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May 30, 2023

U.S. Environmental Protection Agency
Office of Water
Health and Ecological Criteria Division
Washington, DC

RE: MassDEP Comments on PFAS National Primary Drinking Water Regulation Rulemaking
Docket ID No. EPA-HQ-OW-2022-0114

Dear EPA Reviewers:

The Massachusetts Department of Environmental Protection (MassDEP) commends the U.S. Environmental Protection Agency (EPA) for working to develop a National Primary Drinking Water Regulation (NPDWR) for Per- and Polyfluoroalkyl Substances (PFAS) and is pleased to submit comments on EPA's PFAS National Primary Drinking Water Regulation Rulemaking, published March 29, 2023 (88 Fed. Reg. 18638).

The Commonwealth of Massachusetts has a strong record of addressing emerging contaminants in drinking water and is committed to continuing to protect public health through ensuring safe drinking water from public water systems (PWS). Specifically, MassDEP has been at the forefront of regulating PFAS in drinking water. In October 2020, Massachusetts established one of the most protective, enforceable drinking water standards in the nation of 20 nanograms per liter (ng/L) (or parts per trillion (ppt)) for the sum of six PFAS and required all PWS to test for PFAS in their drinking water. In addition to these requirements, between July 2020 and June 2022, MassDEP implemented a PFAS Free Analyses Program for PWS and select private well owners to provide the opportunity for one round of free PFAS drinking water analysis and technical assistance. 1,171 public water systems and 1,668 private wells were sampled as part of this initiative. To date, all PWS in Massachusetts have completed at least one round of sampling of their finished water sources for PFAS and MassDEP continues to work with systems to reduce levels.

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In addition to regulatory and technical assistance activities, Massachusetts has already provided PWS in the state with financial assistance to address PFAS. MassDEP and the Massachusetts Clean Water Trust have provided 0% interest rate loans totaling more than \$149 million to remove PFAS contamination from drinking water in communities across the Commonwealth.

Massachusetts is committed to continuing its strong track record of addressing emerging contaminants in drinking water. MassDEP is preparing Massachusetts PWS for the adoption of EPA's PFAS NPDWR and is pleased to offer these comments.

1. Preventing PFAS Releases

This proposed NPDWR for PFAS is a critical step to protect drinking water, but EPA must continue working to prevent PFAS from entering drinking water sources. MassDEP commends EPA's efforts using all the Agency's authorities, both regulatory and non-regulatory, to address PFAS contamination across media and recommends that these efforts be accelerated.

Holistic Approach

MassDEP recommends that EPA extend its efforts using a holistic lifecycle approach that includes close coordination with other Federal agencies to utilize all possible Federal statutory and regulatory authorities to address PFAS concerns.

Using a holistic approach to reduce or eliminate the use of PFAS and to prevent these compounds from entering the environment and drinking water sources throughout any part of these chemicals' lifecycle - from manufacturing through processing, distribution, and disposal - is much more effective and less expensive than removing PFAS once contamination has occurred. Protecting drinking water sources (and preventing contamination) is essential for sustaining safe drinking water supplies, protecting public health and the economy, and has many additional environmental benefits.

The PFAS NPDWR is an important step in addressing PFAS contamination; however, numerous other regulatory decisions may be made based on drinking water standards (e.g., ground water remediation determinations, National Pollution Discharge Elimination System (NPDES) permits, and surface water standards). EPA should expand coordination across all the Agency's offices and with other federal Agencies (i.e., the Department of Defense, the Food and Drug Administration, and Centers for Disease Control and Prevention) to reduce PFAS contamination. This should include consideration of post-treatment impacts from disposal and incineration under each regulatory authority to ensure that the responsibility and cost for removing PFAS are not passed on from one media to another. This should also include consistent messaging to regulators, regulated entities, and the public.

Wastewater and Stormwater

MassDEP supports EPA's work to address PFAS under the Agency's PFAS Strategic Roadmap. The Agency's approach to "get upstream of the problem" is paramount to the long-term protection of both surface water and ground water sources of drinking water.

EPA must expedite the Agency's work to address PFAS in wastewater and stormwater inflows and discharges, including the development of rulemakings for PFAS effluent limitation guidelines for the organic chemicals, plastics and synthetic fibers, and metal finishing and electroplating point source categories, as well as studying PFAS inputs and discharges from landfills, paper and textile mills, and electrical and electronic components. The Agency should work to finalize Draft Method 1633 in a timely manner for laboratories to analyze samples of surface water, groundwater, and other media. EPA should also finalize the national recommended ambient water quality criteria for PFAS. MassDEP awaits EPA's assistance and guidance in these areas in connection with the development of water quality standards and future regulation of the discharge of PFAS in wastewater effluent. Further Clean Water Act actions should continue to be taken simultaneously with the Agency's other efforts. PFAS will remain a problem for drinking water systems so long as all sources of PFAS contamination are not addressed.

Waste Disposal

MassDEP recommends that EPA prioritize research on waste disposal methods and move to regulate PFAS waste disposal as soon as possible to ensure that PFAS contamination is not being moved from one media type to another. EPA should finalize its Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances ahead of the final rule.

The current information on other environmental impacts of PFAS disposal is limited, and the Best Available Technologies (BATs) listed for complying with the Maximum Contaminant Level (MCL) have waste streams that will need to be appropriately addressed, including spent Granular Activated Carbon (GAC) media or ion exchange resin, Nanofiltration (NF) and Reverse Osmosis (RO) brine water, and spent Point of Use/Point of Entry (POU/POE) devices. Although PFAS has not yet been designated under the Comprehensive Environmental Response, Compensation, and Liability Act as a hazardous substance, some systems have already reported being unable to dispose of their PFAS-containing media as some waste disposal sites are refusing to accept the material. PFAS is only included in a limited number of NPDES permits, and so PFAS-containing reject water from NF/RO applications going to wastewater treatment facilities may not be removed, returning to source water locations. There is limited research on using underground injection control wells for NF/RO reject water. There is also limited research on thermal regeneration of GAC and the release of PFAS to the atmosphere. MassDEP strongly recommends that EPA continue to pursue research on waste disposal options for PFAS to ensure long-term mitigation. As these waste disposal options are developed and regulated, EPA should ensure that systems are able to reasonably comply with those options. Additionally, MassDEP recommends that EPA update and finalize the Agency's Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances in advance of the final rule.

2. Guidance and Training Needed

MassDEP recommends EPA prioritize the development of robust guidance, training, and implementation tools as part of the promulgation of the final rule.

PFAS will be the first new nationally regulated drinking water contaminant in over twenty years. State agencies and water systems should have clear guidance from EPA on rule implementation. Guidance, training, and implementation tools should be released when the rule is finalized, or as soon thereafter as feasible, so that all stakeholders are able to effectively implement the rule ahead of the compliance date. EPA should partner with the states in the development of guidance, training, and tools, which should include the following:

- Regulatory implementation guidance to ensure consistency across primacy agencies and EPA regions, including details on initial monitoring, compliance determinations, the trigger level for reduced monitoring, and using previously collected data for monitoring determinations.
- Templates for public notice, including minimum required elements.
- Detailed information for water systems on the available PFAS mitigation strategies that consider scalability, including considerations for using an alternative water source, POU and POE devices, and BAT installation.
- Updated guidance regarding residual waste handling and disposal, ideally including for POU devices.
- Detailed information for primacy agencies to aid in the review of PFAS mitigation strategies (i.e., installation of BAT, use of POU/POE devices, or switching to an alternative source), including best practices for ensuring the long-term maintenance of each strategy. This information should include recommended sampling plans for each option to ensure efficacy.
- Best practices for pilot testing BATs, including examples of successful pilot test results. To the extent practical, baseline water quality should be considered to guide pilot testing and effective treatment.
- Updated guidance on simultaneous compliance, especially in consideration of chemical contaminants, lead, corrosion control, and disinfection byproducts.
- Information on the expected compliance timelines for mitigating an MCL violation.
- Funding roadmap targeted at small and disadvantaged communities, outlining options across state and federal programs to ensure systems are funded in the most effective way possible.
- Guidance for water systems considering their treatment and non-treatment options to address the PFAS MCLs. EPA should include considerations such as the necessary operator skill level, the fraction of water wasted, waste disposal, maintenance and O&M costs in that guidance to ensure systems fully evaluate their options and understand the challenges associated with the various options.
- Updated in-depth simultaneous compliance guidance to help ensure that compliance with one contaminant is not being traded for another. Drinking water chemistry is very complex and we want to ensure treatment is protecting consumers from all NPDWR contaminants.

3. EPA Analysis of Primacy Agency Staff and Resource Burden

EPA's analysis of primacy agency resource implications does not fully capture all the activities that primacy agencies will undertake to implement the PFAS NPDWR and underestimates the number of hours for primacy agency tasks. MassDEP has been regulating PFAS in drinking water since October 2020

and has significant experience estimating the impacts of rule implementation on MassDEP's staff. EPA should substantially increase support to states to facilitate implementing the rule.

EPA underestimates the time for MassDEP to read and understand the rule, as well as adopt regulatory requirements. The amount of time needed to adopt regulatory requirements will vary greatly across the country. MassDEP has requirements for robust public comment periods as a component of new rule adoption. Additionally, MassDEP may need to modify its laboratory accreditation program which will increase the amount of staff resources needed for implementation.

EPA assumes that the amount of time a primacy agency will need to review treatment plans directly correlates with the size of the water system, but this assumption is inaccurate. Assisting small systems often takes the most time, as they need significant support navigating the process for the design and construction of new treatment to get into compliance. MassDEP often works with these systems to locate consultants for preliminary engineering reports (PERs), develop construction plans and specifications, help obtain funding, and manage construction. Additionally, this assistance often lasts beyond the construction and start-up of the treatment to include ongoing operation and maintenance (O&M) support.

EPA's assumption that the proposed regulation would not cause any additional primacy agency staff time to be needed to comply with the reporting requirements of 40 CFR § 142.15 is inaccurate. The proposal will be a new regulation that will impact several hundred systems in Massachusetts and is likely to result in many violations once finalized. Reporting such violations and other elements of § 142.15 (variances and exemptions, enforcement actions, and general operations of primacy agency programs) will take additional time and effort.

EPA's estimate of four hours for the primacy agencies to review source water changes is inaccurate. Changing sources typically has significant implications on finished water quality, such as implications for corrosion control, disinfection by-products and disinfectant residual, that need to be carefully considered. This analysis of the potential for unintended consequences from source water changes will take significantly longer than four hours.

EPA's estimates do not appropriately consider the amount of primacy agency staff time needed to implement pilot testing for new treatment. Staff review time will be needed for both designing the pilot and analyzing all the pilot testing data, ranging from a desktop analysis to bench-scale testing to a full pilot plant. EPA underestimates the amount of technical assistance that will be needed for systems to come into compliance. The complexities of the PFAS regulation will drive the development and delivery of a significant amount of in-person training. This is the case even in the Commonwealth, despite our prior experience implementing the Massachusetts PFAS MCL, because the federal standard, if adopted, would require additional training due to the differences between the state and federal rules and would cover many additional public water systems that have not previously had to treat or otherwise remediate PFAS.

EPA's trigger level for quarterly monitoring is very low - right at the detection limit of these compounds. Although a PWS may qualify for reduced monitoring, subsequent rounds of monitoring could identify

trace amounts of PFAS that would return the PWS to quarterly monitoring. Primacy agencies will spend significant resources developing reduced monitoring schedules, and making determinations to change monitoring frequencies, and tracking compliance schedules for systems that go back and forth between quarterly monitoring and reduced monitoring.

EPA's proposal does not allow the state sufficient time to develop appropriate reporting mechanisms. Due to initial monitoring that may begin immediately after final rule promulgation, reporting of this data will likely have to be either via paper, which will introduce a burden on states that currently receive such results electronically, or via an electronic process that is not CROMERR compliant as there will be insufficient time to develop, test and launch a new system or to modify an existing system.

4. Data Management

EPA should take steps to ensure that DW-SFTIES is capable of fully managing the data of the proposed rule.

The importance of data management in the effective implementation of any rule cannot be understated. Massachusetts currently uses a database developed in-house, the Water Quality Testing System (WQTS), to store system inventory, system staffing, monitoring schedules, water quality results, inspections, rule milestones, violations and enforcements. WQTS records are used to meet our primacy agency reporting obligations and to keep the public informed of the quality of their drinking water. WQTS has been modified to implement the Massachusetts PFAS rule but will likely need additional changes to reflect EPA's PFAS NPDWR and its new reporting requirements. MassDEP intends to transition into EPA's modernized system, the Drinking Water State Federal and Tribal Information Exchange System (DW-SFTIES) after its anticipated release date of January 1, 2025. DW-SFTIES must include all the fields and functions necessary to manage the new PFAS rule.

EPA should develop a mechanism for migrating UCMR5 data into state data systems to reduce or eliminate state burden.

Managing PFAS data across multiple systems presents a challenge for water systems that have submitted Unregulated Contaminant Monitoring Rule (UCMR5) data to EPA through the Safe Drinking Water Accession and Review System (SDWARS) and that request reduced monitoring based on those data. No process exists to migrate these data into state data systems. The existing SDWARS data download option is missing key data elements (Laboratory IDs, Minimum Reporting Levels (MRLs), Date Extracted, Date Analyzed, etc.) necessary to determine its applicability to substitute for initial monitoring. Furthermore, the inability to download quality control data, which must be viewed in SDWARS one analyte at a time, may complicate the process. Full electronic data packages of UCMR5 samples which include the results of field reagent blanks (FRBs) required by the method are needed for states to consider using these results for compliance. Absent this capability, MassDEP may not be in a position to offer public water systems the opportunity to substitute UCMR5 data for initial monitoring.

EPA must provide Data Entry Instructions (DEIs) within six months of the promulgation of the rule to allow primacy agencies, particularly "SDWIS Free" programs, to prepare their systems.

MassDEP will need time to prepare its current database, WQTS, to meet the new requirements. To ensure WQTS is prepared to manage the data and to ensure timely reporting to EPA, access to the Data Entry Instructions (DEIs) within at least six months of promulgation of the rule is critical. This need is especially great as MassDEP is a “SDWIS Free” program that cannot begin this work without a final DEI.

5. Public Communication

Risk communication

MassDEP recommends that EPA work directly with the Association of State Drinking Water Administrators (ASDWA) and its members as well as other stakeholders on developing risk communication materials for the PFAS NPDWR before the rule is final, including identifying and addressing gaps in currently available materials.

A substantial number of helpful risk communication resources, such as the Water Research Foundation’s toolkit, as well as state-specific fact sheets and web pages, have been developed and released over the past few years. While these materials are helpful, EPA should provide additional risk communication resources for broad use across the water sector.

MassDEP appreciates EPA’s willingness to work with the primacy agencies on risk communication after the Agency’s health advisories were released in 2022. MassDEP recommends that EPA continue to ask the primacy agencies for feedback on the materials released by the Agency to identify areas that require clarification or improvement. These opportunities allow for engagement with primacy agency staff with expertise in public communication to substantially improve these materials. MassDEP recommends that EPA work directly with ASDWA and its members as well as other stakeholders on the risk communication materials for the PFAS NPDWR. Further, MassDEP recommends that EPA work with the primacy agencies prior to publication of the final rule to identify and address communication gaps. MassDEP recognizes that some materials will not be able to be publicly distributed ahead of time, but state staff can provide valuable insights to help improve EPA’s communications materials.

To assist with the development of the risk communication materials, we’ve identified the following focus areas for EPA’s materials:

- Explain the differences between the 2022 health advisories, the Maximum Contaminant Level Goal (MCLG), and the MCL, and what they mean from the perspectives of human health and feasibility.
- Explain the differences between Practical Quantitation Limit (PQL), Method Detection Limit (MDL), MRL, etc., and ensure that this explanation is consistently applied throughout EPA’s materials, the rule language, and the preamble.
- Provide language for water systems to use when the results of PFAS testing are above detection and the health advisory but below the PQL.
- Further explain the rationale behind the trigger levels EPA has chosen for determining reduced monitoring. These levels are above the health advisories and therefore might require a more detailed explanation to the public.
- Provide further information as to what the Hazard Index (HI) is and how it relates to the MCLs.

Public notice

MassDEP supports EPA's decision to utilize Tier 2 public notification (PN) for the PFAS NPDWR. Note that, as the proposed rule is presented in the Federal Register, the proposed updates to Appendices A and B of Subpart Q of 40 CFR Part 141 appear incomplete. The new PFAS entries under the Synthetic Organic Chemicals (SOC) heading, rows 31-33 in Appendix A, lack Contaminant names and the citations for "Monitoring & testing procedure violations" are incomplete ("141.XX") (88 Fed. Reg. 18638, 18749). The new PFAS rows in Appendix B to Subpart Q of Part 141 lack the row numbers 90-92 (88 Fed. Reg. at 18750). Additionally, based on the existing SOC entries, when the MCLG is zero the word is spelled out rather than listing the number "0." The "MCLG mg/L" and "MCL mg/L" headers need to be modified to add "(unless otherwise noted)" to accommodate the HI. If the intent of footnote 24 is to refer to the HI definition, then move the footnote to the Contaminant entry.

Laboratory capacity

MassDEP believes that tripling the number of PWSs needing laboratory services, as the PFAS NPDWR is expected to do, will likely affect laboratory capacity. MassDEP recommends staggering the initial monitoring requirements across the three years between the effective and compliance dates of the final rule, as was done in the Stage 2 Disinfectants/Disinfection Byproduct Rule, to avoid overwhelming laboratories. States are obligated, pursuant to 40 CFR § 142.16(e)(2)(i), to include a plan in their primacy applications that addresses scheduling of initial monitoring and "demonstrate[s] that analytical workload on certified laboratories has been taken into account", to identify and/or develop contingencies should capacity issues arise. While it is possible that this NPDWR will encourage more laboratories to establish PFAS analytical capabilities, EPA should work with the states to plan sufficient laboratory capacity until any such increased capacity is established.

EPA should revise the use of significant figures to ensure accuracy and consistency throughout the proposed rule and supporting materials.

The proposed rule uses an inconsistent number of significant figures for numeric values in the proposed rule. For example, the footnote to the table at 40 CFR § 141.50(b) shows the Health-Based Water Concentration (HBWC) for HFPO-DA as "10.0" ppt (three significant figures), but the formula used for the HI in that same footnote uses "10" (one significant figure). This inconsistency also occurs for PFBS ("2000.0" followed by "2000"). EPA's June 21, 2022, FR notice for the HAs upon which these HBWCs are based uses "10" (one significant figure) for GenX (HFPO-DA) and "2,000" (one significant figure) for PFBS. The same issue arises in the footnote to the table in § 141.61(c) where, in addition to the above examples, the HBWC for PFNA is shown as "10.0" and "10." EPA should ensure that all references to numeric values in the rule and all supporting materials, including presentations and fact sheets, use a consistent number of significant figures. As different labs may report results with different numbers of significant figures, it is important that EPA establish a consistent regulatory standard so that when results are used for compliance, appropriate rounding practices are applied. Compliance is often determined on a fine line between one value and another and will be even more so in this NPDWR as the MCL is being set so close to the limit of analytical capabilities.

Consumer Confidence Reports (CCR)

Edits to 40 CFR § 141.151(d) reference “levels prescribed § 141.902(a)(9)” which appears to be missing the word “by” prior to the citation. Note also that § 141.902 appears as “§ 141.XX” on page 18751 of the Federal Register notice. § 141.902(a)(9) defines a “reportable detection” as those “at or above one-third of the levels described in the table outlined in § 141.903(f)(1)(i)(3).” This table contains the PQLs, which, by definition in § 141.2, are “the minimum concentration of an analyte (substance) that can be measured with a high degree of confidence that the analyte is present at or above that concentration.” This requirement would mean reporting PFAS detections in the CCR below the PQL which would be estimated concentrations (qualified results). As the proposal does not use these estimated concentrations when calculating compliance with the MCLs, reporting these in the CCR would generate public confusion and suggest these are the true levels. Rather than citing § 141.902(a)(9), the CCR revision should cite § 141.903(f)(1)(i)(3) directly and only require CCR reporting of detections at or above the PQL.

The revision to Appendix A to Subpart O of Part 141 – Regulated Contaminants should include an edit to the “Traditional MCL in mg/L” header to add “(unless otherwise noted)” as was proposed to the table in §141.61(c). The purpose of footnote 2 on the HI MCLG value is also not clear (on page 18749 of the Federal Register notice). If the intent is to refer to the HI definition, then move the footnote to the Contaminant entry.

6. Monitoring, Analyses, Recordkeeping and Violations

Compliance dates

40 CFR § 141.900(b) does not include any proposed Compliance dates (or a formula based on the date of final promulgation). EPA should include the usual placeholder that allows for three years after the date of the final rule promulgation.

Analytical requirements

MassDEP submits the following comments and questions related to the analytical requirements set forth in 40 CFR § 141.901 of the proposed rule (beginning on page 18750 of the Federal Register notice):

- There appears to be a table missing from the proposed rule as referenced in § 141.901(b)(2)(i) “Beginning...report quantitative data for concentrations at least as low as the ones listed in *the following table* [emphasis added] for all PFAS samples analyzed for compliance with § 141.902 (Monitoring Requirements).”
- It is unclear why a new Subpart would have a [Reserved] section at § 141.901(b)(2)(ii).
- MassDEP notes that EPA Method 537.1 v 2.0 (March 2020, EPA/600/R-20/006) is omitted from 40 CFR § 141.901(a)(2). Is it EPA’s intent not to accept this updated version of Method 537.1?

Similarly, was direct EPA certification of laboratories intentionally omitted in § 141.901(b)(2)? EPA certified laboratories are acceptable for other SOC analyses as per § 141.24(f)(17).

Monitoring and compliance requirements

MassDEP submits the following comments and questions related to the monitoring and compliance requirements set forth in 40 CFR § 141.902 and § 141.903 of the proposed rule (beginning on page 18751 of the Federal Register notice):

- The end of § 141.902(a)(7) should be reworded, “and 0.33 for the PFAS Hazard Index.” Are these triggers evaluated using qualified (“J” estimated) sample results or are individual results below the PQL replaced with zeros as is proposed for MCL compliance calculations?
- Does § 141.902(a)(8) require quarterly monitoring based on individual detections at or above the trigger level during initial monitoring, or does this evaluation occur once initial monitoring is completed comparing the average of either the two or four samples to the trigger levels? What does it mean to “monitor quarterly...beginning in the next quarter.” If a PWS collects its initial monitoring in the first year after final rule promulgation and exceeds the trigger, must they immediately begin quarterly monitoring even though the compliance date is still two years away? If so, this will cause most PWS to delay initial monitoring until the last year prior to the compliance date. MassDEP recommends that EPA clarify that quarterly monitoring must begin on the compliance date of the final rule.
- § 141.902(a)(9) requires reporting of detections at or above 1/3 the PQL, which by definition is below the concentration that can be confidently quantified. Estimated concentrations should not be used to establish the compliance monitoring frequency or to trigger quarterly monitoring under § 141.902(b)(2)(ii) and § 141.903(d).
- § 141.902(b)(1)(i) should refer to Subpart H systems if that is what is meant by “surface water CWS and NTNCWS.” This would make § 141.902(b)(1)(iii) unnecessary. Additionally, the language in § 141.902(b)(1)(iii), “based on system size” is irrelevant as all sizes of Subpart H systems must collect four consecutive quarterly samples.
- The requirement in § 141.902(b)(1)(iv) to collect quarterly samples “at least ninety days apart” introduces an unnecessary complexity. If the intent is to space consecutive samples apart this can be done in several ways such as reducing this period to at least 30 or 60 days or by requiring all samples be collected in the middle month of the quarter. These options allow for flexibility within the quarter without potentially causing a monitoring violation if, for example, samples were collected a reasonable 80 days apart in separate quarters.
- § 141.902(b)(1)(vi) appears to require only that supplemental monitoring necessary to complete the requirements of Table 1 to Paragraph (b)(1)(iv) be completed by three years after final promulgation (the presumptive compliance date). There is a need to clarify whether all initial monitoring, using new samples, existing samples, or a combination of the two, must be

completed by this same date. If the intent is to complete all initial monitoring by this date, MassDEP recommends that the final sentence of § 141.902(b)(1)(vi) be moved to a new subparagraph (vii).

- There is an inconsistency between § 141.902(b)(2)(ii) and (iii). The former states that quarterly monitoring is required when the trigger level is *exceeded* whereas the latter states that systems that are *at or exceed* the trigger levels must conduct quarterly monitoring. MassDEP recommends that the trigger level must be exceeded to require increased monitoring. MassDEP also recommends that the same criteria apply to making the “reliably and consistently below the MCL” determinations in § 141.902(b)(2)(iii) – anything at or below the trigger level should be acceptable.
- Criteria for sample invalidation needs to be added to accommodate issues such as Quality Control failures including but not limited to detections of target analytes in the FRB, as well as whether replacement samples must be collected along with a timeline for doing so.
- MassDEP supports EPA’s proposal to not allow samples to be composited.
- Given the importance of the HBWCs, it would be appropriate to list them in a table in § 141.903 rather than referring to a footnote to the table in § 141.61 as is done in § 141.903(f)(2)(i).
- MassDEP supports EPA’s proposal to substitute zero for sample results less than the PQL in both § 141.903(f)(1)(iii) and § 141.903(f)(2)(iii). MassDEP may consider establishing lower PQLs than are in the proposed rule, if appropriate.
- MassDEP suggests that EPA clarify why the language of § 141.903(f)(2)(ii) doesn’t match the corresponding language in § 141.903(f)(1)(ii). In the first case the requirement is to “report the results of each sampling event” whereas the requirement to “report” is missing in the second case.
- In § 141.903(f)(2)(ii)(B), the process to deal with multiple results for one or more of the HI PFAS during a quarter is not clear and doesn’t appear to address the situation where multiple results exist for some but not all of the HI PFAS. MassDEP recommends that the set of results for each of the HI PFAS be averaged for the quarter and one set of Hazard Quotients (HQ) be derived to generate one HI (e.g., average all the PFBS results for the quarter, divide that average by the PFBS HBWC to get one PFBS HQ for the quarter add this to the other three HQs to obtain the HI for the quarter).

Monitoring and special primacy requirements

Given that initial monitoring may occur anytime between final rule promulgation and the compliance date (three years later), it is unclear why states are required to include an initial monitoring plan in their primacy application. Primacy applications wouldn’t normally be due until two years after final rule promulgation. Two-thirds of the initial monitoring period would have already passed by that date. Moreover, states will not be able to demonstrate that this monitoring plan is enforceable under state law

until state regulations have been promulgated which, again, will likely occur well into the initial monitoring period.

Table 2 to Paragraph (a) in § 142.62(a) includes “B” in the Limitations for GAC. It is unclear if this refers to footnote “b.” If so, it should be lower case. Footnote c to this same table should not refer to EPA’s “proposed” MCLs as this language will not be accurate after the MCLs are final.

MassDEP recommends that EPA allows water systems to have different monitoring schedules for different entry points.

MassDEP recommends that EPA does not require that all entry points be monitored on the same monitoring frequency. This allows systems to reduce analytical costs. This would align with the current approach for chemical monitoring, especially at systems that have several sources.

MassDEP recommends that EPA clarify and allow maximum flexibility to use previously acquired state sampling data to satisfy initial monitoring.

MassDEP recommends that maximum flexibility be allowed for using existing state data to meet the initial monitoring requirements and for allowing the use of both state and UCMR5 data.

The final rule should explicitly state that water systems that conduct UCMR5 monitoring do not need to conduct initial monitoring. While the UCMR5 only requires large groundwater systems to sample twice, this should be sufficient, even though the proposed rule requires quarterly sampling. Is EPA requiring UCMR5 laboratories to report qualified results, or nonqualified results where the lab used an MRL lower than that required by UCMR5, or are all results below EPA’s MRLs reported as “<MRL?” This could affect whether MassDEP would allow the use of UCMR5 results to satisfy the initial monitoring requirements as we require lower MRLs than are being used in UCMR5.

Using zeros for any results below 4.0 ppt miscalculates the Running Annual Average (RAA) if these results are non-qualified detections. Such a system’s RAA could exceed the MCL when these results are included. For example, the set of quarterly results: 4.2, 4.2, 4.1 and 3.8 exceeds the MCL when all four results are used (4.1) but does not (3.1) when zero replaces the lowest result. Public communication surrounding the use of zeros for compliance calculations when there is a quantified detection will be challenging especially where including such detections is the difference between a violation or not.

Reporting and recordkeeping

MassDEP submits the following comments related to the reporting and recordkeeping requirements set forth in 40 CFR § 141.904 of the proposed rule (page 18753 of the Federal Register notice):

- In Table 1 to § 141.904 it appears that the reference to § 141.902 in item 3 for systems monitoring quarterly should point to § 141.903 as that is where the MCL compliance calculation is described.

- Systems monitoring quarterly should not have a requirement to report whether the trigger level was met or exceeded. If a system is already subject to quarterly monitoring the relationship of its PFAS concentrations to the trigger would be meaningless because the only consequence of exceeding the trigger would be to be put on quarterly monitoring.
- Systems monitoring less frequently than quarterly should not have a requirement to report a Running Annual Average (RAA). According to § 141.903(d), a RAA isn't calculated unless a system is triggered into quarterly monitoring and then completes one year of quarterly monitoring.

Violations

MassDEP submits the following comments and questions related to violations, as set forth in 40 CFR § 141.905 of the proposed rule (page 18753 of the Federal Register notice):

- § 141.905(a) is missing full citations (“§ 141.XX.d” and “§ 141.XX.c”).
- § 141.905(2) states that “[s]ystems monitoring triennially whose sample result *is at or* [emphasis added] exceeds the trigger level as defined by § 141.902(a)(7) of this section must begin quarterly sampling.” According to § 141.902(b)(2)(ii) the trigger level must be exceeded before quarterly monitoring is required. Since there is inconsistent language throughout the proposal, it is unclear what EPA’s intent is and therefore which sections need correction.
- It is unclear why the same language is repeated, with small variations, in § 141.903 and § 141.905: § 141.903(b) matches § 141.905(b)(1); § 141.903(c) matches § 141.905(2)(ii); § 141.903(d) matches § 141.905(b)(2); § 141.903(e) matches § 141.905(b)(2)(i) and § 141.903(f)(1)(iii) and § 141.903(f)(2)(iii) match § 141.905(b)(2)(iii). Excessive language makes the rule more difficult to interpret, easier to miscite and more confusing to the regulated community.

7. Evaluation of Toxicology and Scientific Basis for Standard Setting

MassDEP has several comments on EPA’s proposed HI approach and the derivation of the MCLG, including comments on the draft document entitled “Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS¹,” (hereinafter referred to as the “Mixture document”) which serves as a basis of EPA’s proposed HI approach. Specifically, our comments address the following: (1) inclusion of additional PFAS in the HI; (2) use of body weight-adjusted drinking water intakes (DWI-BWs) in establishing the MCLG; (3) the calculation of the PFHxS health-based water concentration (HBWC); (4) the application of potency subgroups to the HI; (5) identification and use of the PQL in establishing the PFOS and PFOA proposed MCLs; and (6) the compliance averaging period.

¹ EPA 2023a. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS, Public Review Draft. U.S. Environmental Protection Agency, Office of Water (4304T), Office of Science and Technology, Health and Ecological Criteria Division, Washington, DC 20460. EPA-822-P-23-004.

Inclusion of additional PFAS in the Hazard Index

EPA selected four PFAS for inclusion in an HI approach for MCLG development: hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt (also known as GenX chemicals), perfluorobutane sulfonic acid and its related compound potassium perfluorobutane sulfonate (PFBS), perfluorononanoic acid (PFNA), and perfluorohexanesulfonic acid (PFHxS). EPA identified these PFAS as having continued co-occurrence in drinking water and HBWCs that were available or could be calculated using recently published, peer-reviewed, publicly available assessments. MassDEP is supportive of the HI approach due to its ability to address co-exposures of PFAS in drinking water, but we recommend that EPA clarify its intent to incorporate additional PFAS into the HI. The EPA Integrated Risk Information System (IRIS) assessments for perfluorobutanoic acid (PFBA) and perfluorohexanoic acid (PFHxA) were finalized in December 2022 and April 2023, respectively, and could be used to derive HBWCs for inclusion in the HI approach. The IRIS Program also has assessments in development for perfluorodecanoic acid (PFDA), PFHxS, and PFNA that could be incorporated into the HI once finalized. Further, EPA should consider applying read across approaches to address additional PFAS with continued co-occurrence such as perfluoroheptanoic acid (PFHpA). EPA should clarify the inclusion criteria for PFAS compounds in the HI and the process for updating HBWCs as additional assessments and occurrence data become available to ensure that the MCLG and MCL are adequately protective of public health.

Use of body weight-adjusted drinking water intakes (DWI-BWs)

EPA selected DWI-BWs for each PFAS included in the HI approach based on evaluation of the critical study used to derive the chronic reference dose. This led to selection of the DWI-BW for lactating women for HFPO-DA and PFNA, the DWI-BW for women of childbearing age for PFBS, and the DWI-BW for adults within the general population for PFHxS. MassDEP disagrees with this application of variable DWI-BWs. MassDEP recommends that EPA select the drinking water intake for the most sensitive population or life stage identified from evaluation of the database as a whole, rather than solely based on the critical study for a particular PFAS.

Two lines of evidence support the use of the DWI-BW for the most sensitive population or life stage for HFPO-DA, PFNA, PFBS, and PFHxS. *First*, EPA's 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal in Drinking Water documents for PFOA² and PFOS³, the PFAS with the largest databases, provide evidence for the similarity of noncancer health effects and effect levels across the life stages, health outcomes and endpoints. The candidate Reference Doses (RfDs) for PFOA and PFOS were developed from different health outcomes and endpoints evaluated at different life stages, yet the health outcome specific RfDs EPA developed for PFOA and PFOS were both within a factor of 2 across the four health outcomes with sufficient evidence for evaluation. PFAS with smaller databases may not have data to evaluate a full array of health outcomes, limiting the certainty that the critical effects to the most sensitive life stage have been sufficiently evaluated. Given the growing body of evidence supporting a

² EPA 2023b. Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water, Public Comment Draft. U.S. Environmental Protection Agency, Office of Water (4304T), Health and Ecological Criteria Division, Washington, DC 20460. EPA-822-P-23-005.

³ EPA 2023c. Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water, Public Comment Draft. U.S. Environmental Protection Agency, Office of Water (4304T), Health and Ecological Criteria Division, Washington, DC 20460. EPA-822-P-23-007.

wide range of health outcomes across life stages, it is prudent to assume that, until demonstrated otherwise, PFAS may have effects at sensitive life stages.

Second, as described in the Mixture document, evidence supports dose-additive effects from co-exposure to PFAS. However, the relative contribution of any particular PFAS to produce additive response to any of the multiple health outcomes associated with different life stage sensitivities is not known.

While the difference in drinking water concentrations (MCLGs) derived using the lowest and highest DWI-BW is small, i.e., well within the margin of uncertainty assumed for the RfD, adopting the ingestion rate for the most sensitive population best represents the available evidence on the health effects of PFAS.

PFHxS Health-Based Water Concentrations

EPA appears to have an error in the calculation of the PFHxS HBWC in the Mixture document (Section 2.4.4, pages 16-17). The chronic reference value of 2×10^{-6} mg/kg-day divided by the DWI-BW of 0.034 L/kg-day times the RSC of 0.2 should yield a value of 12 ng/L, not 9.2 ng/L rounded to 9 ng/L. The PFHxS HBWC should be corrected to reflect the values included in the document.

Application of potency subgroups to the Hazard Index

EPA should consider an alternative approach to calculating the HI based on potency subgroups that differ by factors of 3- or 10-fold rather than the current approach using individual HBWCs described in the Mixture document. The modest differences between the HFPO-DA HBWC of 10 ppt, PFNA HBWC of 10 ppt, and PFHxS HBWC of 9 ppt (10 ppt if calculated as above) for example are not supported as being distinct values given the differences in factors such as database extent, study execution, and inter-lab variability. The use of potency subgroups would better reflect the uncertainty in calculating PFAS drinking water values as well as simplify the calculation of the HI. As an example, for a drinking water system with detections of HFPO-DA, PFNA, and PFHxS, the current approach would require dividing the HFPO-DA drinking water concentration by the HFPO-DA HBWC, the PFNA drinking water concentration by the PFNA HBWC, and the PFHxS drinking water concentration by the PFHxS HBWC. For an approach based on potency subgroups, the HFPO-DA, PFNA, and PFHxS drinking water concentrations would all be divided by the same potency subgroup factor, as the HBWC values do not differ by more than a factor of 3-fold in the current draft Mixture document. This potency subgroup approach should also be applied to additional PFAS if added to the HI approach.

Running Annual Average Approach

EPA's proposal in the NPDWR to utilize a RAA approach to calculate compliance with the proposed MCLs is not adequately protective of development effects. An alternative approach should be considered, such as the use of a shorter duration averaging period.

Setting the PFOA and PFOS MCL at a Practical Quantitation Limit

Setting the PFOA and PFOS MCL at a PQL, established at a level of 4.0 ppt, raises a number of issues. Extensive experience among states that are already regulating PFOA and PFOS support a current PQL of 2.0 ppt. That said, setting an MCL at a PQL raises a risk of compliance "yo-yoing", where systems with concentrations hovering near the PQL will bounce into and out of compliance simply based on analytical

variability within the range that is acceptable for the method. To avoid that problem, we recommend setting the MCL at a level above the PQL that reasonably exceeds (say by a factor of 2-3) the acceptable method variability, based on a lower PQL.

Conclusion

MassDEP is committed to the protection of public health and the environment against the impacts of PFAS contamination and strongly supports EPA's efforts to establish drinking water standards for PFAS. We urge EPA to carefully consider our comments, which are based on three years of experience implementing one of the most stringent PFAS limits for drinking water in the nation, urge EPA to take swift action in implementing its own standards, and applaud EPA for its ongoing efforts to develop this NPDWR.

Sincerely,



Bonnie Heiple
Commissioner, MassDEP