

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**CENTER FOR ENVIRONMENTAL
HEALTH**

2201 Broadway, Suite 508
Oakland, CA 94612

**PUBLIC EMPLOYEES FOR
ENVIRONMENTAL
RESPONSIBILITY**

962 Wayne Avenue, Suite 610
Silver Spring, MD 20910

Plaintiffs,

v.

INHANCE TECHNOLOGIES USA

22008 N. Berwick Drive
Houston, Texas 77095

Defendant.

Case No.

**COMPLAINT FOR
DECLARATORY
AND INJUNCTIVE RELIEF**

**COMPLAINT FOR DECLARATORY AND
INJUNCTIVE RELIEF**

Introductory Statement

1. This is a citizens' enforcement suit brought by the Center for Environmental Health ("CEH") and Public Employees for Environmental Responsibility ("PEER") to enjoin and

prevent ongoing violations of significant new use notification rule (“SNUR”) requirements for chemical substances under the federal Toxic Substances Control Act (“TSCA”).

2. Plaintiff CEH is a 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. It envisions a world where everyone lives, works, learns, and plays in a healthy environment; CEH protects people from toxic chemicals by working with communities, businesses, and the government to demand and support business practices that are safe for human health and the environment.

3. Plaintiff PEER is a non-profit organization headquartered in Silver Spring, Maryland, that 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. PEER works to seek a higher standard of environmental ethics, scientific integrity, and legal accountability within health and environmental agencies. PEER accomplishes this by defending whistleblowers, shining the light on improper or illegal actions by government and regulated entities, working to improve enforcement and implementation of laws and regulations, and securing a higher level of protection of health and the environment.

4. Defendant Inhance Technologies USA (“Inhance”) is a corporation headquartered in Houston, Texas, engaged in treating high-density polyethylene (“HDPE”) and other plastic containers by “fluorination,” a process in which fluorine gas is applied to the container in varying concentrations under high temperatures in order to improve its barrier properties.

5. Inhance conducts fluorination activities at several locations across the United States and in other countries and is the principal supplier of post-mold fluorination services in the U.S.

6. Plaintiffs file this Complaint pursuant to the Declaratory Judgment Act, 28 U.S.C. §2201, and section 20(a) of TSCA, 15 U.S.C. § 2619(a), seeking declaratory and injunctive relief to prevent and restrain defendant's continuing violations of TSCA and recovery of plaintiffs' reasonable fees and costs.

7. Inhance has violated, and continues to violate, the SNUR for long-chain perfluoroalkyl carboxylate ("LCPFAC") chemical substances promulgated by the U.S. Environmental Protection Agency ("EPA") on July 27, 2020, (85 Fed. Reg. 45109), 40 C.F.R. § 721.10536.

8. Defendant's violations of the SNUR consist of: (i) its failure to submit a timely significant new use notice ("SNUN") as required by the SNUR and section 5(a)(1) of TSCA for LCPFAC substances formed during the fluorination of plastic containers and (ii) its manufacture of these substances before completion of the requisite 90 day SNUN review period, EPA determinations of the safety of the significant new use, and issuance of any EPA orders under sections 5(e) or (f) of TSCA restricting or prohibiting the new use to protect health and the environment.

9. The LCPFACs manufactured by Inhance in violation of the SNUR include perfluorooctanoic acid ("PFOA") and other per- and polyfluoroalkyl substances ("PFAS"). Often called "forever" chemicals because they do not break down or degrade over time, EPA and

other authorities have generally found that PFAS have properties of high persistence, significant bio-accumulation and severe toxicity to human health.

10. In light of their harmful effects, EPA has issued stringent “health advisories” for PFOA and other PFAS under the Safe Drinking Water Act that determine that exposure to very low levels of these substances is dangerous to people and is taking numerous actions under applicable environmental laws to require their remediation at contaminated sites and limit their presence in drinking water.

11. Because of the formation of these PFAS during the fluorination process and their presence in the contents and surfaces of containers, workers and consumers who use or otherwise come into contact with fluorinated containers or their contents are exposed to harmful levels of PFOA and other PFAS that may cause adverse effects to their health.

12. Plaintiffs notified Inhance of the alleged violations of TSCA in a notice served on October 24, 2022 pursuant to section 20(b)(1) of TSCA but these violations continued during and after the ensuing 60-day period. Accordingly, absent an order from this Court requiring defendant to comply with the LCPFAC SNUR, Inhance will continue to be in violation of TSCA.

TSCA Citizens’ Suit Provisions

13. Under section 20(a)(1) of TSCA, 15 U.S.C. §2619(a)(1), “any person may commence a civil action . . . against any person . . . who is alleged to be in violation of this Act or any rule promulgated under section [5] . . . to restrain such violation.”

14. Section 20(b)(1)(A), 15 U.S.C. §2619(b)(1)(A), provides that no action to restrain a violation of TSCA may be commenced “before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator and (ii) to the person who is alleged to have committed such violation.”

15. Civil actions under section 20(a)(1) of TSCA “shall be brought in the United States District Court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant’s principal place of business is located . . . without regard to the amount in controversy or the citizenship of the parties.”

16. Under section 20(c)(2), 15 U.S.C. §2619(c)(2), the court in an action to restrain a violation under section 20(a)(1) “may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.”

Relevant TSCA Provisions

17. TSCA was enacted in 1976 to create a national program for assessing and managing the risks of chemicals to human health and the environment. Among the goals stated in TSCA section 2(b), 15 U.S.C. § 2601(b), are that: (1) “adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment” and (2) “adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment.”

18. 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.

19. 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. These TSCA amendments enhance the law’s chemical regulatory authorities in section 6, 15 U.S.C. §2605, by establishing a new integrated process for (1) prioritizing chemicals, (2) conducting risk evaluations on high-priority chemicals, and (3) promulgating rules to eliminate unreasonable risks identified in risk evaluations. Congress set strict deadlines for each of these steps and directed EPA to address a minimum number of chemicals by these deadlines.

20. In section 6(a), 15 U.S.C. §2605(a), Congress also removed the impediments to effective regulation imposed by the original law by eliminating any consideration of costs and other non-risk factors in determining whether chemicals present an unreasonable risk of injury and directing EPA to impose requirements “necessary so that the chemical no longer presents such [unreasonable] risk.” Similar language was added to sections 5(a)(3), 5(e) and 5(f) specifying that EPA’s determinations of safety for new substances and significant new uses and the orders it issues protecting against unreasonable risks cannot consider costs and other non-risk factors.

SNUR Requirements under TSCA

21. 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 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. Pursuant to that process, EPA must review the SNUN and determine whether the new use may present an unreasonable risk of injury to health or the environment under section 5(a)(3). EPA must then prohibit or restrict the use to the extent necessary to protect against an unreasonable risk by issuing an order under section 5(e) of TSCA if it makes one of three findings: (i) the use may present an unreasonable risk of injury, (ii) there is insufficient information for a reasoned evaluation of the use’s health or environmental effects, or (iii) the substance is or will be produced in substantial quantities for the use and either enters or may reasonably be anticipated to enter the environment in substantial quantities or give rise to significant or substantial human exposure. The substance may be manufactured or processed for the significant new use without restriction only if EPA determines under section 5(a)(3)(C) of TSCA that the use is not likely to present an unreasonable risk to human health or the environment.

22. Section 15 of TSCA, 15 U.S.C. §2614, provides that it is unlawful for any person to:

"(1) fail or refuse to comply with any requirement of this title or any rule promulgated . . . under this title; or . . . "(3) fail or refuse to ... submit reports, notices, or other information; . . . as required by this Act or a rule thereunder;"

Under section 15 of TSCA, manufacture (including import) of substances subject to a SNUR without complying with its notification requirements is an unlawful act in violation of both section 5(a)(1) and a rule promulgated under section 5(a)(2) and is therefore subject to a citizens' civil action under section 20(a) seeking to restrain the violation.

23. EPA regulations governing the submission and review of SNURs (40 C.F.R. Part 721) provide that violation of SNUR requirements is a prohibited act under section 15(1) of TSCA. 40 C.F.R. § 721.35. Section 15(2) provides that using a chemical substance for commercial purposes that a person knew or had reason to know was manufactured or processed in violation of Part 721 also is a prohibited act under TSCA.

Jurisdiction and Venue

24. Under 40 C.F.R. § 720.40(a)(2), SNUNs must be submitted to EPA's Central Data Exchange (CDX), an electronic site used for submission of reports to the Agency which is maintained at EPA headquarters at 1200 Pennsylvania Avenue NW, in Washington DC.

25. SNUNs are reviewed and analyzed by EPA's Office of Chemical Safety and Pollution Prevention ("OCSPP"), which is located at EPA headquarters.

26. Defendant's violations of the LPCFAC SNUR accordingly occurred and are continuing to occur in the District of Columbia.

27. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 15 U.S.C. § 2619(a), under which citizens' suits to restrain violations of TSCA "shall be brought in the United States District Court for the district in which the alleged violation occurred."

28. Venue is proper in the District of Columbia under 28 U.S.C. § 1391(b)(2) and 15 U.S.C. § 2619(a), which provide that the district courts "shall have jurisdiction over suits brought under this section, without regard . . . to the citizenship of the parties" and "process may be served on the defendant in any judicial district in which the defendant resides or may be found."

29. The Court also has jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, which authorizes it to enter a declaratory judgment that defendant has been and remains in violation of section 15 of TSCA, 15 U.S.C. § 2614, because of its ongoing manufacture of LCPFACs without compliance with SNUR requirements in section 5 of TSCA.

Plaintiffs' Notices of Intent to Sue

30. On October 21, 2022, plaintiffs CEH and PEER sent a notice of intent to sue under TSCA section 20(b)(1) to defendant Inhance and EPA Administrator Michael Regan.

31. This notice described with particularity defendant's violations of the LPCFAC SNUR and provided the information called for in 40 C.F.R. § 702.62(b).

32. According to the signed receipts returned to plaintiffs, defendant Inhance received the notice on October 24, 2022, and EPA Administrator Regan received the notice on October 27, 2022.

33. Defendant contacted plaintiffs during the 60-day notice period but did not agree to cease the alleged violations, as requested in the notice of intent to sue.

34. After a telephone conversation with plaintiffs on December 6, 2022 following receipt of their 60-day notice, EPA through its counsel filed a heavily redacted Complaint against Enhance in the Eastern District of Pennsylvania on December 19, 2021.

35. Because of the many redactions in the Complaint and the lengthy two-year delay between EPA's initiation of discussions with Enhance and the filing of its suit, plaintiffs are concerned that EPA will not "diligently prosecute" its action in the Eastern District of Pennsylvania, removing a possible bar to plaintiffs' suit in this Court under TSCA section 20(b)(1)(B) and enabling plaintiffs to seek all relief authorized by law in this action.

Requirements of LCPFAC SNUR

36. EPA proposed a SNUR for LCPFAC substances on January 21, 2015 (80 Fed. Reg. 2885) and supplemented the proposal on March 3, 2020, (85 Fed. Reg. 12479). On July 27, 2020, EPA finalized the LCPFAC SNUR (85 Fed. Reg. 45109).

37. 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 states, "[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.

38. The SNUR explains that the "term LCPFAC refers to the long-chain category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths equal to

or greater than seven carbons and less than or equal to 20 carbons. The category of LCPFAC chemical substances also includes the salts and precursors of these perfluorinated carboxylates.” *Id.* at 45112. The rule provides several non-exclusive examples of LCPFAC substances, including PFOA.

39. The SNUR indicates 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 explains that “PFOA and its salts, which are considered LCPFAC chemical substances, 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.” According to EPA, “[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.*

40. According to the SNUR, “[i]n the absence of a regulation, manufacture or processing for the significant new uses proposed on January 21, 2015, may begin at any time, without prior notice to EPA. As explained in the January 21, 2015, proposal, EPA is concerned that commencement of the manufacture or processing for any new uses, including resumption of

past uses, of LCPFAC and perfluoroalkyl sulfonate chemical substances could increase the magnitude and duration of exposure to humans and the environment.” Id.

41. The SNUR identifies and exempts a number of “existing” uses of LCPFACs that were ongoing as of January 21, 2015, but fluorination of plastic containers is not identified as such an exempt use. The final rule rejects proposals to establish a “safe harbor” for ongoing uses that were not identified during the rulemaking, explaining that “EPA does not believe there should be a safe-harbor provision for uses not identified as ongoing uses in the SNUR, particularly since notice of the requirements of this action were provided five years ago.” Id. at 45120.

42. The LCPFAC SNUR took effect on September 25, 2020. Id., at 45109. As of that date, manufacture and processing of LCPFACs subject to the SNUR without complying with the rule’s notification requirements violated TSCA.

Evidence of the Formation of LCPFACs during Fluorination of Plastic Containers

43. The presence of LCPFACs in fluorinated containers has been demonstrated in multiple analytical studies conducted by EPA and others.

44. An EPA [report](#) dated March 4, 2021, detailed the results of the Agency’s container testing. It concluded that “through the fluorination process of HDPE containers, PFAS compounds may be formed and then partly leach into the products inside the containers. Based on information given to us by a company that performs fluorination on plastic containers, 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 polymers and possibly fully fluorinated short chain polymers.”

45. According to a [March 16, 2022](#), open letter to industry, “[t]he agency is notifying companies of their obligation to comply with existing requirements under the [TSCA] to ensure unintentional PFAS contamination does not occur.” It explained that “long-chain PFAS as defined in EPA’s 2020 long-chain perfluoroalkyl carboxylate (LCPFAC) [SNUR] that are found to be present in or on fluorinated polyolefins may be subject to TSCA regulations and enforcement.” As EPA elaborated, these PFAS “would be considered byproducts” of the fluorination process that “do not have a separate commercial intent” and, as such, their formation during “the fluorination of polyolefins [would] be a significant new use under TSCA.”

46. 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 brands of HDPE fluorinated containers. The detailed August 12, 2022 [report](#) issued by EPA concluded that:

- a. 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.
- b. 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.
- c. The total PFAS leached into the solutions generally increased gradually over the 20-week test period.
- d. 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.”

47. EPA reiterated that formation of certain PFAS from the fluorination of polyolefins is subject to its LCPFAC SNUR under TSCA, which “requires industry to notify EPA at least 90 days before starting manufacturing or processing of these chemical substances for this significant new use, so that EPA could review any associated risks and impose any needed protections.” It emphasized that the “failure to submit such a notification would be a violation of TSCA.”

48. EPA testing has been confirmed by studies in the reported literature and by recent studies by researchers at the University of Notre Dame.

Defendant’s Past and Ongoing Violations of the LCPFAC SNUR and Necessary Remedy

49. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 48 as if fully set forth herein.

50. As the principal provider of post-mold fluorination services in the US, defendant Inhance fluorinated the plastic containers that were determined to contain LCPFACs in analytical testing performed by EPA and other entities.

51. Containers fluorinated by Inhance have been and continue to be used as packaging for “chemical substances” and “mixtures” as defined in section 3 of TSCA.

52. The fluorination of containers for TSCA-regulated purposes was and is subject to the requirements of the LCPFAC SNUR.

53. By causing LCPFAC substances to be formed during fluorination, defendant Inhance has been and continues to be a “manufacturer” and “processor” of these substances subject to the SNUR but has failed to cease manufacture and processing of the LCPFACs until submission of a SNUN and completion of the EPA review and regulatory process as required by the SNUR and section 5(a)(2) of TSCA.

54. These violations of the SNUR and TSCA began when the SNUR took effect on September 25, 2020 and are ongoing.

55. Defendant’s SNUR violations comprise “prohibited acts” under TSCA section 15 and represent “violations of this Act” and of a “rule promulgated under section” 5 for purposes of citizens’ suits under section 20(a)(1).

56. Plaintiffs have satisfied the prerequisites for seeking to restrain and enjoin defendant’s unlawful conduct under section 20(b)(1)(A) of TSCA.

57. The Court should accordingly order defendant to: (i) cease and desist from all manufacture and processing of LCPFAC substances during the fluorination of plastic containers until and unless it has fully complied with the requirements of the LCPFAC SNUR and TSCA section 5(a)(3) and EPA has completed its review of the its SNUN and taken all actions necessary under TSCA section 5 to protect human health and the environment, (ii) stop distributing all such fluorinated containers in commerce, and (iii) inform all purchasers and users of these containers of the presence of PFOA and other harmful LCPFACs and the need to prevent human and environmental exposure to these substances.

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request judgment in their favor and against defendant upon its claims and, further, request that this Honorable Court enter judgment against defendant:

- (1) Declaring that defendant's ongoing manufacture of LCPFAC substances during its fluorination of plastic containers without compliance with the SNUR requirements of section 5(a) of TSCA and related EPA review and regulatory process was and is a violation of the SNUR for LCPFAC substances promulgated by EPA on July 27, 2020 (85 Fed. Reg. 45109); was and is a "prohibited act" under section 15 of TSCA; and was and is a "violation of this Act" and of a rule promulgated under TSCA section 5 that is actionable in a citizen's suit under section 20(a)(1) of TSCA;
- (2) Declaring that plaintiffs have met the notice requirements and other prerequisites for relief under TSCA section 20;
- (3) Ordering defendant to cease and desist from all manufacture and processing of LCPFAC substances during the fluorination of plastic containers until and unless it has fully complied with the requirements of the LCPFAC SNUR and TSCA section 5(a)(3) and EPA has completed its review of defendant's SNUN and taken all follow-up actions to protect human health and the environment required under TSCA;
- (4) Ordering defendant to stop distributing in commerce all fluorinated containers in its possession until and unless it has fully complied with the

requirements of the LCPFAC SNUR and TSCA section 5(a)(1) and EPA has completed its review of defendants' SNUN and taken all follow-up actions under TSCA;

- (5) Ordering defendant to inform all purchasers and users of containers fluorinated by Inhance of the presence of PFOA and other harmful LCPFACs and the need to prevent human exposure to these substances;
- (6) Awarding plaintiffs their costs of suit and reasonable fees for attorneys and expert witnesses in this action pursuant to 15 U.S.C. § 2619(c)(2); and
- (7) Granting plaintiffs such further and additional relief as the Court may deem just and proper.

Respectfully submitted this 27th day of December 2022.

/s/ Robert M. Sussman

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