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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2020-0565; FRL-10019-39]

TSCA Section 21 Petition for Rulemaking; Reasons for Agency Response; Denial of Requested Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This document provides the reasons for the Environmental Protection Agency's (EPA's) response to a petition it received under the Toxic Substances Control Act (TSCA) from the Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, and the NC Black Alliance on October 14, 2020. Generally, the petitioners requested that EPA initiate a rulemaking proceeding or issue an order under TSCA compelling health and environmental effects testing on 54 Per- and Polyfluoroalkyl Substances (PFAS) that the petitioners assert are manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. The petitioners also request that EPA ask the National Academy of Sciences to create an independent science panel to oversee all aspects of the testing program requested by the petitioners. After careful consideration, EPA denied the TSCA petition for reasons discussed in this document.

DATES: EPA's response to this TSCA section 21 petition was signed January 7, 2021.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0565, is available online at *https://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Public Reading Room are closed to visitors with limited exceptions. The EPA/DC staff continue to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Daniel R. Ruedy, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-7974; email address: *ruedy.daniel@epa.gov.*

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action, however, may be of particular interest to those persons who manufacture (which includes import), distribute in commerce, process, use, or dispose of one or more of the 54 Per- and Polyfluoroalkyl Substances (PFAS) identified in the petition. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). A TSCA section 21 petition must set forth the facts which it is claimed establish that it is necessary to initiate the action requested. EPA is

required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the Federal Register. A petitioner may commence a civil action in a U.S. district court seeking to compel initiation of the requested proceeding within 60 days of a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

C. What criteria apply to a decision on a TSCA section 21 petition?

1. Legal standard regarding TSCA section 21 petitions.

TSCA section 21(b)(1) requires that the petition "set forth the facts which it is claimed establish that it is necessary" to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested in evaluating this TSCA section 21 petition.

2. Legal standard regarding TSCA section 4(a)(1)(A)(i).

EPA must make several findings in order to require testing under TSCA section 4(a)(1)(A)(i) through a rule or order. EPA must find that the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment; that information and experience are insufficient to reasonably determine or predict the effects of a chemical substance on health or the environment; and that testing of the chemical substance is necessary to develop the missing information. Further, TSCA section 4(h) requires EPA to reduce and replace the use of vertebrate animals in the testing of chemical substances or mixtures, to the extent practicable, scientifically justified, and consistent with the policies of TSCA.

3. Legal standard regarding TSCA section 26.

TSCA section 26(h) requires EPA, in carrying out TSCA sections 4, 5, and 6, to make a

decision using "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science," while also taking into account six considerations, including the relevance of information and any uncertainties. TSCA section 26(i) requires that decisions under TSCA sections 4, 5, and 6 be "based on the weight of scientific evidence." TSCA section 26(k) requires that EPA consider information that is reasonably available in carrying out TSCA sections 4, 5, and 6.

II. Summary of the TSCA Section 21 Petition

A. What action was requested?

On October 14, 2020, Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, and the NC Black Alliance (petitioners) petitioned EPA to initiate a rulemaking proceeding or issue an order under TSCA section 4(a)(1)(A)(i), compelling health and environmental effects testing, including studies of communities exposed to PFAS-contaminated drinking water, on 54 PFAS that the petitioners assert are manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. The petitioners also request that EPA ask the National Academy of Sciences to create an independent science panel to oversee all aspects of the testing program requested by the petitioners (Ref. 1).

B. What support did the petitioners offer?

The petitioners assert that TSCA section 4(a)(1)(A)(i) requires EPA to direct testing on a chemical substance or mixture if all three of the following findings are made:

• The manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment;

• There is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be

determined or predicted; and

• Testing of such substance or mixture with respect to such effects is necessary to develop such information.

1. May present an unreasonable risk of injury to health or the environment.

The petitioners assert that the 54 PFAS "may present an unreasonable risk of injury to health or the environment" because there allegedly is substantial evidence that PFAS may be toxic, pointing to the following documents:

• The Agency for Toxic Substances and Disease Registry's (ATSDR's) draft 2018 Toxicological Profile for Perfluoroalkyls (Ref. 2) and EPA's PFAS Action Plan (Ref. 3), as well as other literature, in support of the contention that exposure to certain, specific PFAS are associated with adverse health effects.

• EPA's Significant New Use Rule (SNUR) for Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (Ref. 4), which states "[w]hile most studies to date have focused primarily on PFOS, structure-activity relationship analysis indicates that the results of those studies are applicable to the entire category of PFAS, which includes PFOS. Available test data have raised concerns about their potential developmental, reproductive, and systemic toxicity."

• EPA's Consent Order regarding DuPont Premanufacture Notices (Ref. 5), which states in part "[t]oxicity studies on the analogs PFOA (perfluorooctanoic acid) and PFOS (perfluorooctanesulfonic acid) indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife."

The petitioners conclude, based on the references provided, that "all PFAS have the potential for causing the adverse health and environmental effects linked to well-characterized substances like PFOS and PFOA because of their common structural characteristics," and that "there is a strong basis to conclude that the 54 PFAS covered by this petition 'may present an

unreasonable risk of injury'" (Ref. 1, pg. 18).

2. Insufficiency of information.

The petitioners assert that for these 54 PFAS, there is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted. To support their assertion, the petitioners point to:

• ATSDR's draft 2018 Toxicological Profile for Perfluoroalkyls (Ref. 2), which the petitioners assert underscores the absence of toxicological data; and

• EPA's PFAS Action Plan (Ref. 3), which states "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects."

On page 21 of their petition, the petitioners assert: "[k]ey data gaps include measurement of physical-chemical properties, methods of analysis, assessment of partitioning, bioaccumulation, and degradation, pharmacokinetics, and toxicity, especially for the endpoints commonly observed for the better studied PFAS, such as liver toxicity, and effects on the immune system, lipid metabolism, kidney, thyroid, development, reproduction, and cancer. In addition, despite their widespread detection in environmental media, ecotoxicity data are generally lacking."

3. Need for testing.

The petitioners assert that the mechanisms of PFAS toxic effects are not defined, and that in vitro assays or other predictive, computational approaches are not validated or available. The petitioners also request animal toxicity studies on three mixtures of PFAS that are allegedly representative of exposure for residents in the Cape Fear Watershed.

Finally, the petitioners request ecotoxicity studies, and studies of physical chemical

properties and environmental fate and transport, which they say EPA "has previously determined are necessary because of the widespread presence and mobility of PFAS in environmental media."

4. Testing framework and specific studies.

The petitioners propose a testing approach that they call for Chemours to perform. The list of 54 PFAS was divided into Tier 1 substances for which there is "known human exposure based on detection in blood, food, or drinking water," and Tier 2 substances for which "human exposure is probable based on detection in environmental media" (Ref. 1, pg.12). The testing approach includes human health effects studies in experimental animals, animal studies on PFAS mixtures, studies of communities exposed to PFAS-contaminated drinking water, human half-life studies, physical-chemical properties and fate and transport studies, and ecotoxicity testing.

III. Background Considerations: Review of EPA Actions, Activities, and Regulations Relating to PFAS

To understand EPA's reasons for denying the petitioners' requests, it is important to first review the details of EPA's ongoing actions involving PFAS. EPA is committed to supporting states, tribes, and local communities in addressing challenges with PFAS. As a part of this effort, EPA is already taking action to identify solutions to address PFAS in the environment. Examples of such ongoing actions are detailed in this unit.

A. PFAS Action Plan: Program Update

In May 2018, EPA convened a two-day National Leadership Summit on PFAS that brought together more than 200 federal, state, and local leaders to discuss steps to address PFAS. The Summit set the following goals: evaluate the need for a maximum contaminant level for PFOA and PFOS in drinking water, evaluate designating PFOA and PFOS as hazardous substances, issue groundwater cleanup guidances for PFOA and PFOS, and develop toxicity values for GenX and perfluorobutane sulfonic acid (PFBS). Following the Summit, EPA interacted with more than 1,000 people during PFAS-focused community engagement events in

Exeter, New Hampshire; Horsham, Pennsylvania; Colorado Springs, Colorado; Fayetteville, North Carolina; and Leavenworth, Kansas, as well as through a roundtable in Kalamazoo, Michigan, and an event with tribal representatives in Spokane, Washington. As a result of these meetings and building on the goals identified at the Summit and the approximately 120,000 public comments received by the agency, EPA developed the PFAS Action Plan, which was issued in February 2019 (Ref. 3).

The PFAS Action Plan is the first multi-media, multi-program, national research, management, and risk communication plan to address an emerging contaminant like PFAS. The PFAS Action Plan outlines the tools EPA is developing to, among other things, address PFAS in drinking water, identify and clean up PFAS contamination, expand monitoring of PFAS, increase PFAS scientific research, and exercise effective enforcement tools. The Action Plan outlines EPA's commitment to take a wide variety of actions to address this emerging contaminant in both short-term and long-term timeframes. Together, these efforts are helping EPA and its partners identify and better understand PFAS contaminants generally, clean up current PFAS contamination, prevent future contamination, and effectively communicate risk with the public. In February 2020, EPA issued the *PFAS Action Plan: Program Update* (available at *https://www.epa.gov/pfas/pfas-action-plan-program-update-february-2020*) to provide an update on all of the actions taken and work completed in the year since the PFAS Action Plan was issued. As it continues to implement the PFAS Action Plan, EPA is committed to coordinating closely with multiple entities, including other federal agencies, states, tribes, local governments, water utilities, industry, and the public.

B. Interim Strategy for PFAS in Federally Issued National Pollutant Discharge Elimination System (NPDES) Permits

EPA's Office of Water (OW) is currently leading multiple actions in the PFAS Action Plan that will help the Agency better understand and effectively manage risk from exposure to PFAS. These OW-led actions include developing analytical methods for detecting PFAS in

drinking water and other environmental media, evaluating PFAS treatment techniques, conducting data collection and analysis to evaluate the need for regulations to control PFAS discharges from certain categories of point sources, understanding PFAS exposure from various environmental media, and evaluating statutory and regulatory mechanisms to manage adverse human health and environmental impacts from PFAS exposure.

While OW's work is advancing, a need for an interim strategy to address point source discharges of PFAS in EPA-issued NPDES permits was identified. On February 6, 2020, a workgroup was established to develop an interim NPDES permitting strategy to address PFAS in EPA-issued CWA section 402 permits. The workgroup was charged with exploring options for how to address these pollutants while the CWA framework for addressing PFAS discharges pursuant to the NPDES program is under development. The workgroup's goal was to develop a strategy that would serve to guide the Agency's CWA NPDES permitting approach on an interim basis across the EPA Regions as informed by input from state partners. Each of the ten EPA Regions appointed a representative to the workgroup.

To develop potential recommendations for an interim PFAS NPDES strategy, the workgroup conducted a thorough review of the NPDES permitting process, with a specific focus on PFAS. This included examining CWA section 402 authorities and permit writing practices to understand where unregulated contaminants, such as PFAS, may fit into the permit development process; analyzing existing state-issued NPDES permits with PFAS monitoring requirements (identified through EPA's NPDES Integrated Compliance Information System (ICIS)) to understand the prescribed analytical methods for detecting PFAS, monitoring frequency, and detection benchmarks in current permits; and obtaining input and perspectives from state partners. In November 2020, EPA issued a memo detailing an interim NPDES permitting strategy for PFAS. This strategy is being implemented for EPA-issued NPDES permits.

C. Workshop on Federal Government Human Health PFAS Research with the National Academies of Sciences, Engineering and Medicine

On October 26-27, 2020, the National Academies of Science, Engineering, and Medicine (NASEM) held a Workshop on Federal Government Human Health PFAS Research. This workshop was the result of collaboration between EPA, the U.S. Department of Defense (DoD), the U.S. Department of Agriculture (USDA), and the U.S. Department of Health and Human Services (HHS) and will help further coordinate PFAS research across the federal government. Aggressively addressing PFAS has been an active and ongoing priority for this Administration, and the goal of the workshop was to discuss ongoing federal research and data gaps. Following the workshop, NASEM will compile a report summarizing the discussion and views of workshop participants on how to ensure that the federal research program for PFAS is robust and focused on addressing the highest priority human health research. Workshop proceedings will be published in early 2021.

D. Safe Drinking Water Act (SDWA) Actions for PFOA and PFOS

EPA has taken a number of actions under SDWA, consistent with the PFAS Action Plan and its statutory and regulatory authorities. In 2016, EPA established health advisories for PFOA and PFOS (Ref. 6) based on the Agency's assessment of the latest peer-reviewed science to provide drinking water system operators, and state, tribal and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents. To provide Americans, including the most sensitive populations, with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water, EPA established the health advisory levels at 70 parts per trillion.

EPA is committed to following the regulatory process established under SDWA and supporting states and public water systems as they determine the appropriate steps to reduce exposure to PFOA and PFOS in drinking water.

E. National Primary Drinking Water Regulation for PFOA and PFOS

On March 10, 2020, EPA published a notice (85 FR 14098, FRL-10005-88) seeking

comment on proposed determinations to regulate PFOA and PFOS. EPA is considering the public comments on this notice and expects to issue final regulatory determination in January 2021. If EPA issues final determinations to regulate PFOA and PFOS, SDWA requires that the EPA publish a proposed regulation within 24 months of the final determination and promulgate a final regulation within 18 months of proposal (SDWA allows the Agency to extend that final rule deadline by 9 months).

Under the third Unregulated Contaminant Monitoring Rule (UCMR 3) (85 FR 26072, FRL-9660-4), from 2013 to 2015, EPA required almost 5,000 public water systems to monitor for six PFAS (see *https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule*). The results of this monitoring were used by EPA in making the proposed regulatory determination for PFOA and PFOS. EPA has committed to monitoring for more PFAS in the UCMR 5 and at lower levels than was possible under the UCMR 3. EPA expects to publish a proposed UCMR 5 in January 2021.

F. PFOA Stewardship Program

EPA launched the PFOA Stewardship Program (Ref. 7) in January, 2006 because of concerns about the impact of PFOA and long-chain PFAS on human health and the environment, including concerns about their persistence, presence in the environment and in the blood of the general U.S. population, long half-life in people, and developmental and other adverse effects in laboratory animals.

By March 1, 2006, the eight major companies in the PFAS industry submitted commitments to the PFOA Stewardship Program. Specifically, these companies committed to reducing PFOA from facility emissions and product content by 95 percent no later than 2010, and to work toward eliminating PFOA from emissions and product content no later than 2015. The companies participating in the PFOA Stewardship Program were global companies with business operations in the United States and other countries.

To meet the program goals, most companies stopped the manufacture and import of long-

chain PFAS, and then transitioned to alternative chemicals. Other companies exited the PFAS industry altogether. All participating companies state that they met the PFOA Stewardship Program goals. In July 2020 EPA codified and expanded the impact of the PFOA Stewardship program through the issuance of the long chain PFAS SNUR, as discussed in Unit III.H.

G. Addition of Certain PFAS to the Toxics Release Inventory (TRI) Regulations

The National Defense Authorization Act for Fiscal Year 2020 (NDAA) (Pub. L. 116-92) added certain PFAS to the list of chemicals required to be reported to the TRI and established a 100-pound reporting threshold for these substances. EPA's TRI is an important tool that provides the public with information about the use of certain chemicals by tracking their management and associated activities. U.S. facilities in different industry sectors must report annually how much of each chemical is released to the environment and/or managed through recycling, energy recovery, and treatment. TRI helps support informed decision-making by companies, government agencies, non-governmental organizations and the public. For example, EPA uses TRI information to understand releases and potential exposures to chemicals being assessed under TSCA.

In June 2020, the Agency published a final rule (85 FR 37354, June 22, 2020; FRL-10008-09) that updated the regulations to reflect the addition of these PFAS to the TRI by the NDAA. Per the NDAA requirements, the PFAS additions became effective as of January 1, 2020. Reporting for these PFAS will be due to EPA by July 1, 2021, for calendar year 2020 data. By July 31, 2021, EPA expects to release raw data concerning the TRI-listed PFAS from information collected. Additionally, the NDAA provides a framework for additional PFAS to be added automatically to the TRI list on January 1 of the year following certain EPA actions (NDAA section 7321(c)). For example, the NDAA automatically adds a PFAS to the TRI list in response to the EPA finalizing a toxicity value for it.

H. Regulatory Actions Under TSCA

EPA has taken a range of regulatory actions under TSCA to address potential exposures

and/or risks associated with manufacturing, processing, and use of PFAS. EPA's New Chemicals program reviews alternatives for PFOA and related chemicals before they enter the marketplace to identify whether the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances may be present in order to ensure that the new chemicals do not present an unreasonable risk to health or the environment.

TSCA Section 5(a) SNURs can be used to require notice to EPA before chemical substances and mixtures are used in new ways that might create concerns. Under TSCA section 5(a), EPA can determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2):

• Projected volume of manufacturing and processing of a chemical substance.

• Extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance.

• Extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance.

• Reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Once EPA designates a use of a chemical substance as a significant new use, TSCA section 5(a) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use. The SNUN obligates EPA to assess risks that may be associated with that significant new use, including risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use; make a determination under the statute; and, if appropriate, regulate the proposed activity before it occurs.

EPA has issued the following SNURs for PFOS and PFAS:

• On March 11, 2002, EPA issued a final SNUR (Ref. 8) for 13 PFAS specifically

included in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002.

• On December 9, 2002, EPA issued a final SNUR (Ref. 9) for 75 PFAS specifically included in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002.

• On October 9, 2007, EPA issued a final SNUR (Ref. 10) for 183 PFAS that were on the public TSCA Inventory and have the characteristic PFAS chemical structure of a perfluorinated carbon chain (Rf) greater than, or equal to, C5 attached to an SO2 group connected to the rest of the molecule. In addition, the proposal also included those chemicals with Rf ranges of perfluorinated carbon chains shorter than C5, and greater than C5, for example, C4-C12 and C6-C12.

• On October 22, 2013, EPA issued a final SNUR (Ref. 11) for certain PFOA-related chemicals as part of carpets, a category of potentially harmful chemicals once used on carpets to impart soil, water, and stain resistance.

• On July 27, 2020, EPA issued a final SNUR (Ref. 12) for certain PFOA-related chemicals. The SNUR modifies the requirements for a subset of LCPFAC chemical substances in the existing SNUR at 40 CFR 721.10536 in the following ways: 1) Designating manufacturing (including importing) or processing of LCPFAC chemical substances listed in the list of LCPFAC chemical substances for any use that was no longer ongoing after December 31, 2015, as a significant new use; and 2) Designating manufacturing (including importing) or processing of PFOA or its salts, which are considered LCPFAC chemical substances, and all other LCPFAC chemical substances for any use not ongoing as of January 21, 2015, the date on which the proposed rule was published, as a significant new use. For this final SNUR, EPA also made an exemption at 40 CFR 721.45(f) inapplicable for persons who import LCPFAC chemical substances listed in the list of LCPFAC chemical substances in this unit and PFOA or its salts as part of a surface coating on articles because there is reasonable potential for exposure to LCPFAC chemical substances, including PFOA, if these chemical substances are incorporated as surface coatings in articles and then imported.

In addition, in December 2020, EPA issued draft guidance (Ref. 13) for public comment outlining which imported articles are covered by the July 2020 final rule for certain long-chain PFAS. After considering comments, EPA intends to issue the final guidance promptly.

PFOS was not reported as manufactured (including imported) into the United States as part of the 2012 Chemical Data Reporting (CDR) effort or the previous collection effort in 2006. CDR requires manufacturers (including importers) to report if they meet certain production volume thresholds, generally 25,000 lbs at a single site. The last time PFOS manufacture was reported to EPA as part of this collection effort was 2002; nonetheless, there are some limited ongoing uses of PFOS (see 40 CFR 721.9582).

I. Increasing Research and Understanding PFAS

Building on the work outlined in the February 2019 PFAS Action Plan, the Agency expanded its research efforts and capabilities by launching the PFAS Innovative Treatment Team (PITT) in spring 2020. The PITT was a full-time, multi-disciplinary research team that concentrated their efforts and expertise on a single problem for six months: how to remove, destroy, and test PFAS-contaminated media and waste. The PITT's goals were to:

• Assess current and emerging destruction methods being explored by EPA, universities, other research organizations, and industry;

• Explore the efficacy of destruction methods while considering by-products to avoid creating new environmental hazards; and

• Evaluate destruction methods' feasibility, performance, and costs to validate potential solutions.

This work initiated under the PITT will add practical knowledge to EPA's efforts under the PFAS Action Plan. States, tribes, and local governments will be able to use this information to select the approach that best fits their circumstances, leading to greater confidence in cleanup operations and safer communities.

Besides the innovative work of PITT, EPA and its researchers continue to work hard in

many other areas to help the nation address PFAS and protect public health. This work includes:

• Validating methods to detect and quantify PFAS in various environmental media, such as water, air, and biosolids. EPA has already released a number of these methods, including Methods 533 and 537.1 that together can measure 29 PFAS in drinking water;

• Evaluating treatment technologies that remove PFAS from drinking water. For example, researchers are investigating the effectiveness of point-of-use systems and have recently published research on commercially available systems that use both reverse osmosis and granular activated carbon;

• Developing standard human health toxicity reference values for certain PFAS. For example, Agency scientists are working on a toxicity assessment for PFBS, GenX chemicals, and five other PFAS that will help states, tribes, and local communities understand the toxicity of these substances so that they can make more informed choices to protect the public's health;

• Providing technical assistance to states and tribes as they work to address a variety of PFAS challenges; and

• Funding external researchers to better understand the potential impacts of PFAS on water quality and availability in rural communities and agricultural operations across the United States.

IV. Disposition of TSCA Section 21 Petition

A. What was EPA's response?

After careful consideration, EPA has denied the petition. A copy of the Agency's response, which consists of the letter to the petitioners and this document, is psoted on the EPA petition website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#reporting*. The response, the petition (Ref. 1) and other information is available in the docket for this TSCA section 21 petition (see **ADDRESSES)**.

The denial is not based on lack of concern with PFAS. In fact, EPA's high concern for these chemicals is detailed in Unit III. of this document. EPA is leading the national efforts to

understand PFAS and reduce PFAS risks to the public through implementation of its PFAS Action Plan and through active engagement and partnership with other federal agencies, states, tribes, industry groups, associations, local communities, and the public. Instead, EPA finds the petitioners have not met their burden under TSCA section 21, as explained in Unit IV.B. of this document.

B. What was EPA's reason for this response?

In considering the petition within the statutory 90-day petition review period, EPA evaluated the information presented or referenced in the petition and considered that information in the context of the applicable authorities and requirements contained in TSCA sections 4, 21, and 26. Also, notwithstanding that the burden is on the petitioners to present "the facts which it is claimed establish that it is necessary" for EPA to initiate the rule or issue the order sought, EPA nonetheless also evaluated relevant information that was reasonably available to the Agency during the 90-day petition review period.

As detailed extensively in the units that follow, EPA finds the petitioners have not provided the facts necessary for the Agency to determine for each of the 54 PFAS that existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information. These deficiencies, among other findings, are detailed in this document.

1. Insufficient information and experience.

The petition does not set forth the facts necessary to demonstrate that there is "insufficient information and experience" for each of the 54 PFAS. The petitioners state, in part, "[f]or the 54 PFAS, the sufficiency of available information should be determined by comparing available data with the known adverse effects of other PFAS. The goal should be to conduct a scientifically sound assessment of each of the 54 chemicals for the critical toxic endpoints that have been identified in studies on PFOS, PFOA and other well-characterized studies" (Ref. 1, pg. 21). However, the petitioners do not provide evidence that they conducted an assessment to

support a finding of insufficient information and experience.

The petitioners instead point to broad statements in the EPA PFAS Action Plan, such as "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects" (Ref. 3, pg. 31). The petitioners base the fate and transport studies they request on EPA's PFAS Action Plan, which the petitioners quote as stating "information for many PFAS sources, fate and transport, and human and ecological exposure is sparse, both spatially and temporally" (Ref. 3, pg. 31). However, the PFAS Action Plan broadly states only that such information for "many PFAS sources" is sparse; nowhere does it state or conclude that such information is sparse for each of the 54 PFAS the petitioners identify.
To further demonstrate that the information and experience on the 54 PFAS is allegedly insufficient, the petitioners cite ATSDR's 2018 Toxicological Profile for perfluoroalkyls, which the petitioners acknowledge "identifies numerous critical data gaps for PFAS ***as a class***" (emphasis added). The ATSDR 2018 Toxicological Profile for perfluoroalkyls remains in draft form and discusses information on 14 perfluoroalkyl compounds, none of which are among the 54 the petitioners identify. Importantly, the ATSDR 2018 Toxicological Profile further states that "[t]he term 'perfluoroalkyls' used throughout the toxicological profile is referring to these 14 compounds and the information may not be applicable to other perfluoroalkyl compounds" (Ref. 2, pg. 1). Despite this qualifying statement, the petitioners proceed to state without reference or additional explanation that "[t]he 54 substances covered by this petition fit this pattern" (Ref. 1, pg. 21). This extrapolation is fundamentally important to the petitioners' argument, yet there are no facts in the petition to support the statement. The petitioners are not clear as to what "pattern" the 54 PFAS fit, and no other sources are provided.

Absent any factual support in the petition, EPA finds that mere reference to these broad statements from the EPA PFAS Action Plan and ATSDR's 2018 Toxicological Profile for perfluoroalkyls does not provide the facts necessary for the Agency to determine there is

insufficient information or experience for these 54 PFAS.

To further characterize this baseline deficiency, EPA performed a cursory search of public literature and databases for reasonably available information on any of the 54 PFAS identified by the petitioners. Representative findings of this cursory review are summarized as follows:

• On June 8, 1987, EPA issued a Final Test Rule for Fluoroalkenes (Ref. 14) requiring testing for certain health effects for four fluoroalkenes, two of which are among the 54 PFAS the petitioners identify: hexafluoropropylene (CAS No. 116-15-4) and tetrafluoroethylene (CAS No. 116-14-3). The petitioners do not identify this test rule and the testing it required, nor do the petitioners explore and explain why the testing the rule ordered did not generate the health effects data the petitioners are now requesting.

• EPA's web-based CompTox Chemistry Dashboard integrates various types of data for curated substances linked to chemical structures, including physicochemical, environmental fate and transport, exposure, usage, in vivo toxicity, and in vitro bioassay data (Ref. 15). A query for some of the 54 PFAS in CompTox returned physical/chemical property and hazard data. For example, CompTox has published experimental averages for melting point, boiling point, water solubility, and vapor pressure, and some hazard data and sources for tetrafluoroethylene (CAS No. 116-14-3). CompTox also has published some hazard data for hexafluoropropylene (CAS No. 116-15-4) and perflouromethylperfluorovinyl ether (CAS No. 1187-93-5). Finally, some physical/chemical data for perfluoro (4-methyl-3, 6- dioxaoct-7-ene) sulfonyl fluoride (CAS No. 16090-14-5) are also readily available. The petitioners mention none of these data, nor have they provided the facts necessary to show that the information in CompTox is insufficient.

• ChemView provides the public access to reports and dataset information including data submitted to EPA, EPA Assessments and Actions, and data provided by other EPA Offices and federal organizations (Ref. 16). A query for each of the 54 PFAS in ChemView returned records for 17 of the 54 PFAS. For example, for perflouromethylperfluorovinyl ether (CAS No. 1187-93-

5), a substantial risk report is available from DuPont Haskell Global Centers on reproduction/developmental toxicity screening tests (OECD 422/OPPTS 870.3650, one of the methods identified in the petitioners' testing program) in rats (Ref. 17). The petitioners do not mention this report, nor do they explain why the report fails to provide the data being sought. In this way, the petitioners once again have not provided the facts necessary to show that the information in ChemView is insufficient.

• Tetrafluoroethylene (CAS No. 116-14-3) is pre-registered under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. The European Chemicals Agency (ECHA) has compiled chemical/physical property data (partition coefficient, potential for bioaccumulation, etc.) for this PFAS. Hexafluoropropylene (CAS No. 116-15-4) is also pre-registered under REACH, and ECHA has compiled some chemical/physical property data for this PFAS. The petitioners mention none of these data, nor have they provided the facts necessary to show that this information is insufficient.

TSCA section 21 requires the petitioner, not EPA, to "set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under TSCA sections 4, 6, or 8, or an order under TSCA sections 4 or 5(e)." Because EPA, upon a cursory review, has been able to easily identify existing, reasonably available information not mentioned in the petition, the petitioners have failed in carrying their burden of setting forth facts which are necessary to demonstrate that there is insufficient information, thereby necessitating the requested action.

For one of the 54 PFAS, identified only as N1AF, the petitioners provide no structurally-descriptive chemical name, structure, or molecular formula. Absent such identifying information, the petitioners have not provided the facts necessary to determine whether there is "insufficient information or experience" for this chemical.

Because the petitioners are seeking tests for each of the 54 PFAS, the petitioners must set forth facts that establish it is necessary to pursue the rule or issue the order the petitioners seek under TSCA section 4. The petitioners must affirmatively demonstrate, through facts, that there

is “insufficient information and experience” for each of the 54 PFAS. For the reasons described in this document, EPA finds the petition does not set forth facts necessary to demonstrate “insufficient information and experience” for each of the 54 PFAS, and has therefore not demonstrated that the rule or order requested is necessary.

2. Testing of such substance or mixture with respect to such effects is necessary to develop such information.

The petitioners do not demonstrate “testing of such substance or mixture with respect to such effects is necessary to develop such information.” EPA finds that the petitioners failed to address ongoing testing and data collections for some of the 54 PFAS, thereby failing to set forth facts that are necessary to establish there is a need for the testing sought in the petition. This research may provide information that overlaps with testing the petitioners requested, which would render the information unnecessary under TSCA section 4(a)(1)(A)(i)(III). Testing, both planned and underway, on some of the 54 PFAS that the petitioners identify is described in this unit:

• Five of the 54 PFAS have been subjected to all Tier 1 in vitro, toxicokinetic, and clearance studies: hepatotoxicity, developmental toxicity, immunotoxicity, mitochondrial toxicity, developmental neurotoxicity, endocrine disruption, general toxicity, intrinsic hepatic clearance, plasma protein binding (PPB), and renal reuptake. These studies are ongoing and results are expected by April 2021. Data are expected to be available via the PFAS Dashboard by the end of June 2021.

• An additional six of the 54 PFAS have results from some Tier 1 in vitro testing. Two have been included in systematic evidence mapping (SEM), a systematic review approach used to identify available data and characterize knowledge gaps.

• Three of the 54 PFAS have in vivo data identified from a non-EPA source.

In addition, the following studies are planned or in process by EPA’s Office of Research and Development (ORD).

• ORD will test for nuclear receptor and stress gene responses of a PFAS library in HepG2 cells. This research will apply a high-throughput assay for transcription factor activation to screening the first and second PFAS screening sets totaling 150 samples. Additional samples may be added to meet developing needs. This assay platform contains known targets of several PFAS including the estrogen receptor and peroxisome proliferator-activator receptors, as well as many other potential targets. Well-studied PFAS such as PFOA and PFOS will be included to help put findings for data-poor chemicals in better context. Data sets will support development of read-across and category approaches for this class of chemicals.

• Bioactivity of PFAS as determined using gene expression and in vitro cellular pathology is another area of ongoing research at EPA. This research will apply broad-based high-content screening assays to characterize the bioactivity of a set of PFAS in multiple human cell types. The resulting dataset will contribute to an overall assessment of the effects of PFAS on important physiological functions that overlap with effects measured in the testing the petitioners requested.

• ORD will also conduct high-throughput in vitro testing of PFAS to fill data gaps and refine structural and mechanistic groupings. This project falls under the Human Health Testing/Toxicokinetics research area that will generate and analyze a large data set on ~150 PFAS using a variety of New Approach Methodologies (NAMs) in support of EPA's mission to manage and regulate PFAS. This research effort will add a dataset of NAMs testing results for 15 PFAS. Selection of these 15 chemicals will be driven by the initial analysis of the 150 chemicals and provide the ability to fill identified data gaps and potentially test hypotheses developed from the initial analysis. Testing of these 15 PFAS will include transcription factor activity profiling; estrogen-dependent cell proliferation; high-content, cellular phenotypic imaging; high-throughput transcriptomics; zebrafish embryo development; and developmental neurotoxicity. The results will support the overarching EPA PFAS research to: (1) Develop a hierarchical scheme of chemical structural categories that are enriched by NAM data; (2) Use categories as

predefined neighborhoods to evaluate degree of concordance in NAM results within categories and across categories as a means to infer in vivo toxicity; (3) Predict categorization of larger PFAS inventory and read-across coverage; and (4) Recommend further in vivo testing for PFAS categories.

• In the FY2020 Further Consolidated Appropriations Act (P.L. 116-94), Congress appropriated funds for EPA to address research needs in support of designating PFAS as hazardous substances under CERCLA. The research needed to help support this designation include: Chemical and physical characteristics of PFAS; Toxicity and kinetic information; environmental prevalence; Manufacturing and use information; and Information on the regulatory status of PFAS. This ongoing research will add significantly to currently available hazard information for PFAS that could be used for this designation, as well as for risk assessment use broadly by Program Offices.

NDAA section 7351 amended TSCA section 8(a) to include a one-time reporting event of PFAS manufactured (including imported) in any year since January 1, 2011. TSCA section 8(a)(7) authorizes EPA to collect "[a]ll existing information concerning the environmental and health effects of such substance or mixture." Under this rule, EPA may collect information that overlaps with some of the information requested by petitioners. A final TSCA section 8(a) rule for these PFAS must be issued by January 1, 2023, and EPA has initiated the relevant rulemaking process for the proposed rule that is expected to be issued in 2021.

The petitioners also call for an epidemiologic study consisting of 100,000 participants from communities exposed to PFAS-contaminated drinking water. A similar, multi-site health study is being implemented through the Centers for Disease Control and Prevention and ATSDR cooperative agreements. As ATSDR states, "[i]nformation learned from the multi-site study will help all communities in the U.S. with PFAS exposures, including those that were not part of the study." The petitioners mention this multi-site study but provide no analysis of overlap or what testing might be duplicative with what is proposed and thus might not be necessary, whether

based on community characteristics, demographics, specific PFAS or mixture, or levels of exposure.

For some of the 54 PFAS, only a degradant is detected in the Cape Fear River per the information provided by petitioners, not the parent chemical for which the petitioners have requested testing. The petitioners have not identified why it is necessary to test the parent chemicals and not the degradants actually detected in the Cape Fear River. For example, the petitioners do not demonstrate that testing of the parent chemical would identify effects relevant to the degradants.

The petitioners specifically identify and acknowledge that "5 of the 54 listed chemicals in this petition are also designated for testing in the Chemours North Carolina consent decree. These tests would not need to be replicated in response to this petition" (Ref. 1, pg. 30). EPA finds this avoidance of duplicative testing tacitly acknowledges that for these five PFAS, testing is not necessary to develop information on health or environmental effects. The petitioners' attempt to avoid duplicative testing as a result of the Chemours North Carolina consent decree, but no other duplicative testing, further emphasizes their failure to address readily available information concerning the other activities EPA has identified in this unit.

3. Class-based approach to testing.

TSCA section 4(h)(1)(B)(ii) "encourage[s]" EPA to consider "the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category." Accordingly, EPA is currently investigating ways to group similar PFAS by likeness into subcategories for purposes of research, data collection, hazard determinations, and other activities (Ref. 18). EPA and the National Toxicology Program collaborated to construct a PFAS screening library subset composed of 75 PFAS on a structural category basis and considerations such as structural diversity within a category, data availability, and read-across category-level weight (e.g., value of substance for anchoring read-across trends

within a category, serving as an analog); four of the 54 PFAS the petitioners identify are included in this subset (Ref. 19). The petitioners mention this effort, but incorrectly state that just two of the 54 PFAS the petitioners cover are included in the EPA testing (Ref. 1, pg. 22).

The petitioners take the opposite approach, requesting testing on each of the 54 PFAS individually. The petitioners fail to address why a class-based approach is not appropriate, while also indirectly referring to the efforts to address PFAS as a class. For example, the petitioners allege that conclusions about all 54 PFAS can be based on the ATSDR 2018 Toxicological Profile even though none of the 54 PFAS are addressed in the toxicological profile, and concedes that the ATSDR 2018 Toxicological Profile "identifies numerous critical data gaps for PFAS ***as a class***" (emphasis added). Additionally, among the references allegedly supporting the assertion that PFAS present serious health and environmental concerns, the petitioners cite a commentary entitled "Scientific Basis for Managing PFAS as a Chemical Class" (Ref. 20). This commentary acknowledges PFAS "demand a more efficient and effective approach" when it comes to testing and seeks to "provide scientific justification for why a class-based approach is appropriate and necessary for all PFAS." Because the petitioners acknowledge the 54 PFAS share similarities with other members of the class, and the petitioners do not explore these similarities as a means of streamlining the extent of the testing requested, or to inform the petitioners' "tiered screening and testing process," EPA finds the petitioners have not provided the facts necessary to determine, for each of the 54 PFAS, that "testing of such substance or mixture with respect to such effects is necessary to develop such information." Therefore, they have not demonstrated that the rule or order they requested is necessary.

4. Practicability of National Academy of Sciences oversight.

The petitioners also request that the National Academy of Sciences (NAS) oversee all aspects of the proposed testing program. EPA finds such an oversight arrangement is not within the scope of what a TSCA section 21 petitioner can request when seeking the initiation of a rule or the issuance of an order under TSCA section 4. Further, projects and studies must meet certain

conditions for the NAS to accept private funding. As an example, NAS does not generally oversee studies where the study sponsor would have a direct financial interest in the outcome of the testing program. EPA is not in a position to require NAS to oversee the testing requested by the petitioners, and the petitioners provide no administrative or organizational procedures for implementation.

5. Selection of PFAS for health and environmental effects testing.

Attachment 2 of the petition divides the 54 PFAS at issue into Tier 1 substances "for which there is known human exposure based on detection in blood, food or drinking water," and Tier 2 substances "for which human exposure is probable based on detection in environmental media." However, the petitioners do not set forth facts showing that for all 40 PFAS it ranks as Tier 2 substances, "human exposure is probable based on detection in environmental media" or that "a strong inference of exposure can be drawn from their presence in surface water, stormwater, wastewater, sediment, groundwater, soil, private wells, and/or air emissions" (Ref. 1, pg. 19). The petitioners support their assertion that some of the Tier 2 PFAS were detected in environmental media with two studies (Ref. 21, 22); for nine of these, no other studies are provided for inclusion based on presence in environmental media (Ref. 1, Attachment 2). Three of these nine PFAS were not directly detected in the two studies. Further, for some of these nine PFAS, only degradant products were detected in the Cape Fear River; the parent compounds the petitioners specifically identify for testing were not. Thus, for nine of the 54 PFAS, the petitioners provide weak or no evidence for presence in environmental media upon which to base its "strong inference of exposure" assertion (Ref. 1, pg. 19).

6. Scientific standards.

EPA finds the petitioners have not evaluated the quality of the data they have provided or indicated how they conducted their searches, evaluated the quality of the sources, or indicated what gaps were located and then explained why the specific tests requested, as compared to others, would provide the data being sought. Such an evaluation is necessary for EPA to conduct

the considerations under TSCA section 26(h).

7. Vertebrate testing.

TSCA section 4(h) requires that EPA reduce and replace the use of vertebrate animals in the testing of chemical substances under TSCA section 4. EPA must consider "as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including (i) Toxicity information; (ii) Computational toxicology and bioinformatics; and (iii) High-throughput screening methods and the prediction models of those methods."

The testing program the petitioners request would require testing on vertebrates. For example, OCSPP Test Guidelines 850.2300, 870.3650, and 870.7800, among other test guidelines, require vertebrate testing. Due to the number of PFAS involved and tests requested, the petitioners' request would require testing on a large number of vertebrates. Yet, as previously discussed, the petition fails to provide reasonably available existing toxicity information on the 54 PFAS, and as such the petition has not provided sufficient facts for EPA to consider reasonably available existing information and encourage and facilitate the use of test methods that reduce or replace the use of vertebrates, group chemical substances as appropriate to reduce the use of vertebrates, and facilitate the formation of consortia for jointly conducted testing.

C. What was EPA's Conclusions?

EPA denied the request to initiate a rule or issue an order under TSCA section 4 because the TSCA section 21 petition does not set forth the facts necessary for the Agency to determine for each of the 54 PFAS that existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information. Therefore, the petitioners have not demonstrated that the rule or order they requested is necessary.

V. References

The following is a listing of the documents that are specifically referenced in this

document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, The NC Black Alliance to Andrew Wheeler, Administrator, Environmental Protection Agency. Petition to Require Health and Environmental Testing Under the Toxic Substances Control Act on Certain PFAS Manufactured by Chemours in Fayetteville, North Carolina. October 13, 2020.

2. Agency for Toxic Substances and Disease Registry (ATSDR). Notice; Availability of Draft Toxicological Profile: Perfluoroalkyls. ***Federal Register.*** 83 FR 28849, June 21, 2018 (Docket No. ATSDR-2015-0004).

3. EPA. EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan. EPA 823R18004. February 14, 2019. *https://www.epa.gov/pfas/epas-pfas-action-plan.*

4. EPA. Proposed Rule; Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. ***Federal Register.*** 80 FR 2885, January 21, 2015 (FRL-9915-63).

5. EPA. Consent Order regarding DuPont Premanufacture Notices P08-508 and P09-509. (2009). *https://chemview.epa.gov/chemview/proxy?filename=sanitized_consent_order_p_08_0508c.pdf.*

6. EPA. Notice of Availability; Lifetime Health Advisories and Health Effects Support Documents for Perfluorooctanoic Acid and Perfluorooctane Sulfonate. ***Federal Register.*** 81 FR 33250, May 25, 2016 (FRL-9946-91-OW).

7. EPA. Fact Sheet: 2010/2015 PFOA Stewardship Program. Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics.

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program.

8. EPA. Final Rule; Perfluoroalkyl Sulfonates; Significant New Use Rule. ***Federal Register.*** 67 FR 11008, March 11, 2002 (FRL-6823-6).

9. EPA. Final Rule; Perfluoroalkyl Sulfonates; Significant New Use Rule. ***Federal Register.*** 67 FR 72854, December 9, 2002 (FRL-7279-1).

10. EPA. Final Rule; Perfluoroalkyl Sulfonates; Significant New Use Rule. ***Federal Register.*** 72 FR 57222, October 9, 2007 (FRL-8150-4).

11. EPA. Final Rule; Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances; Final Significant New Use Rule. ***Federal Register.*** 78 FR 62443, October 22, 2013 (FRL-9397-1).

12. EPA. Final Rule; Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. ***Federal Register.*** 85 FR 45109, July 27, 2020 (FRL-10010-44).

13. EPA. Draft Compliance Guide for Imported Articles Containing Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule; Notice of Availability and Request for Comment. ***Federal Register.*** 85 FR 81466, December 16, 2020 (FRL-10017-86).

14. EPA. Final Rule; Fluoroalkenes; Final Test Rule. ***Federal Register.*** 52 FR 21516, June 8, 1987 (FRL-3214-8).

15. Williams, A.J., Grulke, C.M., Edwards, J. et al. The CompTox Chemistry Dashboard: a community data resource for environmental chemistry. *Journal of Cheminformatics.* 9**,** 61. 2017.

16. EPA. Introduction to ChemView. May 28, 2020. *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview.*

17. DuPont Haskell Global Centers to 8(e) Coordinator, Office of Pollution Prevention

and Toxics, Environmental Protection Agency. Substantial Risk Report for 3,3,3-Trifluoromethyl-1,2,2-trifluorovinyl ether, CAS #1187-93-5. November 8, 2007. *https://chemview.epa.gov/chemview/proxy?filename=2007-11-8EHQ-07-16360B_8ehq_1107_16360b.pdf*.

18. EPA. EPA and Partners Describe a Chemical Category Prioritization Approach to Select 75 PFAS for Testing using New Approach Methods. February 26, 2019. *https://www.epa.gov/sciencematters/epa-and-partners-describe-chemical-category-prioritization-approach-select-75-pfas.*

19. Patlewicz, G. et al. A Chemical Category-Based Prioritization Approach for Selecting 75 Per- and Polyfluoroalkyl Substances (PFAS) for Tier Toxicity and Toxicokinetic Testing. *Environmental Health Perspectives* 127(1). January 11, 2019. *https://doi.org/10.1289/EHP4555*.

20. Kwiatkowski, C. et al. Scientific Basis for Managing PFAS as a Chemical Class. *Environmental Science & Technology Letters*. 7,8:532-543. 2020. *https://doi.org/10.1021/acs.estlett.0c00255*.

21. Strynar, M. et al. Identification of Novel Perfluoroalkyl Ether Carboxylic Acids (PFECAs) and Sulfonic Acids (PFESAs) in Natural Waters Using Accurate Mass Time-of-Flight Mass Spectrometry (TOFMS). *Environmental Science & Technology*. 49: 11622-116302015. *https://pubs.acs.org/doi/abs/10.1021/acs.est.5b01215*

22. McCord, J. and M. Strynar. Identification of Per- and Polyfluoroalkyl Substances in the Cape Fear River by High Resolution Mass Spectrometry and Nontargeted Screening. *Environmental Science & Technology* 53(9): 4717-4727. 2019. *https://doi.org/10.1186/s13321-017-0247-6*.

Authority: 15 U.S.C. 2601 *et seq*.

Dated: January 7, 2021.

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