Tulane Institute on Water Resources Law & Policy

Per- and Polyfluoroalkyl Substances (PFAS):

Background Regarding the Environmental Protection Agency's Proposal to Regulate PFOA and PFOS

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I. Introduction

A. What are PFAS?

Per- and polyfluoroalkyl substances (PFAS) are a group of man-made, persistent organic pollutants that are known as "forever chemicals" because they do not break down and can accumulate over time, thus making them persistent in both the environment and in the human body.[2] The common characteristics of all PFAS are their structure and chemical composition.[3] That is, all PFAS are composed of fluorinated carbon chains that are attached to functional groups, such as carboxylic acids, sulfonic acids, alcohols, etc.[4] PFAS are typically described as long-chain or short-chain, depending upon the number of carbon atoms they contain.[5] Long-chain and short-chain PFAS occur as the result of manufacturing or the degrading of more complex PFAS.[6] This memorandum provides additional information on PFAS, including the

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[2] *PFOA, PFOS and Other PFASs: Basic Information on PFAS*, EPA.Gov, https://www.epa.gov/pfas/basic-information-pfas.

[3] Per- and Polyfluoroalkyl Substance (PFAS), AWWA.ORG, https://www.awwa.org/Portals/0/AWWA/ETS/Resources/Per-andPolyfluoroalkylSubstances(PFAS)-OverviewandPrevalence.pdf?ver=2019-08-14-090234-873.

[4] *Id.*

[5] *Id.* (Long-chain PFAS are those designated as perfluoroalkyl sulfonic acids containing ≥ 6 carbons, such as perfluorooctanoic acid (PFOA), and perfluoroalkyl carboxylic acids with ≥ 7 carbons. Short-chain PFAS are those with fewer carbons, such as perfluorobutanoic acid (PFBA)).

[6] *Id.*

prevalence of PFAS and health concerns surrounding PFAS contamination, as well as a discussion of the EPA's recent efforts to regulate certain PFAS. The aim is to provide background information for informed public comment regarding these efforts by the EPA.

B. Background

Since the 1940s, PFAS have been in use in the United States for industrial purposes, such as firefighting, oil production, and consumer uses, such as cosmetics and non-stick metal pans.[7] However, in light of health concerns surrounding PFAS contamination, which concerns are discussed more fully below, efforts have been made to address the prevalence of PFAS. For example, in 2006, in an effort to phase out the manufacturing of Perfluorooctanoic Acid (PFOA), which is one of the most prevalent types of long-chain PFAS, the Environmental Protection Agency (EPA) invited major leading companies in the PFAS industry to join the PFOA Stewardship Program[8] with two aims:[9]

> To commit to achieve, no later than 2010, a 95 percent reduction, measured from a year 2000 baseline, in both facility emissions to all media of perfluorooctanoic acid (PFOA), precursor chemicals that can break down to PFOA, and related higher homologue chemicals, and product content levels of these chemicals.
>
> To commit to working toward the elimination of these chemicals from emissions and products by 2015.

According to the EPA, all the participating companies achieved the goals of the PFOA Stewardship Program: some companies did so by discontinuing the manufacture and import of

[7] *PFOA, PFOS and Other PFASs: Basic Information on PFAS*, EPA.GOV, https://www.epa.gov/pfas/basic-information-pfas.
[8] The eight companies that participated in the PFOA Stewardship Program were Arkema, Asahi, BASF Corporation (successor to Ciba), Clariant, Daikin, 3M/Dyneon, DuPont, and Solvay Solexis.
[9] *Assessing and Managing Chemicals under TSCA: Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA*, EPA.GOV, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas#tab-3.

long-chain PFAS and transitioning to alternative chemicals, while some companies simply exited the PFAS industry.[10]

In addition to addressing the manufacture of PFAS in the country, the EPA has taken other steps to monitor the importation of PFAS into the United States. On January 21, 2015, EPA proposed a Significant New Use Rule (SNUR) under the Toxic Substances Control Act (TSCA) to require manufacturers, including importers, of PFOA and related chemicals to notify the EPA at least 90 days before starting or resuming new uses of these chemicals in any products.[11] Upon receiving notification and evaluating the use, the EPA can prohibit or limit the new activity.[12] The EPA subsequently narrowed this notification requirement on February 20, 2020 when the Agency proposed a supplemental SNUR under the TSCA.[13] Under the original SNUR, the notification requirement applied to all imported articles containing a listed PFAS, but the supplemental SNUR requires notification only if the article contains a listed PFAS substance in a surface coating.[14]

In addition to these federal actions, many individual states have taken actions to address PFAS contamination.[15] Most of the states that have addressed PFAS have centered their efforts around protecting drinking water. For example, Michigan adopted a groundwater maximum

[10] *Assessing and Managing Chemicals under TSCA: Fact Sheet: 2010/2015 PFOA Stewardship Program*, EPA.GOV, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program#meet.
[11] *Assessing and Managing Chemicals under TSCA: Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA*, EPA.GOV, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas.
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Per- and Polyfluoroalkyl Substance (PFAS)*, AWWA.ORG, https://www.awwa.org/Portals/0/AWWA/ETS/Resources/Per-andPolyfluoroalkylSubstances(PFAS)-OverviewandPrevalence.pdf?ver=2019-08-14-090234-873.

contamination level of 70 parts per trillion (ppt) for PFAS;[16] New Jersey adopted a drinking water contamination level of 14 ppt; and Vermont adopted a level of 20 ppt.[17] State efforts also include PFAS-related testing, such as a New York bill that requires the department of health to perform biomonitoring studies (i.e., to examine the prevalence of PFAS in people) and a Washington Department of Health effort to test water systems for traces of PFAS.[18] Despite such federal and state efforts, PFAS are still prevalent in the environment.

C. Effects of PFAS on Human Health

1. Methods of Exposure

People are exposed to PFAS in a variety of ways. For example, PFAS can make their way into drinking water supply, hence the previously discussed state efforts to address this problem.[19] Typically the PFAS that end up in drinking water supply come from specific facilities, such as manufacturers, landfills, wastewater treatment plants, and firefighter training facilities.[20] They can appear in food if the food was packaged in materials containing PFAS; processed with equipment that utilized PFAS; or grown in soil contaminated by PFAS.[21] People can also be exposed to releases of PFAS during the normal use, biodegradation, or disposal of consumer products that contain PFAS, such as carpets, leather and apparel, textiles, paper and packaging

[16] This is in line with the drinking water health advisory level of 70 ppt that the EPA has established regarding exposure to PFOA and PFOS from drinking water. *See Ground Water and Drinking Water: Drinking Water Health Advisories for PFOA and PFOS*, EPA.GOV, https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos.
[17] *Per- and polyfluoroalkyl Substances (PFAS) | State Legislation*, NCSL.ORG (March 11, 2020), https://www.ncsl.org/research/environment-and-natural-resources/per-and-polyfluoroalkyl-substances-pfas-state-laws.aspx.
[18] *Id.*
[19] *PFOA, PFOS and Other PFASs: Basic Information on PFAS*, EPA.GOV, https://www.epa.gov/pfas/basic-information-pfas.
[20] *Id.*
[21] *Id.*

material, and non-stick cookware.[22] Oftentimes, products like these have been treated commercially with PFAS to make them stain- and water-repellent or nonstick.[23] Additionally, from an occupational standpoint, people who work at facilities that produce PFAS or at facilities that produce goods made with PFAS are susceptible to breathing in air that has been contaminated by PFAS.[24] Given the prevalence of PFAS, most people have been exposed to them. In fact, one source asserts that PFAS are found in over 95 percent of people in the United States.[25]

2. Health Effects of PFAS Exposure

The most studied PFAS are PFOA and Perfluorooctanesulfonic Acid (PFOS). Studies indicate that PFOA and PFOS can cause reproductive, developmental, liver, kidney, and immunological effects.[26] Additionally, they have caused tumors in animal studies.[27] In human epidemiology studies, PFOA and PFOS have consistently led to increased cholesterol levels among exposed populations and, in more limited circumstances, low infant birth weights, effects on the immune system, cancer (for PFOA), and thyroid hormone disruption (for PFOS).[28] Due to their widespread use, PFAS pollution has become a pressing environmental and health problem across the country.

In terms of health concerns, persistence and bioaccumulation are pressing problems because long-chain PFAS, such as PFOA and PFOS, are highly stable and thus accumulate in both the

[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Per- and polyfluoroalkyl Substances (PFAS) | State Legislation*, NCSL.ORG (March 11, 2020), https://www.ncsl.org/research/environment-and-natural-resources/per-and-polyfluoroalkyl-substances-pfas-state-laws.aspx.
[26] *PFOA, PFOS and Other PFASs: Basic Information on PFAS*, EPA.GOV, https://www.epa.gov/pfas/basic-information-pfas.
[27] *Id.*
[28] *Id.*

environment and the human body. Long-chain PFAS have been found to have a bioaccumulation potential equivalent to other well-known contaminants like polychlorinated biphenyls (PCBs) and dichlorodiphenyltrichloroethane (DDT), which have a half-life in the human body that range from 6 to 10 years and 10 to 15 years, respectively.[29] By comparison, the half-life in the human body of certain long-chain PFAS, such as PFOS and perfluorohexane sulfonic acid (PFHxS), is upwards of 5 years.[30] Reversing long-chain PFAS exposure can be difficult due to slow elimination kinetics in humans, or alternatively, due to continuous environmental exposure. The realization that long-chain PFAS are so problematic is what led to the previously discussed PFOA Stewardship Program, which effectively eliminated production of long-chain PFAS in the United States.

Short-chain PFAS such as perfluorobutane sulfonate (PFBS), perfluorobutanoic acid (PFBA), and perfluorohexanoic acid (PFHxA), have been marketed as safer alternatives to long-chain PFAS and are widely used in both commercial and industrial settings. These include the popular Chemours trademarked Gen-X chemical, which is touted as a safe replacement of PFOA in the popular "Teflon" brand. One reason these are marketed as safer alternatives to long-chain PFAS is because data indicates that short-chain PFAS, like Gen-X, have a much faster elimination rate in humans compared to their long-chain counterparts. However, PFHxA is actually an exception and has a longer half-life in humans than PFOA and PFOS. Though bioaccumulation is less of a problem with most short-chain PFAS, this is not conclusive that short-chain PFAS should be considered a safer alternative. Moreover, short-chain PFAS are

[29] *Per- and Polyfluoroalkyl Substance (PFAS)*, AWWA.ORG, https://www.awwa.org/Portals/0/AWWA/ETS/Resources/Per-andPolyfluoroalkylSubstances(PFAS)-OverviewandPrevalence.pdf?ver=2019-08-14-090234-873.
[30] *Id.*

more water soluble than long-chain PFAS, thus having a lower potential for sorption to particles. As such, it is more difficult to remove short-chain PFAS from a water supply using technology such as granular activated carbon (GAC) filters, which is one of the most utilized and studied PFAS removal methods. For example, both PFBS and PFBA cannot be removed with GAC. GAC and other PFAS removal technologies also require disposal of highly contaminated concentrates, which is typically accomplished via high-temperature incineration. Because of the lack of removal technology and high potential for continuous exposure, some argue that short-chain PFAS, as well as additional long-chain PFAS, should be monitored and regulated as a group.

II. Recent EPA Actions Concerning PFAS

A. Announcement to Regulate PFOA and PFOS

On February 14, 2019, the Environmental Protection Agency (EPA) issued the "EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan," which provided short-term solutions and long-term strategies to address PFAS as an emerging chemical of concern.[31] Among the actions listed in the PFAS Action Plan were developing a maximum containment level for states and local water utilities via the Safe Drinking Water Act (SDWA); listing PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation and Liability Act; considering listing PFAS in the Toxic Release Inventory; and developing new and better methods to detect the chemicals in drinking water, soil, and groundwater.[32] In the "EPA PFAS Action Plan: Program Update" issued on February 26, 2020, the EPA included a summary

[31] *PFOA, PFOS and Other PFASs: EPA Actions to Address PFAS*, EPA.GOV, https://www.epa.gov/pfas/epa-actions-address-pfas.
[32] *Per- and polyfluoroalkyl Substances (PFAS) | State Legislation*, NCSL.ORG (March 11, 2020), https://www.ncsl.org/research/environment-and-natural-resources/per-and-polyfluoroalkyl-substances-pfas-state-laws.aspx.

of key actions the agency has taken since it issued the Action Plan.[33] The actions include announcing a supplemental proposal to ensure that new uses of certain persistent long-chain PFAS chemicals in surface coatings cannot be manufactured or imported into the United States without notification and review under the TSCA (as discussed above); developing new methods to accurately test for an additional eleven PFAS in drinking water; issuing interim recommendations for addressing groundwater contaminated with PFOA and PFOS; and issuing preliminary determinations to regulate PFOA and PFOS.[34] In this latter regard, on March 10, 2020, the EPA published an "Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List" in the Federal Register (hereinafter referred to as "Announcement").[35] The Announcement invited public comment on the EPA's proposal to regulate PFOA and PFOS, with a public comment deadline of June 10, 2020.

B. Safe Drinking Water Act Regulatory Process

The EPA's Announcement to regulate PFOA and PFOS came under the purview of the SDWA, which requires the EPA to make a regulatory determination on at least five unregulated drinking water contaminants every five years. The EPA chooses the unregulated contaminants from the Contaminant Candidate List (CCL), which the SDWA requires the EPA to publish every five years. The Contaminant Candidate List (CCL) filters through three phases. The first phase, known as the data availability phase, identifies contaminants that have sufficient health

[33] *PFOA, PFOS and Other PFASs: EPA Actions to Address PFAS*, EPA.GOV, https://www.epa.gov/pfas/epa-actions-address-pfas.
[34] *Id.*
[35] Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. 14098, 14098 (proposed Mar. 10, 2020) (to be codified at 40 C.F.R. pt. 141).

data to move on to the second phase, which is the data evaluation phase. During the data evaluation phase, the Agency identifies contaminants that are eligible for the third and final phase, the regulatory determination phase.

Even once a contaminant makes it to the aforementioned third and final phase, the regulatory determination phase, in order for the Agency to make a positive preliminary determination to regulate the contaminant, three statutory criteria must be met.[36] First, the data must show that the contaminant may have an adverse effect on the health of persons.[37] Second, the data must demonstrate that the contaminant is known to occur or that there is a substantial likelihood that it will occur in public water systems with a frequency and at levels of public health concern. Third, the EPA Administrator must determine that regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The EPA published the most recent CCL, which is the fourth CCL (CCL 4), in the Federal Register on November 17, 2016. Of the 109 contaminants contained in CCL 4, the Announcement includes preliminary regulatory determinations and supporting rationale for eight of the contaminants, namely PFOS, PFOA, 1,1-dichloroethane, acetochlor, methyl bromide (bromomethane), metolachlor, nitrobenzene, and Royal Demolition eXplosive (RDX). In the Announcement, the Agency has made the "preliminary determinations to regulate two contaminants (i.e., PFOS and PFOA) and not to regulate six contaminants (i.e., 1,1-

[36] *Id.* at 14106.
[37] On March 3, 2020 the EPA announced a Supplemental Notice of Proposed Rulemaking to its Strengthening Transparency in Regulatory Science proposed rule, which would require scientists disclose all their raw data, including confidential medical records, before the Agency could consider an academic study's conclusions. As of the date of this writing, the public comment period for the Supplemental Notice of Proposed Rulemaking to the Strengthening Transparency in Regulatory Science proposed rule has ended, but the Rule has not gone into effect. If the EPA does implement the Rule in the future, it will possibly affect this step of the SDWA regulatory evaluation process, i.e. the use of data to demonstrate that a contaminant may have an adverse effect on the health of persons.

dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene, and RDX)."[38] After the close of the public comment period, if the Agency decides that regulation is necessary, this will mark the beginning of the Agency's regulatory development process, not the end. Subsequently, the EPA will follow different analysis protocols to determine whether to promulgate a Maximum Contaminant Level Goal (MCLG) and a National Primary Drinking Water Regulation (NPDWR) regarding these contaminants.

C. Potential PFAS Regulatory Schemes

One issue presented in the Announcement is whether the EPA should regulate PFAS as a group or classification under the SDWA. The Agency requests comments on three potential regulatory schemes, namely whether to "1) evaluate each additional PFAS on an individual basis; 2) evaluate additional PFAS by different grouping approaches; and 3) evaluate PFAS based on drinking water treatment techniques."[39] Many scientists assert that PFAS should be regulated as a single class, rather than by individual compound, in order to account for the complex biological impact and numerous sub-classes of PFAS. Given that there are nearly 602 types of commercially active PFAS, a one-by-one regulatory scheme seems unrealistic and time-consuming.[40] However, industry and regulatory leaders advocate for the compound-by-compound approach due to logistical problems posed by regulating a class of chemicals. Additionally, proponents of this approach cite innovation concerns because a ban on PFAS could

[38] Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. 14098, 14098 (proposed Mar. 10, 2020) (to be codified at 40 C.F.R. pt. 141).
[39] Preliminary Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. at 14122.
[40] Preliminary Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. at 14122.

potentially eliminate chemicals necessary for essential products, such as firefighting foam or medical equipment.

Part of the motivation behind regulating PFAS as a class is the precautionary principle. One accepted definition of this principle is contained in Principle 15 of the Rio Declaration on Environment and Development, which states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[41] Some argue that the persistence of a chemical should indicate the pertinence of applying the precautionary principle in chemicals management.[42] For example, in the European chemicals regulation, REACH, designations of persistence, bioaccumulation, and toxicity are key classification tools in the regulatory scheme.[43]

Given the unique circumstances presented by these substances, leading scientists and environmental health experts advocate for the second regulatory approach proposed by the EPA, which is to evaluate additional PFAS by different grouping approaches.[44] Dr. Linda Birnbaum, Director of the National Health Institute of Environmental Health Sciences, is a proponent of this view as the "most prudent approach to protect public health." She proposes that understanding the cumulative effects of PFAS requires examining human health in the context of total lifetime exposure.[45] The European Environment Agency takes the view that regulation by individual

[41] Ian T. Cousins et al., *The precautionary principle and chemicals management: The example of perfluoroalkyl acids in groundwater*, 94 ENVIRONMENTAL INTERNATIONAL 331, 334 (2016). http://dx.doi.org/10.1016/j.envint.2016.04.044.
[42] *Id.*
[43] *Id.*
[44] Preliminary Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. at 14122.
[45] *Hearing on Examining the federal response to the risks associated with per- and polyfluoroalkyl substances (PFAS)*, Senate Committee on Environment and Public Works, 116th Cong. 13 (2019) (testimony of Linda

compound is not adequate to protect human health and is currently evaluating a proposal to establish a new "group limit" on PFAS of 0.5 μg/L (micrograms per liter), as well as limits for sixteen individual PFAS of 0.1 μg/L, in drinking water.[46] The EPA has recognized the limits of the compound-by-compound approach. Collaborating with the National Toxicology Program (NTP), the EPA recently developed a risk-based approach for conducting PFAS testing, which included constructing a targeted subset of 75 PFAS.[47] Even industry leaders have conceded that a category-based approach to chemical regulation is prudent, encouraging the EPA to identify the toxicological properties of different PFAS and prioritizing those that present more serious health impacts.[48] With input received during the public comment period concerning the EPA's Announcement to regulate PFOA and PFOS, the EPA will determine which approach to follow in future PFAS regulation.

III. Conclusion

Though the EPA and certain states have undertaken some efforts to address PFAS contamination, these aptly nicknamed forever chemicals persist in the environment. Hence, future action will be crucial to address the prevalence of PFAS and to prevent adverse health effects. In this effort, public input is crucial as the EPA continues to develop its strategy, and the

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Birnbaum, Director, National Institute of Environmental Health Sciences and National Toxicology Program). https://www.epw.senate.gov/public/index.cfm/2019/3/examining-the-federal-response-to-the-risks-associated-with-per-and-polyfluoroalkyl-substances-pfas.

[46] EUROPEAN ENVIRONMENT AGENCY, *Emerging chemical risks in Europe — 'PFAS'*, https://www.eea.europa.eu/themes/human/chemicals/emerging-chemical-risks-in-europe (last visited May 21, 2020).

[47] Grace Patlewicz et al., *A Chemical Category-Based Prioritization Approach for Selecting 75 Per- and Polyfluoroalkyl Substances (PFAS) for Tiered Toxicity and Toxicokinetic Testing*, ENVIRONMENTAL HEALTH PERSPECTIVES, January 2019, at 014501, 1. https://doi.org/10.1289/EHP3889.

[48] Jessica Bowman, *INSIGHT: With PFAS One-Size-Fits-All Isn't the Answer*, BLOOMBERG LAW (May 20, 2019, 5:00 AM), https://news.bloomberglaw.com/environment-and-energy/insight-with-pfas-one-size-fits-all-isnt-the-answer.

hope is that this memorandum serves as a starting point for public discourse. Regarding the Agency's above-discussed Announcement to regulate PFOA and PFOS and its proposed methods for regulating PFAS (i.e., on an individual basis, by different grouping approaches, or based on drinking water treatment techniques), the EPA set a public comment deadline of June 10, 2020.