

Proposed PFAS Water Standards Will Likely Face Pushback

By **Stephanie Feingold** and **Drew Cleary Jordan** (May 2, 2023, 4:46 PM EDT)

After months of anticipation, the U.S. Environmental Protection Agency released its proposed rule for the first enforceable national drinking water standards for perfluorooctanoic acid, or PFOA, and perfluorooctane sulfonic acid, or PFOS, in March.

The EPA also proposes to regulate four other per- and polyfluoroalkyl substances — perfluorononanoic acid, or PFNA; perfluorohexanesulfonic acid, or PFHxS; perfluorobutane sulfonic acid, or PFBS; and hexafluoropropylene oxide dimer acid and its ammonium salt, more commonly known as GenX chemicals — as a mixture through the novel use of a hazard index calculation.

If finalized, this rule will be the first national primary drinking water regulation, or NPDWR, under the Safe Drinking Water Act in decades. Published in the Federal Register on March 29, the landmark proposed rule seeks to regulate these PFAS chemicals at the lowest feasible and technically achievable levels possible.[1]

Simultaneously broad and complex, the rule's implications will be far-reaching, and not limited to the estimated 66,000 public water systems it is expected to directly affect. The proposed rule is viewed as a cornerstone of the EPA's whole-of-agency approach in regulating PFAS.

But critiques of this approach — including the agency's choice and manner of application of the hazard index, its decision to collectively regulate four unique PFAS based on their potentially additive dose toxicity, the underlying science, and the EPA's risk, cost and benefit analysis — are anticipated. Challenges to the proposed rule can be expected as the rulemaking process continues.

Of note, while the EPA has issued interim health advisories and health advisory levels for PFOA (0.004 parts per trillion) and PFOS (0.02 ppt), as well as final health advisory levels for PFBS (2,000 ppt) and GenX chemicals (10 ppt), no health advisories or health advisory levels have previously been issued for PFNA or PFHxS.

Moreover, health advisories and health advisory levels are nonbinding and nonenforceable. Following the issuance of an NPDWR, the EPA intends to evaluate and update or withdraw the interim and final health advisories for the referenced chemicals.

Maximum Contaminant Levels



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The EPA's proposed rule identifies a maximum contaminant level, or MCL, of 4 ppt, for PFOA and PFOA, which is the lowest concentration level of these chemicals that most laboratories are able to reliably detect.[2]

The EPA has also described the 4 ppt level as the "lowest feasible level" for which PFOA and PFOS can be removed from drinking water.[3] This level is also below any state-issued MCLs to date.

If promulgated, the NPDWR would preempt any state-issued regulations that allow greater MCLs than those provided in the NPDWR. It also would require any state with primary enforcement responsibilities that does not have a drinking water standard to implement regulations that are at least as strict as the federal MCLs. In the meantime, duly promulgated state standards remain in effect and are enforceable.

The EPA also intends to set an MCL for any mixture containing one or more of PFNA, PFHxS, PFBS and GenX chemicals by utilizing the hazard index and setting the MCL at no greater than one. In a first-of-its-kind approach to NPDWRs, water systems will be required to monitor the amount of each PFAS from this group based on the associated health-based water concentration of each chemical, as calculated by the EPA:

- PFNA: 10 ppt
- PFHxS: 9 ppt
- PFBS: 2000 ppt
- GenX Chemicals: 10 ppt

The comparison values, or hazard quotients, of each PFAS contained within the mixture are then added.[4] Any total value that exceeds 1 would be considered to exceed the MCL for these PFAS.[5]

The EPA states that the hazard index provides an indication of the overall potential risk of a mixture, as well as of individual PFAS that are potential drivers of risk, and that a hazard index of 1 represents a level at which no known or anticipated adverse health effects could be anticipated.

Maximum Contaminant Level Goals

The EPA also published proposed nonenforceable maximum contaminant level goals, or MCLGs, of zero for PFOA and PFOS, based on its determination that each chemical is likely to cause cancer. While PFOA was previously identified as a likely carcinogen by the agency, the designation of PFOS as such is new.[6]

MCLGs are the levels at which no adverse health effects are anticipated. MCLs are set as close as possible to the MCLGs, while also taking technical feasibility and cost into account.

The EPA also proposed MCLGs for PFNA, PFHxS, PFBS and GenX chemicals using its novel hazard index approach, and setting that value at 1.

Anticipated Effects and Challenges

The EPA signaled its intent to stringently regulate PFAS when it released its new PFAS health advisory levels in June 2022 — reflecting interim levels for PFOA and PFOS that were orders of magnitude lower than the 2016 levels.[7]

But the agency's proposed NPDWR is a significant next step — and likely the first in a series of legally enforceable standards in the agency's continued aggressive approach to regulating PFAS, and reducing PFAS in the environment to the lowest possible levels.

If promulgated, the rule will impose monitoring requirements on water systems that account for variables such as the service size of the utilities and prior testing results in determining the frequency of testing. Public water systems will also be required to provide notice to the public if detected levels exceed the relevant MCLs, and to treat drinking water to reduce the levels of PFAS below the MCLs.

The EPA has estimated that 3,400 to 6,300 public water systems — out of over 66,000 systems expected to be subject to the rule — are anticipated to exceed one or more MCL. Funds are being made available through the Bipartisan Infrastructure Law to assist water providers to come into compliance with the proposed new rules.

The effects of the rule will be felt upstream and downstream, and across industries and environmental programs at the federal and state levels. For example, the NPDWR, once promulgated, would provide a unified standard across jurisdictions, and would coalesce the current state-by-state patchwork regulatory landscape.

As noted, however, the proposed rule sets MCLs at levels well below any current state enforceable drinking water standard for PFOA or PFOS, and state programs will be required to implement these much stricter MCLs. Additionally, it is not uncommon for states to use MCLs as generic cleanup standards for groundwater.

At the federal level, the new MCLs would become applicable or relevant and appropriate requirements at Superfund sites, having a potentially significant impact on site cleanups. The EPA's novel proposed use of the hazard index approach to regulating PFAS also raises a number of questions — and may foreshadow future actions by the agency to regulate PFAS as a class, or subclasses, rather than on a chemical-by-chemical basis.

And while a hazard index approach is not a new concept, the EPA's application of this methodology to set an enforceable drinking water standard certainly is. This cumulative approach to evaluating PFAS also leaves the door open for the agency to potentially add more PFAS to the hazard index in the future.

In support of its proposed hazard index approach, the EPA relies on its finding that the group of four PFAS are likely to co-occur in drinking water and the environment, and at different levels and combinations — and that exposure to any mixture of these PFAS can act in a dose-additive manner.

This has the practical effect of resulting in a hazard index-level exceedance of a combination of the four PFAS substances, even where none individually is detected in concentrations that exceed the individual health-based water concentration for the particular substances. The EPA also uses this dose additivity to justify the combination of PFAS with different health endpoints and target organs.

While the EPA has anticipated many potential questions by the regulated community — as reflected in the various fact sheets and FAQs posted on its website — additional questions concerning implementation and calculation of the hazard index values are nonetheless likely.[8]

Challenges to the proposed rule — including to the associated costs of implementation, the technical feasibility, the procedural mechanisms, and the associated justification employed by the EPA in

advancing its preliminary regulatory determination for PFHxS, PFNA, PFBS and GenX in the proposed rule, and the sufficiency of the agency's supporting science — are also anticipated.

As to the last point, the Safe Drinking Water Act requires the EPA to use the "best available science" when setting standards. Many of the forthcoming challenges will likely echo the challenges previously lodged in connection with the agency's issuances of its health advisory levels for PFOA, PFOS and GenX chemicals.

Whether stakeholders also challenge the EPA's decision to regulate PFHxS and PFNA via the hazard index approach also bears watching, given the current absence of final toxicity values for those two chemicals. Further, the fact that the group of four PFAS that the agency intends to regulate under its hazard index approach do not have uniform toxicity endpoints, as identified by the EPA, also may be an area of challenge.

The proposed rule and the underlying conclusions made by the EPA concerning potential risks will also affect PFAS-related litigation, as litigants look to the rule — even before it is finalized — to support their claims. The new monitoring, testing and reporting requirements under the proposed rule will also likely lead to an increase in litigation by water systems and their consumers.

Finally, as we have seen with the EPA's various PFAS health advisories, the agency's announced MCLGs cannot be overlooked — in particular, its MCLGs for PFOA and PFOS of 0 ppt — along with its designation of PFOS as a likely carcinogen. These goals and designations will likely affect litigation and factor into future regulation and guidance decisions at the federal and state levels, especially as detection and treatment methods continue to advance.

Additionally, because MCLs must be set as close to the MCLG as feasible, the EPA could potentially revisit its MCLs once more reliable testing techniques become available, and set the enforceable standard closer to, or at, zero.

Next Steps

The EPA has 18 months from the issuance of the proposed rule to finalize a proposed NPDWR — i.e., until Sept. 15, 2024 — although the agency has indicated that it plans to finalize the rule by the end of this year. If the rule is promulgated, water systems will have three years from the date of the final rule to come into compliance with any MCLs issued.

Comments on the proposed rule are due by May 30, although there have already been public calls to extend the comment period an additional 30 days or more beyond the typical 60-day comment period. Given the complexity and breadth of the proposed rule, the novel use of the hazard index, the sheer number of technical and other supporting documents in the docket, and the expected economic impacts, a variety of stakeholders have argued that an extension is justified.

Interested parties can take the following steps:

- Submit comments on the proposed rule. Comments may be submitted through the public docket, identified by Docket ID No. EPA-HQ-OW-2022-0114, at www.regulations.gov.

- Make sure you know if any PFAS are in your processes and waste streams. If you have not already performed an environmental audit of your manufacturing operations and supply chains, now is the time to do so, and to assess options for proactive risk mitigation and compliance.
- Attend EPA information sessions and public hearings. The agency has announced a public hearing on May 4, to solicit public comment on the proposed rule. It has also held two informational webinars, on March 16 and March 29. The March 16 webinar provided a general overview of the proposed rule, and the March 29 webinar provided a technical overview of the proposed rule. Recordings and copies of the presentation materials for each have been made available online by the EPA.

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[1] PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (March 29, 2023) (to be codified at 40 C.F.R. 141-2), <https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfas-national-primary-drinking-water-regulation-rulemaking>.

[2] Per the EPA, this captured approximately 75% of laboratories in the U.S., as of December 2021. These numbers are based on the practical quantitation level, defined as "the lowest concentration of a contaminant that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions." See EPA, Proposed PFAS National Primary Drinking Water Regulation FAQs for Drinking Water Primary Agencies, Question 6, https://www.epa.gov/system/files/documents/2023-03/FAQs_PFAS_States_NPDWR_Final_3.14.23_0.pdf.

[3] *Id.* at Question 5.

[4] The hazard quotient is calculated by dividing the measured level of each of the four PFAS in drinking water by the health-based water concentration for each of the four PFAS. For more detail concerning the calculation of the PFAS mixture hazard index MCLG and the EPA's associated requests for comment, see PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. at 18639, 18641-42, 18663-668 (March 29, 2023), <https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfas-national-primary-drinking-water-regulation-rulemaking>.

[5] The EPA has promised to provide water systems with a web-based form that will automatically calculate the hazard index.

[6] Of note, only four of the PFAS identified in the EPA's proposed rule — PFOA, PFOS, PFBS and GenX chemicals — have final toxicity values. In the EPA's draft mixtures document, however, it suggests that the hazard index approach could consider other PFAS toxicity values, including Agency for Toxic Substances and Disease Registry minimum risk levels. The registry has set minimum risk levels for PFHxS and PFNA.

[7] Stephanie R. Feingold, Laurie Matthews and Drew Cleary Jordan, Near Zero: EPA Sets New Stringent

PFAS Lifetime Health Advisories, Morgan Lewis LawFlash (June 17, 2022), <https://www.morganlewis.com/pubs/2022/06/near-zero-epa-sets-new-stringent-pfas-lifetime-health-advisories>.

[8] EPA, Proposed PFAS National Primary Drinking Water Regulation, <https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas>.