Comments of the Independent Regulatory Review Commission

Environmental Quality Board Regulation #7-569 (IRRC #3334)

Safe Drinking Water PFAS MCL Rule

May 27, 2022

We submit for your consideration the following comments on the proposed rulemaking published in the February 26, 2022 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Environmental Quality Board (Board) to respond to all comments received from us or any other source.

1. **Determining whether the regulation is in the public interest; Economic or fiscal impacts; Protection of the public health, safety, and welfare; Reasonableness; Implementation; Acceptable data.**

This proposed regulation from the Board amends Chapter 109 (relating to safe drinking water) to set maximum contaminant level goals (MCLG) and maximum contaminant levels (MCL) in drinking water for two chemicals – perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), which are part of a larger group of perfluoroalkyl and polyfluoroalkyl substances (PFAS). The proposed rulemaking also establishes monitoring requirements for public water systems to demonstrate compliance with the PFOA and PFOS standards. These contaminants presently are not regulated in drinking water at the federal level or in Pennsylvania. Currently, the United States (U.S.) Environmental Protection Agency (EPA) has established a lifetime health advisory level (HAL) for PFOA and PFOS of 70 parts per trillion (ppt) combined.

In December 2019, the Department of Environmental Protection (DEP) Safe Drinking Water Program executed a toxicology services contract with Drexel University (Drexel) to review other state and federal agency work on MCLs, independently review the data, science, and studies, and develop recommended MCLGs for select PFAS. MCLGs are nonenforceable, developed solely based on health effects and do not take into consideration other factors, such as technical limitations and cost. MCLGs are the starting point for determining MCLs. Drexel provided an MCLG report, "MCLG Drinking Water Recommendations for PFAS in the Commonwealth of Pennsylvania," developed by the Drexel PFAS Advisory Group, a multidisciplinary team of experts in toxicology, epidemiology, and drinking water standards, and risk assessment. Based on the recommendations from the Drexel PFAS Advisory Group, the Board is proposing an MCL of 14 nanograms per liter (ng/L) for PFOA and an MCL of 18 ng/L for PFOS. The Board states that implementation of these proposed drinking water standards will protect Pennsylvanians from the adverse health effects of these contaminants.

This proposal from the Board has generated significant interest from the regulated community, including environmental groups, health advocates, water companies, local governments, and various trade associations, as well as, the House Environmental Resources and Energy Committee (Committee), 31 members of the General Assembly, a member of the U.S. Congress, and the EPA. We address the comments of the Committee and those of the legislators which relate to our criteria throughout the pertinent sections below. We note that all commenters support the concept of safe drinking water in varying degrees, from those strongly supporting the proposal and expressing the need to make the final regulation even more protective to those expressing concerns related to issues such as economic or fiscal impacts, implementation, and acceptable data.

Protection of the public health, safety, and welfare

A commenter points out that numerous scientific institutions support grouping PFAS as a class given shared hazard traits. The commenter states that Vermont has an MCL of 20 ppt for the combined levels of five different PFAS, and both Maine and Massachusetts similarly have a 20 ppt MCL for the sum of six PFAS, recognizing that PFAS compounds target the same health endpoints. We ask the Board to explain the reasonableness of addressing PFOA and PFOS as individual compounds rather than as a class.

Implementation: forthcoming federal regulation

We note that the Board states in the Preamble, "With the proposed amendments, the Commonwealth would move ahead of the [EPA] in addressing PFOA and PFOS in drinking water and join a small group of states that have set MCLs for select PFAS in drinking water." Regarding the EPA, in response to Question 9 of the Regulatory Analysis Form (RAF), the Board states,

> HALs are not enforceable standards, but the Department has the regulatory authority to require corrective actions if HALs are exceeded, as well as having the statutory authority to set state [MCLs] in drinking water. Current research indicates that the HAL is not sufficiently protective of public health. On February 22, 2021, EPA issued final regulatory determinations for contaminants of the fourth Contaminant Candidate List, which included a final determination to regulate PFOA and PFOS in drinking water. **This determination was published in the Federal Register on March 3, 2021 (86 FR 12272), which starts a 24-month time clock for EPA to publish a proposed rulemaking.** In the meantime, one of the goals of the PFAS Action Team in Pennsylvania, created by Executive Order 2018-08 signed in September 2018 by Governor Wolf, is the establishment of a state MCL in drinking water. Until EPA publishes a final rulemaking for PFOA and PFOS, a state drinking water standard is needed to improve public health protection. [Emphasis added.]

Commenters raise concerns regarding the timing and alignment of this regulatory package and the forthcoming federal regulation. A commenter states that, according to EPA's PFAS Strategic Roadmap, the agency plans to propose a National Primary Drinking Water Regulation (NPDWR) for PFOA and PFOS in the fall of 2022, with a final regulation expected in the fall of

2023. The commenter notes that there is a distinct possibility that EPA's NPDWR could be promulgated before the effective date of this final-form regulation. Other commenters express concern that the overlap of the two rulemakings could cause confusion among the regulated community. Commenters raise questions, including:

- Has the Board engaged the EPA regarding the nearly simultaneous development of MCLs for PFOA and PFOS at the federal and state levels?
- Has the Board considered delaying implementation to avoid conflicting requirements and duplicate sampling?
- How will the Board address a situation where EPA's drinking water standards for PFOA and/or PFOS are either more stringent or less stringent than the Board's corresponding final standards for PFOA and/or PFOS?

We ask the Board to address commenters' implementation concerns regarding the promulgation of potentially overlapping and potentially differing state and federal regulations related to PFOA and PFOS in the Preamble to the final-form regulation.

Commenters further note that the EPA sampling is anticipated to occur simultaneously with initial monitoring requirements of this rulemaking and ask the Board to use the EPA data for compliance with the initial monitoring period. Commenters also question whether there may be a shortage of certified laboratories to perform testing due to the overlap in timing of the federal and state regulations. In response to Question 19 of the RAF, the Board explains its staggered approach to implementation based on the population served. The Board further explains the intention is "to evenly split initial monitoring across two years **in order to ease laboratory capacity issues** and allow small systems more time to prepare for compliance monitoring." [Emphasis added.] We ask the Board to provide information on the number and capacity of laboratories certified to perform required testing for implementation of the final regulation.

Implementation: costs

A commenter states that drinking water facilities are passive entities that are subject to this regulation due to the action of others. The commenter further notes that "[m]ost, if not all, of these facilities were not designed to treat emerging contaminants such as PFAS." The commenter urges the Department to undertake regulatory initiatives that address, at a minimum, source control requirements related to PFAS to eliminate or substantially reduce, among other things, the costs of PFAS treatment, management, and monitoring that will be directly borne by the regulated community. We ask the Board to address the impact of other regulatory initiatives related to PFAS source control requirements on the economic impacts of the final regulation.

A commenter notes that the Board's cost estimate purports to include capital costs, monitoring, sampling, and annual operation and maintenance costs associated with the rulemaking but fails to fully explain the basis for these figures. The commenter further notes that the proposal identifies a few sources of funding, but does not address whether the funding will be sufficient to enable public water systems to afford the costs. The commenter states that the proposal fails to address whether public water systems will need to make rate adjustments to accommodate the additional capital and operational costs or explain how rate adjustments will affect ratepayers. We note that in response to RAF Question 15, the Board acknowledges that "complying with this rule will

result in some cost increases to [public water systems], which may be passed on to the customers they serve." We ask the Board to amend the RAF to the final-form regulation to address the basis for the cost-estimate figures and the economic or fiscal impacts on water systems if insufficient funding is available for implementation. Also, we ask the Board to amend its response to RAF Question 17 relating to the financial and economic impact of the regulation on individuals to include ratepayers.

A commenter advocates for greater clarity related to costs of treatment and monitoring. The commenter notes the following from the Preamble: "Treatment cost estimates are based on the costs to install and maintain treatment for a 1 [million gallons per day (MGD)] treatment plant. The actual costs would be expected to be proportionally less for a treatment plant with a smaller design capacity." The commenter questions what data, other than the proportional calculations provided in the proposal, form the basis for this assumption. The commenter further questions if the same proportional analysis would be valid for treatment plants with a design capacity above 1 MGD. We ask the Board to amend the Preamble and RAF to the final-form regulation to address these concerns and provide greater clarity related to economic and fiscal impacts of treatment and monitoring.

Implementation: byproducts

A commenter raises concerns related to byproducts of treatment technologies, noting that "treatment technologies for PFAS are still being developed, and there is limited capacity for the disposal of byproducts from newly-developed technologies." The commenter notes that the regulated community will need to safely dispose of the byproducts of such treatment technologies used to treat PFAS in drinking water. The commenter states that "[t]his is another area where [the EPA] is taking action, both to expand research and accelerate deployment of treatment, remediation, destruction, disposal, and control technologies for PFAS. The [Board] should await guidance from [the EPA] on these issues before taking actions that could stress limited PFAS treatment and disposal capacity." We ask the Board to address implementation concerns related to byproducts of treatment technologies for PFAS.

Cost/benefit analysis

In response to RAF Question 17 addressing the cost/benefit of the regulation, the Board states, "Improved health benefits expected to result from implementation of the proposed rule include a reduction in instances of developmental effects (including neurobehavioral and skeletal effects) and decreased immune response." A commenter notes that the Board does not quantify or estimate these benefits. Other commenters assert that the benefits indicated by the Board are overstated and the costs understated. These commenters seek clarification regarding the Board's conclusion that "[c]ompared to the HAL, the proposed MCL of 14 ppt for PFOA represents a 90 percent increase in public health protection and the proposed MCL of 18 ppt for PFOS represents a 93 percent increase in health protection."

Commenters also seek clarification on the basis for selection of 90 percent as a goal. They assert that the Board does not adequately explain the basis for the figures, providing no citation for this formula or any basis for such an assumption. Specifically, the commenters argue that "the

[Board] assumes a linear improvement in health protection between the [HAL] and the [Drexel PFAS Advisory Group]-recommended MCLG but provides no scientific support for assuming a linear improvement" and that the Board "has not identified any data or information demonstrating that increasingly stringent MCLs yield corresponding increases in health protection." Another commenter similarly states that the Board unreasonably relies on a flawed analysis of cost-effectiveness. This commenter argues that the benefits of setting MCLs at levels equal to the recommended MCLGs would vastly exceed costs. Did the Board consider the cost/benefit of setting MCLs at MCLG levels? The commenter also asserts that the Board does not follow the Department's guidance document for drinking water standards, which provides that a cost-benefit analysis for a proposed action involves an evaluation of the costs versus benefits to society. We ask the Board to address these concerns regarding the Board's method of cost/benefit analysis, including clarifying the basis for selection of 90 percent as a goal, in the Preamble to the final-form regulation. We also ask the Board to explain how increasingly stringent drinking water values affect health outcomes and provide supporting data. We also ask the Board to provide data for and explain the reasoning behind its assumption of linear improvement.

Acceptable data

The Board states in the Preamble that "PFAS are considered emerging contaminants because **research is ongoing** to better understand the potential impacts PFAS pose to human and animal health and the environment." [Emphasis added.] Commenters note "conflicting toxicology information from an evolving state-of-the-science" and assert that the EPA's Science Advisory Board PFAS Review Panel in 2021 and other state approaches to regulating PFOA and PFAS point to disagreement on what the standards should be. Another commenter states that the proposed regulation "is based on problematic studies that do not reflect the weight of scientific evidence regarding PFOS and PFOA. As a result, the proposed MCLs are overly conservative and technically flawed." Other commenters raise questions such as:

- Was additional independent peer review undertaken with respect to the conclusions set forth in the proposed regulation?
- Were there documents (e.g., health, toxicological, epidemiological) that the Board reviewed, but for some reason, chose not to include in its evaluation process?
- Is the EPA HAL unsafe for public drinking water?
- Does the Board plan to review additional information that may not have been available during the time that the regulation was being drafted as it prepares the final-form regulation?

We ask the Board to address commenters' concerns related to acceptable data, and explain how the data supporting the final regulation protects the public health, safety, and welfare. We also ask the Board to explain how it will revise standards based on improved scientific understanding about exposure, dose, and toxicology.

Additionally, a commenter questions whether members of the Drexel PFAS Advisory Group have sufficient expertise in the toxicological properties of PFAS or with regulatory risk assessment. The commenter argues that for PFOA, "the advisory group focused on the reports of

developmental effects in laboratory animals exposed to a single dose which severely limits the ability to assess dose-response. For PFOS, the group selected a study reporting immune system effects in laboratory animals despite the fact the results conflict with the findings of other researchers." Similarly, another commenter states that "[t]here are major technical concerns associated with these two published studies [selected as the critical studies for PFOA] with respect to their use in any human risk assessment." The commenter further asserts that the Drexel PFAS Advisory Group excluded numerous relevant studies from its analysis without explanation. We ask the Board to address these concerns related to the source of the data and basis for the MCL standards in the final-form regulation, and explain how the data provided as the basis for the final regulation is acceptable.

We will review the Board's responses to these concerns related to economic or fiscal impacts, protection of the public health, safety, and welfare, reasonableness, implementation, and acceptable data in order to make a determination as to whether the final regulation is in the public interest.

2. Comments, objections, or recommendations of a committee.

On May 24, 2022, the House Environmental Resources and Energy Committee (Committee) voted in favor of sending a comment to express "concerns with [the Department's] pursuit of this regulation, particularly considering the federal government's actions in this area." The comment is signed by nearly all majority members and one minority member. The Committee states, "As [the Department] has acknowledged, this would be the first time that they would be setting a [MCL] in our state's history. This is an action that has always been taken by the EPA in the past, with Pennsylvania adopting the standards set at the federal level." The Committee further asserts that "EPA's far greater resources will allow them to more accurately estimate the health impacts of an MCL, more accurately assess the water treatment technologies available to address PFAS, and more accurately estimate the cost of various treatment and monitoring systems to our water providers throughout the Commonwealth." The Committee urges the Board and Department to "rethink their approach and to defer to the EPA's experience and expertise to provide certainty to the regulated community."

One criterion of the RRA that this Commission must consider when determining if a regulation is in the public interest is the comments, objections, or recommendations of a committee. As noted, the Committee has expressed concerns with the regulation. If the Board proceeds with this rulemaking, we note that the concerns raised by the Committee could be the basis for a disapproval by this Commission. However, a goal of the RRA and the regulatory review process is the resolution of objections to a regulation and reaching of consensus among this Commission, the designated standing committees, interested parties, and the promulgating agency. We ask the Board to work with all parties with an interest in this rulemaking, particularly the Committee and members of the Legislature, to create a regulatory environment that is consistent with the intent of the General Assembly, is reasonable, provides certainty to the regulated community, and is protective of the public health, safety, and welfare.

3. Section 109.202. State MCLs, [Maximum Residual Disinfectant Level] and treatment technique requirements. – Protection of the public health, safety, and welfare; Acceptable data.

Subparagraph (4)(ii)(A) provides for an MCLG of 8 ng/L and an MCL of 14 ng/L for PFOA, and Subparagraph (4)(ii)(B) provides for an MCLG of 14 ng/L and an MCL of 18 ng/L for PFOS. Legislators and other commenters argue that drinking water standards should be more protective of children. These commenters assert that the proposed MCL standards for PFOA and PFOS are flawed when considering Cambridge Environmental Consulting's (CEC) toxicological analysis recommendations. The commenters quote the following from the CEC report:

> CEC's recommendation of a MCL of 1 ppt is consistent with the values found pursuant to the immunotoxic epidemiologic study and/or animal studies showing adverse developmental effects. However, if these values are excluded, the CEC has identified that the PFOA MCL should be no greater than 6 ppt to assure protection of children.

These commenters encourage the Board to emulate the CEC's findings by making the PFOA MCL 1 ppt but not to exceed 6 ppt and making the PFOS MCL no greater than 5 ppt. We ask the Board to address the concern that the CEC findings seem to indicate that the Board's proposed levels would not be protective of children. Some commenters assert that the MCLs should not be greater than the MCLGs, while others recommend that the levels be non-detectable. The Board states in the Preamble that the proposed MCLs for PFOA and PFOS are based on the health effects and proposed MCLGs, occurrence data, technical feasibility, and costs and benefits. We ask the Board to address commenters' concerns related to acceptable data and explain how it determined that the MCLs for PFOA and PFOS in the final regulation protect the health, safety, and welfare of children, particularly young children.

4. Section 109.301. General monitoring requirements. – Economic impacts; Protection of the public health, safety, and welfare; Clarity; Reasonableness; Implementation.

Paragraph (16)(i) requires monitoring to begin January 1, 2024, for systems serving more than 350 persons, and January 1, 2025 for systems serving 350 or fewer persons. Legislators and many commenters assert that the final rulemaking should be implemented immediately upon finalization. These commenters argue that it will be another two to three years before verifiably clean drinking water is available for Pennsylvania residents. We ask the Board to explain how it determined that the effective dates in the final regulation balance protection of the public, health, safety, and welfare with the economic impacts of implementation.

Subparagraph (16)(ii)(A) addresses repeat monitoring for entry points at which at least one of the PFAS with an MCL is detected, stating, "Monitoring for compliance with the MCLs for PFAS established under [Section] 109.202(a) shall be repeated quarterly, beginning the quarter following the detection, until reduced monitoring is granted in accordance with this subparagraph." Legislators and commenters assert that for systems with detections over the MCL, the Board should require monthly sampling until the levels are reduced below the MCL. Did the Board consider a shorter monitoring timeframe following detection? Also, could a water system remain in this state of repeat monitoring, never reaching compliance? We ask the Board to explain how the frequency of monitoring required in the final regulation is reasonable and

protects the public health, safety, and welfare. We also ask the Board to explain how it will ensure compliance is achieved by water systems.

Subparagraph (16)(ii)(B) states, "The Department may decrease the quarterly monitoring requirement specified in clause (A) if it has determined that monitoring results are **reliably and consistently below all MCLs** for PFAS established under [Section] 109.202(a)." [Emphasis added.] We ask the Board to amend this provision to use the term defined in Section 109.1, "reliably and consistently below **the MCL**," for clarity. [Emphasis added.] Otherwise, we ask the Board to amend the final-form regulation to clarify what standards would be applied to measure "reliably and consistently" relevant to reduced frequency of repeat monitoring.

Paragraph (16)(iv) provides for waivers. Legislators and many commenters urge the Board to amend the rulemaking to require all water systems to be monitored on at least an annual basis with no waivers being granted. These commenters argue that PFOA and PFOS are highly mobile in water and persistent in the environment, making their migration from a source of contamination a threat that is unpredictable and can occur rapidly. We ask the Board to explain how it determined that the granting of waivers will not negate the protection of the public health, safety, and welfare afforded by consistent testing.

Subparagraph (16)(viii)(A) addresses invalidation of PFAS samples, stating, "The Department may invalidate results of obvious sampling errors." What are the standards for determining an "obvious" sampling error and how will the samples be evaluated consistently? We ask the Board to clarify implementation related to the invalidation of PFAS samples.

Subparagraph (16)(ix)(A) states, "For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average of all samples taken at each entry point." We ask the Board to clarify how compliance determination will be implemented for water systems choosing to sample more frequently than required.

Subparagraph (16)(ix)(C) states, "If any sample result will cause the running annual average to exceed the MCL at any entry point, the system is out of compliance with the MCL immediately." We ask the Board to clarify implementation of the final regulation and explain whether the determination of "out of compliance" will begin with the first sampling done following the effective date of the regulation.

5. Section 109.303. Sampling requirements. – Economic impacts; Clarity; Implementation.

Subparagraph (a)(6)(ii) states, "Samples shall be collected by a person properly trained by a laboratory accredited by the Department to conduct PFAS analysis." We ask the Board to amend the final regulation to address the following concerns:

- Does this provision require a trained member of the accredited laboratory to conduct compliance sampling on behalf of the water system? If so, we ask the Department to address implementation concerns related to laboratory staff capacity, geographic availability, and the economic impact of associated costs.

- Does this provision indicate that a water system's sample collection staff can obtain training from an accredited laboratory in order to collect samples? If so, we ask the Department to address the economic impacts of training costs, and clarify any certification or documentation needed for a trainee.

6. Section 109.304. Analytical requirements. – Need; Reasonableness.

A commenter recommends analytical requirements be removed from the final rulemaking and instead be placed in guidance documents. The commenter states,

> [T]there are now places to consolidate and capture standardized analytical requirements, such as through 25 Pa Code [Section] 252 and [National Environmental Laboratory Accreditation Conference] Institute standards, which are overseen in Pennsylvania by [the Department's] Laboratory Accreditation Program. Including analytical requirements in a Chapter 109 rule may lead to confusion and discrepancies between other laboratory rule requirements. As analytical methods and lab practice requirements may change over time, it is better for those to be addressed in the rules and standards that environmental laboratories are already subject to, without also then needing to update the relevant section(s) in Chapter 109.

We ask the Board to explain the need for and reasonableness of retaining analytical requirements in the final regulation.

7. Section 109.602. Acceptable design. – Economic impacts; Clarity; Implementation.

Under Paragraph (j)(1), the Department identifies a list of treatment technologies that are acceptable for achieving compliance with the MCLs for PFAS. A commenter questions if the use of one of the listed methods indicates that a water system can move forward with that treatment technology, or would the Board require piloting systems in order to have a construction permit accepted and reviewed by the Department? The commenter notes that requiring a pilot system is costly, adding $100,000-$125,000 to design costs per treatment unit, and delays the installation of treatment. We ask the Board to clarify if piloting systems for the listed accepted treatment technologies will be required, and if so, to amend the Preamble and RAF to the final-form regulation to take these costs and economic impacts into consideration.

Under Paragraph (j)(2), the Board states that other treatment technologies may be approved by the Department if the applicant demonstrates the alternate technology is capable of providing an adequate and reliable quantity and quality of water to the public. What standards would determine whether adequacy has been demonstrated? We ask the Board to clarify in the final regulation how this provision will be implemented.