Post-Hearing Questions for the Record
Submitted to Peter C. Grevatt, Ph.D.
Office of Ground Water and Drinking Water
Office of Water
U.S. Environmental Protection Agency

Senate Committee on Homeland Security and Governmental Affairs
Subcommittee on Federal Spending Oversight and Emergency Management
"The Federal Role in the Toxic PFAS Chemical Crisis" – September 26, 2018

The Honorable Gary C. Peters

1. What steps is EPA taking to establish the methods for measuring PFAS in soil and groundwater? What is the expected timeframe for these methods to be established and agreed upon nationally?

The EPA validated and published its original method (Method 537) for monitoring 14 PFAS in drinking water (including drinking water obtained from groundwater sources) in 2009. This method was expanded in November 2018 (published as Method 537.1) and can now measure 18 different PFAS. The EPA is working to develop additional drinking water analytical methods for other PFAS as well as two different methods for quantifying 24 PFAS in surface water, groundwater, and wastewater matrices (non-drinking water) and solids (e.g., soil and sediment). The EPA anticipates completing these new methods in 2019. These new methods will include multi lab validations to document repeatability and will be added to the EPA's Hazardous Waste Test Methods SW-846. The EPA has developed and continues to conduct research to develop new analytical methods which can be used to measure a wide variety of PFAS in different media.

2. As recently as five years ago, EPA had to rely upon industry provided records to understand what PFAS chemicals were manufactured or utilized. The Agency's Significant New Use Rule authority provided by the recent TSCA reauthorization was intended to help the agency better understand what chemicals are being produced or used here in the United States. Can you elaborate on EPA's use of the "Significant New Use Rule" authority to potentially understand new uses of PFAS chemicals before they are commercialized? Specifically, will the Significant New Use Rule help EPA better understand the implications of PFAS chemicals as a class, or does EPA interpret the authority provided by Congress to be more narrowly tailored to assess the two specific chemicals, PFOA and PFOS?

The EPA has published several SNURs under TSCA to require manufacturers (including importers) and processors of some PFAS chemicals to notify the EPA at least 90 days before starting or resuming new uses of these chemicals. The EPA action prohibits new uses of PFAS chemicals until notice is submitted, EPA reviews, and makes a determination regarding unreasonable risk posed by the new use. The EPA is required to take action, as appropriate, to address any unreasonable risk. The SNURs apply to all PFAS chemicals included in the SNURs, not just PFOA and PFOS.

Relevant to understanding which PFAS chemicals on the TSCA Inventory are active in U.S. commerce, the EPA will soon be publishing an updated version of the TSCA Inventory that will include all substances designated as either active over the past 10 years or inactive per reporting under the TSCA Inventory Notification (Active/Inactive) framework rule.

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The Honorable Margaret Wood Hassan

1. How many Americans are known or expected to have been exposed to PFAS in their drinking water? Is this estimate you provide for people on public water supplies or does it include people on private drinking water wells?

The EPA worked with states and public water systems (PWSs) to characterize the occurrence of six PFAS in the nation's drinking water served by public water systems (PWSs) by including six PFAS in the third Unregulated Contaminant Monitoring Rule (UCMR) under the Safe Drinking Water Act (SDWA) (UCMR does not sample private wells.). From 2013-2015, drinking water samples were collected and analyzed for six PFAS in nearly 5,000 PWSs across the nation, accounting for approximately 80 percent of the U.S. population served by PWSs (approximately 250 million people).

The EPA found 4.0 percent of PWSs (198 out of 4,920 systems) reported results for which one or more of the six PFAS (PFOA, PFOS, perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS), (perfluoroheptanoic acid) PFHpA, or perfluorobutane sulfonate (PFBS)) was measured at or above the minimum reporting limit during one or more sampling events at one or more sampling locations. The minimum reporting limit is lower than EPA's lifetime HA. The UCMR data are the best-available data on the frequency and level of occurrence of these PFAS in public water systems nationally, but they do not provide information on the occurrence in private wells.

2. How many Americans have been exposed to levels of PFOA and PFOS that exceed the EPA drinking water guideline?

To provide Americans, including the most sensitive populations, with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water, the EPA has established the health advisory levels at 70 parts per trillion. When both PFOA and PFOS are found in drinking water, the combined concentrations of PFOA and PFOS should be compared with the 70 parts per trillion health advisory level. This health advisory level offers a margin of protection for all Americans throughout their life from adverse health effects resulting from exposure to PFOA and PFOS in drinking water. The health advisory value is derived based upon peer-reviewed studies of the effects of PFOA and PFOS on laboratory animals (rodents) demonstrating the potential for developmental effects. Under the third Unregulated Contaminant Monitoring Rule, discussed in the response to the preceding question, the EPA found that 1.3 percent of the participating PWSs (63 out of 4,920 PWSs reporting) had at least one sample that measured PFOA and/or PFOS at concentrations greater than 70 ppt. The EPA believes the UCMR3 data provide the best-available data regarding the frequency and level of contaminant occurrence in public water systems. However, the EPA has not developed estimates of the national population served by public water systems at levels greater than the Health Advisory. The EPA also does not have nationally representative data on PFOA and PFOS levels associated with private wells.

3. When did the EPA begin developing its drinking water guideline for PFOA and PFOS?

The EPA initiated its health assessments for PFOA and PFOS in 2009. Draft Health Effects Support Documents for PFOS and PFOA were released for public comment in February 2014. The final Health Effects Support Documents and Lifetime Health Advisories were published in May 2016. See Health Effects Support Documents and Health Advisories for PFOA and PFOS at https://www.epa.gov/ground-water-and-drinking-water/supporting-documents-drinking-water-health-advisories-pfoa-and-pfos.

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4. When were the guidelines publicly available?

The non-regulatory Lifetime Health Advisory levels for the sum of PFOA and PFOS concentrations was released in May 2016.

5. When were the data documenting the presence of PFAS under the Safe Drinking Water Act's Unregulated Contaminant Monitoring Rule analyzed? When were they made publicly available?

The UCMR 3 data were collected from 2013-2016 and were analyzed thereafter. The EPA published UCMR 3 data approximately quarterly throughout the monitoring program following review. The data summary was published in January 2017, available at https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf. The EPA continues to assess the data.

6. How many years have passed since the EPA has known that PFAS – including PFOA and PFOS are present in public drinking water supplies?

The EPA conducted a nationwide survey of drinking water systems under the third Unregulated Contaminant Monitoring Rule, which began sampling drinking water in 2013.

7. What is the difference between a guideline and a standard?

Standards, such as maximum contaminant levels set under the Safe Drinking Water Act (SDWA), are enforceable requirements that drinking water systems must follow. Guidelines, such as the EPA's Health Advisories, are non-enforceable and non-regulatory. They are intended to provide technical information to state agencies and other public health officials on potential health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. The health advisory level for PFOA and PFOS were calculated to offer a margin of protection for fetuses during pregnancy and breastfed infants as well as for all Americans throughout their life.

8. If an EPA standard is developed, are all states required to meet the standard?

Yes, when the EPA establishes a standard under SDWA, states, territories, and tribes are required to meet that standard. In addition, states, territories, and tribes that have been delegated primary enforcement responsibility (primacy) must adopt standards that are no less stringent than the EPA's regulations.

9. If an EPA standard is developed, are DoD facilities required to meet the very same standard(s)? Why or why not?

DoD facilities that are public water systems and are located within the United States (including territories) are required to meet SDWA requirements, including meeting any applicable drinking water standards.

10. The Centers for Disease Control Agency for Toxic Substances and Disease Registry released its Toxicity Profile for PFAS this summer. The ATSDR guidelines for PFOA and PFOS are almost 10 times less than the EPA drinking water guidelines. Why is this?

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On June 20, 2018, ATSDR released a draft Toxicological Profile for perfluoroalkyls for public comment. This document includes Minimal Risk Levels (MRLs) for four PFAS – Perfluorooctanoic acid (PFOA), Perfluorooctane sulfonic acid (PFOS), Perfluorononanoic acid (PFNA), and Perfluorohexane sulfonic acid (PFHxS). ATSDR released the draft Toxicological Profile after working collaboratively with the EPA, the Food and Drug Administration, the National Institutes of Health (including the National Institute of Environmental Health Sciences), the National Toxicology Program, the U.S. Geological Survey, and the Department of Defense (DoD).

ATSDR's MRLs and the EPA's Health Advisories (HAs) are two different tools that are used in different situations. Drinking Water HAs provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. They are a concentration in drinking water that is not expected to cause any adverse human health effects over an exposure period (e.g. 1-day, 10-day, lifetime). The EPA's health advisories are non-enforceable and non-regulatory and provide technical information to states agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. Drinking water HAs are calculated incorporating toxicity (i.e., reference doses or RfDs) and exposure parameters (i.e., drinking water intake, body weight, and other potential sources of exposure).

ATSDR's MRLs are toxicity values that are intended to be used to help public health professionals determine areas and populations potentially at risk for health effects from exposure to a particular chemical. MRLs do not take into account specific exposures like a drinking water HA. MRLs are intended only to serve as a screening tool to help public health professionals decide where to look more closely; they are not intended to indicate a maximum safe exposure level. Drinking water HAs provide non-enforceable technical guidance to state agencies and other public health officials who have the primary responsibility for overseeing drinking water systems. The health advisory level for PFOA and PFOS offer a margin of protection for fetuses during pregnancy and breastfed infants as well as for all Americans throughout their life.

ATSDR's MRLs for PFOA and PFOS differ by an order of magnitude from the toxicity values that were derived by EPA in development of the drinking water HAs due to differences in the critical study selected (PFOA) and uncertainty factors applied (PFOS). Other health agencies may issue different values based on their own analyses, including more stringent values that may reflect more conservative assumptions. The EPA supports the efforts of other federal partners, including ATSDR, to develop information related to PFAS. The EPA continues to take concrete steps, in cooperation with our federal and state partners, to address PFAS and ensure all Americans have access to clean and safe drinking water. The EPA will continue to carefully review the draft ATSDR Toxicological Profile and will consider any information that may inform our approach to PFOA, PFOS, and other PFAS.

11. In your opinion, do the EPA guidelines meaningfully reduce risk to human health?

The EPA's health advisories are non-enforceable and non-regulatory and provide technical information to states agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. The EPA's health advisory level for PFOA and PFOS offers a margin of protection for all Americans throughout their life from adverse health effects resulting from exposure to PFOA and PFOS in drinking water.

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12. Based on the scientific evidence, do you think that the EPA guidelines set for PFOA and PFOS are health protective? Are they specifically protecting infants who are bottle fed with water from their contaminated home source or those who are breast fed where moms are drinking contaminated water?

Based on the available scientific evidence, the EPA believes the Health Advisory levels for PFOA and PFOS are protective of human health. These levels include margins of safety and consider sensitive individuals, including fetuses during pregnancy and breastfed and bottle-fed infants.

13. Do you think that the EPA drinking water guidelines should be developed for the suite of chemicals measured in the UCMR and not just for PFOA and PFOS?

The EPA will work with our federal, state, tribal, and local partners on response actions and research into the health and environmental impacts of these PFAS substances. The EPA is continuing to work to develop a PFAS Management Plan that will outline the Agency's approach to addressing the PFAS challenge.

14. The last drinking water standard EPA developed was way back in the 1990s and in fact was only a lowering of the arsenic standard. Does EPA have the person power and technical abilities to develop PFAS federal drinking water standards?

The EPA's technical experts are dedicated to assuring that National Primary Drinking Water regulations assure public health protection in accordance with SDWA. The EPA has promulgated a number of drinking water regulations that strengthen public health protection since the 1996 amendments to SDWA. These regulations, including those designed to reduce risks from arsenic, disinfection byproducts, radionuclides, and microbial pathogens that can come from a variety of sources including surface water, ground water and airplane drinking water systems, were developed in consultation with states, the EPA's National Drinking Water Advisory Council, the Science Advisory Board and/or other interested stakeholders.

Additionally, SDWA requires the EPA to regularly assess and evaluate unregulated contaminants. The EPA has published four Contaminant Candidate Lists, promulgated and implemented four Unregulated Contaminant Monitoring Regulations, and made regulatory determinations for 25 contaminants in accordance with SDWA. The EPA must also review each national primary drinking water regulation at least once every six years and revise them, if appropriate. As part of the "Six-Year Review," the EPA evaluates any newly available data, information and technologies to determine if any regulatory revisions are needed. Revisions must maintain or strengthen public health protection. The EPA's third Six-Year Review evaluated thousands of peer reviewed studies and millions of data points from drinking water treatment systems and was published in January 2017. The results of that review identified rules the EPA can evaluate whether to modify to strengthen public health protection in future years. This review ensures that existing rules are offering the maximum public health benefit feasible.

For more information about the timelines under which drinking water regulations were promulgated, please see https://www.epa.gov/sites/production/files/2015-10/documents/dw_regulation_timeline.pdf.

15. If so, how long would it take to develop and promulgate a standard?

Under the SDWA-mandated regulatory determination process, the EPA must consider three criteria when making a determination to regulate a contaminant:

- *The contaminant may have an adverse effect on the health of persons*
- *The contaminant is known to occur or there is a high chance that the contaminant will occur in public water systems often enough and at levels of public health concern*
- *In the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems*

When making a determination, the EPA first publishes a preliminary regulatory determination in the Federal Register (FR) and provides an opportunity for public comment. After review and consideration of public comments, the EPA would publish a final FR notice with the regulatory determination decisions. If the EPA were to make a final determination to regulate a particular contaminant, the Agency would start the rulemaking process to establish the National Primary Drinking Water Regulation (NPDWR). The SDWA requires that the EPA propose a regulation within 24 months of making a determination to regulate a contaminant, and to promulgate a regulation within 18 months of proposal (with an option of extending this time frame by up to 9 months).

The EPA believes the time frame allotted for promulgating drinking water regulations is appropriate because of the steps required under SDWA. As part of this process, the EPA reviews health effects data that the Agency would use to set a maximum contaminant level goal (MCLG). The MCLG is 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. Once the MCLG is determined, the EPA sets an enforceable standard, which is established as either a maximum contaminant level (MCL) or a "treatment technique." The MCL is the maximum allowed level of a contaminant in water which is delivered to any user of a public water system.

The EPA must consider feasibility of treatment and monitoring when selecting an enforceable limit. SDWA also requires the EPA to prepare a health risk reduction and cost analysis in support of any NPDWR. The EPA must analyze the quantifiable and non-quantifiable costs and benefits that are likely to occur as the result of compliance with the proposed standard. The EPA must determine if the benefits of the regulation justify or do not justify the costs. Finally, the EPA must consult with experts and stakeholders including the National Drinking Water Advisory Council and the Science Advisory Board. These analyses and consultations can take significant time but assure that state and local resources are focused upon the most important public health priorities.

16. How many people's health will be harmed in the time it takes to develop a national standard?

Protecting public health is the EPA's primary mission. The EPA will continue to carry out the requirements of SDWA in order to ensure that citizens across the United States continue to have safe and clean drinking water.

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17. When we know that very small amounts of PFAS can negatively affect health, why is EPA treating results below the UCMR minimum reporting levels (MRLs) [20 ppt PFOA; 40 ppt PFOS] as "zero"? Are they zero or are they levels that we need to be concerned about?

The HA for PFOS and PFOA is 70 ppt.

The EPA set the MRLs for UCMR 3 after looking at the performance of multiple laboratories that conducted studies to determine how low they could reliably measure the concentration of contaminants. To establish these levels, the EPA vetted those MRLs through the notice-and-comment UCMR 3 rulemaking. The EPA set the UCMR 3 MRLs such that we would have high confidence that a capable analyst/laboratory could meet those levels and report numeric results. Per the rule, no results below that level were reported.

The EPA is aware that some laboratories are able to reliably measure PFAS in drinking water at lower levels. The EPA advises states or others who may be leading the collection of PFAS data since the UCMR to consider establishing lower MRLs to meet any project-specific data quality objectives, provided the laboratories can demonstrate acceptable performance at the specified concentrations of interest.

18. The PFASs have been in commerce for tens of years. Can the Lautenberg Amendment to the Toxics Substances Control Act be used to require pre-market testing of all of the PFASs? What is preventing this from happening?

The EPA's new chemicals review program reviews all new PFAS chemicals intended for TSCA uses before they are allowed to commercialize and must make a determination regarding unreasonable risk of injury to health or the environment. The EPA reviews new substances to identify whether the range of toxicity, fate, and bioaccumulation issues that have caused past concerns with long-chain PFAS may be present, as well as any concerns that may be raised by new chemistries, in order to make an affirmative safety determination. In addition to being able to require testing under TSCA section 5(e), the EPA will also restrict uses pending development of additional information related to the chemical (e.g. testing), where appropriate. Whether and what type of testing may be necessary depends on a number of factors such as the specific uses of the new chemical, and the similarities or differences of the new chemical relative to other PFAS chemicals Many of the PFAS on the active TSCA inventory have been through the new chemical review described above, PFAS that were in use prior to the enactment of TSCA were not subject to such a review. Approximately 200 of the PFAS that have been through EPA's new chemicals program have an associated consent order. Most of those orders contain a requirement for testing if certain conditions are met. Of these, approximately 140 have commenced production.

19. Filtration is the currently feasible technology to remove PFAS from water. The filters that contain the PFAS are then disposed of. Where are they disposed of? Are these toxic? Does this mean that PFAS should be listed as Superfund chemicals and disposed of in hazardous waste facilities?

Currently available methods for removing certain PFAS from drinking water include granular or powdered activated carbon, anion exchange, or high-pressure membrane separation techniques including reverse osmosis or nanofiltration. These methods may generate PFAS-contaminated waste, which should be managed consistent with state, tribal, and local requirements and in a manner that will minimize the potential for environmental releases.

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The Resource Conservation and Recovery Act (RCRA) regulates hazardous waste disposal. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, aka Superfund) regulates the cleanup of hazardous substances released to the environment. All chemicals designated as RCRA hazardous waste are CERCLA hazardous substances, though not all chemicals designated as CERCLA hazardous substances are RCRA hazardous waste. The EPA is currently evaluating all statutory mechanisms available to address PFOA and PFOS.

20. PFASs are measured in waste water and in sewage sludge. Does this mean that PFASs are now in our rivers, streams and lakes? Are our fish contaminated? If yes, why is EPA not regulating discharge to waterways?

PFAS are very persistent and mobile in environmental media, including wastewater and sludge. Some evidence shows that certain PFAS have been accumulating in the environment and in wildlife (including fish). The EPA and states regulate discharges of pollutants to Waters of the United States under the National Pollution Discharge Elimination System. The EPA and states are evaluating approaches to ensure that PFAS discharges to the environment are minimized.

21. What is EPA's plan to further engage with the community in NH and get direct input from Granite Staters about PFAS contamination in their waters?

The EPA held a community engagement meeting in Exeter, NH in June 2018. The EPA received input from community members at this meeting as well as through a public docket, which closed on September 28, 2018. The EPA is continuing to work to develop a PFAS Management Plan that will outline the Agency's approach to addressing the PFAS challenge. The Agency is working to release the plan as soon as possible.

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