IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 5:22-cv-05055-JFM
	)	
INHANCE TECHNOLOGIES, LLC,	)	
	)	
Defendant.	)	

INTERVENOR-PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND INJUNCTIVE RELIEF

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Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Paragraph 9 of Judge Murphy's Policies and Procedures, intervenor-plaintiffs hereby submit the following statement of material facts as to which there is no genuine dispute in support of their motion for summary judgment and injunctive relief.

I. PARTIES

Intervenor-Plaintiff Public Employees for Environmental Responsibility

1. Public Employees for Environmental Responsibility ("PEER") is a non-profit organization incorporated in the District of Columbia in 1992 and 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's purpose includes assisting those who speak out on behalf of environmental ethics and protecting the integrity of individual employees and scientists within the government who dissent for ethical reasons. [Ex. 4 Declaration of Timothy Whitehouse A-22 ¶ 3; Ex. 5 Declaration of Kyla Bennett A-45 ¶ 3].

2. Mr. Timothy Whitehouse, Executive Director, Board Member and supporter of PEER, and Dr. Kyla Bennett, senior staff member and supporter of PEER, have extensive contact with plastic containers in their daily lives. [A-24 ¶ 10; A-47-48 ¶ 11, 12]. Due to the nature of their use, it is highly likely that these containers are fluorinated. Further, the absence of labeling means that information on the presence of harmful substances in these containers is unavailable [A-24-25 ¶ 11; A-48 ¶ 15].

3. Mr. Timothy Whitehouse and Dr. Kyla Bennett both experience anxiety for their health and the environment surrounding their use of potentially fluorinated plastic containers that

would be largely alleviated if defendant Inhance were ordered to stop fluorination of containers that creates PFAS. [A-24-25 ¶ 11; A-48 ¶ 14].

Intervenor-Plaintiff Center for Environmental Health

4. Plaintiff Center for Environmental Health ("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. It envisions a world where everyone lives, works, learns, and plays in a healthy environment. Intervenor-plaintiff Complaint (ECF 36) ¶ 12. CEH's mission "is to protect people from toxic chemicals by working with communities, consumers, workers, government, and the private sector to demand and support business practices that are safe for public health and the environment." [Ex. 2, Declaration of Kaya Sugarman at A-11 ¶ 7].

5. Mr. Jose Bravo, a member of CEH's Board, and Ms. Kaya Sugerman, a senior manager at CEH, also have extensive contact with plastic containers. [Ex. 1, Declaration of Jose Bravo at A-6 ¶ 8; Ex. 2 at A-10 ¶ 3]. Due to the nature of their use, it is highly likely that these containers are fluorinated. Further, the absence of labeling means that information on the presence of hazardous substances in these containers is unavailable. [A-6-7 ¶ 9; A-10-11 ¶ 5]

6. Mr. Jose Bravo and Ms. Kaya Sugerman both experience anxiety for their health surrounding their use of potentially fluorinated plastic containers that would be largely alleviated if Inhance were ordered to cease fluorination of plastic containers that creates PFAS. [A-6-7 ¶ 9; A-10 ¶ 3]

Intervenor-Plaintiff Jay De La Rosa

7. Plaintiff Jay De La Rosa, a resident of Los Angeles, has a part-time business building and restoring wooden furniture. He is also a part-time car mechanic and maintains and repairs cars. [Ex. 3 Declaration of Jay De La Rosa A-16 ¶¶ 1-4].

8. During these activities, Mr. De La Rosa is an extensive user of plastic containers and has handled these containers and their liquid contents on numerous occasions. [A-17 ¶ 5]. There is a significant possibility that these containers have been fluorinated and that Mr. De La Rosa has been and continues to be exposed to several per- and polyfluoroalkyl substances ("PFAS") when coming into contact with the container surfaces and/or their contents.

9. Mr. De La Rosa is concerned that exposure to PFAS from his frequent use of plastic containers is putting his health at risk but he has no ability to protect himself without avoiding plastic containers, which is very difficult in the work he does. [A-17-18 ¶¶ 5,7]. He joined this lawsuit as a plaintiff because a ban on unsafe fluorinated containers or a shift to fluorinated packaging that does not contain PFAS would provide the health protection he now lacks. [A-18 ¶ 9].

Defendant Inhance Technologies LLC

10. Defendant Inhance Technologies LLC ("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 to improve its barrier properties (i.e. its impermeability) and prevent loss of its contents. [Ex. 10 SNUN Attachment Number: 005 at A-221].

11. Inhance conducts fluorination across the United States and in other countries. Its U.S. facilities are in Allentown, Pennsylvania; Forest Park, Georgia; Homerville, Georgia;

Centerville, Iowa; Mt. Pleasant, Iowa; West Chicago, Illinois; Columbus, Ohio; Houston, Texas; St. Louis, Missouri; Yuma, Arizona; and Troy, Alabama. [Ex. 49 Subpoena Response at A-1209].

II. THE FLUORINATION PROCESS

12. Inhance describes its Fluoro-Seal Process® as "the standard by which fluorinated barrier packages are benchmarked." It claims to be the "the sole fluorination provider, worldwide, so enabled to deliver the cost benefits, high barrier performance and superior consistency of fluorination." [Ex. 19, Inhance Technologies: Extending its barrier technology to the agrichemical packaging market in Latin America A-627].

13. In the post-mold fluorination process, plastic manufacturers heat and then extrude High Density Polyethylene ("HPDE") resin in the presence of oxygen and mold the resin into containers of various shapes and sizes. [Ex. 18, PEER CEH Comments at A-578]. After molding, these containers are shipped to Inhance facilities by truck. Following fluorination treatment by Inhance, they are returned to their manufacturers or sent to distributors or product suppliers who add their contents and ship the filled containers to downstream users. *Id.*

14. Inhance fluorinates over 200 million containers and other items per year. [Ex. 20, Presentation titled Making the Impossible Possible at A-634].

15. The HDPE containers that undergo fluorination vary in size from around 24 ounces (for household products) to 1,000 liters (for industrial chemicals). [Ex. 9, SNUN Attachment Number: 005 at A-217].

16. According to Inhance, "[t]he chemistry of fluorination of HDPE is well-known and has been well studied for decades. . . Fluorine gas reacts with the HDPE at the exposed surfaces of the HDPE container to form a thin layer of partially fluorinated polyethylene that will

impart the [desired] barrier properties . . . The depth of [the] partially fluorinated polyethylene layer varies from a few nanometers to a few microns from the surface. The actual amount of fluorination achieved, and the depth of partially fluorinated polyethylene formed, is determined by a variety of factors including fluorine concentration, pressure, temperature, and length of time of exposure." [A-221].

17. Inhance fluorinates HDPE containers to different levels, classified as low, medium, and high. The "required level of container barrier protection drives the fluorination level, with higher amounts of fluorination used for greater degrees of barrier protection." [Ex. 9 at A-257]. "'Level of fluorination' refers to the extent of fluorine atoms substitution for hydrogen atoms on the polymer molecule and the depth of the fluorination on the article's surface. Higher levels are often required for more aggressive permeants or longer storage life." [A-221].

18. HDPE containers fluorinated by Inhance are widely used for a variety of consumer, commercial and industrial products. Examples cited by Inhance include 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. [A-217, 257]

19. In a presentation to the Petroleum Packaging Council (PPC) in 2015, Inhance identified these additional applications for fluorinated containers:

Inhance Technologies provide a highly effective barrier against a wide range of contents found in many markets.

Acids	Hazardous Waste
Adhesives	Hydrogen Bromide
Agricultural Chemicals	Industrial Chemicals
Alcohols	Janitorial Supplies
Bleaching Compounds	Lab Packs
Cleaners	**Lubricants**
Commercial Chemicals	Medical Waste
Corrosive Chemicals	**Paint and Related Products**
Detergents	Pastes
Dyes and Pigments	Peroxides
Edible Oils	Personal Care Products
Fire-Fighting Foams	Pharmaceuticals
Flammable Liquids	Photochemicals
Flavors	Poisons
Foodstuffs	**Refined Petroleum Products**
Fragrances	Sanitation Supplies
Fuels	**Solvents**
Grease	Water Treatment Chemicals

[Ex. 21, The Benefits of Fluorination for the Petroleum Industry at A-651]

20. As described in the SNUNs, Inhance "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) (Figure 1). Capacities of these components can range from around 6 ounces (small, handheld equipment) to approximately 180 gallons (marine fuel tanks)." [Ex. 13, SNUN Attachment Number: 003 at A-396].

21. These fuel-using products are depicted in the SNUNs as follows:

Figure 1. Example fluorinated fuel tanks, fuel storage containers, and associated equipment

[A-396].

III. EPA SIGNIFICANT NEW USE RULE FOR LONG-CHAIN PERFLUOROALKYL CARBOXYLATE ("LCPFAC") SUBSTANCES

22. EPA proposed a Significant New Use Rule for Long-Chain Perfluoroalkyl Carboxylate ("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).

23. 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." 85 Fed. Reg. 45109. 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 are required in association with that determination." 85 Fed. Reg. at 45110.

24. 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.

25. The SNUR defines a "significant new use" of LCPFACs as any "[m]anufacture (including import) or processing for any use after December 31, 2015." 40 C.F.R. § 721.10536(b)(4)(ii).

26. The SNUR exempts several uses of LCPFACs that existed prior to January 21, 2015 at 40 C.F.R. § 721.9582(c)(5) based on information from industry and EPA's own research.

27. However, Inhance did not inform EPA during the LCPFAC rulemaking that it had produced LCPFACs during fluorination of plastic containers before January 2015 and was continuing to do so. The final rule contains no exemption for Inhance's activities and there is no mechanism in the rule for granting such an exemption after-the-fact.

28. In the final SNUR, EPA denied requests to establish an exemption for *de minimis* levels of LCPFACs (85 Fed. Reg. at 45120).

IV. FORMATION OF PFAS DURING FLUORINATION

29. Inhance recognizes that "an apparently unavoidable aspect of fluorination of HDPE containers" is the production of PFAS; Ex. 8, SNUN Attachment Number: 011 at A-209,

and "there is no easy solution to the problem of [PFAS] formation" [Ex. 8 at A-213]. Inhance admits that "[t]he fluorination of HDPE containers unintentionally forms small amounts of LCPFACs. This is the result of fluorination of carboxylic acids formed during the processing of HDPE during molding, prior to molding." [A-212]. A patent application filed by Inhance in 2019 reflects an understanding of the connection between the chemistry of fluorination and PFAS. [Ex. 29, United States Patent for Systems and Methods for Processing Fluoropolymer Materials and Related Workpieces at A-794].

30. As Inhance explains in the SNUNs:

> The fuel tank and fuel container manufacturing process involves the heating and then extrusion of HDPE resin in the presence of oxygen prior to shaping the HDPE into fuel tanks and fuel containers. This heating and extrusion causes some of the HDPE resin to break down into carboxylic acids and certain other lower-molecular weight species. The fluorination process exposes those carboxylic acids and other species, along with the HDPE itself, to fluorine gas (F2). The HDPE reacts with the fluorine to form a layer of fluoropolymer, which acts as the barrier needed to prevent permeation of fuel. At the same time, the carboxylic acids react with the fluorine also, unintentionally forming LCPFACs. Much of the LCPFACs remain in the barrier layer of the fuel tanks and fuel containers, but some amounts may be expected to migrate into the fuel contained in those tanks and containers over time.

[A-209, Ex 49, SNUN Attachment Number: 010 at A-1194].

31. Because F_2 is so reactive, it is not very selective in the chemical reactions it causes. During the fluorination of polyethylene, a small amount of chain scission occurs. Chain scission refers to the breaking of carbon – carbon bonds in the polymer chain. A likely reaction mechanism for this is where a chain is broken to form two segments, one with a double bond and one with a free radical. In the presence of oxygen (O_2) or water (H_2O), fluorine will react with the carbon chain radicals and double bonds to form perfluorinated carboxylic acid structures. [A-586-87].

32. Consistent with Inhance's analysis, since there are oxidation products on the surface of the polyethylene containers being fluorinated,[1] these will undergo fluorination and ultimately create perfluorocarboxylic acids. Examples of oxidation products that can be converted to perfluorinated carboxylic acids include alcohols, aldehydes, and carboxylic acids. In addition, the post-mold fluorination process itself is a source of oxygen, making it essentially impossible to eliminate O_2 and H_2O during fluorination of plastic containers. *Id.*

33. The chemical reactions in the post-mold fluorination process form a large number of short-chain and long-chain perfluorinated carboxylic acids (PFCAs). In addition to PFCAs, the post-mold process is likely to result in perfluoroalkanes, another type of PFAS. Molded polyethylene has very small concentrations of short-chain alkyl groups, primarily formed during the molding process, and these will be fluorinated along with the longer polymer chains. In addition, the highly exothermic fluorination reactions are expected to cause some amounts of chain scission, which will generate perfluoroalkanes. *Id.*

V. STUDIES DEMONSTRATING THE PRESENCE OF PFAS IN FLUORINATED CONTAINERS AND THEIR CONTENTS

34. Based on its own studies, Inhance has identified the following LCPFACs in its fluorinated containers and their contents:

[1] Syed Raihan Alam; "Revising The Mechanism of Polyolefin Degradation and Stabilization: Insights from Chemiluminescence, Volatiles and Extractables"; Ph.D. Thesis from Manchester Metropolitan University , 2019; *see also* Gugumus, F.; "Physico-chemical aspects of polyethylene processing in an open mixer, Part 27: Formal kinetics of aldehyde and carboxylic acid formation in the initial stages"; Polymer Degradation and Stability 92 (1) 2007: p. 125 – 142 *and* Ceretti, D.V.A.; Edeleva, M.; Cardon, L.; D'hooge, D.R.; " Molecular Pathways for Polymer Degradation during Conventional Processing, Additive Manufacturing, and Mechanical Recycling" Molecules (2023), 28 2344. P. 1 – 30

Table 1. Identified LCPFACs in HDPE containers

Compound Abbreviation	Compound Name	CAS Number	Number of Carbons	Species Number	Consolidated SNUN Number
PFOA	Perfluorooctanoic acid	335-67-1	8	1	1
PFNA	Perfluorononanoic acid	375-95-1	9	2	1
PFDA	Perfluorodecanoic acid	335-76-2	10	3	1
PFuDA	Perfluoroundecanoic acid	2058-94-8	11	4	1
PFDoA	Perfluorododecanoic acid	307-55-1	12	5	1
PFTrDA	Perfluorotridecanoic acid	72629-94-8	13	6	2
PFTeDA	Perfluorotetradecanoic acid	376-06-7	14	7	2
PFHxDA	Perfluorohexadecanoic acid	67905-19-5	16	8	2
PFODA	Perfluorostearic acid	16517-11-6	18	9	2

[Ex. 12, SNUN Attachment Number: 012 at A-252].

35. The declaration of CEH's Science Director, Dr. Jimena Diaz Leiva, reviews six studies examining the presence in fluorinated containers and their contents of perfluoroalkyl carboxylic acids (PFCAs), a subset of PFAS that includes LCPFACs and short-chain perfluoroalkyl carboxylates. Dr. Leiva's declaration summarizes the findings of these studies as follows:

> The evidence from the literature presented in this declaration demonstrates that Inhance Technologies' direct, post-mold fluorination process causes PFCAs to form in the surface layer of high-density polyethylene (HDPE) containers. These PFCAs have been found to leach into a variety of solvents, including methanol, water, and even food. The ability for PFCAs to leach into the contents of fluorinated containers constitutes an important exposure pathway for workers and consumers that come into contact with or consume products held in these containers.

[Ex. 7 at A-139-40].

36. As Dr. Leiva indicates, across the various studies, 13 PFCAs have been found in fluorinated containers and their contents, including 9 LCPFACs subject to EPA's SNUR and 4 short chain PFCAs. These substances are identified in Table 1:

Table 1. Perfluoroalkyl carboxylic acids (PFCAs) positively identified in extracts from post-mold fluorinated HDPE plastic containers by study. PFCAs ordered by carbon chain length.

PFAS Compound (C-chain length)	Eurofins (2023)	Whitehead and Peaslee (2023)	Vitale et al. (2022)	EPA (2022)	EPA (2021)	Rand and Mabury (2011)
TFA (C2)						X
PFPrA (C3)						X
PFBA (C4)	X	X	X	X	X	X
PFPeA (C5)	X	X	X	X	X	X
PFHxA (C6)	X	X	X	X	X	X
PFHpA (C7)	X	X	X	X	X	X
PFOA (C8)	X	X	X	X	X	X
PFNA (C9)	X	X	X	X	X	X
PFDA (C10)	X	X	X	X	X	X
PFUnDA (C11)	X	X	X	X	X	
PFDoDA (C12)		X	X			
PFTrDA (C13)		X	X			
PFTDA (C14)		X	X			
PFHxDA (C16)		X				
PFODA (C18)		X				

[A-153].

37. As Dr. Leiva notes, PFOA was consistently found in extracts and solvents in fluorinated containers at levels ranging from .13 ppb to 4.49 ppb. [A-153].

Table 2. Comparison of the concentrations of PFOA (ng/g plastic, ppb) found in extracts and solvents held within fluorinated HDPE containers reported across studies reviewed herein that listed specific analyte concentrations.

Solvent used for Leaching Experiment	Eurofins (2023)[1]	Whitehead and Peaslee (2023)[2]	Vitale et al. (2022)	EPA (2021)
Methanol (Extraction)		4.49		0.22 - 1.59**
Methanol	4.07 ± 0.96	< LOD	0.13 - 3.1*	
Water	<LOD	0.29		
Acetone	4.93 ± 0.50	3.64		
Olive Oil		< LOD		
Ketchup		<LOD		
Mayonnaise		1.4		

*Results reported as the range of PFOA concentrations for leaching experiments using methanol held in containers over a 4-week period.
** Results reported as the range of PFOA concentrations in methanol rinsate from different fluorinated HDPE containers.
1. Average concentrations of PFOA ± 1 standard deviation derived from three replicate results reported in Eurofins (2023). All leaching experiments were conducted over a 7-day period.
2. Average concentrations of PFOA derived from replicate results reported in Whitehead and Peaslee (2023). All leaching experiments were conducted over a 7-day period.

38. Dr. Leiva's declaration describes the findings of Rand and Mabury (2011) as follows:

> Rand and Mabury (2011) presented the first evidence in the peer-reviewed literature of the formation of PFCAs in directly fluorinated plastic containers. Studies from the EPA (2021, 2022), Vitale et al. (2022), and Whitehead and Peaslee (2023), build off of this work and provide further evidence of the potential for PFCAs to leach from directly fluorinated plastic containers into solvents and foodstuffs held in these containers. Rand and Mabury extracted PFCAs from directly fluorinated HDPE bottles treated with differing levels of fluorination. They compared their results to unfluorinated bottles, finding that the total concentration of PFCAs from fluorinated bottles increased with level of fluorination and was significantly higher than the levels in unfluorinated bottles. The authors note that,

> The amount of PFCAs formed on directly fluorinated HDPE is proportional to the amount of fluorination the HDPE receives, and presumably the amount of oxygen within the fluorination chamber… (p. 8057).

In the fluorinated bottles, the authors reported total PFCA concentrations in methanol extract ranging from 8.5 ± 0.53 ng/cm^2 in the least fluorinated bottles (Level 1) up to 113 ± 2.5 ng/cm^2 in the most fluorinated bottles (Level 5). Many of the PFCAs identified in the methanol extract were LCPFACs including PFOA, PFNA, and PFDA. These long-chain PFCAs were more common in the extracts from higher fluorination levels. After identifying and quantifying PFCAs in extract from fluorinated HDPE bottles, Rand and Mabury performed a one-year leaching experiment using water to show that these PFCAs migrate into solvents held in the bottles.

After one year, the total concentration of PFCAs in water held in fluorinated HDPE bottles (Level 3), exceeded the total concentration of PFCAs in methanol extracts from bottles treated with all levels of fluorination.

[A-140-41].

39. Dr. Leiva's declaration describes 2021 testing by EPA's Analytical Chemistry Branch as follows:

> On March 4, 2021, a decade after Rand and Mabury's (2011) seminal study, the US EPA released a memorandum describing their results from testing fluorinated HDPE containers. This testing followed reports of PFAS compounds detected in a mosquito pesticide held in a fluorinated HDPE container. The EPA tested fluorinated containers by rinsing them with methanol and then analyzing the rinsate for PFAS compounds. The agency tested both used and unused, fluorinated and non-fluorinated containers, and found that the rinsate from all fluorinated containers had detectable concentrations of PFAS, including PFOA and other PFCAs. In non-fluorinated containers, the agency found PFAS concentrations in the rinsate from the containers of 1 ppb or less. In fluorinated containers, the EPA found PFAS concentrations that ranged from 20-50 ppb in the rinsate. The agency found a greater number of PFAS compounds in the rinsate of the fluorinated containers. All of the compounds detected were PFCAs, with 5 of the 8 compounds being LCPFCAs. EPA's analysis of these results indicate that the agency believes that the fluorination process results in the formation of PFCAs. They state,
>
> > Based on the results of the rinsate samples as described above and the preliminary results of the product samples…the EPA believes that through the fluorination process of HDPE containers, PFAS compounds may be formed and then partly leach into the products inside the containers (p. 3).

A-143.

40. EPA reported additional test results in August 2022, which Dr. Leiva has summarized as follows:

> Through this additional testing, the Agency set out to determine whether PFAS compounds leached into different solvents held in fluorinated HDPE containers. EPA filled fluorinated and non-fluorinated containers with water and methanol and held these solvents in the containers for a 20-week period to determine whether PFAS would leach into the solvents from the container and whether longer residence times would lead to greater concentrations of PFAS. The agency analyzed an aliquot of the solvents held in these containers after 1 day, 1 week, 4 weeks, 10 weeks, and 20 weeks. The EPA detected PFAS compounds in both water and methanol at every interval but noted that the methanol contained higher concentrations of PFAS compared to water. Of the 31 PFAS compounds screened, the agency positively identified eight compounds in the leachate from fluorinated bottles. These eight compounds were all PFCAs, and five were LCPFCAs including PFOA.
>
> Importantly, the Agency noted that while the sum concentration of PFAS analyzed in the leachate from fluorinated containers varied amongst the three types of HDPE containers that they tested, in comparison to unfluorinated containers, the concentration of PFAS was elevated in all fluorinated containers. Moreover, EPA found that with increasing residence time, the sum concentration of PFAS in both solvents increased, indicating that PFAS continued to leach from the containers over time. For the containers holding water, the total PFAS concentration ranged from 0.016 ppb to 2.888 ppb whereas for the methanol the total PFAS concentration ranged from 0.977 to 14.720 ppb. The Agency's two memorandums are in agreement with the findings of Rand and Mabury (2011), showing that PFCAs leach from fluorinated containers into their contents and will continue to leach over time.

A-143-44.

41. Vitale et al. (2022) conducted a series of leaching experiments using fluorinated and non-fluorinated HDPE bottles. As Dr. Leiva describes the results:

> In accordance with the findings from Rand and Mabury (2011) and EPA (2022), Vitale et al. (2022) found that post-mold fluorinated HDPE bottles leached PFCAs at every interval during the 12-week study period. At each interval, PFCAs including PFOA, were detected in the methanol leachate. The most frequently detected PFCAs from the post-mold fluorinated leachate were those in the C5-C7 chain length. Consistent with the results from EPA (2022), the sum concentration of PFAS increased in the leachate with longer residence periods. After 12 weeks, the total PFAS concentration in the leachate from post-mold fluorinated bottles reached up to 9,700 ng/L or 9.7 ppb. The authors did not measure PFAS compounds above the limit of quantitation of any specific analyte in HDPE bottles treated with in-mold fluorination.

A-145.

42. Whitehead and Peaslee (2023) provided evidence of leaching of PFCAs from directly fluorinated HDPE containers into different solvents and foodstuffs that may be held in these types of containers. According to Dr. Leiva:

> Whitehead and Peaslee found that the sum of PFAS concentrations in fluorinated containers was greater than 200 times the concentrations in non-fluorinated containers. In fluorinated containers, the sum of PFAS concentrations was 63.75 ± 13.12 ng/g (ppb) plastic compared to 0.29 ± 0.30 ng/g (ppb) plastic in non-fluorinated containers. These data confirm that plastic containers subjected to direct, post-mold fluorination, contain high concentrations of PFAS chemicals. The authors identified 20 different PFAS chemicals including many short-chain carboxylic acids like PFBA and PFPeA, as well as 10 long-chain compounds including PFOA and PFNA. While these PFAS compounds were detected in the fluorinated plastic containers themselves, the authors also conducted numerous leaching experiments to determine whether these compounds migrated from the containers into solvents and foodstuffs.
>
> Whitehead and Peaslee (2023) present evidence of PFCA leaching from fluorinated containers into water, acetone, and methanol. After a seven-day leaching experiment, they found that each of these three solvents contained PFCAs, with the highest concentration of PFCAs found in methanol. The sum of PFAS concentrations that they measured in the solvents were comparable to the results obtained from the EPA (2022) studies. Finally, the authors conducted a leach test using common foods that might be stored in fluorinated containers such as olive oil, mayonnaise, and ketchup. The results of this experiment are perhaps most concerning for the uses of fluorinated containers that involve food contact. After seven days, PFAS were found in each of the three foodstuffs and in particular, short-chain PFCAs were found to have leached into all foods. In the olive oil, ketchup, and mayonnaise, the sum of PFAS concentrations were 2.66 ± 0.82, 5.95 ± 1.59, and 7.19 ± 3.39 ng/g (ppb), respectively. The sum of PFAS concentrations for these foodstuffs also exceeded the sum of PFAS concentrations that leached into water after seven days indicating that these foodstuffs acted as better solvents to pull out PFCAs from the fluorinated plastic containers.
>
> The authors used the sum of PFAS concentrations in foodstuffs to derive an estimated value for PFAS that would be consumed by an average weight adult, using guidance on serving sizes. They found that,
>
> > Using an estimated five servings per week and the average body weight of a North American adult (80.7 kg), the weekly intake of PFAS from these containers in just one food container would range between 0.77−2.68 ng/kg body weight per week (p. D).

A-146-47.

43. "More recently, fluorinated and non-fluorinated HDPE containers were sent by PEER to Eurofins Lancaster Laboratories Environment Testing, LLC - a third-party accredited analytical laboratory – to corroborate the results of Whitehead and Peaslee's study. Seven day leaching experiments were conducted with water, methanol, and acetone to determine whether PFCAs leached from fluorinated containers into the contents. Eight different PFCAs were detected in the leachate, including five LCPFCAs. The highest concentrations of PFCAs were detected in the acetone followed by the methanol solvent." A-149, 155-206.

44. Additional unpublished work by Whitehead (2023) evaluated whether in-mold fluorinated HDPE containers contained PFCAs by performing targeted analyte extracts of these containers. As summarized by Dr. Leiva, "[i]n line with the findings of Vitale et al. (2022), Whitehead found that none of the target analytes measured above their limit of quantitation in the extracts from in-mold fluorinated containers. Only one short-chain PFCA, perfluoro-heptanoic acid (PFHpA), was measured just above the limit of quantitation in this level 3 in-mold fluorinated container."A-148-49.[2]

45. Whitehead (2023) also measured the amount of PFAS that would leach from post mold fluorinated HDPE containers into indoor and outdoor home products. As Dr. Leiva summarized the results:

> [An] indoor carpet cleaner and an indoor/outdoor insecticide were found to contain PFCAs of the same chain length and identities as observed in the extraction of containers and solvent leaching experiments described in Whitehead and Peaslee (2023). The average sum of PFAS concentration in the indoor carpet cleaner was 20.7 ± 4.9 ng/g (ppb) plastic and was 6.9 ± 2.5 ng/g (ppb) plastic in the insecticide. Between the carpet cleaner and insecticide, Whitehead detected 13 different PFCAs, including 9 LCPFACs.

[2] In the in-mold process, fluorine is applied during the molding of the plastic into its container form.

Id.

46. Summarizing the various studies, Dr. Leiva underscored that combined PFAS levels in container leachate have consistently been in ppb levels as shown in Table 3:

Table 3. Sum of PFAS concentrations (ng/g plastic, ppb) reported in extracts and leachate from fluorinated HDPE bottles.

Sum of PFAS Concentration	Whitehead and Peaslee (2023)[1]	Vitale et al. (2022)[2]	EPA (2022)[3]	EPA (2021)[4]
Fluorinated bottle extracted with methanol	63.75 ± 13.12	N/A	N/A	20-50
Methanol	69.72 ± 7.75	9.7	0.977 - 14.720	N/A
Acetone	50.13 ± 4.41	N/A	N/A	N/A
Water	0.99 ± 0.46	N/A	0.016 - 2.888	N/A

1. Results reported as the average sum of PFAS concentrations ± 1 standard deviation. Methanol, water, and acetone were used in 7-day leaching experiments.
2. Results reported as the maximum sum of PFAS concentration measured in methanol held in post-mold fluorinated containers for 4 weeks.
3. Results reported as the range of sum of PFAS concentrations measured during a 20-week leaching experiment using water and methanol held in fluorinated HDPE containers.
4. Results reported as the range of sum of PFAS concentrations measured in methanol rinsate from fluorinated HDPE containers.

[A-154].

47. Looking at the data as a whole, Dr. Leiva found that "[t]here is a high level of concurrence amongst the results from these studies. For PFOA, the concentrations of this analyte measured in extracts from fluorinated HDPE containers and in different solvents held in these containers, are all comparable across studies where specific analyte concentrations are reported. [A-153]. Moreover, the evidence from these studies indicates that hazardous PFCAs are readily able to leach from HDPE containers into their contents.

Chemically and materially distinct solvents like methanol, acetone, and water, as well as household products and foodstuffs like insecticides, carpet cleaners, and mayonnaise, have all been shown to contain PFCAs from fluorinated containers. Adding to the risk of exposure for consumers, over time, the concentration of PFCAs in the contents of these containers increases due to continual leaching from the containers." A-150.

48. The SNUNs also describe testing conducted by Inhance to determine concentrations of LCPFACs in small engine fluorinated fuel tanks and the fuels they contain. In addition to finding high LCPFAC levels in tank materials, Inhance found substantial concentrations of LCPFAC leaching to the fuel itself, with the exact amount depending on the level of fluorination (high, medium and low) used to treat the tank. Thus, for tanks receiving high levels of fluorination, combined LCPFAC levels in fuel totaled 138 ug/L, as shown below:

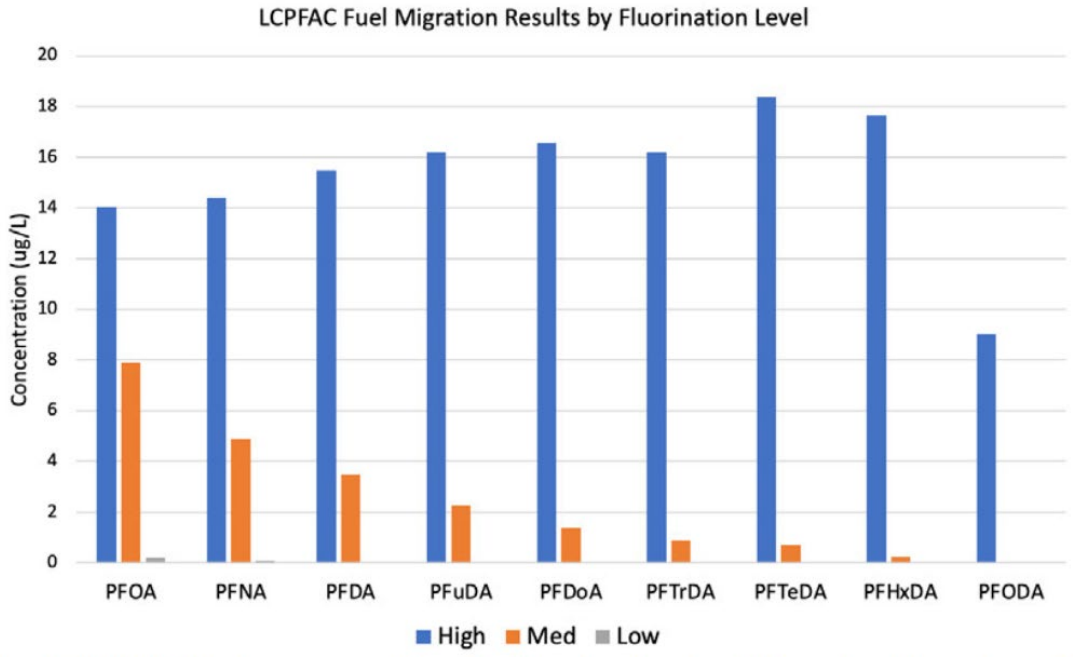

Figure 4. LCPFAC fuel concentrations by fluorination level from land-based small combustion engine fuel tanks

A-404.

VI. EPA ACTIONS ON INHANCE AND FLUORINATED CONTAINERS DURING 2020-2022

49. Between August and October 20, 2020, 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 subject to the LCPFAC SNUR. Government Complaint ("Gov Com") (ECF 3) at ¶ 33.

50. In December 2020, the EPA received unused fluorinated HDPE containers from the distributor of Anvil 10+10®. Govt Com at ¶ 34.

51. EPA tested these HDPE containers and detected several PFAS subject to the SNUR in the rinsates (a solvent used to extract chemical compounds). *Id.* at ¶35.,

52. On January 14. 2021, EPA issued a press release "making new information available about EPA testing that shows PFAS contamination from fluorinated containers." [Ex. 22, EPA Takes Action to Investigate PFAS Contamination at A-691]. The Agency emphasized that it "considers any level of PFAS to be potentially toxicologically significant." A-701.

53. On January 14, 2021, EPA issued a subpoena to Inhance pursuant to Section 11(c) of TSCA, 15 U.S.C. § 2610(c), to obtain information concerning Inhance's fluorination processes. Govt Com at ¶ 37; [A-1204]

54. On February 1 and 8, 2021, Inhance responded to EPA's subpoena. Govt Com ¶ 38; [A-1201].

55. Based on Inhance's response to the subpoena, "EPA determined that Inhance's processes for fluorinating containers results in the manufacturing for a significant new use of PFAS subject to the Long-Chain PFAS Rule because PFAS are produced as byproducts of the fluorination process." Govt Com at ¶ 39.

56. On February 10, 2021, as part of EPA's outreach to state officials on Anvil 10+10®, the Acting Director of EPA's Office of Pesticide Programs wrote to the Texas Commission on Environmental Quality that "[b]ecause multiple products might be using fluorinated containers, including not just for pesticides, the chances are high that there are other products in fluorinated HDPE containers that might contain PFAS chemicals." [Ex. 50, Correspondence between Acting Director of EPA's Office of Pesticide Programs and the Texas Commission on Environmental Quality at A-1211].

57. 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." [Ex. 23, EPA Website Per- and Polyfluoroalkyl Substances (PFAS) in Pesticide and Other Packaging at A-706]. EPA committed to "use all available regulatory and non-regulatory tools to determine the scope of this emerging issue and its potential impact on human health and the environment." [A-707]. The Agency noted that on January 13, 2021, it had "asked states with existing stock of the mosquito product distributed in fluorinated HDPE containers to discontinue use and hold that inventory until its final disposition is determined" and was "encouraging the pesticide industry to explore alternative packaging options, like steel drums or non-fluorinated HDPE." [Ex. 24, EPA Releases Testing Data Showing PFAS Contamination from Fluorinated Containers at A-717-18].

58. Despite the EPA and PEER testing and the Agency's subpoena, Inhance maintained that "we have been, and continue to be, in full compliance with all relevant regulations and regulatory guidance, and are operating safely, responsibly and lawfully." [Ex. 25, Inhance Technologies Statement on Regulatory Compliance at A-724].

59. At a meeting with EPA on September 8. 2021, Inhance minimized the results of the Agency's testing by maintaining that nearly all the PFAS found in the Anvil 10+10 pesticide were "not attributable to fluorinated barrier packaging" and that, "under actual conditions of use, PFAS levels attributable to Anvil 10+10 in fluorinated packaging will be insignificant, and likely unmeasurable." [Ex. 26, Inhance Presentation to EPA at A-735, 738].

60. On March 1, 2022, EPA issued a Notice of Violation ("NOV") to Inhance determining that its process for fluorinating HDPE containers produces PFAS subject to the SNUR and that Inhance's manufacturing or processing of such PFAS is a violation of the SNUR. Govt Com at ¶ 40.

61. The NOV requested any information on any changes Inhance may have made to its fluorination process and any information that would confirm that any such changes eliminated the manufacture of PFAS subject to the SNUR. *Id.* at ¶ 41.

62. The NOV further stated that if Inhance had not changed its process for fluorinating HDPE containers to prevent the manufacture of long-chain PFAS substances, Inhance must immediately cease the manufacture of PFAS subject to the Long-Chain PFAS Rule and may not resume manufacture until it has submitted SNUNs and the EPA issues a determination on that SNUN. *Id.* ¶ Two weeks later, on March 16, 2022, EPA published an open letter to industry stating that it "determined via testing that certain per- and polyfluoroalkyl substances (PFAS) have formed and migrated from these fluorinated polyolefins." [Ex. 27, EPA Open Letter to Industry A-742]. 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" because "their formation during "the fluorination of polyolefins

[would] be a significant new use under TSCA." [A-743]. In the event SNUNs are filed for PFAS subject to the SNUR, EPA advised, "[e]ntities may not commence manufacturing (including import) or processing for the significant new use 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." *Id.* As a result, "[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." [Ex. 46, EPA Continues to take Actions to Address PFAS in Commerce at A-1181].

63. On March 21, 2022, Inhance issued a press release stating that it "is pleased to announce that its Enkase barrier technology does not impart long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances to high-density polyethylene (HDPE) packaging." [Ex. 28, Inhance Technologies Announces its Enkase Technology Does not Impart LCPFACs to HDPE Packaging at A-745]. Inhance cited testing (which it did not release to the public) purportedly documenting the absence of LCPFACs but did not mention EPA's own testing showing the opposite or the NOV it had received from EPA three weeks earlier.

64. Between April and August 2022, EPA reviewed additional information submitted by Inhance and again determined that Inhance's fluorination of fuel tanks and containers constituted manufacture of PFAS subject to the SNUR. Govt Com ¶ 43.

65. In August 2022, EPA determined that the information Inhance provided on its fluorination processes was inadequate to support a determination that the process does not result in the manufacture of PFAS subject to the LCPFAC SNUR. Govt Comp. ¶ 44.

66. On September 8, 2022, EPA announced release of the report of a new round of testing on fluorinated containers which found that "[w]ater 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." [Ex. 30, EPA Releases Data on Leaching of PFAS in Fluorinated Packaging at A-771]. Based on these results, 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. In addition, the total amount of PFAS leached into the products could increase over storage time and cause undisclosed levels of PFAS in a pesticide (or other) product." *Id.*

67. Emphasizing that "EPA considers any level of PFAS to be potentially toxicologically significant," the September 8, 2022 announcement reiterated that "the manufacturing of certain PFAS from the fluorination of polyolefins [is] subject" to the 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." [A-772]. It underscored that the "failure to submit such a notification would be a violation of TSCA" and that "[i]f companies find PFAS in their products, they should notify EPA and take action to remove contaminated products." *Id.*

68. On September 7, 2022, the day before EPA's announcement, Inhance informed the Agency that it intended to submit SNUNs for LCPFACs formed during fluorination that were subject to the SNUR but would not cease producing these PFAS during the fluorination process before filing the SNUNs or while EPA was reviewing them. Govt Com at ¶ 45.

69. In a Webinar on sustainable packaging technology the same month, Inhance stated that its "Enkase barrier technology does not impart long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances to HPDE, as confirmed by independent testing" and that it was "not sure where EPA thinks it's seeing perfluorinated species but it's not from Inhance."[3] [Ex. 31, Inhance Webinar at A-779].

VII. INHANCE'S SUBMISSION OF SNUNS UNDER THE SNUR

70. On December 30, 2022, EPA received from Inhance nine consolidated SNUNs on LCPFACs subject to the SNUR.

71. EPA announced receipt of these SNUNs on February 17, 2023 (88 Fed. Reg. 10320) and solicited public comments.

72. The Agency received nine additional SNUNs relating to fuel tank uses of fluorinated containers on March 7-8, 2023. 88 Fed. Reg. 24416 (April 20, 2023).

73. According to a March 17, 2023 letter from an Inhance representative to EPA, the initial and additional SNUNs under review and the nine LCPFACs they cover are as follows:

Species #	Compound Abbreviation	CAS Number	Fuel Uses	Consolidated groupings		Container Uses
1	PFOA	335-67-1	SN-23-0002	Fuel SNUNs 1	Container SNUNs 1	SN-23-0017
2	PFNA	375-95-1	SN-23-0003			SN-23-0018
3	PFDA	335-76-2	SN-23-0004			SN-23-0019
4	PFuDA	2058-94-8	SN-23-0005			SN-23-0020
5	PFDoA	307-55-1	SN-23-0006			SN-23-0021
6	PFtrDA	72629-94-8	SN-23-0013	Fuel SNUNs 2	Container SNUNs 2	SN-23-0008
7	PFteDA	376-06-7	SN-23-0014			SN-23-0009
8	PFHxDA	67905-19-5	SN-23-0015			SN-23-0010
9	PFODA	16517-11-6	SN-23-0016			SN-23-0011

[3] The quote "not sure where EPA thinks it's seeing perfluorinated species but it's not from Inhance." was stated orally during the webinar and has been transcribed here.

[Ex. 32, Letter from Inhance Consultant to EPA at A-781].

VIII. PUBLIC HEALTH IMPACTS OF PFAS IN FLUORINATED CONTAINERS AND THEIR CONTENTS

Urgency of the PFAS Threat

74. EPA has recognized that PFAS pose a serious threat to all Americans:

> Harmful per- and poly-fluoroalkyl substances (PFAS) are an urgent public health and environmental issue facing communities across the United States. PFAS have been manufactured and used in a variety of industries in the United States and around the globe since the 1940s, and they are still being used today. Because of the duration and breadth of use, PFAS can be found in surface water, groundwater, soil, and air—from remote rural areas to densely-populated urban centers. A growing body of scientific evidence shows that exposure at certain levels to specific PFAS can adversely impact human health and other living things. Despite these concerns, PFAS are still used in a wide range of consumer products and industrial applications.

[Ex. 34, EPA PFAS Action Plan at A-790].

75. As EPA has explained, "[d]ue to their strong carbon-fluorine bonds, many PFAS can be very persistent in the environment with degradation periods of years, decades, or longer under natural conditions." [A-825]. Often called "forever chemicals," the "chemical structures of some PFAS cause them to repel water as well as oil, remain chemically and thermally stable, and exhibit surfactant properties, . . . making them resistant to hydrolysis, photolysis, microbial degradation, and metabolism. These properties are what make . . . some PFAS extremely persistent in the human body and the environment." *EPA PFAS National Primary Drinking Water Regulation Rulemaking,* 88 Fed. Reg. 18638, 18643 (March 29, 2023) (citations omitted).

76. EPA has determined that people may be exposed to PFAS "through certain consumer products such as textiles (*e.g.,* seat covers, sail covers, weather protection, leather shoes as well as shoe polish/wax, along with cooking/baking wares), occupational contact,

and/or by consuming food and drinking water that contain PFAS. Due to their widespread use, physicochemical properties, and prolonged persistence, many PFAS co-occur in exposure media (*e.g.,* air, water, ice, sediment), and bioaccumulate in tissues and blood of aquatic as well as terrestrial organisms, including humans." 88 Fed. Reg. at 18642.

77. 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. 88 Fed. Reg. at 18643.

78. PFAS are associated with "significant and diverse" "adverse health effects," that "include (but are not limited to): cancer and effects on the liver (*e.g.,* liver cell death), growth and development (*e.g.,* low birth weight), hormone levels, kidney, immune system, lipid levels (*e.g.,* high cholesterol), the nervous system, and reproduction." *Id.*

Health and Environmental Concerns Supporting the LCPFAC SNUR

79. The July 2020 SNUR applies to a class of PFAS that two decades ago were recognized by EPA and industry as presenting serious health and environmental concerns that warranted elimination of manufacture and use. In the early 2000s, one member of this class -- PFOA – was implicated in large-scale contamination of drinking water near a DuPont facility in West Virginia. [Ex. 35, Dupont PFOA Study A-884-86]. Follow-up studies funded by the company as part of a legal settlement demonstrated links to a host of health problems in the exposed population.[4]

[4] Emmett, E. A. *et al.* Community exposure to perfluorooctanoate: relationships between serum levels and certain health parameters. *J Occup Environ Med* 48, 771-779, doi:10.1097/01.jom.0000233380.13087.37 (2006). Nolan, L. A., Nolan, J. M., Shofer, F. S., Rodway, N. V. & Emmett, E. A. The relationship between birth weight, gestational age and perfluorooctanoic acid (PFOA)-contaminated public drinking water. *Reprod Toxicol* 27, 231-238, doi:10.1016/j.reprotox.2008.11.001 (2009).

80. Against this backdrop, at EPA's urging, in 2006, the principal manufacturers and processors of PFOA and other LCPFACs 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.

81. The LCPFAC SNUR proposed in 2015 was prompted by EPA's concern that "commencement of manufacture or processing for any new uses, including resumption of past uses, of LCPFAC . . . substances could increase the magnitude and duration of exposure to humans and the environment." *Id.* As a result of the restrictions imposed by the SNUR, "EPA expect[ed] the presence of LCPFAC substances in humans and the environment to decline over time as has been observed in the past when production and use of persistent chemicals have ceased." *Id.*

82. 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." *Id.*

83. 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.*

Determination of PFOA and PFNA Health Risks in EPA's Proposed NPDWR

84. The National Primary Drinking Water Regulations ("NPDWRs") proposed by EPA on March 29, 2023 under the Safe Drinking Water Act ("SDWA") apply to two LCPFACs, PFOA and perfluorononanoic acid ("PFNA"). 88 Fed. Reg. 18638 These substances are subject to the 2020 SNUR and have been measured in fluorinated containers and their contents. *See* ¶ 76 above.

85. As defined by SDWA, a health-based Maximum Contaminant Level Goals ("MCLG") is the "maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety." A Maximum Contaminant Level ("MCL") is "the maximum level allowed of a contaminant or a group of contaminants (*i.e.,* mixture of contaminants) in water which is delivered to any user of a public water system." The SDWA generally requires EPA to set an MCL "as close as feasible to" the MCLG. 88 Fed. Reg. 18639.

86. To determine the MCLG for PFOA, EPA's NPDWR examines both cancer and non-cancer health effects, drawing on previous toxicity assessments peer reviewed by EPA's Science Advisory Board ("SAB").

87. For carcinogenicity, EPA "determined that PFOA is *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals and has also determined that a linear default extrapolation approach is appropriate as there is no evidence demonstrating a threshold level of exposure below which there is no

appreciable cancer risk (USEPA, 2005) and therefore, it is assumed that there is no known threshold for carcinogenicity." 88 Fed. Reg. at 18660. Accordingly, "[b]ased upon a consideration of the best available peer reviewed science and a consideration of an adequate margin of safety, EPA proposes a MCLG of zero for PFOA in drinking water." *Id.*

88. 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.

89. As summarized in the report of Dr. Drake Phelps and Professor Jamie DeWitt, 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 at 3×10^{-8} mg/kg/day, equivalent to 0.03 ng/kg/day." [Ex. 6 at A-63]. 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.

90. In its proposal, EPA "determined that 4.0 ppt is the lowest concentration that PFOA . . . can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions." On this basis, it proposed 4.0 ppt as the MCL for PFOA on the ground that it was the concentration as "close as feasible to the MCLG" of zero. 88 Fed. Reg. at 18666-8. By comparison, as Dr. Leiva notes in her declaration, PFOA was consistently

found in extracts and solvents in fluorinated containers at significantly higher levels ranging from .13 ppb to 4.49 ppb. [A-153].

91. EPA's proposal also reviewed the adverse health effects of PFNA, concluding that "[a]nimal toxicity studies have reported adverse health effects, specifically on development, reproduction, immune function, and the liver, after oral exposure to PFNA." 88 Fed. Reg. at 18646. The report of Dr. Drake Phelps and Professor Jamie DeWitt provides more details on the reported studies, highlighting the following adverse effects:

- Reproductive and developmental toxicity, including increased odds of endometriosis, decreased sperm quality, early onset puberty in females, delayed puberty in males, decreased birth weight and/or birth length;
- Immunotoxicity, including increased odds of allergic disease and asthma, increased autoimmune-related antibodies, decreased antibody titers, and increased risk of certain infections;
- Hepatotoxicity, including higher alanine transaminase (ALT) levels, a marker of liver injury;
- Endocrine disruption, including altered levels of testosterone and thyroid hormones;
- Metabolic disorders, including decreased bone parameters and an increased marker of gestational diabetes;
- Neurotoxicity, including decreased personal-social skills and impaired neurodevelopment;
- Cardiovascular toxicity, including increased total cholesterol and low-density lipoprotein, increased odds of heart attack and coronary heart disease, increased blood pressure, and decreased pulmonary function in asthmatic patients.

[A-56 (footnotes omitted)].

92. As explained by Drs. Phelps and DeWitt, based on developmental toxicity in rodents, EPA derived a health-based water concentration for PFNA of 0.00001 mg/L or 10 ppt. [A-64].

93. In the Whitehead and Peaslee study, PFNA was measured at concentrations up to 3.61 ng/g in fluorinated HDPE containers, equivalent to 3.61 ppb or 3,610 ppt. In one gram of fluorinated HDPE, accordingly, there is more than 360 times the acceptable level of PFNA, according to EPA's calculations. *Id.*

Health Effects of Other LCPFACs Found in Fluorinated Containers and their Contents

94. The report of Dr. Phelps and Professor DeWitt also reviews the literature on the reported health effects of the other 7 LCPFACs found in the fluorinated containers and their contents. [A-57-63].

95. As described in the Phelps/DeWitt report, the health effects linked to the seven LCPFACs are as follows:

PFDA

- Immunotoxicity, including increased odds of allergic disease, increased autoimmune-related antibodies, decreased antibody titers[12,13,37], and increased risk of certain infections
- Reproductive and developmental toxicity, including decreased sperm quality, decreased birth weight and/or length[18,30], early onset of puberty in females, and delayed puberty in males
- Endocrine disruption, including decreased anogenital distance and testosterone levels in males, altered thyroid hormones, and increased aromatase levels in placentas of prenatally exposed infants
- Neurotoxicity, including decreased personal-social skills
- Cardiovascular toxicity, including increased odds of coronary heart disease
- Metabolic disorders, including an increased marker of gestational diabetes

PFUnDA

- Metabolic disorders, including an increased marker of gestational diabetes
- Immunotoxicity, including increased odds of allergic disease, decreased antibody titers, and increased risk of certain infections
- Reproductive toxicity, including decreased sperm quality
- Endocrine disruption, including decreased anogenital distance in males, increased testosterone, decreased follicle stimulating hormone in females, and altered thyroid hormones
- Cardiovascular toxicity, including increased odds of coronary heart disease and angina pectoris

PFDoDA

- Endocrine disruption, including increased anogenital distance, decreased testosterone in females, and altered thyroid hormones
- Immunotoxicity, including increased odds of allergic disease, decreased antibody titers, and increased risk of certain infections
- Cardiovascular toxicity, including increased odds of congestive heart failure and angina pectoris

- Metabolic disorders, including an increased marker of gestational diabetes

  PFTrDA

- Endocrine disruption, including increased anogenital distance and altered thyroid hormone levels
- Immunotoxicity, including increased odds of allergic disease and asthma
- Developmental toxicity, including decreased birth weight for females

  PFTeDA

- cardiovascular toxicity, including increased cholesterol and increased low-density lipoprotein (LDL).

  PFHxDA/PFODA

- Limited data available.

[A-57-63].

96. As explained by Dr. Phelps and Professor DeWitt, since the toxicity profiles of these LCPFACs are essentially identical to those of PFOA and PFNA, a prudent and health-protective approach is to treat them as a class, with a common mode of toxicity and the same health effects as PFOA. [A-66].

Health Effects of Short-Chain PFCAs Co-occurring in Fluorinated Containers

97. As described in Dr. Diaz Leiva's declaration, four short-chain PFCAs were consistently detected in fluorinated containers in addition to the nine LCPFACs subject to the EPA SNUR: perfluorobutanoic acid ("PFBA"), perfluoropentanoic acid ("PFPeA"), perfluorohexanoic acid ("PFHxA") and perfluoroheptanoic acid ("PFHpA"). [A-152].

98. As discussed in the report of Dr. DeWitt and Dr. Phelps, these short-chain PFCAs have caused many of the same health effects as the LCPFACs. For example, it has been reported that PFBA and PFHxA are equally potent to PFOA for hepatoxicity in rodents. [A-68]. Drs. DeWitt and Phelps emphasize that, "[w]hile not covered under the SNURs in this case, the

presence of these compounds [in fluorinated containers] may also prove problematic in terms of their individual toxicity and their toxicity as part of a PFAS mixture." *Id*. They recommend basing a health-protective risk assessment for PFCAs formed during fluorination on the combined health effects of the nine LCPFACs and the four short-chain PFCAs. *Id.*

Use of Dose Additivity to Determine MCLGs for Chemicals with Similar Observed Effects

99. For PFNA and three other PFAS, the drinking water proposal sets MCLGs and MCLs based on a Hazard Index (HI) methodology that accounts for their combined health effects when they co-occur as a mixture in drinking water. As EPA explains: "Studies with PFAS and other classes of chemicals support the health protective assumption that a mixture of chemicals with similar observed effects should be assumed to also act in a dose additive manner unless data demonstrate otherwise (USEPA, 2023d). Dose additivity means that each of the component chemicals in the mixture (in this case, PFHxS, HFPO–DA, PFNA, and PFBS) behaves as a concentration or dilution of every other chemical in the mixture differing only in relative toxicity." 88 Fed. Reg. at 18647.

100. According to the proposal, "EPA's SAB opined that where the health effects of the chosen compounds are similar, 'the HI methodology is a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media. The HI is an approach based on dose additivity (DA) that has been validated and used by EPA.' (USEPA, 2022a). This proposal is based on the Agency's finding that the general HI approach is the most efficient and effective approach for establishing an MCLG for PFAS mixtures." 88 Fed. Reg. at 18654. EPA elaborated that an assumption of additivity "provides the most health protective endpoint for multiple PFAS in a mixture to ensure there would be no known or anticipated adverse effects on the health of persons." *Id.* EPA further emphasized that

"[i]f the Agency only established an individual MCLG, the Agency would not provide any protection against dose-additivity from regulated co-occurring PFAS." 88 Fed. Reg. at 18655.

101. As Dr. Phelps and Professor DeWitt concluded, a dose-additivity approach is justified for the nine LCPFACs found in fluorinated containers and their contents because they are similar in chemical structure, exhibit similar adverse effects in human and animal studies, and co-occur during fluorination and the use of fluorinated containers, resulting in simultaneous exposure to all nine substances by workers and consumers who come in contact with these containers. [A-65-67]. By contrast, comparing toxicity values for each individual LCPFAC to its levels in containers in isolation would greatly understate health risks by failing to consider the additive toxicities of multiple LCPFACs to which container users are exposed. *Id.*

102. Drs. DeWitt and Phelps provide an illustration to put in perspective the level of risk from combined exposure to the 13 long- and short-chain carboxylates formed during fluorination of HPDE containers. Total PFCA levels measured in container contents by Whitehead and Peaslee ranged from 0.47 ppb to 94.81 ppb. If PFOA is used as a surrogate to represent all PFCAs in HDPE, the total sum of all PFAS exceeds the RfD for PFOA used by the EPA to derive the proposed MCL *by more than 15,000 – 3,000,000 fold on a ng/g (ppb) basis.* [A-67].

Comparison between LCPFAC Levels in Fluorinated Containers and Blood Levels Associated with Adverse Effects in Human Studies

103. In the DeWitt/Phelps report, "data from Whitehead and Peaslee were compared to data published in scientific literature reporting statistically significant adverse health outcomes in human populations." [A-53]. In this analysis, "the minimum and maximum concentrations for each PFAS were identified from the Whitehead and Peaslee dataset . . . to establish a range of concentrations to which humans may be exposed." *Id.* These concentrations "were then compared to the published human epidemiological studies where statistically significant adverse

health outcomes were observed and reported in association with each of the nine PFAS in question. As done with the data from the Whitehead and Peaslee report, the minimum and maximum serum concentrations were used to establish a range of serum concentrations for each human epidemiological report. To compare between the Whitehead and Peaslee data and human serum concentrations, the concentrations were converted to parts per billion (ppb)." A-54. (Footnotes omitted)

104. The literature review conducted by DeWitt/Phelps identified six LCPFACs for which human studies were available that reported statistically significant adverse health effects and associated levels of the LCPFAC in human blood (serum): PFOA, PFNA, PFDA, PFUnDA, PFDoDA and PFTrDA. In each case, for each of these endpoints, "adverse health outcomes were observed at serum concentrations that overlap with or are exceeded by the range of concentrations reported for . . . fluorinated HDPE by Whitehead and Peaslee." [A-55, 57-60]

IX. WORKER AND COINSUMER EXPOSURE PATHWAYS FOR LCPFACS AND OTHER PFAS IN FLUORINATED CONTAINERS AND THEIR CONTENTS

105. The Inhance SNUNs provide the following overview of exposure pathways throughout the fluorinated container life-cycle:

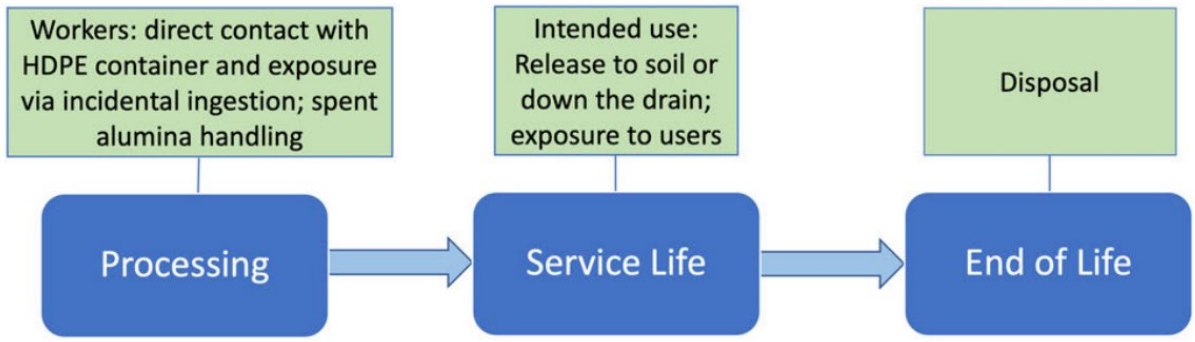

Figure 1 Conceptual exposure model throughout life cycle

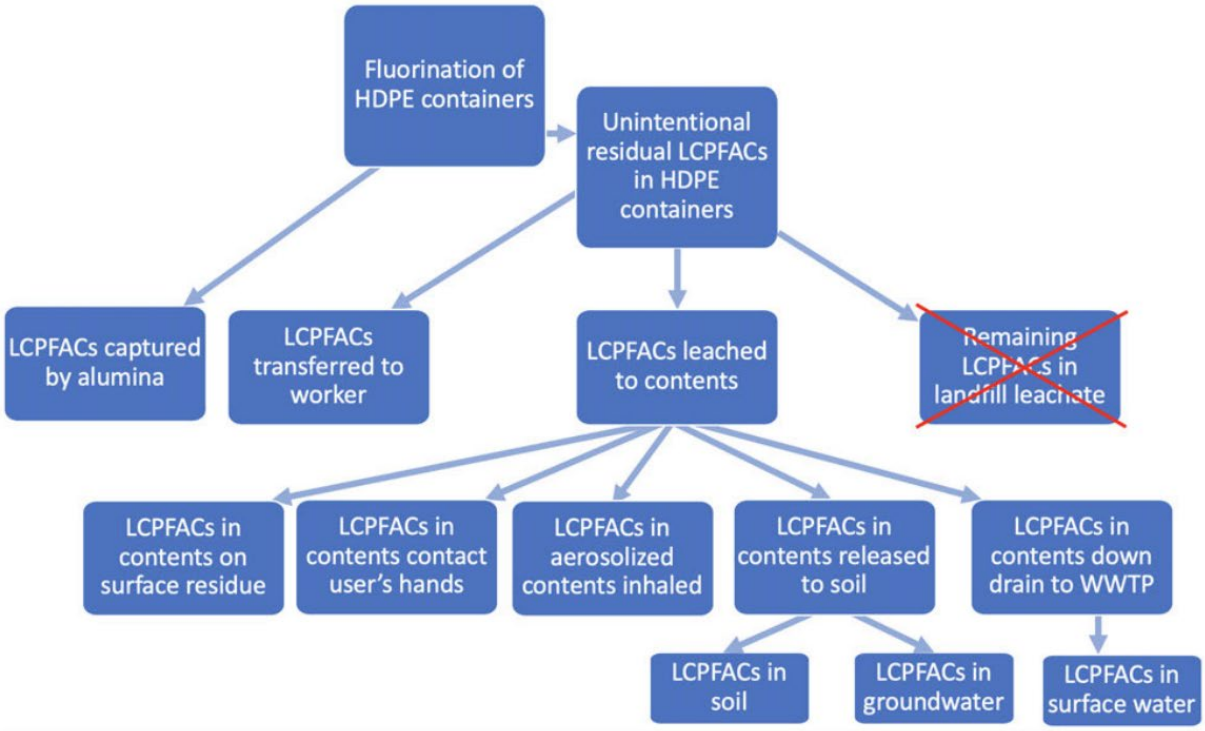

Figure 2 Exposure scenarios modeled by mass balance on HDPE container unit basis

[A-258].

106. The SNUNs also describe the pathways of exposure of a number of specific products packaged in fluorinated containers. An example is this exposure model for fluorinated floor products:

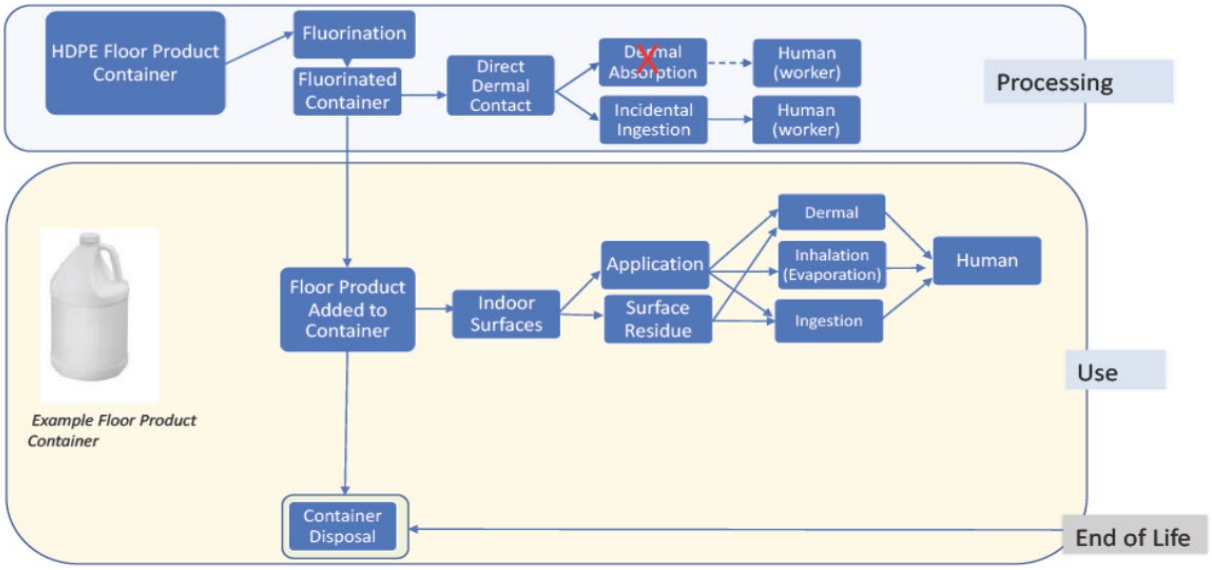

Figure 4. Conceptual exposure model for fluorinated HDPE container used for floor products

[A-286]

Another example shows fluorinated containers used for indoor spray products:

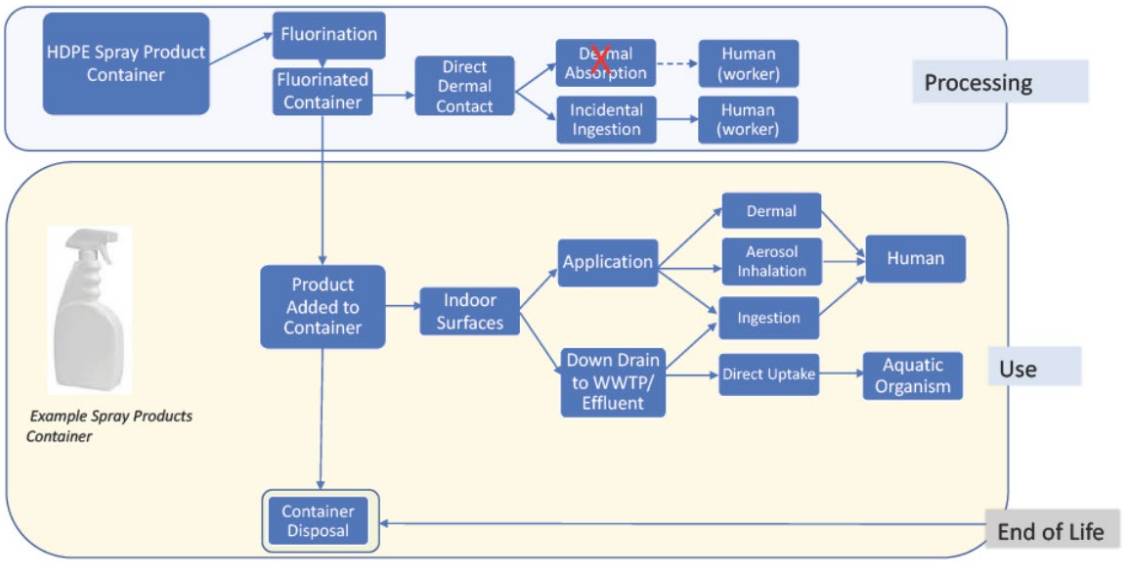

Figure 3. Conceptual exposure model for fluorinated HDPE container used for indoor spray products

[A-280]

107. As described in the SNUNs, other household applications for fluorinated containers have similar exposure profiles. These include products used for cleaning or degreasing surfaces inside the home, such as household trigger-spray bathroom and kitchen cleaners; liquid concentrate or spray products used to seal, deodorize, or degrease carpet, hardwood, and other types of indoor flooring; products that require direct hand contact with an applicator, such as single-use furniture wipes and furniture or countertop polish or color restorer applied with a microfiber cloth or mitt; and products applied at the end of a hose, such as pesticides and herbicides applied to lawns and gardens. [A-257].

108. The Inhance SNUNs depict opportunities for LCPFAC exposure during the life-cycle of fluorinated fuel tanks as follows:

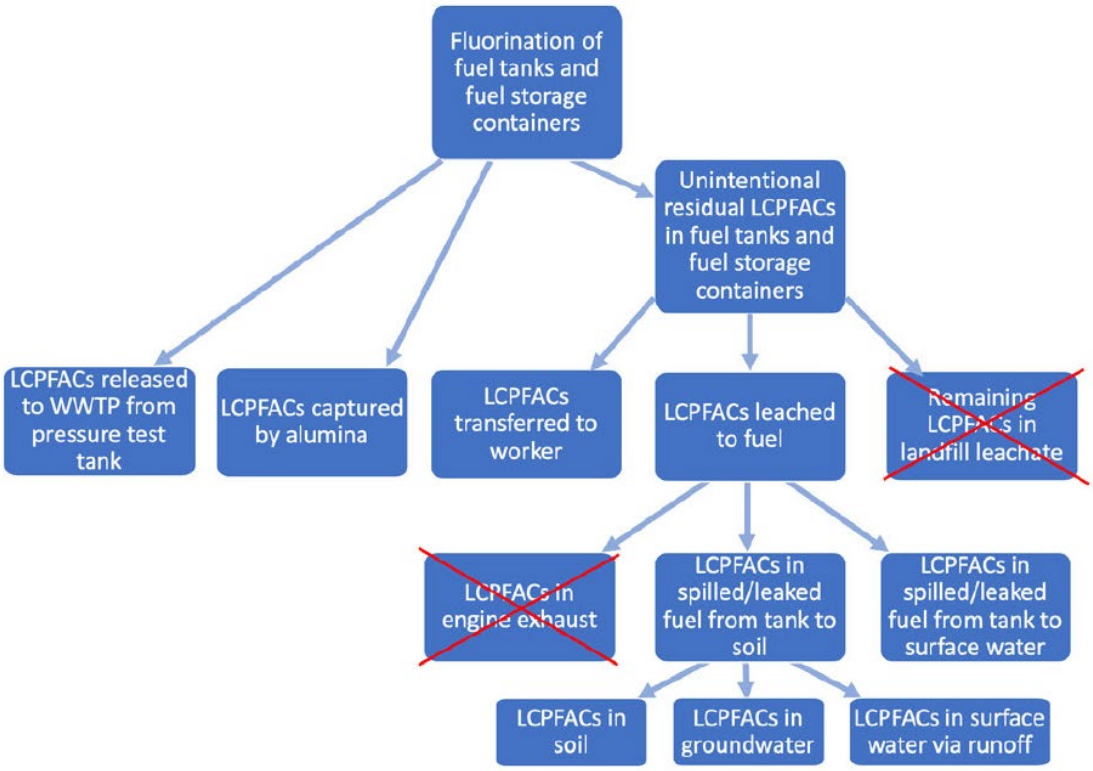

Figure 3 Exposure scenarios modeled by mass balance on a fuel tank and fuel storage container unit basis

[A-258].

109. Worker and consumer subpopulations exposed to PFCA formed during fluorination include:

- Workers directly engaged in fluorination at Inhance's 11 U.S. treatment facilities or exposed to LCPFACs during equipment cleanup and maintenance and handling of fluorinated containers;
- Fenceline communities, including environmental justice communities, living near Inhance's 11 facilities exposed to airborne PFAS and PFAS in the wastewater coming out of these facilities;
- Inhance workers who ship fluorinated containers to distributors or packaging sites;
- Workers at packaging sites who fill fluorinated containers with liquid or solid products and prepare them for shipment to downstream users;
- Workers at end-use sites who handle fluorinated containers and access their contents during commercial or industrial tasks;
- Workers in container recycling and disposal operations;
- Consumers who purchase or otherwise use fluorinated containers in residences or commercial establishments and may be exposed to PFAS when handling or discarding containers and their contents;
- People living near farms or pesticide applicators who are spraying pesticides from fluorinated containers;
- People living near landfills where fluorinated containers are disposed, given that the PFAS will end up in the landfill leachate and subsequently in the groundwater; and
- People with private wells near a landfill with fluorinated containers, a recycling facility, or people who drink water from a source where Inhance is discharging to a wastewater treatment plant (WWTP).

[A-612-13].

110. As Drs. Phelps and DeWitt emphasize, "[t]he ubiquity of PFAS in the environment leads to exposure via ingestion, dermal absorption, and inhalation concurrently." [A-70].

111. The description in the SNUNs of exposure pathways for various fluorinated products indicate that skin contact with containers and their contacts is a common and frequent occurrence for workers and consumers who handle or use these products. [A-256-59, A-261-72, A-280, A-286-91, A-297, A-302, A-415, A-428].

112. Data from a 2012 study "suggest that PFOA is dermally absorbed and that under certain conditions the skin may be a significant route of exposure." [A-614]. EPA's SAB recently concluded that "[e]vidence that PFOA is absorbed following dermal exposure remains unchanged since 2005, with in vitro percutaneous absorption studies of PFOA through rat and human skin allowing calculation of permeability coefficients for PFOA in rat skin to be 3.25 × 10−5 cm/hr, and that of human skin to be 9.49 × 10−7 cm/hr (Fasano et al., 2005)." [Ex. 36, EPA SAB Report at A-892]. As emphasized by Drs. Phelps and DeWitt, "[t]hese data underscore that dermal absorption of PFAS – long- and short-chain – occurs and can induce adverse health outcomes." [A-69].

113. As the SNUNs recognize, solvents, fuels and oily mixtures packaged in fluorinated containers are known to penetrate skin and PFOA and other LCPFACs that leach into these liquids from containers would likewise undergo dermal absorption. [A-273].

114. The SNUNs also recognize that incidental ingestion of liquids packaged in fluorinated containers is a likely route of PFAS exposure. A-269, A-271, A-279, A-288. A-297, A-305

115. Evaporation of the contents of consumer and commercial products stored in fluorinated containers during use can release PFAS-containing vapors or aerosol particles which are inhaled. Many of these containers are exposed to elevated temperatures during processing, distribution and use, which would increase volatilization of their contents. [A-615].

116. Based on a comprehensive literature review, EPA's SAB recently found that "[s]everal studies suggest that PFOA and its precursors in indoor air and/or house dust may be an important exposure source for some individuals" and that PFOA "is generally a

dominant ionic PFAS constituent in indoor air and dust, frequently occurring above detection limits and at relatively high concentrations in all or most samples." [A-891]. The SAB also notes that studies show that "PFOA plasma concentrations increased proportional to aerosol exposure concentrations," demonstrating "absorption of PFOA via inhalation." [A-892]. As Drs. Phelps and DeWitt note, a "systematic review of occupational PFAS exposure across different sectors reviewed the presence of PFOA, PFNA, PFDA, PFDoDA, and PFTeDA in dust." [A-69].

117. The Agency for Toxic Substances and Disease Registry ("ATSDR") states that "Workers may be exposed to PFAS by inhaling them, getting them on their skin, and swallowing them, but inhaling them is the most likely route for exposure." [Ex. 37, ASTDR Report at A-895].

118. As noted above, a large portion of the containers fluorinated by Inhance are used as fuel tanks and portable fuel storage containers for engines in boats, lawn mowers and other household products. *See* ¶ ¶ 20, 48 above. As one example of the widespread distribution of these products, more than 5 million gas-powered mowers are sold in the United States each year. [Ex. 47, Cleaner Air: Gas Mower Pollution Facts at A-1189]. Inhance testing (described above) demonstrates high concentrations of all nine LCPFACs in fuel stored in fluorinated tanks and portable fuel containers. The combustion of this fuel is a potentially significant emissions source. EPA has estimated that gas-powered landscape maintenance equipment is responsible for 24%−45% of all nonroad gasoline emissions. [A-620].

119. A 2020 White House survey of PFAS disposal methods emphasizes that "[i]ncineration of PFAS-containing wastes can emit harmful air pollutants, such as fluorinated

greenhouse gases and products of incomplete combustion, and some PFAS may remain in the incinerator ash." [Ex. 42, White House National Science and Technology Council Report at A-1074]. EPA's 2020 "Interim Guidance on Destruction and Disposal of PFAS" recognizes that "PFAS are difficult to destroy due to the strength of the carbon-fluorine bond—a result of fluorine's electronegativity and the chemical stability of fluorinated compounds. Incomplete destruction or recombination of reactive intermediates can potentially result in the formation of new PFAS or other PICs [Products of Incomplete Combustion] of concern." [Ex. 38, EPA Interim Guidance on the Destruction and Disposal of Perfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances at A-939].

120. Thus, inhalation of PFAS is a significant concern when fuel containing LCPFACs is combusted, releasing fumes and particles containing PFAS. Inhance has touted the recyclability of fluorinated containers in its marketing materials. [Ex. 39, Inhance Statement titled Fully Recyclable Barrier Packaging at A-1006.] Significant volumes of HDPE plastics are recycled and the recycling stream likely includes a large quantity of discarded fluorinated containers. [Ex. 40, Plastics: Material-Specific Data at A-1009-12].

121. Recycling facilities apply high heat to HDPE plastic wastes so they can be melted and formed into sheets or pellets that can be remolded into containers or other articles. [A-584, 620]. Thus, the PFAS may be present in vapors or aerosols emitted from the facility, resulting in inhalation exposure to PFAS or harmful combustion byproducts by workers and nearby communities. *Id.*

122. High levels of PFAS compounds have been found in recycled HDPE from fluorinated containers:

PACE ANALYTICAL SERVICES, LLC

Detection Summary
BP Polymers
Lot Number: WG21045
Project Name: ATTORNEY- CLIENT PRIVILEGED
Project Number:

Sample	Sample ID	Matrix	Parameter	Method	Result	Q	Units	Page
001	One Bag of PCR	Solid	PFBA	PFAS by ID	20	S	ug/kg	5
001	One Bag of PCR	Solid	PFDA	PFAS by ID	0.16	J	ug/kg	5
001	One Bag of PCR	Solid	PFHpA	PFAS by ID	1.5		ug/kg	5
001	One Bag of PCR	Solid	PFHxA	PFAS by ID	3.5		ug/kg	5
001	One Bag of PCR	Solid	PFNA	PFAS by ID	0.35	J	ug/kg	5
001	One Bag of PCR	Solid	PFOA	PFAS by ID	0.72	J	ug/kg	5
001	One Bag of PCR	Solid	PFPeA	PFAS by ID	7.9		ug/kg	5

(7 detections)

[Ex. 41, PACE Analytical Report on PFAS in Recycled HPDE at A-1019].

123. When recycled HPDE sheets or pellets containing PFAS are reintroduced into the plastic manufacturing process, the PFAS are further distributed throughout the economy, including in containers that are not fluorinated. This creates further opportunities for substantial PFAS exposure by numerous workers and consumers. [A-620].

124. Inhance has not notified commercial and industrial processors of fluorinated containers, consumer and commercial end-users of these containers, or recycling entities and users of recycled fluorinated plastics of the presence of LPCFACs and other PFAS and the risks to health and the environment they present.

X. VIABLE ALTERNATIVES TO POST-MOLD FLUORINATION

125. EPA has noted that it "is aware of alternative fluorination processes that use fluorine gas in the presence of gaseous inert (e.g., nitrogen) without the presence of oxygen that could reduce the potential for unintentional manufacture of PFAS." [A-742].

126. The March 2023 report of the National Science and Technology Council stated:

> Regarding pesticide packaging, diluted fluorine gas is used to fluorinate high density polyethylene (HDPE) plastic packaging to improve container stability, and to make

> containers less permeable, reactive and dissolvable. PFAS may migrate from these containers and contaminate the pesticide formulation itself. Steel drums and non-PFAS coated HDPE containers are alternatives to PFAS-containing packaging. There are also alternative fluorination processes that reduce the potential for unintentional manufacture of PFAS, which the EPA and United States Department of Agriculture (USDA) have communicated to manufacturers.

[A-1082].

127. The company Baritainer uses a proprietary barrier resin additive that creates a laminar microstructure; it forms stacks of overlapping layers within the walls of the containers, creating a 'tortuous path' preventing hydrocarbon permeation. [Ex. 43, Baritainer Overview A-1164].

128. When PEER first discovered PFAS in Anvil 10+10, the insecticide used in at least 26 states to combat arboviruses, EPA required Clarke, the manufacturer of Anvil, to discontinue use of Inhance's fluorinated containers. [Ex. 44, Clarke Website at A-1167-77]. Clarke switched to containers with the non-fluorinated barrier, and EPA determined that it was "unlikely that the use of non-fluorinated containers including Baritainer (Kortrax®) would contribute to the contamination of PFAS in products stored in these containers. The acceptability of the new container type is confirmed." [Ex. 45, Approval of Baritainer Substitute by EPA A-1179].

Respectfully submitted this 12th day of June, 2023.

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