PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

To revoke the approval of approximately 600 per- and polyfluoroalkyl substances (PFAS) that were granted through low-volume or low-release and low-exposure exemptions to the premanufacture notice requirements of the Toxic Substances Control Act

SUBMITTED ON BEHALF OF:

Advance Carolina; Alaska Community Action on Toxics; BlueGreen Alliance; Buxmont Coalition for Safer Water; Clean Cape Fear; Defend Our Health; Democracy Green; Delaware Riverkeeper Network; Environmental Defense Fund; Environmental Working Group; Merrimack Citizens for Clean Water; Natural Resources Defense Council; PFOAProject NY; Safer Chemicals Healthy Families/Toxic-Free Future; Sierra Club; Union of Concerned Scientists

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October 13, 2022

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Via mail and e-mail

Michael Regan, Administrator
Michal Freedhoff, Assistant Administrator Office of Chemical Safety and Pollution Prevention
Denise Keehner, Director of the Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: Petition to revoke low-volume and low-release & low-exposure exemptions to the premanufacture notice requirements of the Toxic Substances Control Act for ~600 per- and polyfluoroalkyl substances

Dear Administrator Regan, Assistant Administrator Freedhoff, and Director Keehner,

Earthjustice, on behalf of the Petitioners,[1] submits this Petition requesting that the Environmental Protection Agency (EPA) revoke the approval of all per- and polyfluoroalkyl substances ("PFAS") granted through the low volume exemption ("LVE") or low release and low exposure exemption ("LoREX") to the pre-manufacture notice requirement under the Toxic Substances Control Act ("TSCA"). This Petition builds upon the April 27, 2021 Petition filed by Earthjustice on behalf of many of the same petitioners, which is incorporated by reference into the instant Petition. *See* Petition from Advance Carolina et al. to Michael Regan, Administrator, EPA (Apr. 27, 2021) (asking EPA to prohibit the use of certain exemptions to the premanufacture notice requirements of TSCA for PFAS),

[1] Petitioners are: Advance Carolina; Alaska Community Action on Toxics; BlueGreen Alliance; Buxmont Coalition for Safer Water; Clean Cape Fear; Defend Our Health; Democracy Green; Delaware Riverkeeper Network; Environmental Defense Fund; Environmental Working Group; Merrimack Citizens for Clean Water; Natural Resources Defense Council; PFOAProject NY; Safer Chemicals Healthy Families/ Toxic-Free Future; Sierra Club; and Union of Concerned Scientists.

https://earthjustice.org/sites/default/files/files/pfas_pmn_exemptions_petition_04-27-2021.pdf, (the "2021 Petition") attached as Exhibit A.[2]

INTRODUCTION

Pre-manufacture notice ("PMN") is a requirement under TSCA section 5 for the safety review of new chemicals. 15 U.S.C. § 2604(3).[3] PMN exemptions, if granted, allow EPA to forego full section 5 safety review of the chemical substance. Therefore, they are allowed only if EPA determines that the chemical "will not present an unreasonable risk" to humans or the environment. 15 U.S.C. § 2604(h)(4).

The weight of the scientific evidence, summarized in the 2021 Petition and updated in this Petition, is unequivocal that PFAS, even in very small quantities, pose a risk of cancers, immune system suppression, cardiovascular diseases, as well as human development harms and liver disease in children. *See infra* at 9–13 and 2021 Petition at 7–8, 13, 39. Cumulative exposure to PFAS increase the risks and disproportionately impact potentially exposed or susceptible subpopulations such as nursing mothers, women of reproductive age, and communities near where PFAS are manufactured, processed, used, and disposed of. *See infra* at 14–15.

This evidence is relevant to PFAS as a class based on the consensus view that all PFAS have the capability to exert similar, serious harm to human and environmental health, that all PFAS are highly persistent, that many PFAS are mobile in environmental media and are difficult

[2] The 2021 Petition asked EPA to amend regulations that create four exemptions from the PMN process—the LVE, the LoREX, the Byproducts Exemption, and the Polymer Exemption—to prohibit their use for PFAS.

[3] *See* discussion of the PMN process and the modifications in the 2016 TSCA reform law to ensure that dangerous chemicals do not enter commerce in the 2021 Petition at 17–20.

to contain once released, and that PFAS precursors[4] can transform into other PFAS in the environment, including long- and short-chain PFAS. As the federal government's own scientists have recognized, the entire class of PFAS is comprised of structurally similar compounds that scientists can "reasonably expect to act through the same pathways and have similar effects."[5]

As a result of the well-established harms that PFAS pose to human health and the environment, EPA cannot continue to conclude that PFAS "will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation"—the finding that is required for an LVE or LoREX application to satisfy TSCA. 15 U.S.C. § 2605(h)(4). By continuing to allow the manufacture and use of PFAS that have not undergone the full PMN review process, while simultaneously relying on ineffective voluntary programs that fail to meaningfully limit manufacture, processing, use and disposal of PFAS LVEs and LoREXs, EPA is violating TSCA, its own regulations, and the Administrative Procedure Act.

[4] PFAS precursors refer to larger PFAS and PFAS polymers that degrade via abiotic or biotic transformation in the environment to form terminal PFAS byproducts, including PFOS, PFOA, and other long- and short-chain PFAS. *See* Buck, R. C., Franklin, J., Berger, U., Conder, J. M., Cousins, I. T., de Voogt, P., Jensen, A. A., Kannan, K., Mabury, S. A., & van Leeuwen, S. P. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. *Integrated environmental assessment and management*, *7*(4), 513–541. https://doi.org/10.1002/ieam.258.

[5] *See Examining the Federal Response to the Risks Associated with Per- and Polyfluoroalkyl Substances (PFAS): Hearing Before the S. Comm. on Env't & Pub. Works*, 116th Cong. 2 (Mar. 28, 2019) (testimony of Linda S. Birnbaum, Dir., Nat'l Inst. Env't Health Sci. & Nat'l Toxicology Program, Nat'l Ins. Health); Wang, Z., DeWitt, J. C., Higgins, C. P., & Cousins, I. T. (2017). A Never-Ending Story of Per- and Polyfluoroalkyl Substances (PFASs)?. *Environmental science & technology*, *51*(5), 2508–2518. https://doi.org/10.1021/acs.est.6b04806.

STATUTORY AND REGULATORY FRAMEWORK FOR PMN EXEMPTIONS

TSCA's PMN requirement is designed to identify and protect against chemical substances that may present unreasonable risks.[6] A company intending to manufacture a new chemical substance must submit to EPA a PMN at least 90 days before the date it wishes to commence manufacture.[7] During this period, EPA must conduct a safety review for the new chemical through which it determines whether the chemical "presents an unreasonable risk of injury," "is not likely to present an unreasonable risk," or that the information available is "insufficient to permit a reasoned evaluation of the health and environmental effects." 15 U.S.C. § 2604(3).[8]

If EPA determines that the substance "is not likely to present an unreasonable risk," the chemical can enter commerce unrestricted. 15 U.S.C. § 2604(g). If the Administrator determines that the substance "presents an unreasonable risk," s/he must take actions "to the extent necessary to protect against such risk," including prohibiting or limiting its manufacture. 15 U.S.C. §§ 2604(a)(3), (f). EPA must also regulate the chemical if: it lacks information to make a reasoned evaluation; given that lack of information, determines that the chemical may present an unreasonable risk; or the quantities of manufacture or exposure to the substance may reach the "substantial" level. *See* 15 U.S.C. § 2604(e).

Under TSCA section 5(h)(4), EPA may "exempt the manufacturer of any new chemical substance from all or part of the [PMN] requirements." However, the statute expressly

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[6] *See* 2021 Petition at 17 n.65.

[7] *See* full discussion of the PMN process in 2021 Petition at 17–20.

[8] Since the 2016 amendments to TSCA, EPA's safety review must evaluate whether the chemical may pose an unreasonable risk to "potentially exposed or susceptible subpopulations," 15 U.S.C. § 2604(a)(3), and EPA must rely on the best available science and make decisions based on the weight of the scientific evidence, 15 U.S.C. §§ 2625(h), (i), when conducting those reviews.

conditions exemptions on a determination that the chemical "will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(h)(4). EPA's implementing regulations prohibit PMN exemptions if the chemical substance, its environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance "may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance: (1) [s]erious acute (lethal or sublethal) effects[;] (2) [s]erious chronic (including carcinogenic and teratogenic) effects[;] [or] (3) [s]ignificant environmental effects." 40 C.F.R. § 723.50(d).

EPA may revoke a previously granted LVE or LoREX "at any time" that it determines that the legal standard for an exemption is no longer met, even if the chemical is already in commerce. *See* 40 C.F.R. § 723.50(h)(2)(i)(A). Moreover, once EPA makes a "preliminary determination" that the chemical substance in question "does not meet the terms of the section," it *must* start the revocation process. *Id*. If EPA makes a final determination that manufacture of the new chemical substance does not meet the standards for a PMN exemption (after reviewing any objections from manufacturers), the manufacturer must submit a PMN or cease manufacturing the substance. 40 C.F.R. § 723.50(h)(2)(v), (vi).[9]

REASONS TO GRANT THIS PETITION

EPA has an ongoing duty to ensure that chemical substances that are approved through section 5(h)(4) PMN exemptions continue to meet the legal standards for such an exemption. If the agency preliminarily determines that the standard is no longer met, it must start the process

[9] Whether the manufacturer must cease manufacturing while the PMN is pending depends on whether EPA finds that it acted with due diligence and in good faith in meeting the requirements for PMN exemptions. 40 C.F.R. § 723.50(h)(2)(v), (vi).

of revoking the exemption and then, upon a final determination, require the manufacturer to go through the PMN process in order to continue manufacturing. As shown below, EPA cannot conclude that PFAS meet the "will not present an unreasonable risk"[10] standard because the weight of the scientific evidence establishes that PFAS "may cause" adverse effects.[11] Accordingly, EPA must revoke all PMN exemptions previously granted for PFAS.

A. EPA Has an Ongoing Duty to Consider Whether Previously Granted LVEs and LoREXs Meet the Legal Standard.

EPA has an ongoing duty to consider new scientific information about chemicals approved through PMN exemptions and to revoke exemptions if the legal standards are not met.

The duty is clear on the face of the agency's regulations establishing the LVE and LoREX. Under 40 C.F.R. § 723.50(h), there are two distinct time periods in which EPA must notify a chemical manufacturer if it determines or believes that a substance is not eligible for a PMN exemption: a) "during the [initial] review period," 40 C.F.R. § 723.50(h)(1), and (b) "at any time after the [initial 30-day] review period," 40 C.F.R. § 723.50(h)(2)(i)(A). Implicit in the fact that EPA must notify a manufacturer "at any time after the [initial] review period," *id*., if it determines that a previously-granted exemption no longer meets the legal standard, is that EPA must continue to evaluate chemicals' eligibility for PMN exemptions in light of new information.

This duty to consider new scientific information is also evident from EPA's recognition that ongoing revocation authority is foundational to the LVE and LoREX exemptions being permissible under TSCA section 5(h)(4). When EPA adopted the LVE, and then the LoREX, it explained that the ongoing duty to consider whether previously granted LVEs and LoREXs continue to meet the legal standard is a critical safeguard against unreasonable risk, which is

[10] 15 U.S.C. § 2604(h)(4).

[11] 40 C.F.R. § 723.50(d).

foundational to the very legality of the exemptions. In particular, at the time EPA adopted the LVE, it described revocation as the "most important" safeguard against unreasonably risky chemicals being approved through this exemption. Premanufacture Notification Exemption; Exemption for Chemical Substances Manufactured in Quantities of 1,000 Kg or Less Per Year, 50 Fed. Reg. 16,477, 16,487 (Apr. 26, 1985). It explained that the authority to revoke based on new scientific evidence "ensure[s] that eligibility for the exemption will be determined on the basis of the best available information, regardless of when the information becomes available." *Id*.; *see also id*. at 16,478 (stating that safeguards, most significantly the safeguard of revocation, are necessary because the agency "determined that it could not reduce the procedural safeguards in the rule and still make the finding of no unreasonable risk [for a given PMN exemption]."). *Id*. The agency assured commenters who were concerned about dangerous chemicals entering commerce through the exemption that it "will revoke an exemption if new information indicates that the chemical substance does not meet the criteria for an exemption." *Id*.; *see also id*. at 16,487 ("[T]he rule establishes procedures for revocation of the exemption if EPA later determines that the substance does not meet the conditions of the exemption.").

Ten years later when EPA adopted the LoREX, it continued to describe revocation-in-light-of-"new information" as the "[m]ost important" safeguard against unreasonable risk, even in the face of industry criticism that revocation would cause "business interruptions and loss of credibility with customers." Premanufacture Notification Exemption; Revision of Exemption for Chemical Substances Manufactured in Small Quantities; Low Release and Exposure Exemption; Final Rule, 60 Fed. Reg. 16,336, 16,346 (Mar. 29, 1995). It stated that the exemption rules "will ensure that eligibility for and *continuation of the exemption will be determined on the basis of the best available information*, regardless of when the information becomes available." *Id.* at 16,346

(emphasis added). In sum, EPA has repeatedly affirmed its duty to reconsider and revoke PMN exemptions based on new information.

Finally, EPA also has a general duty to consider new scientific information that may bear on whether the agency's past decisions or standards are health-protective, and to modify past decisions to ensure legal requirements are met. For example, in another TSCA context, the Ninth Circuit Court of Appeals has twice held that EPA has an ongoing duty to account for new scientific information regarding the level of lead that presents a hazard, whenever that information becomes available. *See A Cmty. Voice v. EPA*, 997 F.3d 983, 993-94 (9th Cir. 2021) (finding that EPA had "ongoing" duty to use new information to update lead hazard standards under TSCA subchapter IV to "account for new information and modify initial standards when necessary to further Congress's intent") (internal quotation omitted); *In re A Cmty. Voice*, 878 F.3d 779, 784 (9th Cir. 2017) (same).

Courts have similarly ruled that scientific advances compel revision of rules and standards that are intended to be health protective in other contexts too. For example, in *Pub. Citizen Health Rsch. Grp. v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983), a citizen group sought a court-ordered deadline for the Occupational Safety and Health Administration ("OSHA") to lower the permissible exposure limit for ethylene oxide ("EtO"). The governing statute there did not explicitly compel OSHA to take the regulatory action sought, but the D.C. Circuit nevertheless ordered the agency to issue a proposed rulemaking within thirty days, noting the "obvious need, apparent to OSHA, for an EtO standard that reflects, as the current standard does not, the mutagenic and carcinogenic potential of the chemical" revealed by studies over the previous decade. *Pub. Citizen Health Rsch. Grp.*, 702 F. 2d at 1154; *see also In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1150 (D.C. Cir. 1992) (finding that OSHA must exercise its

authority to revise permissible exposure limit for cadmium where new science shows that a lower standard "is necessary to workers' well-being").

For these reasons, EPA cannot exempt chemicals from the PMN process "and then walk away"; rather, it has an ongoing duty to "account[] for new information," and "modify" its prior actions "when necessary to further Congress's intent."[12] *In re A Cmty. Voice*, 878 F.3d at 784. Here, EPA has an ongoing duty to ensure that PFAS approved through PMN exemptions meet the TSCA section 5(h)(4) standard, and to take action if they do not.

B. Based on the Scientific Evidence About PFAS As a Class, EPA Must Determine That PFAS Do Not Meet the Legal Standard for PMN Exemption.

The weight of the scientific evidence makes it impossible for EPA to conclude that PFAS "will not present an unreasonable risk of injury to health or the environment,"[13] and compels the conclusion that the presence of PFAS in the environment at the threshold levels expected from chemicals subject to LVEs and LoREXs "may cause" unreasonable risk to human health and the environment, precluding the lawful continuation of a PMN exemption.[14]

1. The weight of the scientific evidence demonstrates that PFAS may cause harm. [15]

In the 2021 Petition, we described the extensive scientific evidence demonstrating that PFAS do not meet the legal standards for a PMN exemption. This evidence shows that PFAS exert serious harm to human and environmental health, are highly persistent and mobile in

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[12] Congress intended that no chemical would enter or remain in commerce without going through PMN review unless the science demonstrates that "the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use." 15 U.S.C. § 2604(h)(4).

[13] 15 U.S.C. § 2604(h)(4).

[14] *See* 40 C.F.R. § 723.50(h)(2)(i)(A); *id.* at § 723.50(d).

[15] In this section, citations appear as endnotes rather than footnotes.

environmental media, and have a tendency to undergo abiotic- or biotic transformation into other PFAS, including long-chain PFAS like PFOA and PFOS, and short-chain PFAS (3-6 fluorinated carbons), like PFBA, PFHxA, PFPeA, and GenX,[a] which have all been associated with serious health harms.[b] *See* 2021 Petition at 7–16.

Collectively, the dozens of peer-reviewed studies published in the last year further underscore what was established in the 2021 Petition—that all studied PFAS are linked to adverse health outcomes—and expand the list of adverse health outcomes resulting from PFAS exposure, even at low levels. In just over the past year, more than 40 new peer-review studies were published citing associations between PFAS exposure and liver toxicity,[c] metabolic toxicity,[d] developmental toxicity,[e] reproductive toxicity,[f] immunotoxicity,[g] cancer,[h] thyroid disruption,[i] epigenetic alterations,[j] and ecotoxicity.[k] This new body of scientific evidence largely corroborates and adds to the weight of the scientific evidence for a number of established PFAS related outcomes, including kidney and testicular cancers,[l] suppression of the immune system,[m] hypertension,[n] and increased cholesterol.[o] For example, a recent *in vitro* toxicity screening study examining over 200 cancer-related cellular outcomes for 23 PFAS found that the majority of the examined PFAS were associated with at least one cancer-related outcome, expanding the number of PFAS potentially linked to cancer.[p] Recent epidemiological studies also linked *in utero* PFAS exposures to motor and adaptive impairments in infants[q] and an increased risk of liver injury associated with non-alcoholic fatty liver disease in children,[r] a disease that is now estimated to affect up to 1 in 10 children living in the United States.[s]

These newer studies also link adverse health effects in both humans and wildlife to "environmentally-relevant" PFAS exposures, or low-dose PFAS exposures that reflect exposures

occurring from the environment. For example, several recent human birth cohort studies cited associations between environmental PFAS exposures during pregnancy and serious adverse health outcomes, including: an increased risk of gestational diabetes and altered glucose levels in pregnancy;[t] and altered levels of thyroid hormones in pregnant mothers[u] and newborns.[v] In an epidemiological study involving Swedish women aged 20-50 years, high levels of exposure to certain PFAS through drinking water was associated with a higher likelihood of developing polycystic ovarian syndrome.[w] Recent animal studies are consistent with and expanded upon the reproductive and developmental harm seen in humans. For example, exposure to an environmentally-relevant PFAS mixture containing 10 unique PFAS during pregnancy in rabbits was associated with a number of adverse developmental and reproductive effects, including maternal weight gain, kidney damage, and placental malformations.[x]

Environmentally-relevant PFAS exposures have also been linked to harmful effects in wildlife that are similar to those seen in humans and laboratory animals, including immunotoxicity and thyroid disruption. For example, a recent study found that a perch population from a lake in Sweden contaminated with PFAS had lower levels of white blood cells and lower circulating levels of a thyroid-related hormone compared to perch from a non-contaminated reference site.[y] Another recent study linked plasma PFAS concentrations in nestling peregrine falcons from the Laurentian Great Lakes Basin in Ontario with altered levels of thyroid hormones and impaired immunity.[z] In Western honey bee colonies, low-dose PFOS exposures increased mortality, prevented brood development, and negatively impacted colony-related behaviors, including overall colony activity, hive maintenance, and hive defense.[aa]

To reflect the growing body of scientific evidence underscoring the toxicity of and exposure to PFAS, federal agencies recently updated hazard assessments and/or Health Advisory

Levels ("HALs") for several well-studied PFAS. For example, in May 2021, the Agency for Toxic Substances and Disease Registry strengthened its Toxicological Profile for 12 perfluoroalkyl compounds, citing substantial evidence for their associated cardiovascular toxicity, hepatic toxicity, immunotoxicity, reproductive toxicity, developmental toxicity, and carcinogenicity and a number of associated adverse health outcomes, including pre-eclampsia, liver injury, elevated cholesterol, immunosuppression, decreased birth weight, neuro-developmental harm, impaired mammary gland development, postnatal mortality, and renal injury.[bb] The updated Toxicological Profile also increased the number of PFAS that have been determined to suppress antibody response in humans by adding PFHxS and PFDA to this grouping.

In October 2021, EPA established subchronic and chronic reference dose values for GenX, a short-chain replacement compound for PFOA, based on the mounting scientific evidence demonstrating that exposure to GenX is associated with many of the same health effects as PFOA, including liver, developmental, and immuno-toxicity.[cc] In June 2022, EPA subsequently updated its drinking water HALs for PFOS and PFOA based on the growing body of evidence that these substances pose extreme danger to human and environmental health. The new HALs for each compound are 3,500 and 17,500 times lower, respectively, than previous levels established by the agency.[dd]

EPA has recognized that the standards applicable to PFOS and PFOA can serve as guideposts from which the risk posed by other PFAS should be evaluated. EPA recently proposed a hazard-index ("HI") approach to assessing the noncancer risk of PFAS mixtures in water containing PFOS, PFOA, PFBS, and/or GenX, with an HI value greater than 1 indicating "an exceedance of the health protective level" and "potential human health risk for noncancer effects from the PFAS mixture in water."[ee] Based on the new HALs for PFOS and PFOA, EPA

concluded that "any detectable level of PFOA or PFOS will result in an HI greater than 1 for the whole mixture."[ff] In the Federal Register notice announcing the HALs, EPA notes that it based the new advisory levels on known health impacts of PFAS, which include harms to the "immune system, the cardiovascular system, human development (e.g., decreased birth weight), and cancer." Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances, 87 Fed. Reg. 36,848, 36,849 (June 21, 2022). These effects are the same as those researchers have recently identified for PFAS as a category of chemicals. *See supra* at pages 10–11 and 2021 Petition at 7–9, 15–16.[gg]

2. EPA cannot conclude that PFAS exposure levels allowed by the LVE and LoREX "will not present an unreasonable risk."

In light of the science on the toxicity of PFAS at extremely low levels, the levels of PFAS that are likely to enter the environment under the LVE and LoREX regulations, and the persistence of every substance in this class, EPA cannot conclude that PFAS LVEs and LoREXs "will not present unreasonable risk. . . including . . . to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2605(h)(4).

EPA has acknowledged that it expects chemicals entering commerce through both the LVE and LoREX exemptions to result in contamination levels far in excess of what are now thought to be safe levels for PFAS (though even these may turn out to be unsafe). For example, EPA estimated that chemical manufacturing up to the LVE threshold of 10,000 kilograms per year of a chemical substance would result in releases of the chemical substance corresponding to a concentration of 500 to 5,200,000 parts per trillion (ppt) in surface water. 60 Fed. Reg. at 16,343. But concentrations in that range would correspond to very dangerous levels of PFAS in drinking water. EPA's recently adopted HALs for drinking water for four PFAS identified 0.004 ppt for PFOA, 0.02 ppt for PFOS, 10 ppt for GenX and 2,000 ppt for PFBS as the "concentration

of chemicals in drinking water at or below which adverse health effects are not anticipated to occur." 87 Fed. Reg. at 36,848. In other words, EPA has determined that one or more of these PFAS could present risk in drinking water at levels up to 1.3 billion times lower than the level of surface water contamination permitted for chemicals approved through LVEs and LoREXs.

Moreover, as noted above, these and other related PFAS are terminal breakdown products of PFAS precursors that undergo abiotic or biotic transformation in the environment. This means that the release of PFAS precursors that are approved through LVEs and LoREXs could result in the presence in the environment of terminal PFAS breakdown products that are known to be toxic at very low levels. Because this transformation can occur as a result of many conditions of use of precursor PFAS—including manufacturing, processing, use, and disposal of precursors[16]— EPA cannot continue to conclude that PFAS approved through TSCA section 5(h)(4) exemptions "will not present an unreasonable risk" to human health or the environment.

When considering the ongoing validity of a PMN exemption for PFAS, EPA must also take into account the risks that exposure to PFAS may pose to "potentially exposed or susceptible subpopulation[s]." 15 U.S.C. § 2604(h)(4). The 2021 Petition provided substantial evidence that certain subpopulations are more vulnerable to the adverse health effects of PFAS exposure; these include occupational workers, firefighters, communities living in polar regions, nursing mothers and women of childbearing age, children, infants, and the developing fetus. *See*

[16] *See, e.g.,* Buck et al, 2011; Schlummer, M., Sölch, C., Meisel, T., Still, M., Gruber, L., & Wolz, G. (2015). Emission of perfluoroalkyl carboxylic acids (PFCA) from heated surfaces made of polytetrafluoroethylene (PTFE) applied in food contact materials and consumer products. Chemosphere, 129, 46–53. https://doi.org/10.1016/j.chemosphere.2014.11.036; Kwiatkowski, C. F., Andrews, D. Q., Birnbaum, L. S., Bruton, T. A., DeWitt, J. C., Knappe, D., Maffini, M. V., Miller, M. F., Pelch, K. E., Reade, A., Soehl, A., Trier, X., Venier, M., Wagner, C. C., Wang, Z., & Blum, A. (2020). Scientific Basis for Managing PFAS as a Chemical Class. Environmental science & technology letters, 7(8), 532–543. https://doi.org/10.1021/acs.estlett.0c00255.

2021 Petition at 12–14. LVEs and LoREXs for PFAS would likely result in concentrations of PFAS in humans and the environment that would disproportionately harm these subpopulations. 2021 Petition at 33–36. This is especially so considering their cumulative exposure to multiple PFAS. [17] Moreover, the communities where a toxic chemical is manufactured, used, and disposed are potentially exposed or susceptible subpopulations, as they face greater exposures to the chemical and often more susceptibility to harm based on their cumulative exposures to multiple chemicals and non-chemical stressors.[18] EPA did not consider risks to potentially exposed or susceptible subpopulations when it granted PFAS LVEs and LoREXs (at least prior to 2016 and likely since then[19]), which further undermines the ongoing validity of PFAS LVEs and LoREXs.

3. Any scientific uncertainty underscores that no PFAS are eligible for PMN exemptions.

EPA has acknowledged that "exposure to different PFAS can lead to a variety of health effects,"[20] and that "[r]esearchers are working to better understand *how* toxic or harmful PFAS

[17] EPA recognizes the potential for cumulative risk. *See* EPA, *PFAS Strategic Roadmap; EPA's Commitments to Action, 2021-2024* (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf, at 8 ("EPA will also collect more data and develop new methodologies to understand … to what extent PFAS pollution contributes to the cumulative burden of exposures from multiple sources in these communities"); *id*. at 15 ("Tribes and states use EPA-recommended water quality criteria to develop water quality standards to protect and restore waters, issue permits to control PFAS discharges, and assess the cumulative impact of PFAS pollution on local communities.").

[18] *See* 2021 Petition at 47–48 (explaining that exposure to multiple PFAS may present additional risks on top of those presented by one but EPA did not consider that when approving LVE or LoREX for PFAS).

[19] Given the secrecy surrounding the process of approving chemicals through PMN exemptions, we do not know if EPA considered susceptible subpopulations after 2016. *See* 2021 Petition at 20–21.

[20] EPA, *Our Current Understanding of the Human Health and Environmental Risks of PFAS*, PFOA, PFOS and Other PFAS, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas (last updated Mar.16, 2022).

are to people and the environment"[21]—not *whether* they are toxic. Any uncertainties about the risks presented by PFAS only underscores that the agency lacks the evidence needed to conclude that PFAS "will not present an unreasonable risk," as required for LVEs and LoREXs.

Indeed, this was precisely the conclusion EPA reached in 2010 when it determined that it could "no longer make the determination that the manufacturing, processing, distribution in commerce, use, or disposal of polymers containing PFAS…. 'will not present an unreasonable risk to human health or the environment'… as required under TSCA section 5(h)(4)," and therefore revoked the polymer exemption for PFAS as a class.[22] Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers, 75 Fed. Reg. 4,295, 4,296 (Jan. 27, 2010). EPA explained that revocation was necessary because it had "received information which *suggests* that polymers containing [many] PFAS. . . *may* degrade and release fluorochemical residual compounds into the environment [that] . . . are expected to persist in the environment, *may* bioaccumulate, and *may* be highly toxic." *Id*. (emphases added).

The evidence is only stronger now, twelve years later, that all PFAS (or their transformation products or byproducts) are persistent, may bioaccumulate and may be toxic.

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[21] EPA, *Increasing Our Understanding of the Health Risks from PFAS and How to Address Them*, PFOA, PFOS and Other PFAS, https://www.epa.gov/pfas/increasing-our-understanding-health-risks-pfas-and-how-address-them (last updated Nov. 3, 2021).

[22] EPA's revocation of the polymer exemption applied only to PFAS where the perfluoroalkyl moiety is bound to either a carbon or sulfur atom that is an integral part of the polymer molecule. *See* 40 C.F.R. § 723.250(d). As discussed in the 2021 Petition at 52–53, this definition is unclear and not consistent with the most current scientific definition of PFAS, and should be revised to make clear that PFAS encompass any substance that is defined by having at least one perfluoroalkyl moiety, or a carbon atom from which all bonded H atoms have been replaced with F atoms.

Moreover, the most common means of disposing waste do not safely destroy or contain PFAS.[23] This means that even if controls are adopted that prevent PFAS from entering the environment during manufacture and use (which is doubtful), PFAS often enter the environment when they, or the products containing them, are disposed.[24] As a result, PFAS "may cause" health or environmental effects under their known or reasonably seen conditions of use, making them ineligible for LVEs or LoREXs under EPA's regulations. 40 C.F.R. § 723.50(d); *Id.* at § 723.50(h).

In sum, any uncertainties about risks posed by PFAS only serve to confirm that the "will not present unreasonable risk" standard for PMN exemptions cannot be satisfied.

C. EPA Must Revoke Previously Granted LVEs And LoREXs For PFAS as a Class.

As shown above and in the 2021 Petition, EPA has ample scientific evidence that under known, intended, and reasonably foreseen condition of use, including disposal, PFAS "may cause" harm to human health and the environment in violation of 40 C.F.R. § 723.50(d), meaning that PFAS do not meet the "will not present an unreasonable risk" standard required for chemicals exempted from the PMN process under TSCA section 5(h)(4).

Indeed, EPA has effectively already made this determination. Eighteen months ago, EPA announced that going forward PFAS are "unlikely to be eligible" for LVEs, and that it "generally expects that … LVE submissions for PFAS would be denied."[25] EPA explained that given the

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[23] Stoiber, T., Evans, S., & Naidenko, O. V. (2020). Disposal of products and materials containing per- and polyfluoroalkyl substances (PFAS): A cyclical problem. *Chemosphere*, *260*, 127659. https://doi.org/10.1016/j.chemosphere.2020.127659.

[24] *Id*.

[25] Press Release, EPA, EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market (Apr. 27, 2021), https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market.

"scientific complexities" associated with assessing PFAS, and "the hazard potential associated with various sub-classes of PFAS," EPA could not "conduct an appropriately robust review" for an LVE request for a PFAS within the 30 days specified by regulation.[26] Accordingly, EPA expressed an "expect[ation]" of denying future LVE submissions for PFAS so it will have "additional time to conduct a more thorough review through the pre-manufacture notice review process and, as appropriate, put measures in place to mitigate the potential risk of these chemicals . . . ."[27] If —as EPA has stated—PFAS will not be eligible for LVEs *in the future* because of the "hazard potential" and "scientific complexities,"[28] then it must also be true that previously-granted PFAS LVEs do not meet the eligibility criteria.

EPA cannot lawfully ignore the fact that approximately 600 PFAS are in commerce without having gone through the legally mandated PMN safety review, including for potentially exposed or susceptible subpopulations, such as people who are pregnant or nursing. To comply with TSCA, its own regulations and the Administrative Procedure Act, EPA must revoke previously granted LVEs and LoREXs for PFAS.[29]

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[26] *Id*.

[27] *Id.* Petitioners have identified at least three PFAS LVEs granted since EPA announced it expected to deny all PFAS LVEs. These are:

> (1) L-21-0248, Alkanoic acid PFAS class chemical (Granted November 30, 2021, within 81 days of application);
>
> (2) L-21-0216, 2-Propenoic acid PFAS class chemical (Granted November 30, 2021, within 110 days of application);
>
> (3) L-21-0146, Polyfluorinated hetercyclic compounds (Granted June 30, 2021, within 47 days of application).

[28] *Id.*

[29] If revocation were not in fact required under this circumstance, there would be no meaningful safeguard against unreasonable risk when new information arises about potential health effects linked to LVE and LoREX substances, and EPA's assurances that its exemption rules comply with TSCA section 5(h)(4) would be hollow.

In light of EPA's duty to consider new evidence about potential risk presented by chemicals in commerce through PMN exemptions, the overwhelming scientific evidence that all PFAS are persistent and may cause harm at very low levels, EPA's own determination that PFAS are unlikely to be eligible for LVEs in the future, and the regulatory requirement to notify manufacturers once EPA makes a preliminary determination of ineligibility, EPA cannot articulate a "satisfactory explanation" for a decision to take no action with respect to previously-granted LVEs and LoREXs for PFAS. *Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Ins. Co*., 463 U.S. 29, 43 (1983); *see League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 697–700 (9th Cir. 2021) (holding that EPA's failure to make a safety determination for chlorpyrifos after receiving a tolerance revocation petition violated the APA, especially in light of the new information made available to the agency).[30] Therefore, denying this petition and/or failing to revoke previously granted LVEs and LoREXs for PFAS would constitute unreasonable, arbitrary and capricious agency action. *See* 5 U.S.C. § 706(2)(A).

D. EPA's Prior Initiatives To Address PFAS LVEs Do Not Adequately Address the Health Risks

The PFAS LVE stewardship program that EPA announced in the spring and summer of 2021 does not absolve EPA of its legal duty to revoke previously granted LVEs. First, the stewardship program merely solicits voluntary withdrawal of previously granted LVEs for PFAS.[31] Unsurprisingly, very few PFAS manufacturers have voluntarily agreed to withdraw

[30] If the agency decides not to revoke granted LVEs and LoREXs for PFAS as a category of chemical substances, EPA must individually re-assess each of the chemical substances that meet the definition of PFAS (as defined by scientists, such as the Organisation for Economic Co-operation and Development, *see infra* note 35) for which an LVE or LoREX was issued to determine if they meet the statutory and regulatory criteria for a PMN exemption.

[31] Press Release, EPA, EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market (Apr. 27, 2021), https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-

existing approvals of their chemicals. Indeed, according to EPA's website only 17 PFAS LVEs have been withdrawn as part of the stewardship program, which amounts to a withdrawal rate of less than 3 percent based on EPA's estimation that there are 600 PFAS in commerce through LVEs.[32, 33]

Moreover, the program does not apply to all chemicals that meet the widely understood definition of PFAS.[34] Using an internationally recognized definition of PFAS that is broader than the definition used by EPA in its TSCA program, [35] there may be even more LVEs for PFAS than EPA is counting.[36]

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prevent-unsafe-new-pfas-entering-market; EPA, *PFAS Low Volume Exemption Stewardship*, Program Participation (July 14, 2021), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption (last updated Aug. 3, 2022).

[32] EPA, *PFAS Low Volume Exemption Stewardship*, Program Participation (July 14, 2021), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption (last updated Aug. 3, 2022).

[33] Moreover, even if a manufacturer does participate, EPA "does not prohibit [manufacturers or their] customers from continuing to process, distribute in commerce, or use *existing stocks* of the chemical substance." which could prolong the use of these substances for years. *Id.*

[34] EPA limits the definition of PFAS to "chemicals that structurally contain the unit R-(CF2)-C(F)(R')R"…[where] [b]oth the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen." EPA, *PFAS Low Volume Exemption Stewardship*, Program Participation (July 14, 2021), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption (last updated Aug. 3, 2022).

[35] *See* Organisation for Economic Co-operation and Development (OECD) (2021). *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*. https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=En.

[36] As described in greater detail in the 2021 Petition at 52-53, EPA's definition excludes several types of PFAS, such as polyvinylidene fluoride ("PVDF"), a fluoropolymer that EPA has previously identified as PFAS and that is widely used to line plastic shipping containers. PVDF would not meet EPA's definition of PFAS under the LVE stewardship program, because it possesses an alternating fully fluorinated carbon structure.

In addition, EPA has not announced any action with respect to the remaining PMN exemptions, including LoREXs. This is concerning for two reasons. First, existing PFAS exempted under the LoREX continue to enter the environment and subject humans to exposure through their manufacture, use, and disposal. In addition, if EPA is in fact denying PFAS LVEs pursuant to its stated presumption against granting LVEs, manufacturers have a strong incentive to seek more LoREXs for new PFAS. Leaving the door open for that is a serious obstacle to stopping the flow of PFAS into the environment and an additional reason to grant this Petition.

CONCLUSION

The weight of the scientific evidence precludes a finding that PFAS, as a class or individually, "will not present an unreasonable risk," the TSCA section 5(h)(4) standard for PMN exemptions. The weight of the evidence also establishes that under known, intended, and reasonably foreseen condition of use, PFAS "may cause" harm to human health and the environment, EPA's regulatory standard for PMN exemptions. Under these circumstances, EPA must revoke previously granted LVEs and LoREXs for PFAS. Revocation is not discretionary because PFAS do not meet the legal standards for PMN exemptions.

AGENCY ACTION REQUESTED

For the foregoing reasons, we urge EPA to take the following actions:

1. For all outstanding LVEs and LoREXs granted for PFAS, EPA must make a preliminary determination that these LVEs and LoREXs do not meet the terms of TSCA section 5(h)(4) or 40 C.F.R. § 723.50(d).

2. For all outstanding LVEs and LoREXs granted for PFAS, EPA must notify their manufacturers that it believes their substance does not meet the requirements for a PMN exemption, and then proceed to make a final determination based on the current science that no PFAS meets the TSCA section 5(h)(4) standard for PMN exemption, taking into account potentially exposed or susceptible subpopulations, all in accordance with the protocols set forth in 40 C.F.R. § 723.50(h).

3. In the alternative, EPA must individually re-assess all PFAS chemical substances for which there is an outstanding LVE and/or LoREX to determine whether the substance meets the standard set forth in 40 C.F.R. § 723.50(d) and in TSCA section 5(h)(4).

4. Finally, Petitioners incorporate by reference all of the requests set forth in the 2021 Petition and reiterate the same requests here.

If you have any questions, please contact Eve Gartner at egartner@earthjustice.org.

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Respectfully Submitted,

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Defend Our Health
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Democracy Green
Environmental Defense Fund
Environmental Working Group
Merrimack Citizens for Clean Water
Natural Resources Defense Council
PFOAProject NY
Safer Chemicals Healthy Families/Toxic-Free Future
Sierra Club
Union of Concerned Scientists

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[a] *See* Robert C. Buck et al., Perfluoroalkyl and Polyfluoroalkyl Substances in The Environment: Terminology, Classification, and Origins, 7 Integrated Env't Assessment & Mgmt. 513 (2011), https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.258; Lee, H., D'eon, J., & Mabury, S. A. (2010). Biodegradation of polyfluoroalkyl phosphates as a source of perfluorinated acids to the environment. Environmental science & technology, 44(9), 3305–3310. https://doi.org/10.1021/es9028183; Zhang, C., Hopkins, Z. R., McCord, J., Strynar, M. J., & Knappe, D. (2019). Fate of Per- and Polyfluoroalkyl Ether Acids in the Total Oxidizable Precursor Assay and Implications for the Analysis of Impacted Water. Environmental science & technology letters, 6(11), 662–668. https://doi.org/10.1021/acs.estlett.9b00525.

[b] Pelch, K.E., Reade, A., Kwiatkowski, C.F., Wolffe, T., Merced-Nieves, F.M., Cavalier, H., Schultz, K., Rose, K., Varshavsky, J. (2021). PFAS-Tox Database. Available at https://pfastoxdatabase.org.

[c] *See* Ducatman, A., & Fenton, S. E. (2022). Invited Perspective: PFAS and Liver Disease: Bringing All the Evidence Together. *Environmental health perspectives*, *130*(4), 41303. https://doi.org/10.1289/EHP11149; Costello, E., Rock, S., Stratakis, N., Eckel, S. P., Walker, D. I., Valvi, D., Cserbik, D., Jenkins, T., Xanthakos, S. A., Kohli, R., Sisley, S., Vasiliou, V., La Merrill, M. A., Rosen, H., Conti, D. V., McConnell, R., & Chatzi, L. (2022). Exposure to per- and Polyfluoroalkyl Substances and Markers of Liver Injury: A Systematic Review and Meta-Analysis. *Environmental health perspectives*, *130*(4), 46001. https://doi.org/10.1289/EHP10092; Sen, P., Qadri, S., Luukkonen, P. K., Ragnarsdottir, O., McGlinchey, A., Jäntti, S., Juuti, A., Arola, J., Schlezinger, J. J., Webster, T. F., Orešič, M., Yki-Järvinen, H., & Hyötyläinen, T. (2022). Exposure to environmental contaminants is associated with altered hepatic lipid metabolism in non-alcoholic fatty liver disease. *Journal of hepatology*, *76*(2), 283–293. https://doi.org/10.1016/j.jhep.2021.09.039; Roth, K., Yang, Z., Agarwal, M., Liu, W., Peng, Z., Long, Z., Birbeck, J., Westrick, J., Liu, W., & Petriello, M. C. (2021). Exposure to a mixture of legacy, alternative, and replacement per- and polyfluoroalkyl substances (PFAS) results in sex-dependent modulation of cholesterol metabolism and liver injury. *Environment international*, *157*, 106843. https://doi.org/10.1016/j.envint.2021.106843.

[d] *See* Yu, G., Jin, M., Huang, Y., Aimuzi, R., Zheng, T., Nian, M., Tian, Y., Wang, W., Luo, Z., Shen, L., Wang, X., Du, Q., Xu, W., Zhang, J., & Shanghai Birth Cohort Study (2021). Environmental exposure to perfluoroalkyl substances in early pregnancy, maternal glucose homeostasis and the risk of gestational diabetes: A prospective cohort study. Environment international, 156, 106621. https://doi.org/10.1016/j.envint.2021.106621; Canova, C., Di Nisio, A., Barbieri, G., Russo, F., Fletcher, T., Batzella, E., Dalla Zuanna, T., & Pitter, G. (2021). PFAS Concentrations and Cardiometabolic Traits in Highly Exposed Children and Adolescents. International journal of environmental research and public health, 18(24), 12881. https://doi.org/10.3390/ijerph182412881; Chen, J., Li, H., Yao, J., Guo, H., Zhang, H., Guo, Y., Sheng, N., Wang, J., & Dai, J. (2021). Chronic exposure to PFO4DA and PFO5DoDA, two perfluoroalkyl ether carboxylic acids (PFECAs), suppresses hepatic stress signals and disturbs glucose and lipid metabolism in male mice. Journal of hazardous materials, 411, 124963. https://doi.org/10.1016/j.jhazmat.2020.124963; Liu, X., Zhang, L., Chen, L., Li, J., Wang, J., Zhao, Y., Liu, L., & Wu, Y. (2021). Identification and prioritization of the potent components for

combined exposure of multiple persistent organic pollutants associated with gestational diabetes mellitus. Journal of hazardous materials, 409, 124905. https://doi.org/10.1016/j.jhazmat.2020.124905; Birru, R. L., Liang, H. W., Farooq, F., Bedi, M., Feghali, M., Haggerty, C. L., Mendez, D. D., Catov, J. M., Ng, C. A., & Adibi, J. J. (2021). A pathway level analysis of PFAS exposure and risk of gestational diabetes mellitus. Environmental health : a global access science source, 20(1), 63. https://doi.org/10.1186/s12940-021-00740-z.

[e] Midya, V., Colicino, E., Conti, D. V., Berhane, K., Garcia, E., Stratakis, N., Andrusaityte, S., Basagaña, X., Casas, M., Fossati, S., Gražuleviciene, R., Haug, L. S., Heude, B., Maitre, L., McEachan, R., Papadopoulou, E., Roumeliotaki, T., Philippat, C., Thomsen, C., Urquiza, J., … Valvi, D. (2022). Association of Prenatal Exposure to Endocrine-Disrupting Chemicals With Liver Injury in Children. JAMA network open, 5(7), e2220176. https://doi.org/10.1001/jamanetworkopen.2022.20176; Guo, J., Zhang, J., Wang, Z., Zhang, L., Qi, X., Zhang, Y., Chang, X., Wu, C., & Zhou, Z. (2021). Umbilical cord serum perfluoroalkyl substance mixtures in relation to thyroid function of newborns: Findings from Sheyang Mini Birth Cohort Study. *Chemosphere*, *273*, 129664. https://doi.org/10.1016/j.chemosphere.2021.129664; Yao, Q., Vinturache, A., Lei, X., Wang, Z., Pan, C., Shi, R., Yuan, T., Gao, Y., & Tian, Y. (2022). Prenatal exposure to per- and polyfluoroalkyl substances, fetal thyroid hormones, and infant neurodevelopment. *Environmental research*, *206*, 112561. https://doi.org/10.1016/j.envres.2021.112561; Cope, H. A., Blake, B. E., Love, C., McCord, J., Elmore, S. A., Harvey, J. B., Chappell, V. A., & Fenton, S. E. (2021). Latent, sex-specific metabolic health effects in CD-1 mouse offspring exposed to PFOA or HFPO-DA (GenX) during gestation. *Emerging contaminants*, *7*, 219–235. https://doi.org/10.1016/j.emcon.2021.10.004; Crute, C. E., Hall, S. M., Landon, C. D., Garner, A., Everitt, J. I., Zhang, S., Blake, B., Olofsson, D., Chen, H., Murphy, S. K., Stapleton, H. M., & Feng, L. (2022). Evaluating maternal exposure to an environmental per and polyfluoroalkyl substances (PFAS) mixture during pregnancy: Adverse maternal and fetoplacental effects in a New Zealand White (NZW) rabbit model. *The Science of the total environment*, *838*(Pt 4), 156499. https://doi.org/10.1016/j.scitotenv.2022.156499; Blake, B. E., Rickard, B. P., & Fenton, S. E. (2022). A High-Throughput Toxicity Screen of 42 Per- and Polyfluoroalkyl Substances (PFAS) and Functional Assessment of Migration and Gene Expression in Human Placental Trophoblast Cells. *Frontiers in toxicology*, *4*, 881347. https://doi.org/10.3389/ftox.2022.881347; Sun, M., Cao, X., Wu, Y., Shen, L., & Wei, G. (2022). Prenatal exposure to endocrine-disrupting chemicals and thyroid function in neonates: A systematic review and meta-analysis. Ecotoxicology and environmental safety, 231, 113215. https://doi.org/10.1016/j.ecoenv.2022.113215.

[f] *See* Erinc, A., Davis, M. B., Padmanabhan, V., Langen, E., & Goodrich, J. M. (2021). Considering environmental exposures to per- and polyfluoroalkyl substances (PFAS) as risk factors for hypertensive disorders of pregnancy. Environmental research, 197, 111113. https://doi.org/10.1016/j.envres.2021.111113; Hammarstrand, S., Jakobsson, K., Andersson, E., Xu, Y., Li, Y., Olovsson, M., & Andersson, E. M. (2021). Perfluoroalkyl substances (PFAS) in drinking water and risk for polycystic ovarian syndrome, uterine leiomyoma, and endometriosis:

A Swedish cohort study. *Environment international*, *157*, 106819. https://doi.org/10.1016/j.envint.2021.106819; Petersen, K. U., Hærvig, K. K., Flachs, E. M., Bonde, J. P., Lindh, C., Hougaard, K. S., Toft, G., Ramlau-Hansen, C. H., & Tøttenborg, S. S. (2022). Per- and polyfluoroalkyl substances (PFAS) and male reproductive function in young adulthood; a cross-sectional study. *Environmental research*, *212*(Pt A), 113157. https://doi.org/10.1016/j.envres.2022.113157; Luo, K., Liu, X., Nian, M., Wang, Y., Qiu, J., Yu, H., Chen, X., Zhang, J., & Shanghai Birth Cohort (2021). Environmental exposure to per- and polyfluoroalkyl substances mixture and male reproductive hormones. *Environment international*, *152*, 106496. https://doi.org/10.1016/j.envint.2021.106496; Chambers, W. S., Hopkins, J. G., & Richards, S. M. (2021). A Review of Per- and Polyfluorinated Alkyl Substance Impairment of Reproduction. *Frontiers in toxicology*, *3*, 732436. https://doi.org/10.3389/ftox.2021.732436; Rickard, B. P., Rizvi, I., & Fenton, S. E. (2022). Per- and poly-fluoroalkyl substances (PFAS) and female reproductive outcomes: PFAS elimination, endocrine-mediated effects, and disease. *Toxicology*, *465*, 153031. https://doi.org/10.1016/j.tox.2021.153031.

[g] Zhang, Y., Mustieles, V., Sun, Y., Oulhote, Y., Wang, Y. X., & Messerlian, C. (2022). Association between serum per- and polyfluoroalkyl substances concentrations and common cold among children and adolescents in the United States. Environment international, 164, 107239. https://doi.org/10.1016/j.envint.2022.107239; Woodlief, T.; Vance, S.; Hu, Q.; DeWitt, J. Immunotoxicity of Per- and Polyfluoroalkyl Substances: Insights into Short-Chain PFAS Exposure. Toxics 2021, 9, 100. https://doi.org/10.3390/toxics9050100; Wang, L. Q., Liu, T., Yang, S., Sun, L., Zhao, Z. Y., Li, L. Y., She, Y. C., Zheng, Y. Y., Ye, X. Y., Bao, Q., Dong, G. H., Li, C. W., & Cui, J. (2021). Perfluoroalkyl substance pollutants activate the innate immune system through the AIM2 inflammasome. Nature communications, 12(1), 2915. https://doi.org/10.1038/s41467-021-23201-0.

[h] Bartell, S. M., & Vieira, V. M. (2021). Critical review on PFOA, kidney cancer, and testicular cancer. Journal of the Air & Waste Management Association (1995), 71(6), 663–679. https://doi.org/10.1080/10962247.2021.1909668; Cao, L., Guo, Y., Chen, Y., Hong, J., Wu, J., & Hangbiao, J. (2022). Per-/polyfluoroalkyl substance concentrations in human serum and their associations with liver cancer. Chemosphere, 296, 134083. https://doi.org/10.1016/j.chemosphere.2022.134083; Goodrich, Jesse A. et al. (2022). Exposure to perfluoroalkyl substances and risk of hepatocellular carcinoma in a multiethnic cohort. JHEP Reports, Volume 0, Issue 0, 100550. https://www.jhep-reports.eu/article/S2589-5559(22)00122-7/fulltext; Velarde, M. C., Chan, A., Sajo, M., Zakharevich, I., Melamed, J., Uy, G., Teves, J., Corachea, A., Valparaiso, A. P., Macalindong, S. S., Cabaluna, N. D., Dofitas, R. B., Giudice, L. C., & Gerona, R. R. (2022). Elevated levels of perfluoroalkyl substances in breast cancer patients within the Greater Manila Area. Chemosphere, 286(Pt 1), https://doi.org/10.1016/j.chemosphere.2021.131545; Messmer, M. F., Salloway, J., Shara, N., Locwin, B., Harvey, M. W., & Traviss, N. (2022). Risk of Cancer in a Community Exposed to Per- and Poly-Fluoroalkyl Substances. Environmental health insights, 16, 11786302221076707. https://doi.org/10.1177/11786302221076707; Singh, N., & Hsieh, C. (2021). Exploring Potential Carcinogenic Activity of Per- and Polyfluorinated Alkyl Substances

Utilizing High-Throughput Toxicity Screening Data. International journal of toxicology, 40(4), 355–366. https://doi.org/10.1177/10915818211010490.

[i] Sarzo, B., Ballesteros, V., Iñiguez, C., Manzano-Salgado, C. B., Casas, M., Llop, S., Murcia, M., Guxens, M., Vrijheid, M., Marina, L. S., Schettgen, T., Espada, M., Irizar, A., Fernandez-Jimenez, N., Ballester, F., & Lopez-Espinosa, M. J. (2021). Maternal Perfluoroalkyl Substances, Thyroid Hormones, and *DIO* Genes: A Spanish Cross-sectional Study. *Environmental science & technology*, 10.1021/acs.est.1c01452. Advance online publication. https://doi.org/10.1021/acs.est.1c01452; Derakhshan, A., Kortenkamp, A., Shu, H., Broeren, M., Lindh, C. H., Peeters, R. P., Bornehag, C. G., Demeneix, B., & Korevaar, T. (2022). Association of per- and polyfluoroalkyl substances with thyroid homeostasis during pregnancy in the SELMA study. *Environment international*, *167*, 107420. https://doi.org/10.1016/j.envint.2022.107420; Jensen, R. C., Glintborg, D., Timmermann, C., Nielsen, F., Boye, H., Madsen, J. B., Bilenberg, N., Grandjean, P., Jensen, T. K., & Andersen, M. S. (2022). Higher free thyroxine associated with PFAS exposure in first trimester. The Odense Child Cohort. *Environmental research*, *212*(Pt D), 113492. https://doi.org/10.1016/j.envres.2022.113492; Gallo, E., Barbiellini Amidei, C., Barbieri, G., Fabricio, A., Gion, M., Pitter, G., Daprà, F., Russo, F., Gregori, D., Fletcher, T., & Canova, C. (2022). Perfluoroalkyl substances and thyroid stimulating hormone levels in a highly exposed population in the Veneto Region. *Environmental research*, *203*, 111794. https://doi.org/10.1016/j.envres.2021.111794; Davidsen, N., Ramhøj, L., Lykkebo, C. A., Kugathas, I., Poulsen, R., Rosenmai, A. K., Evrard, B., Darde, T. A., Axelstad, M., Bahl, M. I., Hansen, M., Chalmel, F., Licht, T. R., & Svingen, T. (2022). PFOS-induced thyroid hormone system disrupted rats display organ-specific changes in their transcriptomes. *Environmental pollution (Barking, Essex : 1987)*, *305*, 119340. https://doi.org/10.1016/j.envpol.2022.119340; Zhang, S., Chen, K., Li, W., Chai, Y., Zhu, J., Chu, B., Li, N., Yan, J., Zhang, S., & Yang, Y. (2021). Varied thyroid disrupting effects of perfluorooctanoic acid (PFOA) and its novel alternatives hexafluoropropylene-oxide-dimer-acid (GenX) and ammonium 4,8-dioxa-3H-perfluorononanoate (ADONA) in vitro. *Environment international*, *156*, 106745. https://doi.org/10.1016/j.envint.2021.106745; De Toni, L., Di Nisio, A., Rocca, M. S., Pedrucci, F., Garolla, A., Dall'Acqua, S., Guidolin, D., Ferlin, A., & Foresta, C. (2022). Comparative Evaluation of the Effects of Legacy and New Generation Perfluoralkyl Substances (PFAS) on Thyroid Cells *In Vitro*. *Frontiers in endocrinology*, *13*, 915096. https://doi.org/10.3389/fendo.2022.915096.

[j] Kim, S., Thapar, I., & Brooks, B. W. (2021). Epigenetic changes by per- and polyfluoroalkyl substances (PFAS). Environmental pollution (Barking, Essex : 1987), 279, 116929. https://doi.org/10.1016/j.envpol.2021.116929.

[k] Tornabene, B. J., Chislock, M. F., Gannon, M. E., Sepúlveda, M. S., & Hoverman, J. T. (2021). Relative acute toxicity of three per- and polyfluoroalkyl substances on nine species of larval amphibians. Integrated environmental assessment and management, 17(4), 684–690. https://doi.org/10.1002/ieam.4391; Birgersson, L., Jouve, J., Jönsson, E., Asker, N., Andreasson, F., Golovko, O., Ahrens, L., & Sturve, J. (2021). Thyroid function and immune status in perch (Perca fluviatilis) from lakes contaminated with PFASs or PCBs. Ecotoxicology and

environmental safety, 222, 112495. https://doi.org/10.1016/j.ecoenv.2021.112495; Sun, J., Letcher, R. J., Waugh, C. A., Jaspers, V., Covaci, A., & Fernie, K. J. (2021). Influence of perfluoroalkyl acids and other parameters on circulating thyroid hormones and immune-related microRNA expression in free-ranging nestling peregrine falcons. The Science of the total environment, 770, 145346. https://doi.org/10.1016/j.scitotenv.2021.145346; Flynn, R. W., Hoover, G., Iacchetta, M., Guffey, S., de Perre, C., Huerta, B., Li, W., Hoverman, J. T., Lee, L., & Sepúlveda, M. S. (2022). Comparative Toxicity of Aquatic Per- and Polyfluoroalkyl Substance Exposure in Three Species of Amphibians. Environmental toxicology and chemistry, 41(6), 1407–1415. https://doi.org/10.1002/etc.5319; Sonter, C. A., Rader, R., Stevenson, G., Stavert, J. R., & Wilson, S. C. (2021). Biological and behavioral responses of European honey bee (Apis mellifera) colonies to perfluorooctane sulfonate exposure. Integrated environmental assessment and management, 17(4), 673–683. https://doi.org/10.1002/ieam.4421.

[l] Bartell, S.M., *et al,* 2021.

[m] Zhang, Y., *et al,* 2022.

[n] Ding, N., Karvonen-Gutierrez, C. A., Mukherjee, B., Calafat, A. M., Harlow, S. D., & Park, S. K. (2022). Per- and Polyfluoroalkyl Substances and Incident Hypertension in Multi-Racial/Ethnic Women: The Study of Women's Health Across the Nation. Hypertension (Dallas, Tex. : 1979), 79(8), 1876–1886. https://doi.org/10.1161/HYPERTENSIONAHA.121.18809; Erinc A., *et al,* 2021.

[o] Canova, C., *et al,* 2021.

[p] Singh, N., & Hsieh, C. (2021). Exploring Potential Carcinogenic Activity of Per- and Polyfluorinated Alkyl Substances Utilizing High-Throughput Toxicity Screening Data. International journal of toxicology, 40(4), 355–366. https://doi.org/10.1177/10915818211010490.

[q] Yao, Q., *et al,* 2022.

[r] Midya, V., *et al,* 2022.

[s] Yu, E. L., & Schwimmer, J. B. (2021). Epidemiology of Pediatric Nonalcoholic Fatty Liver Disease. Clinical liver disease, 17(3), 196–199. https://doi.org/10.1002/cld.1027.

[t] Liu, X., Zhang, L., Chen, L., Li, J., Wang, J., Zhao, Y., Liu, L., & Wu, Y. (2021). Identification and prioritization of the potent components for combined exposure of multiple persistent organic pollutants associated with gestational diabetes mellitus. Journal of hazardous materials, 409, 124905. https://doi.org/10.1016/j.jhazmat.2020.124905; Yu, G., *et al,* 2021; Birru R.L., *et al,* 2021.

[u] Sarzo. B., *et al,* 2021; Derakhshan, A., *et al*, 2022; Jensen, R.C., *et al*, 2022.

[v] Guo, J., *et al,* 2021; Yao, Q., *et al,* 2022.

[w] Hammarstrand, S., Jakobsson, K., Andersson, E., Xu, Y., Li, Y., Olovsson, M., & Andersson, E. M. (2021). Perfluoroalkyl substances (PFAS) in drinking water and risk for polycystic ovarian syndrome, uterine leiomyoma, and endometriosis: A Swedish cohort study. *Environment international*, *157*, 106819. https://doi.org/10.1016/j.envint.2021.106819.

[x] Crute, C.E., *et al,* 2022.

[y] Birgersson, L., Jouve, J., Jönsson, E., Asker, N., Andreasson, F., Golovko, O., Ahrens, L., & Sturve, J. (2021). Thyroid function and immune status in perch (Perca fluviatilis) from lakes contaminated with PFASs or PCBs. *Ecotoxicology and environmental safety*, *222*, 112495. https://doi.org/10.1016/j.ecoenv.2021.112495.

[z] Sun, J., *et al,* 2021.

[aa] Sonter, C. A., Rader, R., Stevenson, G., Stavert, J. R., & Wilson, S. C. (2021). Biological and behavioral responses of European honey bee (Apis mellifera) colonies to perfluorooctane sulfonate exposure. *Integrated environmental assessment and management*, *17*(4), 673–683. https://doi.org/10.1002/ieam.4421.

[bb] Agency for Toxic Substances and Disease Registry, *Toxicology Profile for Perfluoroalkyls,* Toxicology Profiles (May 2021), https://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf.

[cc] EPA, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3),* Office of Water (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf.

[dd] EPA, Technical Fact Sheet: Drinking Water Health Advisories for Four PFAS (PFOA, PFOS, GenX chemicals, and PFBS), Office of Water (June 2022), https://www.epa.gov/system/files/documents/2022-06/technical-factsheet-four-PFAS.pdf.

[ee] See, *e.g.* EPA, *Interim Drinking Water Health Advisory: Perfluorooctanoic Acid (PFOA) CASRN 335-67-1*, Office of Water, at 17 (June 2022), https://www.epa.gov/system/files/documents/2022-06/interim-pfoa-2022.pdf.

[ff] *Id*.

[gg] The toxicity of PFOA and PFOS at extremely low levels is highly relevant to PFAS as a class because many PFAS are precursors that can degrade or transform into PFOA and/or PFOS, including by microbes in soil, sludge, and wastewater and through abiotic chemical reactions. *See* Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 Fed. Reg. 54,415, 54,417 (Sept.6, 2022); *see also id*. ("[e]nvironmental contamination and resulting human exposure to PFOA and PFOS are anticipated to continue for the foreseeable future due [in part] to … formation from precursor compounds…").

EXHIBIT A

to

PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

To revoke the approval of approximately 600 per- and polyfluoroalkyl substances (PFAS) that were granted through low-volume or low-release and low-exposure exemptions to the premanufacture notice requirements of the Toxic Substances Control Act

PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

To prohibit the use of certain exemptions to the premanufacture notice requirements of the Toxic Substances Control Act for per- and polyfluoroalkyl substances (PFAS)

SUBMITTED ON BEHALF OF:

Advance Carolina; Alaska Community Action on Toxics; BlueGreen Alliance; Buxmont Coalition for Safer Water; Clean Cape Fear; Defend Our Health; Delaware Riverkeeper Network; Democracy Green; Environmental Defense Fund; International Association of Fire Fighters; Merrimack Citizens for Clean Water; the National PFAS Contamination Coalition; Natural Resources Defense Council; Safer Chemicals, Healthy Families; and Union of Concerned Scientists

BY: **EARTHJUSTICE**
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DATE: April 27, 2021

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April 27, 2021

Via mail and e-mail

Michael Regan, Administrator
Michal Freedhoff, Principal Deputy Assistant Administrator Office of Chemical Safety and Pollution Prevention
Yvette Collazo Reyes, Director of the Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: Petition to prohibit the use of certain exemptions to the premanufacture notice requirements of the Toxic Substances Control Act for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan, Deputy Assistant Administrator Freedhoff, and Director Collazo Reyes,

Earthjustice, on behalf of Advance Carolina; Alaska Community Action on Toxics; BlueGreen Alliance; Buxmont Coalition for Safer Water; Clean Cape Fear; Defend Our Health; Delaware Riverkeeper Network; Democracy Green; Environmental Defense Fund; International Association of Fire Fighters; Merrimack Citizens for Clean Water; the National PFAS Contamination Coalition; Natural Resources Defense Council; Safer Chemicals, Healthy Families; and Union of Concerned Scientists (collectively, "Petitioners")[1] submit this petition requesting that the Environmental Protection Agency (EPA) amend regulations relating to the new chemical review process under the Toxic Substances Control Act (TSCA). *See* 5 U.S.C. § 553(e) (providing that each agency shall provide persons the right to petition for the "issuance, amendment, or repeal of a rule"). More specifically, Petitioners respectfully request that EPA

[1] Statements of interest from each Petitioner are set forth in Appendix A.

amend four EPA-created exemptions from TSCA's pre-manufacture notice (PMN) requirement—the Byproducts Exemption, the Low Volume Exemption (LVE), the Low Release and Exposure Exemption (LoREX), and the Polymer Exemption—to prohibit their use for per- and polyfluoroalkyl substances ("PFAS").

INTRODUCTION

The United States is awash with PFAS: human-made, long-lasting, toxic, and often bioaccumulative chemicals. Thousands of these structurally similar and largely unregulated chemicals have been used across various industries and goods, including in firefighting foam, non-stick cookware, food packaging, and many other household products. People are exposed to PFAS through various sources, including the products we use, the food we eat, the air we breathe, and the water we drink, and PFAS from those various sources accumulate in our bodies. PFAS are pervasive in the environment and present in the bodies of virtually every person in the U.S.

The weight of the scientific evidence developed over the past few years has shown that exposure to even small amounts of a variety of PFAS is associated with numerous adverse health effects, including cancer and immune suppression. And PFAS pose even greater risks to potentially exposed or susceptible subpopulations ("greater risk populations"), including firefighters, communities living in polar regions, communities living near facilities that release PFAS, infants, children, and developing fetuses. Scientists agree that all yet-unstudied PFAS may have similar effects on human health.

Wide usage and poor regulation of PFAS have led to extensive contamination throughout the United States and an emerging public health crisis. Yet, EPA continues to permit new PFAS

to enter commerce through TSCA's new chemicals program, despite the risks they pose. Moreover, in recent years, most of those approvals occurred through exemptions to EPA's PMN program—thereby curtailing or entirely sidestepping a process designed to require an individual safety review of potentially toxic chemicals and keep the public apprised of those reviews. Three of those exemptions are the primary subjects of this petition—the Byproducts Exemption, the LVE, and the LoREX Exemption (collectively, "Challenged Exemptions"). At least one environmental contamination crisis in the Cape Fear River Basin in North Carolina involved PFAS released into communities through such a loophole; yet it is unknown how many other similar crises exist or are in the making since there is little public information about PFAS approved through such loopholes.

TSCA permits use of PMN exemptions only for chemicals that EPA determines *will not* present an unreasonable risk of injury to human health or the environment. Thus, as EPA has acknowledged, if a class of chemicals cannot or no longer can meet that high standard for a particular exemption, TSCA requires EPA to make that class of chemicals ineligible for the exemption. The Byproduct, LVE, and LoREX Exemptions were enacted decades ago, long before the risks associated with exposure to even low levels of PFAS were known and before TSCA required EPA to consider risks to greater risk populations when deciding whether the "will not present an unreasonable risk" standard had been met. In light of the information now known about PFAS and the changes made by the 2016 amendments to TSCA's "unreasonable risk" assessment, EPA cannot conclude that new PFAS that would otherwise meet the non-risk criteria for the Byproduct, LVE, and LoREX Exemptions will not present an unreasonable risk. As discussed further herein, it is legally impermissible—as well as dangerous—to continue to permit approval of new PFAS via the Byproduct, LVE, and LoREX Exemptions. EPA therefore

must and should grant this Petition and make PFAS ineligible for those Challenged Exemptions. For similar reasons, EPA should also amend the Polymer Exemption—which already makes certain PFAS ineligible for it—to ensure the exclusion of all PFAS polymers.

FACTUAL BACKGROUND

A. Overview of PFAS Characteristics and Uses

Per- and polyfluoroalkyl substances ("PFAS") are a "large, complex, and ever-expanding" family of human-made organic chemicals used in hundreds of products and industrial processes, including airplane jet engines, firefighting foam, and everyday products like waterproof jackets, nonstick pans, and paints.[2] PFAS typically have a linear or branched carbon chain or "backbone," characterized by the replacement of hydrogen (H) atoms with fluorine (F) atoms that are bonded to the carbon chain.[3] PFAS, for purposes of this Petition, are defined by having at least one perfluoroalkyl moiety, or a carbon atom from which all bonded H atoms have been replaced with F atoms.[4] The carbon-fluorine bond is "one of the strongest ever created by man," making PFAS extremely persistent in the environment and difficult to break down or remediate.[5] PFAS also often have bioaccumulative qualities (they can build up in the human

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[2] *See* EPA, *Per- and Polyfluoroalkyl Substances (PFASs): Chemistry and Behavior*, CLU-IN, https://clu-in.org/contaminantfocus/default.focus/sec/Per-_and_Polyfluoroalkyl_Substances_(PFASs)/cat/Chemistry_and_Behavior/ (last updated Apr. 20, 2021). *See also* Organisation for Economic Co-operation and Development (OECD), *Toward a New Comprehensive Global Database of Per- And Polyfluoroalkyl Substances (PFASs): Summary Report on Updating the OECD 2007 List of Per- And Polyfluoroalkyl Substances (PFASs)* (2018), https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2018)7&doclanguage=en; KEMI Swedish Chemicals Agency, *Occurrence and Use of Highly Fluorinated Substances and Alternatives* (2015), https://www kemi.se/download/18.6df1d3df171c243fb23a98ea/1591454109137/report-7-15-occurrence-and-use-of-highly-fluorinated-substances-and-alternatives.pdf; Julian Glüge et al., *An Overview of the Uses of Per- and Polyfluoroalkyl Substances (PFAS)*, 12 Env't Sci: Process & Impacts 2345 (2020), https://pubs rsc.org/en/content/articlelanding/2020/EM/D0EM00291G#!divAbstract.

[3] Robert C. Buck et al., *Perfluoroalkyl and Polyfluoroalkyl Substances in The Environment: Terminology, Classification, and Origins*, 7 Integrated Env't Assessment & Mgmt. 513 (2011), https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.258.

[4] *Id*.

[5] *See Examining the Federal Response to the Risks Associated with Per- and Polyfluoroalkyl Substances (PFAS): Hearing Before the S. Comm. on Env't & Pub. Works*, 116th Cong. 2 (2019) (testimony of Linda S. Birnbaum, Dir., Nat'l Inst. Env't Health Sci. & Nat'l Toxicology Program, Nat'l Ins. Health); Zhanyun Wang et al., *A Never-Ending Story of Per- and Polyfluoroalkyl Substances (PFASs)?*, 51 Env't Sci. & Tech. 2508 (2017), https://pubs.acs.org/doi/10.1021/acs.est.6b04806.

body over time) and, as discussed further herein, have been shown to be toxic at very low levels.[6]

PFAS encompass a wide array of chemicals with varying size, structure, and chemical composition. The original PFAS, such as PFOA and PFOS, are referred to as "long-chain" (because of the length of the carbon chain and the number of fluorine atoms bonded to the carbon chain). In an attempt to address growing concerns over the toxicity, environmental persistence, and biological uptake of long-chain PFAS, manufacturers shifted towards producing and using shorter-chain or "replacement" PFAS in more recent years,[7] resulting in significant increases of those PFAS in the environment.[8] EPA estimates there are over 6,000 known PFAS, for over 1,000 of which EPA does not have a defined chemical structure.[9] These known PFAS include short- and long-chain PFAS, PFAS polymers, and PFAS "precursors," or compounds that may degrade to long- and short-chain PFAS in the environment.[10]

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[6] *See, e.g.*, Carol F. Kwiatkowski et al., *Scientific Basis for Managing PFAS as a Chemical Class*, 7 Env't Sci. & Tech. Letters 532 (2020), https://pubs.acs.org/doi/abs/10.1021/acs.estlett.0c00255.

[7] Stephen K. Ritter, *Fluorochemicals Go Short*, c&en (Feb. 1, 2020), https://cen.acs.org/articles/88/i5/Fluorochemicals-Short.html.

[8] Buck et al., *supra* note 3, at 524. *See also* Mei Sun et al., *Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed Of North Carolina*, 3 Env't Sci. & Tech. Letters 415 (2016), https://pubs.acs.org/doi/full/10.1021/acs.estlett.6b00398; Xianming Zhang et al., *Source Attribution of Poly- and Perfluoroalkyl Substances (PFASs) in Surface Waters from Rhode Island and the New York Metropolitan Area*, 3 Env't Sci. & Tech. Letters 316 (2016), https://pubs.acs.org/doi/abs/10.1021/acs.estlett.6b00255.

[9] *PFAS Master List of PFAS Substances (Version 2)*, EPA, https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster (last updated Sept. 16, 2020). Lists PFAS "from within and outside EPA, encompass PFAS of potential interest based on environmental occurrence (through literature reports and analytical detection) and manufacturing process data, as well as lists of PFAS chemicals procured for testing within EPA research programs. The consolidated list contains 6330 PFAS CAS-name substances, with 5264 represented with a defined chemical structure."

[10] Kwiatkowski et al., *supra* note 6; Buck et al., *supra* note 3.

B. A Growing Body of Research Demonstrates the Serious Risks PFAS Pose to Human Health

Human exposure to several well-studied and widely-produced PFAS has been linked to a variety of adverse health effects, including cancer, elevated cholesterol, obesity, immune suppression, pre-eclampsia, liver and kidney damage, and endocrine disruption.[11] Some of these adverse effects have been linked to both short- and long-term exposures at extremely low concentrations.[12] For purposes of comparison, most chemicals that have been deemed toxic at low levels of exposure, like cyanide, are considered toxic at exposure concentrations of parts per billion. However, some PFAS exert toxicity at the parts per trillion level; this means that these PFAS are linked to harm at exposure levels 1,000 times lower than cyanide.[13]

The link between PFAS exposure and cancer has garnered increasing attention over the past few years. Most members of the Science Advisory Board to EPA concluded that PFOA is "likely to be carcinogenic to humans," and the International Agency for Research on Cancer (IARC), a branch of the World Health Organization, has characterized PFOA as "possibly carcinogenic to humans."[14] Several epidemiological studies have established a link between PFOA exposure and certain cancers. For example, a 2013 study examining a group of people residing near a chemical plant in the Mid-Ohio Valley found significant associations between exposure to PFOA and kidney and testicular cancer.[15] Short-chain "replacement" PFAS were

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[11] Agency for Toxic Substances and Disease Registry (ATSDR), U.S. Dep't Health & Hum. Servs., *Toxicological Profile for Perfluoroalkyls: Draft for Public Comment* (2018), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.
[12] *Id.*
[13] *See Ground Water and Drinking Water*, EPA, https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations (last updated Jan. 5, 2021).
[14] Letter from Dr. M. Granger Morgan, Chair, EPA Sci. Advisory Bd., & Dr. Deborah Cory-Slechta, Chair, PFOA Risk Assessment Rev. Panel, to Stephan L. Johnson, Adm'r, EPA at 3 (May 30, 2006), https://nepis.epa.gov/Exe/ZyPDF.cgi/901S0J00.PDF?Dockey=901S0J00.PDF; IARC Working Grp. on the Evaluation of Carcinogenic Risks to Hums., *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 110: Some Chemicals Used as Solvents and in Polymer Manufacture* ch. 6.3 (Int'l Agency for Rsch. on Cancer 2017), https://www ncbi.nlm.nih.gov/books/NBK436276/#a006.sec6.3.
[15] Vaughn Barry et al., *Perfluorooctanoic Acid (PFOA) Exposures and Incident Cancers Among Adults Living Near a Chemical Plant*, 121 Env't Health Persp. 1313 (2013) https://pubmed.ncbi nlm.nih.gov/24007715/.

also detected in North Carolina's Cape Fear River watershed,[16] which serves as the drinking water supply for several counties that have been identified as potential cancer clusters for testicular and thyroid cancer.[17] Studies are currently underway to establish possible associations between the PFAS and those cancer clusters.[18]

Amidst the global COVID-19 pandemic, the effects of certain PFAS on the immune system are especially concerning. In 2016, the National Toxicology Program concluded that PFOA and PFOS are presumed to pose "an immune hazard to humans based on a high level of evidence that PFOA [and PFOS] suppressed the antibody response."[19] These conclusions were based in part upon a study examining a cohort of children that linked high serum concentrations of PFOA and PFOS in the children to a weakened antibody response following vaccination.[20]

C. Research Also Demonstrates PFAS's Risks to Aquatic Organisms

PFAS exposure is also associated with acute and chronic toxicity in many aquatic species, including algae, invertebrates, amphibians, and fish. In these species, PFAS exposure was associated with increased mortality, immunotoxicity, and a range of growth and developmental effects.[21] For example, high serum levels of PFAS were detected in striped bass

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[16] Sun et al., *supra* note 8.
[17] N.C. Dep't Health & Hum. Servs., *Summary of Selected Cancer Rates for Bladen, Brunswick, New Hanover and Pender Counties, 1996 – 2015, and Comparison to Statewide Rates* (2018), https://epi.dph ncdhhs.gov/oee/pfas/Summary%20of%20Selected%20Cancer%20Rates_all%20counties_7Nov2018.pdf.
[18] Stapleton Lab, *PFAS Research*, Duke Nicholas School of the Environment, https://sites nicholas.duke.edu/stapletonlab/research/pfas-research/ (last visited Mar. 15, 2021).
[19] Nat'l Toxicology Program, U.S. Dep't Health & Hum. Servs., *NTP Monograph on Immunotoxicity Associated with Exposure to Perfluorooctanoic Acid (PFOA) or Perfluorooctane Sulfonate (PFOS)* 1 (2016), https://ntp niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf.
[20] Philippe Grandjean et al., *Serum Vaccine Antibody Concentrations in Children Exposed to Perfluorinated Compounds*, 307 JAMA 1142 (2012), https://pubmed.ncbi nlm nih.gov/22274686/.
[21] Lutz Ahrens & Mirco Bundschuh, *Fate and Effects of Poly- and Perfluoroalkyl Substances in the Aquatic Environment: A Review*, 33 Env't Toxicology & Chemistry 1921 (2014), https://setac.onlinelibrary.wiley.com/doi/full/10.1002/etc.2663; John P. Giesy et al., *Aquatic Toxicology of Perfluorinated Chemicals*, 202 Rev. Env't Contamination & Toxicology 1 (2010), https://link.springer.com/chapter/10.1007%2F978-1-4419-1157-5_1; R. Wesley Flynn et al., *Chronic Per-/Polyfluoroalkyl Substance Exposure Under Environmentally Relevant Conditions Delays Development in Northern*

in North Carolina's Cape Fear River, an economically important, yet declining, commercial and recreational fish population in the region. The levels were the highest recorded of any fish species studied in the country, and were associated with immune and liver dysfunction, potentially reducing survival for this commercially important fish population.[22]

PFAS also biomagnify along ecosystem food chains, which results in greater risks of adverse health effects to both larger animals and to people who eat them. More specifically, PFAS can be absorbed by plants and algae that are then subsequently ingested by wildlife, accumulating up the food chain.[23] This phenomenon results in the buildup of PFAS in larger organisms, like marine mammals.

D. PFAS Contamination Is a Widespread Problem Throughout the United States

As a result of their: chemical characteristics; widespread use; and limited regulation of their manufacture, disposal, and releases into the environment, PFAS are now pervasive environmental contaminants.[24] PFAS enter the environment in several ways, including from the

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Leopard Frog (Rana pipiens) Larvae, 40 Evn't Toxicology & Chemistry 711 (2020), https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.4690; R. Wesley Flynn et al., *Dietary Exposure and Accumulation of Per- and Polyfluoroalkyl Substances Alters Growth and Reduces Body Condition of Post-Metamorphic Salamanders*, 765 Sci. Total Env't 142730 (2021), https://www.sciencedirect.com/science/article/abs/pii/S0048969720362598; Gerald T. Ankley et al., *Assessing the Ecological Risks of Per- and Polyfluoroalkyl Substances: Current State-of-the Science and a Proposed Path Forward*, 40 Env't Toxicology & Chemistry 564 (2020), https://setac.onlinelibrary.wiley.com/doi/10.1002/etc.4869; Georgia M. Sinclair et al., *What Are the Effects of PFAS Exposure at Environmentally Relevant Concentrations?*, 258 Chemosphere 127340 (2020), https://www.sciencedirect.com/science/article/pii/S0045653520315332#bib53.

[22] Theresa C. Guillette et al., *Elevated Levels of Per-And Polyfluoroalkyl Substances in Cape Fear River Striped Bass (Morone Saxatilis) Are Associated with Biomarkers of Altered Immune and Liver Function*, 136 Env't Int'l 105358 (2020), https://www.sciencedirect.com/science/article/pii/S0160412019334762.

[23] *See, e.g.*, Claudia E. Müller et al., *Biomagnification of Perfluorinated Compounds in a Remote Terrestrial Food Chain: Lichen–Caribou–Wolf*, 45 Env't Sci. & Tech. 8665 (2011), https://pubs.acs.org/doi/10.1021/es201353v.

[24] *See, e.g.*, Xindi C. Hu et al., *Detection of Poly- and Perfluoroalkyl Substances (PFASs) in US Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants*, 3 Env't Sci. & Tech. Letters 344 (2016), https://pubs.acs.org/doi/abs/10.1021/acs.estlett.6b00260; Keegan Rankin et al., *A North American and Global Survey of Perfluoroalkyl Substances in Surface Soils: Distribution Patterns and Mode of Occurrence*, 161 Chemosphere 333 (2016), https://www researchgate net/publication/305498037_A_North_American_and_global_survey_of_perfluoroalkyl_substances_in_surface_soils_Distribution_patterns_and_mode_of_occurrence; Belén González-Gaya et al., Perfluoroalkylated Substances in the Global Tropical and Subtropical Surface Oceans. 48 Env't Sci. & Tech. 13076 (2014), https://pubs.acs.org/doi/10.1021/es503490z.

manufacturing, processing, use, and disposal of PFAS and products that either contain PFAS or generate PFAS as a waste byproduct.[25] In addition, PFAS precursors that are emitted or released into the environment via these pathways can biotransform into other PFAS, including long-chain PFAS like PFOA that have been largely phased out.[26]

People are then routinely exposed to these chemicals from multiple sources, including their water, food, and products and materials they use or contact. PFAS exposure occurs inside homes through treated furniture and rugs, cookware and cleaning supplies, and inhalation of household dust particles carrying PFAS molecules. As a result of these varied and continuing exposures, PFAS have been detected in nearly 99 percent of Americans.[27]

In the United States, PFAS-contaminated drinking water is a significant exposure route of concern.[28] A 2016 study estimated that 16.5 million Americans across 33 states and three American territories were supplied drinking water with detectable levels of PFAS. For six million of these individuals, PFOS and PFOA levels exceeded EPA's health advisory level of 70 ppt.[29] The 2016 study, however, likely underestimates how many people in the U.S. are drinking

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[25] Buck et al., *supra* note 3, at 518; Martin Scheringer & Zhanyun Wang, OECD & UNEP Global PFC Group, *Synthesis Paper on Per- and Polyfluorinated Chemicals (PFCs)* 21 (2013), https://www.oecd.org/chemicalsafety/risk-management/synthesis-paper-on-per-and-polyfluorinated-chemicals.htm. *See also* Andrew B. Lindstrom et al., *Application of WWTP Biosolids and Resulting Perfluorinated Compound Contamination of Surface and Well Water in Decatur, Alabama, USA*, 45 Env't Sci. & Tech. 8-15 (2011), https://pubs.acs.org/doi/10.1021/es1039425; N.C. Dep't Env't Quality, *GenX Frequently Asked Questions* (2017), https://files.nc.gov/ncdeq/GenX/FAQ_updated_100417-5.pdf (stating that GenX is "also produced as a byproduct during other manufacturing processes and it may have been present in the environment for many years before being produced commercially as GenX.").

[26] Kwiatkowski et al., *supra* note 6; Craig Butt et al., *Biotransformation Pathways of Fluorotelomer-based Polyfluoroalkyl Substances: A Review*, 33 Env't Toxicology & Chemistry 243 (2013), https://doi.org/10.1002/etc.2407; Buck et al., *supra* note 3.

[27] Antonia M. Calafat et al., *Polyfluoroalkyl Chemicals in the US population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000*, 115 Env't Health Persps. 1596 (2007), https://www ncbi nlm nih.gov/pmc/articles/PMC2072821/. *See also* CDC, ATSDR, *An Overview of Perfluoroalkyl and Polyfluoroalkyl Substances and Interim Guidance for Clinicians Responding to Patient Exposure Concerns* (2018), https://stacks.cdc.gov/view/cdc/77114.

[28] Hu et al., *supra* note 24.

[29] *Id.* at 344.

water contaminated with PFAS, the level of PFAS in U.S. drinking water, and the extent to which individuals are potentially harmed by this PFAS contamination because: 1) EPA's available water testing methods have the capability to detect only a few dozen out of the thousands of PFAS in circulation; and 2) adverse health effects are associated with exposure to PFAS at lower levels than PFAS are tested for in the environment, or reported.[30]

Once PFAS enter the environment, they can stay there for decades or longer.[31] In fact, DuPont scientists have confirmed that certain PFAS take between "1200 and 1700 years" to degrade. Due to their persistent nature and high mobility in water, PFAS undergo a process called global distillation, or the "grasshopper effect," that causes PFAS in the environment to migrate to polar regions over time.[32] Global ocean current patterns represent a significant pathway for this long-range transport of PFAS to the Arctic; for example, an estimated two to twelve metric tons of PFOA are transported to the Arctic every year.[33] Recent studies also detected the replacement PFAS GenX in remote Arctic waters.[34] The transported PFAS accumulate over time in the environment and in biological organisms.[35] Arctic mammals and

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[30] Jody Shoemaker & Dan Tettenhorst, EPA, Office Rsch. & Dev., EPA/600/R-18/352, *Method 537.1: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)* (2018), https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=343042&Lab=NERL&simpleSearch=0&showCriteria=2&searchAll=Determination+of+Selected+Per-+and+Polyfluorinated+Alkyl+Substances+&TIMSType=&dateBeginPublishedPresented=11%2F02%2F2016.

[31] Wang et al., *supra* note 5.

[32] Samuel Byrne et al., *Exposure to Polybrominated Diphenyl Ethers and Perfluoroalkyl Substances in a Remote Population of Alaska Natives*, 231 Env't Pollution 387 (2017), https://www ncbi.nlm.nih.gov/pmc/articles/PMC6945979/pdf/nihms-967862.pdf.

[33] Konstantinos Prevedouros et al., *Sources, Fate and Transport of Perfluorocarboxylates*, 40 Env't Sci. & Tech. 32 (2006), https://pubmed ncbi.nlm.nih.gov/16433330/.

[34] Hanna Joerss et al., *Transport of Legacy Perfluoroalkyl Substances and the Replacement Compound HFPO-DA through the Atlantic Gateway to the Arctic Ocean—Is the Arctic a Sink or a Source?*, 54 Env't Sci. & Tech. 9958 (2020), https://pubs.acs.org/doi/abs/10.1021/acs.est.0c00228.

[35] Inputs of PFOA to the Arctic via ocean currents are nearly two times greater than those from atmospheric deposition of precursor breakdown products. Derek C. G. Muir & Cynthia A. de Wit, *Trends of Legacy and New Persistent Organic Pollutants in the Circumpolar Arctic: Overview, Conclusions, and Recommendations*, 408 Sci. Total Env't 3044 (2010), https://www.sciencedirect.com/science/article/abs/pii/S0048969709011474; Prevedouros et al., *supra* note 33.

birds inhabiting supposedly pristine habitats have detectable PFAS concentrations in their blood serum, liver, and fat tissues.[36] This includes sensitive species such as beluga whales and polar bears.[37]

E. Greater Risk Populations Experience Greater Risks of Harm from PFAS Exposure

While PFAS are pervasive environmental contaminants and are detectable in the blood serum of most Americans,[38] scientific studies have identified certain subpopulations that are more vulnerable to the adverse health effects of PFAS exposure due to either greater exposure or greater susceptibility to harm than the general population. Such greater risk populations include occupational workers, firefighters, communities living in polar regions, communities living near facilities that release PFAS, children, infants, and the developing fetus. Firefighters, for instance, are highly exposed to PFAS from both their presence in the fire-fighting foam as well as the PFAS-coated protective gear for heat resistance (i.e. "turnout gear") and combusted PFAS-treated household items like carpets and furniture.[39] Additionally, biomonitoring data of workers in the fluorochemical industry over decades have demonstrated consistently higher levels of PFAS in blood serum compared to the general population.[40] Arctic communities, including Alaskan Indigenous Tribal Communities, particularly those that subsist on fish and marine mammals, also experience disproportionately high levels of PFAS exposure due to the

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[36] *See, e.g.*, Wouter A. Gebbink et al., *Observation of Emerging Per- and Polyfluoroalkyl Substances (PFASs) in Greenland Marine Mammals*, 144 Chemosphere 2384 (2016), https://pubmed ncbi nlm nih.gov/26610298/.
[37] *Id*; Jonathan W. Martin et al., *Identification of Long-Chain Perfluorinated Acids in Biota from the Canadian Arctic*, 38 Env't Sci. & Tech. 373 (2004), https://pubs.acs.org/doi/10.1021/es034727%2B.
[38] Calafat et al., *supra* note 27. *See also* ATSDR *Overview of Perfluoroalkyl and Polyfluoroalkyl Substances*, *supra* note 27.
[39] *See UArizona Researchers Study Health Risks of Chemicals in Firefighter Foam, Gear*, FireEngineering (Feb. 13, 2020), https://www fireengineering.com/2020/02/13/484059/uarizona-researchers-study-health-risks-of-chemicals-in-firefighter-foam-gear/#gref.
[40] *See* Geary W. Olsen, *PFAS Biomonitoring in Higher Exposed Populations*, *in* Toxicological Effects of Perfluoroalkyl and Polyfluoroalkyl Substances 77, 80–99 (Jamie C. DeWitt ed., Springer Int'l Publ'g 2015).

aforementioned long-range transport of PFAS to polar regions and bioaccumulation in Arctic aquatic organisms.[41]

Children, infants, and the developing fetus are also exposed to higher levels of PFAS and are more susceptible to harm from these exposures. PFAS can transfer across the placenta, and have been found in umbilical cord blood,[42] putting the developing fetus at risk of exposure.[43] Exposure to even low levels of certain PFAS during pregnancy has been linked to decreased birth weight,[44] and altered growth, learning, and immune responses in infants and older children.[45] PFAS have also been detected in breast milk, prolonging exposures beyond pregnancy and into infancy and early childhood.[46] And because of their small size, dietary intake, and increased likelihood of hand-to-mouth behaviors, children and infants bear higher body burdens (i.e. have higher serum concentration per body weight) and experience higher PFAS exposures than older individuals.[47]

Scientists describe the period of early life, spanning from early pregnancy to early childhood as a "critical window" of development during which rapid growth, differentiation,

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[41] Samuel C. Byrne et al., *Exposure to Polybrominated Diphenyl Ethers and Perfluoroalkyl Substances in a Remote Population of Alaska Natives*, 231 Env't Pollution 387 (2017), https://doi.org/10.1016/j.envpol.2017.08.020; Samuel C. Byrne et al., *Exposure to Perfluoroalkyl Substances and Associations with Serum Thyroid Hormones in a Remote Population of Alaska Natives*, 166 Env't Rsch. 537 (2018), https://doi.org/10.1016/j.envres.2018.06.014.

[42] *See, e.g.*, Tye E. Arbuckle et al., *Umbilical Cord Blood Levels of Perfluoroalkyl Acids and Polybrominated Flame Retardants*, 216 Int'l J. Hygiene & Env't Health 184 (2013), https://www.sciencedirect.com/science/article/abs/pii/S143846391200034X.

[43] Kerstin Winkens et al., *Early Life Exposure to Per- and Polyfluoroalkyl Substances (PFASs): A Critical Review*, 3 Emerging Contaminants 55 (2017), https://www.sciencedirect.com/science/article/pii/S2405665017300033.

[44] ATSDR *Toxicological Profile for Perfluoroalkyls*, *supra* note 11, at 12–14; Cathrine C. Bach et al., *Perfluoroalkyl and Polyfluoroalkyl Substances and Human Fetal Growth: A Systematic Review*, 45 Critical Revs. in Toxicology 53, https://doi.org/10.3109/10408444.2014.952400; Paula I. Johnson et al., *The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Systematic Review of Human Evidence for PFOA Effects on Fetal Growth*, 122 Env't Health Persps. 1028, https://doi.org/10.1289/ehp.1307893.

[45] Kristen M. Rappazzo et al., *Exposure to Perfluorinated Alkyl Substances and Health Outcomes in Children: A Systematic Review of the Epidemiologic Literature*, 14 Int'l J. Env't Rsch. & Pub. Health 691 (2017), https://www ncbi.nlm.nih.gov/pmc/articles/PMC5551129/.

[46] *See, e.g.*, Arbuckle et al., *supra* note 42.

[47] Winkens et al., *supra* note 43.

nutrition uptake, and formation of final organ structures occur. For these reasons, toxic chemicals can have devastating, life-long impacts even at low levels of exposure during early development.[48] Studies have linked early life exposures to some PFAS—including both long-chain and replacement PFAS—to impaired growth, learning, and immune response, [49] as well as delayed puberty[50] and decreased antibody response following childhood vaccinations.[51] This early life sensitivity to PFAS exposure is reflected in scientific assessments conducted by federal agencies: ATSDR calculated that the minimal risk levels ("MRLs") (an estimate of the amount of a chemical a person can eat, drink, or breathe each day without a detectable risk to health) for children who drink water contaminated with certain PFAS, including PFOA, PFOS, PFHxS, and PFNA, are a quarter to a third of the MRLs for healthy adults.[52]

Finally, communities residing near PFAS-contaminated sites should also be considered greater risk populations because they experience higher levels of PFAS exposure and could be additionally burdened by other non-chemical stressors that increase susceptibility to harm from PFAS.

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[48] Jerrold J. Heindel et al., *Developmental Origins of Health and Disease: Integrating Environmental Influences*, 156 Endocrinology 3416 (2015), https://bit.ly/3b3ibNZ; Deborah Bennett et al., *Project TENDR: Targeting Environmental Neuro-Developmental Risks the TENDR Consensus Statement*, 124 Env't Health Persps. A118 (2016), https://www.ncbi nlm nih.gov/pmc/articles/PMC4937840/.

[49] Rappazzo et al., *supra* note 45; Chunyuan Fei, *Perfluorinated Chemicals and Fetal Growth: A Study within the Danish National Birth Cohor*t, 115 Env't Health Persps. 1677 (2007), https://www ncbi.nlm.nih.gov/pmc/articles/PMC2072850/.

[50] Maria-Jose Lopez-Espinosa et al., *Association of Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate* (PFOS) with *Age* of *P*uberty among *Children Living Near* a *Chemical Plant*, 45 Env't Sci. & Tech. 8160 (2011), https://pubs.acs.org/doi/10.1021/es1038694.

[51] *See, e.g.*, Berit Granum et al., *Pre-Natal Exposure to Perfluoroalkyl Substances May Be Associated with Altered Vaccine Antibody Levels and Immune-Related Health Outcomes in Early Childhood*, 10 J. Immunotoxicology 373 (2013), https://www.tandfonline.com/doi/full/10.3109/1547691X.2012.755580; Winkens et al., *supra* note 43.

[52] ATSDR converted the MRL to drinking water concentrations by accounting for an average adult's or child's weight and water intake. ATSDR, *ATSDR's Minimal Risk Levels (MRLs) and Environmental Media Evaluation Guides (EMEGs) for PFAS* (2018), https://www.atsdr.cdc.gov/pfas/docs/PFAS-MRL-HA-H.pdf.

F. Replacement PFAS Can Be Presumed to Pose Similar Risks to Human Health and the Environment

Scientists agree that PFAS—including both long-chains and their replacements—have the capability to exert similar, serious harm to human and environmental health. As the federal government's own scientists have recognized, the entire class of PFAS is comprised of structurally similar compounds that scientists can "reasonably expect to act through the same pathways and have similar effects."[53] Recent studies examining toxicity of the shorter-chain, replacement PFAS support this idea.[54] For example, an animal toxicity study demonstrated that exposure to the widely used short-chain replacement GenX was associated with many of the same health effects as long-chain PFAS, including developmental toxicity.[55] In particular, "[m]ultiple lines of evidence," including human and animal studies, indicate that old and new PFAS are immunotoxicants.[56]

By virtue of their carbon-fluorine bonds, PFAS, including short-chain replacement compounds, are expected to persist in the body and environment.[57] A group of the world's top scientists in PFAS research stated that "replacement[] [PFAS] will be similarly resistant to ultimate degradation, i.e. persistent, in the environment as long-chain PFAS[]."[58] Indeed, EPA itself has stated that "[s]hort-chain PFAS are as persistent in the environment as their longer-

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[53] Testimony of Linda S. Birnbaum, *supra* note 5, at 4; *see also* Wang et al., *supra* note 5.
[54] *See PFAS-Tox Database: Easy Access to Health and Toxicology Data on PFAS*, PFAS-TOX Database, https://pfastoxdatabase.org/ (last visited Apr. 23, 2021).
[55] Justin M. Conley et al., *Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats*, 127 Env't Health Persps. 037008 (2019), https://www ncbi.nlm.nih.gov/pmc/articles/PMC6768323/.
[56] Kwiatkowski et al., *supra* note 6, at 534.
[57] Geary W. Olsen et al., *Half-life of Serum Elimination of Perfluorooctanesulfonate, Perfluorohexanesulfonate, and Perfluorooctanoate in Retired Fluorochemical Production Workers*, 115 Env't Health Persps. 1298 (2007), https://pubmed.ncbi nlm nih.gov/17805419/. *See also* ATSDR *Toxicological Profile for Perfluoroalkyls*, *supra* note 11, at 4.
[58] Martin Scheringer et al., *Helsingør Statement on Poly-and Perfluorinated Alkyl Substances (PFASs)*, 114 Chemosphere 337, 337 (2014), https://www.sciencedirect.com/science/article/pii/S004565351400678X.

chain analogues."[59] As a result, as mentioned above, both old and new PFAS have been detected in remote and pristine lands near the Arctic, reflecting their similar long-range mobility and persistence.[60] Some replacement PFAS may present even greater risks to the environment than the long-chain PFAS they replaced. The weight of the scientific evidence shows that replacement PFAS may be equally, if not more, mobile in aqueous environmental media and in soil,[61] potentially resulting in contamination across greater distances.[62] And, recent studies suggest that traditional water treatment systems used to remove long-chain PFAS may be less efficient at absorbing and capturing shorter-chain, replacement PFAS.[63]

Large-scale biomonitoring studies are already showing an increasing trend of unidentified PFAS compounds in people,[64] which suggests that people are being exposed to new and unidentifiable PFAS, likely as a result of: environmental releases of complex mixtures of older and newer PFAS from industrial processes; poorly regulated or unregulated disposal of PFAS and PFAS-containing mixtures and products; and from use of products containing PFAS.

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[59] EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* 13 (2019), https://nepis.epa.gov/Exe/ZyPDF.cgi/P100W32I.PDF?Dockey=P100W32I.PDF.
[60] *See* Joerss et al., *supra* note 34; Muir & de Wit, *supra* note 35.
[61] John W. Washington et al., *Nontargeted Mass-Spectral Detection of Chloroperfluoropolyether Carboxylates in New Jersey Soils*, 368 Science 1103 (2020), https://science.sciencemag.org/content/368/6495/1103.
[62] Stephan Brendel et al., *Short-chain Perfluoroalkyl Acids: Environmental Concerns and a Regulatory Strategy under REACH*, 30 Env't Scis. Eur. 9 (2018), https://enveurope.springeropen.com/articles/10.1186/s12302-018-0134-4.
[63] Philip McCleaf et al., *Removal Efficiency of Multiple Poly-and Perfluoroalkyl Substances (PFASs) in Drinking Water Using Granular Activated Carbon (GAC) and Anion Exchange (AE) Column Tests*, 120 Water Rsch. 77 (2017), Water research, https://pubmed ncbi nlm nih.gov/28478297/.
[64] Leo W. Y. Yeung & Scott A. Mabury, *Are Humans Exposed to Increasing Amounts of Unidentified Organofluorine?*, 13 Env't Chemistry 102 (2015), http://www.publish.csiro.au/en/EN15041.

BACKGROUND & LEGAL FRAMEWORK

A. Pre-Manufacture Notice—Safety Review and Approval of New Chemicals

TSCA's Pre-Manufacture Notice (PMN) requirement is designed to identify and protect against substances that may present unreasonable risks—*before* those substances enter the market.[65] A company intending to manufacture (which TSCA defines as encompassing both domestic production and import) a new chemical substance[66] for commercial purposes in the United States must submit to EPA a PMN at least 90 days before the date it wishes to commence manufacture. 15 U.S.C. § 2604(a)(1); *id.* at (i)(1) (defining manufacture as meaning manufacturing for commercial purposes); 15 U.S.C. § 2602 (defining manufacture to mean manufacture, produce, or import); 40 C.F.R. § 720.22. The applicable review period is 90 days, which the Administrator may extend for up to an additional 90 days when necessary to review all relevant information.[67] 15 U.S.C. §§ 2604(a)(1)(B), 2604(c), 2604(i). During this period, EPA must conduct a safety review for the new chemical and make one of five determinations:

> (1) that the substance "presents an unreasonable risk of injury to health or the environment;"

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[65] *See* S. Rep. No.94-698, at 10 (1976) ("[Tlhe premarket notification provisions of the committee bill forms the backbone of the preventive aspects of health protection sought by this legislation."); *see also* Env't & Nat'l Res. Pol'y Div, Libr. of Cong., *Legislative History of the Toxic Substances Control Act Together with a Section-By-Section Index* 215 (1976), http://fluoridealert.org/wp-content/uploads/tsca.legislative-history.pdf ("[A] strong premarket screening process is a key factor in effective operation of this legislation.") (Remarks of Sen. Tunney) ("TSCA Legislative History"); H.R. Rep. No.94-1341, at 1 (1976) ("[T]hrough its testing and premarket notification provisions, the bill provides for the evaluation of the hazard-causing potential of new chemicals before commercial production begins."); TSCA Legislative History at 534 ("This bill principally is intended to have new chemicals coming on the market regularly tested to see that they are not going to harm people or the environment.") (Remarks of Rep. Staggers); TSCA Legislative History at 208 (Remarks of Sen. Tunney); *Id.* at 216 (Remarks of Sen. Hartke); *Id.* at 539 (Remarks of Rep. Metcalfe); *Id.* at 734 (Remarks of Sen. Moss); *Id.* at 735 (Remarks of Sen. Pearson); *Id.* at 740 (Remarks of Sen. Magnuson); and *Id.* at 747 (Remarks of Rep. Murphy).

[66] A "new chemical substance" is defined as any chemical substance that is not included on the TSCA Chemical Substance Inventory. 15 U.S.C. § 2602(11); 40 C.F.R. § 710.3.

[67] *See Reviewing New Chemicals Under the Toxic Substances Control Act (TSCA): Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table*, EPA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and (last updated Apr. 23, 2021).

(2) that "the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects" of the substance;

(3) that "the manufacture, processing, distribution in commerce, use, or disposal of [the] substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment,"

(4) that the "substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance," or

(5) "that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment."

15 U.S.C. § 2604(a)(3). Amendments to TSCA in 2016 ("the Lautenberg Amendments") specifically require EPA to evaluate whether the chemical may pose an unreasonable risk to "potentially exposed or susceptible subpopulations," 15 U.S.C. § 2604(a)(3) (referred to in this Petition as "greater risk populations"),[68] and EPA must rely on the best available science and make decisions based on the weight of the scientific evidence[69] when conducting those reviews.

If EPA determines that the substance "is not likely to present an unreasonable risk," the chemical can enter commerce unrestricted. 15 U.S.C. § 2604(g). If the Administrator determines that the substance "presents an unreasonable risk," s/he must take actions "to the extent necessary to protect against such risk," including prohibiting or limiting its manufacture. 15 U.S.C. §§ 2604(a)(3), (f). EPA must also regulate the chemical if: it lacks information to

[68] 15 U.S.C. § 2602(12) defines "potentially exposed or susceptible subpopulation" as, "a group of individuals within the general population identified by the [EPA] Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." The statutory provision includes "infants, children, pregnant women, workers, or the elderly" in a non-exhaustive list of examples of such populations. In the context of PFAS contamination the language of this statutory provision covers the developing fetus, occupational workers, firefighters, communities living in polar regions, and communities living near facilities that release PFAS. *See supra* Factual Background § E.
[69] *Id*. §§ 2625(h), (i).

make a reasoned evaluation; given that lack of information, determines that the chemical may present an unreasonable risk; or the quantities of manufacture or exposure to the substance may reach the "substantial" level. *See* 15 U.S.C. § 2604(e).

The PMN process was designed to further TSCA's overarching purpose, which is to "prevent the general environment from becoming the laboratory in which harmful effects of chemicals are discovered." *Cf. Dow Chem. Co. v. U.S. E.P.A.*, 605 F.2d 673, 676 (3d Cir. 1979); *see* S. Rep. No. 94-698, at 3 (1976) ("[W]e have become literally surrounded by a man-made chemical environment. … [T]oo frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers."). To more fully align TSCA with its purpose, Congress amended the statute in 2016, and one of the most significant amendments was to require EPA to review and make an affirmative determination on each PMN before manufacturing could commence. *See* 15 U.S.C. § 2604(a)(1)(B)(ii). Before the amendments, a PMN was "deemed approved" even if EPA failed to act within the allotted timeframe.[70] Under the amended TSCA, PMNs can no longer be "deemed approved," even if EPA fails to act within the review period. *See* 15 U.S.C. § 2604(a)(4)(A). That change was a recognition that allowing manufacture of new chemicals to proceed when EPA has not been able to affirmatively evaluate potential risks and impose needed conditions endangers public health.

PMNs must contain certain information so that EPA can conduct the required safety review during the review period. They must include information on: the chemical's identity, structure, and formula; byproducts and impurities; environmental releases; intended uses; and, disposal practices. 15 U.S.C. § 2604(d)(1); *see also* 40 C.F.R. § 720.45. The applicant must

[70] S. Rep. No. 114-67 (2015); Kevin McLean, Harv. L. Sch., *Three Years After— Where Does Implementation of the Lautenberg Act Stand?* 19 (2020), http://eelp.law.harvard.edu/wp-content/uploads/McLean-TSCA.pdf.

provide a diagram and description of its production process, inform EPA of its estimated maximum production volume, and provide all test data in the applicant's possession or control and a description of all other data the applicant knows of or can reasonably ascertain. *See* 40 C.F.R. §§ 720.45 and 720.50; EPA Sample PMN Form at 1,[71] attached as Exhibit A. If the submitter becomes aware of new relevant information during the review period, it must provide it to EPA within ten days of receiving it and no later than five days before the review period expires. 40 C.F.R. § 720.40(f).

B. Exemptions to the PMN Process

Exemptions to the PMN process are tightly circumscribed. TSCA includes a few, very limited exceptions to the PMN requirement in the statute itself. *See, e.g.*, 15 U.S.C. § 2604(h)(1) (test marketing exemption); *id.* § 2604(h)(3) (research and development exemption). It also authorizes EPA to promulgate rules granting additional exemptions from the PMN requirement, but only if EPA determines that the chemicals falling within the exemption "*will not present* an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(h)(4) (emphasis added). Thus, while EPA may permit a specific new chemical assessed through the PMN process to be manufactured if it determines that the chemical is "*not likely*" to present an unreasonable risk, a new chemical or group of new chemicals may circumvent the PMN process *altogether* if and only if a much higher level of certainty is met—that those chemicals "*will not*" present an unreasonable risk.

[71] EPA, OMB No. 2070-0012, Premanufacture Notice for New Chemical Substances Form, https://www.epa.gov/sites/production/files/2020-02/documents/section_5_main_form_updated_omb_and_expiration_01142020.pdf.

And, as with the assessment of chemicals under the PMN process, the 2016 TSCA Amendments required that the high bar of "will not present" for an exemption to be valid must take into consideration and ensure protection of greater risk populations. 15 U.S.C. § 2604(h)(4) (2016). In other words, EPA cannot allow an exemption to the PMN process to be used to approve chemicals where the best available science establishes that those chemicals may present an unreasonable risk to a greater risk population, regardless of its assessment of risk for the population as a whole.

C. The PMN Exemptions to Which this Petition Seeks Amendment

This Petition seeks to make PFAS ineligible for approval under the following four EPA-created exemptions: the Byproducts Exemption, the LVE, the LoREX Exemption, and the Polymer Exemption. These exemptions, described further below, were created several decades ago. The Byproducts, LVE, and Polymer exemptions were promulgated in the 1980s, soon after TSCA's enactment. *See* Premanufacture Notice Requirements and Review Procedures, 48 Fed. Reg. 21,722 (May 13, 1987) (codified at 40 C.F.R. pt. 720) (Byproducts); Premanufacture Notification Exemption; Exemption for Chemical Substances Manufactured in Quantities of 1,000 Kg or Less Per Year, 50 Fed. Reg. 16,477 (Apr. 26, 1985) (codified at 40 C.F.R. pt. 723) (LVE); Exemptions for Polymers, 49 Fed. Reg. 46,066, 46,066 (Nov. 21, 1984) (to be codified at 40 C.F.R. pt. 723). The LoREX exemption was enacted in the 1990s. *See* Low Release and Exposure Exemption, 60 Fed. Reg. 16,336 (Mar. 29, 1995) (codified at 30 C.F.R. pt. 723) (LoREX).[72]

[72] Excerpts of relevant statutes and regulations pertaining to these exemptions can be found in the Appendix to this petition.

1. The Byproducts Exemption

For purposes of this petition, the "Byproducts Exemption" refers to all new chemicals that are byproducts within the meaning of 40 C.F.R. §§ 720.30(g) or (h)(2) for which EPA does not require submission of a PMN. Understanding what is exempted under those provisions first requires an understanding of how TSCA treats new chemical byproducts.

Under TSCA, PMNs are required for byproducts. More specifically, PMNs must be submitted for new "chemical substances" manufactured, processed, or imported "for commercial purposes." *See* 15 U.S.C. § 2604(a)(1), *see also id.* at (i)(1) (defining manufacture as meaning manufacturing for commercial purposes). Chemical byproducts meet the definition of chemicals substances. *See* 15 U.S.C. § 2602(2); 40 C.F.R. § 720.3(d). And when a parent chemical is manufactured "for commercial purposes" the byproducts of that chemical are also manufactured "for commercial purposes." The term "manufacture *for* commercial purposes" is defined to mean "[t]o produce, with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer." 40 C.F.R. § 716.3 (emphasis added). The term includes byproducts because "[b]yproducts . . . without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes." 40 C.F.R. § 710.3. Thus, when new byproducts are produced during an activity with a purpose of obtaining a commercial advantage, a PMN is required for them.

EPA, however, has created an exemption for a subset of byproducts manufactured *for* commercial purposes—those byproducts that are not *used* for commercial purposes. 40 C.F.R. § 720.30(h)(2). In its regulations, EPA interprets TSCA as differentiating between when a chemical is manufactured *for* a commercial purpose and when it is *used* for a commercial

purpose: "Although [byproducts not *used for* commercial purposes] are *manufactured for* commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part." *Id*; *see also* 40 C.F.R. § 720.3(d) (defining "byproduct" as "a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture"). Thus, a byproduct could be *manufactured for* a commercial purpose—and thus fall within the definition of chemical substance under TSCA requiring a PMN—but, under EPA's interpretation of TSCA, if the byproduct is discarded and not itself used commercially, it is not *used for* a commercial purpose and is exempt from the PMN requirement under EPA regulations.

And even when a byproduct is used for a commercial purpose, EPA's regulations provide that a PMN still need not be submitted for byproducts in the following three circumstances: "[a]ny byproduct if its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes." 40 C.F.R. § 720.30(g).

Byproducts are subject to virtually no review under this exemption, as described further in Reasons to Grant the Petition § II.A.

2. The Low Volume Exemption

Under the "Low Volume Exemption" or LVE, PMNs need not be filed for new "[c]hemical substances manufactured in quantities of 10,000 kilograms [approximately 11.02

tons] or less per year." 40 C.F.R. § 723.50(a)(1)(i).[73] The review process for LVE applications allows approval by default after just 30 days. 40 C.F.R. § 723.50(g)(2). In contrast to PMN applications, if EPA experiences a backlog and simply is unable to complete its review, the manufacturer may commence production.

3. The Low Release and Exposure Exemption

Under the "Low Release and Exposure Exemption" or LoREX Exemption, PMNs need not be filed for what EPA considers "[c]hemical substances with low environmental releases and human exposures." 40 C.F.R. § 723.50(a)(1)(ii). In order to qualify for the LoREX Exemption, a manufacturer must show that the substance would meet certain specified criteria such as no dermal exposure, no inhalation exposure (except from certain air releases from incineration), and drinking water exposure and surface water concentrations under a certain amount. 40 C.F.R. § 723.50(c)(2).[74] When EPA reviews a LoREX application, it principally focuses on release and

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[73] 10,000 kg per year is not considered "low volume" by other regulatory agencies around the world. The EU, Canada, China, Japan, Korea, Taiwan, Australia and the Philippines all maintain a 1,000 kg/year threshold in recognition of the dangers that even small quantities of chemicals can pose. *See Comparison of Small Volume New Substance Registration*, ChemSafetyPRO (Feb. 8, 2017), www.chemsafetypro.com/Topics/Registration/Comparison_of_Small_Volume_Exemption_for_New_Chemical_Substance_Registrations.html.

[74] The full non-risk criteria to meet the LoREX exemption are as follows:
(i) Consumers and the general population. For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:
(A) No dermal exposure.
(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section.
(C) Exposure in drinking water no greater than a 1 milligram per year….
(ii) Workers. For exposure of workers to the new chemical substance during all manufacturing, processing, distribution in commerce, use and disposal of the substance:
(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).
(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).
(iii) Ambient surface water. For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion…unless EPA has approved a higher surface water concentration….
(iv) Incineration. For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration….

exposure and not toxicity. *See* 60 Fed. Reg. at 16,337. Like with the LVE exemption, the review process for LoREX Exemption applications is just 30 days. 40 C.F.R. § 723.50(g)(2). And similar to the LVE, if EPA experiences a backlog and is not able to complete its 30-day review of a LoREX exemption application, the manufacturer may commence production. *Id*.

4. The Polymer Exemption

The Polymer Exemption allows polymers meeting a list of criteria pertaining to the molecular weight (MW) of the polymer and its composition to enter commerce without going through PMN review. *See* 40 C.F.R. § 723.250(e). The Polymer Exemption lists six categories of polymers that, despite otherwise meeting the eligibility criteria for the exemption, may not use it and must undergo PMN review. *See* 40 C.F.R. § 723.250(d). As described further below, one of these categories contains certain PFAS polymers. *See id.* 40 C.F.R. § 723.250(d)(6).

(v) Land or groundwater. For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential. 40 C.F.R. § 723.50(c)(2).

REASONS TO GRANT THE PETITION

I. TSCA REQUIRES EPA TO MAKE PFAS INELIGIBLE FOR THE BYPRODUCTS, LVE, AND LOREX EXEMPTIONS

Developments in PFAS research and in the law have made it untenable to allow new PFAS to gain entry to the market through the Challenged Exemptions. These three exemptions were created long before the risks associated PFAS were understood.[75] A tremendous amount of information has come to light since the promulgation of the Challenged Exemptions demonstrating that PFAS share similar characteristics with respect to toxicity and persistence, and in many cases bioaccumulation, resulting in similar effects.[76] The agency also created the Challenged Exemptions before enactment of the 2016 Lautenberg Amendments to TSCA, which mandate that EPA consider the risks posed to greater risk populations when making unreasonable risk determinations regarding new chemicals.

EPA cannot conclude that PFAS chemicals produced as byproducts, or in the amounts or conditions permitted under the LVE and LoREX exemptions "will not present an unreasonable risk" to human health and the environment, including to greater risk populations. *See* 15 U.S.C. § 2604(h)(4). Scientific evidence developed over the last decade has shown that: 1) new PFAS meeting the non-risk criteria for the Challenged Exemptions at issue may present unreasonable risks, including to greater risk populations; and 2) in some instances, EPA lacks sufficient data or time to make a determination about whether new PFAS meeting the non-risk criteria for the Challenged Exemptions will not present an unreasonable risk. Because EPA cannot make the § 2604(h)(4) "will not present" finding for any PFAS, even if they meet the non-risk criteria for the Challenged Exemptions, EPA may not continue to approve PFAS under those exemptions.

[75] *See supra* Background & Legal Framework § C.
[76] *See supra* Factual Background §§ A–B.

40 C.F.R. § 723.50(d) similarly requires EPA to make new PFAS ineligible for the LVE and LoREX exemptions. That provision prohibits the approval under these two exemptions of substances that may cause serious acute, serious chronic, or significant environmental effects. All PFAS may cause these deleterious effects.

A. TSCA Requires EPA to Make Chemical Substances Ineligible for a PMN Exemption if EPA Cannot Conclude Those Chemicals "Will Not Present an Unreasonable Risk of Injury," Including to a Greater Risk Population

TSCA is clear: PMN exemptions are only for new chemicals that can meet the high burden that they "will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(h)(4). Thus, EPA has acknowledged a corollary to that standard: *excluding* a group of chemicals from eligibility for an exemption is "necessary [when] . . . EPA can no longer conclude that [such chemicals] 'will not present an unreasonable risk to human health or the environment,' which is the determination necessary to support an exemption under TSCA." Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers, 71 Fed. Reg. 11,484, 11,484 (Mar. 7, 2006) (codified at 40 C.F.R. pt. 723.250); *see also* Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers, 75 Fed. Reg. 4,295, 4,295 (Jan. 27, 2010) (codified at 40 C.F.R. § 723.250); 71 Fed. Reg. at 11,498 (explaining that 15 U.S.C. § 2604(h)(4) authorizes EPA to amend and repeal rules it enacted under that section).[77]

Indeed, EPA has previously excluded certain PFAS from one of the several exemptions to the PMN process precisely because it was unable to make the "will not present an unreasonable risk" finding. And it reached this conclusion even before TSCA was amended to

[77] Wendy Wagner et al., *Dynamic Rulemaking*, 92 N.Y.U. L. Rev. 183, 206 (2017).

require consideration of greater risk populations when making a finding of "no unreasonable risk."

In 2010, EPA enacted a rule excluding certain PFAS from being eligible for the "polymer exemption" to the PMN requirement. 75 Fed. Reg. at 4,295.[78] EPA noted that, by their very nature, exemptions under § 2604(h)(4) are for chemicals EPA believes pose a low risk of injury to health or the environment. 71 Fed. Reg. at 11,498. Thus, it explained, certain chemicals have and must be excluded from using such an exemption when EPA either: (1) has information suggesting that the conditions for an exemption under § 2604(h)(4) are not met for certain chemicals/ those chemicals may present unreasonable risks; or (2) has insufficient data and review experience to support a finding that such chemicals falling under the exemption will not present an unreasonable risk. *Id.*[79]

Based on those criteria, EPA determined that it must exclude the group of PFAS from eligibility to use the polymer exemption because it could no longer conclude that those polymers will not present an unreasonable risk to human health or the environment. 71 Fed. Reg. at 11,484; 11,488; *see also* 75 Fed. Reg. at 4,295. EPA explained that polymers containing certain PFAS may degrade and release PFAS into the environment, which "are expected to persist in the environment, may bioaccumulate, and may be highly toxic." 75 Fed. Reg. at 4,296. EPA acknowledged that of the thousands of PFAS, the most well studied are PFOA and PFOS, which studies show have a "high level of toxicity . . . at very low dose levels in exposed laboratory

[78] The proposed and final rule making certain PFAS ineligible to use the polymer exemption applies to only a subcategory of PFAS. As explained in Reasons to Grant the Petition § III, petitioners urge EPA to further amend the Polymer Exemption to ensure it includes all PFAS.

[79] This two-part rule is a corollary of TSCA section 2604(h) and is echoed in other regulatory text. *See, e.g.*, 60 Fed. Reg. at 16,337 (stating that "Any [LVE] exemption application will be denied if the Agency is unable to affirmatively find that manufacture, processing, distribution in commerce, use, and disposal of the exempted substance pursuant to the exemption will not present an unreasonable risk of injury to human health or the environment.").

animals." 71 Fed. Reg. at 11,498. It emphasized that, in prohibiting approval of new polymers containing PFAS via the exemption, it was not concluding that other PFAS "*categorically share* similar toxicity, bioaccumulation, and persistence characteristics with PFOS and PFOA." 75 Fed. Reg. at 4,298 (emphasis added). Rather, it was concluding "that they *may, or are expected to, share similar characteristics*, based on available information and its professional judgment and experience." 75 Fed. Reg. at 4,298–99. Thus, EPA could no longer make a generally applicable finding that the manufacture, processing, distribution in commerce, use, and/or disposal of the PFAS at issue would not present an unreasonable risk of injury to health or the environment, and therefore it could no longer allow such PFAS to enter commerce under this exemption. 71 Fed. Reg. at 11,498; 75 Fed. Reg. at 4,301.

EPA also rejected a proposal to limit the carve-out from the exemption to only those PFAS at issue that contain greater than four carbons in the alkyl chain. 71 Fed. Reg. at 11,499. The agency stated that: (1) "based on available information, EPA cannot continue to find that" the PFAS polymers at issue containing fewer than five carbon atoms "will not present an unreasonable risk to human health and the environment," *id.*; and (2) "EPA has insufficient evidence at this time . . . to definitively establish a lower carbon chain length limit to meet the 'will not present an unreasonable risk' finding, which is the determination necessary to support an exemption under . . . TSCA." 71 Fed. Reg. at 11,486 (citation omitted).[80]

In sum, as EPA concluded in the 2010 polymer exemption exclusion, when a new chemical or group of chemicals may share characteristics that prevent EPA from concluding that

[80] Notably, EPA concluded that it had "insufficient evidence . . . to definitively establish a carbon chain length at which" the PFAS at issue "[would] not present an unreasonable risk." 71 Fed. Reg. at 11,499; *see also* 75 Fed. Reg. at 4,299.

they "will not present an unreasonable risk," section 2604(h)(4) requires that they be excluded from the exemption. In such circumstances, individual chemicals and the potential risks to the environment and human health they present "should be evaluated during the 90-day PMN review period that Congress contemplated for new chemicals under section 5(a)(1)(A) of TSCA … so that EPA can better evaluate and address the[] concerns" posed by such chemicals. 71 Fed. Reg. at 11,497–98; *see also* 75 Fed. Reg. at 4,301.

EPA's decision to exclude PFAS from the Polymer Exemption is consistent with (and, indeed, required by) TSCA's mandate that chemicals *even possibly* presenting an unreasonable risk to the environment must undergo a full PMN safety review. *See* 15 U.S.C. 2604(h)(4). For the same reason that TSCA required EPA's decision to exclude certain PFAS polymers from the Polymer Exemption, it must exclude PFAS from the other Section 2604(h) exemptions that are the subject of this petition. A refusal to apply that reasoning when considering this petition would be akin to having "a rule for Monday, another for Tuesday." *Shaw's Supermarkets, Inc. v. Nat'l Lab. Rels. Bd.*, 884 F.2d 34, 37 (1st Cir. 1989).

As discussed further below, those mandates of TSCA section 2604(h), considered together with: (1) the requirement that EPA now consider potentially exposed or susceptible subpopulations when assessing whether it can make a finding of "will not present an unreasonable risk;" and (2) the growing body of scientific evidence that PFAS as a class may present unreasonable risk, compels EPA to make any PFAS ineligible to use the Challenged Exemptions.

B. TSCA Requires EPA to Make New PFAS Ineligible for the Byproducts, LVE, and LoREX Exemptions Because EPA Cannot Conclude that PFAS Manufactured, Used, Disposed of, or Distributed under these Exemptions "Will Not Present an Unreasonable Risk of Injury"

As a matter of law, EPA must prohibit the use of the Byproducts Exemption, LVE, and LoREX Exemptions for PFAS because the agency cannot conclude that PFAS manufactured, used, disposed of, or distributed under these exemptions "will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(h)(4).[81] As discussed above, EPA must make a group of chemicals ineligible to use an exemption when either: 1) the agency has information suggesting that those chemicals may, or are expected to, present an unreasonable risk; or 2) has insufficient data and review experience to support a finding that such chemicals falling under the exemption will not present an unreasonable risk. *See* 75 Fed. Reg. at 4,301.[82] The best available science demonstrates that all PFAS *may* present unreasonable risk because the studied members of the class are associated with severe hazards often at extremely low levels of exposure, as well as having persistent and bioaccumulative characteristics, and none of the exemption criteria eliminate the inherent potential risk these chemicals pose.

1. EPA is required to make PFAS ineligible for the Byproducts Exemption because the agency has information demonstrating that PFAS byproducts may present an unreasonable risk.

The Byproducts Exemption includes no limitations on the amounts of a PFAS manufactured or released. Rather, under EPA's current approach, the availability of the Byproduct Exemption turns on the purpose for which the chemical will be used, meaning that

[81] Because there is no independent statutory basis for excluding byproducts produced during the manufacture of a commercial chemical from the PMN process, Petitioners presume, for the sake of argument, that this exemption was promulgated under 15 U.S.C. § 2604(h)(4).
[82] *See supra* Reasons to Grant the Petition § I.A.

PFAS may qualify for this exemption as long as they are used for non-commercial purposes, or one of a handful of commercial purposes, even if it is reasonably foreseen that they will enter the environment at high volume. 40 C.F.R. §§ 720.30(g); (h)(2). There is no statutory basis on which to exempt PFAS from PMN review based on the purpose for which they are used. Whether manufactured as a parent chemical or a byproduct, PFAS are PFAS. The weight of the scientific evidence shows that PFAS may present unreasonable risks to human health and the environment based on the class of chemicals' similar toxic, persistent, and bioaccumulative characteristics.[83] The weight of the scientific evidence also suggests that PFAS exposure increases risk of adverse health outcomes, including harm to vital organs, the immune system, and reproductive health.[84] While EPA does not know that every unstudied PFAS will behave akin to well-understood PFAS, such a determination is not necessary. *See* 75 Fed. Reg. at 4,298–99 (acknowledging that EPA was required to prohibit certain PFAS from using polymer exemption because chemicals may or were expected to share similar characteristics to PFOA and PFOS and that the agency did not and need not make a finding that other PFAS "categorically share similar toxicity, bioaccumulation, and persistence characteristics with PFOS and PFOA").[85] Because EPA can no longer make a finding that the manufacture, processing, distribution in commerce, use, and/or disposal of PFAS byproducts "will not present an unreasonable risk of injury to health or the environment," it can no longer allow such PFAS to escape PMN review under the Byproducts Exemption. 71 Fed. Reg. at 11,498; 75 Fed. Reg. at

[83] *See* Wang et al., *supra* note 5; Testimony of Linda S. Birnbaum, *supra* note 5 (PFAS are structurally similar compounds that scientists can "reasonably expect to act through the same pathways and have similar effects"); *see also supra* Factual Background § F.
[84] Testimony of Linda S. Birnbaum, *supra* note 5; Kwiatkoswki et al., *supra* note 6; ATSDR *Toxicological Profile for Perfluoroalkyls*, *supra* note 11.
[85] *See supra* Reasons to Grant the Petition § I.A.

4,301 (making similar finding with respect to Polymer Exemption); 75 Fed. Reg. at 4,298–99 (same).

Indeed, the case for excluding PFAS from the Byproducts Exemption has grown only stronger in the years since EPA excluded certain PFAS from the Polymer Exemption in 2010. Not only has the weight of the scientific evidence about PFAS confirmed what was expected in 2010, but the 2016 Lautenberg Amendments now require EPA's "will not present unreasonable risk" assessment for exemptions to consider risks to greater risk populations before approving new chemicals.[86] Studies highlighted earlier in this petition demonstrate that PFAS present greater risks to subpopulations such as firefighters, communities living in polar regions, infants, children, and developing fetuses.

Thus, EPA must initiate a rulemaking to prohibit future use of the Byproducts Exemption for new PFAS. That rulemaking should also prohibit the continued manufacture of any PFAS byproduct under the auspices of the Byproducts Exemption unless and until such PFAS has undergone a full PMN review and been approved by EPA, with a two-year window for manufacturers to receive such approval.

2. EPA is required to make new PFAS ineligible for the LoREX and LVE exemptions because the agency has information demonstrating that PFAS manufactured, distributed, disposed of, or used under these exemptions may present an unreasonable risk.

EPA must also exclude the manufacture of new PFAS from eligibility for the LVE and LoREX Exemptions because accumulating scientific evidence shows that contamination

[86] *See supra* Background & Legal Framework § A.

expected from those exemption thresholds may present unreasonable risk, meaning they cannot meet the "will not present an unreasonable risk" criterion for PMN exemptions.

For example, under both the LVE and LoREX exemptions, EPA expects levels of contamination far in excess of what can be presumed safe for PFAS. This is a grave public health concern as 200 million people in the United States rely on surface water as a source of drinking water.[87] EPA estimates the LVE threshold of manufacturing 10,000 kilograms per year of a chemical substance will result in releases of the chemical substance that correspond to a range of concentrations from 500 to 5,200,000 parts per trillion (ppt) in surface water. 60 Fed. Reg. at 16,343. But concentrations in that range would correspond to levels of PFAS contamination in drinking water that are unsafe. Surface water concentrations at the lower end of that range translate to drinking water concentrations that could result in exposure levels that are 20 times higher than levels even ATSDR considers unsafe for PFOA, PFNA, and PFOS,[88] levels that have been criticized as not being health protective.[89] 60 Fed. Reg. at 16,338. The LoREX Exemption allows PFAS contamination levels in drinking water that could similarly result in exposures[90] that are significantly higher than EPA's own national drinking water health advisories for PFOA and PFOS, state health-based water guidance and contamination limits for

[87] EPA, *FACTOIDS: Drinking Water and Ground Water Statistics for 2007* 4 (2008), https://nepis.epa.gov/Exe/ZyPDF.cgi/P100N2VG.PDF?Dockey=P100N2VG.PDF.

[88] ATSDR has set its minimum risk level dosage for PFOS and PFNA at 3 nanograms per kilogram bodyweight per day, and 2 ng/kg/day for PFOA. Using the agency's standard calculation at 80 kg bodyweight for adults, that level translates to 0.05 milligrams per year, or 20 times 1,000 ppt. See ATSDR *Toxicological Profile for Perfluoroalkyls*, *supra* note 11, at 15.

[89] *See* Letter from Anna Reade, Staff Scientist, Nat. Res. Def. Council, to ATSDR (Sept. 6, 2018), https://www.nrdc.org/sites/default/files/comments-on-atsdr-toxicological-profile-on-perfluoroalkyls-2018-draft_2018-08-21.pdf.

[90] The exemption allows up to 1 milligram PFAS in drinking water per year. 40 C.F.R. § 723.50(c)(2)(i), *see also* (iii). For ATSDR minimum risk levels corresponding to yearly exposure levels in drinking water, *see supra* note 88.

various PFAS, and ATSDR's minimum risk level dosage for PFOA and PFOS in drinking water.[91]

The high level of expected surface and drinking water contamination that could be expected from PFAS that are approved through the LVE and LoREX exemptions puts infants and children—greater risk populations EPA must now take into account when assessing eligibility for a PMN exemption—at especially high risk. These subpopulations are at risk of harm from exposure to PFAS through drinking water at much lower concentrations than those that pose risk to healthy adults.[92] For example, in 2018, the ATSDR set minimum risk levels ("MRLs")[93] for PFAS and converted these values into drinking water concentrations for children at 21 ppt for PFOA and 14 ppt for PFOS compared to 78 ppt and 52 ppt, respectively, for adults.[94] Those concentration conversions, however, have been criticized for relying on calculations that underestimate exposures to infants.[95] Using EPA's drinking water assumptions and parameters specific to infants,[96] drinking water concentrations as low as 3 and 2 ppt for PFOA and PFOS, respectively, would pose health risks to infants.[97] While EPA has failed to adopt any enforceable drinking water limits for PFAS, several states have enacted protective

[91] *See infra* p. 35.
[92] *Minimum Risk Levels (MRLs)*, ATSDR, https://www.atsdr.cdc.gov/minimalrisklevels/index html (last updated June 4, 2018).
[93] ATSDR defines MRL as "an estimate of the amount of a chemical a person can eat, drink, or breathe each day without a detectable risk to health. MRLs are developed for health effects other than cancer." *See id.*
[94] ATSDR *Minimum Risk Levels*, *supra* note 92; *See* Letter from Anna Reade, *supra* note 89.
[95] Anna Reade et al., NRDC, *Scientific and Policy Assessment for Addressing Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* 37, 77–81 (2019), https://www nrdc.org/sites/default/files/assessment-for-addressing-pfas-chemicals-in-michigan-drinking-water.pdf.
[96] *See, e.g.*, Memorandum from Mark A. Levine, Comm'r, Vt. Dep't Health, to Emily Boedecker, Comm'r, Vt. Dep't Health 4 (July 10, 2018), https://www healthvermont.gov/sites/default/files/documents/pdf/ENV_DW_PFAS_HealthAdvisory.pdf (using EPA-recommended body weight adjusted water intake rates and relative source contribution values specific to infants to calculate protective drinking water health advisory levels for four PFAS).
[97] Reade et al. *Scientific and Policy Assessment*, *supra* note 95, at 37, 77–81.

drinking water limits for PFAS that account for risk to infants and children at levels considerably lower than those calculated by ATSDR.[98]

Thus, on the basis of risk of PFAS in water alone, EPA cannot conclude that new PFAS manufactured at the thresholds allowed by the LVE and LoREX exemptions "will not present an unreasonable risk," as required for PMN exemptions.[99] At the very least, "a closer examination of the conditions of manufacturing, processing, distribution, use, and disposal [of said chemical] during a full 90-day PMN review" is necessary. *See* 75 Fed. Reg. at 4,301.

An additional example of unsafe contamination that would result if EPA continued to make the LVE and LoREX Exemptions eligible for new PFAS relates to ambient air releases. The LoREX Exemption permits ambient air releases of chemicals from incineration in amounts up to "1 microgram per cubic meter maximum annual average concentration." 40 C.F.R. § 723.50(c)(2)(iv). It is likely, however, that 1 microgram per cubic meter maximum annual average concentration of PFAS would be too high a threshold to ensure that the chemical "will not present an unreasonable risk." Indeed, Michigan's Department of Air Quality recently developed health-based PFOA and PFOS air emissions screening levels to be protective of sensitive individuals, including children and the elderly, at 0.07 microgram per cubic meter with

[98] *See* Chart collecting state action levels, *Per- and Polyfluoroalkyl Substances (PFAS)*, Association of State Water Administrators, www.asdwa.org/pfas/ (last visited April 26, 2021).

[99] The majority of the health-based drinking water guidance and legal limits mentioned above were developed specifically to be protective of sensitive and more highly exposed subpopulations. S*ee, e.g.*, Helen M. Goeden et al., *A Transgenerational Toxicokinetic Model and its Use in Derivation of Minnesota PFOA Water Guidance*, 29 J. Exposure Sci. & Env't Epidemiology 183, https://www nature.com/articles/s41370-018-0110-5. These are precisely the kinds of populations Congress had in mind when it instructed EPA, through revisions to 15 U.S.C. § 2604(h), to ensure that greater risk populations would be protected.

a 24-hour averaging time,[100] more than 10 times lower than the ambient air release concentration allowed by the LoREX.

3. EPA is required to make new PFAS ineligible for the LoREX and LVE Exemptions because the agency has insufficient information on which to conclude that PFAS manufactured, distributed, disposed of, or used under these exemptions will not present an unreasonable risk.

EPA also has insufficient data to support a finding that new PFAS falling under the LVE and LoREX exemptions "will not present an unreasonable risk" from expected air emissions. In short, this is because EPA has no adequate method for assessing the safety of PFAS air emissions at the thresholds permitted by the two exemptions. Indeed, EPA's own publications suggest that the agency's air emission tests do not supply "sufficient information to" to establish that a new PFAS will not present an unreasonable risk. [101]

For example, under the LVE, EPA assumes that if a chemical is manufactured at the LVE threshold of 10,000 kilograms per year, expected air emissions will not present an unreasonable risk to human health or the environment. Specifically, the agency estimates that a facility that manufactures 10,000 kilograms of a chemical per year will release 300 to 2,000 kilograms per year of the substance into the air. 60 Fed. Reg. at 16,343. But the agency cannot draw inferences about the health effects of PFAS from these figures with the level of certainty required to approve a new chemical under 15 U.S.C. § 2604(h)(4). A complete LVE safety review would require an estimation of inhalation exposure based upon the concentration of PFAS in the air and the duration of exposure. EPA's release estimates do not offer that

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[100] *Michigan PFAS Action Response Team: Air Quality Related Issues*, Michigan.gov, https://www michigan.gov/pfasresponse/0,9038,7-365-86704_94366---,00 html (select "What health-based screening levels exist for air?" drop down) (last visited Apr. 16, 2021).

[101] *See* Letter from Timothy Watkins, Dir., EPA Ctr. for Env't Measurement & Modeling, to Steven E. Flint, Dir. Div. Air Res., N.Y. Dep't Env't Conservation (Dec. 2, 2019), https://www.dec ny.gov/docs/remediation_hudson_pdf/nysdecrept12219.pdf.

information. *See, e.g.*, 60 Fed. Reg. at 16,343. Thus, the agency has insufficient information to determine that PFAS air emissions permitted under the LVE will not present an unreasonable risk.

Similarly, EPA has admitted that it lacks the standardized and validated methodology to properly collect data on PFAS air emissions resulting from incineration, which the agency needs in order to adequately confirm whether a PFAS subject to a LoREX application can be incinerated in compliance with the exemption's 1 microgram per cubic meter maximum annual average ambient air release threshold for incineration.[102] *See* 40 C.F.R. § 723.50(c)(2)(iv). Without the ability to accurately measure whether or not a PFAS can be incinerated in compliance with the LoREX ambient air release threshold, EPA cannot determine that a PFAS for which a LoREX exemption is sought will not present an unreasonable risk.

That EPA has insufficient data to conclude that new PFAS that meet the LVE and LoREX Exemption non-risk criteria will not present an unreasonable risk provides an additional reason why EPA must exclude PFAS from the LVE and LoREX exemptions.

C. EPA Must also Make PFAS Ineligible for the LVE and LoREX Exemptions in Order to Faithfully Apply 40 C.F.R. § 723.50(d)

Approving PFAS under the LVE and LoREX exemptions would also violate 40 C.F.R. § 723.50(d). That provision states that chemicals cannot be approved under the LVE or LoREX exemptions when the substances[103] "*may* cause …(1) Serious acute (lethal or sublethal) effects[;] (2) Serious chronic (including carcinogenic and teratogenic) effects[; or] (3) Significant

[102] *See, e.g.*, Interim Guidance on PFAS Destruction and Disposal at 45, Dkt. No. EPA-HQ-OLEM-2020-0527-0002 (Dec. 18, 2020), https://www.regulations.gov/document/EPA-HQ-OLEM-2020-0527-0002.

[103] The provision also applies to "any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance." 40 C.F.R. § 723.50(d). As a result, this statutory provision may create additional hurdles for the approval of long-chain PFAS, which have significant issues with transformation products.

environmental effects." 40 C.F.R. § 723.50(d) (emphasis added). The inquiry into whether or not a chemical has lethal, carcinogenic, or teratogenic effects is purely evidence-based. The answer is based on existing data and studies, and leaves little to no room for administrative discretion. When making science-based decisions, EPA is required both to use "the best available science" and to make the decisions "based on the weight of the scientific evidence." 15 U.S.C. §§ 2625(h), (i). The weight of scientific evidence demonstrates that exposure to PFAS meeting the non-risk criteria for manufacture, release, and exposure permitted under these exemptions *may* cause the adverse health and environmental effects set forth in § 723.50(d). For example, they may cause cancer, liver damage, and immunosuppression, which constitute serious acute and/or chronic health effects. *See* 40 C.F.R. §§ 723.50(b)(6)–(8); *see also id.* § 720.30(b)(10); *id.* § 720.3.[104]

The weight of the scientific evidence also demonstrates that PFAS at the LVE and LoREX non-risk thresholds may also cause significant environmental effects, including growth impairment and lethality in aquatic organisms.[105] Indeed, growth impairment was observed in fish exposed to PFAS at concentrations nearly 10,000 times lower than the higher end of the allowable range under LVE. [106] PFAS also induced adverse effects in a species of salamander that is closely related to the endangered California Tiger Salamander. Given the bioaccumulative nature of many PFAS, these effects are likely to persist for long periods of time.

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[104] *See supra* Factual Background § B.

[105] Gerald T. Ankley et al., *Assessing the Ecological Risks of Per- and Polyfluoroalkyl Substances: Current State-of-the Science and a Proposed Path Forward*, 40 Env't Toxicology & Chemistry 564 (2020), https://setac.onlinelibrary.wiley.com/doi/10.1002/etc.4869; Georgia M. Sinclair et al., *What Are the Effects of PFAS Exposure at Environmentally Relevant Concentrations?*, 258 Chemosphere 127340 (2020), https://www.sciencedirect.com/science/article/pii/S0045653520315332#bib53.

[106] Susanne Keiter et al., *Long-term Effects of a Binary Mixture of Perfluorooctane Sulfonate (PFOS) and bisphenol A (BPA) in Zebrafish (Danio rerio)*, 118–119 Aquatic Toxicology 116 (2012), https://www.sciencedirect.com/science/article/pii/S0166445X12001300?via%3Dihub.

Thus, PFAS that meet the non-risk criteria for LVE and LoREX may cause significant environmental effects, as defined by EPA. *See* 40 C.F.R. § 723.50(b)(8).[107]

Thus, the faithful application of 40 C.F.R. § 723.50(d) requires any new PFAS to be made ineligible for the LoREX and LVE exemptions and EPA must formalize the blanket ineligibility of these substances through an explicit regulatory amendment. Such an amendment would provide clear notice to PFAS manufacturers that EPA will not approve new PFAS via exemptions to the PMN review process. The amendment would also alleviate the inefficiencies involved in EPA making individual determinations on applications to manufacture new PFAS via PMN exemptions given that no PFAS can meet the "will not present" standard.[108]

Put simply, PFAS simply cannot meet the "will not present an unreasonable risk" standard. When a category of chemicals cannot meet the statute's "will not present an unreasonable risk" standard, that category of chemicals must be excluded from eligibility for the exemption, and must go through the more detailed PMN review process. EPA must immediately stop accepting and approving LVE and LoREX notices for new PFAS and initiate a rulemaking to amend § 723.50 in order to codify this change.[109]

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[107] R. Wesley Flynn et al., *Dietary Exposure and Accumulation of Per- and Polyfluoroalkyl Substances Alters Growth and Reduces Body Condition of Post-Metamorphic Salamanders*, 765 Sci. Total Env't 142730 (2021), https://www.sciencedirect.com/science/article/abs/pii/S0048969720362598.

[108] It is also questionable whether EPA could make an individualized safety determination for new PFAS under 40 C.F.R. § 723.50(d) in the allotted 30 days. A manufacturer would need to submit test data demonstrating that a new PFAS is safe in order to overcome the weight of the scientific evidence on the risks that may be posed by PFAS. EPA itself has admitted that the agency "will generally be unable to conduct a thorough review of any submitted test data within the allotted review period" and that "manufacturers with submissions which involve extensive data reviews may, in some cases, be better served under a PMN review." 60 Fed. Reg. at 16,337.

[109] EPA has the authority to prohibit use of the LVE and LoREX exemptions for the reasons set forth in 40 C.F.R. § 723.50(d) for the entire category of PFAS. *See* 15 U.S.C. § 2625(c).

II. EPA HAS PLACED COMMUNITIES AROUND THE COUNTRY IN HARM'S WAY BY FAILING TO REGULATE PFAS BYPRODUCTS AND ALLOWING MANUFACTURERS TO BRING PFAS TO MARKET UNDER THE LVE AND LOREX EXEMPTIONS

EPA is legally compelled to amend the Challenged Exemptions to ensure that PFAS will no longer be approved under these loopholes for the reasons stated above. But even if the Agency disagrees with the legal arguments above, it still has reason to grant this Petition.

15 U.S.C. § 2604(h)(4) provides EPA with discretion to create, modify, and revoke exemptions to the PMN process. EPA is not required to exercise its discretion to create an exemption, but when the agency does so it must act in accordance with the purposes of TSCA. Chief among these purposes is the prevention of "unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances."[110] Unfortunately, as written, the Challenged Exemptions put the public at increased risk of exposure to PFAS substances in ways that are at odds with this fundamental purpose of TSCA.

The Challenged Exemptions are bad public policy. They prevent EPA from sufficiently reviewing and regulating PFAS before these chemicals are released into communities and nature. Inadequate review and regulation are compounded by the lack of robust disclosure requirements. Without adequate information about PFAS that slip through these exemptions, the public is unable to take steps to protect itself. Thus, EPA should exercise its discretion and amend the Challenged Exemptions as requested by Petitioners.

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[110] David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 Wash. Univ. J. L. & Pol'y 333 (2010) (quoting S. Rep. No. 94-698, at 1 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491, 4491), https://openscholarship.wustl.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1084&context=law_journal_law_policy.

A. PFAS Byproducts Are Subject to Virtually No TSCA Regulatory Oversight to the Detriment of Human Health and the Environment

Allowing PFAS manufacturers to take advantage of the Byproducts Exemption results in minimal, if any, EPA review and regulation of these chemicals. The Exemption does not require manufacturers to submit an application for approval of the byproduct to the agency. Rather, any premanufacture information EPA collects on the byproduct comes only from the PMN application for the parent chemical. And that application simply requires "[a] description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance." 40 C.F.R. § 720.45(d). More specifically, a PMN applicant must submit the name of the byproduct; or "a class or range of structures (e.g., C_6 - C_{18} fatty acid salts or polychlorinated cyclic and acyclic hydrocarbons in the range C_5 - C_{12}); or the source (e.g., pyrolysis products of cellulose or coal tar residues)." [111]

As EPA has explained, test data on byproducts[112]—even if it is reasonably discoverable or within the manufacturer's possession—is *not* required as part of a manufacturers' PMN application for the parent chemical in which the byproduct is present. *See* Toxic Substances; Revisions of Premanufacture Notification Regulations, 51 Fed. Reg. 15,096, 15,100 (Apr. 22, 1986) (codified at 40 C.F.R. pt. 720). That EPA does not even require such data when it exists suggests that the agency does not assess risks associated with byproducts or take appropriate regulatory action to prevent harm they might cause to the public.

[111] *See* EPA, Instruction Manual for Reporting Under the TSCA §5 New Chemicals Program 43 (2015), https://www.epa.gov/sites/production/files/2015-06/documents/instruction_manual_2015_5-26-2015.pdf.
[112] Such data includes "information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment." 40 C.F.R. § 720.3(ff).

EPA cannot justify its failure to regulate PFAS byproducts. Real life circumstances have demonstrated that excluding PFAS byproducts from PMN review can be as dangerous to humans and the environment as failing to review and regulate PFAS that are used for a commercial purpose. As mentioned above, one of the key paths through which PFAS enter the environment is from the manufacturing, processing, use, and disposal of products that contain PFAS or generate PFAS as a waste byproduct.[113] PFAS precursors that are emitted or released into the environment via these pathways can biotransform into other PFAS, including long-chain PFAS like PFOA and PFOS.[114]

One vivid example of such contamination of the environment by PFAS byproducts and the attendant human consequences is the drinking water tragedy involving the Cape Fear River in North Carolina—a tragedy that might have been avoided through PMN review. In 2017, officials from Chemours admitted that one of their plants, formerly owned by DuPont, had been discharging GenX, a toxic shorter-chain PFAS, into Cape Fear River for close to 40 years.[115] EPA did not regulate under TSCA the GenX discharge into the river because the PFAS chemical was likely a byproduct of a vinyl ether process.[116] Levels of GenX in the drinking water of the Cape Fear Public Utility Authority average 631 ppt.[117] EPA's own drinking water exposure

[113] Buck et al., *supra* note 3, at 518; Scheringer & Wang, *supra* note 25. *See also* Lindstrom et al., *supra* note 25; N.C. Dep't Env't Quality, *supra* note 25.
[114] Buck et al., *supra* note 3, at 518; Scheringer & Wang, *supra* note 25. *See also* Lindstrom et al., *supra* note 25.
[115] Adam Wagner & Tim Buckland, *Chemours: GenX Polluting the Cape Fear since 1980*, StarNews Online (June 15, 2017), https://www.starnewsonline.com/news/20170615/chemours-genx-polluting-cape-fear-since-1980#:~:text=WILMINGTON%20%2D%2D%20A%20former%20DuPont,from%20DuPont%2Dspinoff%20Chemours%20Co.
[116] *Id*.
[117] Sharon Lerner, *New Teflon Toxin Found in North Carolina Drinking Water*, The Intercept (June 17, 2017), .https://theintercept.com/2017/06/17/new-teflon-toxin-found-in-north-carolina-drinking-water/.

limits for PFOA and PFOS suggest that GenX levels at 296 ppt would be hazardous to lactating mothers and 91 ppt in drinking water would be hazardous to infants, a greater risk population.[118]

The only reason researchers were even able to identify GenX as a chemical in the residents' drinking water was because more than a decade after DuPont began dumping the chemical as a byproduct into Cape Fear River, it decided to use GenX commercially in another context and thus submitted a PMN for it.[119] GenX, when produced commercially, was regulated in a consent order as a result of the PMN process; GenX as a byproduct, however, both before and after a PMN was submitted for its commercial use, was not. The consent order—a seemingly standard consent order by EPA—explicitly stated that it did not apply to GenX as a byproduct. Indeed, the high levels of toxic GenX contamination were discovered not because it was subject to EPA regulation, but only because an academic researcher decided to test the water from the river.[120]

The revelations about GenX discovered in the Cape Fear River raised alarm among residents of Wilmington, North Carolina, some of whom stopped drinking their GenX-contaminated tap water.[121] The revelations also led to more testing. Researchers found hydrolyzed GenX (hexafluoropropylene) in the urine of several Wilmington residents.[122] And compounding the problem, the researchers looking for GenX contamination in Wilmington

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[118] Anna Reade et al., *PFAS in Drinking Water 2019* 42, 85–86 (2019), https://www nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf.
[119] *See GenX Chemicals Studies*, EPA, https://www.epa.gov/pfas/genx-chemicals-studies (last updated Apr. 30, 2018).
[120] Sharon Lerner, *A Chemical Shell Game: How DuPont Concealed the Dangers of the New Teflon Toxin*, The Intercept (Mar. 3, 2016), https://theintercept.com/2016/03/03/how-dupont-concealed-the-dangers-of-the-new-teflon-toxin/.
[121] Cheryl Hogue, *The Hunt Is on for GenX Chemicals in People*, c&en (Apr. 7, 2019), https://cen.acs.org/environment/persistent-pollutants/hunt-GenX-chemicals-people/97/i14.
[122] *Id*.

residents also discovered several other novel PFAS in blood samples.[123] These novel PFAS were all byproducts produced by Chemours.[124] Animal studies—conducted in response to this avoidable tragedy and not any sort of regulation of byproducts—have thus far linked at least one of those PFAS byproducts with harmful liver effects.[125]

B. Companies Regularly Circumvent the PMN Process for New PFAS Via the LVE and LoREX Exemptions

When proposing the LVE and LoREX exemptions, EPA explained that the exemption would not lead to unreasonable risk because, among other things, "the benefits to the public and the Agency from the Agency's enhanced ability to utilize its limited resources to focus on reviewing new chemical substances and uses of *higher risk and concern*." 60 Fed. Reg. at 16,345 (emphasis added). But PFAS are precisely the kinds of "higher risk and concern" substances that EPA should focus on. Indeed, EPA has repeatedly acknowledged both that "[m]any Americans are concerned about potential health impacts from exposure to [PFAS],"[126] and that "[a]ggressively addressing PFAS has been an active and ongoing priority" for EPA.[127] Yet, permitting new PFAS to enter commerce via the LVE and LoREX exemptions *undermines* EPA's goal of closely reviewing new chemical substances that are of higher risk and concern to both the public and the agency.

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[123] *Id*.
[124] *Id*.
[125] Hua Guo et al., *Comparative Hepatotoxicity of Novel PFOA Alternatives (Perfluoropolyether Carboxylic Acids) on Male Mice*, 53 Env't Sci. & Tech. 3929 (2019), https://pubs.acs.org/doi/abs/10.1021/acs.est.9b00148?source=cen.
[126] EPA *PFAS Action Plan*, *supra* note 59, at 8.
[127] Press Release, EPA, *Federal Partners Kick Off Workshop on Federal Government Human Health PFAS Research with the National Academies of Sciences, Engineering and Medicine* (Oct. 26, 2020), https://www.epa.gov/newsreleases/federal-partners-kick-workshop-federal-government-human-health-pfas-research-national; *see also* Press Release, EPA, *EPA Releases Testing Data Showing PFAS Contamination from Fluorinated Containers* (Mar. 5, 2021), https://www.epa.gov/newsreleases/epa-releases-testing-data-showing-pfas-contamination-fluorinated-containers ("As the U.S. Environmental Protection Agency (EPA) pursues its mission to protect human health and the environment, addressing risks related to PFAS is a priority.").

The repercussions of this failure of adequate regulatory oversight are not hypothetical. To the contrary, chemical manufacturers use the LVE for new PFAS, thereby evading full PMN review for such chemicals, with tremendous frequency. EPA's own calculations show that from 2006-2016, companies sought approval for PFAS through the LVE far more often than through the PMN process.[128] This trend continued after the 2016 TSCA amendments.[129]

EPA also approves a high proportion of LVE exemption notices. Between the summer of 2016 and the March of 2021, EPA approved over 85 percent of all LVE applications.[130] The approval rate specifically for PFAS is just as high. Between 2006 and June 2016, EPA received 328 LVEs for PFAS and granted 272—equivalent to 83 percent—of them.[131] Thus, not only do the many individual, minimally assessed PFAS present dangers on their own, but the rapid and relatively easy approval of multiple new PFAS present additional concerns: simultaneous human exposure to multiple PFAS that can have compounding negative effects.[132]

Manufacturers—understandably for them, but alarmingly to the public—see the LVE option as a boon. Industry uses the LVE loophole to avoid precisely what Congress intended when amending the PMN provisions in 2016: a close review and regulation when necessary for toxic chemicals, with no approval by default.[133] As one law firm explained, the LVE is "an

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[128] Off. Pollution, Prevention, & Toxics, EPA, *Per- and Polyfluoroalkyl Substances (PFAS) Summary Report* 4-4 fig.4-5 (2018). Attached as Exhibit B.
[129] *See* Richard Denison, *Greasing the Skids: The Trump EPA is Green-Lighting Dozens of New PFAS under TSCA*, EDF (July 28, 2020), http://blogs.edf.org/health/2020/07/28/greasing-the-skids-the-trump-epa-is-green-lighting-dozens-of-new-pfas-under-tsca/.
[130] *Id*. - Richard Denison, *Greasing the Skids: The Trump EPA is Green-Lighting Dozens of New PFAS under TSCA*, EDF (July 28, 2020), http://blogs.edf.org/health/2020/07/28/greasing-the-skids-the-trump-epa-is-green-lighting-dozens-of-new-pfas-under-tsca/.
[131] Letter from Troy M. Lyons, Assoc. Adm'r, EPA, to Paul D. Tonko, Representative, U.S. H.R. (June 6, 2019). Attached as Exhibit C.
[132] *See infra* Reasons to Grant the Petition § II.C.
[133] EPA recently stated that it reviewed more than 300 LVE notices for PFAS substances since 2006, "most of which were granted based on restrictions/controls in the original or amended submissions." EPA *PFAS Action Plan*, *supra*

attractive option for high-toxicity substances," noting that "[if] submitted as a PMN, the same substance might well wind up being regulated under section 5(e)."[134] While the LoREX Exemption is not presently used with the same frequency as the LVE, it is crucial that the agency closes both loopholes in the regulation of PFAS concurrently. If the LVE loophole is closed, the LoREX Exemption may become the new "attractive option for high-toxicity substances" to evade PMN review and appropriate regulation.

C. Exposure to Multiple PFAS Can Have Compounding Negative Health Effects that Are Not Taken into Account When PFAS Come to Market Through the Challenged Exemptions

EPA should also exclude PFAS from the Challenged Exemptions because exposure to multiple PFAS may present additional risks on top of those presented by one, yet none of the Challenged Exemptions require such risks to be taken into account before allowing PFAS to get to market through them. Simultaneous exposure to multiple PFAS—an example of cumulative exposure—has become increasingly prevalent as a result of environmental contamination, which can result in more frequent and higher exposures to multiple PFAS in humans over the same time period, and consequentially increase the potential for compounding adverse health effects. Because PFAS are persistent and many have bioaccumulative qualities, they can build up in the human body over time and linger in certain tissues for as long as decades before being excreted,

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note 59, at 18. Even if EPA's approvals of LVE applications for PFAS have sometimes been premised on restrictions or controls in the manufacturer's submission, it would not cure the fundamental problems outlined in this petition. Ad hoc regulation of PFAS under the LVE cannot justify upholding an otherwise invalid regulation that violates the letter and purpose of a statute. *See F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 536 (2009) (citing 5 U.S.C. § 706(2)(C)) ("the agency action must not be 'in excess of statutory jurisdiction, authority, or limitations, or short of statutory right'").

[134] Keller and Heckman LLP, *The Constantly Pending PMN: Low Volume Exemption Applications Are Living Documents*, Martindale (Mar. 11, 2011), https://www.martindale.com/chemicals/article_Keller-Heckman-LLP_1255440 htm.

extending the window of opportunity to adversely affect health.[135] This raises additional concerns; several studies have indicated that simultaneous exposure to multiple PFAS in humans and animals can have compounding negative effects.[136]

Yet the Challenged Exemptions do not take these potential cumulative risks into account. For example, the LoREX Exemption sets limits on a chemical's release, but only one chemical at a time. But assessing the potential adverse effects of these PFAS individually does not sufficiently protect the public. Each new PFAS released into the environment has the potential to compound the adverse effects of the last. Thus, the only way to mitigate the PFAS contamination crisis our country faces is to stop the manufacturing and release of new PFAS altogether; at the very least, EPA should ensure that any new PFAS go through a full PMN review that accounts for cumulative exposures and risks.

D. Because the Byproducts, LVE, and LoREX Exemptions Fail to Provide for Adequate Public Notification, Use of Such Exemptions for PFAS Places Communities Across the Country at Heightened Risk of Harm

The Challenged Exemptions allow manufacturers to place PFAS into commerce while making it difficult for communities to know about their existence or the risks they pose. Congress recognized that when a new chemical is brought to market, it is critical that the public—whose health and well-being could be at risk—be able to learn about it.[137] The public, particularly those residents living near chemical manufacturing facilities, has a pressing interest

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[135] Paul Jones et al., *Binding of Perfluorinated Fatty Acids to Serum Proteins*, 22 Env't Toxicology & Chemistry 2639 (2003); Suzanne Fenton et al., *Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research*, 40 Env't Toxicology & Chemistry 606 (2020), https://setac.onlinelibrary.wiley.com/doi/full/10.1002/etc.4890.

[136] *See, e.g.*, Caroline Carr et al., *Testing for Departures from Additivity in Mixtures of Perfluoroalkyl Acids (PFAAs)*, 306 Toxicology 169 (2013), https://pubmed.ncbi nlm.nih.gov/23470359/; Guanghui Ding et al., *Combined Effects of PFOS and PFOA on Zebrafish (Danio rerio) Embryos*, 64 Archives Env't Contamination & Toxicology 668 (2013), https://pubmed.ncbi nlm nih.gov/23479250/.

[137] *See* H.R. Rep. No. 94-1679, at 67 (1976) (Conf. Rep.) (explaining that the public notice requirement in TSCA § 5(d)(2) was included "[i]n order that the public receive timely notification of any new chemical substance …."); 162 Cong. Rec. S3,511–12 (2016) (statement of Sen. Mark Udall); 162 Cong. Rec. E785-02 (2016) (statement of Rep. Loretta Sanchez).

both in knowing when manufacturers seek to market substances that could threaten public health or the environment, and in closely following decisions EPA makes about such requests. EPA has acknowledged as much, stating that "Congress intended informed citizen involvement in review of new chemical substances. . . Public participation cannot be effective unless meaningful information is made available to interested persons." Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures, 48 Fed. Reg. 21,722, 21,737 (May 13, 1983).

The PMN process is designed to meet these goals. TSCA requires EPA to alert the public when a PMN has been submitted and to provide the public with access to information about the PMN chemical. 15 U.S.C. § 2604(d)(1). Within five business days of receiving a PMN application, EPA is required to publish in the Federal Register a notice of the chemical substance proposed to be manufactured, a list of the substance's uses as identified in the application, and a description of the tests performed on the substance and any information EPA required to submitter to develop. 15 U.S.C. § 2604(d)(2). It must make all PMNs and Significant New Use Notices (SNUNs) publicly available to any interested person, *id*. § 2604(d)(1), as well as all information submitted with the notices, *id*. § 2604(b)(3) and 40 C.F.R. § 720.95. EPA must also make the public files electronically available. 40 C.F.R. §§ 700.17(b)(1), 720.95. And although companies may request that certain confidential business information be redacted from public disclosure, TSCA explicitly forbids withholding health and safety studies or associated information. 15 U.S.C. § 2613(b)(2).[138]

[138] *See generally* 15 U.S.C. § 2613(d). Congress underscored its commitment to transparency in this domain through the 2016 Lautenberg amendments, which required upfront justification and EPA review of most claims of confidentiality of business information. Even information traditionally considered confidential must be disclosed if EPA determines that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment, including to greater risk populations. *Id.* § 2613(d)(3).

If EPA determines after the safety review that the reviewed substance "is not likely to present an unreasonable risk," EPA must make a public statement of such a finding, which is then required to be published in the Federal Register as soon as practicable. 15 U.S.C. § 2604(g). Unfortunately, the public has not been able to track PMN applications because EPA has not been faithfully implementing the public notice provisions of TSCA and EPA's own regulations.[139]

The Challenged Exemptions do not even offer the public much in the way of transparency on paper. Instead, the Challenged Exemptions deny the public access to much of the information required when new chemical approval is sought by means of a PMN. Unlike for PMNs, a notice of receipt of an exemption application does not need to be published in the Federal Register. If EPA allows a chemical falling under an exemption to come to market, it does not publish a decision-making document containing an assessment or finding that the chemical will not present an unreasonable risk public. *Cf.* 15 U.S.C. § 2604(g) (requiring public statement and publishing in Federal Register for a PMN-reviewed chemical that EPA determined was not likely to present an unreasonable risk). As described in Reasons to Grant the Petition § II.B, manufacturers that produce PFAS under the Byproducts Exemption are required to submit only a few sparse details on the chemicals. The only information EPA makes publicly accessible about PFAS submitted through the LVE and LoREX Exemption is that in EPA's TSCA Exemptions Table, and the table makes it impossible to know whether any of the substances

[139] *See, e.g.*, Erin Fitzgerald, *Report: Trump's EPA Sued for Concealing Health Studies, Violating Its Chemical Laws*, Earthjustice (Mar. 18, 2020), https://earthjustice.org/news/press/2020/report-trumps-epa-sued-for-concealing-health-studies-violating-its-chemical-laws; Richard Denison, *EPA Is Keeping the Public in the Dark on Premanufacture Notices for New Chemicals under TSCA*, EDF (Apr. 2, 2018), http://blogs.edf.org/health/2018/04/02/epa-is-keeping-the-public-in-the-dark-on-premanufacture-notices-for-new-chemicals-under-tsca/ (detailing the nonprofit Environmental Defense Fund's frustrated efforts to obtain information on PMNs).

listed on it are PFAS, as no chemical names are provided.[140] This table merely lists a case number, receipt date, focus meeting date, status, and effective date.

Using Cape Fear's tragedy as an example, one can see why approving new PFAS under the Challenged Exemptions hinders communities' ability to protect themselves. Had the PFAS byproducts undergone PMN review, information about their existence and the risks they presented to the public may have been disseminated prior to, rather than after, North Carolinians were exposed. EPA has itself recognized that communities expect the agency to "communicate effectively with the public and to be transparent in sharing what is known and unknown [about PFAS] in a timely manner" and that such information can help these communities engage in risk management.[141] Such communication and ability to engage in risk management is absent when new PFAS are permitted to circumvent the PMN process.

Requiring PFAS—toxic at low levels and ubiquitous in our lives—to proceed through the PMN process would bring assessment of new PFAS a step closer to fulfilling the mandate of Congress to make information about potentially dangerous chemicals available to the public and allow communities impacted by contamination to take steps to protect themselves.

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[140] *Reviewing New Chemicals Under the Toxic Substances Control Act (TSCA): Exemptions Table*, EPA, www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/exemptions-table (last updated Apr. 22, 2021). Limited information on PFAS submitted through the LVE and/or LoREX Exemption is available on US EPA's ChemView, but this information can be accessed only when searching by chemical name or other chemical identifiers (e.g., CAS number, etc.).

[141] EPA *PFAS Action Plan*, *supra* note 59, at 37–38.

III. TSCA REQUIRES EPA TO ENSURE THAT ALL PFAS POLYMER ARE INELIGIBLE FOR THE POLYMER EXEMPTION

As mentioned earlier, EPA's current regulations make certain PFAS ineligible for approval under the Polymer Exemption. *See* 40 C.F.R. § 723.250(d). Specifically, a PFAS polymer is ineligible for the exemption only if it "contains as an integral part of its composition, except as impurities" the following specific perfluoroalkyl moieties: "Perfluoroalkyl sulfonates . . ., perfluoroalkyl carboxylates . . . , fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule." *Id*.

This exemption carve-out hinges on whether the perfluoroalkyl moiety is bound to either a carbon or sulfur atom that is an integral part of the polymer molecule, which is unclear and not consistent with the most current scientific definition of PFAS. —As discussed at length throughout this petition, 15 U.S.C. § 2604(h)(4) requires EPA to make substances ineligible for EPA-created exemptions like the Polymer Exemption unless those substances *will not* present an unreasonable risk to human health and the environment. And as EPA itself has admitted, the agency is statutorily required to make PFAS containing polymers ineligible for the Polymer Exemption if the substances "may, or are expected to, share similar characteristics" with known hazardous PFAS. 75 Fed. Reg. at 4,298.

The weight of the scientific evidence demonstrates that a polymer of any chain length containing any perfluoroalkyl moiety may present an unreasonable risk, regardless of whether the perfluoroalkyl moiety is bound to either a carbon or sulfur atom that is an integral part of the polymer molecule. EPA therefore must notify manufacturers via a Federal Register notice that

they should not use this exemption for any new PFAS polymers as defined in this Petition.[142] EPA must also initiate a rulemaking to amend the PFAS exception to the Polymer Exemption in 40 C.F.R. § 723.250(d)(6) to ensure that it includes all PFAS as defined in this Petition. That rulemaking should also establish a two-year window after which the continued manufacture of any PFAS polymer previously manufactured under the Polymer Exemption is prohibited unless such PFAS has undergone a full PMN review and been approved by EPA.

IV. WHEN NEW PFAS ARE SUBJECTED TO PMN REVIEW, EPA WILL BE UNABLE TO MAKE "NOT LIKELY TO PRESENT UNREASONABLE RISK" FINDINGS

This Petition explains why PFAS as a class cannot as a matter of law be eligible for certain exemptions to the PMN review process; rather, we argue, TSCA requires all proposed new PFAS to go through PMN review. This Petition further explains how EPA's increasingly frequent practice of approving PFAS via PMN exemptions rather than via the PMN review process has put communities and the environment at risk and deprived the public of information about proposed new PFAS that it would be entitled to during the PMN process. Nothing in these arguments should be read to suggest that Petitioners believe EPA could lawfully find that any proposed new PFAS "is not likely to present an unreasonable risk of injury to health or the environment," 15 U.S.C. § 2604(a)(3), the legal standard that must be met for manufacture to commence after submission of a PMN.

Rather, we submit that if EPA complies with the requirements of 15 U.S.C. § 2604 by ceasing to allow PFAS to enter commerce and/or the environment via PMN exemptions, and requiring manufacturers of proposed new PFAS to use the PMN process, the Agency will have

[142] EPA should use its inspection powers under 40 C.F.R. § 723.250(m) ensure that manufacturers do not bring any new PFAS polymers to market through the Polymer Exemption.

more time and information[143] on which to make science-based determinations regarding whether the PFAS is "not likely" to present unreasonable risk (including to greater risk populations), and the public will have the opportunity, intended by Congress, to provide input into that determination. We further submit that if EPA follows the law and the science, it will cease approving PMNs for new PFAS.

[143] During a PMN review, EPA has the authority to request additional time to conduct a safety review. *See* 15 U.S.C. 2604(c); *see also supra* Background & Legal Framework § A. The agency may also require a manufacturer to provide additional information if the PMN notice is incomplete and/or order testing if test data supplied by the manufacturer is insufficient to conduct a safety review. *See* 40 C.F.R. § 720.65(c); 15 U.S.C. § 2604(e).

REQUESTED AGENCY ACTION

Allowing manufacturers of PFAS to circumvent the PMN process and instead to seek approval of new PFAS via the Byproducts, LVE, LoREX, and/or Polymer exemptions threatens public health and contravenes the text and intent of TSCA. We therefore ask EPA to prohibit the use of these exemptions for PFAS as follows:

1. EPA must initiate a rulemaking to prohibit: a) future use of the Byproducts Exemption for new PFAS, and b) continued manufacture of any PFAS byproduct under the auspices of the Byproducts Exemption unless and until such PFAS has undergone a full PMN review and been approved by EPA, with a two-year window for manufacturers to receive such approval.
2. EPA should immediately stop permitting the use of the LVE, LoREX, and Polymer exemptions for any new PFAS.

EPA must codify these changes and should do so by making the following amendments and revisions to its regulations:

PART 720—[AMENDED]

1. Section 720.30 is amended by revising paragraphs (g) and (h)(2) to read as follows:

§ 720.30 Chemicals not subject to notification requirements.

…

> (g) Any byproduct <u>that does not contain one or more perfluoroalkyl moieties,</u> if its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.) <u>Any byproduct that does contain one or more perfluoroalkyl moieties that has been manufactured previously under this section prior to [insert effective date of amendment] may no</u>

longer be manufactured under this section after [insert two years after effective date of amendment].

…

(h) …

(2) Any byproduct which is not used for commercial purposes and which does not contain at least one perfluoroalkyl moiety. Any byproduct that does contain one or more perfluoroalkyl moieties that has been manufactured previously under this section prior to [insert effective date of this regulatory amendment] may no longer be manufactured under this section after [insert two years after effective date of this regulatory amendment].

PART 723—[AMENDED]

1. Section 723.250 is amended by revising paragraph (d)(6) to read as follows:

§ 723.250 Polymers. …

(d) …

(6) *Polymers which contain ~~certain~~ perfluoroalkyl moieties ~~consisting of a CF3- or longer chain length~~*. ~~Except as provided in paragraph (d)(6)(i), after February 26, 2010, a~~ A polymer cannot be manufactured under this section if the polymer contains ~~as an integral part of its composition, except as impurities,~~ one or more ~~of the following~~ perfluoroalkyl moieties ~~consisting of a CF3- or longer chain length: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule~~.

(i) Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to ~~February 26, 2010~~ [insert effective date of amendment] may no longer be manufactured under this section after ~~January 27, 2012~~ [insert two years after effective date of amendment].

2. Section 723.50 is amended by adding a new paragraph (o) to read as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

…

(o) *Chemical substances which contain perfluoroalkyl moieties.* A chemical substance cannot be manufactured under this section if the chemical substance contains one or more perfluoroalkyl moieties.

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Respectfully Submitted,

EARTHJUSTICE*

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Submitted on behalf of Advance Carolina; Alaska Community Action on Toxics; BlueGreen Alliance; Buxmont Coalition for Safer Water; Clean Cape Fear; Defend Our Health; Delaware Riverkeeper Network; Democracy Green; Environmental Defense Fund; International Association of Fire Fighters; Merrimack Citizens for Clean Water; National PFAS Contamination Coalition; Natural Resources Defense Council; Safer Chemicals, Healthy Families; and Union of Concerned Scientists.

* Earthjustice is grateful to Laura Dumais and Claire Huang, former Earthjustice employees, and Amy Chyao, former summer clerk, for their significant contributions to this Petition.
** Non-lawyer signatories contributed to the scientific, research, and/or factual portions of this document, and did not provide legal services or legal analysis.

Appendix A

APPENDIX A: PETITIONER STATEMENTS OF INTEREST

Advance Carolina

Advance Carolina was formed to help advocate for Black and Brown North Carolina residents, who have historically been under attack. Advance Carolina reimagines and works to ensure the safety of these communities along several dimensions including, but not limited to: safety from multiple catastrophic hurricanes; safety from racist, state-sanctioned violence; and safety from voter intimidation.

One key focus of the group's work involves drawing attention to and working to reverse racial health disparities in North Carolina. The organization is committed to ensuring Black and Brown communities are safe from toxic pollutants released into communities by corporations and industry. To this end, Advance Carolina prioritizes the safety of Black and Brown North Carolina residents impacted by PFAS pollution in Cape Fear. This commitment has become pronounced in light of the coronavirus pandemic, the effects of which have been exacerbated by such pollutants. Thus, Advance Carolina has an interest in this petition, which seeks to limit PFAS contamination across the country.

Alaska Community Action on Toxics

Alaska Community Action on Toxics ("ACAT") was founded in 1997 to assist Alaskans coping with the consequences of environmental contaminants. ACAT's goals include protecting everyone's right to know about the health and environmental hazards of chemicals that are present in air, water, soil, and foods; and having chemicals that are persistent, bioaccumulative, and harmful to health—such as PFAS—phased out and replaced with safe alternatives. ACAT engages in research, policy advocacy, and education to further its goals. For example, in September 2019, ACAT published a report on pervasive PFAS contamination throughout Alaska to aid residents and state and federal policymakers in making informed decisions to protect current and future generations from continued exposure to PFAS.

ACAT has an interest in this petition because the introduction of new PFAS into Alaska's communities and environment would compound the crisis of PFAS contamination in the state. Alaskans have unique exposure to new potentially hazardous PFAS because PFAS can undergo a process known as "global distillation," or the "grasshopper effect." Through this phenomenon, PFAS emitted to the air or entering water from polluting sources in Europe, Asia, and North America are picked up by oceanic and atmospheric currents and deposited in colder climates, often in the polar regions including the Arctic and Alaska. Alaskan Indigenous Tribal Communities are especially vulnerable to PFAS exposure because once in the Arctic ecosystem, PFAS, together with other persistent pollutants, can accumulate in living organisms, reaching high concentrations in larger animals like marine mammals, including seals and whales, which serve as integral components of the traditional diets and cultures of Indigenous peoples of Alaska and the Arctic.

The BlueGreen Alliance

The BlueGreen Alliance unites labor unions and environmental organizations to solve today's environmental challenges in ways that create and maintain quality jobs and build a clean, thriving, and equitable economy. The organization is guided by the principle that there cannot be a choice between good jobs and a clean environment—that the actions taken to create quality jobs and to protect working people and the environment must go hand-in-hand, and that by working together it will be possible to build a clean, thriving, and fair economy. The organization's mission includes reducing the impact of hazardous toxics such as PFAS, and eliminating them altogether if at all possible. PFAS has deleterious health effects to individuals and the communities represented by the BlueGreen Alliance generally, but particularly those most vulnerable. As an organization committed to addressing unsafe workplaces and communities, the BlueGreen Alliance stands in solidarity with colleagues at various organizations to stop the approval of PFAS through PMN exemptions.

Buxmont Coalition for Safer Water

Petitioner Buxmont Coalition for Safer Water ("Buxmont") is a nonprofit formed by residents of Pennsylvania's Bucks and Montgomery counties in response to growing awareness of the risks posed and harms caused by the historical use of PFAS-laden firefighting foam at Naval Air Development Center in Warminster, PA and The Willow Grove Naval Air Base and Air Reserve Station in Horsham PA. Blood samples taken in 2018 from more than 200 residents who live near these military bases showed a troublingly high amount of PFAS exposure on average. These residents had twice as much PFOS and more than five and half times as much PFHxS in their blood samples as the national average, along with elevated levels of PFOA and other PFAS.

The organization advocates on behalf of the 85,000 residents of Pennsylvania's Bucks and Montgomery counties at risk of PFAS exposure to PFAS. The organization helps raise public awareness through avenues such as local and national media and its website. Buxmont also engages in legislative and administrative advocacy for the regulation of PFAS, including by testifying before the U.S. Congress and the Senate. Buxmont joins this Petition because the organization is concerned that the regulatory exemptions at issue place communities, including their own already burdened local community, at increased risk of even more exposure to PFAS. Buxmont is aware that at least two manufacturers with facilities in Bucks and Montgomery County, Gelest Inc. and Heraeus Precious Metals, brought two new PFAS to market through the Low Volume Exemption.

Clean Cape Fear

Clean Cape Fear is an organization based in the Wilmington, North Carolina area, with a mission to stop and remediate PFAS contamination. The organization formed after information came to light that a Chemours plant, formerly owned by DuPont, had been discharging PFAS into the Cape Fear River for nearly 40 years. This news raised alarm as the lower Cape Fear River serves as the primary source of drinking water for approximately 300,000 people in three counties. Community fears were substantiated by a number of revelations, including a 2018 study which found that Wilmington residents had two times as much PFOS and three times as much PFOA in their blood as the national average. Clean Cape Fear has attempted to mitigate this crisis through public awareness campaigns about PFAS contamination in the river and efforts to ensure that residents have access to contaminant-free water.

Clean Cape Fear has a particular interest in closing the exemptions that are the subject of the petition because manufacturers' use of at least one of the exemptions contributed to the contamination of the Cape Fear River. The PFAS GenX initially escaped regulatory review and was discharged into the Cape Fear River, likely as a byproduct of a vinyl ether process at the facility. Indeed, researchers were able to identify GenX as a chemical in the residents' drinking water decades after DuPont began dumping the substance only because DuPont eventually sought regulatory approval for it so that it could use GenX commercially. Researchers have since discovered several other previously unknown PFAS byproducts manufactured at the Chemours plant in blood samples of Wilmington residents.

Defend Our Health

Defend Our Health works to create a world where all people are thriving, with equal access to safe food and drinking water, healthy homes, and products that are toxic-free and climate-friendly. The organization has worked directly with communities impacted by PFAS in its home state of Maine, which has seen widespread contamination of land and drinking water as the result of land application of contaminated sludge. Defend Our Health is advancing efforts on a state and national level to control existing PFAS pollution, and thus the organization has an interest in the petition. The organization is particularly concerned that EPA is continuing to approve new sources of exposure through exemptions to the PMN process.

Delaware Riverkeeper Network

Petitioner Delaware Riverkeeper Network ("DRN") is a Pennsylvania non-profit organization whose mission is to protect and restore the Delaware River and its tributaries, habitats, and resources. It was established in 1988 and has approximately 25,000 members. DRN has been working on the problems posed by the presence of PFAS in the communities served by the organization since 2005, when its staff collected tap water samples containing PFOA from homes in the neighborhoods close to DuPont's Chambers Works facility in Deepwater, New

Jersey on the Delaware River. After this revelation, DRN began an advocacy campaign, which, over the years, has involved raising public awareness about PFAS contamination and the submission of technical information, scientific analysis, and policy analysis through comments, testimony, and correspondence to government agencies.

An ongoing matter of concern for DRN has been PFAS contamination from the Solvay Specialty Polymers USA, LLC manufacturing facility in Gloucester County, New Jersey. This facility has released PFAS compounds into New Jersey's water and air for decades and continues to do so. Perfluorononanoic acid (PFNA), a PFAS compound, was found near the facility at the highest reported water concentration in the world at the time through sampling of groundwater supplies by the New Jersey Department of Environmental Protection. DRN continues to be concerned about PFAS contamination in the Delaware River area and the lack of transparency about those chemicals and their potential risks. The New Jersey Department of Environmental Protection recently became aware of the release of "replacement" PFAS substances from Solvay into the environment. The agency, however, has been unable to ascertain the chemical identities of the majority of these potentially hazardous compounds. Making matters worse, Solvay has been unwilling to release important emissions and safety information and data on the replacement PFAS. DRN believes closing the regulatory loopholes described in this petition is one important step towards ensuring more oversight of PFAS and transparency about potential exposure to them.

Democracy Green

Democracy Green does work at the intersection of democracy and environmental justice and prioritizes community expertise to inform equitable solutions for Black and Brown communities in North Carolina. The organization was formed in response to the historic use of Black neighborhoods as dumping grounds, which has poisoned the air, water, and food of these frontline communities. The organization knows that environmental justice must be prioritized in democracy reform efforts, policy, and litigation.

To this end, Democracy Green has made PFAS contamination a priority. Black and Brown communities across the state, with a concentration along the Cape Fear Neuse River, have experienced cumulative impacts and layered exposure to this class of chemicals through groundwater contamination, fast food exposure in food-insecure areas, and contamination in confinement facilities. In particular, essential franchise and plant workers as well as renters in PFAS-contaminated infrastructure have been subject to troubling levels of exposure by these substances. To deal with this contamination crisis, Democracy Green demands corporate accountability, stricter permit enforcement, community resource support to remediate the harms of contamination, equitable testing of contamination levels, research into improving clinical guidelines, and policy shifts to address racial inequities in this area. The organization has an interest in this petition because it outlines a set of actions EPA could undertake to address a part of this crisis.

Environmental Defense Fund

Founded in 1967, EDF is a 501(c)(3) nonprofit organization, with more than 2.5 million members and activists located in all 50 states and the District of Columbia, that uses science, economics, and law to restore the quality of our air, water, and other natural resources. EDF's Health Program aims to reduce human health risks and disparities posed by exposure to industrial and commercial chemicals and chemicals in everyday products, food, and drinking water. To accomplish our mission, EDF advocates for appropriate implementation of the Toxic Substances Control Act. Our efforts rely on the Environmental Protection Agency conducting robust safety reviews and disclosing information about new chemicals, including chemicals such as PFAS that may present risks if allowed to enter commerce without adequate review and transparency. For years, EDF has repeatedly raised concerns over industry's use of exemptions from the full pre-manufacture review process, which result in curtailed safety reviews and are shrouded in secrecy. This petition seeks to address these concerns.

The International Association of Fire Fighters

The International Association of Fire Fighters (IAFF) represents more than 324,000 full-time professional fire fighters and paramedics in more than 3,500 affiliates in the United States and Canada. IAFF members protect more than 85 percent of the population in communities throughout the two countries.

Over the last 100 years, the IAFF has been the driving force behind nearly every advance in fire and emergency services in the 21st century and is the nation's leading voice on health and safety issues impacting the fire service. Fire fighters face significant exposures to PFAS on the job due to the vast quantity of such substances added to building materials, consumer products, firefighting foam, and the gear our members use every day. Scientific studies have linked PFAS to cancer, which is today the leading cause of death of firefighters. The IAFF joins this petition because the health and safety of fire fighters depends upon EPA actively safeguarding the public and the environment against the potential health hazards posed by new PFAS.

Merrimack Citizens for Clean Water

Merrimack Citizens for Clean Water was founded in 2016 by residents who had no choice but to become their own self-educated advocates about PFAS contamination in Merrimack, NH. Two of the town's six water wells and hundreds of private water wells in the greater Merrimack area have tested over the New Hampshire regulatory limit at that time for the combined PFOA/PFOS total of 70 ppt. The organization has since learned that air emissions and industry discharges from two significant users of PFAS, Saint Gobain Performance Plastics and TCI, have resulted in

the presence of 21 additional PFAS chemicals in the entire community's water supply as well as in the drinking water of six surrounding communities.

Merrimack Citizens for Clean Water has an interest in this petition because the town would benefit from more affirmative regulation of PFAS by the EPA. The organization would welcome regulatory action on PFAS in addition to PFOA and PFOS, as the residents of Merrimack have had to deal with contamination from an array of substances in this class, including unidentified PFAS suspected of being byproducts. This petition would help ensure that the agency would take measures to protect the residents of Merrimack before any new PFAS are introduced into their community.

The National PFAS Contamination

The National PFAS Contamination Coalition was formed in June 2017 by community leaders who were concerned about the PFAS drinking water contamination in their neighborhoods. The coalition seeks to better support local organizing for clean water and health protection by sharing local campaign stories and information and connecting to experts. The coalition also aims to build a bigger movement for national change on these issues by working on state and national campaigns together for solutions and building a collaborative and powerful force to take on big polluters. The coalition has grown to be 30 community groups in 17 states. The National PFAS Contamination Coalition has an interest in this petition because the manufacture, release, and distribution of new PFAS threaten the water and health of the communities the coalition was established to support.

Natural Resources Defense Council

Natural Resources Defense Council's ("NRDC") mission is to safeguard the Earth: its people, its plants and animals, and the natural systems on which all life depends. NRDC strives to advance the long-term welfare of present and future generations. NRDC's Health and Communities Program works to protect the public from exposure to toxic chemicals that pose a risk to human health. This includes work to eliminate exposures to toxic chemicals from drinking water, food, and household products, and to the pollution created by industrial production and disposal of products. As part of NRDC's mission to protect people from toxics, we regularly submit comments on agency rulemakings relating to industrial and household chemicals and advocate for vigorous implementation of the Toxic Substances Control Act (TSCA).

NRDC has an interest in this petition as an organization working extensively at both the state and federal level to address the ongoing PFAS crisis. This work has included advocacy in support of state laws imposing restrictions on specific uses of PFAS and setting strong health protective standards for drinking water in states such as California, Michigan, New York, and New Hampshire. NRDC has testified before House and Senate committees on the need for numerous pieces of legislation to regulate PFAS. NRDC has also commented to EPA in opposition to its

continued approval of new PFAS through the PMN program, and the need to adopt stronger protections from existing PFAS by strengthening and expanding the use of Significant New Use Rules. NRDC has also played a leading role in market-based campaigns to remove PFAS from consumer products, including rugs, carpets, and building materials. NRDC has also played a leadership role in developing scientific understanding of PFAS, including co-authoring papers on the need to regulate PFAS as a class and creating a database of more than 700 health studies of PFAS.

Safer Chemicals, Healthy Families

Safer Chemicals, Healthy Families fights for strong chemical policy, works with retailers to phase out hazardous chemicals, and educates the public about ways to protect our families from toxic chemicals. The organization advocates solutions to the PFAS crisis that "turn off the tap" on these "forever" chemicals by supporting strong federal and state policies to protect public health and the environment. Safer Chemicals Healthy Families is a program of Toxic Free Future.

Union of Concerned Scientists

The Union of Concerned Scientists is a national nonprofit organization working to ensure science informs decisions that affect our health, safety, and environment. As the Union of Concerned Scientists works to elevate the role of evidence in policymaking and the regulatory process, the organization has an interest in ensuring the process by which chemicals like PFAS are assessed for safety under the Toxic Substances Control Act relies on the best available science and is protective of overburdened and vulnerable populations.

Appendix B

APPENDIX B: SELECT RELEVANT STATUTES AND REGULATIONS

Pre-Manufacture Notice (PMN) Requirement: 15 U.S.C. § 2604(a)(1)(B)

A person may [manufacture a new chemical substance] if—

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice . . . of such person's intention to manufacture or process such substance and . . .

(ii) the Administrator—

> (I) conducts a review of the notice; and
> (II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

Permitted Exemptions from PMN Requirement When Substances Will Not Present Unreasonable Risk: 15 U.S.C. § 2604(h)(4)

The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

Byproducts Exemption to the PMN Requirement: 40 C.F.R. § 720.30(g), 40 C.F.R. § 720.30(h)(2) (emphases added)

The following substances are not subject to the notification requirements of this part:

> . . .
>
> (g) Any byproduct if its only commercial purpose is for *use* by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)
>
> (h) The chemical substances described below: (Although they are manufactured *for commercial purposes* under the Act, they are not manufactured for distribution in

commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)

. . .

(2) Any byproduct which is not *used for* commercial purposes.

Low Volume Exemption to the PMN Requirement: 40 C.F.R. § 723.50(a)(1)(i)

(a) Purpose and scope.

(1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

(i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.[145]

Low Release and Exposure Exemption to the PMN Requirement: 40 C.F.R. § 723.50

(a) Purpose and scope.

(1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of: …

(ii) Chemical substances with low environmental releases and human exposures. …

(c) Exemption categories …

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) Consumers and the general population. For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance: …

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section). …

(iii) Ambient surface water. For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion …

[145] 10,000 kilograms is equal to approximately 11.02 tons.

(iv) Incineration. For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

(kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

Polymer Exemption to the PMN Requirement: 40 C.F.R. § 723.250

(a) Purpose and scope.
(1) This section grants an exemption from certain of the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of certain polymers…

(d) Polymers that cannot be manufactured under this section—…

(6) Polymers which contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length. Except as provided in paragraph (d)(6)(i), after February 26, 2010, a polymer cannot be manufactured under this section if the polymer contains as an integral part of its composition, except as impurities, one or more of the following perfluoroalkyl moieties consisting of a CF3- or longer chain length: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

(i) Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to February 26, 2010 may no longer be manufactured under this section after January 27, 2012. …

Exhibit A

PMN Page 1

Form Approved. O.M.B. No. 2070-0012. Approval Expires 12/31/2022

U.S. ENVIRONMENTAL PROTECTION AGENCY

AGENCY USE ONLY

EPA

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

Date of receipt:

When completed, send this form to:

If sending by Courier
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
US EPA, 1201 Constitution Ave NW
WASHINGTON, D.C. 20460
Contact Numbers 202-564-8930/8940

If sending by US Mail
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
US EPA, 1200 Pennsylvania Ave NW
WASHINGTON, D.C. 20460

Submission Report Number

Total Number of Pages

18

TS Number

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS fee identification number you have generated. Remember, your fee ID number must also appear on your corresponding fee remittance. For mailing address information see the Help instructions in the e-PMN tool.

Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS fee identification number. For all Section 5 Notice submissions (paper or electronic) you must submit an original notice including all test data; if you claimed any information as confidential, an original sanitized copy must also be submitted.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

Part III – LIST OF ATTACHMENTS

For paper submissions, attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 3 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance. "Binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . The intention is to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Checking a "binding" box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form; however, in the case of exemption applications (such as TMEA, LVE, LOREX) certain information provided in such notifications is binding on the submitter when the Agency approves the exemption application, especially if the production volume "binding" box is chosen in a LVE.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

- ☐ Environmental fate data
- ☐ Health effects data
- ☐ Environmental effects data
- ☐ Other Data
- ☐ Risk Assessments
- ☐ Structure/activity relationships
- ☐ Physical/Chemical Properties (A physical and chemical properties worksheet is located on the last page of this form.)
- ☐ Test data not in the possession or control of the submitter

TYPE OF NOTICE (Check Only One)

- ☐ **PMN** (Premanufacture Notice)
- ☐ **SNUN** (Significant New Use Notice)
- ☐ **TMEA** (Test Marketing Exemption Application)
- ☐ **LVE** (Low Volume Exemption) @ 40 CFR 723.50(c)(1)
- ☐ **LOREX** (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)
- ☐ **LVE** Modification
- ☐ **LOREX** Modification
- ☐ **Mock Submission**
- ☐ Mark (X) if pending Letter of Support

N — IS THIS A CONSOLIDATED PMN (Y/N)?

0 — # of chemicals or polymers (Prenotice Communication # required, enter # on p. 3).

☐ Mark (X) if any information in this notice is claimed as confidential.

PMN Page 2

The public reporting and recordkeeping burden for this collection of information is estimated to average 93 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed EPA Form 7710-25 to this address.

CERTIFICATION -- A printed copy of this signature page, with original signature, must be submitted with CD or paper submission.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the pu lic under any other Federal law

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial arm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse ngineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Additional Certification Statements:

If you are submitting a PMN, SNUN, LoREX, LVE, or TMEA, check the following Fees Certification statement that applies:

- ☐ The Company named in Part I, Section A is a "small business conc rn" as defined under 40 CFR 700.43 and will remit the fee as specified in 40 CFR 700.45(c).
- ☐ The Company named in Part I, Section A will remit the fee as sp cified in 40 CFR 700.45(c).
- ☐ This joint submission includes at least on Company which is a "small business concern" and at least one Company which is not a "small business concern," as defined der 40 FR 700.43. The fee will be remitted with the joint submission. Any remaining balance due for this joint submission is to be paid by the secondary submitter(s).
- ☐ The company named in Part I, Sect n A is submitting a sustainable futures TME. The company has graduated from EPA's Sustainable Futures program and is herefore exempt from fees for this sustainable futures TME.

If you are submitting a **Low Volume Exemption (LVE)** application in accordance with 40 CFR 723.50(c)(1) or a **Low Release and Low Exposure Exemption (LoRex)** application in accordance with 40 CFR 723.50(c)(2), check the following certification statements:

- ☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.
- ☐ The man facturer is familiar with the terms of this section and will comply with those terms; and
- ☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.
- ☐ If this application is for an LVE in accordance with 40 CFR 723.50(c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

				Confidential
Signature and title of Authorized Official (Original Signature Required)		Date		☐

PMN Page 3

Part I -- GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential

1a.	Person Submitting Notice (in U.S.)					Confidential
Name of Authorized Official	(first)		(last)			☐
Position						
Company						
Mailing Address (number & street)						
City		State		Postal Code		
email						

b.	Agent (if Applicable)					Confidential
Name of Authorized Official	(first)		(last)			☐
Position						
Company						
Mailing Address (number & street)						
City		State		Postal Code		
e-mail		Telephone (include area code)				

c.	Joint Submitter (if applicable)					Confidential
If you are submitting this notice as part of a joint submission, mark (X)					☐	☐
Name of Authorized Official	(first)		(last)			
Position						
Company						
Mailing Address (number & street)						
City		State		Postal Code		
e-mail		Telephone (include area code)				

2.	Technical Contact (in U.S.)					Confidential
Name of Authorized Official	(first)		(last)			☐
Position						
Company						
Mailing Address (number & street)						
City		State		Postal Code		
e-mail		Telephone (include area code)				

			Mark (X) if none	Confidential
3.	If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number.		☐	☐
4.	If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete).		☐	☐
5.	If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA.		☐	☐

6.	Type of Notice – Mark (X)						
1.	Manufacture Only ☐ Binding Option ☐	2.	Import Only ☐ Binding Option ☐	3.	Both ☐		

PMN Page 4

Part I – GENERAL INFORMATION -- Continued

Section B – CHEMICAL IDENTITY INFORMATION: You must provide a currently correct Chemical Abstracts (CA) name of the substance based on current CA index nomenclature rules and conventions.

Mark (X) the "Confidential" box next to any item you claim as confidential

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either Item 1 or 2), mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. ☐

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)	Class 1	Class 2	CBI
a. Class of substance - Mark (X)	☐	☐	☐

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, which ever is appropriate based on current CA index nomenclature rules and conventions). ☐

CAS Registry Number (if a number already exists for the substance)

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice: (check one).

Method 1 (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Services must be submitted as an attachment to this notice) ☐	IES Order Number		**Method 2** (Other Source) ☐

Enter Attachment filename for Part I, Section B, 1. c. ☐

d. Molecular formula ☐

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance, provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained. ☐

Enter Attachment filename for Part I, Section B, 1. e. ☐

PMN Page 4a

For a class 2 substance - (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate).	Confidential

e. (1) List the immediate precursor substance names with their respective CAS Registry Numbers. ☐

Enter Attachment filename for Part I, Section B, 1. e. (1)		☐

e. (2) Describe the nature of the reaction or process. ☐

Enter Attachment filename for Part I, Section B, 1. e. (2)		☐

e. (3) Indicate the range of composition and the typical composition (where appropriate). ☐

Enter Attachment filename for Part I, Section B, 1. e. (3)		☐

Part I -- GENERAL INFORMATION – Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

2. Polymers (For a definition of polymer, see the Instructions Manual.)	Confidential
a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.	☐

Describe the methods of measurement or the basis for your estimates:

GPC ☐	**Other** (Specify Below) ☐	

Specify Other:

(i) lowest number average molecular weight:	(ii) maximum weight % below 500 molecular weight:	(iii) maximum weight % below 1000 molecular weigh :

Enter Attachment filename for Part I, Section B, 2. a. ☐

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential

(1) - Provide the specific chemical name and CAS Registry Number (if a number exists) of each mon m r or other reactant used in the manufacture of the polymer.
(2) - Mark (X) this column if entry in column (1) is confidential.
(3) - Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) - Choose "yes" from drop down menu if you want a monomer or other reactant used at two w ight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) - Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) - Indicate the maximum weight percent of each monomer or other reactant tha may be present as a residual in the polymer as manufactured for commercial purposes.
(7) - Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant specific chemical name (1)	CBI (2)	Typical composition (3)	Include in identity (4)	CBI (5)	Max residual (6)	CBI (7)
CAS Registry Number (1)						
CAS Registry Number (1)						
CAS Registry Number (1)						
CAS Registry Number (1)						
CAS Registry Number (1)						

Mark (X) this box if the data continues on the next page. ☐

PMN Page 5a

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice (check one).				CBI
Method 1 (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to this notice) ☐	IES Order Number		**Method 2** (other source) ☐	
Enter Attachment filename for Part I, Section B, 2. c.				☐

d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.	☐

CAS Registry Number (if a number already exists for the substance)		

e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.	☐

Enter Attachment filename for Part I, Section B, 2. e.		☐

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

3. Impurities
   (a) - Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purpose. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
   (b) - Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity (a)	CAS Registry Number (a)	Maximum Percent % (b)	Confi-dential

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part I, Section B, 3. ☐

4. Synonyms - Enter any chemical synonyms for the new chemical identified in subsection 1 or 2. ☐

Enter Attachment filename for Part I, Section B, ☐

5. Trade identification - List trade names for the new chemical substance identified in subsection 1 or 2. ☐

Enter Attachment filename for Part I, Section B, 5. ☐

6. Generic chemical name - If you claim chemical identity as confidential, you must provide a generic name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

Enter Attachment filename for Part I, Section B, 6.

7. Byproducts - Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confi-dential

Mark (X) this box if the data continues on the next page. ☐

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

The information on this page refers to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume -- Estimate the **maximum** production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume.

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confidential	Binding Option Mark (X)
		☐	☐

Enter Attachment filename for Part I, Section C, 1.		CBI ☐

2. Use Information -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

a. (1) --Describe each intended category of use of the new chemical substance by function and application.
(2) --Mark (X) this column if entry column (1) is confidential business information (CBI).
(3) --Indicate your willingness to have the information provided in column (1) binding.
(4) --Estimate the percent of total production for the first three years devoted to each category of use.
(5) --Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) --Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) --Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) --Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the use type provided in (8) binding.
(9) --Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (**1**) (by function and application i.e. a dispersive dye for finishing polyester fibers)	CBI (**2**)	Binding Option Mark (X) (**3**)	Production % (**4**)	CBI (**5**)	% in Formulation (**6**)	CBI (**7**)	% of substance expected per use (**8**)					CBI (**9**)
							Site-limited	Consumer*	Industrial	Commercial	Binding Option	

* If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

Mark (X) this box if the data continues on the next page. ☐

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instruction Manual for examples of generic use descriptions.

Enter Attachment filename for Part I, Section C, 2. b.		CBI ☐

3. Hazard Information -- Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handing, transport, use, or disposal of the new substance. List in part III hazard information you include.

Mark (X) this box if you attach hazard information. ☐	Binding Option Mark (X) ☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Mark (X) the "Confidential" box next to any item you claim as confidential

The information on pages 8 and 8a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control. Importers do not have to complete this section for operations outside the U.S.; however, you may still have reporting requirements if there are further industrial processing or use operations after import. You must describe these operations. See instructions manual

1. Operation description

a. Identity -- Enter the identity of the site at which the operation will occur.

				Confi-dential
Name				
Site address (number and street)				☐
City		County		
State		ZIP code		

If the same operation will occur at more than one site, enter the number of sites. Identify the additiona sites on a continuation sheet, and if any of the sites have significantly different production rates o operations, include all the information requested in this section for those sites as attachm nts. → ☐

Mark (X) this box if the data continues on the next page. ☐

b. Type -- Mark (X) Manufacturing ☐ Processing ☐ Use ☐ ☐

c. Amount and Duration -- Complete 1 or 2 as appropriate

				Confi-dential
1. Batch	Maximum kg/batch (100% new chemical substance)	Hours/batch	Batches/year	☐
2. Continuous	Maximum kg/d y (100% new chemical substa ce)	Hours/day	Days/year	☐

d. Process description — Mark (X) to indicate your willingness to have your process description binding. → ☐

(1) Diagram the major unit operation st p and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tan truck, etc.).
(2) Provide the identity, the approxim te weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (incl ding r ctants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not sed daily or per batch.).
(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

☐

PMN Page 8a

Diagram of the major unit operation steps.	Confidential ☐

Enter Attachment filename for Part II, Section A, 1. d.	☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

The information on pages 9 and 9a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

2. Occupational Exposure -- You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) -- Describe the activities (i.e. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to the substance.
(2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) -- Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) -- Indicate your willingness to have the information provided in column (3) or (5) binding.
(5) -- Indicate the physical form(s) of the new chemical substance (e.g., solid: crystal, granule, powder, or dust) and % new chemical substance (if part of a mixture) at the time of exposure.
(7) -- Mark (X) this column if entries in columns (3) and (5) are confidential business information (CBI).
(8) -- Estimate the maximum number of workers involved in each activity for all sites combined.
(9) -- Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) -- Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (i.e., bag dumping, filling drums) (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (X) (4)	Physical form(s) & % new substance (5)	Binding Option Mark (X) (6)	CBI ( )	# of Wor ers Expos d 8)	BI (9)	Maximum Duration		CBI (12)
									Hrs/Day (10)	Days/Yr (11)	
Mark (X) this box if the data continues on the next page.										☐	
Enter Attachment filename for Part II, Section A on the bottom of page 9a.											☐

PMN Page 9a

3. Environmental Release and Disposal -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) -- Identify the media (stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify)) to which the new substance will be released from that release point.
(5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) -- Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct discharges or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number	Amount of New Substance Released		CBI	Medium of release e.g. Stack air	Control technology and efficiency (you may wish to optionally attach efficie cy data)			CBI
(1)	(2a)	(2b)	(3)	(4)	(5a)	B nding Mark (X)	(5b)	(6)
Mark (X) this box if the data continues on the next page.							☐	

(7) Mark (X) the destination(s) of releases to water.		NPDES#	CBI
☐ POTW--provide name(s)			☐
☐ Navigable waterway- - provide name(s)			☐
☐ Other--Specify			☐
Enter Attachment filename for Part II, Section A.			☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

The information on pages 10 and 10a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. *Complete a separate section B for each type of processing, or use operation involving the new chemical substance*. If the same operation is performed at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.

1(a). Operation Description -- To claim information in this section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

(1) -- Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify - e.g. 5 gallon pails, 55 gallon drums, rail cars, tank trucks, etc). On the diagram, identify by letter and briefly describe each worker activity.

(2) -- Either in the diagram or in the text field 1(b) below, provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch).

(3) -- Either in the diagram or in the text field 1(b) below, identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.

(4) -- Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet):

	Number of Sites ◆		Confidential ☐

1(b). (Optional) This space is for a text description to clarify the diagram above. Confidential ☐

Enter Attachment filename for Part II, Section B on the bottom of page 10a.	☐

PMN Page 10a

2. Worker Exposure/Environmental Release

(1) -- From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) -- Estimate the number of workers exposed for all sites combined.
(4) -- Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) -- Describe physical form of exposure and % new chemical substance (if in mixture), and any protective equipment and engineering controls, if any, used to protect workers.
(7) -- Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) -- From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
(10) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) -- Describe media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) -- Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) -- Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity	# of Workers Exposed	CBI	Duration of Exposure		CBI	Protective Equip./Engineering Controls/Physical Form	% new subst nce	% in Formulation	CBI
(1)	(2)	(3)	(4a)	(4b)	(5)	(6)	( )	(7)	(8)

Release Number	Amount of New Substance Released		CBI	Media of Release & Control Technology	CBI
(9)	(10a)	(10b)	(11)	(12)	(13)

Mark (X) this box if the data continues on the next page. ☐

(14) Byproducts: | **(15) CBI** ☐

Enter Attachment filename for Part II, Section B. | ☐

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in the following section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, and/or raw materials substitution. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Quantitative or qualitative descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction in addition to compliance with existing regulatory requirements. The EPA is interested in the information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other media (e.g., air to water) or nonenvironmental areas (e.g., occupational or consumer exposure). To the extent known, information about the technology being replaced will assist EPA in its relative risk determination. In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided.

Describe the expected net benefits, such as

(1) an overall reduction in risk to human health or the environment;
(2) a reduction in the generation of waste materials through recycling, source reduction or other means;
(3) a reduction in the use of hazardous starting materials, reagents, or feedstocks;
(4) a reduction in potential toxicity, human exposure and/or environmental release; or
(5) the extent to which the new chemical substance may be a substitute for an existing substance that poses gre te overall risk to human health or the environment.

Information provided in this section will be taken into consideration during the review of this sub t nce. See PMN Instructions Manual and Pollution Prevention Guidance manual for guidance and examples.

Enter Attachment filename for Pollution Prevention Page 11.		☐

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form, test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of any paper attachments. In the Number of Pages column below, enter the inclusive page numbers of each attachment for paper submissions or enter the total number of pages for each attachment for electronic submissions. Electronic attachments can be identified by filename.
Mark (X) the "Confidential" box next to any attachment name or filename you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

#	Attachment Name	Attachment Filename	Number of Pages	Associated PMN Section Number	CBI

Mark (X) this box if the data continues on the next page. ☐

PMN Page 13

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

The information on this page refers to chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. Give the attachment number (found on page 12) in column (b). The physical state of the neat substance should be provided. These measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in __). You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify the review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)		Unit	Mark X if Provided	Attachment Number (b)	Value (c)			Measured or Estimate (M or E)	CBI Mark (X) (d)
					(solid)	(liquid)	(gas)		
Physical state of neat substance			☐		☐	☐	☐		
Vapor Pressure @ Temperature		°C	☐				Torr		
Density/relative density			☐				g/cm3		
Solubility			☐				g/L		
@ Temperature		°C							
Solvent									
Solubility in Water @ Temperature		°C	☐				g/L		
Melting Temperature			☐				°C		
Boiling / Sublimation temperature @		Torr	☐				°C		
Spectra			☐						
Dissociation constant			☐						
Octanol / water partition coefficient			☐						
Henry's Law constant			☐						
Volatilization from water			☐						
Volatilization from soil			☐						
pH@ concentration			☐						
Flammability			☐						
Explodability			☐						
Adsorption / Coefficient			☐						
Particle Size Distribution			☐						
Other – Specify			☐						

Exhibit B

Per- and Polyfluoroalkyl Substances (PFAS) Summary Report

Final

September 5, 2018

Economic and Policy Analysis Branch
Chemistry, Economics & Sustainable Strategies Division
Office of Pollution, Prevention, and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460

Table of Contents

1. Introduction

Per- and polyfluoroalkyl substances (PFAS) are a group of manmade chemicals that includes perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), GenX, and many other chemicals. PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s. PFAS are found in a wide range of consumer products that people use daily such as cookware, pizza boxes, and stain repellants (U.S. Environmental Protection Agency (EPA) 2018b).

Most people have been exposed to PFAS. Certain PFAS, such as PFOA and PFOS, can accumulate and stay in the human body for long periods of time. There is evidence that exposure to PFAS can lead to adverse health outcomes in humans. PFOA and PFOS have been the most extensively produced and studied of these chemicals. Studies indicate that PFOA and PFOS can cause reproductive and developmental, liver and kidney, and immunological effects in laboratory animals. Both chemical groups have caused tumors in animals. The most consistent findings are increased cholesterol levels among exposed populations, with more limited findings related to

- low infant birth weights,
- effects on the immune system,
- cancer (for PFOA), and
- thyroid hormone disruption (for PFOS; EPA 2018b).

The purpose of this summary report is to provide information on all PFAS[1] in the Toxic Substances Control Act (TSCA) Chemicals Substances Inventory (hereafter referred to as the Inventory), rather than only on a subset such as PFOA or long-chain perfluoroalkyl carboxylic acids (PFCAs). Section 1 provides a definition of PFAS and describes how PFAS are classified in this report. Section 2 provides a brief overview of regulatory actions impacting PFAS manufacture and use. Section 3 describes PFAS manufacturing and import, and Section 4 presents an overview of PFAS uses and applications.

1.1 PFAS Definition and Classification

PFAS refer to a sub-group of per- and polyfluorinated chemicals (PFCs).[2,3] PFCs are organic compounds with fluorine replacing some or all of the chemical's hydrogen (OECD 2018b). Though EPA has historically used the term PFC to refer to fluorinated compounds more generally, the accepted terminology within the Agency has shifted to PFAS. The term includes chemicals such as PFOA and PFOS. EPA previously used the PFAS abbreviation for perfluoroalkyl sulfonic acid, which now is abbreviated as PFSA. For the purpose of this summary report, the term PFAS is used to describe the broader categories of chemicals.

Thousands of PFAS have been produced and used globally. The Organization for Economic Co-operation and Development (OECD) classifies the chemicals as shown in Figure 1-1.[4] The Figure presents commonly recognized categories of PFAS in OECD's Global Database. The classification is

[1] PFAS include per- and polyfluorinated substances of C2 and greater for the purpose of this report (and the underlying TSCA data utilized in it).

[2] PFCs has also been used to abbreviate a related group of fluorinated chemicals called perfluorocarbons.

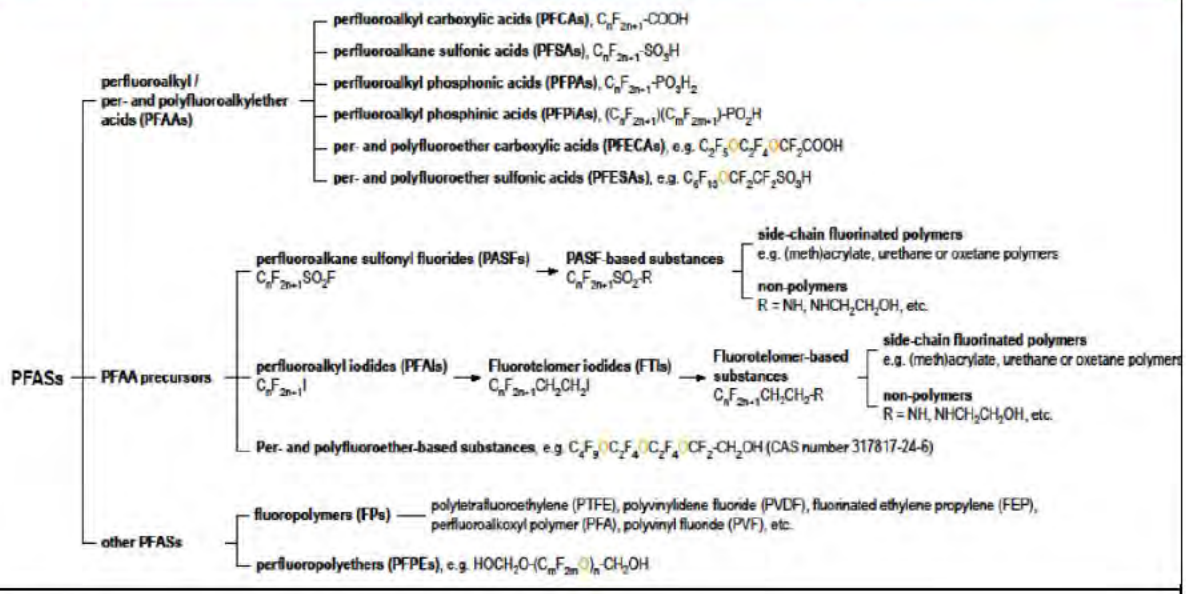
[3] See https://www.epa.gov/pfas/what-are-pfcs-and-how-do-they-relate-and-polyfluoroalkyl-substances-pfass

[4] The structural parameters that constitute PFAS can differ between countries and organizations.

being adopted in this market report to help facilitate the discussion. PFAS are broken into three major categories

1. perfluoroalkyl/per- and polyfluoroalkylether acids (PFAAs),
2. PFAA precursors,
3. and other PFAS.

Figure 1-1: General Classification of Per- and Polyfluoroalkyl Substances (PFAS)



Source(s):
OECD (2018b)

Historically, EPA was interested in two broad categories of PFAS within the PFAA group, long-chain perfluoroalkyl sulfonic acids (PFSAs), which include PFOS, and long-chain perfluoroalkyl carboxylic acids (PFCAs), which include PFOA. The focus of this report has expanded this traditional focus to include all PFAS, both short- and long-chain.

PFSAs and PFCAs are classified as either long-chain or short-chain depending on the number of perfluoroalkyl carbons or the number of total carbons. Definitions for long-chain versus short-chain PFAS vary. For example, long-chain PFSAs have been defined as chemicals with 6 or more perfluoroalkyl carbons (or 6 or more total carbons). Long-chain PFCAs have been defined as chemicals with 7 or more perfluoroalkyl carbons (or 8 or more total carbons). OECD only defines long-chain for PFSAs and PFCAs. However, Buck et al. (2011) considers other PFAS with 7 or more perfluoroalkyl carbons as long-chain. For the purposes of TSCA, definitions of short and long chain have also varied, particularly between PFAS sub-categories, for example, in the Significant New Use Rule (SNUR) amendment for long-chain perfluoroalkyl carboxylate (LCPFAC). For simplicity and illustration in this summary report, short-chain PFAS are defined as (< 7 CF_2) and long chain as (≥ 7 CF_2).

The first step in identifying chemicals within the PFAS universe was to search the Inventory for the presence of these chemicals. This was done by searching for the term poly- and perfluoro (with 2 or

greater carbons) in the chemicals names listed on the Inventory. The list of Chemical Abstracts Services (CAS) registry numbers that fit this description was provided by the Industrial Chemistry Branch (ICB) of the Environmental Protection Agency (EPA) and includes 1,220 PFAS. Of the 1,220 PFAS, 824 are non-CBI and 396 are CBI (see Table 1-1).

Table 1-1: Summary of PFAS in the Inventory

Parameter	Number of Chemicals
Total Number of PFAS	1,220
Non-CBI PFAS	824
CBI-PFAS	396

Table 1-2 presents the commercial status designation of the 1,220 PFAS chemicals on the Inventory. A total of 551 chemicals are of known active status. Active status indicates that the chemical was commercially active during the 10 years prior to June 22nd 2016 when TSCA was reauthorized. Chemical processors are still reporting to EPA regarding the chemicals they manufacture and import. The reporting period for processors closes on October 5, 2018, after which, all Inventory substances will be classified with either an active or inactive designation.

Table 1-2: Commercial Status Designation of PFAS in the Inventory

TSCA Chemicals	Total	Active
Non-CBI PFAS	**824**	322
CBI PFAS	**396**	229
Total	**1,220**	**551**

Table 1-3 presents the TSCA Inventory PFAS list according to eight major PFAS subcategories that are derived from the hierarchy provided in Figure 1-1. Chemical categories were applied by searching the OECD global database by the CAS number, and assigning the corresponding PFAS category to each chemical. The perfluoroalkane sulfonyl compounds (e.g., PFSAs) group comprised the largest number of PFAS with a total of 310 (68 active). This was followed by the fluorotelomer-related compounds (e.g. FTIs) group, which comprises a total of 212 PFAS (97 active). Table A-1 presents a more detailed description of the PFAS subcategories and respective chemical groups within each subcategory.

Table 1-3: Non-CBI TSCA Inventory PFAS by PFAS Category

PFAS Category	Total	Active
perfluoroalkyl carbonyl compounds (e.g., PFCA)	78	22
perfluoroalkane sulfonyl compounds (e.g., PFSA)	310	68
perfluoroalkyl phosphate compounds (e.g., PFPA)	2	2
fluorotelomer-related compounds (e.g., FTI)	212	97
per- and polyfluoroalkyl ether-based compounds (e.g. PFECA)	58	31
other PFAA precursors and related compounds - perfluoroalkyl ones	38	22
other PFAA precursors or related compounds – semi fluorinated (e.g., HFE)	15	13
fluoropolymers (e.g., PTFE)	54	40
Not Classified	57	27
Total	**824**	**322**

For the remainder of this report, only Active substances will be discussed. The next step was to determine the number of short- and long-chain PFAS. In this report, perfluoroalkyl carbon chain length thresholds for short- and long-chain PFAS are defined as less than 7 CF_2 for short-chain and greater than or equal to 7 CF_2 for long-chain. These definitions are based on Buck et al. (2011). Table 1-4 presents the number of active short-chain and long-chain PFAS. The chain lengths were extracted from the OECD global database. It is important to note that not all of the 322 Active Inventory chemicals could be categorized in the OECD database and the data presented in Table 1-4 reflect this limitation. A total of 254 PFAS (of the 322) could be classified as short- or long-chain, these are presented in Table 1-4.[5] A total of 68 PFAS were excluded from the table, 27 because they were not in the OECD global database and 41 because they have multiple perfluoroalkyl carbon chain lengths reported or have unclear chemical descriptions.[6,7] Of the 254 active PFAS summarized in Table 1-4, 111 are short-chain and 143 are long-chain PFAS.

Table 1-4: Perfluoroalkyl Carbon Chain Length of Active PFAS in the Inventory

PFAS Category	Total	Perfluoroalkyl Carbon Chain Length[1,2]	
		Short-chain (< 7 CF_2)	Long-chain (≥ 7 CF_2)
perfluoroalkyl carbonyl compounds (e.g., PFCA)	21	14	7
perfluoroalkane sulfonyl compounds (e.g., PFSA)	64	37	27
perfluoroalkyl phosphate compounds (e.g., PFPA)	0	0	0
fluorotelomer-related compounds (e.g., FTI)	65	27	38
per- and polyfluoroalkyl ether-based compounds (e.g. PFECA)	31	10	21
other PFAA precursors and related compounds - perfluoroalkyl ones	21	14	7
other PFAA precursors or related compounds – semi fluorinated (e.g., HFE)	12	9	3
fluoropolymers (e.g., PTFE)	40	0	40
Total	**254**	**111**	**143**

Note(s):

[1] Only PFAS in the OECD global database are categorized by perfluoroalkyl carbon chain length. Of the 322 Active PFAS, the 254 Active PFAS are summarized in this table. A total of 68 Active PFAS are excluded from the table, 27 because they were not in the OECD global database and 41 because they have variable or unclear perfluoroalkyl carbon chain lengths.

[2] Perfluoroalkyl carbon chain length thresholds presented in this table (short-chain, < 7; long-chain, $CF_2 \geq 7$ CF_2) are guideline thresholds appearing in Buck et al. (2011). Only PFSAs and PFCAs have thresholds defined by OECD. According to OECD, long-chain PFSAs refer to PFSAs with 6 or more perfluoroalkyl carbons and long-chain PFCAs refer to PFCAs with 7 or more perfluoroalkyl carbons.

Table 1-5 presents the number of PFAS reported in the Chemical Data Reporting (CDR) database from 2006 to 2016. The total number of PFAS (824) in the Inventory were cross-referenced with all of the chemicals reported in the 2006, 2012, and 2016 CDR by CAS number. A total of 161 were reported in 2016, of which 90 were listed as non-CBI PFAS. Note that three chemicals reported in the 2006 CDR are not active in the current Inventory. The largest category was FTI chemicals with 38 non-CBI reported in 2016.

[5] According to OECD, long chain PFSAs refer to PFSAs with 6 or more perfluoroalkyl carbons and long chain PFCAs refer to PFCAs with 7 or more perfluoroalkyl carbons.

[6] Many of the chemicals that have multiple chain lengths reported have unspecified or partially unspecified chemical formulas (OECD 2018a). For chemicals that have specified chemical formulas, it is unclear why each has multiple chain lengths reported.

[7] Unclear descriptions include chemicals described with ambiguous descriptions such as "reaction products", described with unclear terms, or registered with only trade names and general descriptions (OECD2018b).

Table 1-5: Number of PFAS Reported in the CDR			
PFAS Category	**2006 CDR**	**2012 CDR**	**2016 CDR**
Non CBI			
perfluoroalkyl carbonyl compounds (e.g., PFCA)	4	4	4
perfluoroalkane sulfonyl compounds (e.g., PFSA)	3	5	8
perfluoroalkyl phosphate compounds (e.g., PFPA)	0	0	2
fluorotelomer-related compounds (e.g., FTI)	27	28	38
per- and polyfluoroalkyl ether-based compounds (e.g. PFECA)	8	13	12
other PFAA precursors and related compounds - perfluoroalkyl ones	5	4	8
other PFAA precursors or related compounds – semi fluorinated (e.g., HFE)	5	8	9
fluoropolymers (e.g., PTFE)	0	0	1
Not Classified	10	8	8
Total	**62**	**70**	**90**
CBI			
Total		**29**	**71**
Non-CBI and CBI			
Total		**99**	**161**

2. Regulatory Background

EPA has undertaken several key regulatory actions to address PFAS. Table 2-1 provides a chronological overview of some of these major efforts. In particular, EPA has published significant new use rules (SNURs) for PFAS, beginning in 2002, that require manufacturers to notify EPA at least 90 days before manufacturing, importing, or processing PFAS. Table 2-2 provides more details about those SNURs.

Table 2-1: EPA Actions to on PFAS			
Title	**EPA Office**	**Date**	**Summary**
New Chemicals Program Review of Alternatives for PFOA and Related Chemicals	OPPT	Ongoing	EPA reviewed hundreds of new chemical substitutes for PFOA, PFOS, and other long-chain PFAS under EPA's New Chemicals Program since 2000. EPA reviews the new substances to identify whether the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances may be present, as well as any issues that may arise by new chemistries, to ensure that the new chemical may not present an unreasonable risk to health or the environment. One outcome of EPA's review of a PMN or MCAN for a new chemical substance or review of a SNUN for a significant new use is the issuance of an order under section 5(e) of TSCA. Most TSCA section 5(e) Orders issued by EPA are Consent Orders that are negotiated with the submitter of the notification.
Lifetime Health Advisories and Health Effects Support Documents for PFOA and PFOS	OW	May 16th 2016	EPA announced the release of lifetime health advisories (HAs) and health effects support documents for PFOA and PFOS. EPA's HAs, which identify the concentration of PFOA and PFOS in drinking water at or below which adverse health effects are not anticipated to occur over a lifetime of exposure, are: 70 parts per trillion (ppt) for PFOA and PFOS.
Significant New Use Rules (SNURs): Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Proposed Rule	OPPT	January 21st 2015	EPA proposed a SNUR for Long-Chain Perfluoroalkyl Carboxylate (LCPFAC) chemical substances that would require manufacturers (including importers) of PFOA and PFOA-related chemicals, including as part of articles, and processors of these chemicals to notify EPA at least 90 days before starting or resuming new uses of these chemicals in any products.
Significant New Use Rules: Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances (Final)	OPPT	October 22nd 2013	EPA amended a SNUR to designate as a significant new use PFAS that have completed the new chemical review process under TSCA but have not yet commenced production or import and processing. EPA also finalized a SNUR to designate as a significant new use LCPFAC chemical substances used in manufacturing (including importing) and processing of carpets or for treating carpet.
Revisions to the Unregulated Contaminant Monitoring Rule for Public Water Systems	OW	May 2nd 2012	The UCMR3 required monitoring for 30 contaminants (28 chemicals and two viruses) between 2013 and 2015 using analytical methods developed by EPA, consensus organizations, or both. The purpose of UCMR3 was to collect occurrence data for contaminants suspected to be present in drinking water, but that do not have health-based standards set under the SDWA. Six perfluorinated compounds were included in the UCMR3: PFOS, PFOA, PFNA, PFHxS, PFBS, and perfluoroheptanoic acid (PFHpA). Of these 6 compounds, PFOA and PFOS were found in the greatest number of samples. However, less than one percent of the public water systems sampled had results that exceeded the reference dose (lifetime HA limit of 70 ppt or 0.07µg/L).
Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers	OPPT	January 27th 2010	EPA published a final rule that amended the Polymer Exemption Rule to no longer exclude from eligibility polymers that include any one or more of the following: PFAS, PFAC, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule. Compliance date was January 27, 2012.

Table 2-1: EPA Actions to on PFAS

Title	EPA Office	Date	Summary
Provisional Health Advisories for PFOA and PFOS	OW	January 8th 2009	EPA conducted limited testing of agricultural sites in Alabama where sewage sludge was applied from a local wastewater treatment plant that receives wastewater from numerous industrial sources, including facilities that manufacture and use PFOA and other PFAS. The results of this limited testing showed elevated levels of PFAS in sludge and in soil that received the sludge.
Significant New Use Rule: Perfluoroalkyl Sulfonates	OPPT	October 9th 2007	EPA finalized a SNUR on 183 PFAS chemicals believed to be no longer manufactured, imported, or used in the U.S. The SNUR required manufacturers and importers to notify EPA at least 90 days before commencing the manufacture or import of the PFAS chemicals for the significant new uses described.
Significant New Use Rule: Perfluoroalkyl Sulfonates	OPPT	December 9th, 2002 (Origination Date)	EPA issued a SNUR for 75 PFAS, requiring manufacturers and importers to notify EPA at least 90 days before starting the manufacture or importation of these chemical substances for the significant new uses described.
Significant New Use Rule; Final Rule and Supplemental Proposed Rule: Perfluoroalkyl Sulfonates	OPPT	March 11th 2002 (Origination Date)	EPA published a SNUR to require notification to EPA before any future manufacture (including import) of 13 PFAS chemicals specifically included in the voluntary phaseout of PFOS by 3M that took place between 2000 and 2002.

Source(s):
EPA (2018a)

Significant New Use Rules (SNURs) have restricted the manufacture, import, and use of many PFAS. Table 2-2 presents the Significant New Use Rules (SNURs) for existing PFAS. The first SNUR was proposed in 2000 covering 90 long-chain PFSAs, more specifically, long-chain PFOSs. From 2002 to 2007, EPA identified a total of 270 PFSAs. In 2010, EPA amended the Polymer Exemption Rule to exclude from eligibility polymers containing as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF3- or longer chain length. Beginning in 2013, EPA shifted attention to long-chain PFCAs to limit uses in carpets and carpet treatment products.

Table 2-2: Significant New Use Rules for Existing PFAS
October 18, 2000 - Proposed SNUR on 90 perfluorooctyl sulfonyl (PFOS) long-chain chemicals (65 FR 62319)
March 11, 2002 - Final SNUR on 13 perfluoroalkyl sulfonate (PFAS) chemicals (67 FR 11008)
March 11, 2002 -Proposed SNUR on 74 PFAS chemicals, including PFOS (67 FR 11014)
December 9, 2002 - Final SNUR on 74 PFAS/PFOS chemicals (67 FR 72854)
October 9, 2007 - Final SNUR on 183 PFAS chemicals believed to no longer be manufactured (including imported) or used in the United States (72 FR 57222)
January 27, 2010 - Polymer Exemption Rule revoking exemption from full PMN reporting for new PFC polymers (75 FR 4295)
October 22, 2013 - Proposed SNUR amendment at 40 CFR 721.10536 for LCPFAC chemical substances by designating manufacturing (including importing) or processing of LCPFAC chemical substances listed in Table 1 of the Rule for any use that is no longer ongoing after December 31, 2015, as a significant new use; designating manufacturing (including importing) or processing of PFOA or its salts for any use as a significant new use; and designating manufacturing (including importing) or processing of all other LCPFAC chemical substances for any use not ongoing as of the date on which this proposed rule is published as a significant new use.
January 21, 2015 - Proposed SNUR on LCPFAC chemical substances to ensure that perfluorinated chemicals that have been phased out do not re-enter the marketplace without review (80 FR 2885)

In 2006, EPA invited eight major leading companies in PFAS industry to join in a global stewardship program (2010/2015 PFOA Stewardship Program) with two goals:

1. 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 PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals, and product content levels of these chemicals; and
2. To commit to working toward the elimination of these chemicals from emissions and products by 2015.

Participants in the Stewardship Program included

- Arkema
- Asahi Glass Company
- BASF Corporation (successor to Ciba Specialty Chemicals Corporation)
- Clariant

- Daikin
- 3M/Dyneon
- DuPont
- Solvay Solexis

At the time of initiation of the Stewardship Program, these companies represented the majors global manufacturers of long-chain PFCAs. All companies have met the PFOA Stewardship Program goals. Final progress reports are available on EPA's website.[8]

Table 2-3 present the number of active non-CBI and CBI PFAS in the Inventory with any associated regulatory flags. Table 2-3 also indicates if the CBI PFAS is provisional. The regulatory flags provide an indication of rulemakings that impact PFAS in the Inventory and reporting requirements for manufactured or imported PFAS. A total of 202 PFAS are identified in final SNURs, 145 non-CBI PFAS and 57 CBI PFAS (see Table 2-3).

Table 2-3: Regulatory Flags for Active TSCA Inventory PFAS[1]

PFAS Category	Total	PMN	5E	S	SP	XU	FRI
Non-CBI							
perfluoroalkyl carbonyl compounds (e.g., PFCA)	22	0	0	8	3	0	0
perfluoroalkane sulfonyl compounds (e.g., PFSA)	68	7	3	51	0	1	0
perfluoroalkyl phosphate compounds (e.g., PFPA)	2	0	0	2	0	0	0
fluorotelomer-related compounds (e.g., FTI)	97	30	3	67	17	3	0
per- and polyfluoroalkyl ether-based compounds (e.g. PFECA)	31	18	4	5	0	9	0
other PFAA precursors and related compounds - perfluoroalkyl ones	22	5	1	2	0	1	0
other PFAA precursors or related compounds – semi fluorinated (e.g., HFE)	13	12	0	5	0	0	0
fluoropolymers (e.g., PTFE)	40	25	13	2	0	26	1
Not Classified	27	13	0	3	0	6	0
Subtotal	**322**	**110**	**24**	**145**	**20**	**46**	**1**
CBI							
Provisional Status							
Yes	45	44	42	34	0	0	0
No	184	184	75	23	3	77	5
Subtotal	**229**	**228**	**117**	**57**	**3**	**77**	**5**
Non-CBI and CBI							
Total	**551**	**338**	**141**	**202**	**23**	**123**	**6**

Note(s):

[1] Regulatory Flags: PMN - indicates a commenced PMN substance; 5E - indicates a substance that is subject of a TSCA section 5(e) order; S - indicates a substance that is identified in a final Significant New use Rule; SP - indicates a substance that is identified in a proposed Significant New Use Rule; XU -indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711); FRI - indicates a polymeric substance containing no free-radical initiator in its Inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.

[8] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/epas-non-cbi-summary-tables-2015-company-progress

3. Manufacturing and Import of PFAS

Manufacturers and Importers of PFAS chemicals were identified by searching the CDR and the Toxics Release Inventory (TRI). CDR was searched to identify PFAS parent companies that reported manufacturing and\or importing PFAS(s) in the non-CBI 2016 CDR. A total of 14 parent companies were identified and are presented in Table 3-1. Four of these 14 parent companies: 3M Company, AGC Chemicals America, Inc., Daikin America, Inc and Solvay Specialty Polymers USA, LLC took part in the PFOA Stewardship Program (see Chapter 2).

Table 3-2 presents the PFAS parent companies, their related manufacturing sites, and the number of PFAS reported at each site as reported in the 2016 CDR. A total of 31 sites reported 90 different PFAS. One site and at least one parent company are listed as CBI. The Chemours Company manufactured the largest number of PFAS (39 different PFAS). Appendix B, Table B-1 presents the combined manufacture and import volume as well as the national aggregate production volume for each PFAS reported in the 2016 CDR. The manufacturing and import volumes for all PFAS reported were withheld and only 18 of the 90 PFAS reported provide a range of national aggregate production volume (see Table B-1).

Table 3-1: Parent Companies Reporting PFAS in the 2016 CDR

Parent Company[1]
3M COMPANY
AGC CHEMICALS AMERICAS, INC.
ATOTECH USA, INC.
DAIKIN AMERICA, INC.
Dow Corning Corporation
FORD MOTOR COMPANY
HONEYWELL INTERNATIONAL INC
LANXESS CORPORATION
LINDE NORTH AMERICA, INC
PEACH STATE LABS INC
SOLVAY SPECIALTY POLYMERS USA, LLC
SUMITOMO CORPORATION OF AMERICAS
The Chemours Co
TYCO FIRE PRODUCTS LP

Note(s):

[1] Two parent companies were removed because they appeared to be duplicates with slightly different spellings.

Table 3-2: Number of PFAS Chemicals Manufactured by Parent Company and Site in the 2016 CDR				
Parent Company	**Manufacturing Site Name**	**Site State**	**Number of Chemicals Manufactured**	
			Parent Company	**Site**
3M COMPANY	3M COMPANY	MN	4	3
3M COMPANY	3M COMPANY/3M CORDOVA	IL	4	1
AGC CHEMICALS AMERICAS, INC.	AGC CHEM AMER INC BUS & TECH CTR	PA	4	4
ATOTECH USA, INC.	ATOTECH USA	SC	2	2
CBI	3M COMPANY	AL	CBI	4
CBI	3M COMPANY/3M CORDOVA	IL	CBI	13
CBI	3M COTTAGE GROVE CENTER	MN	CBI	2
CBI	AIR PROD & CHEM HAMILTON BLVD FAC	PA	CBI	2
CBI	CBI	CBI	CBI	12
CBI	INNOVATIVE CHEMICAL TECHNOLOGIES INC	GA	CBI	4
CBI	INNOVATIVE CHEMICAL TECHNOLOGY AT ORTEC INC	SC	CBI	1
CBI	SOLENIS LLC	DE	CBI	1
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	CBI	10
DAIKIN AMERICA INC.	DAIKIN AMERICA INC.	NY	1	1
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	8	8
Dow Corning Corporation	DOW CORNING CORP MIDLAND PLANT	MI	1	1
FORD MOTOR COMPANY	Ford Motor Company	MI	1	1
HONEYWELL INTERNATIONAL INC	HONEYWELL INTERNATIONAL INC - BATON ROUGE PLANT	LA	1	1
LANXESS CORPORATION	LANXESS CORP	PA	1	1
LINDE NORTH AMERICA, INC	LINDE ELECTRONICS AND SPECIALTY GASES	NJ	1	1
PEACH STATE LABS INC	PEACH STATE LABS INC COLUMBUS	GA	2	2
Peach State Labs LLC	PEACH STATE LABS, LLC	GA	4	4
SOLVAY SPECIALTY POLYMERS USA, LLC	SOLVAY SPECIALTY POLYMERS USA LLC	TX	2	1
SOLVAY SPECIALTY POLYMERS USA, LLC	SOLVAY SPECIALTY POLYMERS USA, LLC	GA	2	1
SUMITOMO CORPORATION OF AMERICAS	SUMITOMO CORPORATION OF AMERICAS	TX	1	1
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	39	21
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CORPUS CHRISTI)	TX	39	1
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	39	3
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (HEADQUARTERS)	DE	39	5
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (PASCAGOULA)	MS	39	2
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	39	7
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	8	8
Number of Unique Chemicals				**90**

The 2016 TRI List of Reportable Chemicals contained five of the 824 PFAS chemicals identified by EPA (see Table 3-3). Table 3-4 presents the facilities reporting PFAS in the 2016 TRI. Of the five TRI reportable PFAS chemicals, two were reported by nine facilities in the 2016 TRI. Four facilities produce the chemicals that they reported. PFAS as a category of chemicals are not reported to the Toxic Release Inventory. As for the five that are listed, those are among the many CFCs and HCFCs that EPA was petitioned to add during the 1990s.

Figure 3-1 provides a U.S. map illustrating the location of the importing and manufacturing sites as indicated in the 2016 CDR. The map also shows waterbodies of greater than 10 square miles in proximity to the sites.

Table 3-3: PFAS on the 2016 TRI List of Reportable Chemicals

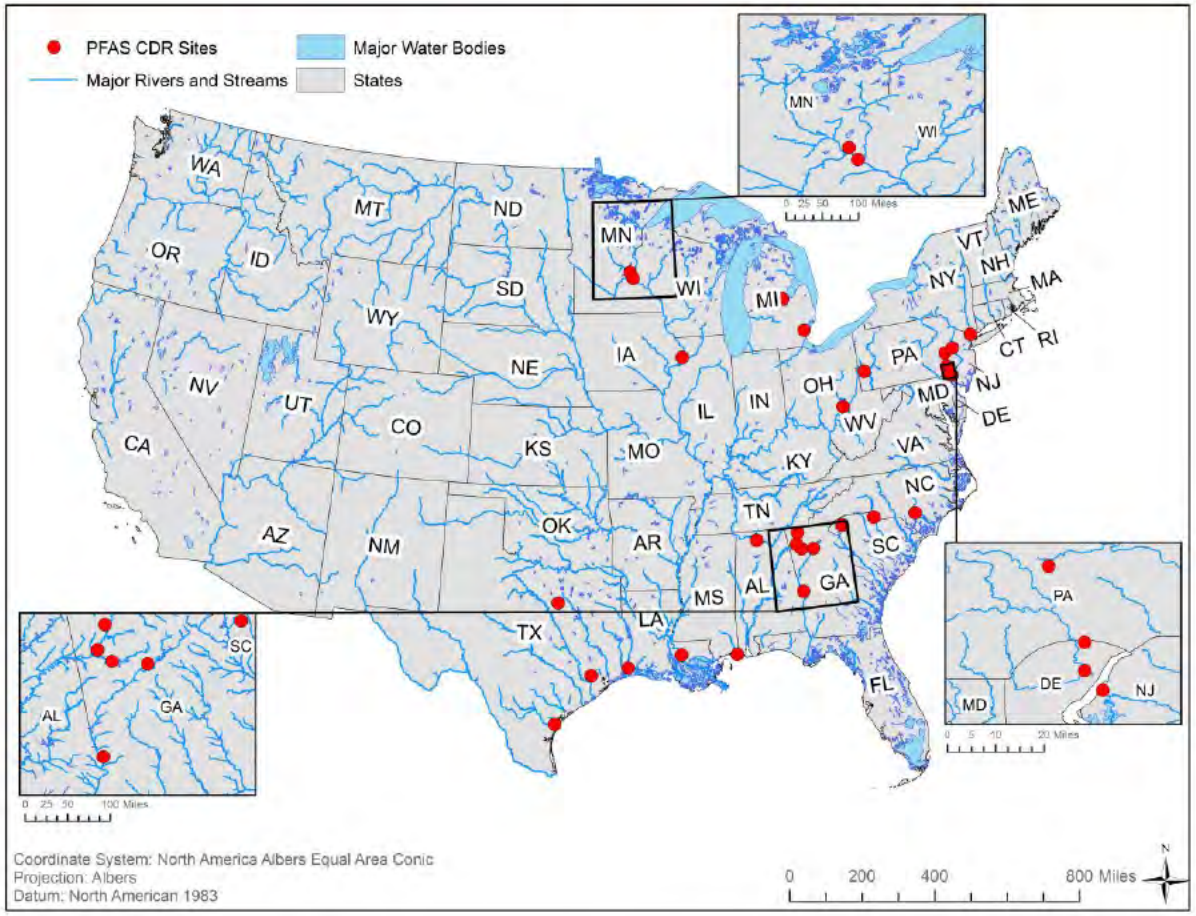
CAS	Chemical	Reported in 2016 TRI
124-73-2	Dibromotetrafluoroethane (Halon 2402)	No
507-55-1	1,3-Dichloro-1,1,2,2,3-pentafluoropropane (HCFC-225cb)	No
422-56-0	3,3-Dichloro-1,1,1,2,2-pentafluoropropane (HCFC-225ca)	No
76-14-2	Dichlorotetrafluoroethane (CFC-114)	Yes
76-15-3	Monochloropentafluoroethane (CFC-115)	Yes

Table 3-4: Facilities Reporting PFAS in the 2016 TRI

Parent Company Name	Manufacturing Facility Name	Manufacturing Facility Address	CAS	Chemical Name	Produce	Import
A-GAS US HOLDINGS INC	A-GAS AMERICAS	1100 HASKINS RD WOOD, OH 43402	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	NO	NO
AIRGAS INC	AIRGAS REFRIGERANTS INC SMYRNA	5211 INDUSTRIAL CT SE COBB, GA 30080	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	NO	NO
HERITAGE-WTI LLC	HERITAGE THERMAL SERVICES	1250 ST GEORGE ST COLUMBIANA, OH 43920	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	NO	NO
HONEYWELL INTERNATIONAL INC	HONEYWELL INTERNATIONAL INC DANVILLE WORKS	209 BREWER RD VERMILION, IL 61834	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	NO	NO
HONEYWELL INTERNATIONAL INC	HONEYWELL INTERNATIONAL INC GEISMAR PLANT	5525 HWY 3115 ASCENSION PARISH, LA 70721	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	YES	NO
HONEYWELL INTERNATIONAL INC	HONEYWELL INTERNATIONAL INC GEISMAR PLANT	5525 HWY 3115 ASCENSION PARISH, LA 70721	76153	MONOCHLOROPENTAFLUOROETHANE	YES	NO
HONEYWELL INTERNATIONAL INC	HONEYWELL INTERNATIONAL INC-BATON ROUGE PLANT	CORNER OF LUPINE & ONTARIO STR EETS EAST BATON ROUGE PARISH, LA 70805	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	YES	NO
THE CHEMOURS CO	CHEMOURS WASHINGTON WORKS	8480 DUPONT RD BUILDING 1 WOOD, WV 26181	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	YES	NO
THE CHEMOURS CO FC LLC	THE CHEMOURS CO FC LLC	HWY 361 SAN PATRICIO, TX 78359	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	YES	NO
THE CHEMOURS CO FC LLC	THE CHEMOURS CO FC LLC	HWY 361 SAN PATRICIO, TX 78359	76153	MONOCHLOROPENTAFLUOROETHANE	YES	NO
US DEPARTMENT OF DEFENSE	US DEFENSE LOGISTICS AGENCY DEFENSE SUPPLY CENTER RICHMOND	8000 JEFFERSON DAVIS HWY CHESTERFIELD, VA 23297	76142	DICHLOROTETRAFLUOROETHANE (CFC-114)	NO	NO

Source(s):
EPA (2017)

Figure 3-1: Location of 2016 PFAS CDR Manufacturing and Importing Sites



Note(s):

[1] The source of the main water bodies and rivers and streams data is a 2014 U.S. Geological Survey (USGS) dataset that includes data on streams and water bodies and wetlands within the contiguous U.S. at a 1:1,000,000 scale.

[2] There are no PFAS sites outside of the contiguous U.S.

4. Uses of PFAS Chemicals

PFAS are a broad class of substances with differing structural features (e.g. varying carbon lengths, differing fluorine content and functional groups) that can impart special properties that have a variety of industrial applications. PFAS provide characteristics such as thermo-stability, ability to adapt to a variety of surface characteristics, high chemical stability, and other characteristics. Fluoropolymers, n particular, have properties that include fire resistance and oil, stain, grease, and water repellency. Fluorotelomers can be used in surface treatment products and impart the following properties: soil, stain, grease, and water resistance. Fluorotelomers can also be used as surfactants to help products flow more evenly (EPA 2009). Table 4-1 presents a list of broad use categories with examples for each use category.

Table 4-1: Summary of PFAS Uses and Applications

Use Category	Example(s)
Adhesive, paint, and coating additive	Nonstick coating in cookware
Chemical manufacturing	Chemical intermediate; polymerization aid
Component of a photoresist substance	Semiconductors
Component of electronic products	Cables and wiring; insulating tape; "solder sleeves"; smudge-resistant touch screens
Component of firefighting foams	Aqueous film-forming foams (AFFFs)
Component of rubber compounds	Hose, tubing, and piping; rubber and plumbing fluxing agents
Foam additive	Flame-retardant insulation in soft furnishings
Lubricant and lubricant additive	Automotive manufacturing
Specialized industrial chemical	Improved mold release for pneumatic tires; liquid crystal displays; wetting agents
Mechanical components	Conveyor belting; low-friction bearings and seals; coating/surfactant on semiconductors, wiring, tubing, seals, etc.
Clothing, footwear, and textiles	Protection against oil, water, and soil; wind and rain barrier; firefighting clothing
Scientific and medical instruments	Photographic film; x-ray film; artificial body parts; medical product packaging
Wetting agent	Floor polishes; metal plating

Source(s):
EPA (2013, 2016, 2018a); OECD (2013); FluoroCouncil (2018)

Table 4-2 presents the industrial sectors associated with PFAS reported in the 2016 CDR. The sectors with the largest number of chemicals included all other basic organic chemical manufacturing (19), all other chemical product and preparation manufacturing (19), plastic material and resin manufacturing (17), and computer and electronic product manufacturing (16). A total of 33 entries were blank and 15 reported as CBI. Table 4-3 provides the number of PFAS by chemical function as reported in the 2016 CDR. This includes the highest categories as intermediates (29), functional fluids (10), solvents (for cleaning and degreasing) (9), and firefighting foam agents (8). A total of 33 entries were blank and 15 reported as CBI. Appendix B, Table B-2 presents the combined use, function, and sector information for all PFAS reported in the 2016 CDR. However, little can be concluded without the production volumes corresponding to each use.

Table 4-4 presents the number of PFAS reported for product categories reported in the 2016 CDR, and whether the product is used in the consumer and/or commercial sector. The majority (76) had

blank entries. The largest number of chemicals were reported to firefighting foam agents (8), electrical and electronic components (5), and cleaning and furnishing care products (4).

Table 4-2: Number of PFAS Manufactured by Sector Reported in the 2016 CDR

Sector	Number of PFAS
(blank)	33
CBI	15
Adhesive manufacturing	2
All other basic inorganic chemical manufacturing	1
All other basic organic chemical manufacturing	19
All other chemical product and preparation manufacturing	19
Computer and electronic product manufacturing	16
Fabricated metal product manufacturing	2
Industrial gas manufacturing	2
Miscellaneous manufacturing	4
Not known or reasonably ascertainable	2
Oil and gas drilling, extraction, and support activities	1
Paint and coating manufacturing	4
Paper manufacturing	1
Pesticide, fertilizer, and other agricultural chemical manufacturing	2
Plastic material and resin manufacturing	17
Primary metal manufacturing	1
Printing ink manufacturing	1
resale of chemicals	1
Soap, cleaning compound, and toilet preparation manufacturing	3
Stored on site in rail cars, no commercial use	1
Textiles, apparel, and leather manufacturing	5
Wholesale and retail trade	1

Table 4-3: Number of PFAS Manufactured by Function Reported in the 2016 CDR	
Function	**Number of PFAS**
(blank)	33
CBI	15
Finishing agents	2
Fire Extinguishing Medium	1
Firefighting foam agents	8
Functional fluids (closed systems)	10
Functional fluids (open systems)	3
Intermediates	29
Lubricants and lubricant additives	1
Not known or reasonably ascertainable	1
Paint additives and coating additives not described by other categories	1
Plating agents and surface treating agents	4
Processing aids, not otherwise listed	5
Processing aids, specific to petroleum production	1
Solvents (for cleaning and degreasing)	9
Solvents (which become part of product formulation or mixture)	1
Stored on site in rail cars, no commercial use	1
Surface active agents	7
Transfilling and purifying	1

Table 4-4: Number of PFAS by Use Category as Reported in the 2016 CDR		
Product Category	**Consumer/Commercial/Both**	**Number of PFAS**
(blank)	(blank)	76
CBI	Commercial	2
Adhesives and sealants	Commercial	1
Automotive care products	Consumer	1
Cleaning and furnishing care products	Both	4
Electrical and electronic products	Commercial	5
Fabric, textile, and leather products not covered elsewhere	Both	1
Fire Extinguishing medium	Commercial	1
Firefighting foam agents	Commercial	8
Food packaging	Both	1
Ink, toner, and colorant products	Consumer	1
Metal products not covered elsewhere	Both	2
Paints and coatings	Both	1

To gain further perspective on recent uses of PFAS, Table 4-5 presents TSCA submission types (including LVEs, premanufacture notices (PMNs), SNUNS, LOREX and TMAs) between 2006 through 2016 and their related use categories and production volume. Thirteen major uses categories are noted. Lubricant and lubricant additive and component of rubber compounds uses categories represent the highest average annual production volume (229,100 kg and 212,200 kg, respectively).

Table 4-5: Categories of Use by Submission Type (FY 2006 to 2016)[1]

Use	LVE	PMN	SNUN	LOREX	TMEA	Average Annual Production Volume (kg/yr)[2]
Adhesive, paint, and coating additive	74	41	2	-	1	13,100
Chemical Intermediate	38	37	-	-	-	12,700
Component of a photoresist substance	99	4	-	1	-	1,600
Component of electronic products	7	5	-	-	-	20,400
Component of firefighting foams	-	10	-	-	-	52,800
Component of rubber compounds	5	5	-	-	-	212,200
Cross-linking agent	1	1	-	-	-	1,000
Finishing agents	64	144	2	-	-	48,100
Foam additive	3	4	-	-	-	15,600
Lubricant and Lubricant Additive	15	5	-	-	-	229,100
Polymerization Aid	7	8	-	-	-	8,000
Specialized Industrial Chemical	8	8	-	-	-	13,400
Tracer Chemical	27	-	-	-	-	400
Total	**348**	**272**	**4**	**1**	**1**	

Note(s):

[1] PMN - Premanufacture Notices; SNUN - Significant New Use Notices; LVE - Low Volume Exemptions; LM - Low Volume Exemption Modifications; LOREX - Low Exposure/Low Release Exemptions; XM - Low Exposure/Low Release Exemption Modifications; TMEA - Test Marketing Exemption Applications.

[2] Reflects average annual production volume for all notice types

[3] Due to the implementation of the PFOA Stewardship Program between the reported years, the average annual production volumes may not be an accurate indicator of the current PFAS use trends.

Appendix A: PFAS Categories

Table A-1: PFAS Categories[1]
perfluoroalkyl carbonyl compounds
perfluoroalkyl carbonyl halides
perfluoroalkyl carboxylic acids (PFCAs), their salts and esters
other perfluoroalkyl carbonyl-based nonpolymers
perfluoroalkyl carbonyl amides / amido ethanols and other alcohols
perfluoroalkyl carbonyl silanes
perfluoroalkyl carbonyl (meth)acrylate
other perfluoroalkyl carbonyl-based side-chain fluorinated polymers
perfluoroalkyl carbonyl (meth)acrylate polymers
perfluoroalkyl carbonyl dicarbonyl halides
perfluoroalkyl carbonyl dicarboxylic acids and non-polymers
1-H perfluoroalkyl carbonyl halides
1-H perfluoroalkyl carboxylic acids
1-H perfluoroalkyl carbonyl-based non-polymers
perfluoroalkane sulfonyl compounds
perfluoroalkane sulfonyl halides
perfluoroalkane sulfonic acids (PFSAs), their salts and esters
perfluoroalkane sulfonyl-based nonpolymers
perfluoroalkane sulfonyl amides/amido ethanols (xFASA/Es) and other alcohols
perfluoroalkane sulfonyl amido ethanols, phosphate esters (SAmPAPs)
perfluoroalkane sulfonyl (meth)acrylates
perfluoroalkane sulfonyl silanes
perfluoroalkane sulfonyl acetic acids & esters
perfluoroalkane sulfonyl-based side-chain fluorinated polymers
perfluoroalkane sulfonyl (meth)acrylate polymers
perfluoroalkane sulfonyl urethane polymers
perfluoroalkane sulfonyl siloxanes/silicon polymers
perfluoroalkane sulfinic acids
1-H perfluoroalkane sulfonic acids
1-H perfluoroalkane sulfonyl-based non-polymers
perfluoroalkane disulfonic acids
perfluoroalkane disulfonyl-based non-polymers
perfluoroalkyl phosphate compounds
perfluoroalkyl phosphate-related halides
bis(perfluoroalkyl) phosphinyl halides
perfluoroalkyl phosphorus halides
perfluoroalkyl phosphonic acids (PFPAs), their salts and esters
perfluoroalkyl phosphinic acids (PFPiAs), their salts and esters
bis(perfluoroalkyl) phosphinyl-based nonpolymers
bis(perfluoroalkyl) phosphinyl amids (PFPiAMs)
fluorotelomer-related compounds
perfluoroalkyl iodides (PFAIs)
n:2 fluorotelomer-based non-polymers
n:2 fluorotelomer iodides (n:2 FTIs)
n:2 fluorotelomer olefins (n:2 FTOs)
n:2 fluorotelomer alcohols (n:2 FTOHs) / thiols
n:2 fluorotelomer alcohol, phosphate esters (PAPs)
n:2 fluorotelomer-based silanes
n:2 fluorotelomer-based (meth)acrylate
n:2 fluorotelomer sulfonic acids (n:2 FTSAs)
n:2 fluorotelomer sulfonyl-based compounds
n:2 fluorotelomer phosphonic / phosphinic acids
n:2 FTOH ethoxylates
n:2 FT amine, amino & derivatives
n:2 FT-thiol derivatives

Table A-1: PFAS Categories[1]
n:2 fluorotelomer carboxylic acids (FTCAs)
n:3 acids
FTAL
n:2 fluorotelomer-based side-chain fluorinated polymers
n:2 fluorotelomer-based (meth)acrylate polymers
n:2 fluorotelomer-based urethane polymers
n:2 fluorotelomer-based siloxanes/silicon polymers
n:2 fluorotelomer-based sulfonyl (meth)acrylate polymers
n:1 fluorotelomer-based non-polymers
n:1 fluorotelomer alcohols
n:1 FT (meth)acrylate
n:1 PAPs
n:1 silanes
n:1 FT sulfonyl-based substances
n:1 FTAL
n:1 fluorotelomer-based side-chain fluorinated polymers
n:1 fluorotelomer-based (meth)acrylic polymers
fluorotelomer epoxides and derivatives
fluorotelomer epoxides
fluorotelomer epoxides derivatives
Hydrofluorotelomer non-polymers
hydrofluorotelomer-based side chain fluorinated polymers
perfluoroalkyl diiodides
1-H n:1 FT
per- and polyfluoroalkyl ether-based compounds
perfluoroalkyl ethers / alkanes + aromatics
perfluoroalkyl ethers / alkanes + aromatics – monoethers
perfluoroalkyl ethers / alkanes + aromatics – diethers
perfluoroalkyl ethers / alkanes + aromatics – triethers
perfluoroalkyl ethers / alkanes + aromatics - 4-10 ether linkages
perfluoroalkyl ethers / alkanes + aromatics - more than 10 ether linkages
per- and polyfluoroalkyl ether carboxylic acids (PFECAs), their salts and esters, as well as derivatives such as amides
PFECAs, salts and esters – monoethers
PFECAs, salts and esters – diethers
PFECAs, salts and esters – triethers
PFECAs, salts and esters - 4-10 ether linkages
PFECAs, salts and esters - more than 10 ether linkages
PFECA-related substances – monoethers
PFECA-related substances – diethers
PFECA-related substances – triethers
PFECA-related substances - 4-10 ether linkages
PFECA-related substances - more than 10 ether linkages
per- and polyfluoroalkyl ether sulfonic acids (PFESAs), their salts and esters, as well as derivatives
PFESAs, salts and esters – monoethers
PFESAs, salts and esters – diethers
PFESAs, salts and esters – triethers
PFESAs, salts and esters - 4-10 ether linkages
PFESAs, salts and esters - more than 10 ether linkages
PFESA-related substances – monoethers
PFESA-related substances – diethers
PFESA-related substances – triethers
PFESA-related substances - 4-10 ether linkages
PFESA-related substances - more than 10 ether linkages
perfluoroethers alkenes and derivatives
perfluoroethers alkenes and derivatives – monoethers
perfluoroethers alkenes and derivatives – diethers

Table A-1: PFAS Categories[1]
perfluoroethers alkenes and derivatives – triethers
perfluoroethers alkenes and derivatives - 4-10 ether linkages
perfluoroethers alkenes and derivatives - more than 10 ether linkages
per- and polyfluoroalkyl ether halides (except F)
per- and polyfluoroalkyl ether halides (except F) – monoethers
per- and polyfluoroalkyl ether halides (except F) – diethers
per- and polyfluoroalkyl ether halides (except F) – triethers
per- and polyfluoroalkyl ether halides (except F) - 4-10 ether linkages
per- and polyfluoroalkyl ether halides (except F) - more than 10 ether linkages
per - and polyfluoroalkyl ether + telomer-based substances
per - and polyfluoroalkyl ether + telomer-based substances - monoethers
per - and polyfluoroalkyl ether + telomer-based substances - diethers
per - and polyfluoroalkyl ether + telomer-based substances - triethers
per - and polyfluoroalkyl ether + telomer-based substances - 4-10 ether linkages
per - and polyfluoroalkyl ether + telomer-based substances - more than 10 ether linkages
other per- and polyfluoroalkyl ether-based compounds
other per- and polyfluoroalkyl ether-based compounds - monoethers
other per- and polyfluoroalkyl ether-based compounds - diethers
other per- and polyfluoroalkyl ether-based compounds - triethers
other per- and polyfluoroalkyl ether-based compounds - 4-10 ether linkages
other per- and polyfluoroalkyl ether-based compounds - more than 10 ether linkages
other PFAA precursors and related compounds - perfluoroalkyl ones
perfluoroalkyl silanes
perfluoroalkyl alcohols
perfluoroalkyl alcohol-based side-chain fluorinated polymers
perfluoroalkanes & aromatics
perfluoroalkenes & derivatives
perfluoroalkyl amines
perfluoroalkyl epoxides & derivatives
perfluoroalkyl ketones
perfluoroalkyl halides (other than iodides)
perfluoroalkyl radicals
perfluoroalkyl cyanide
perfluoroalkyl metal
perfluoroalkyl thiol and derivatives
perfluoroalkyl sulfide
other PFAA precursors or related compounds - semi fluorinated
hydrofluorocarbons (HFCs), semi fluorinated alkanes (SFAs) and their derivatives
HFCs and derivatives
SFAs and derivatives
hydrofluoroethers (HFEs) and derivatives
HFEs
HFE-based silanes
other HFE-based derivatives
hydrofluoroolefins (HFOs)
semi-fluorinated ketones
side-chain fluorinated aromatics
fluoropolymers
polytetrafluoroethylene (PTFE)
non-functionalized PTFE
functionalized PTFE
polyvinylidene fluoride (PVDF)
non-functionalized PVDF
functionalized PVDF
fluorinated ethylene propylene (FEP)
perfluoralkoxyl polymer (PFA)
polyvinyl fluoride (PVF)
Ethylene tetrafluoroethylene (ETFE)

Table A-1: PFAS Categories[1]
VDF-HFP
PCTFE
THV
oxetane polymer
Note(s): [1] Categories as presented in OECD (2018a)

Appendix B: 2016 CDR PFAS Reporting

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
3M COMPANY	3M COMPANY	MN	311-89-7	1-Butanamine, 1,1,2,2,3,3,4,4,4-nonafluoro-N,N-bis(1,1,2,2,3,3,4,4,4-nonafluorobutyl)-	Withheld	Withheld
3M COMPANY	3M COMPANY	MN	34454-97-2	1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-	Withheld	Withheld
3M COMPANY	3M COMPANY	MN	86508-42-1	Perfluoro compounds, C5-18	Withheld	Withheld
3M COMPANY	3M COMPANY/3M CORDOVA	IL	132182-92-4	Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)-	Withheld	Withheld
AGC CHEMICALS AMERICAS, INC.	AGC CHEM AMER INC BUS & TECH CTR	PA	2043-57-4	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-8-iodo-	Withheld	1,000,000 - 10,000,000 lb
AGC CHEMICALS AMERICAS, INC.	AGC CHEM AMER INC BUS & TECH CTR	PA	355-43-1	Hexane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodo-	Withheld	1,000,000 - 10,000,000 lb
AGC CHEMICALS AMERICAS, INC.	AGC CHEM AMER INC BUS & TECH CTR	PA	422-56-0	Propane, 3,3-dichloro-1,1,1,2,2-pentafluoro-	Withheld	< 25,000 lb
AGC CHEMICALS AMERICAS, INC.	AGC CHEM AMER INC BUS & TECH CTR	PA	507-55-1	Propane, 1,3-dichloro-1,1,2,2,3-pentafluoro-	Withheld	< 25,000 lb
ATOTECH USA, INC.	ATOTECH USA	SC	27619-97-2	1-Octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	Withheld
ATOTECH USA, INC.	ATOTECH USA	SC	56773-42-3	Ethanaminium, N,N,N-triethyl-, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-1-octanesulfonate (1:1)	Withheld	< 25,000 lb
CBI	3M COMPANY	AL	212335-64-3	2-Propenoic acid, reaction products with N-[3-(dimethylamino)propyl]-1,1,2,2,3,3,4,4,4-nonafluoro-1-butanesulfonamide	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
CBI	3M COMPANY	AL	332350-90-0	Phosphonium, tributyl(2-methoxypropyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1)	Withheld	Withheld
CBI	3M COMPANY	AL	332350-93-3	Phosphonium, triphenyl(phenylmethyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1)	Withheld	Withheld
CBI	3M COMPANY	AL	34454-97-2	1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	163702-05-4	Butane, 1-ethoxy-1,1,2,2,3,3,4,4,4-nonafluoro-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	163702-06-5	Propane, 2-(ethoxydifluoromethyl)-1,1,1,2,3,3,3-heptafluoro-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	163702-07-6	Butane, 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxy-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	163702-08-7	Propane, 2-(difluoromethoxymethyl)-1,1,1,2,3,3,3-heptafluoro-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	297730-93-9	Hexane, 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	335-42-2	Butanoyl fluoride, 2,2,3,3,4,4,4-heptafluoro-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	375-03-1	Propane, 1,1,1,2,2,3,3-heptafluoro-3-methoxy-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	375-72-4	1-Butanesulfonyl fluoride, 1,1,2,2,3,3,4,4,4-nonafluoro-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	382-28-5	Morpholine, 2,2,3,3,5,5,6,6-octafluoro-4-(trifluoromethyl)-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	756-13-8	3-Pentanone, 1,1,1,2,2,4,5,5,5-nonafluoro-4-(trifluoromethyl)-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	76-19-7	Propane, 1,1,1,2,2,3,3,3-octafluoro-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	813-45-6	3-Hexanone, 1,1,1,2,4,4,5,5,6,6,6-undecafluoro-2-(trifluoromethyl)-	Withheld	Withheld
CBI	3M COMPANY/3M CORDOVA	IL	86508-42-1	Perfluoro compounds, C5-18	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
CBI	3M COTTAGE GROVE CENTER	MN	375-03-1	Propane, 1,1,1,2,2,3,3-heptafluoro-3-methoxy-	Withheld	Withheld
CBI	3M COTTAGE GROVE CENTER	MN	484024-67-1	1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-, ammonium salt (1:1)	Withheld	Withheld
CBI	AIR PROD & CHEM HAMILTON BLVD FAC	PA	559-40-0	Cyclopentene, 1,2,3,3,4,4,5,5-octafluoro-	Withheld	Withheld
CBI	AIR PROD & CHEM HAMILTON BLVD FAC	PA	76-16-4	Ethane, 1,1,1,2,2,2-hexafluoro-	Withheld	Withheld
CBI	CBI	CBI	2043-54-1	Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heneicosafluoro-12-iodo-	Withheld	Withheld
CBI	CBI	CBI	2043-57-4	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-8-iodo-	Withheld	1,000,000 - 10,000,000 lb
CBI	CBI	CBI	27905-45-9	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester	Withheld	< 25,000 lb
CBI	CBI	CBI	422-61-7	Propanoyl fluoride, 2,2,3,3,3-pentafluoro-	Withheld	Withheld
CBI	CBI	CBI	647-42-7	1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	1,000,000 - 10,000,000 lb
CBI	CBI	CBI	67584-55-8	2-Propenoic acid, 2-[methyl[(1,1,2,2,3,3,4,4,4-nonafluorobutyl)sulfonyl]amino]ethyl ester	Withheld	Withheld
CBI	CBI	CBI	68140-18-1	Thiols, C4-10, .gamma.-.omega.-perfluoro	Withheld	Withheld
CBI	CBI	CBI	68140-20-5	Thiols, C6-12, .gamma.-.omega.-perfluoro	Withheld	Withheld
CBI	CBI	CBI	68187-47-3	1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts	Withheld	Withheld
CBI	CBI	CBI	68391-08-2	Alcohols, C8-14, .gamma.-.omega.-perfluoro	Withheld	Withheld
CBI	CBI	CBI	70969-47-0	Thiols, C8-20, .gamma.-.omega.-perfluoro, telomers with acrylamide	Withheld	Withheld
CBI	CBI	CBI	70983-60-7	1-Propanaminium, 2-hydroxy-N,N,N-trimethyl-, 3-[(.gamma.-.omega.-perfluoro-C6-20-alkyl)thio] derivs., chlorides	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
CBI	INNOVATIVE CHEMICAL TECHNOLOGIES INC	GA	142636-88-2	2-Propenoic acid, 2-methyl-, octadecyl ester, polymer with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafluorododecyl 2-propenoate, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl 2-propenoate and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafluorotetradecyl 2-propenoate	Withheld	Withheld
CBI	INNOVATIVE CHEMICAL TECHNOLOGIES INC	GA	65545-80-4	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2-hydroxyethyl)poly(difluoromethylene) (1:1)	Withheld	25,000 - 100,000 lb
CBI	INNOVATIVE CHEMICAL TECHNOLOGIES INC	GA	68412-68-0	Phosphonic acid, perfluoro-C6-12-alkyl derivs.	Withheld	Withheld
CBI	INNOVATIVE CHEMICAL TECHNOLOGIES INC	GA	68412-69-1	Phosphinic acid, bis(perfluoro-C6-12-alkyl) derivs.	Withheld	Withheld
CBI	INNOVATIVE CHEMICAL TECHNOLOGY AT ORTEC INC	SC	142636-88-2	2-Propenoic acid, 2-methyl-, octadecyl ester, polymer with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafluorododecyl 2-propenoate, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl 2-propenoate and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafluorotetradecyl 2-propenoate	Withheld	Withheld
CBI	SOLENIS LLC	DE	355-43-1	Hexane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodo-	Withheld	1,000,000 - 10,000,000 lb
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	10493-43-3	Ethene, 1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)-	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	13252-13-6	Propanoic acid, 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)-	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	16090-14-5	Ethanesulfonyl fluoride, 2-[1-[difluoro[(1,2,2-trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2-tetrafluoro-	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	1623-05-8	Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(1,2,2-trifluoroethenyl)oxy]-	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	2062-98-8	Propanoyl fluoride, 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)-	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	3330-14-1	Propane, 1-[1-[difluoro(1,2,2,2-tetrafluoroethoxy)methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2,3,3,3-heptafluoro-	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	3825-26-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-, ammonium salt (1:1)	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	4089-58-1	Propanoyl fluoride, 2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-[1,1,2,2-tetrafluoro-2-(fluorosulfonyl)ethoxy]propoxy]-	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	62037-80-3	Propanoic acid, 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)-, ammonium salt (1:1)	Withheld	Withheld
CBI	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	69116-73-0	Propanoic acid, 3-[1-[difluoro[1,2,2,2-tetrafluoro-1-(fluorocarbonyl)ethoxy]methyl]-1,2,2,2-tetrafluoroethoxy]-2,2,3,3-tetrafluoro-, methyl ester	Withheld	Withheld
DAIKIN AMERICA INC.	DAIKIN AMERICA INC.	NY	2043-57-4	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-8-iodo-	Withheld	1,000,000 - 10,000,000 lb

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	115-25-3	Cyclobutane, 1,1,2,2,3,3,4,4-octafluoro-	Withheld	1,000,000 - 10,000,000 lb
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	1547-26-8	1-Pentene, 2,3,3,4,4,5,5-heptafluoro-	Withheld	Withheld
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	1623-05-8	Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(1,2,2-trifluoroethenyl)oxy]-	Withheld	Withheld
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	17527-29-6	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	Withheld	1,000,000 - 10,000,000 lb
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	17741-60-5	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafluorododecyl ester	Withheld	Withheld
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	2144-53-8	2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	Withheld	Withheld
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	25291-17-2	1-Octene, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	Withheld
DAIKIN AMERICA, INC.	DAIKIN AMERICA, INC.	AL	27905-45-9	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester	Withheld	< 25,000 lb
Dow Corning Corporation	DOW CORNING CORP MIDLAND PLANT	MI	125476-71-3	Silicic acid (H4SiO4), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol	Withheld	Withheld
FORD MOTOR COMPANY	Ford Motor Company	MI	65545-80-4	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2-hydroxyethyl)poly(difluoromethylene) (1:1)	Withheld	25,000 - 100,000 lb
HONEYWELL INTERNATIONAL INC	HONEYWELL INTERNATIONAL INC - BATON ROUGE PLANT	LA	76-14-2	Ethane, 1,2-dichloro-1,1,2,2-tetrafluoro-	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
LANXESS CORPORATION	LANXESS CORP	PA	56773-42-3	Ethanaminium, N,N,N-triethyl-, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-1-octanesulfonate (1:1)	Withheld	< 25,000 lb
LINDE NORTH AMERICA, INC	LINDE ELECTRONICS AND SPECIALTY GASES	NJ	115-25-3	Cyclobutane, 1,1,2,2,3,3,4,4-octafluoro-	Withheld	1,000,000 - 10,000,000 lb
PEACH STATE LABS INC	PEACH STATE LABS INC COLUMBUS	GA	647-42-7	1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	1,000,000 - 10,000,000 lb
PEACH STATE LABS INC	PEACH STATE LABS INC COLUMBUS	GA	68188-12-5	Alkyl iodides, C4-20, .gamma.-.omega.-perfluoro	Withheld	25,000 - 100,000 lb
Peach State Labs LLC	PEACH STATE LABS, LLC	GA	17527-29-6	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	Withheld	1,000,000 - 10,000,000 lb
Peach State Labs LLC	PEACH STATE LABS, LLC	GA	2043-57-4	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-8-iodo-	Withheld	1,000,000 - 10,000,000 lb
Peach State Labs LLC	PEACH STATE LABS, LLC	GA	647-42-7	1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	1,000,000 - 10,000,000 lb
Peach State Labs LLC	PEACH STATE LABS, LLC	GA	68188-12-5	Alkyl iodides, C4-20, .gamma.-.omega.-perfluoro	Withheld	25,000 - 100,000 lb
SOLVAY SPECIALTY POLYMERS USA, LLC	SOLVAY SPECIALTY POLYMERS USA LLC	TX	35397-13-8	Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(1,2,2-trifluoroethenyl)oxy]-, polymer with 1-chloro-1,2,2-trifluoroethene and ethene	Withheld	Withheld
SOLVAY SPECIALTY POLYMERS USA, LLC	SOLVAY SPECIALTY POLYMERS USA, LLC	GA	200013-65-6	Diphosphoric acid, polymers with ethoxylated reduced Me esters of reduced polymd. oxidized tetrafluoroethylene	Withheld	Withheld
SUMITOMO CORPORATION OF AMERICAS	SUMITOMO CORPORATION OF AMERICAS	TX	17527-29-6	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	Withheld	1,000,000 - 10,000,000 lb

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	1224429-82-6	Phosphoric acid, mixed esters with polyethylene glycol and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol, ammonium salts	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	124-73-2	Ethane, 1,2-dibromo-1,1,2,2-tetrafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	17527-29-6	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	Withheld	1,000,000 - 10,000,000 lb
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	17741-60-5	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafluorododecyl ester	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	19430-93-4	1-Hexene, 3,3,4,4,5,5,6,6,6-nonafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	2043-53-0	Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-10-iodo-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	2043-54-1	Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heneicosafluoro-12-iodo-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	2043-55-2	Hexane, 1,1,1,2,2,3,3,4,4-nonafluoro-6-iodo-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	2043-57-4	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-8-iodo-	Withheld	1,000,000 - 10,000,000 lb

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	2144-53-8	2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	27905-45-9	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester	Withheld	< 25,000 lb
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	30046-31-2	Tetradecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12-pentacosafluoro-14-iodo-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	34362-49-7	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafluorohexadecyl ester	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	34395-24-9	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafluorotetradecyl ester	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	39239-77-5	1-Tetradecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-pentacosafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	60699-51-6	1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	647-42-7	1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	1,000,000 - 10,000,000 lb
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	65510-55-6	Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14-nonacosafluoro-16-iodo-	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	678-39-7	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	76-16-4	Ethane, 1,1,1,2,2,2-hexafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CHAMBERS WORKS)	NJ	865-86-1	1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-heneicosafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (CORPUS CHRISTI)	TX	76-14-2	Ethane, 1,2-dichloro-1,1,2,2-tetrafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	2641-34-1	Propanoyl fluoride, 2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)propoxy]-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	335-66-0	Octanoyl fluoride, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-	Withheld	< 25,000 lb
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (FAYETTEVILLE WORKS)	NC	335-67-1	Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (HEADQUARTERS)	DE	115-25-3	Cyclobutane, 1,1,2,2,3,3,4,4-octafluoro-	Withheld	1,000,000 - 10,000,000 lb
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (HEADQUARTERS)	DE	138495-42-8	Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (HEADQUARTERS)	DE	15290-77-4	Cyclopentane, 1,1,2,2,3,3,4-heptafluoro-	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (HEADQUARTERS)	DE	507-63-1	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (HEADQUARTERS)	DE	62037-80-3	Propanoic acid, 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)-, ammonium salt (1:1)	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (PASCAGOULA)	MS	27619-97-2	1-Octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (PASCAGOULA)	MS	34455-29-3	1-Propanaminium, N-(carboxymethyl)-N,N-dimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulfonyl]amino]-, inner salt	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	115-25-3	Cyclobutane, 1,1,2,2,3,3,4,4-octafluoro-	Withheld	1,000,000 - 10,000,000 lb
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	354-64-3	Ethane, 1,1,1,2,2-pentafluoro-2-iodo-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	355-42-0	Hexane, 1,1,1,2,2,3,3,4,4,5,5,6,6,6-tetradecafluoro-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	355-43-1	Hexane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodo-	Withheld	1,000,000 - 10,000,000 lb
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	423-39-2	Butane, 1,1,1,2,2,3,3,4,4-nonafluoro-4-iodo-	Withheld	Withheld
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	423-62-1	Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heneicosafluoro-10-iodo-	Withheld	Withheld

Table B-1: PFAS Manufacture and Import Reported in the 2016 CDR

Parent Company	Site Name	Site State	CAS	Chemical Name	Manufacture and Import	National Aggregate PV
The Chemours Co	THE CHEMOURS COMPANY FC, LLC (WASHINGTON WORKS)	WV	507-63-1	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-	Withheld	Withheld
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	1078715-61-3	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-[2-[(.gamma.-.omega.-perfluoro-C4-20-alkyl)thio]acetyl] derivs., inner salts	Withheld	25,000 - 100,000 lb
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	27619-89-2	1-Octanesulfonyl chloride, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	Withheld	25,000 - 100,000 lb
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	34455-29-3	1-Propanaminium, N-(carboxymethyl)-N,N-dimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulfonyl]amino]-, inner salt	Withheld	Withheld
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	65545-80-4	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with .alpha.-fluoro-.omega.-(2-hydroxyethyl)poly(difluoromethylene) (1:1)	Withheld	25,000 - 100,000 lb
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	68140-18-1	Thiols, C4-10, .gamma.-.omega.-perfluoro	Withheld	Withheld
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	68140-20-5	Thiols, C6-12, .gamma.-.omega.-perfluoro	Withheld	Withheld
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	68187-47-3	1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gamma.-.omega.-perfluoro-C4-16-alkyl)thio]propyl]amino] derivs., sodium salts	Withheld	Withheld
TYCO FIRE PRODUCTS LP	CHEMGUARD INC	TX	70969-47-0	Thiols, C8-20, .gamma.-.omega.-perfluoro, telomers with acrylamide	Withheld	Withheld

Table B-2: Number of PFAS Manufactured by Use Reported in the 2016 CDR			
Type/Process/Use	**Sector**	**Function**	**Number of PFAS**
(blank)	(blank)	(blank)	33
CBI	CBI	CBI	10
Processing as a reactant	Adhesive manufacturing	Intermediates	1
Processing as a reactant	All other basic organic chemical manufacturing	Intermediates	16
Processing as a reactant	All other basic organic chemical manufacturing	Processing aids, not otherwise listed	2
Processing as a reactant	Computer and electronic product manufacturing	Intermediates	1
Processing as a reactant	Industrial gas manufacturing	Intermediates	1
Processing as a reactant	Miscellaneous manufacturing	Intermediates	1
Processing as a reactant	Not known or reasonably ascertainable	Not known or reasonably ascertainable	1
Processing as a reactant	Paint and coating manufacturing	Intermediates	1
Processing as a reactant	Plastic material and resin manufacturing	Intermediates	13
Processing as a reactant	Textiles, apparel, and leather manufacturing	Intermediates	4
Processing—incorporation into article	Paint and coating manufacturing	Plating agents and surface treating agents	1
Processing—incorporation into article	Paper manufacturing	Finishing agents	1
Processing—incorporation into article	Textiles, apparel, and leather manufacturing	Finishing agents	1
Processing—incorporation into formulation, mixture, or reaction product	Adhesive manufacturing	Surface active agents	1
Processing—incorporation into formulation, mixture, or reaction product	All other basic inorganic chemical manufacturing	Surface active agents	1
Processing—incorporation into formulation, mixture, or reaction product	All other basic organic chemical manufacturing	Processing aids, not otherwise listed	1
Processing—incorporation into formulation, mixture, or reaction product	All other chemical product and preparation manufacturing	Firefighting foam agents	8
Processing—incorporation into formulation, mixture, or reaction product	All other chemical product and preparation manufacturing	Solvents (for cleaning and degreasing)	6
Processing—incorporation into formulation, mixture, or reaction product	All other chemical product and preparation manufacturing	Surface active agents	2
Processing—incorporation into formulation, mixture, or reaction product	CBI	CBI	2
Processing—incorporation into formulation, mixture, or reaction product	CBI	Surface active agents	1
Processing—incorporation into formulation, mixture, or reaction product	Computer and electronic product manufacturing	Functional fluids (closed systems)	1

Table B-2: Number of PFAS Manufactured by Use Reported in the 2016 CDR			
Type/Process/Use	**Sector**	**Function**	**Number of PFAS**
Processing—incorporation into formulation, mixture, or reaction product	Computer and electronic product manufacturing	Solvents (which become part of product formulation or mixture)	1
Processing—incorporation into formulation, mixture, or reaction product	Computer and electronic product manufacturing	Surface active agents	1
Processing—incorporation into formulation, mixture, or reaction product	Miscellaneous manufacturing	Plating agents and surface treating agents	2
Processing—incorporation into formulation, mixture, or reaction product	Oil and gas drilling, extraction, and support activities	Surface active agents	1
Processing—incorporation into formulation, mixture, or reaction product	Paint and coating manufacturing	Paint additives and coating additives not described by other categories	1
Processing—incorporation into formulation, mixture, or reaction product	Paint and coating manufacturing	Surface active agents	1
Processing—incorporation into formulation, mixture, or reaction product	Pesticide, fertilizer, and other agricultural chemical manufacturing	Surface active agents	2
Processing—incorporation into formulation, mixture, or reaction product	Plastic material and resin manufacturing	Processing aids, specific to petroleum production	1
Processing—incorporation into formulation, mixture, or reaction product	Plastic material and resin manufacturing	Solvents (which become part of product formulation or mixture)	1
Processing—incorporation into formulation, mixture, or reaction product	Printing ink manufacturing	Processing aids, not otherwise listed	1
Processing—incorporation into formulation, mixture, or reaction product	resale of chemicals	Plating agents and surface treating agents	1
Processing—incorporation into formulation, mixture, or reaction product	Soap, cleaning compound, and toilet preparation manufacturing	Surface active agents	3
Processing—incorporation into formulation, mixture, or reaction product	Wholesale and retail trade	CBI	1
Processing—repackaging	All other chemical product and preparation manufacturing	Plating agents and surface treating agents	1
Processing—repackaging	All other chemical product and preparation manufacturing	Solvents (for cleaning and degreasing)	1
Processing—repackaging	Industrial gas manufacturing	transfilling and purifying	1
Processing—repackaging	Miscellaneous manufacturing	Solvents (for cleaning and degreasing)	1
Processing—repackaging	Paint and coating manufacturing	Paint additives and coating additives not described by other categories	1
Processing—repackaging	Plastic material and resin manufacturing	Intermediates	1

Table B-2: Number of PFAS Manufactured by Use Reported in the 2016 CDR			
Type/Process/Use	**Sector**	**Function**	**Number of PFAS**
Processing—repackaging	Plastic material and resin manufacturing	Solvents (which become part of product formulation or mixture)	1
Use—non-incorporative activities	All other chemical product and preparation manufacturing	Fire Extinguishing Medium	1
Use—non-incorporative activities	All other chemical product and preparation manufacturing	Functional fluids (open systems)	1
Use—non-incorporative activities	CBI	CBI	2
Use—non-incorporative activities	CBI	Functional fluids (closed systems)	2
Use—non-incorporative activities	Computer and electronic product manufacturing	CBI	1
Use—non-incorporative activities	Computer and electronic product manufacturing	Functional fluids (closed systems)	9
Use—non-incorporative activities	Computer and electronic product manufacturing	Functional fluids (open systems)	1
Use—non-incorporative activities	Computer and electronic product manufacturing	Plating agents and surface treating agents	1
Use—non-incorporative activities	Computer and electronic product manufacturing	Solvents (for cleaning and degreasing)	7
Use—non-incorporative activities	Fabricated metal product manufacturing	Solvents (for cleaning and degreasing)	2
Use—non-incorporative activities	Miscellaneous manufacturing	Solvents (for cleaning and degreasing)	1
Use—non-incorporative activities	Not known or reasonably ascertainable	Lubricants and lubricant additives	1
Use—non-incorporative activities	Plastic material and resin manufacturing	Processing aids, not otherwise listed	2
Use—non-incorporative activities	Primary metal manufacturing	Functional fluids (open systems)	1
Use—non-incorporative activities	Stored on site in rail cars, no commercial use	Stored on site in rail cars, no commercial use	1

Appendix C: References

Buck, R. C., Franklin, J., Berger, U., Conder, J. M., Cousins, I. T., de Voogt, P., . . . van Leeuwen, S. P. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins. *Integrated Environmental Assessment and Management, 7*(4), 513-541. doi:doi:10.1002/ieam.258

FluoroCouncil. (2018). *FluoroCouncil – EPA Meeting on PFAS.*

Organisation for Economic Co-operation and Development (OECD). (2013). *SYNTHESIS PAPER ON PER- AND POLYFLUORINATED CHEMICALS (PFCS).*

Organisation for Economic Co-operation and Development (OECD). (2018a). *GLOBAL DATABASE OF PER- AND POLYFLUOROALKYL SUBSTANCES (PFASs).*

Organisation for Economic Co-operation and Development (OECD). (2018b). *TOWARD A NEW COMPREHENSIVE GLOBAL DATABASE OF PER- AND POLYFLUOROALKYL SUBSTANCES (PFASs): SUMMARY REPORT ON UPDATING THE OECD 2007 LIST OF PER- AND POLYFLUOROALKYL SUBSTANCES (PFASs).*

U.S. Environmental Protection Agency (EPA). (2013). *Market Profile for the Long- Chain Perfluoroalkyl Carboxylate (PFAC) Chemical Substances for Any Use.*

U.S. Environmental Protection Agency (EPA). (2016). *Overview and Current Status and Scientific Understanding of Short Chain (C2 – C6) Per/poly Fluorinated Chemicals (PFCs).*

U.S. Environmental Protection Agency (EPA). (2017). TRI Basic Plus Data Files: 2016 Reporting Year. https://www.epa.gov/toxics-release-inventory-tri-program/tri-basic-plus-data-files-calendar-years-1987-2016

U.S. Environmental Protection Agency (EPA). (2018a). *Draft OW 304m PFAS Review_042018.*

U.S. Environmental Protection Agency (EPA). (2018b). PFOA, PFOS and Other PFASs.

U.S. Environmental Protection Agency (U.S. EPA). (2009). Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers: Basic Information. Retrieved from http://www.epa.gov/oppt/pfoa/pubs/pfoainfo.html

Exhibit C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Ex. C

JUN 0 6 2019

OFFICE OF
CONGRESSIONAL AND
INTERGOVERNMENTAL
RELATIONS

The Honorable Paul D. Tonko
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Tonko:

Thank you for the letter of December 7, 2018, to the Environmental Protection Agency (EPA) concerning per- and polyfluoroalkyl substances (PFAS).

The EPA's New Chemicals Review Program evaluates new chemicals to determine whether they may present unreasonable risk to human health or the environment. Once the EPA's review is complete, submitters may commercialize the chemical substance (subject to any restrictions the Agency may have placed on the manufacture, processing, distribution in commerce or use of the chemical substance) after having submitted a Notice of Commencement (NOC), indicating intent to commence manufacture or import of the chemical. However, it is often the case that submitters either delay or do not choose to commercialize chemicals that have undergone review. Hence, the responses below provide the number of notices for PFAS chemicals for which the EPA received an NOC, as this is the EPA's best indication of whether a PFAS chemical may have entered commerce. The numbers below are current as of early February 2019.

Since 2006, when the PFOA Stewardship Initiative began, the EPA received 148 NOCs for PFAS chemicals that underwent New Chemicals Program review. Of the PFAS chemicals for which EPA has received NOCs, 146 were received prior to June 22, 2016, and 2 after that date.

The Agency also receives exemption notices for chemical substances, which are exempt from full premanufacture notice (PMN) review under TSCA section 5, provided they meet the criteria and maintain certain conditions and controls throughout the duration of the exemption. One such exemption for chemical substances manufactured at 10,000 kg/year or less per year is the Low-Volume Exemption (LVE). Since 2006, the EPA received 328 LVEs for PFAS chemicals and granted 272 of them. Of those granted, 262 were granted prior to June 22, 2016, and 10 after that date.

Regarding new PFAS chemicals entering the market, between 2006 and April 2019, the EPA placed restrictions on new PFAS chemicals through the issuance of 171 orders and 178 significant new use rules (SNURs). As mentioned above, the new chemicals review program evaluates new chemicals and significant new uses of existing chemicals to determine whether

they may present unreasonable risk to human health or the environment. When the EPA determines that a chemical substance may present an unreasonable risk, the EPA must issue an order under TSCA section 5(e). A section 5(e) order typically contains some of the following requirements: limits on specific conditions for manufacturing, processing, distribution or use of the chemical, limits on releases to water and air, toxicity testing, environmental fate testing, worker protection measures (e.g., exposure limits and personal protective equipment), hazard communication language and record-keeping.

The EPA notes that submitters sometimes decide to withdraw their PMN from review once they learn that the EPA has found that the substance may present unreasonable risk and the Agency intends to issue an order under section 5(e). Since 2006, 46 PFAS chemicals have been withdrawn (42 PMN and 2 LVE). Of those withdrawn, 44 were prior to June 22, 2016, and 2 after that date.

Regarding new PFAS chemicals subject to consent orders requiring the development of test data, since 2006, EPA has issued section 5(e) orders that have testing requirements[1] for 157 PFAS chemicals. Of these orders, 34 were issued prior to June 22, 2016, and 122 were issued after that date.

Again, thank you for your letter. If you have further questions, please contact me or our staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-erik@epa.gov or at (202) 566-2753.

Sincerely,

Troy M. Lyons
Associate Administrator

[1] Although all orders generally describe testing requirements or potentially useful information, the Agency works with submitters of like chemicals to tailor testing requirements in order to avoid unnecessary vertebrate tests so the number of orders does not necessarily equal the number of test submissions.