American Water Works Association
Dedicated to the World's Most Important Resource™

Government Affairs Office
1300 Eye Street NW
Suite 701W
Washington, DC 20005-3314
T 202.628.8303
F 202.628.2846

May 21, 2020

Richard Weisman
Office of Ground Water and Drinking Water
Environmental Protection Agency
1200 Pennsylvania Avenue, N. W.
Mail Code: 4607M
Washington, DC 20460

RE: Comments on Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List (Docket ID No: EPA-HQ-OW-2019-0583)

Dear Mr. Weisman,

The American Water Works Association (AWWA) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA's) "Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List". AWWA hopes that these comments will assist EPA to utilize the Safe Drinking Water Act regulatory determination process to effectively focus its regulatory development activities. AWWA supports the eight preliminary regulatory determinations included in EPA's proposal. [1]

The Safe Drinking Water Act (SDWA) appropriately requires that EPA base regulations on the best available public health science and occurrence data. [2] The *Federal Register* notice identifies information gaps, particularly with respect to per- and polyfluoroalkyl substances (PFAS) that EPA must overcome to support sound regulatory decision-making. Addressing these information gaps will not be possible without effectively managed and adequately funded research. Neither the EPA strategic research action plan for chemical safety nor sustainable water demonstrate that the Agency has a focused research plan that will meet the SDWA program's needs described in this notice. [3, 4] A particular gap in the current research plan is a clear strategy for determining how to make the knowledge acquired through EPA research programs actionable in regulatory decision making (e.g., using data acquired to screen contaminants, determining levels of health concern, etc.).

---

[1] 85 *Federal Register* 14098.
[2] National Drinking Water Regulations. 42 U.S. Code § 300g–1(b)(1)(A). 1996.
[3] EPA. "Chemical Safety for Sustainability Strategic Research Action Plan 2019-2022." March 2020. Accessed April 20, 2020.
[4] EPA. "Safe and Sustainable Water Resources Strategic Research Action Plan 2019-2022." March 2020. Accessed April 20, 2020.

The SDWA criteria for determining if a contaminant warrants development of a federal drinking water standard are important guideposts for the EPA drinking water program.[5] They are sound criteria, which the EPA notice aptly addresses. SDWA standard setting is not, and should not be treated as, a surrogate for action to reduce risk to the public and environment through other available statutes. For example, at present it is not clear that either individual states or EPA are effectively applying state or federal statutory authorities including the Toxic Substances Control Act (TSCA), Clean Water Act, Clean Air Act, or the Resource Conservation and Recovery Act to prevent the entry of PFAS into the nation's surface water bodies and ground water aquifers.[6] SDWA standards are not intended to be the trigger for protective actions, but rather the failsafe for when other best available business practices and regulatory barriers have failed. If drinking water standards are to be developed, then these authorities should be used to minimize drinking water supply contamination.

EPA's objective is to finalize these preliminary determinations in less than eight months.[7] With that short administrative timeline in mind AWWA offers the following specific recommendations relating to PFAS:

1. EPA should move forward to develop primary standards for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) expeditiously but not without undertaking the analyses required to ensure that the resulting regulations are sound.

2. EPA has a responsibility to evaluate PFAS other than PFOA and PFOS efficiently and in a timely manner. Doing so will require applying the adequate resources to collect the necessary data and undertake the requisite analyses to prepare a sound regulation.

3. EPA should supplement monitoring data from the Third Unregulated Contaminant Monitoring Rule (UCMR 3) with high quality occurrence data and per EPA policies control for any biases in the datasets when conducting its meta-analysis.[8, 9]

4. Currently the absence of timely health risk assessments prevents EPA from preparing the necessary analyses to support sound regulatory determinations and drinking water standards for PFAS for which EPA already has occurrence data.

5. The Agency must address outstanding data and knowledge gaps regarding PFAS of concern prior to determining a regulatory grouping approach for PFAS.

6. If EPA develops standards for PFOA and PFOS, EPA should adapt the Standardized Monitoring Framework for synthetic organic chemicals to PFAS by using one-half the MCL as the trigger level for quarterly monitoring.

---

[5] National Drinking Water Regulations. 42 U.S. Code § 300g–1(b)(1)(A) and (B)(ii)(II). 1996.
[6] EPA. "EPA Actions to Address PFAS." February 26, 2020. Accessed April 21, 2020.
[7] Office of Information and Regulatory Affairs. "Current Unified Agenda and Regulatory Plan for Fall 2019." November 20, 2019. Accessed April 23, 2020.
[8] EPA. "EPA Information Quality Guidelines." Accessed April 21, 2020.
[9] EPA. "Agency-wide Quality System Documents." Accessed April 21, 2020.

7. EPA should go beyond typical practice to engage an expert panel to develop a science-based evaluation of the state of available PFAS health risk data.

8. EPA's proposed negative regulatory determinations for 1,1-dichloroethane, Acetochlor, Metolachlor, methyl bromide, nitrobenzene, Royal Demolition Explosive are appropriate.

9. Continuing to collect data to support a regulatory determination for 1,4-dioxane, 1,2,3-trichloropropane, and strontium is appropriate at this time.

10. EPA should collaborate with AWWA, the water system community and states to utilize available tools to manage manganese occurrence.

If you have any questions regarding this correspondence or if AWWA can be of assistance in some other way, please contact me or Chris Moody at (202) 326-6127 or cmoody@awwa.org.

Best regards,

G. Tracy Mehan, III
Executive Director – Government Affairs

cc: David Ross, EPA/OW
Jennifer Orme-Zavaleta, EPA/ORD
Brittany Bolen/OP
Jennifer McLain, EPA/OGWDW
Eric Burneson, EPA/OGWDW
Lisa Christ, EPA/OGWDW
Ryan Albert, EPA/OGWDW
Alexandra Dunn, EPA/OCSPP

Who is AWWA

The American Water Works Association is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,000 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

Comments on Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List

(Docket ID No: EPA-HQ-OW-2019-0583)

Prepared by the

American Water Works Association

The American Water Works Association (AWWA) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA's) "Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List". AWWA hopes that these comments will assist EPA to utilize the Safe Drinking Water Act regulatory determination process to effectively focus its regulatory development activities. AWWA supports the eight preliminary regulatory determinations included in EPA's proposal. [10]

1. Overarching Comments

AWWA appreciates the presentation of available data and EPA's decision-making process in the Agency's Federal Register notice. In finalizing this round of regulatory determinations, AWWA requests that EPA summarize the key steps it will be taking to fill information gaps identified in the current notice. The greater specificity EPA provides, the more that stakeholders like AWWA will be able to assist in providing relevant contributions.

AWWA also offers the following specific comments on in response to EPA's request for comment.

2. Per- and Polyfluoroalkyl Substances (PFAS)

AWWA appreciates EPA efforts to initiate the regulatory process for PFAS in drinking water.

Due to the cumulative discharge and global dispersion in the environment per- and polyfluoroalkyl substances (PFAS) have become a growing management and communication challenge for communities across the nation. With the recognition that hundreds of industrial facilities and Department of Defense facilities have released PFAS into the environment contaminating private wells and local water supplies across the nation, public concern that PFAS is a widespread risk to drinking water supplies has steadily grown. In the absence of federal controls on PFAS through EPA's various authorities (such as the Resource Conservation and Recovery Act, Clean Air Act, and Clean Water Act) as well as limited action under the Toxic Substances Control Act, public concern has driven many states to set diverse regulations for PFAS, with nearly half of all states having implemented or proposed PFAS-related regulation for the protection of drinking water supplies. [11] Numerous states have developed finished drinking water standards for PFAS. As shown in Table 1 the proposed or effective enforceable drinking water standards vary by state based both on the levels and PFAS covered. These inconsistencies between state and federal standard setting efforts create a communication challenge for water systems surrounding the public health risks of PFAS exposure, confuse the public, and hurt the credibility and validity of risk assessment processes. As states have developed these standards, challenges surrounding interpreting toxicological data and assessing treatment feasibility have become apparent.

---

[10] 85 *Federal Register* 14098.

[11] AWWA. "Summary of State Policies to Protect Drinking Water." May 1, 2020.

Table 1: Summary of State Drinking Water Standards

State*	Standard	Concentration (ng/L)							
		Sum	PFOS**	PFOA**	PFHxS**	PFNA**	PFHpA**	PFDA**	PFBS**
California	Response Level		40	10					
Massachusetts	Proposed MCL	20	X	X	X	X	X	X	
Michigan	Proposed MCL		16	8	51	6			420
New Hampshire	Effective MCL		15	12	18	11			
New Jersey	Effective MCL					13			
	Proposed MCL		13	14					
New York	Proposed MCL		10	10					
Vermont	Effective MCL	20	X	X	X	X	X		

*Notes: *This table provides an overview of a portion of state standards and guidance to protect drinking water supplies; this table is not an exhaustive list of state regulatory actions. Refer to AWWA's "Summary of State Policies to Protect Drinking Water" for a complete list of drinking water and source protection policies. **PFOA: Perfluorooctanoic acid. PFOS: perfluorooctanesulfonic acid. PFHxS: perfluorohexanesulfonic acid. PFNA: perfluorononanoic acid. PFHpA: Perfluoroheptanoic acid. PFDA: perfluorodecanoic acid. PFBS: perfluorobutanesulfonic acid.*

2.1 Positive Determinations for PFOA and PFOS

In review of the current research and information available for PFOA and PFOS, AWWA is supportive of EPA's positive determination for PFOA and PFOS, which are the most well-known and studied PFAS as well as the most commonly detected PFAS in drinking water. Data from the Third Unregulated Contaminant Monitoring Rule (UCMR 3) demonstrate that PFOA and PFOS were detected in the drinking water supplies with more than 5.5 million Americans exposed to levels exceeding EPA's lifetime health advisory.

The proposal notes that an analysis will be done to "inform future decision making", specifically providing for "further scientific review of new science prior to promulgation of any regulatory standard. AWWA welcomes a robust scientific review of the toxicological research that is available. Attributing specific health effects to PFOA and PFOS is complicated and different toxicologists have come to very different conclusions based on the available data. These conclusions are so different as to have substantial implications for regulatory thresholds and drinking water treatment. This is evident in the significant difference between the reference doses determined by the EPA Office of Water's health advisories for PFOA and PFOS and those determined by the Agency for Toxic Substances and Disease Registry's (ATSDR) Draft "Toxicological Profile for Perfluoroalkyls".[12, 13] These differences illustrate the fact that the scientific community is not certain about which toxicity endpoints (e.g. cancer vs. non-cancer) to use, what are appropriate reference doses, or which uncertainty factors to apply. These differences in assumed

[12] EPA. "Drinking Water Health Advisory for Perfluorooctanesulfonate (PFOS)." May 2016. Accessed April 22, 2020.
[13] ATSDR. "Toxicological Profile for Perfluoroalkyls – Draft for Public Comment." June 2018. Accessed April 22, 2020.

exposures, water concentrations, and/or groupings of PFAS that warrant a drinking water standard, has led to varying state standards with very different compliance requirements.

2.2 Use of State and Independent Research Occurrence Data

EPA relies primarily on data from the UCMR to make regulatory determinations since this monitoring dataset per SDWA:

- Provides EPA, and the public, with scientifically valid data that improves the understanding of the levels present in drinking water, the populations exposed, and other factors such as the drinking water source.
- Captures occurrence that is statistically representative population exposure data to unregulated contaminants through public drinking water supplies throughout the U.S.
- Provides a high degree of quality assurance and control processes to ensure data quality including a laboratory approval program, which ensures all participating laboratories meet minimum criteria for equipment, laboratory performance, and data reporting.
- Coordinates with approved laboratories in advance of monitoring to understand technical limits of monitoring and establish a minimum reporting level such that all laboratories are reporting results on a level playing field. [14]

In the proposal, EPA describes supplementing its UCMR 3 database with data collected by states who have "made their data publicly available at this time". In the absence of more recent UCMR data this approach can be useful, if used appropriately. This additional data should be used in such a way that does not undermine the UCMR 3 database but strengthens it. Specifically, it is necessary that the data be used in a manner reflective of the respective monitoring strategies. As the proposal notes, for instance, several of these datasets are from targeted monitoring (i.e., in areas where PFAS contamination is known or expected to occur). It is important that EPA not extrapolate such datasets to the nation without taking the targeting bias into account. AWWA recommends that a strategic approach be applied on a case-by-case basis for consideration of this data in this regulatory process. If pursued, this is an aspect of developing the proposed rule that would benefit from external input including public feedback.

The following illustrate the opportunities and challenges of using available occurrence datasets:

1. The Colorado Department of Public Health and Environment's (CDPHE's) monitoring program targeted the Widefield aquifer in El Paso County, which was found to have PFAS contamination during monitoring under UCMR 3. This data has limited value since it is only applicable to a single aquifer, which was tested as part of UCMR 3. However, the CDPHE is currently initiating a monitoring program for state-wide public water systems (PWSs) testing for PFAS. This program is providing funding for sampling (18 PFAS based on EPA Method 537.1) of 435 PWSs, which will account for 49% of all Colorado PWSs and

[14] National Drinking Water Regulations. 42 U.S. Code § 300g–1(b)(1)(B)(ii)(II). 1996.

nearly 80% of the state's population. According to the CDPHE, the results will be published and available this summer. [15]

2. The New Hampshire Department of Environmental Services' (NHDES) monitoring program was also targeted but was more broadly focused on PWSs throughout the state but with an emphasis on PWSs near known contaminated sites. This should be strongly considered during data assessment, as many of the samples were performed in dense clusters and would be representative of the same groundwater source. For example, the sampling density in one cluster in Litchfield is as high as 500 water samples per square mile and is representative of private residential wells. Given the targeted approach to this sampling program, and the high density of the samples in some areas, this dataset would be most useful for the Agency to consider the variability of PFAS samples spatially and/or temporally. This data may also be useful for the Agency to further study how different sources of pollution may be associated with specific PFAS compounds.

3. The proposal also cites two state monitoring programs (New Jersey and Michigan) that are focused on statewide, not targeted, monitoring of finished drinking water. These datasets will be very beneficial in re-evaluating PFAS occurrence in PWSs within these states. These datasets are expected to provide better clarity on PFAS prevalence in drinking water supplies, given the lower minimum reporting levels (MRLs) in comparison to UCMR 3. The New Jersey Department of Environmental Protection (NJDEP), for instance, requires that the laboratory performing analysis must be capable of achieving an MRL of 5 nanogram per liter (ng/L) or less for PFNA.

4. In addition to the aforementioned state monitoring programs, EPA should also consider the use the monitoring data that is currently being performed under the direction of the California State Water Resources Control Board (State Board). This targeted monitoring program was initiated in April 2019 and the initial data is has been made publicly available via the State Board's PFAS webpage. This program has, in part, focused on collecting samples from more than 600 drinking water wells from nearly 200 water systems identified in high risk areas for PFAS contamination. The targeted monitoring also required sampling of all wells within 1 mile of any wells sampled as part of UCMR 3 that detected PFOA and PFOS. Finally, this program required re-sampling of wells that were sampled as part of the UCMR 3 monitoring and detected PFAS. [16]

5. There are several other states that are expected to have monitoring data as recent or new drinking water standards become effective. Vermont, for instance, recently amended their Water Supply Rule to include five PFAS. [17] Additionally, Massachusetts and

---

[15]Colorado Department of Public Health and Environment. "PFAS 2020 Sampling Project." March 2, 2020. Accessed April 22, 2020.
[16]California State Water Resources Control Board. "Per- and Polyfluoroalkyl Substances (PFAS)." April 17, 2020. Accessed April 22, 2020.
[17] Vermont Agency of Natural Resources. "Environmental Protection Rules, Chapter 21, Water Supply Rule". March 17, 2020. Accessed April 22, 2020.

New York proposed drinking water standards in 2019; it is possible that the first round of compliance monitoring for these states may be available for consideration during the regulatory timeline. [18, 19] Data from these monitoring programs are not yet available but likely will become available within the timeframe of the regulatory process. The monitoring for these will be varied, but in general would be reflective of the all PWSs within these states and would likely provide improved clarity on occurrence within the state based on lower MRLs.

6. Ohio EPA has begun testing drinking water for PFAS under Ohio PFAS Action Plan, that may provide data for EPA's analysis. [20] As of April 22, 2020 nearly 238 water treatment facilities have sampled and reported their results for PFAS. [21] According to the Ohio PFAS Action Plan, the sampling is expected to be completed by the end of 2020, but the impact of the COVID-19 crisis on the availability of this data is currently unclear.

AWWA is supportive of EPA augmenting UCMR 3 data with state monitoring data provided it will be done so with appropriate quality control standards to ensure that the dataset is reliable and representative. For example, many of the above programs were established to support regulatory efforts and many of these states (California, Michigan, Colorado, and New York, for instance) have also established their own regulatory standards to reduce environmental pollution.[4] Additionally, while many state monitoring programs have had stringent lab certification programs in place, there has generally not been external review of lab data similar to what is done currently for UCMR monitoring data and would be expected for UCMR 5.

2.3 Shortlist of Additional PFAS

EPA has a responsibility to evaluate PFAS beyond PFOA and PFOS efficiently and in a timely manner. Doing so requires applying adequate resources to collect the necessary data and undertake the requisite analyses to prepare a sound regulation.

EPA asked for comment on which PFAS, in addition to PFOA and PFOS, should be included in the current regulatory determination process. In preparing these comments, AWWA reviewed available information on PFAS included in state-specific standards, state monitoring programs, and ongoing EPA research.

At present, the broadly applicable occurrence data is available from UCMR 3 and state monitoring efforts, both of which largely rely on observations using EPA Method 537. As noted in the proposal, four additional PFAS were monitored as a part of UCMR 3 and detected at a small number of PWSs. [22] These PFAS include perfluorobutanesulfonic acid (PFBS), PFNA, PFHxS, and PFHpA. To date, these are the only four additional PFAS for which there is a nationally representative dataset for occurrence in finished

---

[18] New York Department of Health. "Amendment of Subpart 5-1 of Title 10 NYCRR (Maximum Contaminant Levels (MCLs))." July 24, 2019. Accessed April 22, 2020.
[19] Massachusetts Department of Environmental Protection. "PFAS MCL Proposed Regulation Presentation Slides." December 27, 2019. Accessed April 22, 2020.
[20] Ohio EPA. "Ohio EPA Begins Testing Drinking Water Under Ohio PFAS Action Plan." February 27, 2020.
[21] Ohio EPA. "PFAS Testing of Ohio Public Water Systems." Accessed April 22, 2020.
[22] EPA, "The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017". January 2017. Accessed April 20, 2020.

drinking water supplies. Understanding contaminant occurrence is an integral component of a decision to regulate. PFBS and PFNA were detected in less than 0.5% of PWSs while the detection of PFHxS and PFHpA were detected 1.1% and 1.7% of PWSs, respectively.

Table 2: Summary of UCMR 3 Occurrence

PFAS	MRL (ng/L)	Number of Systems Sampling	Number of Systems with Results ≥ MRL	Percent of Systems ≥ MRL	Percent of Systems with at least one sample above ½ HRL / HRL*
PFOA	20	4,920	117	2.4%	1.93% / 0.9%
PFOS	40	4,920	95	1.9%	1.07% / 0.3%
PFHpA	10	4,920	86	1.7%	--
PFHxS	30	4,920	55	1.1%	--
PFNA	20	4,920	14	<0.5%	--
PFBS	90	4,920	8	<0.5%	--

*Note: * One-half the health advisory level for PFOA and PFOS (70 ng/L) is 35 ng/L.*

Importantly, EPA already has plans to supplement the UCMR 3 dataset with additional data to be collected in the fifth UCMR (UCMR 5). UCMR5 is expected to utilize an updated analytical method (EPA Method 537.1) with lower MRLs for the PFAS monitored in UCMR 3. The frequency of detection of PFAS initially monitored in UCMR 3 is expected to increase as the MRLs decrease, as can be seen in available state data. UCMR 5 is also expected to include sample analysis using a newer analytical method (EPA Method 533), collecting occurrence on an additional 11 individual PFAS incorporating an additional suite of PFAS.

The absence of timely health risk assessments prevents EPA from preparing the necessary analyses to support additional regulatory determinations and drinking water standards at this time.

With UCMR 3 occurrence data in hand and supplemented with data from other high-quality sources for these four additional PFAS, only PFBS is expected to have a final toxicity assessment prepared by EPA within the SDWA timeframe for proposing drinking water standards following this regulatory determination cycle. EPA's Integrated Risk Information System (IRIS) program has initiated assessments for PFNA and PFHxS. The anticipated completion of these assessments is not expected to be supportive of an evaluation during this regulatory determination cycle, an accelerated rule development schedule, or the SDWA deadlines for rulemaking following a positive determination. [23] The ATSDR developed a draft "Toxicological Profile for Perfluoroalkyls" that included these PFAS but has not yet finalized these findings. [24] There is not an available schedule for when the ATSDR will be finished. Importantly, while the draft profile from ATSDR used available data to determine toxicity values for PFNA, PFHxS, and PFBS, ATSDR concluded that there was inadequate information to draw conclusions about the toxicity of PFHpA.

[23] EPA. "A Message from the IRIS Program February 2020." February 2020. Accessed April 21, 2020.
[24] ATSDR. "Toxicological Profile for Perfluoroalkyls – Draft for Public Comment." June 2018. Accessed April 21, 2020.

In review of the available information from EPA and other information regarding occurrence and adverse health effects, EPA could only consider making a determination for PFBS based on the available data. Based on the monitoring results under UCMR 3 (and subsequent monitoring efforts) in consideration of the draft toxicity values from EPA and ATSDR, PFBS is not prevalent in finished drinking water supplies at levels of health concern. This information is supportive of an Agency decision to make a negative determination for PFBS. However, since PFBS is a replacement compound for PFOS, it would be prudent that the Agency delay the determination until completion of monitoring as part of UCMR 5 to confirm if occurrence has changed as a result of potentially higher industrial and commercial se.

For the remaining PFAS monitored under UCMR3 there is currently insufficient health risk assessment information to support a regulatory determination for EPA. UCMR 5 is expected to be finalized in 2021 and monitoring data will be publicly available in 2026.[25] EPA's IRIS Program has initiated the process for risk assessments of PFNA, PFBA, PFDA, perfluorohexanoic acid (PFHxA), and PFHxS. These assessments are scheduled to be ready for external peer review beginning next year with subsequent final assessments anticipated to be available beginning in 2024. The Agency will be in a position to make a regulatory determination following the collection occurrence data from the UCMR 5 and the data from toxicity assessments currently in progress.

Table 3: Summary of Shortlisted PFAS for a Delayed Determination and Statutory Criterion

Contaminant	#1: Adverse Health Effects		#2: Drinking Water Occurrence	
	EPA Assessments	ATSDR Profile	UCMR 3	UCMR 5
PFBA	IRIS: In Progress	Insufficient information	Not measured	Anticipated
PFBS	Office of Water: In Progress	Insufficient information	<0.5% of PWSs	Anticipated
PFHxA	IRIS: In Progress	Insufficient information	Not measured	Anticipated
PFHxS	IRIS: In Progress	Draft recommendations	1.1% of PWSs	Anticipated
PFNA	IRIS: In Progress	Draft recommendations	< 0.5% of PWSs	Anticipated
PFDA	IRIS: In Progress	Insufficient information	Not measured	Anticipated
GenX	Office of Water: In Progress	Not evaluated.	Not measured	Anticipated

Note: PFBS detections in UCMR 3 were low, however detection during UCMR 5 monitoring may show increased prevalence due to changes in use patterns.

The *Federal Register* notice describes parallel efforts to develop occurrence and health effects data beyond the PFAS included in UCMR 3. All of the anticipated UCMR 5 PFAS analytes are included in one or more lines of health effects inquiry. However, it is not clear how EPA expects to utilize the information being collected to characterize potential health risks to inform:

1. PFAS risk assessments of individual compounds.
2. Identification of "groups" of PFAS that have common, serious health implications to guide risk management actions.

[25] EPA. "Development of the Fifth Proposed Unregulated Contaminant Monitoring Rule (UCMR 5) for Public Water Systems Meeting Presentations." July 16, 2019. Accessed April 20, 2020.

3. Expeditious efforts to prioritize risk management of PFAS at environmentally relevant exposures.

2.4 Potential Regulatory Approaches

The following comments are intended to support future EPA decision-making processes beyond the current regulatory determination cycle and inform research activities to address existing knowledge gaps. Every approach for incorporating additional PFAS into drinking water standards has advantages and disadvantages. Three broad regulatory approaches are discussed in the *Federal Register* notice and include regulating PFAS based on: (1) individual characteristics, (2) grouping approaches based on shared characteristics, and (3) a treatment technique. Each of these approaches is discussed in the following sections, beginning with the broadest approach and narrowing down to the individual approach.

Context is important when considering potential regulatory approaches. At present EPA has lists of the number of "PFAS" that range in total from 1,072 – 7,866 compounds. Of that PFAS universe, EPA indicates it has characterized the chemical structure of 430 individual PFAS and is conducting research, particularly health effects research, on 165 individual PFAS:

- Conducting 8 formal individual PFAS health risk assessments.
- Collecting health effects literature on 30 individual PFAS.
- Conducting high-throughput toxicity testing on 150 - 180 individual PFAS (two unreconciled lists) [26].
- Evaluated drinking water treatment technologies for 9 individual PFAS.

EPA has completed only two individual PFAS risk assessments to date (i.e., PFOA and PFOS). [27] The Agency has also recognized that within the PFAS it has studied there are at least 64 unique chemical structures, with the associated differences in chemical properties that determine environmental fate and toxicity. Neither a review of EPA's efforts nor the *Federal Register* notice posit a unifying health effects risk assessment premise beyond the final PFOA and PFOS risk assessments.

While the notice describes the Agency having collected information on an additional 27 PFAS in the Health and Environmental Research Online (HERO) database, occurrence and toxicity data on these additional PFAS are very scarce. Monitoring in UCMR5 is expected to provide occurrence information on an additional 15 PFAS for which health effects literature is being compiled in HERO. Occurrence information, for the additional PFAS that EPA is evaluating using toxicity testing, is equally limited. A summary of these PFAS and the corresponding information collection efforts is provided in Appendix A.

Regardless of EPA's future regulatory approach, a sound regulation path forward for PFAS must:

1. Provide meaningful public health benefit through removing an appropriately targeted contaminant or group of contaminants.

2. Rely on an available treatment technology that has been demonstrated to be effective under a robust array of field conditions.

---

[26] EPA. "EPA CompTox Dashboard." Accessed April 22, 2020

[27] EPA. "Drinking Water Health Advisories for PFOA and PFOS." November 2016. Accessed April 22, 2020.

3. Minimize adverse unintended consequences including simultaneous compliance and operational considerations.

4. Avoid forcing water systems to make long-term capital investments, which are subsequently left stranded by shifting regulatory policies.

5. Recognize, that funds utilized by water systems to address poorly characterized potential risks reduce the amount of funding available to use to address well-understood risks and necessary improvements.

2.4.1 Regulation based on a Treatment Technique

There are three central challenges surrounding the regulation of PFAS based on a treatment technique. First, there are reliable analytical methods (EPA Methods 537.1 and 533) that have been widely used to characterize drinking water occurrence and are both economically and technically feasible for PFAS. SDWA requires the EPA to utilize a treatment technique for a contaminant, or a group of contaminants, if "*it is not economically or technologically feasible to so ascertain the level of such contaminant.*" [28] Consequently as a matter of law, this regulatory approach is not appropriate unless the Agency has a basis in a health risk assessment to regulate PFAS beyond the group of PFAS for which there are available analytical methods adequate to support implementation of treatment.

Removing PFAS from water can potentially require treatment technologies such as granular activated carbon (GAC), anion exchange (IX), or membrane treatment (reverse osmosis [RO] or nanofiltration [NF]). Each of these treatment technologies offers its own advantages and disadvantages. Membrane treatment processes, for instance, can provide high removal rates for a wide spectrum of PFAS regardless of functional group or chain-length. However, membrane treatment may affect the stability of the finished water and may complicate or create corrosion control issues. RO generates a concentrated waste stream that will need to be further managed. GAC, IX, and membrane processes typically require additional pumping and so require more maintenance. RO typically requires a substantial amount of energy to operate and are expensive to maintain. In contrast, GAC and IX are less expensive to operate but do not offer the same removal of PFAS. Removal of PFAS tends to depend on the chain length and functional group for GAC and IX. When GAC and IX are used, not only is it necessary to manage the treatment train for target contaminant removal but also for chromatographic peaking, or sloughing, where there are non-target contaminants that represent either a health or aesthetic consideration. Both GAC and IX, like RO require consideration of potential impacts on corrosion control. Both GAC and IX create waste streams as well. IX resins will be disposed of as either solid or hazardous waste based on future regulations. GAC will either be disposed of or re-generated for subsequent uses again based on future regulatory constraints.

Importantly, the resources invested in the implementation of treatment based on a treatment technique regulatory requirement using one of the above treatments would divert water system resources from other pressing issues. As AWWA noted in testimony to Congress in May 2019 regulatory actions need to be prudently implemented to avoid aggravating affordability issues for customers. [29] While the advanced

[28] National Drinking Water Regulations. 42 U.S. Code § 300g–1(b)(4)(E)(i). 1996.
[29] Mehan III, Tracy G. Examining Legislation to Address the Risks Associated with Per- and Polyfluoroalkyl Substances (PFAS) Testimony to Senate Environment and Public Works, May 22, 2019.

technologies for PFAS removal can be effective, they are also expensive and generate waste streams that require specialized disposal methods that are not readily available across the country. For instance, a cost estimate was prepared for Cape Fear Public Utility Authority in response to PFAS detections in the Cape Fear River for GAC, IX, and RO treatment facilities based on a capacity of 44 million gallons per day (MGD). The estimated capital costs ranged from $46 million up to $150 million (or approximately $1.1 to $3.4 million per MGD of capacity). [30] A similar evaluation of treatment alternatives (GAC and IX) was prepared for Merrimack Village District in 2018 to install PFOA treatment for a system with a capacity of 3.4 MGD. This evaluation estimated that a capital investment of upwards of $12 million, or approximately $3.5 million per MGD of drinking water supply capacity. [31] Cost per household served can drastically increase for smaller systems that have fewer households in their rate base across which to distribute the capital and ongoing operating costs for these treatment technologies.

Given the availability of EPA-approved analytical methods, the distribution of recognized PFAS contamination to-date, and the lack of a cohesive health risk assessment premise, it appears unlikely that a treatment technique will be a prudent approach to regulating PFAS. Such an approach deliberately imposes a treatment strategy on all systems that meet certain criteria because the risk of exposure is so great as to warrant proactively applying treatment. Current examples of such risks include pathogens, disinfection byproducts, and lead. The implementation costs of such a regulatory approach would require systems to divert available financial resources away from planned system improvements such as accelerated lead service line replacement programs, improvement projects to address disinfection byproducts, and/or affordability programs.

2.4.2 Regulation Based on Groups

The Agency must address outstanding data and knowledge gaps regarding PFAS of concern prior to determining a regulatory grouping approach for PFAS.

The *Federal Register* notice included six alternative grouping approaches for PFAS (common adverse effects, chain length, functional groups, degradation products, co-occurrence, or a combination of physiochemical and fate characteristics). Regulation of "groups" of contaminants is a viable regulatory strategy and has already used for contaminants like disinfection byproducts, polychlorinated biphenyls, and radionuclides. But as EPA recognized in attempting to craft the carcinogenic volatile organic compound rule, the grouping must support effective regulation, not simply provide administrative convenience to the Agency. [32] EPA identified at that time the following considerations, which continue to be important in crafting a "grouping" approach for PFAS:

1. Groups should be formed and addressed in a manner that will ultimately be protective of public health.

---

[30] Black and Veatch. "Alternative Evaluations Report: Emerging Contaminants Treatment Strategies Study." April 30, 2018. Accessed April 5, 2020.
[31] Underwood Engineers. "Evaluation of PFAS Treatment for Wells 2, 3, 7 & 8 Merrimack Village District (MVD), Merrimack, NH." December 14, 2018. Accessed April 5, 2020.

[32] EPA. "Paradigm for Addressing Drinking Water Contaminants As Groups to Enhance Public Health Protection - EPA Draft Discussion Paper". August 17, 2010.

2. Groups should be formed, and regulations promulgated, in a manner that is consistent with the requirements of SDWA.

3. The standard to address groups should be determined to assure combined exposure of the contaminants within the group should not exceed the threshold of concern for health effects.

4. The group approach should be used only when it is more advantageous to diagnose and mitigate the risks collectively for the group rather than each contaminant individually.

5. The actions to address groups must consider the cost-effectiveness and ease of implementation for the public water systems and primary agencies.

6. Factors that should be considered when evaluating whether the guiding principles would be met by the group approach should include similar health effects, same analytical method, similar treatment / control processes, and common occurrence with other chemicals in the group.

As described herein, there are substantial knowledge gaps associated with the health risks posed by PFAS, the occurrence of PFAS, and cost-effective treatment of PFAS. These same information gaps must be addressed prior to preparing a regulation based on potential groupings. The above considerations do not require less data until there is a basis in available knowledge (e.g., health risk, occurrence, and treatment efficacy) to effectively evaluate regulation of a particular grouping strategy.

In crafting a grouping strategy, it is challenging to balance considerations 1, 3, and 5. A group regulation that includes PFAS with differing toxicities would lead to a regulatory standard that may be too low or too high for certain PFAS. For example, a regulatory group based on the sulfonic acid functional group, would apply to both PFBS and PFOS. Available risk assessments find a markedly different toxicity resulting from exposure to these two PFAS. To be most protective, a standard applicable to both of these PFAS would need to be based on levels of concern for PFOS, which is several magnitudes less than PFBS. While this standard would be protective of public health by reducing both PFBS and PFOS to appropriate levels, it would require water systems to reduce PFBS levels far below what would be necessary to protect public health and could result in an expenditure of system resources (i.e., household water bills) for minimal health benefit from reduction in PFBS.

The absence of well-characterized toxicity for any but a small number of PFAS at environmentally relevant concentrations making it challenging to craft an appropriate grouping for regulation using any initial grouping construct. This challenge is particularly true for the first grouping strategy identified by EPA, grouping based on a shared, common adverse effect. But it is a challenge for other grouping strategies as well because of considerations 1, 2, and 3 in the above list.

Additionally, the proposal indicates a potential grouping for PFAS based on the chain-length of PFAS, specifically short-chain and long-chain. Long-chain PFAS are typically considered perfluoroalkyl sulfonic acids containing six or more carbons and perfluoroalkyl carboxylic acids containing seven or more carbons. This is an approach that has been observed for state-level drinking water regulations. Massachusetts applied this approach, proposing a group drinking water standard for six long-chain PFAS: PFOA, PFOS, PFHxS, PFHpA, PFNA, and PFDA. There is preliminary evidence based on ATSDR's draft "Toxicological Profile for Perfluoroalkyls" to suggest that PFNA may be expected to share similar toxicity

characteristics with PFOA and PFOS, such as the level of potential toxicity and the adverse health effects that result from exposure. PFNA is currently being evaluated by EPA IRIS Program, which will provide additional detail on the adequacy of this conclusion. For other common long-chain PFAS (perfluorodecanesulfonic acid (PFDS), PFDA, perfluorononanesulfonic acid (PFNS), PFHpA, PFHxS), data is not yet available or is not conclusive as discussed under Shortlist of Additional PFAS. This data gap must be addressed before a long-chain PFAS grouping approach could be supported as part of a regulatory proposal. This is true for short-chain, replacement compounds as well, which are less studied currently.

Another potential grouping that was discussed in the proposal is to group potential PFAS based on the functional group (e.g. carboxylic acids or sulfonic acids). While toxicity assessments by EPA found that PFOA and PFNA to be closely similar with respect to toxicity, this is not observed broadly across other PFAS. This suggests that functional groups may not be a contributing factor, at least to a degree that inhibits predicting toxicity based on functional groups. PFBA toxicity has been studied by Minnesota Department of Health and estimated to differ by a factor of 200 in comparison with PFOA. [33, 34] PFBS and PFOS, for instance, are both perfluoroalkyl sulfonic acids but EPA's toxicity assessments have found the applicable reference doses for these two PFAS differ by a factor of 125. [35]

Finally, the proposal notes the possibility of grouping PFAS based on both the physicochemical and fate characteristics. The proposal provides the example of a grouping based specifically on long-chain perfluoroalkyl sulfonic acids, which would potentially include PFHxS, perfluoroheptanesulfonic acid (PFHpS), PFOS, PFNS, and PFDS. To date, there is little available scientific information to support this in regard to both occurrence data and toxicity of these compounds.

The proposal also referred to two additional grouping approaches: co-occurrence and degradation products. According to monitoring data from UCMR 3, there are not well-established co-occurrence patterns. This is likely because of the variation in physicochemical and fate characteristics between different PFAS. Each PFAS is likely to behave differently in the environment based on the specific chain-length, functional groups, and the environmental conditions. Additionally, while there is evidence to demonstrate that some PFAS degrade to shorter chain PFAS, this regulatory approach presents its own challenge. Specifically, regulating PFAS based on the degradation product would assume that the precursor and degradation product share similar toxicity characteristics. Additionally, this approach would likely neglect the actual exposure levels to both the precursor compound and degradation product.

The Agency must address outstanding data and knowledge gaps regarding PFAS of concern prior to determining a regulatory grouping approach for PFAS. UCMR 5, as well as EPA IRIS Program's assessments, are expected to address a portion of these data gaps in the future. Additionally, the ongoing research efforts by both EPA and National Institute of Health (NIH) to test 150 PFAS may provide insights into appropriate approaches for regulating PFAS based on groups. This effort is expected to generate toxicity, toxicokinetic and other types of data to help prioritize PFAS for risk assessment and further research efforts. [36] EPA should, without compromising necessary quality control and quality assurance

---

[33] Minnesota Department of Health. "PFOA and Drinking Water". May 2017. Accessed April 20, 2020.
[34] Minnesota Department of Health. "PFBA and Drinking Water". August 2017. Accessed April 20, 2020.
[35] Environmental Protection Agency. "Fact Sheet: Draft Toxicity Assessments for GenX Chemicals and PFBS." November 14, 2018. Accessed April 20, 2020.
[36] EPA. "PFAS Chemical Lists and Tiered Testing Methods Descriptions." Accessed April 8, 2020.

procedures, make this information available to external scientists for evaluation as quickly as possible, rather than waiting for EPA to complete its own analysis. Sharing this data publicly for rapid evaluation will facilitate both external validation of EPA's work and allow timely prioritization of follow-on analyses. EPA has taken the first steps in such an initiative through EPA's website. Some information is posted to EPA's CompTox Dashboard and ToxCast webpage, but Agency processes are not transparent as to when new data has been posted, data is not uploaded in a timely fashion, and the sites require considerable expertise to utilize effectively. [37, 38]

2.4.3 Individual PFAS

The regulation of PFAS on an individual basis has been the most frequently applied approach at the state level for drinking water regulations, including for PFOA and PFOS. This regulatory approach offers the most flexibility for EPA to consider available information and to evaluate the science surrounding PFAS toxicity. In the absence of science-based grouping approach, regulating PFAS on an individual basis will allow the Agency to conduct an adequate evaluation of the individual PFAS with respect to the statutory criteria required by the Safe Drinking Water Act.

2.5 Potential Monitoring Approaches

If EPA develops standards for PFOA and PFOS, EPA should adapt the Standardized Monitoring Framework for synthetic organic chemicals (SOC) to PFAS analytical methods, by using one-half the MCL as the trigger level for quarterly PFOA and PFOS monitoring.

The *Federal Register* notice presented two potential monitoring approaches for systems.

1. The Standardized Monitoring Framework for Standardized Organic Compounds. [39]
2. Require PWSs to monitor when "data shows presence of PFAS in finished drinking water and *those designated by the Primacy Agency*" [emphasis added].

The second monitoring option EPA presented would specifically adapt the Standardized Monitoring Framework for Synthetic Organic Compounds to allow state primacy agencies to require monitoring at PWSs where information indicates potential PFAS contamination, such as proximity to facilities with historical or on-going use of PFAS products.

AWWA appreciates EPA's effort to identify an approach to monitoring that would minimize the monitoring burden to reduce costs for PWSs that have other risk-reduction resource demands. However, in review of available information to date, it is not clear that the commonly specified risk-factors (such as

---

[37] EPA. "CompTox Chemical Dashboard." Accessed April 23, 2020.

[38] EPA. "Exploring ToxCast Data: Downloadable Data." May 2019. Accessed April 23, 2020.

[39] Standardized Monitor Framework for SOCs as applied to PFOA and PFOS -- This approach establishes three bins for monitoring requirements based on the levels of detection of PFOA and PFOS. The first bin would be applicable to PWSs where PFOA and PFOS are detected at levels not reliably and consistently below the MCL. These PWSs would be required to monitor on a quarterly basis, regardless of the system size. The second bin would be applicable to PWSs detecting PFOA and PFOS at levels consistently below the MCL. All PWSs in this bin would be required to monitor on an annual basis. The last bin is based on PWSs that do not detect PFOA and PFOS. Large systems (service population greater than 3,300) would be required to monitor twice every three years and small systems (service population less than 3,300) would be required to monitor only once every three years. State primacy agencies would also be able to issue waivers for monitoring.

proximity to airports or landfills) is a strong-indicator of PFAS contamination. For example, in review of targeted monitoring data in comparison with UCMR 3 data from the same states, it is not apparent that common use sites are consistently strong indicators of the extent of contamination. For instance, targeted monitoring by New Hampshire identified approximately 1% of PWSs where PFOA and PFOS exceeded the lifetime health advisory limit, which was relatively similar to the results from UCMR 3. This is likely a result of the relatively low levels of contamination that present a concern and the ability of PFAS to be transported throughout the environment at these levels.

In review of available PFAS data from several water systems with frequent monitoring programs, there is evidence that suggests that PFAS levels will not drastically vary over time. Cape Fear Public Utility Authority recently published a figure showing PFOA and PFOS concentrations throughout 2019 and generally shows very little variation. The sensitivity of analytical instrumentation to detect PFAS has improved over the past few decades. Reliably reported PFAS concentrations are much lower today and will likely to be even lower in the future, decreasing to levels indicative of ambient PFAS background concentrations. EPA should instead use a trigger level that is equivalent to one-half of the MCL instead of below the analytical method detection limit to initiate quarterly monitoring. Use of a trigger level based on one-half of the MCL would ensure adequate monitoring of drinking water for PFAS while also reducing the monitoring burden on water systems subject to low-level presence of PFAS.

2.6 Building a Consensus on PFAS Health Risk

EPA should go beyond typical practice to engage an expert panel to develop a science-based evaluation of the state of available PFAS health risk data.

There is extensive public interest as well as a broad diversity of opinion on the health effects associated with PFAS. In 2019, numerous congressional bills were introduced for consideration that focused on addressing PFAS contamination of drinking water; this effort has continued into 2020 with the passage of House Resolution 535: PFAS Action Act of 2019.[40] Given this public interest, the Agency's decision will likely be subject to significant scrutiny. Public confidence in the Agency's decisions, as well as the soundness of the risk mitigation steps required by federal and state regulations, requires charting a course through the available data in a scientifically defensible manner. EPA's typical practice in setting a maximum contaminant level goal (MCLG) will likely not be adequate for this task and will not be sufficient for addressing the Agency's other goals (such as evaluating potential regulatory group approaches). Rather, EPA should go beyond typical practice to engage an expert panel to develop a science-based evaluation of the state of available PFAS health risk data. Ideally such an effort would engage a balanced panel of internationally recognized experts. Often such panels are organized through the National Academy of Sciences, Engineering, and Medicine (NASEM). While a NASEM processes would provide objective, science-based advice, NASEM processes can be very expensive and slow. Whether this analysis is organized through NASEM or conducted by the Agency, the principle elements must include:

1. A panel that is informed of the implications of the recommendations they are offering.
2. A balanced panel with an adequate diversity of expertise including individuals with practical experience as risk managers, drinking water utility managers, and economists as

[40] U.S. Congress. "H.R. 535: PFAS Action Act of 2019." January 10, 2020.

well as pertinent areas of academic expertise in toxicology, chemical fate and transport, etc.

3. A charge to support PFAS management in drinking water in the context of other reasonably likely exposures to PFAS and opportunities to mitigate other reasonably likely routes of PFAS exposure.

4. A process that is transparent to the public and provides for public input.

The recommended standard of care for this panel is higher than that currently used by existing EPA, National Toxicology Program, and Centers for Disease Prevention and Control risk assessment processes (e.g., IRIS, Office of Science and Technology, ATSDR, etc.). AWWA recommends this additional effort in order to ensure that any resulting regulation, as well as, future policies that are developed for PFOA, PFOS, and other PFAS are based on a cohesive risk management approach across the Agency. Given the observed challenges associated with addressing PFAS broadly, this strategy will help improve understanding of PFAS generally and pave the path forward for future policies.

The EPA SDWA rulemaking process should not be influenced by individual state actions. Individual states are implementing standards for a small group of PFAS. Federal decisions are unlikely to change those state policies unless the EPA assessment sets more stringent guidelines. However, a well-constructed, independent expert panel process that weighs the available information will carry considerable weight. It will hopefully increase the possibility of regulatory consistency both within EPA and assist states that continue to contemplate state-specific standards.

2.7 Fully Using Available Statutory Authorities

It is not clear that EPA is planning to use its statutory authorities effectively to understand the PFAS that have been or are being released to the environment, or to more effectively prevent problematic PFAS from entering the nations' water supplies.

It was disappointing that EPA did not address how it would use data being collected from manufacturers under the Frank R. Lautenberg Chemical Safety for the 21st Century Act or release information collected through the Toxics Release Inventory requirements following the National Defense Authorization Act of 2020 to inform prioritization of compound characterization and toxicity testing for PFAS.[41] Such an effort could not only inform our understanding of risk from PFAS that are currently in production and thus reaching water supplies, but also allow EPA's other offices to take action to halt and remediate problematic releases.

In the EPA's PFAS Action Plan, EPA indicated that a detailed study on the industrial sources and discharges of PFAS would be completed in the future.[42] According to the EPA's Preliminary Effluent Limit Guidelines for Program Plan 14, and the PFAS Action Plan: Program Plan Update, the EPA has conducted a preliminary analysis but is constrained by a lack of an analytical method for PFAS in wastewater.[43]

---

[41] 116th Congress. "Senate Bill 1790 – National Defense Authorization Act for Fiscal Year 2020." December 20, 2019.
[42] EPA. "PFAS Action Plan." February 14, 2019. Accessed April 4, 2020.
[43] EPA. "PFAS Action Plan: Program Update." February 2020. Accessed April 23, 2020.

AWWA's comments on the Preliminary Effluent Limit Guidelines Program Plan 14 urged EPA to utilize existing authorities to track PFAS use in commercial and industrial facilities in order to identify PFAS discharges in the absence of a Clean Water Act approved analytical method. [44] AWWA's comments on other recent proposed EPA rulemakings for PFAS have emphasized the need for use of these existing authorities to further collect information about the use and discharge of PFAS at commercial and industrial facilities. [45, 46] While the EPA's PFAS Action Plan notes that the "use of certain PFAS have been discontinued", various legacy PFAS (e.g., PFOA, PFOS, PFHxS, etc) continue to be actively used according to the EPA TSCA Inventory for active chemicals. [47] Recent public comments to the Agency on the proposed "Significant New Use Rule Supplemental Proposal for Long-Chain Perfluoroalkyl Carboxylates and Perfluoroalkyl Sulfonate Chemical Substances" reflect that multiple industries continue to use legacy PFAS. [48] If EPA plans to develop drinking water regulation for PFOA and PFOS, then the Agency should utilize all available TSCA authorities to eliminate these compounds from commerce in the U.S. [49]

Moving forward, the EPA should clearly and definitively identify its next steps to address PFAS at the source. Collection of data through The Toxic Substances Control Act and the Toxics Release Inventory is necessary to characterize the use and discharge patterns of PFAS. While such data has not informed the current regulatory determination notice, it could inform future contaminant candidate lists, regulatory determinations, UCMRs, and drinking water standards.

2.8 Summary of Comments for PFAS

A positive regulatory determination for PFOA and PFOS will initiate the necessary analysis to determine if these PFAS should be regulated and at what levels. While there is interest in setting regulatory limits for additional PFAS, EPA must base its decisions on adequate data and should allow time for necessary data collection and research to be completed. Delaying action regarding additional PFAS will provide time to collect occurrence data through UCMR 5 and progress on additional PFAS health risk characterization and ongoing PFAS health risk assessments. With adequate data EPA will be able to demonstrate which PFAS (or groups of PFAS) meet the statutory criteria from the Safe Drinking Water Act. Ideally, EPA would move forward expeditiously to craft a proposed rule for PFOA and PFOS for notice and comment. EPA should consider the Standardized Monitoring Framework only, applying a trigger of one-half the MCL for returning to quarterly monitoring.

3. Negative Determinations

As part of the proposal six negative determinations were made for contaminants that were included as part of the Fourth Contaminant Candidate List. These contaminants include 1,1-Dichloroethane,

---

[44] AWWA. "Comments on Preliminary Effluent Limit Guidelines Plan 14." November 25, 2019.
[45] AWWA. "Comments on Addition of Certain Per- and Polyfluoroalkyl Substances: Community Right-To-Know Toxic Chemical Release Reporting." February 3, 2020.
[46] AWWA. "Comments on Significant New Use Rule Supplemental Proposal for Long-Chain Perfluoroalkyl Carboxylates and Perfluoroalkyl Sulfonate Chemical Substances." April 17, 2020.
[47] EPA. "TSCA Inventory, Active non-confidential portion." Accessed May 1, 2020.
[48] Regulations.gov. "Significant New Use Rule for Long-Chain Perfluoroalkyl Carboxylates and Perfluoroalkyl Sulfonates." Accessed May 1, 2020.
[49] 15 U.S. Code § 2605 (a) – Prioritization, risk evaluation, and regulation of chemical substances and mixtures. June 22, 2016.

metolachlor, acetochlor, methyl bromide, nitrobenzene, royal demolition explosive (RDX). As shown in Table 3, none of these contaminants occurs frequently at a level above the established levels of health concern. The Agency's negative determination for each of these contaminants is appropriate. Additionally, the Agency's intent to continue evaluating information related to metolachlor given the historical production and use patterns is appropriate.

Table 4: Health Reference Levels and Occurrence of Contaminants with Proposed Negative Determination

Contaminant	Health Risk Level	Occurrence Data
1,1-Dichloroethane	1,000 micrograms per liter (µg/L)	0% above 500 µg/L (UCMR 3)
Acetochlor	100 µg/L	0% above 2 µg/L (UCMR 1) 0% above 2 µg/L (UCMR 2)
Metolachlor	300 µg/L	0% above 150 µg/L (UCMR 2)
Methyl Bromide	100 µg/L	0% above 100 µg/L (UCMR 3)
Nitrobenzene	10 µg/L	0.01% above 10 µg/L (UCMR 1)
RDX	30 µg/L (non-cancer) 0.4 µg/L (cancer)	0.01% above 1 µg/L (UCMR 2)

4. Delayed Determinations

4.1 Strontium

The Agency's decision to conduct further research prior to making a determination regarding strontium is sound.

Under UCMR 3, strontium was detected in approximately 5.8% of the finished drinking water supplies from PWSs at a level above the health reference level used in UCMR 3. While strontium is present at a number of water systems removing strontium from drinking water also removes calcium. As the health effect of concern is based on strontium replacing calcium in developing bones, this co-removal complicates addressing any public health risks from strontium occurrence. The available treatment technologies also require consideration of corrosion control adjustments as well. In the *Federal Register* notice EPA indicates it is delaying a final determination for strontium to continue to research effectiveness of treatment technologies and to consult additional heath assessment.

4.2 1,4-Dioxane

The Agency's decision to conduct further research prior to making a determination regarding 1,4-dioxane is sound.

EPA has also indicated that the regulatory determination for 1,4-dioxane will be delayed. Despite various available health assessments by EPA IRIS Program, World Health Organization, and ATSDR, the Agency has noted the need to review Health Canada's finalized publication (not yet published) and to complete a new risk evaluation. This evaluation is needed in order to quantify potential additional non-cancer effects from 1,4-dioxane exposure, given that the Agency's conservative (high-end) estimate determined less than two baseline cancer cases per year. Consideration of non-cancer effects may demonstrate a greater public health risk due to 1,4-dioxane exposure. Additionally, the proposal notes that the 1,4-dioxane prevalence

is primarily in drinking water supplies in California and New York, both of which are actively pursuing regulatory action currently. At this time, a delayed determination is sound.

4.3 1,2,3-Trichloropropane

EPA should collect additional occurrence data for 1,2,3-trichloropropane using analytical methods and laboratories that can report data at a MRLs adequate to support decision-making.

As a part of UCMR 3, EPA required water systems to monitor for 1,2,3-trichloropropane with an MRL of 0.03 µg/L, which is 75 times higher than the health reference level of 0.0004 µg/L. Results from UCMR 3 suggested that an estimated 6 million people are served by a PWS with 1,2,3-trichloropropane concentration above the MRL of 0.03 µg/L. Since UCMR 3, California and New Jersey have proposed and promulgated drinking water MCLs of 0.005 µg/L and 0.03 µg/L, respectively. AWWA estimates that these MCLs may have potentially reduced national exposure to 1,2,3-trichloropropane (based on a 30 µg/L detection limit) by 50%. Given the lack of occurrence data at levels relevant for the 10^{-6} cancer risk threshold AWWA agrees with EPA's decision to delay this determination. However, AWWA recommends that the Agency take action in the future to address this knowledge gap, such as through monitoring under UCMR. UCMR 5 is expected to be proposed and finalized this year and it may be appropriate for the Agency to include 1,2,3-trichloropropane as part of this proposed rulemaking. It is important that monitoring to better understand occurrence in drinking water employ an MRL at a concentration that is adequate to support decision-making, as noted in the Association's comments in 2011. [50]

5. Manganese

EPA should collaborate with AWWA, the water system community and states to utilize available tools to manage manganese occurrence.

Although the proposal does not directly provide an update on manganese, it remains a contaminant of interest for the drinking water community. Manganese is associated both with health effect concerns and water coloration, which can play a role in reduced consumer confidence and public trust in water systems. According to the proposal, manganese did not proceed to "Phase 3 – Regulatory Determination Assessment Phase" due to research gaps for occurrence in drinking water and health assessments.

Health Canada finalized a maximum allowable concentration of 120 µg/L in June 2019. The EPA IRIS Program had planned to develop an assessment for manganese, but this has been suspended and was noted that it was not identified as a priority in April 2019. [51] Additionally while monitoring data is still being collected under UCMR 4, the preliminary data shows that approximately 2% of PWSs detected manganese above the current EPA health advisory level of 300 µg/L . [52] In review of the UCMR 4 data posted in January 2020, AWWA has estimated that approximately 44.5% of reporting PWSs detected levels above EPA's secondary standard (50 µg/L) and 16.5% detected levels above Health Canada's maximum allowable concentration of 120 µg/L. EPA's decision not to assess manganese for a regulatory

[50] AWWA. "Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems, Docket ID No. OW–2009–0090." May 2, 2011.
[51] EPA. "A Message from the IRIS Program April 2019." April 1, 2019.
[52] EPA. "The Fourth Unregulated Contaminant Monitoring Rule (UCMR 4): Data Summary, January 2020." January 2020.

determination at this time was sound, based on an incomplete dataset for occurrence. However, EPA should make appropriate management of manganese a priority. UCMR 4 data collection will be completed next year. Manganese represents not only a potential health concern but also a consumer confidence concern for water systems. EPA should begin now to collaborate with the water system community and states to utilize available tools to manage manganese occurrence while the Agency re-initiates its health risk assessment process and contemplates pursuing a primary drinking water standard.

Attachment
EPA Data Collection to Support SDWA Decision-Making on PFAS

Note that inclusion in EPA toxicity testing does not ensure decision-relevant information will be forthcoming as the analytical methods being used are exploratory and EPA does not have an established decision-making framework for use of the resulting data.

#	PFAS	CAS#	Support for Health Risk Assessment			Occurrence Assessment
			EPA Monitoring in HERO*	EPA Conducting Toxicity Testing#	NTP Research Ongoing@	Expected in UCMR5^
1	1,1,1,3,3-Pentafluorobutane	406-58-6		Yes		
2	11:1 Fluorotelomer alcohol	423-65-4		Yes		
3	1H,1H,2H-Perfluoro-1-hexene	19430-93-4		Yes		
4	1H,1H,5H-Perfluoropentanol	355-80-6		Yes		
5	1H,1H,8H,8H-Perfluoro-3,6-dioxaoctane-1,8-diol	129301-42-4		Yes		
6	1H,1H-Perfluoropentylamine	355-27-1		Yes		
7	1-Pentafluoroethylethanol	374-40-3		Yes		
8	1-Propenylperfluoropropane	355-95-3		Yes		
9	2-(N-Ethylperfluorooctanesulfona-mido) acetic acid	2991–50–6	Yes			Yes
10	2-(N-Methylperfluorooctanesulfona-mido) acetic acid	2355–31–9	Yes			Yes
11	2-(Trifluoromethoxy)ethyl trifluoromethanesulfonate	329710-76-1		Yes		
12	2,2-Difluoroethyl triflate	74427-22-8		Yes		
13	2-Amino-2H-perfluoropropane	1619-92-7		Yes		
14	2-Aminohexafluoropropan-2-ol	31253-34-6		Yes		
15	2H,2H,3H,3H-Perfluorooctanoic acid	914637–49–3	Yes	Yes		
16	2-Vinylperfluorobutane	239795-57-4		Yes		
17	3-(Perfluoro-2-butyl)propane-1,2-diol	125070-38-4		Yes		
18	3-(Perfluoroisopropyl)-2-propenoic acid	243139-64-2		Yes		
19	3-(Perfluoropropyl)propanol	679-02-7		Yes		
20	3,3-Bis(trifluoromethyl)-2-propenoic acid	1763-28-6		Yes		
21	3H-Perfluoro-2,2,4,4-tetrahydroxypentane	77953-71-0		Yes		
22	3H-Perfluoro-4-hydroxy-3-penten-2-one	1694-30-0		Yes		
23	4,8-dioxa-3H-perfluorononanoic acid	919005–14–4	Yes			Yes

#	PFAS	CAS#	Support for Health Risk Assessment			Occurrence Assessment
			EPA Monitoring in HERO*	EPA Conducting Toxicity Testing#	NTP Research Ongoing@	Expected in UCMR5^
24	4:2 Fluorotelomer alcohol	2043-47-2		Yes		
25	4:2 Fluorotelomer sulfonic acid	757124-72-4		Yes		
26	4:4 Fluorotelomer alcohol	3792-02-7		Yes		
27	4H-Perfluorobutanoic acid	679-12-9		Yes		
28	5H-Octafluoropentanoyl fluoride	813-03-6		Yes		
29	5H-Perfluoropentanal	2648-47-7		Yes		
30	6:2 Fluorotelomer alcohol	647–42–7	Yes	Yes		
31	6:2 Fluorotelomer methacrylate	2144-53-8		Yes		
32	6:2 Fluorotelomer sulfonic acid	27619–97–2	Yes			Yes
33	6:2/8:2 Fluorotelomer phosphate diester	943913–15–3	Yes			
34	6H-Perfluorohex-1-ene	1767-94-8		Yes		
35	8:2 Fluorotelomer alcohol	678–39–7	Yes	Yes	Yes	
36	8:2 Fluorotelomer sulfonic acid	39108–34–4	Yes			Yes
37	Allyl perfluoroisopropyl ether	15242-17-8		Yes		
38	Ammonium perfluorooctanoate	3825-26-1		Yes		
39	Bis(1H,1H-perfluoropropyl)amine	883498-76-8		Yes		
40	Bis[2-(perfluorohexyl)ethyl] phosphate	57677–95–9	Yes			
41	Bis[2-(perfluorooctyl)ethyl] phosphate	678–41–1	Yes			
42	Difluoromethyl 1H,1H-perfluoropropyl	56860-81-2		Yes		
43	Dodecafluoroheptanol	335-99-9		Yes		
44	Ethyl perfluorobutyl ether	163702-05-4		Yes		
45	Flurothyl	333-36-8		Yes		
46	Heptafluorobutanol	375-01-9		Yes		
47	Heptafluorobutyramide	662-50-0		Yes		
48	Heptafluoropropyl trifluorovinyl ether	1623-05-8		Yes		
49	Hexafluoroamylene glycol	376-90-9		Yes		
50	HFPO dimer acid	13252–13–6	Yes	Yes		Yes
51	HFPO dimer acid ammonium salt	62037–80–3	Yes			
52	Methyl 2H,2H,3H,3H-perfluoroheptanoate	132424-36-3		Yes		

#	PFAS	CAS#	Support for Health Risk Assessment			Occurrence Assessment
			EPA Monitoring in HERO*	EPA Conducting Toxicity Testing#	NTP Research Ongoing@	Expected in UCMR5^
53	Methyl heptafluorobutyrate	356-24-1		Yes		
54	Methyl perfluoroethyl ketone	374-41-4		Yes		
55	Methyl perfluorohexanoate	424-18-0		Yes		
56	Mono[2-(perfluorohexyl)ethyl] phosphate	57678–01–0	Yes			
57	Mono[2-(perfluorooctyl)ethyl] phosphate	57678–03–2	Yes			
58	N-Ethyl-N-(2-hydroxyethyl)perfluoro-octanesulfonamide	1691-99-2		Yes		
59	N-Ethylperfluorooctanesulfonamide	4151-50-2		Yes		
60	N-Methylperfluorooctanesulfonamide	31506-32-8		Yes		
61	Nonafluoropentanamide	13485-61-5		Yes		
62	Octafluoroadipamide	355-66-8		Yes		
63	Pentafluoropropanoic anhydride	356-42-3		Yes		
64	Perfluoro(4-methoxybutanoic) acid	863090-89-5		Yes		
65	Perfluoro-3,6,9-trioxatridecanoic acid	330562-41-9		Yes		
66	Perfluoro-3,6-dioxaheptanoic acid	151772-58-6		Yes		
67	Perfluoro-3,6-dioxaoctane-1,8-dioic acid	55621-21-1		Yes		
68	Perfluorobutanesulfonic acid	375–73–5	Yes		Yes	Yes
69	Perfluorobutanesulfonic acid	375-73-5		Yes		
70	Perfluorobutanesulfonyl fluoride	375-72-4		Yes		
71	Perfluorobutanoic acid	375–22–4	Yes	Yes		Yes
72	Perfluorobutyraldehyde	375-02-0		Yes		
73	Perfluorodecanesulfonic acid	335–77–3	Yes			
74	Perfluorodecanoic acid	335–76–2	Yes		Yes	Yes
75	Perfluorododecanoic acid	307–55–1	Yes			Yes
76	Perfluoroglutaryl difluoride	678-78-4		Yes		
77	Perfluoroheptanesulfonic acid	375–92–8	Yes			Yes
78	Perfluoroheptanoic acid	375–85–9	Yes			Yes
79	Perfluorohexanesulfonic acid	355–46–4	Yes			Yes
80	Perfluorohexanoic acid	307–24–4	Yes		Yes	Yes
81	Perfluorohexanoic acid	307-24-4		Yes		

#	PFAS	CAS#	Support for Health Risk Assessment			Occurrence Assessment
			EPA Monitoring in HERO*	EPA Conducting Toxicity Testing#	NTP Research Ongoing@	Expected in UCMR5^
82	Perfluoroisobutyl methyl ether	163702-08-7		Yes		
83	Perfluorononanesulfonic acid	68259–12–1	Yes			
84	Perfluorononanoic acid	375–95–1	Yes		Yes	Yes
85	Perfluorononanoic acid	375-95-1		Yes		
86	Perfluorooctanesulfonamide	754–91–6	Yes	Yes	Yes	
87	Perfluorooctanesulfonamido ammonium iodide	1652-63-7		Yes		
88	Perfluorooctanesulfonic acid	1763–23–1	Yes	Yes	Yes	Yes
89	Perfluorooctanoic acid	335–67–1	Yes	Yes	Yes	Yes
90	Perfluoropentanamide	355-81-7		Yes		
91	Perfluoropentanesulfonic acid	2706–91–4	Yes			Yes
92	Perfluoropentanoic acid	2706–90–3	Yes			Yes
93	Perfluorotetradecanoic acid	376–06–7	Yes			Yes
94	Perfluoroundecanoic acid	2058–94–8	Yes			Yes
95	Potassium perfluorobutanesulfonate	29420-49-3		Yes	Yes	
96	Potassium perfluorohexanesulfonate	3871-99-6		Yes	Yes	
97	Potassium perfluorooctanesulfonate	2795-39-3		Yes		
98	Sevoflurane	28523-86-6		Yes		
99	tris(Trifluoroethoxy)methane	58244-27-2		Yes		

*Note: * List provided by EPA (85 Federal Register 14121); # List referenced by EPA (88 Federal Register 14121) ^ Analytes is EPA 537.1 and 533 (monitoring is required by the National Defense Authorization Act of 2020) @ NTP PFAS Research Overview (accessed April 21, 2020)*