

A Framework for Regulation of New and Existing PFAS by EPA

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Executive Summary: Per- and polyfluoroalkyl substances (PFAS) are a family of chemicals known to be both toxic and highly persistent in both the environment and in humans. Despite decades of widespread recognition among scientists that PFAS are an emerging public health threat, few actions have been taken by Congress or the US Environmental Protection Agency (EPA) until recently. PFAS are prevalent in a variety of industrial processes and consumer products, and the phaseout of “legacy” PFAS—mainly perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS)—has resulted in a proliferation of new PFAS whose identities, properties, toxicities, amounts, locations, and methods of disposal are unknown to the public and health researchers. We recommend that the unique threat posed by PFAS requires EPA to adopt a stringent regulatory framework. EPA should determine a formal definition for PFAS which would allow them to be regulated as a class instead of as individual compounds. PFAS in all new and existing applications should be further classified according to structure and use. PFAS should be evaluated for essentiality in each application and banned in nonessential cases. More stringent requirements for toxicity and degradability testing and reporting should be required, giving EPA additional risk information and incentivizing PFAS phaseout. In applications where PFAS are essential and non-substitutable, existing legislation governing hazardous materials should be applied to reduce the risk to human health and environmental quality.

I. Introduction

Per- and polyfluoroalkyl substances (PFAS) are a family of chemicals widely used in industry for their water- and grease-repellency, resistance to chemical degradation, and flame-retardance. However, since the late 1990s, it has become increasingly apparent that PFAS have broad toxicity (Hekster, Laane, and De Voegt 2003). Unfortunately, the same properties that make PFAS desirable in industrial applications and consumer goods also cause them to be highly persistent in the environment and to accumulate in human tissue (Suja, Pramanik, and Zain 2009). PFAS are a growing risk to public health, but the US

Environmental Protection Agency (EPA) has done little to stop the release of PFAS, nor have they required substantive research on the toxicities of new PFAS prior to use. In this paper, we discuss the policy mechanisms EPA could use to effectively regulate PFAS manufacturing and release.

i. Harmful effects of PFAS exposure

All known PFAS are believed to be toxic, even in low doses (Hurley et al. 2016). While this is true of many industrial chemicals, PFAS are uniquely dangerous because of their chemical inertness and poor water solubility, which prevents them from breaking down

in or leaving the human body, leading to bioaccumulation. As a result, even small PFAS exposures can cause long-term health problems. There are no known medical interventions to remove PFAS from the human body.

Researchers have linked PFAS exposure to a variety of health issues. According to the Agency for Toxic Substances and Disease Registry, certain types of cancer, developmental toxicity, endocrine dysfunction, liver toxicity, and immunotoxicity are linked to exposure to this family of chemicals (Chou et al. 2019). In addition, they found that PFAS interfered with liver, thyroid, and pancreatic function. Other epidemiological studies identify the immune system as a main target of PFAS toxicity (Corsini et al. 2012; Chang et al. 2016). PFAS have been linked to increases in testicular and kidney cancer in human adults (Barry, Winquist, and Steenland 2013). Recent studies have shown that PFOS affects antibody production in the rodent immune system at levels found in the general human population (Corsini et al. 2012). Liver malfunction (Gallo et al. 2012), hypothyroidism (Lopez-Espinosa et al. 2012), high cholesterol (Fitz-Simon et al. 2013; Nelson, Hatch, and Webster 2010), ulcerative colitis (Steenland et al. 2013), lower birth weight and size (Fei et al. 2007), obesity (Halldorsson et al. 2012), decreased immune response to vaccines (Grandjean et al. 2012), reduced hormone levels, and delayed puberty (Lopez-Espinosa et al. 2011) are also associated with PFAS exposure.

It is clear from the growing evidence that PFAS are toxic to humans. Moreover, a study conducted by the Centers for Disease Control and Prevention showed that toxic effects started to occur well below 70 parts per trillion (ppt), EPA's current advisory level for concentrations of PFAS (Chou et al. 2019). While more research is necessary, it is apparent that all PFAS are potentially harmful, and that any PFAS found not to be toxic are the exception rather than the rule.

ii. Structure, uses, and prevalence of PFAS

PFAS have become widespread in industry due to a unique combination of useful properties resulting from their general chemical structure. These properties are common to all PFAS known to be used industrially. The first is high resistance to oxidative degradation, which makes PFAS ideal for use in fire

retardants and chemically resistant coatings. Another property is their ability to form structured layers in a similar manner to soap, making them useful emulsifiers for firefighting foams and fluoropolymer manufacturing. These properties have given PFAS four main industrial uses:

- 1) flame retardants in consumer goods, including furniture
- 2) fire-resistant surfactants in firefighting foams
- 3) chemical-resistant coatings in packaging and goods
- 4) surfactants or precursors in some chemical processes

Prior to 2006, the most well-known industrial PFAS were perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). These “long-chain” (eight or more carbon) compounds have been the focal point of subsequent research, regulation, and environmental activism. They also remain the most pressing challenge for environmental PFAS remediation due to their long history of use and wide range of applications. PFAS have been commercially produced since the 1940s, but their use in consumer products dramatically expanded in the 1950s and 60s (3M n.d.). Emerging research about the dangers of PFOA and PFOS—and pressure from EPA—led to the voluntary phaseout of PFOA and PFOS by US companies starting in 2006 (US EPA 2018).

However, due to a lack of adequate regulations regarding use of PFAS, companies have substituted PFOA and PFOS with hundreds of new PFAS featuring slightly modified chemical structures and exhibiting similar properties: shorter carbon chains, polyfluorinated instead of perfluorinated chains, and more (Brendel et al. 2018). **Studies demonstrate that these modified PFAS have the potential to be equally as toxic as PFOA and PFOS.**

For example, the US Department of Health and Human Services National Toxicology Program is researching the toxicity of short chain PFAS and has determined that they are associated with the same liver and endocrine toxicities as long chain PFAS (National Toxicology Program 2020). Unfortunately, the sheer quantity of new PFAS and the obfuscation of information about their identities, use patterns, and prevalence in waste streams has made it

impossible for independent researchers to study them comprehensively.

PFAS contamination is known to be widespread in the environment, though it is mainly concentrated around chemical plants, airports, and military bases. While little research has been conducted on the demographics of PFAS exposure, PFAS contamination may disproportionately harm low income and minority communities due to their proximity to these sources (Johnston and Cushing 2020). PFAS remediation is challenging compared to remediation of other toxic chemicals. Most current remediation technologies rely on separation from water using activated carbon filtration or ion exchange resins. Destroying the captured PFAS requires incineration at extraordinarily high heat and generates hazardous gases that must be neutralized. These methods are expensive and are not effective for all PFAS (Bartell et al. 2018). The difficulty and high cost of removing PFAS from groundwater and drinking water points toward the need for stricter regulation of manufacturing, use, and environmental release.

iii. Federal PFAS regulatory landscape

Until very recently, PFAS have been largely unregulated at the federal level. As of late 2019, the only PFAS-specific action taken by EPA was the issuing of an advisory level for PFOA and PFOS of 70 ppt in drinking water. That action was criticized for having no enforcement mechanism, for only addressing two compounds, and for promulgating a maximum PFAS concentration that does not adequately protect human health. A wide variety of organizations, including the Natural Resources Defense Council (NRDC) (Olson 2018), the American Water Works Association (Mehan 2019), the Michigan Department of Environmental Quality (EGLE 2018), a coalition of fourteen state governors (Whitmer et al. 2019), and a profusion of environmental and health advocacy groups have pressed EPA in recent years to implement more PFAS-specific regulations.

EPA does regulate PFAS to some extent via the Toxic Substances Control Act (TSCA), which requires companies to provide EPA with a premanufacture notice (PMN) before using new chemicals. However, there are myriad problems with TSCA when applied to PFAS regulation. First, there are no published guidelines for what toxicological data companies

must supply to EPA in the PMN, nor for what is an acceptable level of toxicity. Companies are not required to look for evidence of harm from newly introduced chemicals (Michigan Environmental Council 2018). While they have the ability to block the use of new chemicals due to lack of toxicity information, EPA rarely does so, despite the fact that PFAS have been shown to be broadly toxic (Hekster, Laane, and De Voogt 2003).

There are also a number of cases in which companies can evade TSCA, notably through low volume exemptions, low release and exposure exemptions, and cases where the compound is a byproduct rather than a primary product of manufacture (Lerner 2018). **Companies can also use the screen of confidential business information to obscure key information from the public about compounds submitted to EPA**, including the chemical's identity, place(s) of manufacture, quantities produced, and environmental releases (Igrejas et al. 2016; Lerner 2018). In the case of process byproducts, companies are not even required to submit a PMN. These transparency issues have left the public, researchers, and EPA in the dark about the extent of PFAS contamination and its impacts.

In response to PMNs for some compounds that present a health risk, EPA has issued Significant New Use Rules (SNURs), which require companies to notify EPA before changing aspects of their process, or consent orders, which place restrictions on chemical usage (US EPA 2020a). However, the extent to which these measures actually protect human health is unclear. When the company DuPont filed a PMN for the PFOA replacement GenX, EPA allowed its manufacture and use under a consent order despite indications of toxicity (US EPA 2009). The consent order did not prevent DuPont from releasing enormous quantities of GenX into the Cape Fear River in North Carolina, in that case as a byproduct of fluoromonomer manufacturing (Hogue 2018b; Lerner 2018).

There are several pieces of existing legislation that could be relevant for PFAS regulation, but which have not been applied to date. For instance, the Safe Drinking Water Act is used by EPA to set standards for drinking water quality through non-enforceable maximum contaminant level goals (MCLGs) and enforceable maximum contaminant levels (MCLs) for

specific chemicals. While EPA has established MCLs for a variety of chemicals and microorganisms, there is no MCL for any PFAS, including PFOA or PFOS (US EPA 2019e).

The Clean Water Act created the National Pollutant Discharge Elimination System (NPDES) which regulates pollutant discharge into surface waters and requires companies to seek a permit for discharge of specific pollutants. While EPA maintains a Toxic Pollutants List to evaluate what pollutants are controlled by NPDES, PFAS are not included on the list, neither as a group nor as individual chemicals.

The Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or Superfund) are regulatory frameworks that could be used to list PFAS as hazardous materials. They require active and abandoned sites containing hazardous materials to be monitored through waste disposal and remediation. Importantly, RCRA has an established mechanism for publicizing disposal and remediation data, an essential element for transparency and accountability.

iv. Recent developments in PFAS regulation

The landscape for PFAS regulation at the federal level is changing rapidly at the present time. In response to pressure from states and advocacy groups, EPA released a **PFAS Action Plan** in February 2019 (US EPA 2019a). While the Action Plan is a step towards addressing the PFAS crisis, it has several shortcomings. First, most of EPA's proposed actions do not have explicit timelines and may take far longer to implement than desirable. Moreover, the actions continue to treat PFAS on a compound-by-compound basis; most actions relate only to PFOA and PFOS, while there are thousands of other PFAS (Hogue 2018a). Finally, while the Action Plan points to TSCA as a "gatekeeper" for new compounds, **it does not say how EPA will amend its approach to toxicity evaluations** in the future to ensure that new PFAS do not enter the market without a reasonable understanding of their toxicity. The PFAS Action plan demonstrates that EPA lacks even basic knowledge of the toxicities, exposure paths, and remediation options of these compounds, despite having approved hundreds of PFAS under TSCA since 2006.

Partly in response to the shortcomings of the PFAS Action Plan, a serious congressional push for controls on PFAS began in 2019. Several PFAS-specific items were included in the National Defense Authorization Act for Fiscal Year 2020 (NDAA) (US Congress 2019) and the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2020 (HR 1865, an appropriations bill funding EPA), passed at about the same time (*Further Consolidated Appropriations Act, 2020* 2019).

Many of the NDAA provisions specifically address PFAS release from firefighting foams used at air bases and apply primarily to the Department of Defense (DOD). The NDAA requires DOD to phase out the use of PFAS-based firefighting foams and rations packaging; monitor PFAS levels in the blood of military firefighters; and work with states to disclose, monitor, and remediate PFAS contamination in the environment resulting from DOD activities.

However, the NDAA does include a few provisions relating to EPA's regulatory duties. Under Section 7352, EPA is required to act on their own 2015 proposal to strengthen the SNUR for long chain PFAS. The amended SNUR will restrict the manufacture and import of a specified set of PFAS, including as part of products (US EPA 2015).

Additionally, Section 7351 of the NDAA amends TSCA to require EPA to gather records and information on PFAS production from every manufacturer that has produced PFAS since 2011. However, EPA's deadline for taking this action is January 1, 2023—a roughly three-year timeline for even notifying manufacturers of the reporting requirement.

Finally, the NDAA requires EPA to add a broad array of PFAS to the Toxics Release Inventory, one of the many lists EPA uses to track toxic compounds. The Toxics Release Inventory was established as a provision of the Emergency Planning and Community Right-to-Know Act (EPCRA) and is an open source for tracking the management of certain toxic chemicals. EPA has determined that the NDAA requirements apply to a total of 160 PFAS (US EPA 2020b). The NDAA includes a mechanism by which PFAS are automatically added to the Toxics Release Inventory after EPA's toxicity determination, though this could place a high testing burden on EPA and does not directly alleviate any existing concerns about EPA's

approach to making toxicity determinations. It also does not address the continued problem of key information being obscured as confidential business information, since the NDAA specifically gives EPA leeway to withhold such protected information from the Toxics Release Inventory at their discretion.

HR 1865 includes funding for several EPA activities related to PFAS, in addition to requiring that they report on their progress to Congress within a two-month timeframe (*Further Consolidated Appropriations Act, 2020* 2019). The bill provides funding for EPA to establish MCLs for PFAS under the Safe Drinking Water Act, designate PFAS as hazardous substances under CERCLA, and remediate PFAS in drinking water systems.

Together, these two pieces of legislation have major implications for EPA's regulatory approach to PFAS moving forward. They require that EPA acknowledge the toxicity of PFAS other than PFOA and PFOS, and on a faster timeline than the PFAS Action Plan would have required. The classification of PFAS as hazardous chemicals under CERCLA and EPCRA increases the pressure on EPA to take a stricter stance in applying TSCA restrictions in the manufacturing of new and existing PFAS. Moreover, EPA is required to revisit past assessments of PFAS toxicity, in the directives to amend their SNUR for long-chain PFAS and to gather information from manufacturers. Taken together, these acts are a major step forward in the federal response to PFAS contamination.

However, much more needs to be done to comprehensively address the continued danger to humans and the environment. Recent legislation has been limited in scope and insufficiently proactive while allowing long timelines for implementation. In the subsequent sections of this paper, we will propose changes to EPA's regulatory approach that arguably better address the unique and pressing challenges posed by PFAS.

II. Establishing a formal PFAS class definition for standardized regulatory action

Many researchers (Ellison 2018; Andrews 2019; Griefen et al. 2018) have recommended that any impactful regulation of PFAS will need to encompass all PFAS as a class rather than addressing them individually. We agree with these recommendations,

and many of our subsequent policy remedies rely on this step being taken. **The single most impactful action to streamline the implementation of PFAS regulation would be creating a formal class definition for the family of compounds.** Currently, regulations for PFAS address compounds on a case-by-case basis or refer to the family in vague terms. However, as stated in the introduction, the weight of evidence suggests that while PFAS vary significantly in exact structure and function, PFAS are universally toxic to some extent, and all pose the same problems of bioaccumulation and high resistance to degradation.

There are now more than 4,700 PFAS registered by the American Chemical Society (Hogue 2018a), making their individual regulation intractable. Moreover, at a Senate hearing in September 2018, Linda S. Birnbaum, Director of the National Institute of Environmental Health Sciences, commented that "additional compounds likely exist, formed when intentionally produced PFASs, especially polymers, break down in the environment" (Hogue 2018a). Due to these outstanding issues, scientists and government agencies are advocating a class approach to PFAS regulation (Wang et al. 2017; KEMI 2016). EPA and the National Toxicology Program have begun screening a range of PFAS compounds, and the structural information derived from future research can further inform the designation of the class and any subclasses (Patlewicz et al. 2019).

The argument leveled against a class approach is that each PFAS chemical has a different chemical structure, intended use, and environmental and health profile (Bowman 2019). However, there is precedent for EPA regulating a family of chemicals as a class, even when there is a lack of toxicity data pertaining to certain chemicals of the class. In 1998, EPA established an MCL for five haloacetic acid disinfection byproducts (HAA5), which are a byproduct of drinking water chlorination and associated with an increased risk of cancer (Griefen et al. 2018; US EPA 2019e). Due to the challenges surrounding the regulation of these individual chemicals separately, EPA determined that a group MCL for these compounds would better protect public health.

The NDAA for Fiscal Year 2020 makes some progress towards a class approach for PFAS. It directly lists a

broad array of PFAS for inclusion in the Toxics Release Inventory and adds to it all PFAS listed as active chemical substances in the TSCA inventory. In total, EPA has determined that 160 chemicals qualify for inclusion in the Toxics Release Inventory based on the NDAA (US EPA 2020b), far fewer than the 4,700 PFAS recognized by the American Chemical Society.

HR 1865, the 2020 appropriations bill described in Section I. *iv.* above, requires that PFAS be added to the CERCLA list of hazardous substances using Section 102 of that law. However, the appropriations bill does not define what PFAS should be included on the list, and it is unclear how EPA will interpret the requirement. A class definition for PFAS would clarify what compounds to include in CERCLA.

Several sections of the NDAA define a perfluoroalkyl substance as “a man-made chemical of which all of the carbon atoms are fully fluorinated carbon atoms” and define a polyfluoroalkyl substance as “a man-made chemical containing a mix of fully fluorinated carbon atoms, partially fluorinated carbon atoms, and nonfluorinated carbon atoms.” Elsewhere in the text, PFAS as a single group are defined as “perfluoroalkyl and polyfluoroalkyl substances that are man-made chemicals with at least one fully fluorinated atom” (US Congress 2019). We are concerned that—in addition to being contradictory—these rudimentary definitions misclassify many compounds, while they include many that would not normally be considered PFAS. As such, we cannot recommend the NDAA’s class definition of PFAS for general adoption.

We recommend that EPA, or a group of experts designated by EPA, should determine a considered, comprehensive definition of the PFAS class that accounts for all possible structural variations resulting in the chemical properties associated with PFAS toxicity and persistence. This definition would be standard for PFAS inclusion in a variety of statutes, replacing the current patchwork of lists and definitions in current and proposed law.

III. Classification of PFAS use cases

The extent to which PFAS provide a necessary function in their industrial uses varies considerably. This issue was previously addressed in the regulation of chlorofluorocarbons through the essential use paradigm. Scientists from the Global PFAS Science

Panel recently released an analysis of the essential use paradigm in the context of PFAS (Cousins et al. 2019). The panel groups existing uses into three classes: nonessential, substitutable, and essential.

In *nonessential* use cases, PFAS are not necessary for adequate performance of the product or process when accounting for the environmental and public health costs of the application. In many cases, these products or processes existed before incorporation of PFAS and could revert to earlier strategies.

In other cases where PFAS serve important roles, there is evidence that PFAS functionalities can be supplied by other, less toxic chemicals. Representative *substitutable* applications include textiles and food contact materials, where biodegradable polymers, silicones, and nonhazardous physical barriers are gaining market share (Schellenberger et al. 2019).

Lastly, there are still many *essential* use cases in which there is no appropriate substitute for PFAS. These include fluorinated pharmaceuticals (Zhou et al. 2016), medical and scientific instrumentation (Ebnesajjad and Khaladkar 2017), and industrial membranes. Banning PFAS in these use cases might threaten public health and safety. We will subsequently propose steps to ensure proper waste management and life cycle analyses of essential PFAS as well as incentives to shift more use cases from the essential to substitutable category.

i. Establishing a Federal Advisory Committee for PFAS essentiality review

Drawing the line between these three use categories could be done by EPA regulators with the input of impacted communities, consumers, industry, and independent scientists. **We recommend a Federal Advisory Committee be established by EPA for this purpose, subject to the transparency requirements and all other rules established in the Federal Advisory Committee Act.** This committee would need to quantify and categorize the major existing use cases of PFAS and make recommendations to EPA for classification of each case into nonessential, substitutable, or essential.

EPA has been previously criticized for not supplying sufficient data to justify chemical evaluations and classifications under TSCA, as in the recent case of

Pigment Violet 29 (PV29), which is suspected to be toxic and bioaccumulative, yet which was determined to be “safe” by EPA. In a June 2019 report, the TSCA Science Advisory Committee on Chemicals requested that EPA provide “an improved discussion on why available study data are adequate to reach the conclusions of ‘no unreasonable risk’ from exposure to PV29” (Peterson 2019). These transparency issues could be avoided by transferring the categorization duty to the Federal Advisory Committee.

The Federal Advisory Committee would require extensive data on PFAS use for its essentiality recommendations. To encourage industrial self-reporting, **we recommend that EPA establish a time-sensitive standardized system by which companies can notify EPA about PFAS already being used in the company’s product or process.** While EPA should have this information in the TSCA Chemical Substance Inventory, new reporting procedures will be needed to ensure all uses are covered and that EPA has complete and up-to-date information. Companies that fail to notify EPA of their use of PFAS would be subject to penalties proportional to their estimated economic benefit from nondisclosure. Since producers and industrial users of PFAS operating in the US would be subject to penalties for non-compliance, pressure would propagate up the supply chain to disclose the presence of PFAS in products.

ii. Ban on PFAS in nonessential applications

We recommend that EPA ban the manufacture, use, sale, and import of products and processes employing nonessential PFAS. This ban can be implemented quickly because no substitute chemical is required. Such aggressive action has significant precedent. For instance, methylene chloride, a solvent used as a paint stripper, was recently banned from consumer use by EPA due to acute toxicity hazards. The rule—which went into effect two months after it was announced—bans the import, processing, and distribution of methylene chloride for consumer use (US EPA 2019c). EPA has the authority to make this classification under TSCA section 6(a). Through more rigorous application of TSCA, EPA can eliminate the concern of continued PFAS release from nonessential uses.

IV. Standards for PFAS toxicity and degradability testing with EPA oversight

To promote the adoption of PFAS substitutes, EPA should adopt a regulatory framework which incentivizes PFAS phaseout by requiring adequate proof of safety by manufacturers, driving substitution with less toxic and more biodegradable compounds. Incentivizing PFAS substitution depends on multiple factors:

- transparent reporting processes which maintain the confidentiality needs of manufacturers
- the implementation of PFAS biotoxicity monitoring and biodegradability evaluations
- replacement with demonstrably nontoxic PFAS alternatives

The following standards for toxicity serve the dual purpose of protecting human health by gathering much-needed data about PFAS while also imposing a regulatory burden that will incentivize companies to transition away from PFAS in substitutable use cases.

i. Toxicity and biodegradability evaluations of new and current PFAS under TSCA

The lack of clear toxicity standards for PFAS during TSCA review results in the manufacture and eventual release of harmful chemicals (Singla, Sutton, and Woodruff 2019). Under TSCA, EPA requires that companies report whether chemicals used in their processes demonstrate human and/or environmental health risks. However, companies are not required to look for evidence of harm in their manufactured products or byproducts (Urbina 2013; Michigan Environmental Council 2018). **We recommend requiring that all new and current PFAS, and their manufacturing byproducts, be tested for evidence of harm through biotoxicity assay monitoring in addition to traditional chemical analyses.** EPA should have a clear set of guidelines for how to respond (through a SNUR or consent order) to an evidence of harm report in a way that is most protective of the public.

When evaluating whether a specific PFAS should be substituted, chemical properties such as toxicity and biodegradability are important to consider. A toxicity threshold can be established to evaluate whether essential PFAS compounds of known and unknown

identities should be replaced when possible. For companies, further analysis to determine the potential exposure to PFAS through their products should be conducted. Integrating this information will lead to a substantial risk assessment, which can help companies make final determinations on whether PFAS compounds are essential in their products. If the compounds are essential, companies must justify their use to EPA and to the FAC—as proposed in Section III—by presenting an adequate remediation plan which eliminates the risk of human and environmental exposure to these PFAS.

ii. Total toxicity assessments of industrial PFAS waste

When considering PFAS in waste effluents, regulating total toxicity of wastewater discharged from industrial sites rather than toxicities of known compounds may be valuable. To mitigate the time and resources necessary to conduct full toxicological assessments on PFAS, a low-cost, routine, PFAS-specific toxicological assay can be developed. **We recommend mandating that companies perform routine total toxicity assessments of wastewater (i.e., long-term and short-term exposure assays) to determine the relative health risk of water prior to discharge.** This approach will prevent companies from releasing toxic PFAS as industrial byproducts, even in cases where companies have not disclosed the presence of PFAS. We recommend that routine testing be conducted on-site with oversight by EPA. For cases in which companies do not have on-site laboratories, we recommend that wastewater samples be routinely sent to EPA labs using company funding.

We further recommend that EPA increase their research support for technologies capable of remediating PFAS and their degradation products in order to minimize the risk of exposure. Companies which are directly responsible for the emission of PFAS could be required to contribute funding for the development of these technologies, though determining the appropriate amount in each case would be challenging.

We also recommend that EPA create a standardized format to record companies' use of PFAS and results of the required tests, which will be automatically shared with environmental agencies in states where PFAS are being manufactured, used, or disposed of. Maintaining standardized records will allow

monitoring of the tested contaminants on a local, state, and national level.

iii. Considerations for implementation

The toxicity testing standards in this section should be implemented as soon as possible. New PFAS would be immediately subject to stricter toxicity evaluation. For PFAS in current use, EPA should implement a reasonable timetable for companies to gather needed toxicology data for individual compounds. Companies could then determine whether to begin carrying out testing or to substitute the current PFAS for non-PFAS alternatives before the first testing data is due to EPA. A short grace period may be necessary for toxicity assessments of wastewater, giving companies time to put the necessary testing infrastructure in place.

V. Application of the Clean Water Act, NPDES, and RCRA to PFAS use and disposal

For PFAS that have been identified for essential use, manufacturers must consider the entire process from manufacture to disposal. There are three stages in the process that need to be monitored: material production, waste transport, and waste disposal. A proper waste management plan must be developed for each stage of a process that uses or generates PFAS. Although TSCA has been used to regulate PFAS, it has many exemptions, including for byproducts and low volume production. These exemptions are particularly problematic for PFAS because the compounds persist in the environment and can be toxic even at very low doses. Fortunately, as detailed in the introduction, there are existing laws and policy tools which have not yet been applied to PFAS.

i. Using Clean Water Act and NPDES to reduce PFAS in drinking water

To regulate PFAS disposal in liquid waste, many states (including CA, CO, MA, MI, MN, NJ, and VT) have already implemented MCLs more stringent than EPA's health advisory of 70 ppt of combined PFAS (Bartell et al. 2018). **We recommend that EPA consider more recent toxicological studies and implement a lower MCL than its current health advisory, possibly as low as 2 ppt for combined PFAS.** Additionally, the accompanying MCLG should be 0 ppt. Congress has already set aside funds for this purpose—and mandated that EPA report on their progress in determining an appropriate MCL—in the

December 2019 appropriations bill (*Further Consolidated Appropriations Act, 2020* 2019).

While the direct burden of MCL compliance would fall on water utilities, the NPDES could be a tool for drastically reducing PFAS contamination at the source by requiring companies to seek a permit at the state level to discharge PFAS. A necessary prerequisite for a NPDES permit would be inclusion of the PFAS class on the Toxic Pollutant List, a first step which EPA should take immediately.

The NPDES also oversees the National Pretreatment Program, which sets standards for nondomestic facilities to treat their waste prior to discharge (US EPA 2019d). We recommend that EPA use the NPDES permit and National Pretreatment Program to reduce the burden of PFAS treatment on Water Resource Recovery Facilities and require manufacturers to treat some of the PFAS on-site. EPA will need to determine what standards of treatment are feasible for manufacturers compared to municipal Water Resource Recovery Facilities.

ii. Using RCRA for “cradle-to-grave” monitoring of PFAS

We recommend that waste containing PFAS be listed as a hazardous material under RCRA for more stringent monitoring of its production and disposal. This approach has been previously suggested by other groups (Stade 2019; Olson and Reade 2019). Doing so will require manufacturers to take a “cradle-to-grave” approach toward managing their PFAS production and regulate PFAS use and disposal in all stages of the PFAS lifecycle. RCRA regulates generators of the waste and operators of treatment, storage, or disposal facilities (TSDF) whether the waste is on or off the site of generation. It also requires generators to keep proper records of production and disposal, label products containing PFAS, and report levels of disposal. These requirements make RCRA a more stringent regulatory pathway than TSCA for managing PFAS that cannot be eliminated or substituted.

As with setting MCLs, EPA should carefully consider the limits that they set for allowable disposal at solid waste disposal facilities. In many cases, PFAS in leachate from landfills will need to be treated at Water Resource Recovery Facilities. The limit set by EPA should be low enough that Water Resource Recovery Facilities downstream will be able to meet

the MCL. We recommend that EPA assess the available information on PFAS toxicity—and new information gathered from the toxicity testing proposed in Section IV. *ii.*—to determine if current RCRA quantity limits are compatible with PFAS, and then set the quantity limits to be compatible with the proposed MCL.

RCRA also enables EPA to conduct regular inspections to evaluate whether treatment, storage, or disposal facilities or manufacturers are complying with regulations (US EPA OECA 2015). This would permit implementation of the toxicity testing standards proposed in Section IV. *ii.* without the need for new regulations. Furthermore, since EPA publicizes records on companies’ compliance with RCRA regulations (US EPA 2019b), there is already a mechanism to share information on local and regional PFAS emissions. This will incentivize companies to comply with RCRA agreements and allow individuals and state and non-governmental agencies to access data for research purposes (US EPA OECA 2016).

iii. Considerations for implementation

Due to the large regulatory burden proposed in this section, EPA will need to implement a staggered timetable for compliance, starting with a self-reporting deadline for companies to disclose current PFAS use and draft their essential use justifications. Further deadlines will be needed for establishment of record-keeping practices, inspection protocols, and infrastructure for PFAS capture and disposal under RCRA requirements.

During the “grace period” while PFAS emitters put systems in place to reduce their discharge, EPA should assist utilities and Water Resource Recovery Facilities in water testing and remediation such that they can comply with the new MCL as quickly as possible.

One consequence of PFAS regulation with RCRA is that many landfills will need to be regulated as treatment, storage, or disposal facilities. We recognize that it will be a challenge to list every landfill contaminated with PFAS as a designated treatment, storage, or disposal facility, but RCRA requires that EPA develop interim standards for existing infrastructure that cannot meet newer, stricter standards. To minimize the number of

treatment, storage, or disposal facilities that EPA needs to regulate, we propose that future disposal of waste containing PFAS be limited to designated landfills. Household hazardous waste disposal programs currently implemented at the state level can streamline this process. While new regulatory standards for landfills will pose a significant challenge for EPA, RCRA regulation of PFAS is an essential step for preventing further spread of PFAS in humans and in the environment.

VI. Conclusion

At present, EPA does not effectively regulate the manufacture and sale of PFAS other than PFOA and PFOS, both of which were voluntarily phased out by the companies that had been producing them. While EPA has broad authority to gather information about PFAS and restrict their manufacture and use, EPA has instead allowed thousands of new PFAS (OECD 2018) to pass through its regulatory process with little or no regulation. Moreover, EPA has not made a reasonable attempt to monitor the environmental release of PFAS.

Recent actions by Congress have begun to address some of the deficiencies in federal PFAS regulation, but more must be done. The PFAS Action Act, passed by the House of Representatives in January 2020, would be a major step forward if it is taken up and passed by the Senate. Additionally, we believe that our framework for PFAS regulation provides a comprehensive basis for halting the further release of these toxic compounds. Our recommendations would incentivize companies to reduce their use of PFAS by implementing reasonable barriers to manufacturing while not compromising either the companies' ability to protect their confidential business information or the use of PFAS in truly essential applications. No one knows the full scope of PFAS contamination in the environment, how quickly it is occurring and where, and what detrimental effects it will have on public health. We earnestly hope that EPA and those who oversee it will recognize that timely and forceful regulatory action is needed to minimize the risks posed by PFAS.

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