatic community recovery thereafter. How would these values translate to NPDES permitting and low-flows? I.e., 1 day, 10 year low flow (1Q10), 7Q10, etc.?
- 4. As states consider potential permit limits and sampling analytical methods, and as the granular clarity of analytical methods improves over time, EPA should note in the study summaries:
 - Methods used by each study;
 - Clarify if any non-detect "<" datapoints were used; and,
 - How the study authors and EPA addressed datapoints <detect.
- 5. Since these criteria do not have HHC or Aquatic-Dependent Life endpoints/components, EPA should discuss how the values may affect states that, in Designated Use classifications, combine ALC/HHC.

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- 6. PFOA and PFOS bind to proteins (blood/liver/muscle) in fish more readily than fats. How did this inform the tissue-based criteria, and can any related information in the draft criteria be used to inform fish and recreational water management?
- 7. EPA should discuss treatment options and technologies for states and utilities evaluating options and cost of reducing ambient PFOA and PFOS concentrations should the draft criteria be adopted.

Marine/Estuarine Benchmarks

- 1. The Marine/Estuarine Benchmark section notes that salinity affects PFAS' availability and toxicity. Was this incorporated into derivation calculation? If so, how? If not, why?
- 2. The benchmark may not protect bivalves. While EPA generally followed the 1985 Guidelines in establishing the marine benchmark, one study noted a Mediterranean mussels LOEC of .0001 mg/l with a 27% effect (reduced reproduction). Bivalves are struggling nation-wide and there is concern that the >1mg/l calculation value EPA used, rather than the LOEC, is not protective. EPA or other federal agencies should invest in toxicity assessments of bivalve's acute and chronic sensitivity to PFAS.
- 3. If Web-ICE could be used to fill missing MDRs to establish a water quality benchmark, can it also be used in 304(a) criteria, especially 304(a) criteria that will likely be revised and reissued relatively quickly due to new data availability?
- 4. Validity of new approach methods (NAMs) in place of ALC Guidelines is unproven. The use of experimental modeling that has not been proven to reliably reproduce toxicity results should not be used in place of criteria derived using the 1985 Guidelines. A review of Appendix L of the PFOA and PFOS documents reveals non-causal, spurious correlations exist between most of the predicted and surrogate species. Most of the accepted data in Table L-3 of both documents have strong R-squared values, with few data points (i.e., low degrees of freedom). Of the 48 data points in the PFOA table, only 12 had n>30; 8 of these 12 (n>30) data points were rejected due to low R-squared values and/or high mean square errors, and 31 of 48 (~65%) had 6 or less degrees of freedom. For PFOS, similar issues are found. Of the 36 data points, only 11 had n>30; 7 of 11 (n>30) data points were rejected due to low R-squared values and/or high mean square of low R-squared values and/or high mean square errors, and 23 of 36 (~64%) had 6 or less degrees of freedom. There is no demonstrable causal relationship between toxicity values of organisms belonging to the Animal Kingdom, or subordinate taxa.

References

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