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EPN Comments on EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

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Founded in 2017, the Environmental Protection Network (EPN) harnesses the expertise of more than 550 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

EPN commends EPA for making a preliminary determination to regulate PFHxS, HFPO-DA, PFNA, and PFBS and for proposing health protective MCLs for PFOA and PFOS. We provide comments on the preliminary determination, the MCLGs and MCLs for PFOA and PFOS, the Hazard Index MCLG and MCL for PFAS mixtures, monitoring requirements, public notification requirements, compliance requirements, and the benefit/cost analyses.

Preliminary Determination

The Safe Drinking Water Act (SDWA) requires EPA to consider the following three criteria when making a determination to regulate: 1) the contaminant may have an adverse effect on the health of persons; 2) the contaminant is known to occur or there is a high chance that it will occur in public water systems often enough and at levels of public health concern; and 3) in the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems.

EPA considered many scientific studies demonstrating that these four PFAS chemicals have adverse effects on multiple biological systems and functions, including thyroid hormone levels, lipid synthesis and metabolism, fetal and infant development, and immune and liver function. EPA also considered data from UCMR3 and twelve state monitoring programs showing that these four chemicals occur above levels of concern in public water systems serving millions of people. Clearly the Administrator can conclude that regulation of these four PFAS compounds presents a meaningful opportunity for health risk reductions for persons served by public water systems.

PFOA and PFOS MCLGs

EPA's Science Advisory Board (SAB) supported many of the elements of EPA's proposed PFOA and PFOS health-based values in the agency's 2022 interim drinking water health advisory document. However, the SAB expressed concerns over the systematic review process used to select the critical studies for health effects. EPA has addressed these concerns by providing additional clarity on the systematic review process

and expanding the systematic review steps included in the health effects assessment. EPA has provided technical support documents for this rule that include the updated health effects literature search and new evaluations of models, methods, and data.

EPN supports EPA's finding that PFOA is likely to be carcinogenic and that the cancer slope factor should be based on a study of kidney cancer in human males. EPN also supports EPA's finding that PFOS is likely to be carcinogenic and that the cancer slope factor should be based on a study of liver cancer in male and female rats. As a result, there is no dose below which either chemical can be considered safe, and the MCLGs for PFOA and PFOS are appropriately proposed as zero.

PFOA and PFOS MCLs

Under SDWA section 1412(b)(4)(B), EPA must generally establish an enforceable MCL as close to the MCLG as feasible. Section 1412(b)(4)(d) defines feasibility as "feasible with the use of the best technology, treatment techniques, or other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)." EPN agrees that EPA has appropriately identified Best Available Treatment (BAT) as granulated activated carbon (GAC), anion exchange (AIX), reverse osmosis (RO), and nanofiltration (NF). We further agree that EPA has appropriately identified small system compliance technologies as GAC and AIX for all small systems serving 25 to 10,000 people, with RO and NF also being BAT for systems serving 3,300 to 10,000 people.

While EPA has presented excellent references to support the designation of these technologies as BAT, EPN notes that EPA has omitted some key references. EPA should cite two reports by the New Jersey Drinking Water Quality Institute documenting seven different GAC treatment plants operating for years in the U.S. that removed PFOA, PFOS, and other PFAS chemicals to non-detectable levels.[1,2] EPA should also cite the New Jersey Drinking Water Watch data which documents that seven GAC plants and five AIX plants in the state have been achieving non-detectable levels of PFOA and PFOS since 2019, with detection limits ranging from 0.53 to 5 ppt.[3]

EPN agrees that EPA should set the MCL for PFOA and PFOS at the practical quantitation level of 4 ppt as implementable and feasible. EPA must be clear that this is not a health-based concentration. Four ppt is the lowest concentration that can be reliably quantified using EPA Methods 537.1 and 533 with specific limits of precision and accuracy during routine laboratory operating conditions. We recognize that 49 of the 54 laboratories seeking EPA certification to analyze UCMR5 samples can achieve a calibration standard of

[1]New Jersey Drinking Water Quality Institute. June 2015. Recommendations on Perfluorinated Compound Treatment Options for Drinking Water
[2]New Jersey Drinking Water Quality Institute. November 2017. Second Addendum to Appendix C: Recommendations on Perfluorinated Compound Treatment Options for Drinking Water.
[3]New Jersey Department of Environmental Protection. Drinking Water Watch.

1 ppt or lower, but we accept EPA's statement that there is not sufficient laboratory capacity nationwide if the quantitation level is set below 4 ppt. We support EPA's recommendation that water systems use measurements below 4 ppt as an early warning that treatment may need to be modified to ensure no exceedances of 4 ppt.

EPN agrees with EPA's finding that potential hazardous waste disposal requirements for spent GAC and AIX resins would increase water system costs marginally but not enough to change the determination that the benefits of the rule justify the costs.

Hazard Index MCLG

EPN commends EPA for using a general Hazard Index (HI) approach to address the additive effects of four co-occurring PFAS chemicals. We note that this approach has been used for years by EPA and the states under the Superfund program and is well-suited to address the thousands of PFAS chemicals in the environment. We believe that the general HI provides a framework for all future PFAS drinking water standards because additional compounds can be included as more information becomes available on their health effects, exposures, analytical methods, and treatment efficiency.

Due to widespread use and persistence, many PFAS compounds are known to co-occur in drinking water and the environment, often found in different combinations as mixtures. All the PFAS chemicals studied to date have been found to cause common adverse effects on several biological systems and functions, including thyroid hormone levels, lipid synthesis and metabolism, fetal and infant development, immune and liver function. The general HI allows for component chemicals to have different health effects or endpoints as the basis for their chemical reference values. A target-organ specific HI is less health protective when contaminants like PFAS impact multiple organs, and the target-organ is not the most sensitive endpoint for all the component chemicals.

EPN recommends the use of a HI for the drinking water standard in addition to individual MCLGs and MCLs because the HI accounts for dose additivity and is thus more health protective. We believe EPA should account for dose additivity in order to comply with SDWA's requirement to set drinking water standards with an adequate margin of safety. We recommend that EPA also provide individual MCLGs and MCLs for the four chemicals to improve rule clarity and maintain consistency with previous drinking water standards. EPN recommends against adding PFOA and PFOS to the HI because these chemicals differ from the other four PFAS chemicals in having MCLGs of zero, a level well below analytical quantitation levels, and their addition would obscure the risks posed by the four more-recently manufactured PFAS chemicals.

EPN supports the proposed use of ATSDR's intermediate-duration oral Minimal Risk Levels for PFHxS and PFNA and EPA's reference doses for HFPO-DA and PFBS as representing the best available science on the toxicity of these chemicals. We further support EPA's selection of the relative source contribution and

most sensitive person in calculating the health-based reference values for these four chemicals. We note that the revised PFAS Mixtures Framework provides strong support for the dose additivity of PFAS chemicals and the need for a HI approach.

EPN finds that EPA's analysis of UCMR3 data and state data provides convincing evidence that these four PFAS chemicals co-occur in public water systems serving millions of people at a frequency justifying use of a mixtures approach. EPN agrees with EPA's statement that there should not be a bright line threshold for occurrence in drinking water that triggers whether a contaminant is a public health concern justifying a national drinking water standard. In addition to frequency of occurrence, the potency of the chemical, geographic distribution, impacted population, and type of health effects should be considered in deciding whether to regulate a drinking water contaminant. Based on all of those factors, EPN agrees that a HI of one is an appropriate MCLG indicating no appreciable risk.

EPN recommends that in the final rule, EPA commit to reviewing the results of UCMR5 as soon as data are available to identify any co-occurring PFAS. EPA should further commit to proposing a rule that sets a standard for them as a group using a novel approach currently under development by ORD.

Hazard Index MCL

EPN agrees that EPA's HI MCL of one is implementable and feasible, and we commend EPA for setting the MCL equal to the MCLG. EPN agrees that EPA has appropriately identified BAT achieving this HI of one as GAC, AIX, RO, and NF. EPA asks for public comment on whether these technologies will also remove other PFAS not included in the rule. Studies cited in this rule and EPA's Drinking Water Treatability database show that GAC and AIX removal efficiencies generally increase as PFAS chain length increases. RO and NF have higher removal efficiencies than GAC and AIX for short chain PFAS. EPN recommends that EPA review drinking water treatment data from Massachusetts, Vermont, and Michigan because these states have MCLs for PFAS not included in this rule (PFHxA, PFHpA, PFDA). They should have monitoring data indicating removal efficiencies for these three additional PFAS.

EPA's HI MCL of one is also implementable and feasible because EPA Methods 537.1 and 533 have quantitation levels (ranging from 3 to 5 ppt) below the health-based reference levels for these four PFAS chemicals. These low quantitation levels allow public water systems (PWS) to take early action to modify treatment if monitoring data indicate concentrations of the four PFAS are approaching the health-based reference levels.

Monitoring Requirements

EPN agrees that the PFAS monitoring scheme should be based on the existing standard monitoring framework established for Synthetic Organic Compounds and other chemical regulations, which tailors the

monitoring frequency to previous monitoring results. This reduces monitoring cost if the likely result is already known. The danger is that PWS may not monitor because they believe incorrectly that their monitoring has been waived. It is critical that the primacy state communicates the required monitoring frequency to each PWS large and small and reports a monitoring/reporting violation to EPA and the public. If states fail to do this, there is a high likelihood of severe underreporting of monitoring violations. EPN strongly recommends that the final regulation require all PWS to conduct an initial round of monitoring unless explicitly waived in writing by the state.

The rule proposes running average concentrations to calculate compliance and proposes using zero if the sample result is less than the quantitation level even though labs can reliably measure lower than that level. EPN strongly recommends that EPA use a level that is 1/3 of the MCL (1.3 ppt for PFOA/PFOS, 1.0 ppt PFHxS, 1.7 ppt HFPO-DA, 1.3 ppt PFNA, 1.0 ppt PFBS) instead of zero for samples less than the quantitation level. The use of zero for these samples is not health-protective, as we show in our comments below on section 141.903.

EPN is concerned that the proposed rule does not specifically address monitoring requirements for seasonal non-transient non-community water systems (e.g., schools and camps/resorts) and seasonal sources (e.g., sources that are online as needed to handle peak or seasonal demand above normal levels). We strongly recommend the addition of these monitoring requirements to the final rule in order to ensure health protection.

In the rule sections below, EPN recommends specific changes in order to clarify the monitoring requirements. We also recommend deleting redundant text in several sections because the language is inconsistent and can lead to confusion and poor implementation of the monitoring requirements.
Para (l) – effective date should be the first day of a calendar quarter in order to simplify compliance monitoring. When the final rule is submitted to the Federal Register for publication, EPA should put a date certain rather than basing it on the vagaries of Federal Register publishing schedule. The Office of Ground Water and Drinking Water has done this in the past, including for the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR) and the Long Term 2 Enhanced Surface Water Treatment Rule. This simplifies setting up quarterly monitoring.

§ 141.50

Para (b)(34) footnote 1 – there is inconsistent use of significant figures. For example, PFNA is 10 ppt, while PFHxS is 9.0 ppt, HFPO-DA is 10.0 ppt and PFBS is 2000.0 ppt. Also, the equation at the end of the footnote uses different significant figures. Finally, the use of *i.e.* instead of *e.g.* appears to be more appropriate.

§ 141.60

Para(a)(4) – refers to effective dates for paragraphs not included in the proposal. It appears that the reference should be to 141.61(c)(34)-(36).

§ 141.900

Para (b) – no language proposed.

Para (c) – appears to be at least partially redundant to the requirements in para (a).

§ 141.XX (assume this should be 141.902)

Para (a)(3) – monitoring violations should be for all quarters for which a missed sample would have been used for running annual average calculation, as was done for Stage 2 DBPR. See 141.625(b).

Para (a)(4) – Redundant to 141.903(c). Should be deleted.

Para (a)(6) – New systems and new sources should be required to be in compliance prior to going on line. The proposed language is ambiguous.

Para (b)(1)(i)-(iii) – use the already defined term "subpart H systems" (see 141.2) to refer to systems using either surface water or groundwater under the influence of surface water in paragraphs (i) and (ii). This will make paragraph (iii) redundant. Also, why is there a reference in paragraph (iii) to the State being allowed to require more frequent monitoring but no such reference in paragraphs (i) and (ii)? This could imply that the State couldn't require more frequent monitoring under those paragraphs, which doesn't appear to make sense.

Para (b)(1)(iv) – Table 1 is more specific and clear than paragraphs (b)(i)-(iii) except that systems using GWUDI are not included in the table. Use of "subpart H systems" in the table makes paragraphs (i)-(iii) redundant and reduces inconsistency and ambiguity. Also requiring samples at least 90 days apart for large groundwater systems and all subpart H systems is not practical. The requirement should be for samples to be collected every third month to ensure appropriate spacing while allowing systems and laboratories to collect and analyze samples in a cost-effective manner. EPA and States had implementation issues with the Stage 2 DBPR because of this issue. Finally, it is not clear why the term "taken" is used for one set of systems and "acquired" is used for another set of systems in the table and elsewhere in the rule.

Para (b)(1)(vi) – use "subpart H systems."

Para (b)(2)(i) – allows systems to be on reduced monitoring for some entry points and on routine monitoring for others. It could also be interpreted to allow reduced monitoring for some contaminants but not others at individual EPTDS. This is, at a minimum, a tracking nightmare and makes it difficult to develop and implement a monitoring plan. It also may be less protective of public health. However, Table 2 appears to require that all analytes meet the reduced monitoring requirement for any analyte to be on reduced monitoring. To reduce ambiguity and confusion, requirements should not be repeated if possible. Instead, they should be cross referenced as necessary. Also, tables are generally clearer than text.

Para (b)(2)(iii) – Use "locational running annual average" ("LRAA") in lieu of "running annual average" in this paragraph and elsewhere (*e.g.*, 141.903(b)).

Para (b)(2)(vi) – Requires States to designate monitoring time. This imposes a tremendous and unnecessary

implementation burden on the State. Should be "according to the monitoring plan for the system." The State retains its authority to review and require modifications.

§ 141.903

Para (c) – clarify that this is both a monitoring violation and that RAA/LRAA is calculated by dividing by the actual number of samples (which could also be an MCL violation if the RAA/LRAA exceeds the MCL).

Para (d) – seems partially redundant to 141.902(b)(2)(iii). System must begin quarterly monitoring when a result exceeds the trigger.

Para (e) – should be under paragraph (f) rather than as a separate paragraph.

Para (f)(1) – For clarity, add "determine MCL compliance at each EPTDS by calculating the LRAA for each subpart Z analyte" to the end of the sentence.

Para (f)(1)(ii)(A) – seems redundant and probably less stringent than 141.902(b)(2)(iii). Systems must begin quarterly monitoring when a result exceeds the trigger, not just the MCL.

Para (f)(1)(iii) – use of zero for monitoring results below the PQL for any analyte except PFBS is not protective of health. For example, assume EPTDS PFOA results for 4 consecutive quarters are 3.8, 3.8, 3.8, and 5.2 ppt. Using zero for the 3 quarters with results below the PQL of 4.0 results in an LRAA of 1.3 ppt ((0 + 0 + 0 + 5.2)/4). The system nearly meets criteria for reduced monitoring. If systems must use the detection limit, the LRAA is 4.1 ppt ((3.8 + 3.8 + 3.8 + 5.2)/4), which is an MCL violation. For HI calculations, there is a similar issue. Hazard quotients (HQ) for HFPO-DA <0.5 (<5/10), PFHxS <0.33 (<3/9), and PFNA < 0.4 (<4/10) would be zero for HI compliance calculations, which is not protective.

Para (f)(2)(i) – Last sentence should read "…, the system is in violation of the Hazard Index „„".

Para (f)(2)(ii) – See comments on paragraph (f)(1)(iii) of this section.

§ 141.904

Table 1 – references in 3 and 4 seem to be to 141.903, not to 141.902.

§ 141.905

Para (a) – correct reference to 141.XX.

Para (b)(2) and (b)(2)(i) – see 141.629(a)(1)(iii) for MCL RAA/LRAA violations based on fewer than four quarters of monitoring.

Para (b)(2)(iii) – redundant to 141.903. Also see other comments regarding use of zero for monitoring results < PQL.

Public Notification

EPA proposes that violations of any one or more of the three MCLs would be designated as Tier 2. As a result, the PWS must notify the public of the violation as soon as practicable but no later than 30 days after the system learns of the violation. EPN recommends that EPA clarify that public notification must occur whenever there is a violation at any one distribution point. EPN further recommends that the public notification should remain in place until the public water system returns to compliance, as required.

Compliance Requirements

EPA proposes allowing states to provide extended compliance dates to PWS needing additional time for capital improvements. For small systems serving at or below 3,300 people, the extension can be 14 years after this rule is promulgated. Fourteen years is unjustifiably too long given the availability of effective treatment technologies. EPA asks for public comment on whether there should be specific conditions mandated for PWS to be eligible for these extensions so that they are used only when no other viable alternatives exist. EPN agrees that there should be specific conditions mandated for PWS to be eligible for these extensions and recommends that state consideration of extending compliance dates for PWS with violations be a negotiated compliance agreement under a formal enforcement response to the violation. The specific conditions for extended compliance dates for a PWS should be set as a condition of state primacy for the new regulation. PWS in violation should continue to be reported in violation until they return to compliance under the negotiated compliance agreement.

Benefit and Cost Analyses

EPA developed a comprehensive framework for evaluating the costs and benefits of regulating the six contaminants addressed in this rulemaking. However, given data limitations, the agency's quantitative analysis was limited primarily to PFOA and PFOS, and, to a more limited extent, PFHxS. EPN commends EPA for quantifying benefits from multiple health effects, including reductions in heart attacks and strokes, developmental impacts to fetuses and infants, kidney cancer cases resulting from control of PFOA and PFOS, and reductions in bladder cancer cases from disinfection byproducts as co-benefits. We also commend EPA for describing all the significant health effects they were unable to quantify, as well as clarifying the sources of uncertainty in their analysis. We note that EPA did a more comprehensive quantification of costs, leaving only two types of costs unquantified for PFOA, PFOS and PFHxS (hazardous waste disposal of treatment media and POUs not in compliance). The end result is that EPA estimates the expected value of net annual incremental benefits to be $461M using a 3% discount rate and -$297M using a 7% discount rate. Consideration of all the unquantified benefits would likely result in positive benefits under the 7% discount rate, but the appearance of negative benefits is concerning.

EPA used the 3% and 7% discount rates because those are the default rates recommended by OMB in Circular A-4 which guides federal agencies' regulatory analyses. On April 6, 2023, OMB released an updated Circular A-4 for public comment. OMB is now recommending that the default discount rate should instead be 1.7% based on analyses of the inflation-adjusted average interest rate of federal securities over the past 30 years on a pre-tax basis. OMB further states that using a higher discount rate to account for risk would be inappropriate when evaluating regulations that reduce risk. Accounting for this risk reduction would be

akin to using a lower, not higher, discount rate. EPN recommends that EPA redo their benefit and cost analyses using the 1.7% discount rate which will undoubtedly indicate even greater net annual incremental benefits than the 3% rate and further bolster the justification for these PFAS drinking water standards. In the final rule, EPA should quote this new OMB guidance and eliminate the 7% discount rate analyses, even if the new guidance has not yet been finalized.