
Final Report

of the

Small Business Advocacy Review Panel on

EPA's Planned Proposed Rule

Per- and Polyfluoroalkyl Substances National Primary
Drinking Water Regulation

August 1, 2022

Table of Contents

1. INTRODUCTION.....	4
2. BACKGROUND AND DESCRIPTION OF RULEMAKING	5
2.1 Regulatory History.....	5
2.2 Description of Rulemaking and its and Scope	7
2.3 Overview of Regulatory Options under Consideration.....	8
2.4 Related Federal Rules	11
3. APPLICABLE SMALL ENTITY DEFINITIONS.....	11
4. LIST OF SMALL ENTITY REPRESENTATIVES	12
5. SUMMARY OF SMALL ENTITY OUTREACH AND OTHER OUTREACH	13
6. SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES	15
6.1 Number and Types of Entities Affected	15
6.2 Related Federal Rules	15
6.3 Potential Reporting, Recordkeeping, and Compliance Requirements.....	15
6.4 Regulatory Flexibility Alternatives	16
6.4.1 Monitoring Considerations	16
6.4.2 Treatment and Disposal Considerations.....	17
6.4.3 Public Notification Considerations	19
6.4.4 Health Effects and Regulatory Standards.....	19
6.4.5 Estimated Costs and Resource Considerations	20
7. PANEL FINDINGS	21
7.1 Number and Types of Entities Affected	21
7.2 Related Federal Rules	22
7.3 Potential Reporting, Recordkeeping, and Compliance Requirements.....	22
7.4 Regulatory Flexibility Alternatives	22
7.4.1 Monitoring	22
7.4.2 Treatment and Disposal.....	24
7.4.3 Public Notification.....	26
7.4.4 Health Effects and Regulatory Standards.....	26
7.4.5 Estimated Costs and Resource Considerations	26
APPENDIX A: Materials shared with Small Entity Representatives	28
Appendix A1: Materials EPA Shared with Potential Small Entity Representatives for the Pre-Panel Outreach Meeting, February 15, 2022	28

Appendix A2: Materials EPA Shared with Small Entity Representatives for the Panel Outreach Meeting, June 7, 2022 28

APPENDIX B: Written Comments Submitted by Small Entity Representatives 29

Appendix B1: Written Comments Submitted by Potential Small Entity Representatives following the Pre-Panel Outreach Meeting on February 15, 2022 29

Appendix B2: Written Comments Submitted by Small Entity Representatives following the Panel Outreach Meeting on June 7, 2022..... 29

1. INTRODUCTION

This report is presented by the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened to review the planned proposed rulemaking on the Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR). Under section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Panel is required to be convened prior to publication of the initial regulatory flexibility analysis (IRFA) that an agency may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel consists of the Director of the Standards and Risk Management Division of the EPA Office of Ground Water and Drinking Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration.

This report includes the following:

- Background information on the proposed rule being developed;
- Information on the types of small entities that may be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities; and
- A summary of the comments that have been received to date from those representatives.

Section 609(b) of the RFA directs the Panel to consult with and report on the comments of small entity representatives (SERs) and make findings on issues related to elements of an IRFA under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. This analysis shall discuss any significant alternatives such as:
 - the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
 - the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
 - the use of performance rather than design standards; and
 - an exemption from coverage of the rule, or any part thereof, for such small entities.

Once completed, the Panel Report is provided to the agency issuing the proposed rule and is included in the rulemaking record. The agency is to consider the Panel's findings when completing the draft of the proposed rule. In light of the Panel Report, and where appropriate, the agency is also to consider whether changes are needed to the IRFA for the proposed rule or the decision on whether an IRFA is required.

The Panel's findings and discussion will be based on the information available at the time the final Panel Report is drafted. EPA will continue to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

Any options identified by the Panel for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, and consistent with the Safe Drinking Water Act (SDWA) and its amendments.

2. BACKGROUND AND DESCRIPTION OF RULEMAKING

2.1 Regulatory History

The SDWA is the core statute addressing drinking water at the Federal level. Under SDWA, EPA sets public health goals and enforceable standards for drinking water quality. As a part of the drinking water regulatory development process, SDWA, as amended in 1996, requires EPA to determine whether to regulate at least five contaminants every five years; this is known as the Regulatory Determination Process. The EPA Administrator shall publish a Maximum Contaminant Level Goal (MCLG) and promulgate an NPDWR for a contaminant if the Administrator determines after considering public comments that the following three statutory criteria are met: (1) the contaminant may have an adverse effect on the health of persons, (2) the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern, and (3) regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs. Based on these three statutory criteria, on March 3, 2021, EPA published a [Final Regulatory Determination](#) to regulate perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in drinking water, as well as further evaluate additional PFAS chemicals and consider groups of PFAS for potential regulatory actions as supported by use of the best available science in accordance with SDWA. EPA intends to issue a proposed regulation in late 2022 and a final regulation in late 2023 after considering public comments on the proposal.

PFOA and PFOS may have adverse effects on the health of persons. In 2016, EPA published health assessments for PFOA and PFOS based on the agency's evaluation of the peer reviewed science available at that time. The lifetime Health Advisory (HA) of 70 parts per trillion (ppt) was used as the health reference level (HRL) for the Final Regulatory Determination and reflected concentrations of PFOA and PFOS in drinking water at which adverse health effects were not anticipated to occur over a lifetime. These 2016 health assessment studies, and additional research by the National Toxicology Program in the Department of Health and Human Services, reported that oral exposure to PFAS, including PFOA and/or PFOS, may result in adverse health effects, including developmental effects to fetuses and infants during pregnancy and lactation (e.g., low birth weight), cancer (e.g., kidney), liver effects (e.g., tissue damage), immune effects (e.g., antibody production and immunity), and other effects (e.g., cholesterol changes).

While not directly related to EPA's development of the proposed PFAS NPDWR, in June 2022, based on the agency's evaluation of the best-available peer reviewed science, EPA published interim updated lifetime HAs for PFOA and PFOS, as well as new lifetime HAs for two other PFAS, hexafluoropropylene oxide dimer acid (HFPO-DA) (GenX chemicals) and perfluorobutanesulfonic acid (PFBS). The interim updated lifetime HA values for PFOA and PFOS are 0.004 ppt and 0.02 ppt, respectively, and the final lifetime HA values are 10 ppt and 2000 ppt for GenX and PFBS, respectively. Based on the new data and EPA draft analyses, the levels of which negative health effects could occur are much lower than previously understood when EPA developed the 2016 HAs for PFOA and PFOS. Human epidemiology studies have found associations between PFOA and/or PFOS exposure and effects on the immune system, cardiovascular system, human development (e.g., decreased birth weight), and cancer. EPA notes that the underlying science that EPA used to develop the interim PFOA and PFOS HAs is currently undergoing Science Advisory Board (SAB) review, and therefore, these interim health advisories are subject to change. The final HAs for GenX chemicals and PFBS are based on animal toxicity studies. GenX chemicals have been linked to health effects on the liver, kidneys, immune system, developmental effects, and cancer. PFBS has shown health effects on the thyroid, reproductive organs and tissues, developing fetuses, and kidneys. These HAs utilized final toxicity assessments for GenX chemicals and PFBS that serve as the basis of the toxicity information used to derive the HA values.

EPA is currently developing scientifically rigorous toxicity assessments for five additional PFAS chemicals. The chemicals currently undergoing assessment include PFBA, PFHxS, PFHxA, PFNA, PFDA, all of which are currently scheduled to be completed by 2023.

PFOA and PFOS occur with a frequency and at levels of public health concern at PWSs based on the agency's evaluation of available occurrence information. In accordance with SDWA 1412(b)(1)(B)(ii)(II), EPA determined monitoring data from the third Unregulated Contaminant Monitoring Rule (UCMR 3) are the best available occurrence information for PFOA and PFOS. UCMR 3 monitoring occurred between 2013 and 2015 and are currently the only nationally representative finished water dataset for PFOA and PFOS. Under UCMR 3, 36,972 samples from 4,920 PWSs, including all PWSs serving more than 10,000 people and 800 representative PWSs serving 10,000 or fewer people, were analyzed for PFOA and PFOS, as well as four other PFAS (PFBS, perfluoroheptanoic acid (PFHpA), perfluorononanoic acid (PFNA), and perfluorohexanesulfonic (PFHxS)). The minimum reporting level (MRL) for PFOA was 20 ppt and the MRL for PFOS was 40 ppt. A total of 1.37% of samples or 3.29% of systems serving approximately 14.3 million people had reported detections (greater than or equal to the MRL) of at least one of the two compounds. Further broken down, a total of 0.79% of samples or 1.93% of systems had reported detections of PFOS, and a total of 1.03% of samples or 2.38% of systems had reported detections of PFOA. Table 1 of the Final Regulatory Determination summarizes health and occurrence information and the final determination to regulate PFOA and PFOS. For the other four PFAS monitored under the UCMR 3, the following were the percentages of samples with reported values above the MRL: PFHpA (0.64%), PFHxS (0.56%), PFNA (0.05%), and PFBS (0.05%).

As discussed in the Final Regulatory Determination, data from more recent state monitoring demonstrate occurrence in multiple geographic locations consistent with UCMR 3 monitoring. The more recent data is publicly available from over 20 state monitoring programs and shows continued occurrence of PFOA and PFOS in support of the agency's final determination that PFOA and PFOS occur with a frequency and at levels of public health concern in finished drinking water in the United States. These more recent data were collected using improved analytical methods that have lower reporting limits and include results for PFOA, PFOS, and other PFAS at lower concentrations than measured under the UCMR 3, as well as for more PFAS than were included in the UCMR 3, including, but not limited to, GenX chemicals, perfluorohexanoic acid (PFHxA), perfluorodecanoic acid (PFDA), and perfluorobutanoic acid (PFBA). Moreover, these data show some of these additional PFAS occur frequently in some states.

As a part of the development of the proposed NPDWR, EPA has found through analysis of both UCMR 3 and state data that PFAS frequently co-occur. Within UCMR 3, if PFOA was detected in a sample, 60% of the time another PFAS co-occurred, including PFOS, PFBS, PFNA, PFHxS, and PFHpA. If PFOS was detected in a sample, 73% of the time another PFAS co-occurred, including PFOA, PFBS, PFNA, PFHxS, and PFHpA. Common combinations of PFAS co-occurring in UCMR 3 samples included: PFOS/PFOA/PFHxS/PFHpA, PFOA/PFHpA, PFOS/PFHxS, and PFOA/PFOS. Further, within UCMR 3, 27% of the time there were three or more PFAS present when any PFAS were detected in a sample, and 15.2% of samples with a PFAS reported had one or more PFAS and no PFOA or PFOS (8% PFHpA, 4.5% PFHxS, 1.8% PFNA, 0.5% PFBS, 0.2% PFHxS/PFHpA, and 0.2% PFNA/PFHpA).

In October 2021, EPA released the [PFAS Strategic Roadmap](#) laying out an overall approach to addressing PFAS. Establishing an NPDWR for PFOA and PFOS is a key action in the Roadmap. As discussed in the Roadmap, EPA intends to issue a proposed regulation in late 2022 and a final regulation in late 2023 after considering public comments on the proposal. Another key action under the PFAS Roadmap is nationwide monitoring for 29 PFAS, including PFOA and PFOS, in drinking water under the fifth Unregulated Contaminant Monitoring Rule (UMCR 5). Under SDWA, EPA published the [final UCMR 5](#) in December 2021, and monitoring is scheduled to occur between 2023 through 2025. Consistent with the PFAS Roadmap, UCMR 5 will provide new data that will improve EPA's understanding of the frequency and at what levels that these 29 PFAS are found in the nation's PWSs. This monitoring data could satisfy initial monitoring requirements associated with the proposed PFAS NPDWR which is described in more detail in section 2.3.

2.2 Description of Rulemaking and its and Scope

EPA is developing a proposed NPDWR for PFOS and PFOA, and potentially other PFAS, in accordance with the requirements of SDWA and other applicable statutes. NPDWRs include legally enforceable maximum contaminant levels (MCLs) and/or treatment technique requirements that apply to PWSs. MCLs and treatment techniques are established to protect public health by limiting the levels of contaminants in drinking water to the extent feasible.

In developing an NPDWR, EPA determines the MCLG, the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. MCLGs are non-enforceable public health goals. MCLGs consider only public health and not the limits of detection and treatment technology effectiveness. Therefore, they sometimes are set at levels which water systems cannot meet because of technological limitations.

Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is an MCL. The MCL is the maximum level allowed of a contaminant in water which is delivered to any user of a PWS. EPA must examine technologies that have been demonstrated in the field to remove the contaminants. EPA must set the MCL as close as feasible to the MCLG taking costs and benefits into consideration. EPA may establish an MCL at a level other than the feasible level if the technology, treatment techniques, and other means used to determine the feasible level would result in an increase in health risks from drinking water by increasing the concentration of other contaminants or by interfering with the efficacy of drinking water treatment techniques or processes used to comply with other NPDWRs. When EPA finds it is not economically or technologically feasible to ascertain the level of the contaminant, EPA sets a treatment technique rather than an MCL. A treatment technique is an enforceable procedure or level of technological performance which PWSs must follow to ensure control of a contaminant. EPA is considering practical monitoring options and treatment technology feasibility to control for PFAS as a part of MCL and/or treatment technique requirements.

As discussed in section 2.1, EPA's Final Regulatory Determination outlined avenues that the agency is considering to further evaluate additional PFAS chemicals, other than PFOA and PFOS, and consider groups of PFAS as supported by use of the best available science. Additionally, as part of EPA's PFAS Strategic Roadmap, EPA reaffirmed its commitment to evaluate additional PFAS and consider regulatory actions to address additional PFAS or groups of PFAS as it develops the NPDWR. EPA is currently evaluating additional information related to other individual PFAS and groups or classes of PFAS, including new monitoring and occurrence data, ongoing toxicity work, and guideline development by other federal agencies, state governments, international organizations, industry groups, and other stakeholders. While EPA considers whether to include additional PFAS as part of this proposed regulation, the agency will consider several factors, including whether the same treatment approaches co-remove certain PFAS contaminants and how different PFAS are anticipated to be removed as part of the treatment process (see section 2.3), the likelihood that the PFAS co-occur, the similarity of health effects and chemical structures, the environmental persistence characteristics, and the availability of accepted and approved analytical methods or indicators with comparable costs to those currently identified by EPA to evaluate PFAS removal from drinking water, among other considerations. Moreover, Table 1 in section 3 provides a description of the universe of active "small" PWSs subject to the proposed NPDWR. EPA notes that while the universe of small PWSs subject to the proposed rule is not expected to change irrespective of which PFAS EPA regulates as a part of this action, the number of these small PWSs which may be triggered into certain actions (e.g., treatment) may change depending on the regulated PFAS. Each of the issues and options discussed below in section 2.3 inform EPA's deliberations and development of a proposed PFAS drinking water regulation for PFOA, PFOS, and potentially other PFAS.

2.3 Overview of Regulatory Options under Consideration

Through agency review and stakeholder input, the agency is considering a range of regulatory options that would also provide the most protective impact. The following is an overview of potential regulatory options currently being considered and evaluated by EPA and is not final at this time.

Treatment and Disposal

Small systems that exceed the drinking water standard will need to select a treatment, nontreatment option(s), or a combination to bring their water into compliance. Potential compliance technologies are those that have been demonstrated in the field (and not solely under laboratory conditions) for efficacy in reducing levels of the contaminant. EPA has identified activated carbon, ion exchange (IX), nanofiltration (NF), and reverse osmosis (RO) as technologies that have been demonstrated in the field to reduce levels of PFOS and PFOA in drinking water. These technologies also provide benefits for controlling disinfection byproducts (DBPs) and synthetic organic pollutants. EPA has externally peer-reviewed [work breakdown structure \(WBS\) cost models](#) that are updated annually to efficiently capture changes in labor, construction, and commodities costs, as well as other documentation to assist systems wishing to use the identified technologies.

Based on their structures, PFAS share some similar physical and chemical characteristics; this allows for certain PFAS to be grouped according to known or anticipated behavior. As a result of their inherent nature, treatment processes which work to remove one compound within a classification group will generally work to co-remove most other compounds within the group. Additionally, water quality considerations including total organic carbon, as well as competing ions, will result in greater treatment variation more than the specific suite of PFAS targeted for treatment (e.g., there is more intra-PFAS treatment differences than inter-PFAS treatment differences in treatment) (McCleaf et al., 2017; Water Research Foundation Project 4322; Buck et al., 2011).

EPA is considering the technologies identified above including their PFAS removal effectiveness and potential unintended consequences if not properly managed and operated. As a part of this consideration, EPA is evaluating regulating PFAS that are all able to be removed by the previously identified treatment technologies which also remove PFOA and PFOS. If a given PFAS or subclass of PFAS were to require a separate or different treatment technology compared to what is being considered for the removal of PFOA and PFOS, EPA anticipates that the agency would evaluate those PFAS under a future regulatory action and would convene a separate SBAR Panel if it expects that such action would have a significant impact on a substantial number of small entities.

A non-treatment consideration for controlling PFAS includes switching source waters to meet goals. EPA is considering other non-treatment alternatives or measures that could provide options specifically for small systems.

Potential treatment techniques options are being explored by EPA based on available technologies. EPA is evaluating potential treatment technique options that may be required as a part of the proposed rule regulatory standards. Example treatment technique options include specifying operating requirements for activated carbon or ion exchange resin systems.

The SDWA requires that EPA identify small system compliance technologies (SSCTs). A technology must be both effective and affordable to be designated as an SSCT. The SDWA specifies three small system sizes that it must consider for SSCTs: systems serving 25 to 500 customers, 501 to 3,300, and 3,300 to 10,000. EPA determines if there are any affordable compliance technologies for a given NPDWR by comparing the estimated household costs to national-level affordability criteria based on household income. If EPA does not identify an SSCT for one or more categories of small systems, the agency determines if there are variance technologies that are affordable and “protective of public health” even though it does not achieve compliance with the standard. Furthermore, if EPA determines there are no SSCTs for a particular category of small systems and identifies variance technologies when promulgating a regulation, the SDWA authorizes primacy agencies to determine on a case-by-case basis if they will

grant small system variances which requires those systems to install and maintain a variance technology. EPA is currently evaluating the potential for centralized granular activated carbon (GAC), IX, and RO to meet the SSCT designation criteria of being both effective and affordable. EPA is also considering whether packaged or modular system point-of-entry (POE) or point-of-use (POU) treatment units, which incorporate the compliance technologies previously described, may be designated as SSCTs and may be more cost effective among very small systems than centralized treatment. A POU treatment device is defined under 40 CFR 141.2 as a treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that tap. As required under SDWA, POU and POE units must be owned, controlled, and maintained by the PWS or by a contractor hired by the PWS to ensure proper operation and maintenance of the devices and compliance with regulatory standards. Therefore, water systems would need to ensure they could properly install and maintain these devices in locations where they are utilized for compliance purposes. POU units must also be certified by third parties for contaminant removal effectiveness.

As a part of the proposed PFAS NPDWR, EPA is considering how water systems will address drinking water treatment residuals that contain PFAS. EPA has prioritized research on PFAS disposal options in different environmental media and best management practices in this context. This research includes evaluating single use disposal options as well as reactivation potential of activated carbon and IX media, concentrate disposal for NF and RO, and the uncertainties associated with each residual management option.

Further, EPA is evaluating the actions that water systems must take to dispose of treatment residuals that contain PFAS. EPA recognizes that actions under statutes other than the SDWA, such as the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA), may have direct or indirect implications for drinking water treatment facilities and may influence the residual management options available to them, as well as treatment and disposal costs. EPA will consider the costs associated with management of drinking water treatment residuals and in the Health Risk Reduction and Cost Analysis (HRRCA) for the proposed rulemaking as required by SDWA. Additionally, EPA is currently evaluating data on the costs associated with potential management of residuals as hazardous waste. More information on the actions under other statutes is described in section 2.4.

Monitoring and Reporting

A PFAS NPDWR may require PWSs to conduct monitoring to determine the level of PFAS in their drinking water. EPA currently has approved analytical methods, Methods [533](#) and [537.1](#), to measure for PFAS in drinking water. Using both methods, a total of 29 unique PFAS can be measured in drinking water. These 29 PFAS will be monitored under the UCMR 5 as described in Section 2.1.

EPA is evaluating requirements for PWSs to conduct initial water quality monitoring at every entry point to their distribution system to determine future compliance monitoring requirements. Monitoring requirements may be dependent on system size and drinking water source (e.g., groundwater or surface water). Multiple options for baseline and compliance monitoring are being considered, with the goal of protecting public health while reducing costs to water systems. Baseline monitoring data are expected to be used in determining the required frequency of sampling for rule compliance. Possible options for establishing a system's baseline concentration may include:

- Two or four samples collected over a period of one year, possibly dependent on system size, or
- Use of recent, previously acquired data such as that obtained during participation in the Unregulated Contaminant Monitoring Rule (federal) or state-level drinking water occurrence data collection programs. This option would only apply to those PWSs that participate in such programs.

EPA notes that previously acquired PFAS drinking water occurrence data from PFAS drinking water data collection programs would need to meet specific data quality assurance criteria and requirements (e.g., analyzed by an EPA-approved analytical method for drinking water). EPA is considering what these quality assurance requirements would include if these data are utilized.

EPA is evaluating options for systems to demonstrate compliance with a potential PFAS NPDWR. One option is monitoring at a schedule determined by the Standardized Monitoring Framework (SMF), which is outlined in the Chemical Contaminant Phase II/V Rule.¹ The SMF consists of a 9-year compliance cycle divided into 3-year compliance periods. Under the SMF, systems are categorized by whether there is a detectable concentration of the contaminant present in their system. If the contaminant is present, a further determination is made as to whether the system is reliably and consistently below the MCL. In the context of synthetic organic contaminants (SOCs) such as PFAS, if the system has a detectable concentration and is reliably and consistently below the MCL, systems are required to monitor annually. If the system is not reliably and consistently below the MCL, then quarterly monitoring is required. For systems below the detection limit of the regulated SOC, if the population served is greater than 3,300, then two samples must be taken during every three-year period. If the population served is less than or equal to 3,300, then one sample per three-year period must be collected and analyzed.

Some systems may meet primacy agency criteria for a monitoring waiver, based on a vulnerability assessment. Under the SMF for SOCs, if granted, a waiver would completely remove the requirements for compliance monitoring as long as the waiver is maintained. Systems may be eligible for monitoring waivers if justified by a vulnerability assessment which establishes that:

- The PWS can prove that the contaminant has not been used in the area, or
- The PWS can prove it is not susceptible to contamination from that contaminant.

Under the SMF, vulnerability assessments need to be updated every three years in order to maintain waivers.

If EPA proposes a PFAS NPDWR based on MCL(s) for specific chemicals, compliance monitoring requirements may follow or be adapted from the SMF as previously described. Additional options EPA is evaluating that may further reduce compliance costs for small systems include the possibility of setting trigger level(s), which are generally set at the detection limit under the SMF, to a higher concentration than the detection limit. This may reduce the frequency of required monitoring for some systems with concentrations above the detection limit. If the PFAS rule involves a treatment technique rather than one or more MCLs, other monitoring schedules may be considered.

An additional compliance monitoring option that EPA is considering provides for systems with multiple entry points to consider analyzing composite samples to potentially reduce analytical costs, in that a single analysis may be able to establish a below-detection-limit concentration across multiple entry points. Under such a provision, if a detectable concentration is identified, samples at each entry point would need to be analyzed individually to determine specific concentrations.

Public Notification

Small water systems may be required to issue public notification of a violation to customers at risk of elevated levels of PFAS in drinking water if they exceed the regulatory standards. The Public Notification Rule ensures consumers will know if there is a problem with their drinking water (65 FR 25982, May 4, 2000). There are three potential tiers of public notification. Tier 1 involves an immediate notice where there is the potential for human health to be immediately impacted. Water suppliers have 24 hours to notify people who may be drinking the water about the situation. Tier 2 involves notice as soon as possible. When the levels of a contaminant exceed EPA standards or have not been treated properly, but that do not pose an immediate risk to human health, the water system must notify its customers as soon as possible, but within 30 days of the violation. Tier 3 involves an annual notice. When water systems violate a drinking water standard that does not have direct impact on public health, the water supplier has up to a year to provide notice to its customers. EPA is considering which tier of public notification will be required for the PFAS NPDWR.

¹ <https://www.epa.gov/dwreginfo/chemical-contaminant-rules-compliance-primacy-agencies-state-and-tribal-agencies> and https://www.epa.gov/sites/default/files/2020-05/documents/smf_2020_final_508.pdf

Small systems conducting monitoring may also be required to include PFAS monitoring results in their annual Consumer Confidence Reports (CCR). The CCR Rule requires community water systems to prepare and provide their customers annual CCR on the quality of the water delivered by systems (63 FR 44512, August 19, 1998). The annual water quality report summarizes information regarding source water, detected contaminants, compliance, and educational information. EPA is assessing what information should be included in CCRs regarding PFAS in drinking water.

2.4 Related Federal Rules

There are NPDWRs for over 90 contaminants and when developing drinking water regulations, the agency factors in the water quality impacts of compliance with a new regulation on the system's compliance with existing drinking water regulations. EPA will continue to consider and evaluate how water systems will need to manage simultaneous compliance with the PFAS NPDWR requirements and other EPA drinking water regulations. Further, while the proposed PFAS NPDWR is not anticipated to duplicate, overlap, or conflict with any other federal rules, EPA notes that monitoring under the UCMR 5 discussed above in sections 2.1 and 2.3 may also support monitoring requirements associated with the proposed PFAS NPDWR.

EPA is also addressing PFAS through several of its statutory authorities other than SDWA, including the CERCLA, RCRA, Toxic Substances Control Act (TSCA), Clean Water Act, Clean Air Act, and Emergency Planning and Community Right-to-Know Act. For example, as part of the [EPA PFAS Strategic Roadmap](#), in Summer of 2022, EPA anticipates proposing to designate certain PFAS as CERCLA hazardous substances to require reporting of PFOA and PFOS releases, enhance the availability of data, and ensure agencies can recover cleanup costs. As noted in section 2.3, EPA recognizes that future actions under some of these statutes may have direct or indirect impacts for drinking water treatment facilities and could impact the compliance requirements related to disposal of PFAS treatment residuals that are generated by water systems. EPA has also committed to restrict PFAS discharges from industrial sources through a multi-faceted Effluent Limitations Guidelines program to proactively establish national technology-based regulatory limits. Additionally, EPA is seeking to proactively use National Pollutant Discharge Elimination System (NPDES) authorities to reduce discharges of PFAS at the source and obtain more comprehensive information through monitoring on the sources of PFAS discharges and quantity of PFAS discharged by these sources. EPA notes that these actions may prevent or reduce PFAS entering into sources of drinking water in the future. More information on these statutory authorities and PFAS-related EPA activities can be found in the Roadmap.

3. APPLICABLE SMALL ENTITY DEFINITIONS

The Regulatory Flexibility Act (RFA) defines small entities as including “small businesses,” “small governments,” and “small organizations” (5 USC 601). The RFA references the definition of “small business” found in the Small Business Act, which authorizes the Small Business Administration to further define “small business” by regulation. The SBA definitions of small business by size standards using the North American Industry Classification System (NAICS) can be found at 13 CFR 121.201.

The RFA also authorizes an agency to adopt an alternative definition of “small business” “where appropriate to the activities of the agency” after consultation with the Small Business Administration and opportunity for public comment. For purposes of assessing impacts to small entities, EPA considers small entities to be PWSs serving 10,000 or fewer persons. EPA proposed using this alternative definition, as required by the RFA, in the Federal Register (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration Office of Advocacy, and finalized the alternative definition in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition would be applied to future drinking water regulations. Additionally, SDWA Section 1412(b)(4)(E) defines small systems as those serving 10,000 or fewer for the purpose of identifying SSCTs.

An NPDWR establishes requirements applicable to PWSs. A PWS provides water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serves an average of at least 25 people for at least 60 days a year. A PWS may be publicly or privately owned. EPA defines three types of PWSs:

- Community Water System (CWS): A PWS that supplies water to the same population year-round.
- Non-Transient Non-Community Water System (NTNCWS): A PWS that regularly supplies water to at least 25 of the same people at least six months per year. Some examples are schools, factories, office buildings, and hospitals which have their own water systems.
- Transient Non-Community Water System (TNCWS): A PWS that provides water in a place such as a gas station or campground where people do not remain for long periods of time.

EPA does not anticipate that the PFAS NPDWR will affect transient non-community water systems as those systems will likely not be subject to the rule requirements. Table 1 provides the number CWSs and NTNCWSs, for the size categories of 25-500, 501-3,300, and 3,301-10,000 people served. The percentage of the total number of CWSs or NTNCWSs that each of these categories comprise is also provided. As shown, 91% of CWSs are small and 99.9% of NTNCWSs are small. The small CWSs serve 17% of the total population. A proposed PFAS NPDWR would apply to PWSs subject to the rule requirements including many PWSs serving fewer than 10,000 people.

Table 1: Universe of Active “Small” Public Water Systems Subject to the Proposed NPDWR

The Universe of Active "Small" PWSs Subject to the Proposed NPDWR						
System size (number of people served)	CWS Public	CWS Private	NTNCWS Public	NTNCWS Private	CWS Number and % of all CWSs	NTNCWS Number and % of all NTNCWSs
3,301-10,000	4508	518	70	92	5026 (10%)	162 (0.9%)
501-3,300	10480	2817	1287	1162	13297 (27%)	2449 (14%)
25-500	7817	18624	3690	11061	26441 (54%)	14751 (85%)
Total	22805	21959	5047	12315	44764 (91%)	17362 (99.9%)
Source: The federal version of EPA's Safe Drinking Water Act Information System (SDWIS/Fed, current through December 31, 2020).						
Notes: Small CWSs comprise 91% of the inventory of CWSs (49,154) and NTNCWSs comprise 99.9% of the inventory of NTNCWSs (17,401). The small CWSs serve 17% of the total population.						

4. LIST OF SMALL ENTITY REPRESENTATIVES

EPA consulted with Advocacy to develop the list of small entity representatives (SERs) in Table 2. EPA issued a press release inviting self-nominations by affected small entities to serve as potential SERs. The press release directed interested small entities to a web page where they could indicate their interest in serving as a SER. EPA launched the website October 21, 2021, and accepted self-nominations until November 15, 2021. In addition, EPA supplemented the self-nominations by reaching out directly to many organizations and individuals that represent and work with small PWSs to ensure they were aware of the opportunity to serve as SERs, including those small PWSs that had PFAS detections under UCMR 3, as well as incorporated SER nomination recommendations from Advocacy. EPA sent Advocacy a Formal Notification with the suggested list of potential SERs on November 29, 2021, and Advocacy responded on December 9, 2021. EPA sent Advocacy a Panel Convening notice on May 24, 2022, including an updated list of SERs, and Advocacy responded on June 9, 2022.

Table 2: List of Small Entity Representatives

Name	Affiliation
Tiff Bradshaw	Maryland Environmental Service
Donna Barlow Casey	City of Montpelier, Vermont
Laura Colangelo	Texas Private Schools Association
Lucas Jordan Combs	Maury Service Authority
Lisa Fought	Rural Community Assistance Partnership
Keith Hass	Doylestown Township Municipal Authority
John L. Jones	New Mexico Rural Water Association
Vikki Prettyman	Southeast Rural Community Assistance Project
Liz Royer	Vermont Rural Water Association
Bradley Sawyer	Maine Rural Water Association
Sharon L. Schmeling	Wisconsin Council of Religious & Independent Schools
Steve Via	American Water Works Association
HELPER Mike Keegan	National Rural Water Association
HELPER John Shaffer	EEC Environmental

5. SUMMARY OF SMALL ENTITY OUTREACH AND OTHER OUTREACH

EPA is committed to involving stakeholders on this important initiative. As discussed previously in section 2, EPA released the PFAS Strategic Roadmap in October 2021, laying out an overall approach to addressing PFAS. In addition to establishing an NPDWR for PFAS, another key part of the Roadmap is that EPA is planning engagements in the coming year with affected communities in each EPA Region to hear how PFAS contamination impacts their lives and livelihoods. Additionally, EPA will provide an opportunity for public hearing after the rule is proposed but prior to final rule promulgation. EPA intends to hold this public hearing during the proposed rule public comment period. Opportunities to provide oral input, in addition to submitting written comments, will allow the public to provide input on more specific provisions of the proposed rule. EPA will then consider all public comments provided during the public hearing and within the public docket to inform the final rule.

As a part of the Preliminary Regulatory Determinations for PFOA and PFOS, EPA sought public comment on the preliminary determinations to regulate these two PFAS and regulatory approaches to address other PFAS. EPA received and reviewed public comments from approximately 11,600 organizations and individuals, including organizations representing small entities. For more information on the agency's responses to these comments, please see the response-to-comments document available in the Public Docket at www.regulations.gov under Docket ID No. EPA-HQ-OW-2019-0583.

One of the mechanisms by which EPA works with its stakeholders is through the National Drinking Water Advisory Council (NDWAC). The SDWA requires consultation with the NDWAC regarding NPDWRs. The Council, comprised of members of the general public, state and local agencies, including small PWS representatives, and private groups concerned with safe drinking water, advises the EPA Administrator on drinking water policy, programs, guidance, and rules. The Office of Ground Water and Drinking Water

(OGWDW) consulted with the NDWAC in April 2022 to provide them with information on the development of the proposed PFAS NPDWR and solicit feedback on regulatory options under consideration.

In 1978, Congress established the EPA Science Advisory Board (SAB) to provide scientific advice to the EPA Administrator. The SAB's principal mission includes reviewing the quality and relevance of the scientific and technical information being used or proposed as the basis for agency regulations. The SDWA requires that EPA request comments from the SAB prior to proposing a MCLG and NPDWR. EPA is seeking SAB input on the agency's proposed approaches toward deriving the health-based MCLGs for PFOA and PFOS; a draft framework for estimating noncancer health risks associated with mixtures of PFAS; and the agency's methodology for evaluating reduced cardiovascular disease risks for later use in EPA's Health Risk Reduction and Cost Analysis. The SAB formed a PFAS Review Panel, and the members of that Panel have developed their draft input related to the draft documents and specific charge questions asked by EPA on the information. The SAB PFAS Review Panel held public meetings in December 2021, January 2022, and May 2022. EPA received the draft SAB PFAS Review Panel report in April 2022, and it was provided to the full chartered SAB body. The chartered SAB members are reviewing the SAB PFAS Review Panel report and EPA anticipates the final report will be transmitted to the EPA Administrator in Summer 2022. EPA will consider the SAB's recommendations to inform the development of the proposed MCLGs and NPDWR requirements. More information and materials related to the SAB deliberations can be found on [EPA's SAB website](#).

EPA consulted with federally recognized Indian tribes on the proposed PFAS NPDWR. A PFAS NPDWR rule requirements may impact tribal governments that operate a PWS or that has primary enforcement authority (primacy) for PWS on tribal lands. EPA held two informational webinars for tribal officials on the development of the proposed PFAS NPDWR on February 23 and March 8, 2022. EPA also held a written comment period and requested input from tribal governments on considerations related to the potential regulatory requirements.

EPA held a Federalism consultation with representatives from state and local government organizations to solicit feedback on potential regulatory requirements of the proposed PFAS NPDWR, pursuant to Executive Order 13132. The agency held a meeting on February 24, 2022, to provide information on the development of the proposed rule and seek initial input from these government representatives, as well as drinking water organization representatives. The agency also will take any comments from the consultation into consideration during the regulatory development process.

EPA held two public meetings on March 2 and April 5, 2022, specifically focusing on environmental justice and equity considerations related to the EPA's effort to develop NPDWRs for certain PFAS. EPA is soliciting input from the public regarding ways in which the agency can ensure that disadvantaged communities impacted by PFAS drinking water contamination are fully engaged in solutions.

EPA conducted a meeting/teleconference with potential SERs on February 15, 2022. To help SERs prepare for the meeting/teleconference, on February 1, 2022, EPA sent materials to each of the potential SERs via email. A list of the materials shared with the potential SERs during the pre-Panel outreach meeting is contained in Appendix A. For the February 15, 2022, pre-Panel outreach meeting with the potential SERs, EPA also invited representatives from the Office of Advocacy of the Small Business Administration and the Office of Information and Regulatory Affairs within the Office of Management and Budget. A total of ten potential SERs participated in the meeting. EPA presented an overview of the SBREFA process, an explanation of the planned rulemaking, and technical background. This outreach meeting was held to solicit feedback from the potential SERs on their suggestions for the upcoming rulemaking. EPA asked the potential SERs to provide written comments by March 1, 2022.

The Panel conducted a meeting/teleconference with SERs on June 7, 2022. To help SERs prepare for the meeting/teleconference, EPA sent materials to each of the SERs via email on May 24, 2022. The materials shared with SERs during the Panel outreach meeting are included in Appendix A. A total of eight SERs participated in the meeting. EPA presented an overview of the SBAR Panel process, an explanation of the planned rulemaking, and technical background. A discussion session was held to

obtain advice and recommendations from the individual SERs about the potential impacts of the proposed rule. EPA asked the SERs to provide written comments by June 21, 2022.

Comments and discussion during the pre-Panel and Panel outreach meetings and written comments submitted by the SERs are summarized in section 6. Written comments are included in their entirety as Appendix B.

6. SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES

Section 6 represents a summary of the comments verbally provided by SERs during the pre-Panel and Panel outreach meetings and written comments submitted following each of the meetings. SER comments that were provided both verbally and in written format are denoted with an asterisk (*) following the comment. Subsequently, section 7 provides information on how EPA considered SER comments and information, as well as the Panel recommendations developed based, in part, on SER feedback.

6.1 Number and Types of Entities Affected

One SER provided comment related to the statutory definition of a PWS and the resulting regulatory impacts of complying with NPDWRs on its type of entities which are non-profit, private schools. Moreover, though the SER represents private schools that distribute drinking water which meets the population service numbers or service connections definition of a PWS provided under SDWA, the SER does not believe non-profit, private schools should be regulated as PWSs as they do not have the resources to ensure compliance and request that another type of PWS classification be made for these types of entities. Further, the SER recommends that the local counties where their entities reside should bear the financial responsibility of compliance with the proposed rule after receiving federal funding to install treatment or build water supplies to the schools. Additionally, the SER requests that as a part of the separate PWS classification, EPA should allow schools to utilize bottled water as an alternative means of providing potable water.

6.2 Related Federal Rules

One SER noted that they believe using the EPA-proposed treatment options (e.g., GAC, IX, and RO) will alter the corrosivity of the treated water which will need to be managed to maintain compliance with existing regulations such as the Lead and Copper Rule (LCR), LCRR, Interim Enhanced Surface Water Treatment Rule, Long-Term 1 Surface Water Treatment Rule, Groundwater Rule, Stage 1 and Stage 2 Disinfection Byproduct Rules, and the Arsenic Rule. Additionally, as described in section 6.4.2 below, several SERs commented that potential actions under other statutes including CERCLA, RCRA, and TSCA may have impacts on PFAS drinking water treatment and residual disposal options.* Further, most SERs expressed support that monitoring under the UCMR 5 would result in monitoring burden reductions associated with the proposed PFAS rule for some PWSs.

6.3 Potential Reporting, Recordkeeping, and Compliance Requirements

No specific SER comments were received on potential reporting and recordkeeping requirements of the proposed rule. Detailed SER comments on specific potential rule compliance requirements can be found in section 6.4.

6.4 Regulatory Flexibility Alternatives

SER input on the potential regulatory requirements and regulatory alternatives are described in detail within this section. A summary list of the regulatory flexibility alternatives that SERs identified and/or provided comment on include:

- Creation of a new PWS classification for certain types of small entities
- Use of previously collected PFAS drinking water data that meets a reasonable data quality standard to establish baseline monitoring results
- Allowance of an increased trigger level (above the detection limit) for monitoring result comparison
- Allowance of monitoring waivers based on vulnerability assessments and/or previously collected PFAS drinking water data
- Use of the SMF schedule for compliance monitoring requirements
- Use of POU and POE devices should only be considered if the PFAS removal certification standard for the devices demonstrates performance for achieving appropriate removal of PFAS that meets the regulatory compliance standard

6.4.1 Monitoring Considerations

Several SERs commented supporting the use of previously collected PFAS data (e.g., through the UCMR and state drinking water occurrence collection programs) to establish baseline monitoring results and reduce the monitoring burden for systems.* Another SER stated its belief that EPA needs to set a reasonable standard for using existing monitoring data, as available state-level data varies between state with respect to detection and reporting limits, the number of samples, sampling location, and the date that sampling was conducted. Another SER stated that due to the stability of PFAS monitoring results, water systems should be able to use any PFAS data obtained from recent sampling for both initial water quality monitoring and for use in obtaining a compliance sampling waiver.* A SER noted that the timing of baseline monitoring will also affect the scale of financial burden placed on small systems.

Some SERs commented on EPA's presented strategies to reduce monitoring burdens associated with demonstrating compliance with the potential NPDWR for small systems. A SER recommended that monitoring for the proposed rule should be based on the current UCMR 5 minimum reporting limits for PFAS, as this consistency will facilitate compliance and reduce the opportunity for monitoring and reporting violations for small systems. Several SERs expressed overall support for the use of the Standardized Monitoring Framework (SMF) schedule for compliance, with one SER noting that a triennial lab schedule compared to annual sampling is advantageous for their water authority since PFAS contamination has not changed at all in the past 5 years and that it allows for accurate budgeting for PFAS sampling. Under the SMF, one SER commented favorably on one of EPA's potential monitoring flexibilities that would allow for an increased "trigger level" to a level above detection which may reduce the monitoring burden many small systems will face. The SER also stated that EPA's possible approach to allow composite sampling of systems with multiple entry points in the distribution system will not likely be feasible based on current experience with SOC monitoring under the SMF. The SER recommended that EPA not incorporate mechanisms to alleviate burden that states may not be willing to implement.* Lastly, the SER discussed EPA's proposed application of monitoring waivers for PFAS based on vulnerability analysis. A few SERs expressed support for the inclusion of waivers as a part of the SMF.* Additionally, one SER acknowledged that this approach would likely help reduce monitoring burdens and noted that a vulnerability assessment to support a monitoring waiver issuance should clearly distinguish the types of sources that would establish PFAS use in the area, a task that might be difficult when considering household uses. The SER's current experience is that states are not granting monitoring waivers so it was recommended that EPA not consider a strategy to reduce burden that may not realistically be implemented. The SER suggested consulting with the Association of State Drinking Water Administrators (ASDWA) to ascertain whether their members are amendable to granting waivers for PFAS monitoring and to the use of compositing or representative sampling. Another SER asked what type of evidence a small system would have to provide to be eligible for the waiver for PFAS monitoring, and whether a series of non-detect samples over a period would be sufficient to receive a waiver.

One SER stated that vulnerability assessments are too expensive and cumbersome for small water systems. The SER recommended that agencies should use systems' sampling results when deciding to grant a PFAS sampling waiver, rather than a vulnerability assessment.

Related to sample analysis, a SER stated that it is expensive and that there are no labs in their state certified to perform EPA approved methods for analyzing PFAS in drinking water. Another SER stated that for small systems, the sampling requirements and precautions required to avoid contamination of PFAS samples far exceed the requirements of typical monitoring that these systems are accustomed to, creating a higher chance for sampling errors. The SER stated that EPA should consider the potential for false positives at low part per trillion concentrations and the cost implications of making management decisions at the limits of reliable quantification by commercial laboratories. Additionally, the SER stated that EPA's PFAS health advisories combined with limited laboratory capacity will increase the cost of analytical services, and that small systems will suffer from these high costs.

6.4.2 Treatment and Disposal Considerations

SERs discussed the treatment options presented by EPA, expressing some concern over potential water quality impacts as a result of treatment.* Specifically, one SER questioned if some of the proposed treatment options would change the water chemistry such that additional inputs (treatments) would be required to produce the finished water. Several SERs inquired about unintended consequences that could result from advanced treatment technologies.* One SER described a situation where arsenic was leached when using a coconut fiber carbon.* Another SER discussed a system in Vermont which had manganese introduced into the system during treatment when they had switched from a coconut-based carbon to bituminous carbon.

One SER discussed current research which indicates that total organic carbon (TOC) is a more significant factor influencing PFAS removal by GAC than other considerations including influent concentration. Furthermore, PFAS treatment performance will decrease in waters with higher levels of TOC or other contaminants that compete for reactive sites or interfere with media retention of PFAS. Another SER noted that PFAS treatment in surface water systems is more difficult to implement than in groundwater systems using the technologies listed by EPA and stated that they believe EPA is having difficulty obtaining reliable data about GAC usage at surface water plants. Further, surface water treatment plants (SWTPs) with PFAS contamination may need to use much more GAC than groundwater plants, because SWTPs typically see higher concentrations of TOC.* The SER stated that surface water plants may use three to eight times as much GAC as a typical groundwater plant. Additionally, they stated that onsite regeneration of GAC may be a sufficient way to address the high rate of GAC use in surface water plants but adds a level of complexity beyond what most small systems could manage and maintain. Concern was expressed by one SER with regard to chromatographic peaking and the oxidation of PFOA and PFOS. Specifically, the SER asked if chromatographic peaking could occur during IX or GAC treatment if managing for one contaminant and then there are multiple contaminants in the source water.* Another SER stated that as water systems monitor for additional PFAS chemicals, it will be difficult to predict how effectively GAC and other filtration technologies will remove these chemicals and how often the water system will need to change the filters. A SER stated that the actual performance of GAC or IX is impacted by other constituents in the water that can interfere with adsorption so a general filtration rate or maximum media life would need to be determined on a site-by-site basis that reflects actual monitoring data. One SER asked EPA if they had examined whether IX was truly a viable treatment option since some states have expressed they are unwilling to accept IX as a treatment option. Another SER stated that it was not clear if EPA is considering pre-treatment for iron and manganese and that the installation of GAC or IX, particularly for groundwater supplies could easily require pre-treatment for these substances.

Several SERs discussed the feasibility of using point-of-use (POU) devices.* One SER noted the option of installing POU filters for treatment at small systems and asked if consideration had been given to possible challenges of water systems having the regulatory responsibility of maintenance of the POU

devices in homes.* The SER further described difficulties with the use of POU devices in situations where customers prohibit water system staff from having direct access to their homes. Other concerns over the use of POU devices included one SER's inquiry on whether EPA's analysis of POU devices would follow the same assumptions used in the April 2006 EPA point-of-entry (POE)/POU guidance.* The SER described difficulties with compliance for virtually all community water systems. Specifically, the SER noted the difficulty for system operators to ensure the devices are running correctly and recognized the challenge to assure 100 percent resident participation. Additionally, the SER described the need for POU devices to be able to demonstrate performance at the levels being proposed by EPA if they are used to comply with an NPDWR. For example, if EPA sets an MCL or treatment technique trigger level below 70 ppt for PFOA or PFOS, or for additional PFAS, potential POU devices would need to demonstrate performance for achieving appropriate removal of PFAS before small systems can even consider POU/POE devices as a compliance option. Another SER stated that their state engineering analyses have not recommended POU devices as a remediation option for systems.

One SER discussed EPA POE/POU Guidance document's call for pilot testing for POU/POE devices. This SER stated that POU/POE devices would need to be installed at multiple locations throughout the distribution system which would inevitably exhibit varying operating conditions. The SER questioned how the use of POU/POE devices would simplify, speed up, or reduce the cost of PFAS treatment for CWSs serving multiple households.

One SER asked whether EPA is considering each treatment technology, such as GAC, nanofiltration, and RO, as separate treatment methods. The SER stated that there are circumstances in which water systems will need to use a combination of treatment technologies, such as due to the presence of TOC. Another SER stated that they were surprised by EPA's assumption that GAC provides equivalent removal of PFOA and PFOS. The SER stated that EPA will need to be careful to adequately represent differential removal efficacy when evaluating the efficacy and cost of PFAS treatment for small systems, and that this challenge becomes particularly acute if the regulatory construct is based on the limit of reliable quantitation.*

A SER also provided that while EPA estimated GAC treatment costs for very small systems to average approximately \$25,000, very small systems in their area have encountered total average remediation costs of \$125,000, and that supply chain issues, construction and transportation costs, and unknown media disposal fees have increased actual costs relative to projected costs.

A SER acknowledged the need for managing simultaneous compliance with multiple regulations contributes to the required time and analysis to properly select, prepare for, and install PFAS treatment wisely.* Consideration must be given to the capital, operation, and maintenance costs associated with the installed treatment to achieve compliance with this rule. Another SER stated that their system will consider the following factors when weighing treatment options: the treatment options' effectiveness at removing PFAS, the impacts on water quality, the system's ability to dispose of spent material, staff availability, and the cost of purchasing water from another supplier. The SER also noted their concern with unintended consequences of treatment that other entities have encountered.

One SER stated that chemical manufacturers that created PFAS chemicals should be responsible for paying remediation costs. The SER stated that establishing MCLs for PFAS places substantial burdens on PWSs that are not the source of PFAS contamination.

One SER stated that if EPA does not consider blending as a credible PFAS management strategy then the rule analysis will need to incorporate the costs of new supply development or alternatively assume full treatment of water supplies where PFOA or PFOS are observed. The SER stated that the loss of available water supply would be problematic for small systems and particularly for those systems operating with limited water supplies, partially as a result of climate change.

Several of the SERs raised questions about the disposal of concentrated PFAS residuals.* One SER suggested that the discussion should not only be limited to removal, but that EPA should consider having cross sector coordination between the drinking water sector and wastewater sector to limit the possibility

of the disposed waste leaching back into drinking water. A SER commented that if EPA determines PFAS to be a hazardous waste under other statutes such as RCRA, CERCLA, and/or TSCA, it will substantially complicate water systems' options for disposing of the waste generated through treatment.* The SER stated that if reactivation of GAC is no longer an option, huge amounts of spent carbon will be put into landfills. Another SER suggested that for the purposes of this rulemaking, EPA assume PFOA and PFOS waste will need to be treated as RCRA hazardous waste with appropriate cost treatment options listed accordingly and that EPA's current assumptions for disposal of GAC and IX media significantly underestimate the cost of compliance and are not aligned well with current media supplies and transportation challenges.* Additionally, the same SER stated that another challenge to small systems will be the potential lack of an available sewer connection for managing liquid waste associated with brine and filter start-up, particularly in rural areas.

A SER commented that current waste management options in the proposed rule for generated wastes from PFAS treatment are limited and both the availability and cost of the options are increasingly limiting. The SER noted that some wastewater systems are refusing GAC backwash and there are Subtitle D solid waste landfills that are currently refusing treatment wastes like spent GAC and spent IX resin. Further, the SER stated that EPA's current disposal guidance encourages the storage of PFAS-contaminated wastes until the time EPA specifies appropriate disposal options. The SER said that storage would be substantial and would require the appropriate design and operation. Regarding EPA's Interim Guidance for Destruction and Disposal of PFAS, a SER commented that it was not clear how EPA would use their interim guidance for destruction and disposal of PFAS constructively in the analysis for this rulemaking.

6.4.3 Public Notification Considerations

A few SERs provided comments related to public notification considerations. One SER asked if EPA is considering Tier 1 public notification requirements for PFAS. The SER recommended that EPA require systems to issue a Tier 3 public notification for any PFAS violation. The SER stated that customers have low confidence in the safety of public drinking water, and that providing an immediate notification for a non-acute violation will further erode confidence in PWSs. A different SER stated that issuing a "Do Not Drink" order to customers undermines customers' trust in their water system. Another SER noted that because EPA has not yet fully defined health effects for PFOA and PFOS, it is difficult to respond to the question of the most appropriate public notification tier, but stated that if EPA's proposed MCLGs for PFAS are based on similar health effects of EPA's interim PFOA and PFOS health advisories then it is likely a Tier 2 notification would be appropriate under typical Agency practice. Additionally, one SER stated concern that information that CWSs are required to include in Consumer Confidence Reports (CCRs) is often not understandable for the typical consumer and there will be a need to ensure this language is clear.

One SER stated concern that while private wells are not regulated under SDWA, notification requirements will trigger involvement with landowners beyond system service boundaries. The SER provided that where states recognize private well contamination, pressure may be placed on PWSs to extend service with the associated administrative, capital, operating expenses.

6.4.4 Health Effects and Regulatory Standards

SERs made comments about PFAS health effects and MCLGs. One SER asked how PFAS affects mortality rates currently and how this intervention will help to remedy it. One SER stated that EPA was moving too fast in establishing MCLs, and should take more time to let other agencies such as the CDC establish concrete health risks before moving forward. Another SER asked what the procedure would be if a state had already designated a PFAS standard. A SER asked if EPA could describe how/if they would implement a TT in the rule. Additionally, one SER asked if EPA is intending to implement detection limits/requirements based off of the recently published interim PFOA and PFOS and final PFBS and GenX chemicals health advisories, and how this may be accounted for in cost estimates.

6.4.5 Estimated Costs and Resource Considerations

There were many SERs who commented on the topic of costs, offering that the costs for specific items and processes may not have been fully evaluated and represented, including those incremental system-level monitoring and treatment costs provided by EPA.* Additionally, the SER stated that very small systems in their area have encountered supply chain issues, construction and transportation costs, and unknown media disposal fees that are increasing their actual costs relative to projected costs. Another SER asked if estimates had been developed on the engineering construction costs for the installation of technologies discussed by EPA and stated that project costs for PFAS treatment needs to be viable within the system's capacity to take on additional debt and retain affordable water rates for their customers.* Another SER was interested to know whether EPA had cost structures for IX, GAC, and RO, and noted that they did not believe the current documents cited by EPA in their presentation had design criteria for PFOA and PFOS.* The SER further noted that EPA's cost evaluation through a work breakdown structure (WBS) may be successful in estimating costs of implementing a new treatment system for PFAS for certain systems, but the approach relies on a limited number of factors to determine the costs for potentially complex system conditions. As such, the WBS approach may not fully capture the scope of costs for systems under the potential NPDWR. The SER suggests addressing some of these issues by recommending that the EPA increases the contingency factor applied in the WBS approach to be aligned with what they believe to be a more realistic cost estimate. When comparing actual cost estimates from an existing system to the WBS estimates used by EPA, the SER explained that they believe using the WBS approach significantly underestimates the cost of installing new treatment systems. The SER also added that another important aspect of small system costing that is worth exploring fully is automation.

One SER recommended that EPA include a 20% buffer relative to the MCL within the costing analysis, noting that water systems do not operate at the MCL or assume that they will exceed the MCL. Rather they operate with a margin of safety, and the SER believes that systems will need to plan for performance that maintains water quality below the PFOA and PFOS MRLs as well as for contingency strategies.

One SER asked whether EPA included operator certification considerations within its cost estimates because, in many states, PFAS treatment will require a higher level of certification for system operators.*

One SER declared that GAC replacement could be the single largest line item in a small system's operating budget. Additionally, a few SERs noted that increasing the demand for GAC by regulating PFAS could cause rapid increases in GAC prices and potential supply shortages.

Related to public notification costs estimates provided, a SER commented that they believe EPA's estimated cost of \$1,100 for a Tier 1 notification appeared inadequate. The SER noted that this estimate does not account for the labor and resources needed to fully execute a proper risk communication strategy for systems to maintain consumer confidence and public trust. The SER also requested that EPA look to the duties of state primacy agencies and the materials EPA provides to support them when crafting the public notice requirements for this rule.

SERs commented on the availability of funding to different entities. One SER asked if funding would be available to address PFAS contamination in non-PWSs, as well as non-community water systems such as non-transient non-community water systems (NTNCWSs). Another SER observed the significant challenges to a small system's workforce that a potential NPDWR for PFOA and PFOS would pose. With a limited workforce, small systems will be faced with the installation of advanced treatment technologies, as well as needing to comply with the treatment and monitoring requirements, which could include the maintenance of POU/POE systems. Another SER stated that systems in their area with PFAS exceedances do not employ on-site system operators and must pay for increased assistance from contract operations companies. Multiple SERs noted that the State Revolving Fund (SRF) provides funding for capital costs but does not cover operating costs.* They stated that over the life cycle of a PFAS treatment system, operating costs could be higher than capital costs, particularly if treatment produces hazardous waste.* The SERs stated that these operating costs could significantly impact

PWSs. Another SER stated that even the costs for planning for PFAS abatement are substantial. Another SER stated that state and federal subsidy programs reduce interest costs but do not provide an alternative source of funding for capital investments.

One SER stated that addressing PFAS within the proposed rule structure will exceed or stress the technical, managerial, and financial (TMF) capabilities for some small systems. The SER stated that exceeding or stressing these systems capabilities could induce failures that have broader public health implications. Additionally, the SER stated that investor owned small PWSs are unable to secure rates and charges changes from state corporation commissions until there is a clear regulatory requirement. The SER stated that small PWSs' ability to make proactive investments in capital changes are constrained by increases in the cost of materials and treatment chemicals, challenges obtaining and retaining qualified operators, the need to invest in renewal of existing infrastructure, compliance with the requirements of the Lead and Copper Rule Revisions (LCRR) and anticipated requirements of the Lead and Copper Rule Improvements (LCRI), and retention of adequate water supply.

7. PANEL FINDINGS

Pursuant to section 609(b) of the RFA, the Panel's most significant findings and discussion with respect to the issues related to sections 603(b)(3), (4), (5) and 603(c) of the RFA are summarized below. The Panel's findings are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the planned proposed rule, and additional information may be developed or obtained during this process and from public comment on the proposed rule. Any options the Panel identifies for reducing the planned rule's regulatory impact on small systems may require further analysis and/or data collection to ensure that the options are practical, enforceable, protective of public health, and consistent with the SDWA.

For example, the SDWA requires that any NPDWR must consider the feasible level of contaminant removal for any regulatory standard, and to publish an analysis of the health risk reduction benefits and costs likely to be experienced as a result of compliance with the regulatory standard. At the time EPA proposes a NPDWR, the Administrator must publish a determination as to whether the benefits of the regulation justify the costs.

The information contained with this section was developed, in part, based on the SER comments previously summarized in section 6. Please refer to the corresponding sections in section 6 for more details on Panel findings discussed below.

7.1 Number and Types of Entities Affected

As discussed in section 3, under SDWA, any NPDWR establishes requirements applicable to PWSs which are defined by statute as providing water for human consumption to at least 15 service connections or serving an average of at least 25 people for at least 60 days a year. EPA further defines three types of PWSs to include CWSs, NTNCWSs, and TNCWSs. Of these types of PWSs, 91% of all CWSs are considered small CWSs, and 99.9% of all NTNCWSs are considered small NTNCWSs. EPA does not anticipate that the proposed NPDWR will affect TNCWSs as those systems will likely not be subject to the rule requirements. For a complete description and estimate of the small water systems to which the proposed rule will apply, see section 3. **The Panel recommends that TNCWSs are not subject to the rule requirements. Further, not subjecting TNCWSs to the rule requirements will impose no new regulatory burden for approximately 80,000 small entities (more than 50% of PWSs in the United States) without significantly reducing public health protection. Additionally, the Panel notes that the definition of a PWS (including the definitions of CWS and NTNCWS) is determined by SDWA and is consistent across all NPDWRs; therefore, EPA does not have regulatory authority to create a different definition of a PWS as recommended by a SER.**

7.2 Related Federal Rules

As discussed in section 2.4, there are currently NPDWRs for over 90 contaminants. The Panel notes that EPA's drinking water rules have all been developed with careful attention to the interaction between each new rule that requires treatment changes. **The Panel recommends that EPA continue to ensure that the proposed NPDWR be coordinated with, and does not either duplicate or conflict with, the requirements of these other drinking water rules.**

The Panel also notes that while the proposed PFAS NPDWR is not anticipated to duplicate, overlap, or conflict with any other federal rules, there are other EPA actions and rules that are interrelated as EPA seeks to address PFAS throughout its entire life cycle from manufacturing to disposal. For example, monitoring under the UCMR 5 may support monitoring requirements associated with the proposed PFAS NPDWR. Further, as discussed in section 2.4, EPA is addressing PFAS through several of its statutory authorities other than the SDWA which may prevent or reduce PFAS entering into sources of drinking water in the future. EPA recognizes that some of these actions may have direct or indirect impacts for drinking water treatment facilities and could impact compliance requirements related to disposal of treatment residuals for some water systems. **Therefore, the Panel recommends that EPA continue to coordinate actions under all of its statutory authorities to ensure water systems are able to comply with the requirements of the proposed PFAS NPDWR, and any associated regulatory requirements and impacts from other statutes are adequately reflected within the proposed rule information available for public comment.**

7.3 Potential Reporting, Recordkeeping, and Compliance Requirements

For any drinking water program, EPA must have assurances that the drinking water provided to the public will meet the health-based regulatory standard requirements. Historically, EPA drinking water requirements have included requirements for PWS recordkeeping and reporting. Consistent with other NPDWR requirements, the proposed PFAS NPDWR will include reporting and recordkeeping requirements for monitoring results, public notification, and sampling results. At the same time, the Paperwork Reduction Act (PRA) requires that all reporting and recordkeeping requirements have practical utility and appropriately balance the needs of the government with the burden on the public. As EPA proceeds with any proposed PFAS NPDWR requirements, EPA will also assess the reporting and recordkeeping requirements and will consider them in any estimation of the burden and benefits of the proposed rule. EPA is committed to keeping paperwork requirements to the minimum necessary, and to fulfill its statutory obligations, as required by the PRA.

Detailed information and Panel recommendations on specific potential rule compliance requirements can be found in section 7.4.

7.4 Regulatory Flexibility Alternatives

7.4.1 Monitoring

EPA is evaluating requirements for PWSs to conduct initial and ongoing monitoring to determine the level of PFAS in their drinking water. EPA is considering multiple options and flexibilities for all monitoring. Related to initial monitoring to determine baseline concentrations at PWSs, EPA is assessing the use of recent, previously acquired monitoring data, such as those gathered during the UCMR 5 or a state-level drinking water occurrence data collection program, to be used in lieu of collecting initial water quality samples and to determine the required frequency of sampling for ongoing rule compliance. As a part of this consideration, EPA is evaluating the quality assurance requirements that this data would need to meet if they are utilized. Several SERs commented supporting the use of this previously collected PFAS data to establish baseline monitoring results and reduce the initial monitoring burden for systems. Further, some SERs stated that use of this data is supported by the consistency in measured concentrations demonstrated through their current PFAS sampling efforts. One SER noted the need for EPA to set a

reasonable standard for using existing monitoring data, as available state-level data varies between states with respect to detection and reporting limits, the number of samples, sampling location, and the date that sampling was conducted. **The Panel agrees with these SER recommendations and recommends that EPA, where possible, allow the use of this pre-existing monitoring data as it will significantly reduce the initial monitoring burden for some small systems. Additionally, the Panel recommends that EPA should ensure any data utilized for these purposes meet a consistent quality assurance threshold and provide that information with the proposed rule. To provide for the maximum public health protection feasibly possible these QA requirements could include that the data were collected within an appropriately recent timeframe and analyzed using an EPA-approved method for drinking water. The Panel recommends that EPA provide these QA requirements as a part of the proposed rule and take public comment on the requirements.**

For systems that may not have recently available data to support the determination of initial baseline PFAS concentrations, those systems typically are required to collect four samples at each entry point to the distribution system over a period of one year. EPA is currently evaluating an additional flexibility for groundwater systems serving 10,000 or fewer to reduce that requirement to two samples at each entry point to the distribution system over the period of one year. **The Panel recommends that EPA continue evaluating this potential for reduced monitoring and request public comment on this flexibility.**

To demonstrate compliance with the proposed rule, EPA is considering using the schedule determined by the SMF for SOCs as described in section 2.3. Under this schedule, small systems serving 3,300 or fewer people and below a certain trigger level for the contaminant, are eligible for reduced monitoring which includes collecting one sample at each entry point to the distribution system every three years of the nine-year compliance cycle, whereas all other sized systems that are also below the trigger level must collect and analyze two samples at every entry point to the distribution system every three years of the nine-year compliance cycle. One SER supported the use of a monitoring schedule as it allows systems to accurately budget for future sampling costs. **The Panel suggests EPA incorporate the use of the SMF schedule for the PFAS standard compliance monitoring, including making available all potential flexibilities for reduced monitoring allowed under the SMF for SOCs which will reduce burden and costs for some small systems. The Panel also recommends that EPA request during the public comment period any additional flexibilities that would further reduce burden while maintaining public health protection.**

As a part of the SMF, one flexibility is the use of monitoring waivers which may be allowed if systems meet primacy agency criteria. The monitoring waivers are based on vulnerability assessments as described in section 2.3, and under the SMF for SOCs, if granted, can eliminate all compliance monitoring requirements if the waiver is maintained. Several SERs expressed support for the use of monitoring waivers as they may reduce burden and costs for small systems, while one SER provided that the vulnerability assessment requirements of their primacy agency are expensive and challenging for small PWSs to conduct. Another SER stated that to facilitate the vulnerability assessment eligibility requirements, the types of sources that would establish PFAS use in the area should be identified and cautioned that primacy agencies may not grant monitoring waivers even if they are allowed under the SMF for SOCs. Additionally, a SER recommended that, rather than conducting a separate vulnerability assessment, the sampling results from pre-existing monitoring data should meet the requirements of a compliance monitoring waiver if the results support that PFAS is not detected in the system's water. **Regarding monitoring waivers, the Panel recommends that EPA support this potential additional flexibility for systems and their use under the SMF for SOCs. The Panel also recommends EPA seek public input to identify other possible alternatives to identify systems as low risk and therefore may be eligible for monitoring waivers other than traditional vulnerability assessments.**

EPA is also assessing other options to offer small PWSs additional flexibility related to compliance monitoring, including the utilization of an increased trigger level and composite sampling. The trigger level is generally set at the detection limit (not the reporting limit) of a contaminant, however EPA is evaluating setting this level higher than the contaminant detection limit. A SER commented favorably on the use of this increased trigger level as it may decrease the burden on small systems by reducing the frequency of required monitoring for systems with concentrations exceeding the detection limit. EPA is also

considering the allowance of composite sampling, which would provide systems with multiple entry points the ability to analyze a composite of more than one sample rather than analyzing each sample individually, and potentially allow systems to reduce analytical costs. One SER suggested, however, that allowing composite sampling would likely not be feasible based on their current experience with SOC monitoring under the SMF, and that similar to monitoring waivers, primacy agencies may not allow the use of composite sampling. **Related to possible compliance monitoring flexibilities, such as an increased trigger level or composite sampling, the Panel recommends that EPA continue to consider these and other flexibilities that may be identified in the future.**

A few SERs commented about the adequate laboratory capacity for analyzing drinking water PFAS monitoring data. One SER stated that their state does not currently have any certified laboratories for the EPA-approved methods for analyzing PFAS in drinking water. As described in section 2.1, EPA will be conducting nationwide monitoring for 29 PFAS under the UCMR 5, of which EPA anticipates that the number of small water systems will increase from the typical number included within previous UCMRs. Thus, EPA notes that while there may currently be some laboratory capacity challenges in parts of the country, EPA expects demand for laboratory support to increase significantly based on the greater number of water systems expected to participate in UCMR 5 and in preparation for this increase, EPA is soliciting proposals and award contracts to laboratories to support small system monitoring. Additionally, EPA notes that many systems may not be required to conduct additional monitoring if the use of recent PFAS monitoring data is utilized. **The Panel recommends EPA continue to evaluate potential laboratory capacity-related challenges and consider rule implementation delays if those challenges potentially impact the ability of water systems to monitor for PFAS and reasonably comply with the NPDWR. The Panel also recommends EPA take comment on laboratory capacity considerations during the public comment period.**

Related to other sampling and laboratory issue considerations, a SER expressed concern that laboratories may have constraints related to analyzing to low-level concentrations, as well as the possibility for contamination of drinking water samples which may lead to higher chance for error. Under UCMR 5, EPA developed minimum reporting levels for PFAS which are defined as the minimum quantitation level that, with 95 percent confidence, can be achieved by capable analysts at 75 percent or more of the laboratories using a specified analytical method. Currently, EPA considers these levels to be the lowest reporting levels that can practically and consistently be achieved on a national basis (recognizing that individual laboratories may be able to measure at lower levels). Additionally, use of the EPA approved methods for analyzing PFAS requires collection of a corresponding field reagent blank (FRB) sample from each unique sampling location for each sampling event. An FRB is defined as an aliquot of reagent water treated as a sample including exposure to sampling conditions to determine if interferences or contamination are present from sample collection through analysis. The EPA approved PFAS methods require that the FRB be analyzed if there is a positive result for a PFAS analyte in a corresponding field sample. Consequently, while incorporation of FRB sampling may not alleviate all user sampling error or possible contamination, it will provide for additional QA/QC to help ensure sampling accuracy of any samples and avoid sampling contamination issues. **The Panel recommends EPA take comment on QA/QC considerations and issues related to PFAS drinking water sampling.**

7.4.2 Treatment and Disposal

Small systems that exceed the drinking water regulatory standard will need to select a treatment, nontreatment option, or a combination to bring their water into compliance. EPA has identified multiple treatment technologies that have been demonstrated to reduce levels of PFAS in drinking water. Moreover, EPA is evaluating the potential for centralized GAC, IX, and RO treatments to meet the SSCT designation criteria as detailed in section 2.3. Some SERs expressed concern over other potential water quality impacts and possible unintended consequences resulting from use of these PFAS treatment technologies. A few SERs also noted there may be differences between surface water and groundwater systems with PFAS contamination and surface water systems may need to use much more GAC than groundwater systems due to higher concentrations of TOC. EPA notes that if a water system determines that installation of treatment is their best approach to maintain compliance with the PFAS standard,

systems can choose the type of treatment that is best suited for their water system and water quality characteristics, including both those that have been specifically identified by EPA to remove PFAS or any other technologies that would allow them to achieve compliance. EPA also notes it is evaluating treatment technologies for both groundwater and surface water systems. Further, systems may be able to maintain compliance through non-treatment options or other alternatives. **The Panel recommends that EPA take comment on and continue evaluating any potential unintended consequences of the identified PFAS removal treatment technologies and provide corresponding information to assist water systems in selecting PFAS treatment if needed. The Panel also recommends that EPA request information and input during the proposed rule public comment period regarding any additional treatment technologies that have been shown to reduce levels of PFAS to the proposed regulatory standard.**

As discussed in section 2.2, EPA is currently considering whether to include additional PFAS, other than PFOA and PFOS, within this proposed NPDWR. As such, EPA is evaluating information and factors related to individual PFAS, as well as groups or classes of PFAS. These factors include whether the same treatment approaches and technologies co-remove certain PFAS contaminants and how PFAS are anticipated to be removed as a part of the overall treatment process. A SER expressed concern that different PFAS can exceed the capacity of sorptive media (i.e., GAC) differently and systems would need to be designed to explicitly treat for certain PFAS. EPA acknowledges that while treatment for different PFAS may require more frequent media or resin replacement, EPA also notes that treatment considerations and adjustments associated with different water quality parameters, such as TOC, will lead to greater treatment variation than those adjustments required for targeting of specific suites of PFAS that can be removed by similar technologies. **As such, the Panel recommends that (in the absence of a separate regulatory action and SBAR Panel if it is expected that such action would have a significant impact on a substantial number of small entities) EPA only consider regulation of additional PFAS that can be removed by the identified technologies which also remove PFOA and PFOS. Furthermore, the Panel recommends that EPA consider the adjustments to the design and operation of treatment systems that would be necessary to remove any additional PFAS in EPA's cost analysis for the proposed rule and in the identification of available PFAS removal treatment technologies.**

For all small PWSs serving 10,000 or fewer people, EPA is considering the use of packaged or modular system POU or POE treatment units in lieu of centralized treatment systems which may be more cost effective specifically for very small systems. As described in section 2.3, the SDWA specifies that POU and POE devices units must be owned, controlled, and maintained by the water system. Consequently, some SERs commented on the feasibility of using POU or POE devices and the challenges of water systems having the regulatory responsibility of maintenance of the devices in all locations, including customer homes. Typically, the Panel expects that a POU option is only practicable for those systems that have control over the taps within their system which are used for human consumption. These conditions on POU/POE devices protect consumer's health. While these conditions from SDWA usually make it feasible only for small systems, particularly NTNCWSs, to utilize POU/POE because they are most likely to have control over their taps, any small water system, including CWSs, may choose to utilize POU/POE devices rather than other options for achieving compliance. **As such, the Panel recommends that EPA should continue to consider all available treatment options for small systems to maintain compliance with the standard, including installation and maintenance of POU/POE devices.**

POU/POE devices are certified by third parties for contaminant removal effectiveness and currently the removal standard of home drinking water treatment units for PFOA and PFOS is 70 ppt. EPA notes that the proposed PFAS NPDWR may differ from this current removal standard. Moreover, a SER commented on this current PFAS removal certification standard and the need for the devices to be certified and demonstrate performance for achieving appropriate removal of PFAS before small systems can consider POU/POE devices for regulatory compliance. In the case where the regulatory requirement may be lower than the current removal standard, EPA is consulting with the third-party certifiers, including NSF International, the ANSI designated organization that develops standards for drinking water treatment units, and they are working to develop new more stringent standard for testing home treatment systems for the removal of PFAS from drinking water. While these new certification standards are being developed

and implemented, EPA notes that recent research has found that GAC and RO systems studied were able to reduce PFAS to below laboratory detection limits when used as POE or POE systems. However, as with centralized drinking water treatment, EPA acknowledges that water quality conditions, concentrations of PFAS in the water, and operational conditions were shown to affect each of the systems and their effectiveness. **The Panel recommends that EPA continue consulting with voluntary consensus standard organizations for water treatment devices to ensure these devices may be a viable compliance option for small systems.**

Several of the SERs raised questions about the disposal of concentrated PFAS treatment residuals and potential implications resulting from actions and/or requirements of other EPA statutory authorities. As discussed in section 2.3, EPA is evaluating actions that water systems may need to take to dispose of treatment residuals that contain PFAS and possible direct or indirect impacts that may influence the options available to them. **The Panel recommends that EPA continue to evaluate these impacts, including considering and presenting the costs of both non-hazardous and hazardous waste disposal of treatment residuals. The Panel also recommends that EPA provide information to water systems on the destruction and disposal of PFAS and PFAS-containing materials that are a part of drinking water treatment residuals. Additionally, the Panel recommends EPA take comment on PFAS disposal considerations, including site capacity.**

7.4.3 Public Notification

EPA is considering the tier of public notification for the proposed PFAS NPDWR, as well as the information on PFAS in drinking water that should be included in CCRs. One SER recommended the proposed PFAS NPDWR be a Tier 3 notification, while another SER stated a Tier 2 notification may be more appropriate based on typical Agency practice and recent EPA HA information. As noted by that SER, the public notification tiering will likely be dependent upon the health effects that inform the development of the proposed rule. **As such, the Panel recommends that EPA consider the SAB's review of the PFAS health effects information and their recommendations in making the tiering determination and take comment on it during the proposed rule comment period.**

7.4.4 Health Effects and Regulatory Standards

Some comments were made about PFAS health effects and MCLGs, with one SER expressing caution with EPA's pace in developing the proposed NPDWR. The Panel appreciates the input of SERs related to PFAS health effects and the development of the MCLGs for PFAS. As described in section 5, to inform this component of the proposed rule development, EPA has sought the input of the SAB and will consider their expertise and recommendations in evaluating the health effects impacts of PFAS and determining the health-based MCLGs for the proposed rule. Upon rule proposal, EPA will take comment on the proposed MCLGs and regulatory standards.

Another SER expressed concern with state PFAS drinking water standards and the intersection with those developed by EPA under SDWA. Regarding states that have implemented their own PFAS drinking water regulatory standards, EPA notes that under SDWA, states are required implement NPDWRs that are at least as stringent as the federal government, however based on state-specific laws some states can set their own standards that are more stringent.

7.4.5 Estimated Costs and Resource Considerations

EPA provided information on the preliminary regulatory cost impacts for small PWSs associated with the proposed PFAS NPDWR, including the estimated system-level incremental costs of PFAS monitoring in drinking water, as well as PFAS removal treatment costs for centralized GAC and IX and POU RO and public notification costs. The monitoring cost estimates were based on the average per sample analytical costs from the Final Information Collection Request for the UCMR 5 which were determined from

consultations with national drinking water laboratories. The treatment cost estimates were developed based on peer reviewed WBS models as referenced in section 2.3. In response to the estimated monitoring and treatment costs provided, some SERs commented about their accuracy and representativeness being different than their experiences, while some SERs found them to be within an acceptable range of accuracy. Further, a SER noted that while the WBS models may be successful in estimating costs of implementing a new treatment system for PFAS for certain systems, they rely on a limited number of factors and the approach may not work for determining the costs for potentially complex systems. Related to the models and concerns that it relies on a limited number of factors to estimate costs, EPA acknowledges that treatment costs for a given system can vary depending on site-specific conditions (e.g., raw water quality, climate, local labor rates, and location relative to equipment suppliers), and, in some cases, may be higher or lower depending on these factors, among others. The estimated system treatment costs provided are based on national average assumptions and are intended to encompass the variation in costs that systems would incur to remove PFAS. In addition to direct treatment capital costs, the WBS models estimate add-on costs (e.g., permits and land acquisition), indirect capital costs, and annual O&M costs (labor, materials, energy, non-hazardous residuals management), thereby producing a complete compliance cost estimate. Furthermore, the WBS model also provides for estimates of non-treatment alternative actions including interconnection with another system and drilling of new drinking water wells. As a part of the proposed rule, EPA will present detailed cost estimates which will be available for public comment.

EPA presented estimated annualized monitoring and treatment costs based at a system level. The Agency will continue to evaluate the rule implementation costs and information and seek input during the public comment period.

In regard to public notification costs, a SER expressed concern with the estimates and that the entirety of risk communication planning and activity costs were not included. EPA notes that the Public Notification Rule only includes the requirement of preparing and distributing the public notification, which is the basis for the estimated cost; other potential communications-related costs, not required by the Public Notification rule, are not included. **The Panel recommends that EPA seek comment on the estimated public notification costs and what may be needed for water systems to effectively communicate information about the PFAS NPDWR.**

EPA provided information on the Bipartisan Infrastructure Law, specifically significant funds that are available to support addressing PFAS contamination. A few SERs raised the concern that this funding will not thoroughly support the implementation costs associated with the proposed PFAS NPDWR, particularly because the funding can only be used for certain eligible expenses (e.g., capital-related costs), as required by statute. EPA acknowledges that water systems will need to determine the most appropriate funding sources to support their compliance with rule; nevertheless, EPA believes that these funds will be available to substantially support many water systems as they seek to fund potential costs associated with the PFAS NPDWR. **The Panel recommends that EPA continue to provide information to support water systems and states in using these funds, including information on eligible expenses associated with the implementation costs of the PFAS NPDWR. Furthermore, the Panel requests that EPA distinguish specifically between capital and operating costs when discussing future cost estimates, as well as when presenting information associated with federal funding available to support rule implementation.**

APPENDIX A: Materials shared with Small Entity Representatives

Appendices A1 and A2 (separate documents) are compilations of all outreach materials shared with SERs for the Pre-Panel Outreach meeting and the Panel Outreach meeting. Below are lists of those materials.

Appendix A1: Materials EPA Shared with Potential Small Entity Representatives for the Pre-Panel Outreach Meeting, February 15, 2022

- EPA's Pre-Panel Outreach Meeting Agenda
- Proposed PFAS National Primary Drinking Water Regulation SBREFA Background Document
- Presentation: Proposed PFAS National Primary Drinking Water Regulation (NPDWR): Small Business Advocacy Review Pre-Panel Outreach Meeting with Small Entity Representatives
- SBAC Presentation on the SBAR Panel Process
- Follow-up Correspondences to the PFAS NPDWR Pre-Panel Outreach Meeting

Appendix A2: Materials EPA Shared with Small Entity Representatives for the Panel Outreach Meeting, June 7, 2022

- EPA's Panel Outreach Meeting Agenda
- Updated Proposed PFAS National Primary Drinking Water Regulation SBREFA Background Document
- Presentation: Proposed PFAS National Primary Drinking Water Regulation (NPDWR): Small Business Advocacy Review Panel Outreach Meeting with Small Entity Representatives

APPENDIX B: Written Comments Submitted by Small Entity Representatives

Appendices B1 and B2 (separate documents) are compilations of all written comments submitted by SERs following the Pre-Panel Outreach meeting and the Panel Outreach meeting. Below are the SERs that submitted comments.

Appendix B1: Written Comments Submitted by Potential Small Entity Representatives following the Pre-Panel Outreach Meeting on February 15, 2022

- American Water Works Association
- Maury Service Authority

Appendix B2: Written Comments Submitted by Small Entity Representatives following the Panel Outreach Meeting on June 7, 2022

- American Water Works Association
- Maury Service Authority
- Doylestown Township Municipal Authority
- Wisconsin Council of Religious and Independent Schools
- Vermont Rural Water Association