



May 30, 2023

U.S. Environmental Protection Agency
EPA Docket Center
Office of Ground Water and Drinking Water Docket
Mail Code: 2822IT
1200 Pennsylvania Avenue NW
Washington, DC 20460

Attention: Docket ID EPA-HQ-OW-2022-0114

Dear Administrator Regan:

Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation Rulemaking, published on Wednesday, March 29, 2023 at 88 FR 18638. The Pennsylvania Department of Environmental Protection (DEP) fully supports EPA's efforts to protect public health by setting national drinking water standards for per- and polyfluoroalkyl substances (PFAS). Pennsylvania is one of a handful of states that moved quickly to address PFAS in drinking water and welcomes federal action to improve public health protection and ensure more consistent regulation of PFAS across the country.

DEP supports and agrees with the intent of EPA's proposed rulemaking in the following key areas:

- DEP agrees with EPA's decision to consider PFAS chronic contaminants and to require Tier 2 public notification (PN) for MCL exceedances.
- DEP supports allowing water systems to use previously collected data for initial compliance as one potential way to minimize costs. Additional questions and comments relative to the use of previously collected data are provided later in this letter.
- Based on the substantial science and data used by DEP to promulgate our state PFAS maximum contaminant level (MCL) rule, DEP supports the decision to establish standalone MCLs for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), instead of including them in the hazard index (HI) approach. Additional comments relative to the proposed MCLs for PFOA and PFOS and the combined HI approach for additional PFAS are provided later in this letter.
- DEP supports using zero in the running annual average (RAA) compliance calculation for PFAS levels detected below either a practical quantitation level (PQL) or minimum reporting level (MRL). By definition, the PQL is the lowest level that can be consistently measured with precision and accuracy; therefore, any detections below that level are not accurate or precise and should not be used for compliance determination or any other

Secretary

Rachel Carson State Office Building | P.O. Box 2063 | Harrisburg, PA 17105-2063 | 717.787.2814 | www.dep.pa.gov

regulatory decision making. Additional comments relative to the proposed PQLs and detection and reporting limits are provided later in this letter.

- DEP supports compliance determinations that may allow different entry points (EP) at the same water system to be on different monitoring frequencies, based on monitoring results. Additional comments regarding determination of monitoring frequencies are provided later in this letter.

DEP offers the following comments, questions, and recommendations to EPA to clarify and strengthen the proposed rulemaking. Comments are grouped by topic, as indicated by the heading of each section.

General Requirements

- Effective dates within the proposed rulemaking are inconsistent and are written as both the date of publication of the final rule in the *Federal Register* in some locations, and a date three years after the date of publication of the final rule in the *Federal Register* in other locations. Specifically:
 - § 141.6 lists an effective date three years after date of publication of the final rule for:
 - § 141.50 *Maximum contaminant level goals (MCLG) for organic contaminants.*
 - § 141.60 *Effective dates.* However, § 141.60(a)(4) lists an effective date of the date of publication of the final rule in the *Federal Register* for MCLs and is inconsistent with and contradicts § 141.6. Alternatively, this statement in § 141.60(a)(4) is unimplementable because the statement itself is not effective until three years after the date of publication, as required by § 141.6. Also, if MCLs are in fact effective upon publication, this is inconsistent with MCLGs, which are not effective until three years after publication.
 - § 141.61 *Maximum contaminant levels for organic contaminants.*
 - § 141.154 *Required additional health information.* DEP questions why this is separated out from the list that follows.
 - § 141.151 through 141.155 *Consumer Confidence Report (CCR).*
 - § 141.201 through 141.211 *Public Notification (PN).*
 - § 141.900(b) just reads “Compliance dates” but no compliance dates are identified. Compliance dates for initial monitoring are also not identified in § 141.XX(b)(1) *Initial compliance period.* The timeframe specified in § 141.XX(b)(vi) only applies to monitoring that is needed to supplement previously-acquired data to satisfy the initial monitoring requirements. DEP believes that compliance dates for the start of the initial compliance monitoring period must be identified in the rulemaking.
 - § 141.XX(a)(6) requires new systems, or systems using a new source after the date of publication of the final rule in the *Federal Register* to demonstrate compliance with the MCLs. However, the MCLs (and PN requirements for any

MCL exceedances) are not effective until three years after publication, according to § 141.6.

Consistent with Section 300g–1(b)(10) (relating to national drinking water regulations) of the federal Safe Drinking Water Act and in order to allow states sufficient time to review the final rule and promulgate associated state regulations, DEP strongly encourages EPA to set the effective date of the MCLs and any required monitoring and compliance provisions to take effect on the date that is three years after the date on which the final regulation is promulgated.

- DEP notes that there are missing cross references and cross references to citations or tables that do not exist in the proposed rulemaking. Specifically:
 - § 141.60(a)(4) is missing a cross reference to § 141.61 and should read (*emphasis added to suggested additional language*): “The effective date for paragraphs (c)(34) through (c)(36) *of § 141.61* is ...”
 - § 141.151(d) specifies that the Consumer Confidence Report (CCR) must include PFAS results that are detected, and that “detected means: at or above the levels prescribed by... § 141.902(a)(9) for PFAS...”. However, § 141.902 does not exist.
 - DEP questions whether § 141.XX *Monitoring requirements* is intended to be § 141.902 since it comes between § 141.901 and § 141.903. If that is the case, § 141.902(a)(9) (which is published as § 141.XX(a)(9)) then refers to § 141.903(f)(1)(i)(3) for a reportable detection. This is very confusing to have multiple cross references to multiple citations. The cross reference should be directly to the location containing the referred information.
 - It is also important to note that the second cross reference noted above in § 141.XX(a)(9) – which DEP believes is intended to be § 141.902(a)(9) – to § 141.903(f)(1)(i)(3) is also a citation that does not exist. DEP believes that this may have been intended to refer to the table listing the PQLs, located in § 141.903(f)(1)(iii). If that is the case, DEP has specific concerns relative to those reporting limits; those concerns are noted in separate comments below.
 - Table 1 to § 141.904 refers multiple times to § 141.902. However, as noted above, § 141.902 does not exist (unless 141.XX is intended to be § 141.902).
 - § 141.901(b)(2)(i) states that labs should report “concentrations at least as low as the ones listed in the following table...”. However, the referenced table does not exist; there is no table listing minimum reporting concentrations in the proposed rulemaking.
 - § 141.901(b)(2)(i) also references compliance with § 141.902 *Monitoring requirements*. Again, DEP notes that § 141.902 does not exist, but assumes that § 141.XX is intended to be § 141.902.

- Appendix A to Subpart Q (relating to PN) references § 141.XX as the citation for the PN violation tiers or PFAS. However, as already noted, DEP questions if this is in fact intended to refer to § 141.902.
- DEP has identified several concerns related to definitions, including new proposed definitions in the rulemaking as well as terms that DEP believes should be defined. Specifically:
 - EPA has not added a proposed definition for “PFAS.” This acronym is used in the proposed definition for Hazard Index (HI) and in many other locations in the proposed rulemaking. DEP believes that it should be defined for clarity.
 - EPA has not added a proposed definition for the term “regulated PFAS.” This term is used throughout the proposed rulemaking and is not used consistently in all instances. This term may also have different meaning and significance than the acronym “PFAS” and should be defined separately. For example:
 - § 141.901(b)(1) states that analyses for “regulated PFAS” must be conducted by certified laboratories; it is implied that, in this case, it is referring to all six PFAS for which approved methods have been identified.
 - The HI definition also uses the phrase “regulated PFAS,” but PFOA and PFOS are not included in the HI calculation.
 - DEP believes that the proposed definition for HI should include the calculation for determining compliance with the HI MCL. The calculation is only specified as a footnote to the tables in § 141.50 and § 141.61. DEP believes that it is inappropriate to only list this calculation in a footnote to a table.
 - The proposed definition for HI also includes the phrase “regulated PFAS component” but does not identify the specific PFAS included in the HI MCL. Since PFOA and PFOS would also be considered regulated PFAS under the proposed rulemaking, this definition should clarify which PFAS are included, or the phrase “regulated PFAS component” should be defined.
 - In the proposed definition for Hazard Quotient (HQ), DEP questions the use of the phrase “potential exposure to a substance” when it is actually the measured concentration used in the equation. DEP also suggests that instead of “the level at which no health effects are expected”, the definition should refer to the health-based water concentration (HBWC), which is also a newly defined term.
 - In the proposed definition for HBWC, DEP suggests that instead of “levels protective of health effects” it should read “levels at which no health effects are expected”.
- § 141.900(a) states that “control of certain PFAS is required” for community water systems (CWS) and non-transient non-community water systems (NTNCWS), and that

they must comply with the MCLs “for certain PFAS.” DEP believes that the use of the phrase “certain PFAS” is unclear and misleading, since it implies that water systems must comply with some, but not all, of the MCLs for PFAS. DEP reiterates the need to define the terms “PFAS” and “regulated PFAS” and to use those phrases consistently throughout the proposed rulemaking.

- DEP believes that it is confusing to add PFAS to the best available technology (BAT) table in § 141.61 because it only lists granular activated carbon (GAC) as BAT for the PFAS specified in § 142.62. DEP also questions why PFAS BAT is specified in Part 142, but not in § 141.61 or Subpart Z and questions the appropriateness of this.
- Neither § 141.904 nor § 141.31 provides the option that RAA values need not be reported if the state performs the calculation for the system. DEP notes that this should be explicitly stated if that is the intent of the proposed rulemaking.
- DEP notes that § 141.903(d) states that a system “will not be considered in violation of an MCL until it has completed one year of quarterly sampling”, but § 141.903(e) states that “if any sample result will cause the running annual average to exceed the MCL... the system is out of compliance with the MCL immediately.” These two statements appear to be contradictory. While DEP understands the intent of these paragraphs relative to implementation, it is contradictory to state that a system will **not** be considered in violation until they have a complete year of sampling when they could in fact be in violation after only one quarter if levels are high enough.

Practical Quantitation Levels (PQLs) / Reporting Levels

- DEP recommends that EPA fully evaluate whether PQLs should be set any lower than 4.0 parts per trillion (ppt) for any of the PFAS included in the proposed rule. PQL is defined in 40 CFR § 141.2 as “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 definition makes the PQL essentially equivalent to a reporting level. As part of our state rulemaking process, DEP conducted a survey of laboratories accredited in Pennsylvania for PFAS analysis. While many laboratories indicate that they may be able to detect and report PFAS compounds to approximately 2 ppt, the potential incidence of quality assurance (QA) / quality control (QC) failures increase as reporting limits decrease. EPA states as much in the preamble to the proposed rulemaking, on page 18680: “Establishing a quantitation level that is too low may result in recurring QC failures that will necessitate repeating sample analyses, increase costs, and potentially reduce laboratory capacity.” DEP has experience with this situation. During implementation of the DEP Bureau of Safe Drinking Water’s PFAS Sampling Plan used to generate occurrence data and inform our state PFAS MCL rulemaking process, we utilized the services of two different laboratories. The lab with lower reporting levels, at approximately 2 ppt, experienced significantly more QC failures, and each location with an affected sample needed to be resampled and reanalyzed. The other lab used approximately 4 ppt as a reporting limit and had no QC failures. It is imperative to consistently define across all laboratories what is and is not a detectable level; using a PQL less than 4.0 ppt may not be feasible. EPA should investigate the incidence of QC failures at lower reporting levels before considering lowering the PQLs.

- DEP requests clarification on what levels are to be reported when a PFAS is detected below its respective PQL. DEP also suggests that an MRL should be clearly identified for each regulated PFAS and that MRL should be defined in § 141.2. In § 141.XX(a)(9), the proposed rule states that “a reportable detection means at or above one-third of the levels described in the table outlined in ...” As noted earlier, DEP has identified inconsistencies and inaccuracies in the cross references and citations but believes that this table is referring to the PQLs. This seems to indicate that any detection over one-third of a PQL, or 1.3 ppt for PFOA or PFOS, would be reported as such. However, with the PQL set at 4.0 ppt for PFOA and PFOS, detections below that level would not be considered accurate or precise and would be counted as zero in the RAA calculation. It is critical for EPA to clarify what levels are to be reported.
- Building on the previous comment, DEP believes that the definition of PQL suggests that detections below the PQL – or MRL if that term is defined and utilized – should be reported as not detected or zero since a detection below that level is not expected to be an accurate representation of the actual concentration. Results reported at or above one-third the PQL and up to the PQL would be qualified data and would not be legally defensible as a true detection. Detections below the PQL should be reported as not detected or zero.
- DEP also believes it is confusing to say a reportable detection is “at or above one-third of the levels described in the table” instead of clearly listing the actual numbers for reporting. As noted earlier, the table referenced by § 141.901(b)(2)(i) appears to be intended to list reporting limits, but that table is missing from the proposed rulemaking. DEP cannot comment on information that is missing from the proposed rulemaking. Again, DEP believes this is an important component to include in the rulemaking to clarify reporting limits.
- Reporting levels for calculating MCL compliance and determining monitoring frequencies must be consistently applied and clearly defined. It is not implementable or appropriate to have different reporting levels for use in different parts of the proposed regulation.

MCLs and Trigger Levels for PFOA and PFOS

- DEP is concerned that the proposed MCLs may not be feasible and may result in significant implementation challenges. More specifically, DEP recommends that the MCLs for PFOA and PFOS should not be set at levels equal to the PQL. As noted above, PQL is defined in 40 CFR § 141.2 as “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.” EPA-approved methods, Method 533 and Method 537.1, allow +/- 30% recovery for QC samples. In addition, the proposed regulation requires +/- 30% recovery for performance evaluation (PE) samples. By setting the MCLs equal to the PQL, if QC is biased high by up to 30%, which is acceptable, a low-level detection in a sample that is just over the PQL/MCL may also be biased high. With a PQL of 4.0 ppt for PFOA and PFOS and a +/- 30 % QC allowance, any detection up to 5.2 ppt is within the acceptable analytical margin of error (30% of 4.0 is 1.2, and 4.0 +

1.2 = 5.2). Therefore, with the PQLs set at 4.0 ppt, the lowest the MCLs should be set at is 6 ppt. By setting the MCLs for PFOA and PFOS at a level equal to the PQL, some water systems may exceed the MCL with low-level detections that are within the margin of analytical error. This is not a feasible level for implementation, and it presents significant implementation challenges.

- DEP does not support using the proposed trigger level of 1.3 ppt in the RAA calculation for compliance determinations instead of zero when PFOA and/or PFOS are detected at a level below the PQL. As already noted, detections below the PQL would be reported as qualified data and would not be legally defensible. Using the proposed trigger level of 1.3 ppt in the RAA calculation instead of zero is arbitrary and assigns a value that is not based on actual defensible analytical results for a compliance determination.
- Trigger levels should not be set at levels lower than the PQL. Trigger levels for PFOA and PFOS are specified in § 141.XX(b)(2)(iii) as one-third the MCL, which is also equal to one-third the PQL, or 1.3 ppt. As already noted, by definition, the PQL is the lowest level that can be accurately and precisely measured. Therefore, at a level below the PQL, the measured concentration may not be accurately quantified. It is not feasible to implement drinking water standards based on data that is not accurate or precise and, therefore, not legally defensible. EPA acknowledges in its *FAQs for Drinking Water Primacy Agencies* that “measurements below the PQLs may be less definitive,” but then goes on to argue that those low levels are “appropriate for determining if PFAS are present and establishing monitoring frequency.” However, it is not appropriate to use data that is not legally defensible in any way in a regulation. DEP does not agree with regulating PFAS monitoring frequencies based on levels detected lower than the PQL as a presence/absence detection.
- The use of 1.3 ppt as a trigger level for monitoring frequency for PFOA and PFOS is inconsistent within the proposed rulemaking. § 141.XX(a)(7) defines the trigger levels as 1.3 ppt for PFOA and PFOS and 0.33 for the HI but does not clarify whether these are based on discrete sample results or an RAA. In § 141.XX(a)(8), the trigger level appears intended to be used as a calculated value to determine reduced monitoring frequency based on a RAA calculation for systems on a quarterly initial monitoring frequency. However, the trigger level also appears to be used as a discrete value (i.e., “reliably and consistently below the MCL”) to trigger increased monitoring frequency back to quarterly (§ 141.903(d)). DEP disagrees with using 1.3 ppt as a trigger level for monitoring frequency determination for PFOA and PFOS for several reasons:
 - Based on information gathered by DEP during a survey of laboratories accredited in Pennsylvania to inform our state rulemaking process, and confirmed by the DEP Bureau of Laboratories, very few (if any) laboratories are capable of detecting PFAS at a level of 1.3 ppt. It is therefore not feasible to use the trigger level of 1.3 ppt in a single sample to require an increase to quarterly monitoring.
 - In addition to the lack of laboratory capabilities to detect PFAS at such a low level, detections due to cross contamination should be considered. Because PFAS are generally considered to be ubiquitous, such low-level detections may not be indicative of actual water quality.

- Data reported below the PQL would be reported as qualified data, notated with the “J” qualifier. J-qualified data are considered to be a detection that is an estimated value. Qualified data is not acceptable for compliance determinations. Therefore, it is not appropriate to make regulatory decisions based on J-qualified data, even for monitoring frequency determinations.
- Instead of using the proposed trigger levels of one-third the MCLs for determining monitoring frequencies, DEP recommends using levels that are “reliably and consistently below the MCL” (R&C), to be consistent with existing regulations for chronic contaminants. As per 40 CFR, Part 141, the federal R&C criteria for nitrate (an acute contaminant) is set at 50% of the MCL. EPA defers to the states to set R&C criteria for chronic contaminants. For example, for chronic contaminants, DEP uses a R&C level of 80% of the MCL. Since DEP agrees that PFAS are chronic contaminants, the R&C level for PFAS should be set at a level more appropriate for chronic contaminants. DEP suggests that it would be inconsistent for EPA to set the R&C criteria for a chronic contaminant such as PFAS lower than the R&C criteria for an acute contaminant. However, it is important to note that, if the MCLs for PFOA and PFOS are set at 4.0 ppt, which is the same as the PQL, then even 80% of the MCL, or 3.2 ppt, is still at a level that is below the PQL, which is not feasible. This further supports DEP’s earlier comment that the MCLs should be set at a level that is a minimum of 30% above the PQL.

Proposed Hazard Index (HI) MCL

- DEP supports EPA’s efforts to set a group MCL for PFAS. However, we do not believe that the use of a proposed HI is appropriate or feasible.
- DEP has concerns regarding the use of the HI as a drinking water MCL as it is proposed. It is DEP’s understanding that the HI is typically used as site-specific cleanup criteria, where the full range of contaminants likely to be present at a contamination site is known. Those contaminants, specific to an individual site, can be evaluated for overall risk based on several factors, including how they interact with one another, exposure factors, toxicity values, etc. By attempting to apply the HI concept as an across-the-board drinking water standard, it becomes an arbitrary evaluation of just those four contaminants included in the calculation. Any other contaminants that may be present and may interact with the four HI PFAS are not accounted for. It is important to note that when used appropriately as cleanup criteria at a specific site, the HI would take into account not just other PFAS, but also any other type of interacting contaminant that may contribute to overall risk. As proposed, this HI MCL arbitrarily considers only the four HI PFAS, which DEP believes is not an appropriate application of the HI concept.
- DEP also notes that the HI calculation included in the proposed rulemaking is a shortcut method to estimate HI that does not allow for an actual risk calculation. The proposed HI calculation uses HQs that are determined by comparing the measured concentration of a contaminant to the HBWC. As noted above, this calculation does not include values such as exposure factors and toxicity values that are typically included in HI determinations. Without that additional information, it is not possible to fully quantify the risk level with

the HI. Therefore, it is not appropriate to introduce an HI MCL as a drinking water standard.

- The HBWCs appear to be calculated in the same way as MCLGs. Since they are calculated the same way, it is not clear why EPA introduced the new term HBWC instead of continuing to use the term MCLG. DEP requests clarification on what if any distinction exists between the terms MCLG and HBWC.
- In the document titled *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, PBNA, and PFHxS*, EPA states that the HBWCs for the four PFAS included in the HI MCL are based on the following non-cancer health effects: liver effects for GenX, thyroid effects for PFBS, developmental effects for PFNA, and thyroid effects for PFHxS. DEP concedes that a combined MCL may be most effective for implementation for PFAS with non-cancer health effects, but questions making assumptions about additive effects based on different health endpoints. In the EPA Science Advisory Board's (SAB) *Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS*, the SAB stated that when health endpoints of a group of compounds is similar, the HI is "a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media." However, as noted, the health endpoints for the four PFAS included in the HI are different, with the exception that PFHxS and PFBS both have thyroid effects. Therefore, DEP questions whether it is appropriate to use the HI approach to regulate these four PFAS.
- As previously noted, § 141.901(b)(2)(i) states that laboratories should "report quantitative data for concentrations at least as low as the ones listed in the following table" for PFAS; however, that referenced table appears to be missing from the proposed regulatory language. As such, it is not clear what reporting levels are to be used for any of the six PFAS included in the proposed regulation. DEP is not able to comment on information missing from the proposed rulemaking. However, for the four PFAS components included in the HI calculation, their PQLs are listed in Table 1 to § 141.903(f)(1)(iii) as:

Contaminant	PQL
HFPO-DA	5.0 ppt
PFHxS	3.0 ppt
PFNA	4.0 ppt
PFBS	3.0 ppt

It is not clear whether labs are to report only to these levels, or to levels that are one-third of the PQLs, for inclusion in the HI calculation. As noted previously, results reported below the PQL for any contaminant would be qualified data and would not be legally defensible results for use in determining compliance or monitoring frequencies.

- In § 141.XX(a)(8) of the proposed rulemaking, it is not clear as written how this will apply to the HI MCL. The paragraph states: "Based on initial monitoring results, for each sampling point at which a contaminant listed in § 141.61(c) is detected at a level greater

than or equal to the trigger level, the system must monitor quarterly for all regulated PFAS beginning in the next quarter...” It is not clear whether this is referring to the HI calculated trigger level of 0.33, or whether this is referring to some individual reporting level for the individual component PFAS in the HI calculation.

- DEP notes that in the example calculation on page 18665 of the preamble, which the text identifies as using the proposed PQLs as the measured values for each of the component PFAS, the numerical values entered for each PFAS are whole numbers with only one significant figure. In other words, the values used in the example calculation are 5 ppt for GenX, 3 ppt for PFBS, 4 ppt for PFNA, and 3 ppt for PFHxS. The calculated result of 1.2 for the HI is incorrect in this example, because with only one significant figure in the values used in the calculation, the result should also only have one significant figure and be 1 (not 1.0). However, as noted above, the PQLs as defined in the proposed rulemaking each contain two significant figures. This inconsistency is confusing and further supports DEP’s comments that MRLs need to be clearly identified for each regulated PFAS, including the number of significant figures.
- § 141.903(f)(2)(i) is not consistent on how the HI is to be calculated for systems on a quarterly monitoring frequency. The preamble to the proposed rulemaking, EPA webinars on the proposed rule, and guidance made available with the proposed rule all state that an RAA is to be used. However, the language in this paragraph is different and states (*emphasis added*): “For systems monitoring quarterly, divide observed sample analytical results by the corresponding HBWC listed in § 141.61(c) to obtain a Hazard Quotient for each sampling event at each EPTDS. Sum the resulting Hazard Quotients together to determine the Hazard Index. If more than one compliance sample is available for an analyte in a quarter, systems must average all the results for that analyte in that quarter and then determine the Hazard Quotient(s) from those average values. If the Hazard Index exceeds the MCL, the system is not in compliance with the Hazard Index MCL requirements.” Each sampling event is assumed to be each quarter, and there is no description of how to calculate an RAA; rather, the language seems to indicate that a single quarterly HI exceedance would result in a HI MCL violation. The language in paragraph (i) is very similar to the language in paragraph (ii).
- With regard to the HI calculation, DEP notes that if each component PFAS is detected at a level equal to its PQL, the HI MCLG will be exceeded. Since the MCLG and the MCL are both set at 1.0, this means that the MCL would also be exceeded. This is confirmed by the example calculation on page 18665 of the preamble to the proposed rule, which shows that the resulting HI, when each of the four component PFAS are detected at their respective PQLs, would be 1.2. DEP believes that this low level for the HI MCL may present a significant implementation challenge. DEP recognizes that if compliance with the HI MCL is determined based on an RAA of quarterly HI calculated results, this may partially alleviate this concern, since one individual quarterly result over the HI MCL would not be an immediate violation. However, as noted above, it is not clear or consistently stated in the regulatory language how compliance is to be determined.
- As previously noted, setting an MCL at a level such that a detection at the PQL would cause an MCL exceedance is not feasible. As noted above, detection of each of the HI PFAS at its respective PQL would cause an exceedance of the HI MCL according to the

proposed regulation. This would not allow a water system to demonstrate compliance with the HI MCL unless one or more components are either not detected or detected below the PQL. However, as already noted, detections below the PQL should not be used for compliance determinations or other regulatory purposes and should be treated the same as non-detections. This would complicate a water system's ability to demonstrate compliance, and it also would complicate the public's understanding of this MCL. MCLs should be set at levels that allow for demonstration of continued compliance by allowing a buffer between the MCL and levels that are considered to be accurate and precise detections. The HI MCL should be set at a level that is higher than the MCLG of 1.0.

- DEP notes that since PFAS are emerging contaminants and research is ongoing, there is the potential for more PFAS to be regulated in the future. With the proposed introduction of the HI approach for regulating PFAS in drinking water, it is not clear what approach will be taken in the future for regulating additional PFAS. If more PFAS are added to the HI calculation in the future, that would further reduce the contribution of each PFAS to the HI (i.e., if eight PFAS are included in the HI calculation, each one can be present at only 12.5% of its HBWC before the MCLG/MCL is exceeded). This would continue to drive down not only analytical requirements and capabilities, but also requirements for treatment capability. As such, this proposed regulation sets the stage for an even more significant implementation challenge in the future.
- The health effects required language for PN for an HI MCL exceedance in Appendix A to Subpart O of Part 141 will be confusing to the public. The required language does not sufficiently explain the HI and is likely to cause confusion and fear.
- The health effects required language for CCR reporting for the HI MCL in Appendix A to Subpart Q of Part 141 will be confusing to the public. The required language does not sufficiently explain the HI.
- DEP believes that communication of the HI MCL to the public will be a significant implementation challenge of the proposed rulemaking. As noted above, the required health effects language does not adequately explain the HI, how it is determined, what the significance is, or why it is unitless. This is likely to cause confusion and fear in the public. Communication to the public in a way that does not incite fear and misunderstanding is critical. One key point that will be important to communicate is the relative source contribution of drinking water and the numerous other potential routes of exposure to PFAS. For a public that is concerned about very low detected levels of PFAS in their drinking water, it is important to educate them on other ways to reduce their exposure, since drinking water is only considered a 20% relative source contribution to overall exposure.
- DEP notes that on page 18690 of the preamble to the proposed rulemaking, EPA states that it "has not separately quantified the benefits and costs for the alternative approach to regulate PFHxS, PFNA, PFBS, and HFPO-DA with individual MCLs instead of the HI." In other words, EPA did not show whether it is more cost effective or more feasible to regulate these four PFAS with traditional MCLGs and MCLs instead of the HI, and it did not clearly articulate the costs and benefits associated with regulating these four PFAS in

a more traditional manner. As a result, it is not clear what impact eliminating the HI and regulating the four HI PFAS with traditional MCLGs and MCLs would have on overall costs. DEP believes that this missing information is critical in the evaluation of this proposed rulemaking and in determining the best way to regulate these PFAS, particularly since – as our previous comments detailed – the introduction of the HI MCL does not appear to be an appropriate application of the HI concept.

- Because of the significant implementation challenges noted above with the HI MCL, DEP suggests that it would be better to use an established approach for regulating these four additional PFAS. For example, using a treatment technique, combined MCL, or individual MCLs would be more feasible for implementation. As noted above, DEP believes that the HI MCL concept, as well as a water system's ability to demonstrate compliance, is likely to be confusing to the public. DEP believes that setting a traditional MCLG and MCL, either individually or combined, for the four HI component PFAS (PFHxS, PFNA, PFBS, and HFPO-DA) instead of using the HI approach would improve clarity for primacy agencies, regulated water systems, and the public. The traditional MCLG and MCL framework is an established framework that can be more readily comprehended.

Compliance Monitoring Considerations

- DEP supports allowing water systems to use data collected for compliance with state PFAS MCL rules, including the Commonwealth's PFAS MCL rule, to meet the initial compliance monitoring requirements of EPA's proposed rule. Allowing systems to use this data would provide significant cost savings and reduce burden while maintaining health protection.
- DEP requests clarification on specifically what "previously collected" data will be acceptable to count for initial monitoring.
 - Currently, it appears that state data in general was excluded as a grandfathering option for previously-collected data. DEP believes that more data that falls outside the scope of the state grandfathering allowance in the proposed rule needs to be included.
 - DEP also believes that the rules for previously-collected data need to be consistent. If data for the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) does not need to meet the proposed trigger level, other data should similarly not be required to meet that low level.
 - The trigger level of 1.3 ppt for PFOA and PFOS is too low for the allowance of previously-collected data. As noted previously, laboratories are generally not capable of accurately detecting PFAS to that level.
- For initial monitoring, EPA proposes allowing groundwater systems serving 10,000 or fewer customers to only collect two samples at each EP instead of four consecutive quarterly samples. DEP recommends requiring **all** water systems to conduct monitoring for four consecutive quarters for initial monitoring. Allowing a reduction from four

quarterly samples to only two samples is appropriate for regulated synthetic organic chemicals (SOCs) because monitoring would be required during the quarters in which those chemicals are most likely used and would affect water system sources. However, for PFAS chemicals, there may be seasonal variations, which would not be captured by allowing a system to reduce monitoring to only two samples.

- DEP requests clarification on which systems will be considered “groundwater systems” for the proposed monitoring flexibility allowing groundwater systems serving 10,000 or fewer customers to only monitor twice for initial monitoring. If a system has their own groundwater sources, but also purchases finished water from a surface water system, will the purchasing system still be considered a groundwater system for the purposes of initial monitoring under this proposed rule?
- According to § 109.XX(b)(2)(i) Table 2, reduced triennial monitoring for systems serving more than 3,300 persons consists of two samples per EP in a consecutive 12-month period during each three-year compliance period, at least ninety days apart; for systems serving 3,300 or fewer persons, reduced monitoring consists of just one sample per EP per three-year compliance period. DEP does not agree with this distinction in monitoring frequency based on system population. While this appears to follow the reduced monitoring requirements for SOCs, there does not appear to be sufficient justification for requiring two samples at larger water systems. The differentiation of population is arbitrary.
- In § 141.XX, Table 1 to paragraph (b)(1)(iv) notes a population delineation for initial monitoring requirements of 10,000, but Table 2 to paragraph (b)(2)(iv) notes a population delineation of 3,300 for reduced monitoring level. DEP notes that this difference is confusing, and that it is further evidence that the population delineations are arbitrary, as noted in the previous comment.
- DEP recommends not allowing nine-year monitoring waivers for any regulated PFAS compounds, regardless of the basis for the waiver determination. Allowing nine-year monitoring waivers assumes that changes in contaminant levels are not expected over a long period of time. However, PFAS are still considered emerging contaminants because researchers are still learning more about their fate and transport in the environment. As such, DEP believes it is inappropriate to make that assumption with these contaminants.
- DEP also recommends not allowing any type of vulnerability waiver for PFAS. Since PFAS do not readily break down in the environment, they are considered forever chemicals, and the vulnerability of a water source cannot be assessed. If any waivers are to be allowed, DEP supports only allowing use waivers, where the public water system must document that PFAS have not been used, stored, or transported in their source water protection area. Refer to DEP’s waiver criteria in [25 Pa. Code Chapter 109](#) for more information.

Laboratory and Analytical Method Considerations

- Regarding significant figures and decimal places, since the reporting limits are not clearly defined and appear to be missing from the proposed rulemaking, as already noted, DEP cannot comment on the missing information and can only make assumptions and comment on those assumptions. Since the PQLs for PFOA and PFOS and the four PFAS included in the HI have one decimal place (i.e., two significant figures), laboratories will need to be able to report to two decimal places (i.e. ### ppt). This further means that laboratories will need to be able to read results to three decimal places. Labs will likely need to purchase the appropriate standards in order to meet the required number of significant figures, since they are not likely to be able to make their own standards. DEP notes that availability of standards for purchase, and the availability of vendors to supply those standards, are likely to be a limiting factor in laboratories' ability to read to this level.
- DEP supports inclusion of EPA Method 537 version 1.1 as an approved method for PFAS analysis. While DEP recognizes that EPA Method 537 version 1.1 does not include HFPO-DA (GenX) as an analyte, which would be a regulated PFAS compound under this proposed rulemaking, it is a valid, EPA-approved method for the other PFAS that EPA is proposing to regulate.
- In § 141.901(a)(2)(ii), Method 537.1, version 1.0 from November 2018, is referenced as EPA document ID EPA/600/R-18/352. DEP notes that version 2.0 from March 2020, EPA document ID EPA/600/R-20/006 is not referenced in the proposed rulemaking. DEP has not been accrediting laboratories for version 2.0 because it contains more than just editorial changes from version 1.0. DEP requests clarification as to whether version 2.0 is an acceptable EPA-approved method for analysis of the regulated PFAS in the proposed rulemaking.
- DEP has several concerns with laboratory capacity considerations:
 - Because there does not appear to be an initial compliance monitoring schedule identified in the proposed rulemaking, systems will likely wait until the last minute to complete their monitoring requirements, which will impact overall lab capacity. Therefore, DEP does not believe that it is safe to assume that lab capacity will be evenly spread out over initial monitoring.
 - Because labs will be expected to meet very low reporting limits, the incidence of QA/QC failures will likely increase. This will result in a greater number of samples that will need to be resampled and reanalyzed. This adds to the burden on the laboratory and further reduces its capacity for additional samples.
 - Many laboratories hold secondary accreditation in states other than the state in which they primarily conduct business. Those labs with secondary capacity are not able to accurately determine what percentage of their total capacity will be available to their state. This complicates the ability to estimate lab capacity.

- As noted previously, many labs will need to purchase standards in order to meet the significant figures required by the proposed rulemaking. This poses two complicating factors to overall lab capacity. One, the standards are very expensive, and two, there are a limited number of vendors from which to purchase those standards.
- Analysis of overall laboratory capacity needs to consider not only the additional drinking water compliance monitoring samples, but also performance monitoring for additional treatment systems that will be required, and monitoring of other environmental matrices that will likely increase as a result of this proposed rulemaking.
- EPA has noted an assumption that the demand for increased monitoring will trigger an increase in overall lab capacity because more labs will seek certification/accreditation in more states. However, DEP notes the significant expense of adding capacity for PFAS analysis for a laboratory. DEP estimates a total initial cost of over \$542,000 to add PFAS analytical capacity, broken down as follows:

Items for Accreditation	Cost
Accreditation Fees	\$5,300
Drinking water PTs annually	\$430
Drinking water standards	\$1,598
Dedicated labware	\$2,250
Instrumentation: LC/MS/MS	\$450,000
Analyst: LC/MS Operator	\$83,180
TOTAL	\$542,758

DEP also notes that this estimated expenditure would be sufficient to add capacity for approximately 20 samples per week, at a maximum, using a manual extraction system. An automated extraction system could potentially increase this to up to approximately 40 samples per week but would add approximately \$40,000 to the above cost estimates. Given the significant costs, it is not a given that more laboratories will seek to become accredited to add capacity for more samples.

- Even if labs make the above investment to seek to add capacity for PFAS analysis, there is no guarantee that the lab will be able to meet the extremely low reporting levels required by this proposed rule. If a lab is not able to meet the trigger level of one-third of the PQL for reporting, water systems will not be able to reduce their burden of monitoring frequency and will likely seek the services of a lab that can meet those lower reporting levels. This will likely further discourage labs from adding analysis capacity.

Treatment Considerations

- DEP recommends that EPA reestablish the national Environmental Treatment Verification (ETV) program to streamline and improve efficiencies regarding review and

approval of new treatment technologies. Without this national program, states must approve treatment technologies at the state level, which is neither streamlined nor efficient, and creates an unnecessary burden on limited resources for states, water systems, and treatment technology manufacturers.

- DEP believes that performance monitoring for systems with PFAS removal treatment will be an implementation challenge with regard to the proposed MCLs. Demonstrating treatment efficacy over time is critical for systems with PFAS removal treatment. Monitoring results are a key data point for system operators in knowing when to switch between lead and lag units and when to change out media. However, the proposed MCLs complicate this effort, because it is not clear what is considered a detection or at what level breakthrough would occur. From a treatment design standpoint, operators need room between detection limits and MCLs in order to ensure continuous compliance and treatment efficacy. This is another implementation challenge caused by setting MCLs at levels such that any detection over the PQL will cause an exceedance.
- Pilot testing costs do not appear to have been included in the cost estimates in the proposed rulemaking. However, DEP believes pilot testing will be even more important with inclusion of both short- and long-chain PFAS in the proposed rulemaking, and, with increasingly low levels of PFAS detections required, pilot testing will become ever more critical when planning for effective PFAS removal treatment. The BAT will remove all six PFAS included in this proposed regulation, but which PFAS will break through first will depend on the type of treatment, forms of PFAS, overall water quality, and potential presence of interferences such as total organic carbon (TOC), manganese, volatile organic chemicals (VOCs), etc. For effective operations, water treatment operators will need to know which PFAS are expected to breakthrough first and on what timeframe, with some level of consistency. Pilot testing will be critical in acquiring that knowledge, and the costs should be considered.

DEP would like to again thank you for the opportunity to comment on EPA's proposed PFAS National Primary Drinking Water Regulation Rulemaking.

Sincerely,



Richard Negrin
Acting Secretary