May 30, 2023

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

Re: Docket #EPA-HQ-OW-2022-0114

To whom it may concern:

The New York State Department of Health (Department), in consultation with our partners at the New York State Department of Environmental Conservation (DEC), is pleased to provide comments on the National Primary Drinking Water Regulation (NPDWR) for per- and polyfluoroalkyl substances (PFAS). We appreciate and support the Biden Administration’s decision to address PFAS chemicals through these regulations. New York State has been and continues to be a national leader in PFAS regulation, assessment and mitigation. We hope that our experience in regulating PFOA and PFOS can assist the United States Environmental Protection Agency (EPA) in realizing meaningful public health protections through implementation of its PFAS action plan and regulatory agenda.

The following comments first address regulatory implementation and enforcement consistent with the Department’s primary enforcement authorities under the Safe Drinking Water Act. These comments also address consistency in the application of the underlying health science (reference doses, cancer slope factors) across EPA’s programs, the health basis of the proposed Hazard Index (HI) approach, and additional implications of the proposed MCL rulemaking.

1. The Department has been implementing enforceable maximum contaminant levels (MCLs) of 10 parts per trillion (ppt) for PFOA and PFOS since 2020. Since January 1, 2021, the number of violations issued for PFOA and PFOS is approximately equal to the number of violations that the Department and its local health department (LHD) partners have issued for all remaining compounds for which there is a national primary drinking water regulation (NPDWR) or State Maximum Contaminant Level (MCL). Currently, out of the 2,576 public water systems (PWS) with results, approximately 250 PWS exceed the regulatory standard at 10 ppt. We anticipate nearly 550 PWS in New York State may exceed the regulatory standard at 4 ppt. If compliance with other MCLs remains constant, nearly 70% of all MCL violations issued in New York will be for PFOA and/or PFOS. The workload involved in determining monitoring frequency, modifying schedules in the Safe Drinking Water
Information System (SDWIS), and notifying public water supplies of the schedules is significant and deserves consideration.

Table 1: PFOA and PFOS Occurrence in New York State

<table>
<thead>
<tr>
<th></th>
<th>Number of PWS with Results</th>
<th>Number of PWS with Max Result &gt; 4 ppt</th>
<th>Number of PWS with Max Result &gt; 5 ppt</th>
<th>Number of PWS with Max Result &gt; 10 ppt</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFOA and/or PFOS</td>
<td>2,576</td>
<td>548 (21%)</td>
<td>482 (19%)</td>
<td>252 (10%)</td>
</tr>
</tbody>
</table>

2. While an increase in primacy agency workload is to be expected any time a new MCL standard is promulgated, the workload associated with promulgating these standards is expected to be more significant. Workload for primacy agencies has been increasing to unsustainable levels at a time when the Drinking Water State Revolving Fund (DWSRF) base grant funds, and thus set asides used to fund primacy agency programs, have been reduced by upwards of 50%. These sources have historically been used to fund regulatory program staff and ensure the EPA’s mission is fully executed in accordance with the Department’s primacy enforcement authority. Although the Infrastructure Investment and Jobs Act (IIJA) has provided a much welcome boost to primacy agency programs in the form of set asides, the effective date of this proposed NPDWR is expected to be in late 2026 or early 2027, which is the last year IIJA funds will be awarded. If a regulation with such broad impact is promulgated, EPA must work with Congress to concurrently increase funding to the Public Water System Supervision (PWSS) state and tribal assistance grant to ensure that primacy agencies have a stable source of funding for staff to ensure the public health protection goals in the NPDWR proposal are realized well into the future.

3. EPA solicited comment on establishing the proposed rule trigger level values of 1.3 ppt for PFOA and PFOS and 0.33 for the PFAS regulated by the Hazard Index (HI). Although the Department currently considers any detection above the method detection limit a “detect” and requires quarterly monitoring as a result, there is a mechanism for the water system to reduce monitoring to annually if they are reliably and consistently below the MCL of 10 ppt. The Department recommends that EPA consider allowing water systems with levels between the trigger level and MCL to be permitted to monitor annually if, after 4 quarters of monitoring, levels are consistently between the trigger level and the MCL.

4. EPA requested comment on whether an alternative approach to calculating the running annual averages should be considered. The Department does not object to the compliance calculation as initially proposed, with results below the Practical Quantitation Limit (PQL) considered to be 0.

5. While we support regulatory flexibility for those public water systems that have demonstrated an absence of these compounds, their ubiquitous nature makes developing and implementing science-based criteria to assess a source’s vulnerability to contamination impractical. If waivers are considered, we recommend that eligibility is based on at least 4 consecutive quarters of monitoring data at each source rather than an assessment of vulnerability.

6. The Department notes that EPA has historically recognized that the precision and accuracy of analytical results are sacrificed as reporting limits are set closer to method detection limits
(MDL). EPA has historically used the reduction in health risk as justification for the sacrifice in analytical precision and accuracy, though only three other organic contaminants that are regulated through NPDWR have MCLs at a similar multiple of the MDL proposed for PFOA and PFOS.

In addition, EPA has in the past highlighted vulnerability assessments and the availability of monitoring waivers to respond to concerns about laboratory proficiency and, therefore, laboratory capacity when MCLs are established at such low levels. We posit that in this case the concerns about laboratory capacity are consistent with similar concerns raised in the past, but that the relief afforded by waivers may not be available to offset the burden under the proposed rule.

7. Should the EPA proceed with MCLs of 4 ppt, the Department suggests that EPA evaluate a bin approach similar in structure to the Stage 2 Disinfectants and Disinfection Byproducts Rule or Long-Term Surface Water Treatment Rule. This approach could allow for staggered compliance with additional time for compliance provided to smaller systems. This approach will ease the workload on primacy agencies, ensuring appropriate and timely enforcement as well as equitable distribution of technical assistance resources. In addition, this approach may alleviate some of the competition between small systems and large systems for analytical services, engineering, construction materials and labor that may negatively impact disadvantaged communities.

8. Although the Department recognizes the reasoning behind Entry Point to Distribution System (EPDS) monitoring for organic chemicals, the fate and transport of PFAS compounds, occurrence, and the low MCL makes this approach less conservative, and therefore less protective of public health.

Concentrations of PFAS compounds can vary significantly within a single well field within the same aquifer, and traditional methods of EPDS monitoring may not be appropriate. With a proposed MCL at 4 ppt, there are many instances where a single well that can be operated independently may exceed the MCL, while other wells within the aquifer remain below the standard. Although regulations specify typical operation, a public water system that has source water data can collect samples at EPDS during times when the lower concentration wells are in service to remain in compliance with the proposed standard. The complexity of many water systems makes it challenging for primacy agencies to be able to fully capture what happens during typical operation.

The Department currently requires monitoring at each source, however, we recognize that there may be opportunities to lower costs, particularly at small water systems, while concurrently obtaining a more robust dataset than we believe can be accomplished by entry point monitoring alone. The Department suggests EPA require 4 consecutive quarters of monitoring at each source if a public water system has an EPDS result greater than the trigger level for any PFAS compound during initial monitoring. Using an EPDS to determine compliance should be at the discretion of the primacy agency based on operational conditions of the water system that include but are not limited to number of sources, the presence of treatment to remove PFAS, number of EPDS, and the presence of source water monitoring data.

9. The EPA’s proposed approach to establish a HI as a way to address the additive health effects of mixtures is precedent setting for drinking water standards and presents implementation challenges. Regulators and public water systems will be required to provide
education and communication on the new compliance concept, while also tracking and enforcing PFOA and/or PFOS MCLs in a more traditional way. Based on existing compliance data, the Department does not believe that the added complexity of the HI approach will provide significant additional public health protection, since monitoring conducted in New York State demonstrates that PFAS compounds used to calculate the HI typically co-occur with PFOA and/or PFOS. The Department supports establishing individual MCLs for GenX, PFBS, PFNA and PFHxS. As shown in Table 2, New York State expects 3 water systems to exceed the Hazard Index that do not have PFOA or PFOS greater than 4 ppt.

### Table 2: Hazard Index Impact Assessment

<table>
<thead>
<tr>
<th>Number of Public Water Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI &gt; 1</td>
</tr>
<tr>
<td>&gt; at least one individual HBWC</td>
</tr>
<tr>
<td>&gt; individual HBWCs but PFOA and/or PFOS &lt; 4</td>
</tr>
<tr>
<td>&gt; individual HBWCs but PFOA and/or PFOS &lt; 5</td>
</tr>
<tr>
<td>&gt; individual HBWCs but PFOA and/or PFOS &lt; 10</td>
</tr>
<tr>
<td>N= 1,518 PWS</td>
</tr>
</tbody>
</table>

10. The Department acknowledges the large contribution of benefit that reductions in bladder cancer, due to disinfection byproduct (DBP) precursor removal, has on the total benefit of the proposed rulemaking. However, there are many uncertainties associated with this benefit that do not appear to be addressed in Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits, including:

- This benefit assumes total organic carbon (TOC) reduction due to reverse osmosis (RO), GAC installation, or presence of ion exchange resins that can concurrently remove TOC and PFAS compounds. This proposal also does not recognize emerging treatment technologies such as natural and engineered clays that will have limited TOC reduction benefit, although EPA acknowledges that GAC or RO may not be the selected treatment alternative.
- According to Table 6-53 of the Economic Analysis “EPA uses relationships between TOC levels and changes in THM4 levels among GAC-treating systems from the 1998 DBP ICR…” Although the Department recognizes the importance of TOC precursor removal as a DBP reduction strategy, the EPA does not recognize the uncertainty that there is not always direct correlation between THM4 levels and TOC in all public water systems. (Consonery et. al, 2004)
- In New York State, most PFAS impacted public water systems have groundwater sources and disinfection byproduct levels are negligible. Of the 551 public water supplies New York State expects may exceed one or more proposed MCLs, 12% are surface water or groundwater under the direct influence (GWUDI) of surface water and 88% are groundwater systems. As indicated in 6.7.1.2 Baseline Information on DBP Precursors and Trihalomethane Formation, “the [TOC] levels in Ground Water plants tended to be lower compared to concentrations in Surface Water plants”.
- Of the 12% of public water systems that are surface water or GWUDI systems, approximately 21% have at some time exceeded a THM4 or haloacetic acid (HAA5) MCL. This represents 2.7% of the total number of public water systems expected to exceed a PFAS MCL.
The Department supports rulemaking based on sound science that provides meaningful reduction of all cancers. According to the New York State Department of Health, approximately 5,400 New Yorkers are diagnosed with bladder cancer each year. However, we suggest that reduction of bladder cancers is best addressed by TOC removal benchmarks through the existing practice of treatment technique regulations for disinfection byproducts as well as distribution system controls, rather than indirectly through PFAS MCLs that do not include a treatment optimization component with no mechanism to monitor performance.

11. Rapidly evolving PFAS research complicates cost-forecasting for water testing, treatment technologies and healthcare. Shifting state and federal regulations generate unanticipated expenses in drinking water sampling and filtration, product testing, and treatment of wastewater and landfill leachate. There are uncertainties in how long filters will perform and what their disposal costs may be, treatment methods are rapidly evolving and demand for filtration systems is skyrocketing, driving up costs and causing delays on top of existing supply-chain challenges. Water treatment operators that find PFAS during sampling must test water more frequently, an ongoing expense that drives up operating costs. Treatment add-ons to existing plants will likely require the acquisition of additional land, operators and ancillary equipment.

12. In quantifying the benefits realized through the use of RO, GAC and ion exchange resins to treat PFAS, EPA does not consider the potential health impacts associated with microbiological, organic and inorganic constituents that may leach or be released from the treatment media, potentially offsetting a portion of the benefits. Carbon used for PFAS removal is typically either bituminous or coconut shell-based coals. All coals contain some arsenic (USGS, 2005). While coconut shell-based coals can have lower arsenic levels than their bituminous competitors, many of the largest producers of GAC for PFAS removal use bituminous based coals for PFAS removal. To compensate, many GAC manufacturers have developed acid washed coal to reduce levels of contaminants. Nonetheless, based on our observations in full scale carbon treatment systems, the New York State Department of Health has developed guidance that recommends three consecutive results be provided that show decreasing arsenic concentrations as the forward rinse to waste progresses and for which the last sample concentration is below the arsenic MCL².

The presence of microbiological activity in GAC filters is well documented in scientific literature. Although the presence of heterotrophic bacteria, including total coliform, is not necessarily a public health concern, these issues should be considered during design as well as during operation and maintenance depending on the influent quality. Overall, the presence of GAC filters may require changes in chemical dosages that could impact simultaneous compliance with both the lead and copper rule and the Stage 2 disinfectants and disinfection byproducts rule (Stage 2 DBPR) due to temporary increases in pH. Although these issues can be addressed with proper monitoring and operation, they also may impact the cost of treatment systems as well as operation and maintenance and should be addressed as an uncertainty.

13. The Department reviewed the Drinking Water Treatment Technology Unit Cost models, with particular interest in the granular activated carbon cost model and is concerned that the EPA

has underestimated the cost of this proposal. This cost model does not include an evaluation for PFAS chemicals specifically but includes cost estimates for several organic contaminants. We recognize that there are weaknesses to using the standard design with linear interpolation for cost comparison purposes. We are using it only to illustrate the significant difference in cost between installations in the State of New York and the estimating tools available from EPA. Given the limited time provided for public comment, we were unable to do an in-depth evaluation of the economic analysis and customize the work breakdown structure (WBS) tool to determine if it was plausible to make modifications that would align the tool with New York State costs.

Table 3: New York State Costs for GAC Treatment Installed in the Newburgh Area

<table>
<thead>
<tr>
<th>GAC Location</th>
<th>Design Capacity (MGD)</th>
<th>Capital Cost ($million)</th>
<th>WBS ($million estimate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Town of New Windsor Temporary GAC Butterhill WTP⁴ 2019</td>
<td>2.1</td>
<td>$1.4</td>
<td>$1.9</td>
</tr>
<tr>
<td>Town of New Windsor Permanent GAC Butterhill WTP (estimate)</td>
<td>6.5</td>
<td>8.14</td>
<td>3.8</td>
</tr>
<tr>
<td>Town of New Windsor Permanent GAC Kroll 2019</td>
<td>0.43</td>
<td>1.9</td>
<td>0.34</td>
</tr>
<tr>
<td>Town of Berlin Permanent GAC WTP 2017</td>
<td>0.5</td>
<td>0.64</td>
<td>0.36</td>
</tr>
<tr>
<td>City of Newburgh Washington Lake Filter Plant 2018</td>
<td>8.3</td>
<td>19.75</td>
<td>4.7</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>$31.8</td>
<td>$11.1</td>
</tr>
</tbody>
</table>

Each of the projects listed above were completed prior to the pandemic and prior to inflation experienced during the post-pandemic period. Nonetheless, the EPA estimated costs are considerably lower than the actual costs incurred by New York State prior to inflation.

Additionally, New York State compared data contained in preliminary engineering reports submitted for listing on the 2023 DWSRF Intended Use Plan Final Amendment #2 – Bipartisan Infrastructure Law Emerging Contaminants and compared those costs to the WBS model for organic compounds treating groundwater, using the standard design. New York State recognizes that most of these projects are on Long Island, where labor and construction costs can be higher than the remainder of the State.

Table 4: Cost Comparison of Projects Listed in IUP to EPA Cost Models

<table>
<thead>
<tr>
<th>GAC Location</th>
<th>Design Capacity (MGD)</th>
<th>Capital Cost ($million)</th>
<th>WBS ($million estimate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nyack Village PFAS treatment at water plant (19171)⁶</td>
<td>3</td>
<td>$4.7</td>
<td>$2.8</td>
</tr>
<tr>
<td>Starr Ridge Manor Town of Southeast GAC treatment system (19496)</td>
<td>0.13</td>
<td>2.0</td>
<td>0.149</td>
</tr>
<tr>
<td>Birch Hill Acres Town of Southeast (19495)</td>
<td>0.06</td>
<td>1.2</td>
<td>0.135</td>
</tr>
<tr>
<td>Jericho Water District relocate existing GAC vessels to well 29 and install new GAC vessels at wells 18 and 19 (19393)</td>
<td>4</td>
<td>17.6</td>
<td>3.7⁷</td>
</tr>
<tr>
<td>Port Washington Water District new GAC to remove contamination at well #7 (19485)</td>
<td>0.7</td>
<td>8.1</td>
<td>0.392</td>
</tr>
</tbody>
</table>

³ Estimate used standard design in WBS model with linear interpolation.
⁴ Project did not include permanent enclosures.
⁵ Estimate used standard design in WBS model with linear interpolation.
⁶ Water system may benefit by reduction in TOC by GAC.
⁷ Cost estimate evaluated based on 2.152 MGD standard design.
Table 4: Cost Comparison of Projects Listed in IUP to EPA Cost Models

<table>
<thead>
<tr>
<th>GAC Location</th>
<th>Design Capacity (MGD)</th>
<th>Capital Cost ($million)</th>
<th>WBS ($million estimate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Port Washington Water District new GAC to remove contamination at well #6 (19484)</td>
<td>0.7</td>
<td>8.1</td>
<td>0.392</td>
</tr>
<tr>
<td>Port Washington Water District new GAC to remove PFAS at Hewlett Well #4. (19337)</td>
<td>1.7</td>
<td>6.9</td>
<td>1.6</td>
</tr>
<tr>
<td>Albertson Water District remove PFAS at wells 1, 2, and 5 (19338)</td>
<td>4.68⁸</td>
<td>18.5</td>
<td>4.3⁶,⁷</td>
</tr>
<tr>
<td>Carle Place Water district remove PFAS at wells 3 and 4 (19392)</td>
<td>3.45</td>
<td>7.6</td>
<td>3.2⁶</td>
</tr>
<tr>
<td>Williston Park wells 1A and 2 GAC PFAS treatment (19371)</td>
<td>4⁹</td>
<td>12.0</td>
<td>3.7⁶</td>
</tr>
<tr>
<td>Williston Park well 4 GAC treatment (19369)</td>
<td>2</td>
<td>8.6</td>
<td>1.8</td>
</tr>
<tr>
<td>Sands Point Water District removal of PFAS at wells 3 and 4 (19233)</td>
<td>1.4¹⁰</td>
<td>10.5</td>
<td>0.54</td>
</tr>
<tr>
<td>Sands Point Water District wells 2A and 5A GAC treatment for PFAS removal (19012)</td>
<td>1.3</td>
<td>8.4</td>
<td>0.51</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$114.2</strong></td>
<td><strong>$23.2</strong></td>
</tr>
</tbody>
</table>

While the cost difference can be partially due to increased construction costs in the New York City metropolitan area as well as inflation, it does not fully account for the discrepancy. Again, given the short timeframe states were given to provide comment, it was not feasible to conduct a thorough review of the economic analysis to determine if these discrepancies are addressed by EPA elsewhere in the proposal or in the cost estimating tools. Based on the information available, we estimate that the present value cost to New York State of the proposal based upon 551 supplies that may have violations, is approximately $1.6 billion with annual O&M of approximately $50 million. While the Department appreciates additional funding through the IJJA, this funding accounts for a fraction of the total funding need. We recommend that EPA re-evaluate the cost estimate using data generated through Bipartisan Infrastructure Legislation Emerging Contaminant IUPs as well as current industry data and update estimates to ensure the tools utilized reflect real world current economic conditions and costs, including sector specific costs after inflation. We note that this rule will likely result in increasing inflation pressures on GAC and other construction materials, as well as in the needed labor force given the significant need for PWS treatment. The effect of cross cutters such as Buy American Build America Act (BABAA) is another uncertainty that deserves attention.

14. NYS appreciates the fact that EPA has estimated the net cost/benefit of different regulatory thresholds, 4, 5 and 10 ppt. We note that the estimated net benefit of 4 ppt is only slightly greater than the net benefit at 10 ppt ($240M vs $200M at 3% discount rate) when focusing solely on the direct health benefits of PFOA/PFOS mitigation and not including co-benefits from the removal of disinfection byproducts. As noted, the overwhelming majority of water supplies expected to be impacted by this proposal in New York State will not benefit from co-removal of TOC. Thus, when considering the direct impact of PFOA/PFOS regulation, the Department is pleased to see that EPA’s analysis supports a high degree of net benefit from

---

⁸ Proposal includes 3 treatment systems at 1.5 MGD, 1.44 MGD and 1.73 MGD.
⁹ Proposal includes 2 treatment systems at 2.0 MGD each.
¹⁰ Proposal includes 2 treatment systems at 0.7 MGD each.
the MCLs already in place in NYS since 2020, and that this is not substantially different than the estimated benefit at 4 ppt.

15. Although private wells are excluded from SDWA, they still present challenges for primacy agencies. Private well owners will place an increased demand for analytical services that will further strain analytical capacity. In addition, private well owners will also place demand for carbon media, resins and membranes. To meet the public health concerns raised by PFAS in community groundwater coming from waste sites, landfills, industries and various sources (including septic systems), NYS has already expended more than $30 million on assistance to private well owners for testing and mitigation of PFOA and/or PFOS based upon mitigation when private wells in an investigation area have results above the NYS MCL of 10 ppt separately for each. This number does not include $80M+ that NYS has spent to address both private and public water supplies in the City of Newburgh and Town of New Windsor. Should this public health protective target be reduced further there will be a substantial increase in costs to mitigate the widespread occurrence of PFOA/PFOS below 10 ppt in community groundwater. While EPA may have infrastructure funding targeted for this need, it is not clear that the Agency is aware of the magnitude of the anticipated need in this area.

While many homes with private well contamination may be able to connect to a public water supply, many homes will not, and will instead seek mitigation of their private water supplies. DEC has been providing Point of Entry Treatment (POET) in many areas of the State affected by PFAS contamination. Installation of each POET is approximately $4,000 inclusive of design services and labor and an operation and maintenance cost of $1,500 per POET annually. These costs are reflective of bulk purchase and installation scenarios.

16. EPA requested comment on the regulation of GenX compounds as part of this proposed rulemaking. Based on monitoring conducted in NYS to date, four public water systems are known to be above the health-based standard of 10 ppt. Although we do not oppose regulation of GenX compounds, the benefit of this regulation will not likely be widespread in New York.

17. EPA requested comments on implementation challenges and requested feedback on considerations for setting MCLs at the PQLs. New York State has been implementing enforceable MCLs for PFOA and PFOS since August of 2020. In that time, approximately 250 public water systems have exceeded the MCL. During that same period, the cost of equipment, including treatment vessels and media have been subject to periodic disruptions in the supply chain, and have significantly increased in cost. Shortage of human capital, such as engineering services, has also emerged as a challenge to effective implementation. As the workforce emerges from a global pandemic both regulating and regulated communities are working to fill the voids left through attrition, while navigating a new workforce paradigm.

In addition, it is challenging to enforce regulations at the PQL when there is uncertainty in the analytical method. Enforcing MCLs is a legal proceeding where the respondent is entitled to due process. It is conceivable that public water suppliers will appeal MCL determinations on the grounds that results are within the standard error of the analytical method, further straining state enforcement resources as well as Federal resources in states that do not immediately obtain primacy.
18. EPA is seeking comment on the benefits of treatment technologies such as Reverse Osmosis to co-remove other contaminants. To date New York State has not approved large scale use of reverse osmosis (RO) treatment to address issues associated with PFAS. We recognize the appeal of RO to address co-occurrence of PFAS with organic and inorganic contaminants. However, we caution that any decision to proceed with RO be accompanied by a science-based evaluation of simultaneous compliance with the Lead and Copper Rule and its successors at each public water system proposing its use. We recognize that RO may be suitable for some challenging water quality issues as well as at very small water systems and is an important tool in the regulatory toolbox. At this time, we do not believe that widespread application is practical with current technologies. We anticipate that membrane technologies will continue to evolve with time, and the Department will consider health protective treatment proposals that are supported by site specific engineering evaluations.

19. The HI approach encompasses at least one chemical (PFBS) that is likely to have reduced retention and more rapid breakthrough than the long-chain PFAS. It is unclear if the operation and maintenance costs for PFBS changeout have been considered separately and if there is sufficient science to support such an analysis. Based on data available to New York State, it is unlikely, however, that PFBS will be the driver for media changeout at the 2,000 ppt health-based water concentration.

20. In accordance with Section 141.CC.c(b)(1)(v), data collected between January 1, 2019, and December 31, 2022, may also be used if it is below the rule trigger level of 1.3 ppt for PFOA and PFOS and below an HI of 0.33. It is not clear why results above the trigger level couldn’t also be used to satisfy the initial compliance period.

21. Please see 88 FR 18697, Section XIII.C(1)(f) which indicates that systems that have an MCL exceedance will collect one additional sample from the relevant entry point to confirm the results. This appears to be inconsistent with compliance monitoring prescribed for the running annual average calculation.

22. In accordance with Section 141.XX.c(b)(2)(iv) states may delete results of obvious sampling errors from the compliance calculations. It is not clear what constitutes an obvious sampling error, or if this latitude extends beyond sampling and also affords states the freedom to delete results due to obvious analytical errors or other circumstances. While we appreciate the discretion afforded to states, we believe that this provision is too broad, and provides an opportunity for inconsistent application. Analysis of the field reagent blank (FRB) should identify any sample contamination that occurred during sample collection. States should be given the ability to invalidate results with detections in the FRB as well as the ability to invalidate results with detections in the laboratory blanks.

23. The Department supports allowing systems with multiple entry points to the distribution system (EPDS) to have different monitoring schedules for each EPDS.

24. Proposed Reference Doses and Cancer Potency Factors: The proposed rule identifies reference doses (RfDs) and cancer potency factors for both PFOA and PFOS. If the rule is adopted, it is critical for EPA to clarify the status of these toxicity values. Is the Agency planning to include the PFOA and PFOS RfDs and cancer potency factors on the Integrated Risk Information System, or use them as the basis for guidelines for various environmental media for other EPA programs? For example, the Regional Screening Levels for Chemical
Contaminants at Superfund Sites\textsuperscript{11} currently use the minimal risk levels (MRLs) for PFOA and PFOS (3 and 2 ng/kg/day, respectively) derived by the Agency for Toxic Substances and Disease Registry (ATSDR, 2021). These MRLs lead to residential tap water guidance values of 40 ng/L and 60 ng/L for PFOA and PFOS, respectively, which greatly exceed the proposed MCLs (4 ng/L). Adoption of the reference doses (0.03 and 0.1 ng/kg/day for PFOA and PFOS, respectively) and cancer potency factors (0.0293 and 3.95x10\textsuperscript{-5} per ng/kg/day for PFOA and PFOS, respectively) in the proposed rule will likely result in Regional Screening Levels at Superfund Sites being below the analytical levels of detection. It is critical for the Agency to describe how the underlying toxicological science will be applied consistently across programs.

25. Proposed Hazard Index Approach: The proposed rule would implement a framework for regulating a mixture of additional PFAS in drinking water through a hazard index approach rather than chemical-specific maximum contaminant levels (MCLs). However, the proposed approach is a departure from traditional risk assessment methods. The toxicity values for the four PFAS in the hazard index approach are based on disparate toxic endpoints (i.e., thyroid effects for PFBS and PFHxS, developmental effects for PFNA, and liver effects for GenX). This deviates from guidance on the use of hazard indices provided in the US EPA Risk Assessment Guidance for Superfund (US EPA 1989) and the US EPA Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (US EPA 2000), which indicate that the premise of the hazard index is dose additivity where the component chemicals of the mixture have similar toxic effects on the same organ or biological system. The US EPA (1989) guidance further states that “application of the hazard index equation to a number of compounds that are not expected to induce the same type of effects or that do not act by the same mechanism could overestimate the potential for effects...”

A further anomaly in the hazard index approach concerns the way the hazard quotients are calculated. Hazard quotients are traditionally calculated as a ratio of equivalent measures of exposure. In other words, the contaminant exposure (usually in mg/kg/day) is typically compared to an unadjusted reference dose. The hazard quotients in the proposed rule are analogously calculated using water concentrations, but the water concentration representing the exposure of interest is compared to a health-based water concentration that is adjusted by a 20% relative source contribution. This is a departure from the traditional hazard quotient calculation used in risk assessment, biases the calculation toward non-compliance, and may overestimate the level of noncancer risk.

Grouping PFAS indiscriminately without considering toxic endpoint, mechanism of action or structural similarity is not necessarily the best precedent for EPA to take. We note that EPA’s Science Advisory Board’s (SAB) review of a mixtures framework for PFAS was in the context of the general hazard index approach (involving different reference value health endpoints) being an initial screening tool that would require further evaluation, rather than a regulatory tool for national drinking water standards (Final SAB Report, August 22, 2022 - response to Charge Question #2, page 91). EPA needs to carefully evaluate the proposed hazard index approach both for scientific merit and regulatory precedent. There have been a variety of other PFAS grouping approaches taken in risk assessment and regulatory contexts including a proposed rulemaking package in New York State in which PFAS were grouped on endpoint and structural grounds. We encourage EPA to reconsider how the critically important issue of PFAS mixtures should be addressed within a regulatory context.

\textsuperscript{11} https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables
26. EPA is requesting comment on a drinking water proposal when it is still unknown what the impacts will be on water treatment plant residuals and wastewater treatment plants. EPA assessed residuals costs in its economic analysis and concluded no significant impact. There will not be agreement on this conclusion, particularly for small systems. Clean Water Act regulations, if ultimately promulgated, may restrict water treatment plant discharges to water bodies forcing wastewater treatment plants to look upstream and preclude WTP discharges to the collections system. In addition, a hazardous substance designation under the Resource Conservation Recovery Act (RCRA) will increase costs and a hazardous constituent designation under the Comprehensive Environmental Response, Compensation and Recovery Act may create liability for both water and wastewater treatment plants.

27. As noted above, there are significant variabilities surrounding disposal costs of treatment residuals such as spent activated carbon. In New York, some water treatment facilities are landfiling all residuals while other residuals are being regenerated and reused, resulting in very different costs. Evaluating the cost of managing these residuals is complicated by potential liability, perceived or actual, if PFAS from these residuals end up in landfill leachate or air discharge from thermal treatment facilities. The possibility of a RCRA Hazardous Waste designation for some PFAS-wastes adds even more uncertainty, with much higher costs. Development of a cost-effective solution for treatment or disposal of PFAS-wastes is critical to many aspects of New York's response to PFAS contamination, and we urge EPA to make this a priority.

28. The 60-day time frame for public review and comment does not permit sufficient time to fully analyze the cost estimates, benefits and economic analysis associated with the proposal. The Department is concerned considering the extent to which this proposal shifts the regulatory paradigm.

Again, the State of New York appreciates the leadership of the Administration and the EPA in the preparation of this proposal. We are happy to provide EPA with any data or supporting documentation necessary to finalize the rule and aid implementation.

Sincerely,

Gary Ginsberg, PhD
Director
Center for Environmental Health
New York State Department of Health

Cc: J. McDonald
    B. Seggos
    M. Baldwin
    S. Mahar
    U. Bauer
    D. Lang
    C. Westerman
    E. Lewis-Michl
    T. Johnson
C. Vooris
K. Wheeler
N.S. Alderman
T. Hunt

References


NYS (2022) Amendment of Subpart 5-1 of Title 10 NYCRR (Maximum Contaminant Levels (MCLs)). Accessed at: https://regs.health.ny.gov/volume-title-10/content/subpart-5-1-public-water-supples.

