UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER F0R ENVIORNMENTAL HEALTH and PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY Plaintiffs, vs. MICHAEL REGAN, as Administrator of the United States Environmental Protection Agency, and the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Defendants.	**Civ. No.** 24-2194 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiffs, Center for Environmental Health ("CEH") and Public Employees for Environmental Responsibility ("PEER"), as and for their Complaint, allege as follows against Defendants Michael Regan, Administrator of the United States Environmental Protection Agency ("EPA"), and EPA:

INTRODUCTORY STATEMENT

1. CEH and PEER are non-profit organizations dedicated to protecting the public from environmental and health threats and promoting a high standard of environmental ethics, scientific integrity, and legal accountability within industry and environmental agencies.

2. Plaintiffs file this lawsuit under section 20(a)(2) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2619(a)(2), and the Declaratory Judgment Act, 28 U.S.C. §2201, to compel defendants to perform non-discretionary duties prescribed by TSCA section 4(f), 15 U.S.C. § 2603(f).

3. Section 4(f) is triggered when EPA receives information which indicates "that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings."

4. Within 180 days "of the receipt of the information," EPA "*shall* . . . initiate applicable action under section [5, 6 or 7] to prevent or reduce such risk to a sufficient extent" or determine that the risk is "not unreasonable" (emphasis added).

5. EPA has failed to perform this non-discretionary duty despite receiving compelling evidence of the significant risk of serious or widespread harm caused by the formation of perfluorooctanoic acid ("PFOA") during the fluorination of plastic containers by Inhance Technologies LLC ("Inhance").

6. PFOA is among the most harmful members of a large chemical class called Per- and Polyfluoroalkyl Substances ("PFAS"). Often described as "forever chemicals" because they do not break down or degrade over time, PFOA and other PFAS are uniquely dangerous due to their high persistence, long-term buildup in people and the environment, and numerous serious health effects at extremely low levels of exposure. According to EPA's PFAS action plan, "[h]armful [PFAS] are an urgent public health and environmental issue facing communities across the United States."

7. PFOA and other PFAS have been detected in the blood of the general U.S. population, with 98 percent of those sampled showing detectable levels of these compounds.

8. EPA's obligations under section 4(f) arose on or before March 29, 2023. As of that date and likely earlier, EPA was in possession of conclusive data demonstrating that PFOA (i) is carcinogenic to humans and has no safe level of exposure and (ii) is present in tens of millions of plastic containers fluorinated by Inhance and used to package numerous common commercial and consumer products distributed and used throughout the economy.

9. Once EPA knew that PFOA was a human carcinogen with no safe level of exposure and that millions of people were exposed to PFOA from fluorinated packaging, the Agency was on notice of a "significant risk of serious or widespread harm to humans" that triggered section 4(f).

10. Since EPA has information demonstrating this risk no later than March 29, 2023, it was required by section 4(f) to initiate action to "prevent or reduce" the risk or determine it was "not unreasonable" by September 25, 2023 at the latest.

11. EPA issued an order under TSCA section 5(f) on December 1, 2023 banning formation of PFOA and other PFAS during fluorination, but the order was stayed and then vacated by the Court of Appeals for the Fifth Circuit on March 21, 2024.

12. Since the order never took effect, formation of PFOA during fluorination has continued without any restriction and millions of people remain exposed to the serious health risks of PFOA-contaminated plastic containers.

13. Accordingly, EPA has failed to discharge its non-discretionary duty under section 4(f) to address these risks.

14. Because its section 5(f) order determined that PFOA formation during fluorination presents an unreasonable risk, EPA cannot find that the risks it presents are "not unreasonable."

15. Accordingly, EPA can meet its section 4(f) obligations only by initiating applicable action preventing or reducing these risks to a sufficient extent under TSCA sections 6 and 7.

16. To assure that EPA discharges this duty, the Court should enter an order setting an expeditious deadline for the Agency to propose a rule under TSCA section 6 prohibiting production of PFOA during the Inhance fluorination process.

17. Such a prohibition is the "applicable" remedy under section 6 because EPA has already determined under section 5(f) that only an immediate ban on fluorination will effectively protect the public against the serious risks of PFOA and other PFAS.

18. Under section 7(a)(2) of TSCA, if EPA has not made a section 6(a) rule immediately effective under section 6(d)(3), it "shall" commence a suit for immediate injunctive relief where the substance or mixture subject to the rule is "imminently hazardous."

19. Because TSCA states that such suits "shall" be brought for "imminently hazardous" chemicals, commencing these actions is a non-discretionary duty of the EPA Administrator and is enforceable through citizens' suits under TSCA section 20(a)(2).

20. The information in EPA's possession that triggered section 4(f) and supported the determination of unreasonable risk in its section 5(f) order demonstrates that the production of PFOA during fluorination "presents an imminent and unreasonable risk of serious or widespread injury to health" and "the risk is likely to result in such injury to health or the environment before a final rule" is promulgated.

21. The Court must therefore order EPA to immediately file an imminent hazard action under TSCA section 7 against Inhance to prohibit the formation of PFOA during the fluorination process or to make its proposed rule under section 6(a) imposing such a ban immediately effective upon publication in the Federal Register.

JURISDICTION AND VENUE

22. This action is brought under section 20(a)(2) of TSCA, 15 U.S.C. §2619(a)(2), under which "any person may commence a civil action . . . against the Administrator to perform any act or duty under this Act which is not discretionary." This Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 15 U.S.C. §2619(a)(2).

23. This Court has the authority to grant the requested declaratory and injunctive relief under 28 U.S.C. §§ 2201-2202 and 15 U.S.C. §2619(a)(2).

24. Venue is proper in the District of Columbia pursuant to 28 U.S.C. § 1391(e)(1)(C) and 15 U.S.C. §2619(a) because EPA's non-compliance with section 4(f) took place at its headquarters in the District and suits under TSCA section 20(a)(2) to enforce a non-discretionary duty of the Administrator may be brought in the United States District Court for the District of Columbia.

PARTIES

25. Plaintiff CEH is a national non-profit organization headquartered in Oakland, California, dedicated to protecting the public from environmental and public health hazards, including harmful chemicals in air, food, water, and in everyday products.

26. For 28 years, CEH has worked to protect people and the environment from toxic chemicals by engaging with communities, consumers, workers, government, and the private sector to demand and support business practices that are safe for public and environmental health. Its work has been featured in numerous local, state, national and global news outlets. CEH engages with organizations and members of the public from the grassroots to the global level, and shares information via listservs with a large number of networks and coalitions, and through in-person and virtual events.

27. CEH has a long track record of ground-breaking consumer education and rights victories related to ingredient disclosure, consumer right to know, and corporate accountability for product reformulation and pollution controls. Some key examples are advocating for the establishment of comprehensive federal limits on lead in children's products through the Consumer Product Safety Improvement Act, ending toxic heavy metal threats from jewelry, the elimination of chlorinated tris (or TDCPP) flame retardant chemicals from baby products, and ending lead poisoning risks from candy.

28. CEH has approximately 50,000 supporters and over 100,000 social media followers across the United States. CEH is governed by a Board of Directors, the members of which are influential experts and advocates who are also supporters of CEH. CEH Board Members are actively engaged in helping to shape the direction of CEH's work.

29. Board members, supporters and staff of CEH use a variety of products packaged in plastic containers that may be fluorinated but cannot ascertain whether they contain PFOA and other PFAS because Inhance has claimed confidentiality for its customers and the specific products they sell in fluorinated containers.

30. A significant priority for CEH, at both the state and federal level, has been to enhance protections against the health and environmental risks of PFAS. In California, CEH works to protect people from PFAS in drinking water and consumer products by taking action under existing state law and advocating for additional legislation. CEH has also spearheaded actions under TSCA and other federal environmental laws in protect health and the environment from PFAS.

31. Plaintiff PEER is a non-profit organization incorporated in the District of Columbia in 1992 and headquartered in Silver Spring, Maryland. PEER speaks on behalf of environmental

and public health professionals, land managers, scientists, enforcement officers, and other civil servants dedicated to upholding environmental laws and values. Shining the light on improper or illegal actions by government and regulated entities, PEER defends whistleblowers and works to improve enforcement and implementation of laws and regulations, thereby securing a higher level of protection of health and the environment.

32. PEER has thousands of supporters and subscribers to its publications nationwide. PEER has a feature on its website where its supporters and subscribers and other members of the public can submit information about environmental issues and request help with environmental problems and whistleblower retaliation. PEER's educational and advocacy work is instigated and informed by the input of its supporters.

33. PEER was the first to bring to the attention of government agencies and the public the presence of PFAS in mosquito control pesticides packaged in containers fluorinated by Inhance. EPA testing subsequently confirmed that these containers were in fact the source of the PFAS in the pesticides.

34. Together with CEH, PEER has worked to increase public knowledge and awareness of the presence of PFAS in fluorinated containers and their contents, and has advocated regulatory and judicial action to stop the fluorination of containers that create PFAS. This has included participation in litigation against Inhance at the district court and appellate levels.

35. PEER is also addressing and educating the public about PFAS contamination from other sources such as biosolids (sewage sludge) applied as fertilizers.

36. Board members, supporters and staff of PEER use a variety of products packaged in plastic containers that may be fluorinated but cannot ascertain whether they contain PFOA and

other PFAS because Inhance has claimed confidentiality for its customers and the specific products they sell in fluorinated containers.

37. Defendant Michael Regan, named in his official capacity as Administrator of EPA, has responsibility for the implementation of TSCA and is charged with assuring that the Agency exercises its authorities under TSCA in compliance with the law.

38. Defendant EPA is an agency of the United States Executive Branch and, under the direction of Administrator Regan, is charged with implementing the provisions of TSCA, including by taking the actions required by section 4(f) upon receiving information indicating that there may be a reasonable basis to conclude that a chemical substance presents a significant risk of serious or widespread harm.

STATUTORY BACKGROUND

39. TSCA was enacted in 1976 to create a national program for assessing and managing the risks of chemicals to human health and the environment.

40. The need for this comprehensive framework for managing chemical risks was described as follows in the Senate Report on the original law:

> As the industry has grown, we have become literally surrounded by a man-made chemical environment. We utilize chemicals in a majority of our daily activities. We continually wear, wash with, inhale, and ingest a multitude of chemical substances. Many of these chemicals are essential to protect, prolong, and enhance our lives. Yet, too frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers.

Senate Rept. No. 94-698, 94th Cong. 2d Sess. (1976) at 3.

41. Despite the high hopes of Congress for effective action, progress in regulating unsafe chemicals under the 1976 law was disappointing. After a multi-year effort to overhaul and

strengthen its key provisions, TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA"), which took effect on June 11, 2016.

42. These amendments enhance the core chemical regulatory authorities in section 6 by increasing the number of substances that EPA must evaluate for unreasonable risk and requiring it to place more stringent restrictions on substances determined to present such risks. To remove impediments to effective regulation of unsafe substances, section 6(b)(4)(A) as amended precludes EPA from considering costs and other non-risk factors during risk evaluations and rulemakings to protect against unreasonable risks.

43. Under amended section 6(a) of TSCA, "[i]f the [EPA] Administrator determines . . . that the . . . use . . . of a chemical substance . . . presents an unreasonable risk of injury to health or the environment, the Administrator *shall* by rule" impose one of more of the restrictions authorized in sections 6(a)(1)-(7). 15 U.S.C. § 2605(a) (emphasis added). These restrictions can apply to several phases of a chemical's life-cycle (manufacture, processing, use, disposal etc.) and may include prohibitions or limitations on manufacture, processing use, distribution or disposal either of the regulated chemical as a whole or for particular functions and applications. The requirements imposed by the rule must restrict the chemical "to the extent necessary so that the chemical substance or mixture no longer presents such [unreasonable] risk."

44. The amendments also strengthen section 5, which authorizes the review and regulation of new chemical substances and significant new uses of existing chemicals before they enter commercial production. Under the amendments, EPA must make an affirmative determination of safety under section 5(a)(3) for these chemicals and uses before they enter commerce. EPA cannot consider costs and other non-risk factors when making these determinations and banning or restricting production to protect against unreasonable risks.

45. Section 4(f) was part of the original version of TSCA. The amended law retains section 4(f) but broadens the range of human health effects to which it applies. As amended, Section 4(f) of TSCA is triggered when EPA receives information "which indicates to [the Agency] that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings." Upon acquiring such information, EPA "shall . . . initiate applicable action under section [5, 6 or 7] to prevent or reduce such risk to a sufficient extent" or determine that the risk is "not unreasonable." EPA must discharge this obligation "within the 180-day period beginning on the date of the receipt of the information."

46. The amended law also retains with minor changes the "citizens' civil action" provisions of section 20. As in original TSCA, section 20(a)(2) states that "any person may commence a civil action . . . against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary." 15 U.S.C. §2619(a)(2).

PLAINTIFFS' SIXTY-DAY PRE-SUIT NOTICE

47. Under section 20(b)(2), actions to compel EPA to perform its statutory obligations cannot be filed "before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action." Section 20(b)(2) reduces this notice period to 10 days "in the case of an action. . . for the failure of the Administrator to file an action under section 7," which authorizes expedited judicial and administrative relief to address "imminently hazardous" chemicals.

48. On May 17, 2024, CEH and PEER notified defendant Regan by letter that they intended to file suit under section 20(a)(2) to challenge EPA's failure to perform its non-discretionary duty under section 4(f) of TSCA to initiate applicable action under section 5, 6 or 7 to prevent or reduce the risk posed by PFOA formed during the fluorination of plastic containers. The notice

letter stated that EPA received information triggering section 4(f) by March 29, 2023, if not earlier, and that the mandatory 180-day period for initiating action to prevent or reduce the risk or determining it was not unreasonable expired on or before September 25, 2023.

49. The letter requested that EPA comply with section 4(f) by proposing a rule under section 6(a) prohibiting production of PFOA during fluorination and making that rule immediately effective under section 6(d)(3).

50. Plaintiffs maintained that, in the absence of an immediately effective rule, EPA would have a non-discretionary duty under section 20(a)(2) to file an imminent hazard suit against Inhance seeking an immediate ban on PFOA formation during fluorination relief under TSCA section 7.

51. Defendants did not respond to plaintiffs' notice letter or take any action to satisfy section 4(f) as the letter requested.

EPA's INVESTIGATION, ASSESSMENT AND REGULATION OF PFOA FORMATION DURING FLUORINATION

The Inhance Fluorination Process

52. Inhance, a corporation headquartered in Houston, Texas, treats high-density polyethylene ("HDPE") and other plastic containers by "fluorination," in which fluorine gas is applied to the container in varying concentrations under high temperatures to improve its barrier properties (i.e., its impermeability) and prevent loss of its contents.

53. Inhance fluorinates approximately 200 million containers and other items per year.

54. HDPE containers fluorinated by Inhance are widely used for a variety of consumer, commercial and industrial products, such as household spray cleaners, household countertop polish, floor cleaners and polish, furniture wipes, spray pesticides and herbicides, hose-end sprayer herbicides, commercial pesticides, and industrial chemical storage.

55. According to the Significant New Use Notices ("SNUNs") Inhance submitted to EPA in late 2022, it also "fluorinates fuel tanks and portable fuel storage containers in a number of major markets: handheld and ground-supported outdoor power equipment (e.g., mowers, string trimmers), power sports (e.g., all-terrain vehicles, personal watercraft, 4x4s), marine (e.g., boats), and portable fuel storage containers (e.g., gas cans)."

56. In its SNUNs, Inhance has recognized that "an apparently unavoidable aspect of fluorination of HDPE containers" is the production of PFAS and "there is no easy solution to the problem of [PFAS] formation."

EPA's Investigation and Testing of Fluorinated Containers (2020-2023)

57. Starting in late 2020, EPA obtained extensive evidence that several PFAS, including PFOA, are formed during the Inhance fluorination process and are present in both the walls of containers and their contents.

58. Between August and October 20, 2020, plaintiff PEER and Massachusetts Department of Environmental Protection ("MADEP") sampled and tested containers of Anvil 10+10®, a pesticide, and detected the presence of multiple PFAS, including PFOA.

59. In early September 2020, EPA became aware of the PFAS contamination data for the Anvil 10+10® mosquito control pesticide.

60. In December 2020, EPA received and tested unused fluorinated HDPE containers from the distributor of Anvil 10+10® and detected PFOA and several other PFAS in the rinsates (a solvent used to extract chemical compounds).

61. On January 14. 2021, EPA issued a press release "making new information available about EPA testing that shows PFAS contamination from fluorinated containers."

62. On March 5, 2021, EPA issued another press release "confirm[ing] that it has detected eight different PFAS from the fluorinated HDPE containers, with levels ranging from 20-50 parts per billion." An EPA report dated March 4, 2021 noted that "during the fluorination process, HDPE containers are subjected to fluorine elemental gas at pre-determined concentrations and under elevated temperatures. The anticipated chemical reaction results in formation of partially fluorinated long chain [PFAS] polymers."

63. On September 8, 2022, EPA announced the results of a follow-up study to determine the presence of PFAS in test solutions packaged in different HDPE fluorinated containers. The detailed August 12, 2022 report issued by EPA concluded that:

- Water or methanol used as surrogates for pesticide formulations (or other solutions similar to water or methanol) stored in fluorinated containers had quantifiable PFAS levels, which indicated that PFAS from container walls leached into the contents of the container.
- The total amount of leached PFAS at each point in time varied for different brands of fluorinated containers, which is likely a reflection of different fluorination levels and techniques used to fluorinate these containers.
- The total PFAS leached into the solutions generally increased gradually over the 20-week test period.
- Higher amounts of total PFAS were found in methanol solution than in water for the same containers, an observation consistent with the chemistry of methanol as a stronger solvent in dissolving organic compounds.

Accordingly, EPA "determined that liquid products packaged in HDPE containers treated with fluorination technology could leach certain PFAS into products from the container walls, even with water-based products."

64. The EPA test results were confirmed by studies conducted by independent researchers and reported in the scientific literature as well as by testing performed for Inhance itself. According to a report by CEH's then science director in 2023, in six independent studies, PFOA

was consistently found in extracts and solvents present in fluorinated containers at levels ranging from 0.13 parts per billion ("ppb") to 4.49 ppb.

Application of the LCFAC SNUR to PFAS Formed during Container Fluorination

65. Section 5(a)(2) of TSCA, 15 U.S.C. §2604(a)(2), authorizes EPA to designate by rule certain uses of chemical substances as "significant new uses." Under section 5(a)(1)(A)(ii) and 5(a)(1)(B), upon promulgation of such a significant new use rule ("SNUR"), manufacturing and processing of a substance for the designated uses are prohibited unless the firm seeking to conduct these activities has submitted a SNUN to EPA at least 90 days before their initiation and the Agency has completed the statutory review process, made determinations of unreasonable risk, and taken any necessary regulatory action.

66. EPA proposed a SNUR for a subset of PFAS called long-chain perfluoroalkyl carboxylate ("LCPFAC") substances on January 21, 2015 (80 Fed. Reg. 2885). The Agency supplemented the proposal on March 3, 2020, (85 Fed. Reg. 12479) and finalized its LCPFAC SNUR on July 27, 2020 (85 Fed. Reg. 45109). As defined by EPA, the category of LCPFACs includes PFOA and several other long-chain PFAS formed during the fluorination of plastic containers.

67. The final SNUR "requires persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of these chemical substances for the significant new uses described in this notice." As EPA stated, "[m]anufacturing (including import) or processing [of LCPFACs] for the significant new use are prohibited from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination." 85 Fed. Reg. at 45110.

68. On March 1, 2022, EPA issued a Notice of Violation ("NOV") informing Inhance that its process for fluorinating HDPE containers produces PFAS subject to the LCPFAC SNUR and that Inhance's manufacturing and processing of such PFAS were a violation of the SNUR.

69. The NOV stated that unless Inhance changed its process for fluorinating HDPE containers to prevent the manufacture of long-chain PFAS substances, Inhance was required to immediately cease the manufacture of PFOA and other PFAS subject to the SNUR and could not resume manufacture until it had submitted SNUNs and EPA had completed its review process and any necessary regulatory action.

70. Inhance refused to cease production of PFOA and other LCPFACs in response to the NOV. However, on December 30, 2022, nine months later, Inhance finally submitted SNUNs for PFOA and eight other LCPFACs that were produced during fluorination and found in fluorinated containers and their contents. 88 Fed. Reg. 10320 (Feb. 17, 2023). Inhance continued to produce the nine LCPFACs while the SNUNs were being reviewed by EPA.

EPA Review of Inhance SNUNs and Unreasonable Risk Finding for the Fluorination Process

71. Throughout 2023, EPA reviewed the extensive information in the Inhance SNUNs as well as voluminous materials submitted by the company in response to two EPA subpoenas. Based on these submissions and other information, EPA assessed the risks to health from exposure to the nine LCPFACs during the processing, use, distribution in commerce, and disposal of fluorinated containers.

72. The findings and conclusions of EPA's assessment were embodied in its December 1, 2023 orders under TSCA sections 5(e) and 5(f) and a supporting risk assessment. The orders prohibited the manufacture of PFOA and eight other LCPFACs during fluorination and the processing, distribution in commerce, use, and disposal of fluorinated containers.

73. The first order applied to three LCPFACs – PFOA, perfluorononanoic acid (CASRN 375-95- 1) ("PFNA") and perfluorodecanoic acid (CAS RN 335-76-2) ("PFDA"). It determined under TSCA section 5(a)(3)(A) that "manufacture, processing, distribution in commerce, use, and disposal [of these PFAS] . . . presents an unreasonable risk of injury to health or the environment."

74. This determination obligated EPA to issue an order under section 5(f)(1) of TSCA, 15 U.S.C. § 2604(f)(1), prohibiting or restricting the SNUN substances presenting an unreasonable risk "to the extent necessary to protect against such risk." The order issued by EPA prohibited production of the three PFAS during fluorination and banned the processing, distribution in commerce, use and disposal of fluorinated containers in which these PFAS were present.

75. The second order addressed the other six LCPFACs for which Inhance submitted SNUNs. It determined under TSCA section 5(a)(3)(B)(ii)(I) that "in the absence of sufficient information to permit EPA to make a reasoned evaluation of the health and environmental effects of the" SNUN substances, they "may present an unreasonable risk of injury to health or the environment." As a result of this determination, EPA issued an order under section 5(e) of TSCA, 15 U.S.C. §2604(e), requiring Inhance to conduct testing on the six LCPFACs and directing that "manufacture of the SNUN Chemical Substances [may not] commence while testing is being conducted [b]ased on concerns for persistence, bioaccumulation, and hazards." *Id*. at 5.

76. The comprehensive EPA risk assessment supporting the orders concludes that: "[b]ecause of the persistent and bioaccumulative nature of these PFAS, exposure to each SNUN Chemical Substance will continue over time, long after the immediate

exposure associated with their use;" "the identified hazards of PFOA are so significant that there are no safe levels of exposure;" and extensive exposure and environmental release are the inevitable "result of leaching or migration of [LCPFACs] from fluorinated, plastic storage containers over time into" numerous consumer and industrial products. Thus, the orders conclude that EPA "cannot control potential exposures to the SNUN Chemical Substances through means other than a prohibition on the manufacture of these substances."

Review of the EPA Section 5 Orders by the Fifth Circuit

77. The EPA orders were set to become effective on February 28, 2024 but were stayed by the Fifth Circuit Court of Appeals on December 12, 2023 and then vacated in its March 2, 2024 decision. *Inhance Technologies, LLC v. US Environmental Protection Agency,* 96 F.4th 888 (5th Cir. 2024). As a result, the orders never took effect, and the health threats that they sought to prevent have not yet been addressed.

78. In its decision, the Court concluded that EPA lacked authority to issue the orders because the Inhance fluorination process, which predated the SNUR and continued after it was promulgated, could not be deemed a "significant new use" within the meaning of TSCA.[1]

79. However, the Court took as a given the presence of harmful LCPFACs in fluorinated containers and their contents. It also did not question the scientific justification for the orders and the seriousness of the health threat they sought to remedy. At no point did the decision suggest that EPA's risk findings could not trigger

[1] The plaintiffs believe that the Fifth Circuit's interpretation of TSCA was incorrect.

action under other provisions of TSCA such as section 4(f); the Court in fact expressly recognized that EPA had authority to regulate PFAS formation during fluorination under section 6 even if it could not do so under section 5.

PFOA'S SIGNIFICANT AND SERIOUS RISKS TO HEALTH AT NEAR-ZERO EXPOSURE LEVELS

80. PFOA has been a serious health concern for EPA and the scientific community for at least 25 years and preventing PFOA exposure has been a top priority for federal and state regulators.

81. A large body of evidence in EPA's possession has long demonstrated that the risks to health presented by PFOA at near-zero levels of exposure are "significant" and "serious" under TSCA section 4(f).

82. EPA's longstanding health concerns about PFOA culminated in precedent-setting actions in 2022 and 2023 to stringently control exposure in drinking water and at contaminated waste sites.

83. In 1999, 3M Corporation, the largest manufacturer of PFOA, announced that it was halting manufacture and use because of its persistence and bio-accumulative in people and wildlife.

84. In the early 2000s, PFOA was implicated in large-scale contamination of drinking water near a DuPont facility in West Virginia. Follow-up studies funded by the company as part of a legal settlement demonstrated links to cancer and a host and other health problems in the exposed population.

85. On September 27, 2002, the then-Director of the Office of Pollution Prevention and Toxics wrote a memo stating that, "The reproductive/developmental toxicity data, the carcinogenicity data, and the blood monitoring data reviewed in the interim revised hazard assessment raise the possibility that PFOA might meet the criteria for action under section 4(f) of the Toxic Substances Control Act."

86. In a request for information on PFOA published in the Federal Register on April 16, 2003, EPA reiterated that "developmental toxicity data, the carcinogenicity data, and the blood monitoring data presented in an interim revised hazard assessment raised the possibility that PFOA might meet the criteria for consideration under TSCA section 4(f)." 68 Fed. Reg. 18626.

87. In 2006, under pressure from EPA, the principal manufacturers and processors of PFOA formed a PFOA Stewardship Program with "a goal of reducing facility emissions and product content of LCPFAC chemical substances on a global basis by 95%, no later than 2010, and to eliminate emissions and product content of these chemical substances by 2015." 80 Fed. Reg. 2890.

88. Fulfilling these commitments, LCPFAC producers ceased manufacture of PFOA by 2015, and EPA followed up that same year by proposing the LCPFAC SNUR to prevent "resumption of past uses" which "could increase the magnitude and duration of exposure to humans and the environment." *Id.*

89. The SNUR emphasized that LCPFAC substances "have been found in the blood of the general human population, as well as in wildlife, indicating that exposure to these chemical substances is widespread." *Id.* at 45113. It explained that "PFOA and its salts. . . have been a primary focus of studies related to the LCPFAC class of chemical substances" and that "PFOA is persistent, widely present in humans and the environment, has a half-life in humans of 2.3–3.8 years, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity." *Id.*

90. According to the SNUR, "[h]uman epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney)."

In addition, "PFOA precursors, chemicals which degrade or may degrade to PFOA, are also present worldwide in humans and the environment and, in some cases, might be more toxic and be present at higher concentrations than PFOA." Id.

91. On September 6, 2022, EPA proposed to designate the two PFAS of greatest concern -- PFOA and perfluorooctanesulfonic acid ("PFOS") -- as "hazardous substances" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA'' or ''Superfund''). 87 Fed. Reg. 54415-17. This was the first time since enactment of CERCLA that EPA had included new hazardous substances in the national cleanup program for contaminated waste sites and further demonstrates the Agency's high level of concern about harmful PFOA exposure.

92. The proposal found that "PFOA and PFOS are persistent and mobile in the environment, and exposure can lead to adverse human health effects, including high cholesterol, changes in liver enzymes, decreased immune response to vaccination, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney for PFOA." Based on previous EPA health effects assessments, it concluded that the "totality of evidence . . . demonstrates that [PFOA] can pose substantial danger to public health or welfare or the environment."

93. EPA finalized its CERCLA hazardous substance listing for PFOA and PFOS on May 8, 2024. 89 Fed. Reg. 39124.

94. As concerns about PFAS-contaminated drinking water mounted, the Biden EPA also selected PFOA as one of six PFAS for which it would develop National Primary Drinking Water Regulations ("NPDWRs") under the Safe Drinking Water Act ("SDWA"). The proposed regulations, published on March 29, 2023, stated, "Following a systematic review of available human epidemiological and animal toxicity studies, EPA has determined that PFOA … [is] likely

to cause cancer (*e.g.,* kidney and liver cancer) and that there is no dose below which … [it] is considered safe." 88 Fed. Reg. 18638, 18639 (March 29, 2023).

95. EPA also concluded that PFOA has been "detected in up to 98 percent of human serum samples taken in biomonitoring studies that are representative of the U.S. general population,"(id at 18643) and that there is "widespread occurrence of PFOA …in multiple geographic locations." Id at 18648. Due to the widespread occurrence of PFOA, its presence in virtually every American's blood, and its carcinogenicity, EPA proposed to set the health-based value, or the Maximum Contaminant Level Goal ("MCLG"), at zero. Id. at 18639.

96. To evaluate the non-cancer effects of PFOA, EPA determined a Reference Dose (RfD), which is "an estimate of daily exposure to the human population (including sensitive populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime." 88 Fed. Reg at 18652-3. EPA "considered multiple endpoints for derivation of a reference dose: immunotoxicity (as determined by decreased antibody levels), developmental toxicity (as determined by decreased birth weight), and cardiovascular toxicity (as determined by increased total cholesterol). Ultimately, this allowed for derivation of a reference dose of 3×10^{-8} mg/kg/day, equivalent to 0.03 ng/kg/day. According to EPA, "the available evidence indicates there are effects across immune, developmental, cardiovascular, and hepatic organ systems at the same or approximately the same level of PFOA exposure" and the selected RfD is "protective of effects that may occur in sensitive populations (*i.e.,* infants and children), as well as hepatic effects that may result from PFOA exposure." 88 Fed. Reg. at 18659.

97. Following the EPA proposal, the International Agency for Research on Cancer ("IARC") classified PFOA as "carcinogenic to humans" on December 1, 2023.

98. In its final drinking water regulations, promulgated on April 26, 2024, EPA reiterated that PFOA is "*Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals" and "concluded that there is no known threshold for carcinogenicity." 89 Fed. Reg. 32532. For this reason, EPA finalized a Maximum Contaminant Level Goal ("MCLG") for PFOA in drinking water of zero, determining that there is no level of exposure at which "known or anticipated adverse effects on the health of persons" do not occur and allow for an adequate margin of safety.

WIDESPREAD PFOA EXPOSURE AND RISK FROM THE DISTRIBUTION AND USE OF INHANCE-FLUORINATED PLASTIC CONTAINERS

99. By early 2023, the information available to EPA during its investigation of Inhance's fluorination process demonstrated that the health risks from PFOA formed during the fluorination process were not only significant and serious but widespread within the meaning of section 4(f) of TSCA.

100. With approximately 200 million fluorinated containers entering commerce each year, the evidence demonstrated that the potential for harmful exposure to PFOA extends to multiple sectors of the economy and impacts millions of workers and consumers.

101. It is well established, including from studies conducted by EPA as early as December 2020, that PFAS formed during the Inhance fluorination process leach from fluorinated plastic containers into the many different types of products stored in them.

102. As a result, exposure to PFOA and other PFAS produced during fluorination can occur at all stages of the lifecycles of these containers, including production of PFAS during fluorination and processing, distribution, use, and disposal of fluorinated containers.

103. In its 5(f) order, EPA listed the myriad ways that humans and other organisms are exposed to the long-chain PFAS created by plastic fluorination, including through: dermal absorption from handling fluorinated containers and their contents; consuming contaminated drinking water and fish; groundwater contamination from landfill leachate; inhaling contaminated air; PFAS releases to surface water; and contaminated pesticide spray drift and runoff.

104. The EPA risk assessment also found that, during the use of products packaged in fluorinated containers, PFOA and other PFAS are released to the environment, where they can contaminate soil, groundwater and surface water, exposing humans and aquatic organisms. The disposal of those containers into landfills can further distribute PFAS through landfill leachate. As EPA noted in its risk assessment, long-chain PFAS "are known to be present in leachate from municipal solid waste landfills," indicating that leaching of the PFAS produced during plastic fluorination "can occur and they are expected to migrate through soil, and eventually to groundwater." Exposure can also occur when plastic containers are recycled at the ends of their useful lives or at end-of-life incineration.

105. Magnifying the seriousness of these toxic effects are the persistence and bioaccumulation of LCPFACs in general and PFOA in particular. Both the 5(f) order and risk assessment emphasized that, because of these characteristics, "[s]mall releases to the environment can have a significant long-term contribution to exposure and risk." Accordingly, there is "potential for long-lasting environmental and human exposure . . . that is difficult to control and reverse."

106. Adding further to these risks, users of fluorinated containers are exposed not just to PFOA but to six other long-chain carboxylate PFAS and four short-chain PFAS known to be formed during fluorination. EPA scientists found that because they have common health effects, people who are exposed to multiple PFAS—like those who face exposures to PFOA and the

other 11 PFAS co-produced during fluorination processes—face greater risks of harm from co-exposure than they would from exposure to any of these PFAS individually. As EPA has explained, "PFAS have dose additive impacts." 88 Fed. Reg. at 18649–50. According to its risk assessment, failing to account for the "growing body of evidence on the dose additive effects for mixtures of PFAS . . . will result in underestimating risk."

107. Even without accounting for these risk factors, the levels of PFOA in fluorinated containers are well above the levels of health concern on which EPA based its drinking water standards for PFOA. While EPA set an MCLG for PFOA of zero, the law required it to also establish a Maximum Contaminant Level ("MCL") setting the lowest limit feasible in practice. This MCL was set at 4.0 parts per trillion ("ppt"). By comparison, in a report submitted to EPA during its SNUN review, CEH's science director indicated that PFOA was consistently found in extracts and solvents in fluorinated containers at levels ranging from 0.13 parts per billion ("ppb") to 4.49 ppb, *between 32.5 and 1,122.5 times higher than the EPA MCL.*

FIRST CLAIM FOR RELIEF

108. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 107 as if fully set forth herein.

109. Under TSCA section 20(a)(2), this Court has jurisdiction to compel defendants to perform any act or duty under TSCA w hich is not discretionary.

110. Plaintiffs' May 17, 2024 letter to defendant Regan satisfied their obligation under TSCA section 20(b)(2) to notify the EPA Administrator of his failure to perform non-discretionary duties at least 60 days before filing suit.

111. Section 4(f) of TSCA creates a non-discretionary duty to take action where EPA receives information "which indicates to [the Agency] that there may be a reasonable basis to

conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings."

112. To trigger section 4(f), information need not be definitive or conclusive. Rather, if there "may be a reasonable basis to conclude" that the substance meets the 4(f) risk threshold, that starts the 180-day clock for action to address the risk.

113. EPA's obligations under section 4(f) arose on or before March 29, 2023. As of that date if not earlier, EPA was in possession of conclusive data demonstrating that PFOA (i) is carcinogenic to humans and has no safe level of exposure and (ii) is present in tens of millions of plastic containers used to package numerous common commercial and consumer products distributed and used throughout the economy.

114. Once EPA knew that PFOA was a human carcinogen with no safe level of exposure and that millions of people were exposed to PFOA in fluorinated packaging, the Agency had a "reasonable basis to conclude" that PFOA formed during fluorination presents a "significant risk of serious or widespread harm to humans" within the meaning of section 4(f).

115. According to section 4(f), "within the 180-day period beginning on the date of the receipt of [such] information," EPA "shall . . . initiate applicable action under section [5, 6 or 7] to prevent or reduce such risk to a sufficient extent" or determine that the risk is "not unreasonable."

116. Since section 4(f) was triggered on March 29, 2023 at the latest, it required the Agency to initiate action to "prevent or reduce" the risk from PFOA formation during fluorination or determine that the risk was "not unreasonable" by no later than September 25, 2023, if not much earlier.

117. Because EPA's December 1, 2023 order under TSCA 5(f) determined that fluorination presented an unreasonable risk of injury to health, EPA is now foreclosed from finding that this risk is "not unreasonable" and can only satisfy its duties under section 4(f) by "initiat[ing] "applicable action . . . to "prevent or reduce" the risk.

118. The extensive technical and scientific analysis in EPA's December 1, 2023 order and risk assessment confirmed that PFOA formation during fluorination presents a significant and serious or widespread risk to health under section 4(f). However, the order did not "prevent or reduce such risk to a sufficient extent" because the order was vacated by the Fifth Circuit Court of Appeals and never took effect.

119. Accordingly, EPA has not yet fulfilled its non-discretionary obligations under section 4(f).

120. As EPA found in its 5(f) order, the health risks from fluorination can only be prevented or reduced "to a sufficient extent" under section 4(f) by prohibiting PFOA formation during the fluorination process.

121. The Court must therefore order EPA to comply with section 4(f) by immediately proposing a rule under TSCA section 6(a) prohibiting the production of PFOA during the Inhance fluorination process

122. Since EPA has already completed an extensive investigation and detailed analysis of the risks of fluorination under TSCA section 5, the Court's order should set an expeditious deadline for publishing this proposed rule in the Federal Register.

SECOND CLAIM FOR RELIEF

123. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 107 as if fully set forth herein.

124. TSCA Section 6(d)(3)(A) provides that EPA "may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule."

125. A rule may be made immediately effective where EPA determines that: (i) "the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors," and (ii) "making such proposed rule so effective is necessary to protect the public interest."

126. Under section 7(a)(2) of TSCA, if EPA has not made a section 6(a) rule immediately effective under section 6(d)(3), it "shall" commence a suit for immediate injunctive relief where the substance or mixture subject to the rule is "imminently hazardous."

127. Because TSCA states that such suits "shall" be brought for "imminently hazardous" chemicals, filing these actions is a non-discretionary duty of the EPA Administrator and is enforceable through citizens' suits under TSCA section 20(a)(2).

128. The pre-suit notification requirements for such suits in section 20(b)(2) explicitly apply to the "failure of the Administrator to file an action under section 7" and, recognizing the need to act quickly against imminent hazards, reduce the pre-suit waiting period to 10 days.

129. In its May 17, 2024 notice letter under section 20(b)(2), plaintiffs urged EPA to "use its authority under TSCA section 6(d) to make the proposed rule [banning PFOA formation during fluorination] immediately effective on publication so that the serious and widespread risks [it presents] do not continue for the duration of the rulemaking process."

130. Alternatively, plaintiffs' notice letter said, EPA "must file an action in district court against Inhance using the imminent hazard authority of section 7."

131. TSCA Section 7(f) defines an "imminently hazardous chemical substance or mixture" as:

> "a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other nonrisk factors. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk."

132. The information in EPA's possession that triggered section 4(f) and supported the determination of unreasonable risk in its section 5(f) order demonstrates that the production of PFOA during fluorination "presents an imminent and unreasonable risk of serious or widespread injury to health . . ., without consideration of costs or other nonrisk factors" and "the risk is likely to result in such injury to health or the environment before a final rule" is promulgated.

133. The Court must therefore order EPA to immediately file an imminent hazard action under TSCA section 7 against Inhance to prohibit the formation of PFOA during the fluorination process or make its proposed rule under section 6(a) imposing such a ban immediately effective upon publication in the Federal Register.

REQUEST FOR RELIEF

WHEREFORE, plaintiffs respectfully request judgment in their favor and against defendants upon their claims and, further, request that this Honorable Court enter judgment against defendants:

(1) Declaring that defendants have failed to perform their non-discretionary duty under TSCA section 4(f) to initiate applicable action under section 6 to prevent or reduce

to a sufficient extent the significant and serious or widespread risks to health from the formation of PFOA during fluorination and must carry out that duty immediately;

(2) Declaring that defendants have failed to perform their non-discretionary duty under TSCA section 7 to file suit to protect the public from the imminently hazardous formation of PFOA during fluorination and must carry out that duty immediately;

(3) Ordering defendants to expeditiously publish a proposed rule under TSCA section 6(a) prohibiting the formation of PFOA during fluorination;

(4) Ordering defendants to file suit immediately under TSCA section 7 to protect the public from imminently hazardous fluorinated plastic containers in which PFOA is present or to make its proposed rule under section 6(a) immediately effective upon publication;

(5) Awarding the plaintiffs their reasonable fees, costs and expenses, including attorneys' fees, pursuant to TSCA section 20(c)(2); and

(6) Ordering such other and further relief, in law or in equity, as the Court deems just and proper,

DATED: July 25, 2024

Respectfully submitted,

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