CITY OF LANCASTER

DEPARTMENT OF PUBLIC WORKS
BUREAU OF WATER

April 27, 2022

PA Department of Environmental Protection

Re: Safe Drinking Water PFAS MCL Rule

Ladies and Gentlemen:

The City of Lancaster is in favor of protecting the citizens of the Commonwealth and instituting a PFAS/PFOA mean contaminant level (MCL) at the EPA's Health Advisory Level recommendation of 70 parts per trillion (0.07 µg/L) for the combined concentration of PFOA and PFOS. Please consider the following comments on the Department of Environmental Protection's Safe Drinking Water PFAS MCL Rule.

1. The recommended reference dosages are found on page 3 of the bulletin. When they are compared with the maximum contaminant level goals which are in units of (nanograms/ kilogram of body weight/ per day) the reference dosages seem to conflict with the proposed limits making the proposed MCLs look excessively stringent. The reference dosages are defined as the following:

   "The reference dose (RfD) (mg/kg/day) is the maximum acceptable oral dose of a toxic substance established by the USEPA. The RfD is an estimate of daily oral exposure to the human population (including sensitive subgroups) that is without considerable risk to negative impacts over a lifetime (USEPA, 2002a)."

   When calculated for an average adult at 70 kg and child of 19 kg the recommended MCLs seem exceedingly low compared with what the reference dosages say is acceptable for the body. All potential exposures come from average consumption volumes of 2 liters per adult and 1 liter per child per day.

   -A 70 kg adult daily oral dosage max 273 ng/Day for PFOA and 217 ng/Day for PFOS,

   -A 19 kg child daily oral dosage max 74.1 ng/Day for PFOA and 58.9 ng/Day for PFOS.

   When compared, there is little to no chance of an adult or child ever reaching even the reference dosages at the current 70 ng/L guidance for PFOA. However, it does show that a child exposed to high PFOS source can potentially exceed the reference dosage at current guidance limits. (Please review the suggested alternative measure discussed in item 3.)

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2. Although the Department proposes a very stringent level in its regulations, reducing the levels in water will not eliminate exposure to PFAS species PFOA/PFOS. Please reference the attached article - *Does regulating per- and polyfluoroalkyl substances represent a meaningful opportunity for health risk reduction?* as published by AWWA. Furthermore, testing referenced in these studies (Dong, G.H. (2011)) shows that levels of exposure to PFOS that result in significant response were not significant from the control until dosages went to 5 mg/kg dosage per day (over 1.25 million times greater than reference dosages proposed). Other impacts did not occur significantly until 50 mg/kg dosages (12.5 million times reference dosages) for several factors monitored in the study.

   A toxicological study performed by the group referenced in the (L. Zheng et al (2011)) performed another study on PFOS toxicological behavior based on monitoring short term dosage varied responses. When discussing the results of their study their data was discordant and not matching previous studies. The following was also stated:

   "These discordant results are not apparently isolated to PFOS only. In studies of the effects of PFOA (physiochemically similar to PFOS) on immune functions in female C57BL/6N mice, Dewitt et al. (2008) found that SRBC-specific IgM synthesis was dose-dependently suppressed by PFOA, whereas SRBC-specific IgG titers were increased at lower (and similar to controls at higher) doses of PFOA. In contrast, Yang et al. (2002a) reported that PFOA exposure markedly suppressed the formation of both IgM and IgG antibodies against horse red blood cells."- L.Zhen et al. (2011)

   This shows there are some conflicting dosage response results seen with PFOS and PFOA and these studies warrant more research before relying on them to solely justify a dramatic shift and investment for water systems. The proposed MCL bulletin states there is still not enough data for an MCL for the rest of the PFAS species. With this lack of data, the proposed limits for water being recommended are not warranted.

   Treatment needs to be focused on the communities who have significant levels of PFOA and PFOS in their source waters. Systems that are in danger of exceeding reference dose consumption limits based on standard consumption rates (Adults 2 liters per diem and children 1 liter per diem) need strict monitoring and guidance for mitigating levels to meet reference dosages. All community water systems should not be forced to reduce levels to what is essentially background levels. The City has been monitoring levels in its source waters of the Conestoga and Susquehanna Rivers quarterly for the past couple years. At present PFOA/PFOS levels are below the proposed standards, but the standards are at the parts per trillion. Any increases in background concentrations of the waters will subject the rate payers of the City to exorbitant bills using the PADEP's cost data. Water will become unaffordable.

   Current estimates supplied in this proposed regulation are lacking accurate cost data for larger systems. The bulletin shows only costs for 1 MGD plants. There is no consideration for larger plants, but it is safe to assume prices will be significantly higher. Using the Department numbers for a 1 MGD plant the total annual operating cost to treat and test for the PFOA and PFOS at the proposed limits will average 9.2 million dollars annually. Not

only will this make water unaffordable, but there is no guarantee of the promised 90% increases in health proposed in this rulemaking. This excludes various costs that are factored in with capital projects and facilities larger than 1 MGD. PFOA and PFOS are everywhere including the food we eat due to wrappings and storage choices. Focusing on regulating water systems where the majority of levels are at background levels that are not causing ill health effects does not make sense. Additionally, treatment costs have been increasing at incredible rates. To require a 9.2-million-dollar annual operating cost on systems when the science on these chemicals is still young and being tested to better understand effects/impacts is irresponsible. The scientific data is not available to set these limits and there has not been thorough testing to set the proposed limit. More data is also needed on the capital costs for large facilities and proper treatment for all species of PFAS.

3. The EPA is working on their own MCL research. This is slated for 2024 completion. Given the conflicting data and various unknowns it is recommended to delay promulgating a new MCL until there is a more complete understanding with respect to background levels and health impacts. There is too much uncertainty for many of the species. Additionally, the additional time should allow for better comprehension of how to best treat all PFAS species in question which would allow for a more efficient technical and economical approach. It would also be prudent for systems to monitor quarterly and maintain tracking of each PFAS species per quarter. It is recommended that data for children be reviewed to determine if PFOS should be given its own new action level of 50 ng/L to ensure that reference dosages are never exceeded by acceptable regular consumption. A child has the highest potential for impact and by setting an advisory level for PFOS of 50 ng/L it would allow systems to follow current reference dosage recommendations.

Thank you for consideration of these comments. If you have any questions or require clarification, please contact me at jrieben@cityoflancasterpa.com.

Sincerely

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EMERGING CONTAMINANT ARTICLE

TOPICAL COLLECTION ON PFAS ANALYTICS AND TREATMENT

AWWA WATER SCIENCE

Does regulating per- and polyfluoroalkyl substances represent a meaningful opportunity for health risk reduction?

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Abstract

US Environmental Protection Agency's drinking water contaminant regulations must meet a qualitative "meaningful opportunity" threshold in health risk reduction. Using our Relative Health Indicator (RHI) metric, we quantify the ranges of potential health risk reductions that could be achieved from state and federal per- and polyfluoroalkyl substances regulatory levels (proposed or finalized) and compare them with previous regulatory determinations of other contaminants to create a quantifiable, comparable scale of "meaningful opportunity" justifications. If perfluorooctanoic acid (PFOA) and perfluorooctyl sulfonate (PFOS) were present in 100% of water systems, contaminant concentrations of 227 ng/L PFOS and 2295 ng/L PFOA would be needed to exceed the minimum threshold of percent population*RHI (PopRHI) to justify "meaningful opportunity," based on the current regulatory levels of uranium; these concentrations exceed any levels being proposed. Using this comparison metric, our results demonstrate that the regulatory levels for PFOA and PFOS alone will not achieve a national meaningful health risk reduction as compared with previously regulated contaminants.

KEYWORDS

MCL, PFOA, PFOS, RHI metric, risk analysis

1 | INTRODUCTION

Per- and polyfluoroalkyl substances (PFAS) have been manufactured and used around the world, including in the United States, since the 1940s and encompass a group of over 5000 chemicals according to US Environmental Protection Agency's (USEPA) master list (USEPA, 2021b). Companies continue to replace one PFAS with another, making it difficult to understand the true number of PFAS currently in the marketplace and equally difficult to quantify the human exposure to PFAS compounds as a complete group (Wang et al., 2017). The PFAS receiving the most political and regulatory attention are perfluorooctyl sulfonate (PFOS) and perfluorooctanoic acid (PFOA) (US Agency for Toxic Substances and Disease Registry [ATSDR] 2018; Hekster et al., 2003). Due to their persistence in the environment (ATSDR, 2018; Hekster et al., 2003; Hu et al., 2016) and the human body (USEPA, 2016a, 2016b),

PFOA and PFOS are the most extensively studied forms of the PFAS. Elevated levels of exposure can lead to several adverse health outcomes including hepatic, cardiovascular, endocrine, immune, reproductive, and developmental effects (ATSDR, 2018).

The USEPA generally follows a four-part process in assessing a drinking water contaminant for regulation. Every 5 years, USEPA prepares a Contaminant Candidate List (CCL) of all known contaminants that require further evaluation. At least five contaminants from the CCL must undergo complete evaluation for regulatory determination. Since the passing of the 1996 Safe Drinking Water Act (SDWA) Amendments, there have been four CCLs and the preliminary regulatory determinations for the fourth list were published in March 2020 with final determinations in early 2021 (USEPA, 2020, 2021a); PFOA and PFOS were included in the final list evaluated for regulatory outcomes and are the only two contaminants receiving positive regulatory determinations as part of the fourth CCL. A positive regulatory determination by the USEPA for a specified drinking water contaminant must meet three criteria: considerable contaminant toxicity, national contaminant occurrence, and present a meaningful opportunity for health risk reduction. This third criterion is subjective and comes at the sole judgment of the USEPA Administrator (Roberson & Frey, 2016; USEPA, 1996, 2017). Of the 37 contaminants that have received determinations by the USEPA since 2002, only PFOA and PFOS are currently scheduled for regulation (USEPA, 2002b, 2010, 2014a, 2014b, 2020). However, despite the rigidness of the process, there is no standard metric for assessing meaningful opportunities for health risk reduction (Raucher et al., 2006). Using retrospective analyses of previously regulated contaminants and a comparative Relative Health Indicator (RHI) metric, we can calculate historical levels of "meaningful" (Alfredo et al., 2017; Seidel et al., 2014). We apply the RHI metric to assess the PFOA and PFOS regulatory landscape, contextualizing the different proposed regulatory levels, and place the process in historical perspective.

Article Impact Statement
Placing the 2021 USEPA PFAS positive RegDet in historical context, we evaluate "meaningful opportunity" for health risk reduction.

2 | MATERIALS AND METHODS

2.1 | RHI metric development

The RHI metric was developed as a simplistic tool to assist water utilities and regulatory policy makers with context for current regulated contaminants and prioritize and communicate health risk reduction strategies. The metric itself is dimensionless and is intended to be used as a relative scale for comparing RHI values. The details of the RHI metric development methodology have been described elsewhere (Alfredo et al., 2017; Seidel et al., 2014). The major assumptions and simplifications are as follows:

- Drinking water risks are considered "independent" of risks through other environmental exposures to these compounds, such as food, air, and skin contact.
- Carcinogenic toxicity is estimated separately from noncarcinogenic toxicity using Equations (1 and 2), respectively. Carcinogenic and noncarcinogenic risk is calculated separately using Equation (3) and then summed to generate total risk estimates using Equation (4).
- Risk assessment is performed assuming average sensitivity across the population and using the sensitivity inherent in the established/proposed reference doses. In other words, this analysis does not account for more sensitive subpopulations with respect to age, gender, pre-existing health conditions, and so on. It is important to note that pregnant and lactating women are considered a sensitive subpopulation in some PFAS assessments (USEPA, 2016a, 2016b).
- In our assessment, *Exposure* was equal to the threshold concentrations proposed. In other national assessments, exposure often equals a statistical representation of measured values (Alfredo et al., 2014; USEPA, 2000a).
- The incidence factor of 0.01 derived from Dourson et al. (1996) is equivalent to a 1% incidence rate, meaning that when exposed to the given concentration of the contaminant, 1% of the population is likely to experience the related health effect.
- The $\text{Severity}_{\text{NonCancer}}$ is based on the World Health Organization (WHO) global health estimates for disability weights associated with certain health outcomes. When specific health outcomes were not included in the WHO list, we estimated a value based on available metrics (similar health outcomes) (Seidel et al., 2014; World Health Organization, 2018).

Based on the abovementioned assumptions, the total RHI is calculated for both health outcomes (j) individually (where j is either noncancer or cancer) for each individual contaminant (i) in drinking water using Equations (1)–(4) as follows:

$$\text{Toxicity}_{i,j=\text{NonCancer}} = \frac{0.01 * I}{\text{BW} * \text{RfD} * \text{UF}}, \quad (1)$$

$$\text{Toxicity}_{i,j=\text{Cancer}} = \frac{\text{Cancer Slope Factor} * I}{\text{BW}}, \quad (2)$$

$$\text{RHI}_{i,j} = \text{Toxicity}_{i,j} * \text{Severity}_{i,j} * \text{Exposure}_i, \quad (3)$$

$$\text{RHI}_{i,\text{Total}} = \text{RHI}_{i,j=\text{NonCancer}} + \text{RHI}_{i,j=\text{Cancer}}, \quad (4)$$

$$\text{PopRHI}_i = (\text{Percent population exposed})_i * \text{RHI}_{i,\text{Total}}. \quad (5)$$

For these equations, the following definitions apply:

- I is the daily drinking water intake (L/day). The default adult population intake of 2 L/day is assumed in the RHI calculations.
- BW is the body weight (kg) of the exposed individual. The default adult population body weight of 70 kg is assumed in the RHI calculations.
- The reference dose (RfD) (mg/kg/day) is the maximum acceptable oral dose of a toxic substance established by the USEPA. The RfD is an estimate of daily oral exposure to the human population (including sensitive subgroups) that is without considerable risk to negative impacts over a lifetime (USEPA, 2002a).
- Uncertainty factor (UF) is the product of multiple uncertainty factors used in the development of RfD.
- For $\text{Toxicity}_{\text{NonCancer}}$, a factor of 0.01 equivalent to 1% incidence rate is derived from Dourson et al. (1996).
- Exposure (mg/L) is the contaminant concentration. In our assessment, we are considering exposure equal to the threshold concentrations proposed.
- The $\text{Severity}_{\text{NonCancer}}$ is based on the World Health Organization (WHO) global health estimates for disability weights associated with certain health outcomes (Seidel et al., 2014; World Health Organization, 2018).
- Percent population exposed is the occurrence in terms of percent of national population exposed to certain concentration.

Although certainly with limitations, the RHI metric provides an accounting process that normalizes all contaminant risk onto a single, comparable scale—something not currently done for estimating drinking water contaminant risk in the regulatory process (President's Council of Advisors on Science and Technology, 2016). It is important to note that the metric is not intended to replace epidemiological studies or concerns, but rather the intent is to create a normalized scale to compare health risk reduction that is possible from proposed and established regulations. This is the first step to quantifying a very qualitative requirement of the current USEPA regulatory process.

2.2 | Occurrence and toxicity analysis

To assess national occurrence of the contaminants included in this study, estimates were obtained from a wide variety of sources. Arsenic and uranium provide context for current regulated contaminants as establishing high and low RHI metrics, respectively. Both arsenic and uranium had interim regulations prior to lower, final determinations effective in 2001 (USEPA, 2001) and 2003 (USEPA, 2000b), respectively. Population-based occurrence estimates prior to the enforcement date of the revised regulations were calculated using the data from USEPA's second 6-year review. Data handling techniques associated with processing this data set are contained elsewhere (Alfredo et al., 2014; Alfredo et al., 2017). Although the final determinations for these two interim regulations are slightly different from a regulatory determination originating from a CCL, the basic criteria governing the establishment of regulatory thresholds are the same. For comparison, we included all contaminants with sufficient information that have come under review as part of the USEPA Regulatory Determination adjudication process. For the unregulated contaminants we included, we used occurrence estimates contained within the USEPA Regulatory Determination adjudication process (USEPA, 2002b, 2010, 2014b, 2020, 2021a). Similarly, the regulatory determinations for all the contaminants included in this assessment were obtained from the published preliminary and final results contained within the USEPA section of the Federal Register (40 CFR Part 141). Information related to state-level regulatory thresholds was collected from individual state drinking water regulatory agencies.

Toxicological data including RfD, UF, and critical effects, not contained within the USEPA Integrated Risk Information System, were collected from within the regulatory determination assessments and individual health assessment reports (ATSDR, 2018; OEHHA, 2019; USEPA, 2016a, 2016b). Of the 37 contaminants that have been included in the four published regulatory determinations, 14 contaminants were included in the analysis. Twelve contaminants contained no occurrence (percent population exposed) above the health reference level and were removed from the analysis. This included metribuzin, 2,6-dinitrotoluene, *S*-ethyl propylthiocarbamate, fonofos, terbacil, dimethoate, 1,3-dinitrobenzene, turbufos, 1,1-dichloroethane, acetochlor, bromomethane, and metolachlor. Five contaminants

TABLE 1 Values used for Relative Health Indicator calculations

Contaminant name	Reference dose (mg/kg/day)	Noncancer severity	Uncertainty factor	Cancer slope factor $(mg/kg/day)^{-1}$
Arsenic	0.0003	0.056	1.5	1.5
Uranium	0.003	0.1	100	-
Aldrin	3.00E−05	0.01	1000	17
Dieldrin	5.00E−05	0.01	100	1.60E+01
Hexachlorobutadiene	0.0008	0.2	10	1.6
Manganese	0.14	0.001	1	-
Naphthalene	0.02	0.1	3000	-
Boron	2.00E−01	0.01	66	-
1,3-Dichloropropene (Telone)	3.38E−02	0.01	100	1.00E−01
2,4-Dinitrotoluene	0.002	0.01	100	0.667
1,1,2,2-Tetrachloroethane	0.01	0.01	1000	8.50E−02
Perchlorate	2.20E−03	0.001	3	-
Nitrobenzene	0.002	0.01	1000	-
RDX	0.004	0.3	300	0.08
PFOA (EPA)	0.00002	0.1	300	-
PFOS (EPA)	0.00002	0.1	30	0.07
PFOA (ATSDR)	3.00E−06	0.1	300	-
PFOS (ATSDR)	2.00E−06	0.1	30	-
PFOA (CA)	4.50E−07	0.1	300	143
PFOS (CA)	1.80E−06	0.1	30	45.5

Abbreviations: PFOA, perfluorooctanoic acid; PFOS, perfluorooctyl sulfonate; RDX, hexahydro-1,3,5-trinitro-1,3,5-triazine.

(1,2,3-trichloropropane, *N*-nitrosodimethylamine, chlorate, strontium, and 1,4-dioxane) were delayed or received "no determination" at the end of the determination process (USEPA, 2014b, 2015, 2020, 2021a) and were removed from the analysis. Finally, sodium, sulfate, 1,1-Dichloro-2,2-bis(p-chlorophenyl)ethylene, turbufos sulfone, dacthal mono-acid degradate, and dacthal di-acid degradate were not included due to lack of available toxicological data to perform the RHI calculations. The 14 contaminants included in the analysis in addition to arsenic and uranium are compiled in Table 1 along with the underlying values used in our analyses.

3 | RESULTS AND DISCUSSION

3.1 | Same toxicological data, different regulatory outcomes

In the past 10 years, there have been many individual state health advisory levels proposed, established, and arbitrated across the United States (Association of State Drinking Water Administrators [ASDWA], 2021; Minnesota Department of Health, 2021; New Jersey Register, 2020; New York State, 2019; State of New Hampshire, 2019). In 2009, the USEPA set provisional health advisories for PFOA and PFOS with individual limits of 400 and 200 ng/L (ppt), respectively, and later lowered these values to a combined sum concentration limit of 70 ng/L in 2016. The RfDs considered in the determination of PFOA ranged from 0.00002 to 0.00015 mg/kg/day (USEPA, 2016d). Similarly, the total UFs associated with these studies also vary by an order of magnitude from 30 to 300. PFOS had slightly less variability in considered RfDs (0.00002–0.00005 mg/kg/day) and associated UFs (30–100). It must be noted that both PFOA and PFOS toxicological ranges were determined from point of departure critical effects modeled from rat and mice studies (USEPA, 2016c, 2016d). The ATSDR released their toxicological assessments in 2018 and settled on PFOA and PFOS minimal risk levels of 78 and 52 ng/L for adults, respectively, based on health outcomes from intermediate exposure rodent studies (ATSDR, 2018).

We found many states use similar root toxicological studies as ATSDR, the USEPA, and the US National Toxicology Program, mostly relying on studies conducted in rats (ATSDR, 2018; National Toxicology Program, 2016; Pelch et al., 2019), but with modifications to several key assumptions related to uncertainty factors, individual

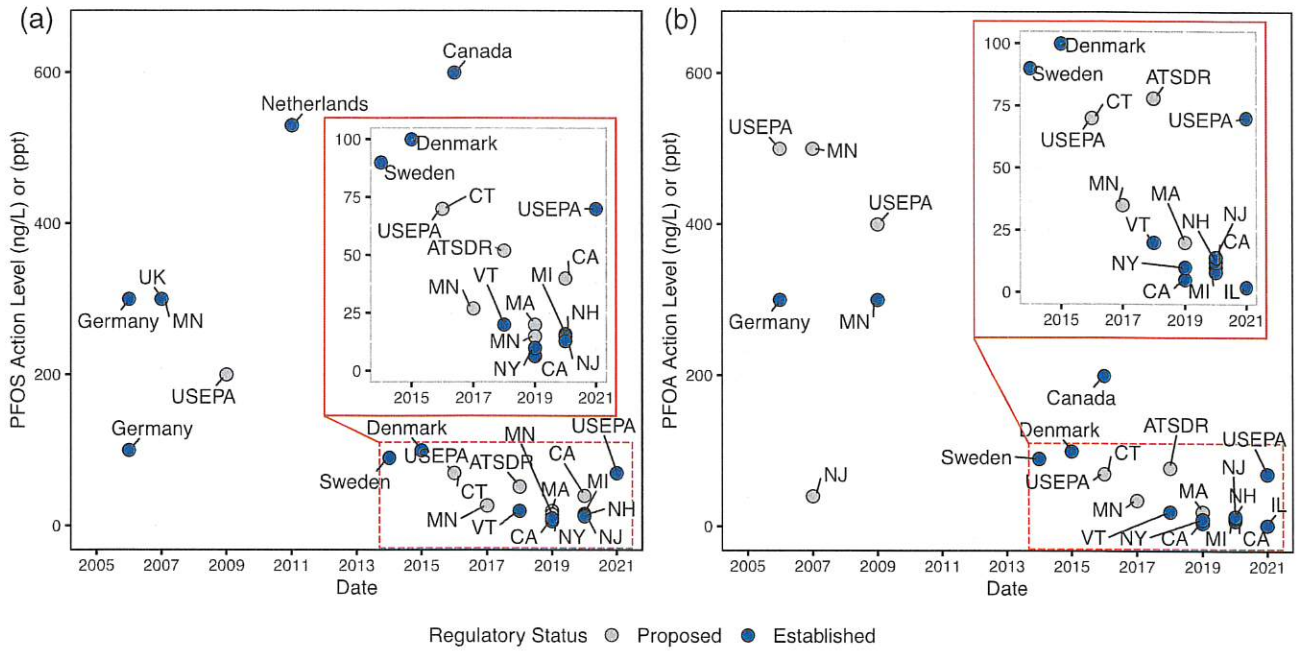

FIGURE 1 Proposed and established regulatory thresholds for (a) PFOS and (b) PFOA by governmental and state agencies. (1) Germany sets two thresholds for PFOS in 2006: a long-term toxicological threshold (300 ng/L) and a precautionary value (100 ng/L). (2) CA includes two established levels: notification level (PFOS = 6.5 ng/L, PFOA = 5.1 ng/L) and response level (PFOS = 40 ng/L, PFOA = 10 ng/L). (3) The recently announced positive determinations for PFOS and PFOA are included at the health advisory levels first proposed in 2016 of 70 ng/L, as depicted on the plot. (4) For those thresholds structured as a "sum" of PFAS, as the scope of this analysis was limited to PFOA and PFOS only, we assumed that potentially 100% of the "sum of PFAS" was contributed by either PFOS alone for plot A or PFOA alone for plot B

intake volumes, and the relative source contribution parameter used in the drinking water contaminant level equation. These modifications can result in threshold concentrations that differ by two orders of magnitude. Most state agencies push the threshold concentrations lower by primarily lowering the RfD values calculated from the selected toxicological studies and by using the default 20% relative source contribution value. Compiling the last decade of proposed and established concentration advisories and enforceable maximum contaminant limits (MCLs) for PFOS in Figure 1a, we can see that, despite little change in toxicological studies, endpoint health reference levels and established regulatory thresholds are vastly different depending on location. Similar to PFOS, PFOA has experienced a continual lowering of proposed and established regulatory thresholds, as presented in Figure 1b. The recently established levels in Michigan are the lowest established for PFOA at 8 ng/L (Ellison, 2020). However, despite a decade of consistently decreasing the proposed contaminant threshold, there exists little guidance and discussion regarding *if* a drinking water regulation is warranted and *what* level is appropriate.

Some of the proposed levels were challenged in recent court cases, such as in New Hampshire. The proposed levels of 12 ng/L PFOA and 15 ng/L PFOS established in late 2019 were nonenforceable for a period of time due to a Merrimack County Supreme Court injunction. The injunction alleged New Hampshire Department of Environmental Services failed to account for the economic feasibility of these rules (State of New Hampshire, 2019). As a result, when the governor of New Hampshire signed into law these MCLs (NH H.B. 1264, [07/23/2020]), the bill also included US$50 million in state funds to support the cleanup of contaminated sites and established a low interest loan program for impacted water and waste water systems.

In the absence of a national regulation, states have initiated their own efforts to implement lower advisories and enforceable standards with New York currently establishing the lowest for PFOS at 10 ng/L (New York State, 2020). Michigan's 2019 proposed levels recently became enforceable in August 2020 at 8 ng/L for PFOA and 16 ng/L PFOS, pushing the established values for PFOA even lower (Ellison, 2020). California had the lowest threshold concentrations of 5.1 ng/L and 6.5 ng/L for PFOS and PFOA, respectively, set as notification levels until recently when Illinois passed health advisory levels for four PFAS to include PFOA at 2 ng/L. Illinois did not include PFOS in these health advisory guidance levels (Illinois Environmental Protection Agency, 2021).

During the public comment period in response to USEPA's positive regulatory determination for PFOA and PFOS that ended in May 2020, submitted comments by

the American Water Works Association (AWWA) on the preliminary determination on PFOA and PFOS supported the development of primary standards but stressed the need to address the large data gaps, a stance also supported by the ASDWA (ASDWA, 2020; AWWA, 2020). A joint letter by ASDWA and the Association of Metropolitan Water Agencies (AMWA) called for USEPA to specifically focus on the issue of risk communication to the public given that so many states have varying (and often lower) PFAS standards (ASDWA & AMWA, 2020). The lack of a consistent discussion evaluating the toxicity and occurrence as it relates to past regulatory determinations by the USEPA further contributes to uncertainty and public concern.

3.2 | Placing PFAS regulation into context using RHI

We use the RHI metric to calculate a potential "RHI reduction" obtained by regulating a contaminant at a certain concentration. The dimensionless RHI value calculated at this specified concentration is then related to the percent population exposed above this threshold. Arsenic and uranium both contain detailed monitoring data prior to the USEPA MCL revisions. Both contaminants were included in the second 6-year review of all regulated contaminants, providing accurate occurrence estimates prior to both MCLs being lowered. Therefore, of all the contaminants currently regulated, only arsenic and uranium have comprehensive occurrence data prior to regulation to calculate the RHI reduction associated with the regulated concentration. We use these two contaminants to set our boundaries for meaningful opportunity for health risk reduction using two different approaches (Figure 2). It is important to note that the absolute values calculated in the proposed approaches are not the focus, but rather the scale that is created to compare contaminants.

Our first approach uses the two quantifiable values (toxicity as a factor in calculating RHI and occurrence in terms of percent of national population exposed to certain concentration) to create a regulatory region of meaningful health risk reduction for recently considered contaminants. On the left side of the Approach #1 graph, the calculated RHI values for PFOS and PFOA are presented for the CA notification level (6.5 and 5.1 ng/L, respectively), ATSDR (52 and 78 ng/L, respectively), and USEPA threshold values (70 ng/L each) with black markers. Using the occurrence data included in the recent Preliminary Regulatory Determination (USEPA, 2020, 2021a), we included the occurrence and RHI values for the USEPA calculations on the right side of the plot as well. The darker shaded box represents the area on the plot where health impact and occurrence are satisfied to create a meaningful opportunity for health risk reduction based on previous regulatory actions for uranium and arsenic. According to this assessment, if PFOS occurrence exceeded 3.8% (occurrence estimates to date indicate it does not [AWWA, 2020]), it would enter the zone of meaningful health risk reduction as the calculated total (cancer + non-cancer) RHI PFOS value exceeds the threshold of 2.86E−06 as established by uranium. PFOA would not cross into the zone of meaningful using this assessment regardless of population exposure since the calculated health risk reduction is not greater than the threshold set by uranium. This calculated RHI value is a normalized scale and is not a prediction of cancer or health risk outcomes.

It is important to note that this is solely based on previous determinations and not a mandate as to what quantifies meaningful exposure. According to Approach #1, if PFOA is regulated using the risk and occurrence data currently available, the new box for meaningful opportunity for health risk reduction would equal the area shaded in light gray. This positive regulatory determination could draw into question previous negative determinations for hexachlorobutadiene, manganese, and potentially Telone (1,3-dichloropropene).

Our second proposed method (Approach #2) of calculating meaningful opportunities for health risk reduction is to multiply the two quantifiable components (percent population above threshold concentration × threshold concentration RHI), creating a minimum threshold value (PopRHI). By multiplying the ordered pairs from Approach #1, we create a one-dimensional scale, essentially a number line, against which we can compare contaminants. A contaminant appearing higher on the line has a greater PopRHI metric. Approach #2 allows for creating theoretical scenarios where regulators could calculate the toxicological impact via the RHI metric and then calculate necessary percent populations to exceed the threshold for meaningfulness; this is the approach taken in our previous evaluations of meaningful opportunities (Alfredo et al., 2017). Again, based on positive regulatory determinations for arsenic and uranium and negative determinations for the other contaminants, an area of meaningful opportunity is established by the dark shaded box. Similar to Approach #1, the EPA positive regulatory determination of PFOA at the current concentration of 70 ng/L means six additional contaminants will fall within this new bounded region of meaningfulness, shaded in light gray.

Using this approach, we can calculate the needed percent population exposure to PFOA and PFOS to surpass the threshold set by uranium. A more robust analysis would include the actual PFAS concentrations and populations exposed; however, these data are not available. Therefore, we consider the percent of the population exceeding the proposed threshold concentration. For PFOS, the ATSDR toxicological analysis produced the

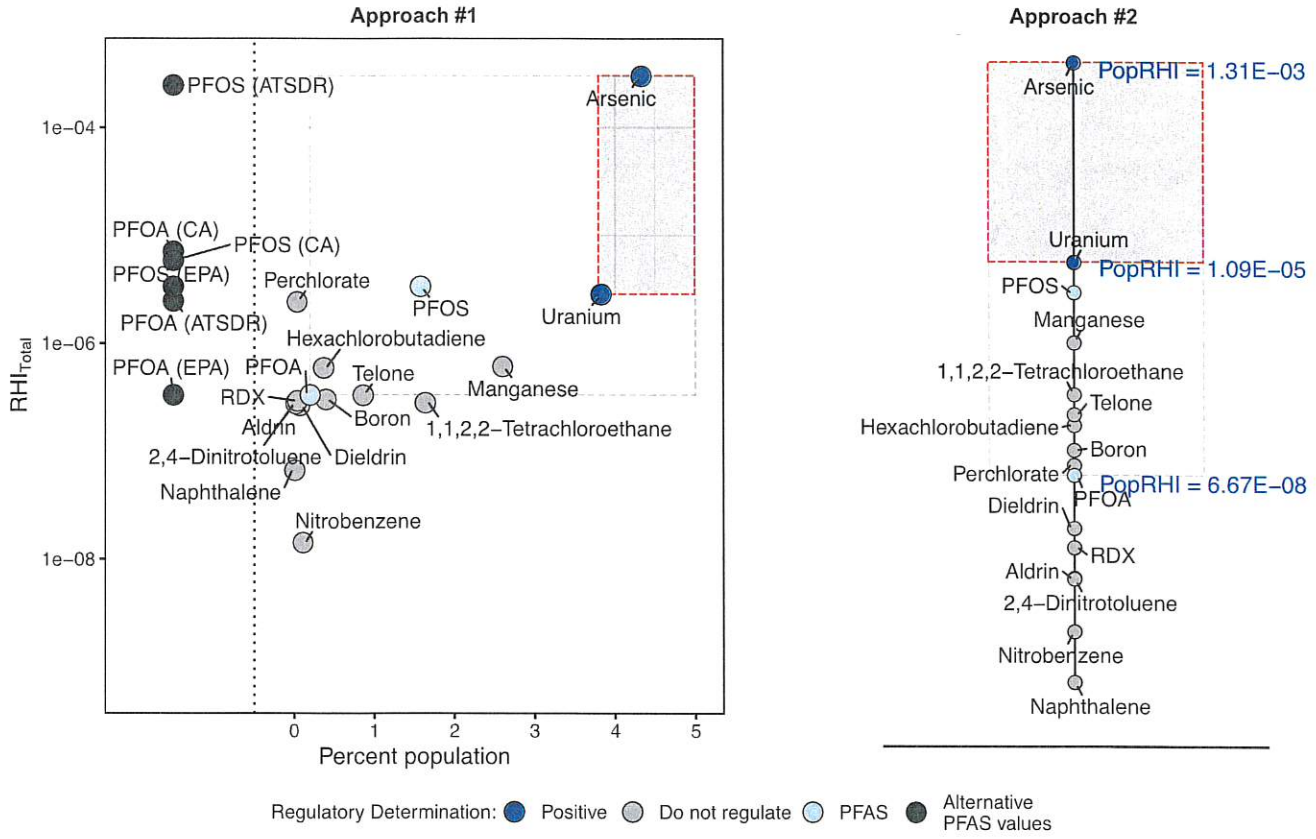

FIGURE 2 Approach #1: creating a zone of meaningful health risk reduction using RHI_{Total} (dimensionless) and occurrence (percent of the population exposed) as separate parameters. The left side of the graph (left of the dotted line, without an *x*-axis label) shows the alternate PFAS RHI values representing the varying proposed regulatory limits for PFOA and PFOS and the corresponding RHI_{Total} concentrations. Approach #2: calculating a threshold PopRHI value by multiplying health impact and occurrence (percent population exposed * RHI). Both models include all contaminants with sufficient data that have regulatory determinations. The PFOS and PFOA RHI calculations based on the concentrations currently set by EPA (70 ng/L each) are included as pending to assist in determining corresponding regulatory zones. EPA, Environmental Protection Agency; PFOA, perfluorooctanoic acid; PFOS, perfluorooctyl sulfonate; RHI, Relative Health Indicator

highest RHI value of 2.48E−04. Even at this RHI, it would require an exposure of 4% of the population to cross the uranium PopRHI threshold. Interpreting this another way, we can ask what concentration is needed to meet meaningfulness if a known percent of the population is exposed. Using the RHI calculations based on the EPA toxicological values and assuming occurrence in 100% of the population, contaminant concentrations of 227 ng/L PFOS and 2295 ng/L PFOA are required to cross the uranium PopRHI threshold; these concentrations exceed any that are being proposed within the US state and federal regulatory framework.

3.3 | Does regulating PFAS represent a meaningful opportunity for health risk reduction?

Given historical precedent, PFOA and PFOS individually regulated do not currently represent a meaningful opportunity for health risk reduction given the toxicological and occurrence data available. This assessment might change if a PFAS class regulation is proposed as a recent analysis supported (Kwiatkowski et al., 2020) and substantiated with health relevance and occurrence information. Many of the comments submitted to EPA in response to the preliminary determination for PFOA and PFOS focused on the uncertainty and expedited regulatory landscape situation at the individual state level, which was created in the absence of a federal MCL. In 2019, AWWA responded to questions by the Congressional Budget Office regarding the costs associated with regulating PFAS compounds (AWWA, 2019). If a combined PFAS regulation is set at 70 ng/L, national capital cost estimates range from 2 to 12 billion USD for granular activated carbon, ion exchange, and reverse osmosis systems with annual operation and maintenance costs estimated at $44–460 million. If EPA uses a Treatment Technique approach instead of a threshold concentration, this could increase capital costs to $130–800 billion and

annual expenditures to $2.7–28 billion. In context and contrast, 2012 cost estimates to replace failing drinking water infrastructure, mainly distribution pipes, needed to maintain existing water supply and quality expectations exceed $0.9 trillion and are over $1.7 trillion to meet the needs of replacement and growth through 2050 (AWWA, 2012). In a world of constrained resources, deciding how and where to spend those resources to maintain and improve public health is paramount.

Almost unanimously, comments submitted to the EPA by professional water organizations have called for more research; however, a delayed regulation creates public health protection uncertainty. At present, the burden of deciding how to proceed falls to individual states with limited and unequal capacities and capabilities to address the uncertainty. We anticipate our analyses will catalyze a beneficial discussion calling into question many of the assumed values integral to the determination of regulated contaminant thresholds and urge the regulatory policy makers to develop and use a comparative metric so that "meaningful" is quantifiable on a comparative scale instead of qualitatively defined on a case-by-case basis. In doing so, we can best achieve the most meaningful health risk reduction for all.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

AUTHOR CONTRIBUTIONS

Katherine A Alfredo: Conceptualization; formal analysis; visualization; methodology; writing – original draft; writing – review and editing. **Chad Seidel:** Conceptualization; formal analysis; methodology; writing – original draft; writing – review and editing. **Amlan Ghosh:** Conceptualization; formal analysis; methodology; writing – original draft; writing – review and editing.

DATA AVAILABILITY STATEMENT

Data derived from public domain resources

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