

August 1, 2022

The Honorable Michael Regan  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Dear Administrator Regan:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemaking entitled "Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR)." This notice of proposed rulemaking is being developed by the U.S. Environmental Protection Agency (EPA) under the Safe Drinking Water Act (SDWA).

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 such, 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 public water systems (PWSs). MCLs and treatment techniques are established to protect public health by limiting the levels of contaminants in drinking water to the extent feasible. Additionally, 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.

In EPA's PFAS Strategic Roadmap, the Agency reaffirmed its commitment to evaluate additional PFAS and consider regulatory actions to address additional PFAS or groups of PFAS as it develops the NDPWR. 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. As 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, 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.

On May 24, 2022, EPA's Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). In addition to its chairperson, the Panel consists of the Director of the Standards and Risk Management Division within EPA's Office of Ground Water and Drinking Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Chief Counsel for Advocacy of the Small Business Administration (SBA). It is

important to note that the Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during this process as well as from public comment on the proposed rule. The options the Panel identified for reducing the rule's economic impact on small entities will require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with the SDWA.

## **SUMMARY OF SMALL ENTITY OUTREACH**

Prior to convening the Panel, EPA conducted outreach with small entities that will potentially be affected by these regulations. In February 2022, EPA invited SBA, OMB, and 10 potentially affected small entity representatives (SERs) to a meeting and solicited comments from them on preliminary information sent to them. EPA shared the small entities' written comments with the Panel as part of the Panel convening document.

After the SBAR Panel was convened, on May 24, 2022, the Panel distributed additional information to the 10 SERs that were provided information prior to the Panel convening, as well as to an additional two new SERs, for their review and comment and in preparation for another outreach meeting. On June 7, 2022, the Panel met with the SERs to hear their comments on the information distributed to them. The SERs were also asked to provide written feedback on ideas under consideration for the proposed rulemaking. The Panel received written comments from the SERs in response to the discussions at this meeting and the outreach materials. See Section 6 of the Panel Report for a complete discussion of SER comments. Their full written comments are also included in Appendix A. In light of these comments, the Panel considered the regulatory flexibility issues specified by RFA/SBREFA and developed the findings and discussion summarized below.

## **PANEL FINDINGS AND DISCUSSION**

Under section 609(b) of the RFA, the Panel is to report its findings related to the following four items:

- 1) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.
- 2) A description of the projected reporting, recordkeeping 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.
- 3) Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.
- 4) A description of any significant alternatives to the planned proposed rule which would minimize any significant economic impact of the proposed rule on small entities consistent with the stated objectives of the authorizing statute.

The Panel's most significant findings and discussion with respect to each of these items are summarized below. To read the full discussion of the Panel findings and recommendations, see Section 7 of the Panel Report.

### **A. Number and Types of Entities Affected**

Under SDWA, any NPDWR establishes requirements applicable to public water systems (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 community water systems (CWSs), non-transient non-community water systems (NTNCWSs), and transient non-community water systems (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. 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.

### **B. Related Federal Rules**

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 fifth Unregulated Contaminant Monitoring Rule (UCMR 5) may support monitoring requirements associated with the proposed PFAS NPDWR. Further, EPA is addressing PFAS through several of its statutory authorities other than the SDWA, including the Comprehensive Environmental Response, Compensation, and Liability Act, Resource Conservation and Recovery Act, Toxic Substances Control Act, Clean Water Act, Clean Air Act, and Emergency Planning and Community Right-to-Know Act, 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 NDPWR, and any associated regulatory requirements and impacts from other statutes are adequately reflected within the proposed rule information available for public comment.

### **C. Recordkeeping, Reporting, and Other 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 D below.

#### **D. Regulatory Flexibility Alternatives**

##### **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. The Panel 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 Standardized Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOCs). 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. 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, and under the SMF for SOCs, if granted, can eliminate all compliance monitoring requirements if the waiver is maintained. 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. 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. 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.

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. Additionally, the Panel recommends EPA take comment on QA/QC considerations and issues related to PFAS drinking water sampling.

### **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 granular activated carbon (GAC), ion exchange (IX), and reverse osmosis (RO) treatments to meet the SDWA Small System Compliance Technology (SSCT) designation criteria. 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.

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. 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 point-of-use (POU) or point-of-entry (POE) treatment units in lieu of centralized treatment systems which may be more cost effective specifically for very small systems. The SDWA specifies that POU and POE devices units must be owned, controlled, and maintained by the water system. 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 parts per trillion (ppt). EPA notes that the proposed PFAS NPDWR may differ from this current removal standard. 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. 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.

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.

#### **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 Consumer Confidence Reports (CCRs). The Panel recommends that EPA consider the Science Advisory Board'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.

#### **Estimated Costs and Resource Considerations**

During the SBAR Panel process, EPA presented estimated annualized monitoring and treatment costs based at a system level associated with the proposed PFAS NPDWR. The Agency will continue to evaluate the rule implementation costs and information and as part of the proposed rule will present detailed cost estimates which will be available for public comment.

In regard to public notification costs, 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. EPA notes that this funding can only be used for certain eligible expenses (e.g., capital-related costs), as required by statute; nevertheless, the Agency believes that these funds will be available to substantially support many water systems as they seek to fund potentially 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.

Sincerely,

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**William Nickerson**  
Small Business Advocacy Chair  
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**Dominic J. Mancini**  
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Enclosure