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United States Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

TSCA SECTION 5 ORDER FOR A SIGNIFICANT NEW USE OF CERTAIN CHEMICAL SUBSTANCES

Significant New Use Notice Numbers:	SN-23-0003/0006 and 0008-0011
Submission Date:	12/30/2022; Amended 03/07/2023, 04/17/2023, 05/19/2023, 09/29/2023, and 11/01/2023

In accordance with the provisions of Section 5(e) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2604(e),

Inhance Technologies, LLC

is prohibited from the manufacture, processing, distribution in commerce, use, or disposal of the SNUN Chemical Substances for the Significant New Use in the United States in accordance with the requirements and conditions described in this Order.

DENISE KEEHNER

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12/01/2023

Denise M. Keehner, Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Date

[redacted]

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Jurisdiction and General Provisions

This Order, pursuant to § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. § 2604(e)), is issued by the United States Environmental Protection Agency (EPA or the Agency) regarding significant new use notices (SNUNs) submitted by Inhance Technologies, LLC (the Company) for the following Chemical Substances (SNUN Chemical Substances):

- Dodecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-tricosafluoro- (PFDoA) (CASRN 307-55-1, SN-23-0003),
- Undecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heneicosafluoro- (PFuDA) (CASRN 2058-94-8, SN-23-0006),
- Tetradecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-heptacosafluoro- (PFTeDA) (CASRN 376-06-7, SN-23-0008),
- Tridecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,13-pentacosafluoro- (PFTrDA) (CASRN 72629-94-8, SN-23-0009),
- Hexadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-hentriacontafluoro- (PFHxDA) (CASRN 67905-19-5, SN-23-0010),
- Octadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,18-pentatriacontafluoro- (PFODA) (CASRN 16517-11-6, SN-23-0011).

The Company submitted SNUNs for nine chemical substances. As indicated earlier, this Order addresses the SNUNs for six of these chemical substances. SN-23-0002, SN-23-0004 and SN-23-0005 are addressed in a separate Order. Four of the six chemical substances addressed in this Order are on the TSCA Inventory. The chemical substances that are the subject of SN-23-0006

and SN-23-0009 are not on the TSCA Inventory.[1] All nine SNUNs were submitted under the long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate significant new use rule (Long Chain PFAS SNUR), 40 C.F.R. § 721.10536.

Based upon EPA's assessment of the SNUN Chemical Substances, the significant new use identified in the SNUNs (the Significant New Use), the documents in the administrative record for this action, and determinations made herein, the Company may manufacture, process, distribute in commerce, use, or dispose of the SNUN Chemical Substances for the Significant New Use in the United States only in accordance with the requirements and conditions described in this Order.

The Company must comply with all provisions of this Order including, but not limited to, all appendices to this Order and all documents incorporated by reference. According to Section 15 of TSCA, 15 U.S.C. § 2614, it is unlawful to fail or refuse to comply with any requirement of TSCA or any rule promulgated, or order issued under TSCA. Any person who violates the terms of this Order may be subject to both criminal and civil liabilities pursuant to Section 16 of TSCA, 15 U.S.C. § 2615, and to specific enforcement and seizures pursuant to Section 17 of TSCA, 15 U.S.C. § 2616. District Courts may restrain prohibited acts under TSCA or compel persons to take any action required by or under TSCA. Falsifying information provided to EPA or concealing

[1] TSCA section 8(b) (15 U.S.C. § 2607(b)) requires EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed [for commercial purposes] in the United States." "EPA periodically amends the inventory to include new chemical substances which are manufactured or imported for a commercial purposes and reported under" TSCA section 5(a)(1) (15 U.S.C. § 2604(a)(1)). 40 C.F.R. § 710.1(a). Specifically, EPA will add a chemical substance to the TSCA Inventory after: (1) completing a review of a Premanufacture Notice (PMN) for a chemical substance; and (2) receiving a notice of commencement of manufacture from the company that submitted the PMN. The submission of a PMN is required if a person intends to manufacture a new chemical substance—*i.e.*, a chemical substance that is not on the TSCA Inventory—unless an exemption or exclusion applies. 40 C.F.R. § 720.22; *see also* 40 C.F.R §§ 720.30-720.38. Similarly, a person "who commences the manufacture of a new chemical substance for a non-exempt commercial purpose for which that person previously submitted" a PMN must submit a "notice of commencement of manufacture." 40 C.F.R. § 720.102. The exemptions and exclusions applicable to the submission of a PMN (and subsequent submittal of a notice of commencement of manufacture) differ from those exclusions and exemptions applicable to the submission of a SNUN. Therefore, the submission of a SNUN, in some instances, may be required for a chemical substance that is not on the TSCA Inventory.

information from EPA is a violation of this Order and is subject to penalties pursuant to 18 U.S.C. § 1001.

Nothing in this Order substitutes for or supersedes any statutory and regulatory requirements under TSCA. The Company must notify EPA if it obtains any information which reasonably supports the conclusion that any of the SNUN Chemical Substances present a substantial risk of injury to health or the environment, as required under Section 8(e) of TSCA, 15 U.S.C. § 2067(e). The notice should reference the appropriate SNUN identification number for the substance(s) and contain a statement that the Significant New Use of any SNUN Chemical Substance is subject to this Order.

The terms not otherwise defined in this order have the meaning assigned to them in TSCA or in regulations promulgated under TSCA. Appendix 1 definitions shall apply to this Order and its appendices.

EPA's Determination under Section 5(a)(3)(B)

TSCA section 5(a)(3), 15 U.S.C. § 2604(a)(3), requires EPA to review significant new use notices and make one of five potential determinations with respect to the unreasonable risk of the significant new use identified in such notice. The five potential determinations are: (1) the significant new use presents unreasonable risk; (2) in the absence of sufficient information to permit a reasoned evaluation of risk from the significant new use, the significant new use may present unreasonable risk; (3) there is insufficient information to permit a reasoned evaluation of risk from the significant new use; (4) the substance is or will be produced in substantial quantities and there may be significant or substantial human and/or environmental exposure; or (5) the significant new use is not likely to present an unreasonable risk. 15 U.S.C. § 2604(a)(3). EPA's determination that a substance presents unreasonable risk, may present unreasonable risk, or is not likely to present an unreasonable risk must consider unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant under the conditions of use. 15 U.S.C. § 2604(a)(3)(A), (a)(3)(B)(ii)(I), (a)(3)(C). Similarly, such determinations must be made "without consideration of costs or other non-risk factors." 15 U.S.C. § 2604(a)(3)(A), (a)(3)(B)(ii)(I), (a)(3)(C).

If EPA determines that a significant new use presents unreasonable risk, EPA must take action under TSCA section 5(f), 15 U.S.C. § 2604(f), to the extent necessary to protect against such risk, without consideration of costs or other non-risk factors. Such action may include the issuance of an order to "prohibit or limit the manufacture, processing, or distribution" of a chemical substance for the significant new use. 15 U.S.C. § 2604(f)(3). If EPA determines that: (1) in the absence of sufficient information to permit a reasoned evaluation of risk from the significant new use, the significant new use may present unreasonable risk; (2) there is insufficient information to permit a reasoned evaluation of risk from the significant new use; or (3) the substance is or will be produced in substantial quantities and there may be significant or substantial human and/or environmental exposure, EPA must issue an order under TSCA section 5(e) to "prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance," or any combination of such activities, to the extent necessary to

protect against unreasonable risk, without consideration of costs or other non-risk factors. 15 U.S.C. § 2604(e)(1). Such order may also specify information required to be developed and submitted. If EPA determines that a significant new use of a chemical substance is not likely to present unreasonable risk, EPA must publish a statement of this determination in the Federal Register. 15 U.S.C. § 2604(g).

The following determination constitutes the basis of this Order issued under section 5(e) of TSCA (15 U.S.C. § 2604(e)):

EPA has determined, pursuant to Sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA (15 U.S.C. § 2604(a)(3)(B)(ii)(I), (a)(3)(B)(ii)(I)), that in the absence of sufficient information to permit EPA to make a reasoned evaluation of the health and environmental effects of the Significant New Use of the SNUN Chemical Substances, the manufacture, processing, distribution in commerce, use, or disposal of the SNUN Chemical Substances when manufactured or processed for the Significant New Use may present an unreasonable risk of injury to health or the environment.

EPA has determined, consistent with the New Chemicals Program PBT Policy, that each of the SNUN Chemical Substances are PBTs and there are expected environmental releases and exposures to human and environmental receptors based on the manufacture, processing, distribution and use of these SNUN Chemical Substances for the Significant New Use. EPA's determination that the Significant New Use of these SNUN Chemical Substances may present an unreasonable risk is based on the following significant and influencing factors:

- The SNUN Chemicals Substances are PFAS and they have strong stable carbon-fluorine (C-F) bonds which cause them to be very persistent in the human body and the environment. Because of the persistent and bioaccumulative nature of these PFAS, exposure to each SNUN Chemical Substance will continue over time, long after the immediate exposure associated with their use.

- Where direct data on a SNUN Chemical Substance is not available, data and information on PFOA and/or other SNUN Chemical Substances with available data were used as analogues to assess potential hazards. There is a robust amount of toxicity data

and information on PFOA. EPA's recent review by the Office of Water under the Safe Drinking Water Act (SDWA) states that human epidemiological and animal toxicity studies show the identified hazards of PFOA are so significant that there are no safe levels of exposure.

• Under the New Chemicals Program, the SNUN Chemical Substances are rated as persistent, bioaccumulative and toxic (PBT) to human health and the environment (they are rated P3B*(high)T2) (see section 3 of EPA's Risk Assessment for detailed discussion on the PBT rating of the SNUN Chemical Substances). Consistent with the 1999 New Chemicals PBT Policy, EPA interprets this to mean that even small exposures over time pose a risk (see also Appendix 4 to this order).

• The Significant New Use of the SNUN Chemical Substances will result in releases of the SNUN Chemical Substances and additional human and environmental exposures to the SNUN Chemical Substances as a result of these uses (see section 1.2.2 of EPA's Risk Assessment document for detailed information on evidence of many of the SNUN Chemical Substances in human serum and in fish tissue and section 4 of EPA's Risk Assessment for detailed information on environmental release and exposure of the SNUN Chemical Substances). These exposures are the result of leaching or migration of the SNUN Chemical Substances from fluorinated, plastic storage containers over time into fuel storage tanks and fuel tanks, various consumer applications (i.e., [redacted]), aerial/ground fogger pesticides, automotive products (i.e., [redacted]), [redacted] and [redacted] and a wide variety of other consumer and industrial uses. Several uses result in direct application in the environment.

• There is insufficient data relating to physical chemical properties, bioaccumulation and toxicity studies for human health and environmental receptors to fully characterize the risk. The significant hazards associated with several well studied PFAS are clear.

However, there are significant gaps related to the impact of certain PFAS, including the SNUN Chemical Substances, on human health and the environment.

EPA is requiring that the full suite of testing be completed and submitted to EPA for review prior to manufacture, known as upfront testing. Upfront testing is being required because the risk cannot otherwise be adequately mitigated. As discussed in Appendix 4: (1) even small releases of PBT PFAS, such as the SNUN Chemical Substances, into the environment over time can contribute to considerable exposure and potential risk; and (2) such releases can occur at any point during the lifecycle of a fluorinated container, from manufacture to disposal. As a result, EPA determined it cannot control potential exposures to the SNUN Chemical Substances through means other than a prohibition on the manufacture of these substances. Thus, EPA is not allowing manufacture of the SNUN Chemical Substances to commence while testing is being conducted. Based on concerns for persistence, bioaccumulation, and hazards identified in the assessment of the SNUN Chemical Substances, prohibiting manufacture while upfront testing is conducted is necessary to ensure that the order is protective against an unreasonable risk of injury to health or the environment until EPA has sufficient information to better determine unreasonable risk. This requirement for upfront testing is also consistent with EPA's 2023 *Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs)*, which states that EPA generally expects to require a full suite of testing to be completed prior to manufacture in situations where consumer exposure to PBT PFAS is expected. After EPA receives the results of testing required under this order, EPA will reevaluate the risks and may require additional testing or impose restrictions to address any identified unreasonable risks.

Therefore, EPA is issuing this order to prohibit manufacture and require certain testing be conducted, submitted to, and evaluated by EPA before EPA will consider modifying the order to permit manufacture. The company may conduct and submit alternative testing for EPA to evaluate the potential risks.

The basis for EPA's determination is attached as Appendix 2 to this order.

Requirements

The Order applies to all manufacturing, processing, distribution in commerce, use and disposal of the following SNUN Chemical Substances for the Significant New Use as described in this Order:

- Dodecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-tricosafluoro- (PFDoA) (CASRN 307-55-1, SN-23-0003),
- Undecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heneicosafluoro- (PFuDA) (CASRN 2058-94-8, SN-23-0006),
- Tetradecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-heptacosafluoro- (PFTeDA) (CASRN 376-06-7, SN-23-0008),
- Tridecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,13-pentacosafluoro- (PFTrDA) (CASRN 72629-94-8, SN-23-0009),
- Hexadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-hentriacontafluoro- (PFHxDA) (CASRN 67905-19-5, SN-23-0010), and
- Octadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,18-pentatriacontafluoro- (PFODA) (CASRN 16517-11-6, SN-23-0011) by the Company, as follows:

Testing and Reporting Requirements

The Company has the following testing and/or reporting requirements:

Required Testing

Consistent with EPA's 2023 *Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs)* (hereafter referred to as the *PFAS Framework*) , EPA is requiring testing for the SNUN Chemical Substances because the reasonably available information does not provide sufficient information for EPA's New Chemicals Program to make a reasoned evaluation of the health and environmental effects of the significant new uses of these PFAS under TSCA section 5. The required testing includes physical-chemical property testing, toxicokinetic testing, and human health and environmental toxicity testing. These tests are required to address uncertainties identified during the review of the SNUNs. Available evidence shows that the SNUN Chemical Substances are PBT substances, but this determination was partially based on analogues.

The Company is prohibited from manufacturing the SNUN Chemical Substances for the Significant New Use described in this Order unless the Company has completed all required testing and submitted to EPA the final reports and data for all such tests, in accordance with the testing provisions outlined in Appendix 3 of this order, and EPA has reviewed that testing and determined that the test results demonstrate that a modification of the terms of this Order is appropriate, and modified the order based on that determination.

Table 1

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	**Tier 1 Studies (Test Guideline)**	**Tier 2 Studies (Test Guideline)**
SN-23-0006 perfluoroundecanoic acid (PFuDA)	• K_{ow} (OECD TG 107) • Boiling Point (OECD 103) • Melting Point (OECD TG 102) • Hydrolysis (OECD TG 111; including at pH 2) • K_{oc} (OECD TG 106 or OECD TG 121) • Surface tension of aqueous solution (OECD 115)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Dependent on OECD TG 417 study) • Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201)

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)

CASRN 2058-94-8	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Henry's Law Constant (Ji C, et al. 2007, and Sander R, et al. 2022)Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Chronic study for sediment dwelling organisms (OECD 233)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0003
 	
perfluorododecanoic acid (PFDoA)
 	
CASRN 307-55-1
	• Water solubility (OECD 105)
	• K_{ow} (OECD TG 107)
	• Hydrolysis (OECD TG 111; including at pH 2))
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Dependent on OECD TG 417 study and existing information with rats)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0009	• Water solubility (OECD 105) • K_{ow} (OECD TG 107) • Vapor Pressure (OECD TG 104) • Boiling Point (OECD 103) • Hydrolysis (OECD TG 111; including at pH 2)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) • Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)

perfluorotridecanoic acid (PFTrDA)
 	
CASRN 72629-94-8
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Henry's Law Constant (Ji C, et al. 2007, and Sander R, et al. 2022)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		for sediment dwelling organisms (OECD 233) (dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0008
 	
perfluorotetradecanoic acid (PFTeDA)
 	
CASRN 376-06-7
	• Water Solubility (OECD TG 105)
	• K_{ow} (OECD TG 107)
	• Vapor Pressure (OECD TG 104)
	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Dependent on OECD TG 417 study)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0010	• Water solubility (OECD 105) • K_{ow} (OECD TG 107) • Vapor Pressure (OECD TG 104)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Applicable if in the OECD TG

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)

perfluorohexadecanoic acid (PFHxDA)
 	
CASRN 67905-19-5
	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		417, mice are determined to be the species with the longer half-life)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0011
 	
perfluorostearic acid (PFODA)
 	
CASRN 16517-11-6)
	• Water solubility (OECD 105)
	• K_{ow} (OECD TG 107)
	• Vapor Pressure (OECD TG 104)
	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Applicable if in the OECD TG 417, mice are determined to be the species with the longer half-life)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

Terms of Manufacturing

A. The Company is prohibited from the manufacture of the SNUN Chemical Substances for the Significant New Use described in this Order.

B. This prohibition does not extend to the manufacture and processing of the chemical substances identified in this Order where such manufacture and processing is exempt from the notification requirements of the Long Chain PFAS SNUR pursuant to 40 C.F.R. § 721.10536 and 40 C.F.R. § 721.45, including but not limited to the manufacture and processing of these chemical substances in small quantities solely for research and development (40 C.F.R. § 721.45(b)).

Recordkeeping

A. The company must maintain records documenting compliance with the requirements for one or more of the exemptions in order to demonstrate it has satisfied the statutory and regulatory requirements applicable to the exemption.

B. The Company must maintain all required records in Section III.A. for a minimum of 5 years after the date they are created and must make them available for inspection and copying by EPA in accordance with Section 11 of TSCA, 15 U.S.C. § 2610.

Modification and Revocation of the Order

EPA may modify or revoke provisions of this Order if EPA determines, upon consideration of test information submitted to EPA, pursuant to this Order or other information that one or more specific requirements of this Order are no longer necessary to protect against unreasonable risk. In addition, the Company may petition the EPA Administrator at any time to initiate a proceeding for the amendment or repeal of this Order in accordance with Section 21 of TSCA, 15 U.S.C. § 2620.

Requests for Information

This Order does not affect EPA's ability to seek information regarding TSCA-regulated chemicals, including the SNUN Chemical Substances. In order to ensure continuing compliance with the terms of this Order, EPA may issue a request for information to the Company at any time after the effective date of this Order. Failure to provide the information requested may be a violation of this Order.

TSCA Section 6 Authority

EPA reserves the right, at any time, to issue a rule under Section 6 of TSCA, 15 U.S.C. § 2605, to regulate any of the SNUN Chemical Substances if EPA determines that any of the SNUN Chemical Substances presents an unreasonable risk of injury to health or the environment when manufactured, processed, distributed in commerce, used, and/or disposed of, including for uses other than the Significant New Use.

OMB Control Number

The collection of information required in this Order has been approved under the currently valid OMB Control Number 2070-0012. Under the Paperwork Reduction Act and its regulations at 5 C.F.R. part 1320, the Company is not required to respond to this collection of information unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB").

Reservation of Rights

Except as specifically provided in this Order, nothing in this Order shall limit the power and authority of EPA to take, direct, or order any action necessary to protect public health, welfare, or the environment. This Order does not prevent EPA from seeking legal or equitable relief to enforce the terms of this Order, from taking other legal or equitable action as it deems appropriate and necessary, or from requiring the Company in the future to perform additional activities pursuant to TSCA or any other applicable law.

Dates

Consistent with 40 C.F.R. 23.5, this order is issued for purposes of TSCA section 19(a)(1) at 1:00pm eastern time on the date that is two weeks after the date the document is signed. This Order is effective on the expiration of the SNUN review period.

Appendix 1: Definitions

Unless otherwise expressly provided in this Order, the following definitions shall apply to the terms used in this Order:

"Company" means Inhance Technologies, LLC and any successor companies.

"EPA" or "the Agency" means the United States Environmental Protection Agency, and any successor agencies.

"Equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to support a reasoned evaluation of the potential risk of injury to human health or the environment of the SNUN Chemical Substance.

"Manufacture" means to produce or manufacture in the United States. This definition also applies to related noun and verb forms of "manufacture."

"PFAS" means per- and polyfluoroalkyl substances.

"Significant New Use" means any use of a SNUN Chemical Substance identified in the Significant New Use Notice submitted by the Company for that SNUN Chemical Substance.

"SNUN Chemical Substance" means the chemical substance described in a Significant New Use Notice submitted by the Company to which this Order pertains. For the purposes of this Order the SNUN Chemical Substances include:

- Dodecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-tricosafluoro- (CASRN 307-55-1, SN-23-0003), commonly known as PFDoA,

- Undecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heneicosafluoro- (CASRN 2058-94-8, SN-23-0006), commonly known as PFuDA,

- Tetradecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-heptacosafluoro- (CASRN 376-06-7, SN-23-0008), commonly known as PFTeDA,

- Tridecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,13-pentacosafluoro- (CASRN 72629-94-8, SN-23-0009), commonly known PFTrDA,

- Hexadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-hentriacontafluoro- (CASRN 67905-19-5, SN-23-0010), commonly known as PFHxDA , and

- Octadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,18-pentatriacontafluoro- (CASRN 16517-11-6, SN-23-0011), commonly known as PFODA.

Appendix 2: Basis for EPA's Determination

Chemical Name:

- Dodecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-tricosafluoro- (PFDoA) (CASRN 307-55-1, SN-23-0003),

- Undecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heneicosafluoro- (PFuDA) (CASRN 2058-94-8, SN-23-0006),

- Tetradecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-heptacosafluoro- (PFTeDA) (CASRN 376-06-7, SN-23-0008),

- Tridecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,13-pentacosafluoro- (PFTrDA) (CASRN 72629-94-8, SN-23-0009),

- Hexadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-hentriacontafluoro- (PFHxDA) (CASRN 67905-19-5, SN-23-0010), and

- Octadecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,18-pentatriacontafluoro- (PFODA) (CASRN 16517-11-6, SN-23-0011).

Conditions of Use (intended, known, or reasonably foreseen)[2]:

[2] Under TSCA § 3(4) (15 U.S.C. § 2602(4)), the term "conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." In general, EPA considers the intended conditions of use of a new chemical substance to be those identified in the section 5(a) notification. Known conditions of use include any condition of use of a chemical substance that EPA believes is ongoing in the United States at the time of submission of the notification, as well as activities within the United States that result from manufacture that is exempt from PMN or SNUN submission requirements. Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the chemical substance may be manufactured, processed, distributed, used, or disposed of. EPA expects that the identification of "reasonably foreseen" conditions of use will be made on a fact-specific, case-by-case basis. EPA will apply its professional judgment and experience when considering factors such as evidence of current use of the new chemical substance outside the United States, information about known or intended uses of chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN

Intended conditions of use (specific): The SNUN Chemical Substances are byproducts of the fluorination of plastic fuel storage containers and tanks used in small combustion engines, ground supported small engines, small motorsport engines, and marine engines, and the fluorination of plastic storage containers used in various consumer applications (i.e., [redacted]), automotive products (i.e., [redacted]), aerial/ground fogger pesticides, and [redacted].

Known conditions of use: Applying such factors as described in footnote 2, EPA evaluated whether there are known conditions of use and identified the manufacture of the SNUN Chemical Substances during the fluorination of high density polyethylene (HDPE) fuel and non-fuel storage containers, as described in the SNUNs submitted by the Company, as well as additional uses of the same chemical substances SNUN Chemical Substances that do not require reporting under 40 CFR 721.10536.

Reasonably foreseen conditions of use: Due to these chemicals being subject to the Long Chain PFAS SNUR at 40 CFR 721.15036, EPA did not identify any reasonably foreseen conditions of use. As written, the SNUR requires the submission of a SNUN for any use of a PFAS chemical subject to the Long Chain PFAS SNUR other than those uses specifically identified in the SNUR.

Pursuant to TSCA section 5(a)(3)(B)(ii)(I) (15 U.S.C. § 2604(a)(3)(B)(ii)(I)), EPA has determined that, in the absence of sufficient information to permit the Agency to make a reasoned evaluation of the health and environmental effects of the Significant New Use of the SNUN Chemical Substances, the manufacture, processing, distribution in commerce, use, or disposal of the SNUN Chemical Substances for the Significant New Use may present an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, based on EPA's Risk Assessment ("Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and

submission that the submitter omits in a revised PMN or SNUN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN or SNUN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

SN-23-0008-0011" (November 2023). A summary of EPA's risk assessment is provided next in this section.

The New Chemicals Program assessment follows the guidance in the Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances policy statement (hereafter referred to as the PBT policy (US EPA, 1999)) and is consistent with the Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) (hereafter referred to as the PFAS Framework; US EPA, 2023a). It further takes into consideration the risk assessments submitted by the Company for these SNUN Chemical Substances; the PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024 (US EPA, 2021a); and the National PFAS Testing Strategy: Identification of Per- and Polyfluoroalkyl Substances (PFAS) for Testing (US EPA, 2021b) to collect data/information on the many PFAS that are in US commerce and have been detected in the environment. As described in detail in EPA's Risk Assessment, based on the PBT policy, EPA concludes that each of the SNUN Chemical Substances is a PBT and that there are potential/expected environmental releases and exposures to human and environmental receptors based on the manufacture, processing, distribution and use of these SNUN Chemical Substances. Finally, data gaps are identified for each of the SNUN Chemical Substances (see section in this order on Required Testing).

Background

The SNUN Chemical Substances are formed during fluorination of the high density polyethylene (HDPE) fuel and non-fuel storage containers. Four of the six SNUN Chemical Substances are existing chemicals; the exceptions are SN-23-0006 (PFuDA) and SN-23-0009 (PFTrDA).

The Company provided information in two consolidated sets. The Company's risk assessments considered risks associated with the six SNUN Chemical Substances addressed in this Order and three chemical substances covered by SNUNs that are addressed in a separate Order. The Company's first risk assessment ("Attachment 003" in the first consolidated SNUN set) states that it considers the hazard, exposure and risk to workers, consumers, the general population and environmental organisms from fluorinated fuel storage containers of various sizes. The

Company's second risk assessment ("Attachment 12" in the second consolidated SNUN set) states that it considers the hazard, exposure and risk to workers, consumers, the general population and environmental organisms from fluorinated containers to be used in a variety of consumer products [redacted], and a variety of pesticide container products). Many exposure scenarios and pathways were evaluated in both of the Company's risk assessments.

Additional information was submitted by the Company on September 29, 2023. This information included:

- Report entitled – "Use of Drinking Water Standards"
- PDF of a 25-slide presentation summarizing the newly submitted information
- Results of sampling fuel containers for the six SNUN Chemical Substances and three chemical substances covered by SNUNs that are addressed in a separate Order (collected from October, 2022 to May, 2023)
- Results of sampling packaging containers for the six SNUN Chemical Substances and three chemical substances covered by SNUNs that are addressed in a separate Order (collected from October, 2022 to May, 2023)
- The analytical method used to measure the six SNUN Chemical Substances and three chemical substances covered by SNUNs that are addressed in a separate Order in the containers
- Customer/sector information for fuel containers
- Customer/sector information for packaging containers

- An economic impact assessment on the loss of the Company fluorination technology on the fuel/packaging systems.[3]

Finally, EPA acknowledges receipt and review of a document entitled *Combined LC/MS/MS Procedure for Measurement and Analysis of PFAS in HDPE* on November 1, 2023.

PFAS Strategic Road Map and the National PFAS Testing Strategy

In October of 2021, EPA released both the PFAS Strategic Roadmap (US EPA, 2021a) with commitments to broad range of actions on PFAS in the environment and a National PFAS Testing Strategy (US EPA, 2021b) to collect data/information on the many PFAS that are in US commerce and have been detected in the environment. One of the key actions in the PFAS Strategic Roadmap includes ensuring a robust review process for new PFAS in the TSCA New Chemicals Program. As a result of the need for a robust review process as identified in the *PFAS Strategic Roadmap* and the challenges associated with accurately quantifying the exposures and risks associated with PBTs, as reflected in the New Chemicals Program PBT policy (see section 1.2.2 of EPA's Risk Assessment), the New Chemicals Program recently released the *PFAS Framework*, which describes the approach and methodology the New Chemicals Program uses to evaluate PFAS new chemical notices (US EPA, 2023a), described in section 1.2.3 of EPA's Risk Assessment.

Challenges to Precisely Quantifying Risks for PBT PFAS

Precisely quantifying the risk posed by PBT PFAS, including the SNUN Chemical Substances, is complicated by: (1) the lack of robust toxicity information on most of the thousands of PFAS

[3] EPA did not request that the Company develop or submit this economic impact assessment. Under TSCA section 5, EPA is required to review SNUNs that it receives, and make a determination as to whether a significant new use presents unreasonable risk "without consideration of costs or other non-risk factors," 15 U.S.C. § 2604(a)(3). Where EPA determines that a significant new use may present or presents unreasonable risk, the Agency is required to take action "to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors." *Id.* § 2605(e)(1)(A) (emphasis added); *see also id.* § 2605(f)(1). Thus, consistent with TSCA section 5, EPA did not consider this economic impact assessment in determining whether the significant new uses identified in the Company's SNUNs present unreasonable risk, nor in determining the action necessary to protect against such unreasonable risk.

(exceptions include PFAS not covered by the SNUNs subject to this order – e.g., PFOA, PFNA, and PFDA, as well as certain other PFAS not covered by the SNUNs – e.g., PFOS, PFHxA, PFBS, GenX); (2) the exceptionally high toxicity of the well-studied PFAS; (3) the likely additive impacts of exposure to multiple PFAS; (4) the persistence of PFAS; (5) the bioaccumulative properties of PFAS; (6) the widespread occurrence of PFAS in the environment; and (7) the apparent widespread existing exposures and body burdens of PFAS in humans. These factors can lead to risks to human health and the environment being underestimated by conventional, quantitative risk assessment methods. Each of these seven complicating factors is further explained in EPA's Risk Assessment in section 1.2.2.

PFAS that are persistent, bioaccumulative, and toxic present several challenges that result in risk to human health and the environment being underestimated by conventional, quantitative risk assessment methods. First, due to the persistence and bioaccumulation potential for a given PBT PFAS, small releases to the environment can have a significant long-term contribution to exposure and risk. Current risk assessment methods used in the New Chemicals Program and in the Company's assessments do not account for chemical substance accumulation over time in environmental media, environmental organisms and humans.[4] Second, there is an undetermined amount of PBT PFAS that currently exists in the environment (including humans) that represents an existing, background PFAS burden that needs to be considered but is difficult to quantify. The National Academy of Sciences (NAS) recently provided an overview of the extent and magnitude of PFAS contamination, stating "(D)ata from the National Health and Nutrition Examination Statistics (NHANES) survey show that nearly 100 percent of people in the United States are exposed to at least one PFAS…" (as cited in NAS, 2022, p. xi; also referred to as NHANES data). These data showing PFAS in human serum include the presence of several of the SNUN Chemical Substances (PFuDA, and PFDoA) as well as PFOA, PFNA and PFDA, which are subject to a separate order. There are other biomonitoring data showing the presence of two more of the SNUN Chemical Substances in human serum in US samples (PFTeDA and PFTrDA).[5]

[4] The two Company risk assessments use conventional methods for quantifying risk that do not account for bioaccumulation. See Sections 2 and 3 of EPA's Risk Assessment for details and more discussion.
[5] Draft report entitled "Report on comparison of cell-based bioactivity concentrations and human population blood concentrations for selected PFAS compounds", which is in the administrative record for this action.

This existing body burden of PFAS in humans is constantly changing as a result of exposures by people to PFAS already in the environment –this makes it extremely difficult to accurately quantify the risk from additional, incremental exposures to the other SNUN Chemical Substances.

Notably, several of the SNUN Chemical Substances have been shown to be widespread in fish tissue in U.S. waters (Table 2). Fish are time-integrating indicators of persistent pollutants, and contaminant bioaccumulation in fish tissue has important human health implications (EPA 2020xa). EPA's National Aquatic Resource Surveys are statistical surveys designed to assess the status of the condition of waterbodies in U.S. and to evaluate changes affecting the quality of these waters over time. The 2013-2014 National Rivers and Streams Assessment (NRSA) and the 2015 National Coastal Condition Assessment (NCCA) demonstrate widespread PFAS contamination in freshwater fish in U.S. rivers and the Great Lakes, respectively (USEPA 2020a, 2020b). Specifically, EPA has detected two of the SNUN Chemical Substances (SN-23-0003, -0006) at high frequencies of detection in its statistical surveys of the nation's rivers and the Great Lakes (shown in Table 2).

Table 2: Detection Frequency of SNUN Chemical Substances in Freshwater Fish Tissue (2013-2014 NRSA and 2015 NCCA)

SNUN Chemical Substance	Detection Frequency 2013-14 NRSA[1] (in percent)	Detection Frequency 2015 NCCA: Great Lakes[2] (in percent)
SN-23-0003 (PFDoA)	70	81
SN-23-0006 (PFuDA)	88	91

[1] Total of 349 fish samples collected at river sites were analyzed for 13 per- and polyfluoroalkyl substances (PFAS)

[2] Total of 152 fish samples collected at Great Lakes nearshore sites were analyzed for 13 per- and polyfluoroalkyl substances (PFAS)

In addition to the seven complicating factors there is uncertainty in determining the amount of the SNUN Chemical Substances that are actually manufactured as byproducts during the fluorination process. This uncertainty makes it difficult to accurately quantify exposures (see section 2.2 of EPA's Risk Assessment for discussion of potential underestimation of the production volume in the Company's risk assessment). Available data also show that other PFAS – besides the SNUN Chemical Substances and the three other PFAS covered by SNUNs that are addressed in a separate Order - are also byproducts from fluorinating containers. The possible contribution of these other PFAS to the bioaccumulation and toxicity potential of the SNUN Chemical Substances is unknown at this time.

Based on these considerations, and as outlined further PFAS Framework, EPA generally expects to evaluate risk for PBT PFAS qualitatively. Thus, EPA's Risk Assessment for these PFAS SNUN Chemical Substances is qualitative.[6]

In 2023, the New Chemicals Program incorporated the 1999 PBT Policy into the *PFAS Framework* for the review of PFAS PMNs and SNUNs. The purpose of the *PFAS Framework* is to provide a clear approach for the New Chemicals Program to review PFAS PMN and SNUN Chemical Substances in light of significant health and environmental concerns associated with, widespread environmental exposure to, and environmental persistence of most PFAS, and to identify any appropriate risk mitigation (including banning manufacture, if warranted) and any appropriate PFAS testing requirements.

When a substance under review is identified as PFAS using the definition outlined in the *PFAS Framework*, including key components of interest such as potential degradants and

[6] Although EPA has concluded that a quantitative risk assessment is not appropriate to capture the full risk associated with these PFAS for the reasons described in section 1.2.2 of the risk assessment and elsewhere in the risk assessment, EPA did perform a sensitivity analysis that calculates risk for PFOA and PFDA using EPA's human health hazard information and the exposure calculations submitted by the Company. EPA's human health hazard information (i.e., PODs) for PFOA and PFDA are different from the ones used by the Company and represent the EPA internal and public review of the available scientific information. Eighty percent of the calculations in the sensitivity analysis showed risk and 20% did not (see "Sensitivity Analysis: Calculating risk using EPA-derived toxicity values with Company-derived exposure values" as part of the administrative record for this action.)

metabolites, a PBT determination is be made by the New Chemicals Program for the submitted PFAS and/or key degradants and metabolites using a weight of evidence approach based on data from the specific new chemical substance or appropriate analogues, as described in section 3.1 of EPA's Risk Assessment. Although it is possible to quantify exposure to an immediate release of a specific amount of PFAS, the estimated exposure would not reflect the overall human health and environmental impact posed by the released PBT PFAS as such substances persist and bioaccumulate over time and humans already have a body burden of PFAS. For PBT PFAS chemicals, EPA will generally qualitatively consider the potential or expected extent of exposures to workers, the general population, consumers and the environment throughout the lifecycle of the PFAS, but will not attempt to quantitatively assess exposures or risk due to the limitations outlined in section 1.2.2 of EPA's Risk Assessment.

The New Chemicals Program's evaluation of whether the SNUN Chemical Substances are PBTs under the PBT Policy is consistent with the PFAS Framework. Then, because the New Chemicals Program has determined these substances to be PBTs, and consistent with the PFAS Framework, it has qualitatively assessed the risk of the SNUN Chemical Substances.

Review of Risk Assessments and Other Information Provided by the Company

Two risk assessments were included in the Company's submissions – one to evaluate the SNUN Chemical Substances formed in fuel storage containers and one to evaluate the SNUN Chemical Substances formed in non-fuel storage containers. As outlined in the *PFAS Framework* and further detailed in Challenges to Precisely Quantifying Risks for PBT PFAS described earlier in this document and in section 1.2.2 of EPA's Risk Assessment, the persistence and bioaccumulation of these substances, and the existing and widespread environmental occurrence and human body burdens of PFAS were not taken into consideration in the Company's risk assessments (though bioaccumulation was acknowledged as an uncertainty by the Company).

During the review process, EPA received more detailed information regarding the optimization of the Company's fluorination process, analytical methods used for testing, and detailed sample

information (i.e., manufacturing location, customer sector, and the amount of PFAS detected). These data do indicate that the Company has adapted its process with respect to certain types of containers to reduce the amount of LCPFAC formed—stating that over 98% of the samples have non-detectable levels for the 9-18 carbon LCPFACs. However, these data also show that the SNUN Chemical Substances are still being manufactured during the Company's fluorination process and detected. In addition, the detection limits used in these studies (~300 ppt in extracts from the plastic container coupons) are much higher than other comparable methods. For instance, EPA's Office of Pesticide Program's (OPP) Biological and Economic Analysis Division (BEAD) has validated a method in the laboratory that is more sensitive than the one employed for these measurements by the Company. The level of detection is 2 ppt and the level of quantification is 20 ppt for most PFAS tested (see "Summary of EPA Container Coupon Method for PFAS Determination" in the administrative record for this action).

The Company did not consider that the SNUN Chemical Substances co-exist when formed as byproducts from the fluorination process. The Company provided evidence for the existence and migration of long-chain PFAS from the HDPE container walls into the container contents (methanol, CE10 fuel, and water were used as media for extraction) in the original risk assessments and provided more evidence in their September 29, 2023 submission of additional information. Because the SNUN Chemical Substances co-exist and are chemically similar, they will likely interact with each other. Considering exposure and hazard for each SNUN Chemical Substance separately does not account for the aggregate exposure and the likely hazard/toxicity interaction (whether it be additive or possibly greater than additive, or something altogether different), thus leading to an underestimation of the risk to human health and the environment.

In addition, EPA is aware of other studies which indicate that other PFAS substances (e.g., PFAS which have fewer than 7 fluorinated carbons) are also expected to leach from fluorinated HDPE containers (US EPA, 2021 and 2022; Whitehead and Peaslee, 2023; Vitale et al., 2022). Thus, these shorter-chain PFAS are likely byproducts of the Company's fluorination process and co-exist with the LCPFAC (the SNUN Chemical Substances and other PFAS subject to a separate

order). For instance, testing conducted by the BEAD Laboratory within EPA's OPP showed that 86% of the mass of PFAS that leached from a fluorinated 55 gallon drum were of the short-chain variety (US EPA, 2021c). Both short- and long-chain PFAS are linked to adverse human health effects, with overlap in toxicities. The possible contribution of these other PFAS to the exposure, bioaccumulation and toxicity potential of the SNUN Chemical Substances may affect the estimation of risk for the SNUN Chemical Substances.

In order to accurately and precisely quantify risk, it is important to have confidence in the estimation of the amount of the SNUN Chemical Substances formed from the Company's fluorination process. The Company provided estimates of production volume which claim that the SNUN Chemical Substances are produced at levels below 400 grams per year for each SNUN Chemical Substance. Estimating the production volumes for these substances is difficult because the volumes can only be determined indirectly, as opposed to using stoichiometric calculations. For example, a PFAS byproduct that is produced upon fluorination may remain entrained within the HDPE matrix, but still have the potential to migrate from the container walls. In this scenario, that PFAS would not be counted in the production volume estimate even though it results from the fluorination process. In order to account for this issue, extraction conditions (e.g., solvent, heat, duration) must be used which are capable of extracting the maximum amount of PFAS possible from the HDPE matrix. Multiple extractions must also be used in order to demonstrate that PFAS is no longer leaching from the container walls and all the PFAS has been extracted. Given the large amount of uncertainty with these production volume estimates, it is impossible to precisely quantify risk using the current information provided by the Company.

EPA does not agree with the Company's risk assessment conclusion that there are no risks to either human health or environmental organisms from exposure to the SNUN Chemical Substances. Not taken into consideration in the Company's risk assessments are the: 1) persistence and bioaccumulation of the SNUN Chemical Substances; 2) widespread existing environmental and human body burdens of different PFAS, including the available *National*

Report on Human Exposure to Environmental Chemicals using the NHANES[7] data documenting the presence of PFuDA and PFDoA in human serum, available public information on the presence of two (PFTeDA and PFTrDA) of the remaining SNUN Chemical Substances in US human serum samples[8], and the EPA National Aquatic Resource Survey data supporting widespread presence in freshwater fish tissue in U.S. rivers and Great Lakes for PFuDA, and PFDoA, which affects the ability to estimate exposure to, and hazard and risk for the SNUN Chemical Substances (US EPA 2020a); and 3) the co-existence and likely interaction of the SNUN Chemical Substances with the possible contributions from other PFAS which may affect the hazard/exposure estimates for the SNUN Chemical Substances. Furthermore, although the estimated production volumes provided by the Company for the SNUN Chemical Substances are uncertain, the exposure calculations and estimates made by the Company in their risk assessments demonstrate that the SNUN Chemical Substances are formed as byproducts from the fluorination process and would be released to the environment (if use were to be permitted).

EPA's Assessment

The New Chemicals Program concludes there is risk from the manufacture, distribution, use, and disposal of the SNUN Chemical Substances based on the PBT nature of the SNUN Chemical Substances and the potential or expected exposures. Because these SNUN Chemical Substances are PBTs, they are expected to accumulate over time. There are substantial scientific limitations on quantifying risk for bioaccumulative substances. Current quantitative risk assessments for such substances consider risk at only a single point in time; as was done in the Company's risk assessments. Thus, the Company's quantitative risk assessments underestimate the risk due to the unquantified buildup of the SNUN Chemical Substances (for both toxicity and exposure)

[7] As cited in NAS, 2022 but all data are available at – cdc.gov/exposurereport/data_tables.html (and searching for individual chemicals).
[8] See Draft ORD report entitled "Report on comparison of cell-based bioactivity concentrations and human population blood concentrations for selected PFAS compounds", which is in the administrative record for this action.

over time. Additional risks may be associated with existing levels of PFAS in both the environment and human serum (i.e., background levels of PFAS) and possible interaction from exposures to the SNUN Chemical Substances together and with other PFAS formed during the fluorination process that are not subject to this order.

Persistence and Bioaccumulation Scores

In 1999, EPA issued a policy statement identifying PBTs as a category of concern (US EPA, 1999). The 2018 *Points to Consider When Preparing TSCA New Chemical Notifications* (US EPA, 2018) document provides guidance on how EPA implements the PBT policy. EPA uses this approach to identify substances that meet the criteria for a score of 2 or more for each of the three key parameters (persistence, bioaccumulation, and toxicity); that is "P2B2T2" or higher. Note that a score of unknown (U) in any category is treated as a 2 or 3 for purposes of identifying PBTs. The criteria for determining scores for persistence and bioaccumulation are shown in Table 4 of EPA's Risk Assessment.

All of the SNUN Chemical Substances are Class 1 chemicals (i.e., their compositions can be represented with definite structural diagrams). They are fully fluorinated alkyl carboxylic acids ranging in chain length from 11 (PFuDA) to 18 (PFODA) carbon atoms. Such compounds exhibit observable environmental persistence and are known to be resistant to biodegradation and hydrolysis due to their highly stable chemical structures (USEPA 2009; Post et al. 2012; Kwiatkowski et al. 2014; Evich et al. 2022). Thus, EPA does not expect them to degrade in aqueous media. While trifluoroacetic acid (TFA) has been identified as a representative incineration product for the SNUN Chemical Substances to reflect the possibility of incomplete combustion in municipal solid waste incinerators, TFA is not driving the PBT determination for the SNUN Chemical Substances.

Persistence: Most PFAS are considered persistent (P3) due to the extreme stability of the C-F bond and the observed, widespread persistence of perfluorinated chemicals (Kwiatkowski et al. 2014 and references therein). The only exceptions are those PFAS that react to produce fluorinated degradation products. In such cases, the parent compound may be rated P1 or P2,

while the degradation products are rated P3. Based on their chemical structures, none of the SNUN Chemical Substances are expected to degrade under environmental conditions. Further, each of them contains multiple C-F bonds, so each is anticipated to be extremely persistent and is therefore rated P3.

Bioaccumulation: EPA rates most PFAS as B*high. Exceptions include those PFAS that react to produce fluorinated degradation products. In such cases, the parent compound may be rated B1 or B*low, while the degradation products are rated B*high. This reflects the observed presence of both long- and short-chain perfluorinated compounds in air, water, environmental organisms, plants, food, beverages, drinking water, and human serum, along with their persistence, and the resulting prolonged exposure times (Brendel et al. 2018, Scheurer and Nödler 2021, Evich et al. 2022, etc.). None of the SNUN Chemical Substances are anticipated to degrade under environmental conditions. All are long-chain PFAS, a class of chemicals which extensive data indicate can bioaccumulate in humans. As such, all the SNUN Chemical Substances are expected to bioaccumulate. Based on these considerations, each of the SNUN Chemical Substances is rated B*high.

Other Fate Considerations for the SNUN Chemical Substances

Manufacture, distribution, use and disposal of the SNUN Chemical Substances for the Significant New Use result in potential or expected releases to the environment. In understanding the environmental fate of the SNUN Chemical Substances throughout this lifecycle, thermal decomposition of PFAS in waste streams (e.g., from manufacture/distribution), through use (e.g., internal combustion engines such as lawn mowers) and from disposal (e.g., spent containers) is an active area of research. There is uncertainty regarding the conditions needed to achieve complete mineralization and the range of possible products of incomplete combustion (PICs) when those conditions are not met. There are indications that temperatures exceeding 1,000–1,100 °C may be sufficient for complete destruction of many PFAS (Shields et al. 2023). However, because the operating parameters of municipal waste incinerators are not standardized and it is not clear these temperatures are

consistently achieved, EPA assesses TFA as a representative incineration product for PFAS to account for potential or expected PIC releases.

Temperatures in internal combustion engines may exceed those in municipal waste incineration (Roberts et al., 2014). Thus, it seems likely that destruction of PFAS would occur given efficient engine operation, but, this has not been verified experimentally. Since complete efficiency in the operation of combustion engines cannot be assumed, the possibility of incidental releases and/or incomplete combustion cannot be ruled out and therefore represents an expected route of exposure.

Based on their physical-chemical properties, LCPFACs associated with discarded materials in landfills may be expected to desorb and be transported through sub-surfaces more slowly than shorter-chain PFAS. The relevant transport times are not well defined, but may be considerable given possible retention of LCPFACs on containers, organic matter, sorbent membranes, etc. Yet, because of the extreme persistence of these compounds, such transport is still possible. In fact, LCPFACs are known to be present in leachate from municipal solid waste landfills; for example, concentrations of PFOA in the parts per billion (ppb) range have been reported in leachates from multiple landfills (Solo-Gabriele et al. 2020). This indicates that, contrary to the Company's claim that landfill leachate would result in "very small incremental releases, if any," leaching of the SNUN Chemical Substances can occur and is expected to migrate through soil and eventually to groundwater[9].

Most wastewater treatment plants are not required to monitor PFAS, so quantitative removal efficiencies are not well characterized. However, conventional wastewater treatment methods may be ineffective at removing perfluoroalkyl acids (Sinclair and Kannan, 2006; Loganath et al., 2007; Leung et al. 2022). Removal by biodegradation is generally not expected, while sorption and stripping are structure-dependent and more difficult to predict. In fact, many treatment plants exhibit higher concentrations of long-chain PFAS in effluent than in influent due to formation from precursors in the treatment train (USEPA 2019). Thus, the SNUN Chemical

[9] EPA notes that the Company has stated that it produces more than 200 million fluorinated containers a year.

Substances would be expected to be released to receiving/surface waters used as sources of drinking water and fish as a food source for humans, and as habitat for aquatic organisms.

Toxicity

The T score in PBT refers to toxicity, and can be based on either chronic toxicity concerns to aquatic organisms or developmental, reproductive or chronic toxicity concerns for human health.

Toxicity to Aquatic Organisms:

The EPA New Chemicals Program uses an aquatic toxicity profile to characterize environmental hazards, which consists of three acute (fish, aquatic invertebrates, and algae) and three chronic (fish, aquatic invertebrates, and algae) ecotoxicity endpoint values. The typical aquatic toxicity profile is established for each substance under review (and expected degradation products) using measured test data, data for analogous substances, and/or modeled data. For this assessment, the majority of available PFAS aquatic toxicity test data are only for PFOA (one of the PFAS covered by SNUNs that are addressed in a separate Order), with most of the SNUN Chemical Substances lacking experimental test data/information applicable to this assessment. Modeled data are not incorporated into the environmental hazard assessment for the SNUN Chemical Substances without sufficient data because aquatic toxicity models based on lipophilic partitioning (e.g., ECOSAR) are unreliable for PFAS.

There is a lack of information to determine environmental hazards for the SNUN Chemical Substances. For PFOA, an HC_5 value of 0.033 mg/L was reported in Li et al. (2021). This value was used by the Company in their risk assessment and has been accepted by EPA to represent the hazard concerns for this qualitative assessment of the SNUN Chemical Substances. For the SNUN Chemical Substances, the environmental toxicity score is considered unknown and thus the PFOA data are used as read-across for this assessment.

The EPA Draft Aquatic Life Ambient Water Quality Criteria for PFOA indicates a chronic water column Criterion Continuous Concentration of 0.094 mg/L (US EPA 2022b). Although this value

is slightly less conservative than the HC_5 submitted by the Company (0.033 mg/L), both values indicate a concern for chronic toxicity to aquatic organisms based on the high environmental hazard and result in a toxicity score of T2 for PFOA.

Toxicity to Human Health:

PFAS present a significant concern for human health based on growing epidemiological and laboratory animal study evidence, widespread and persisting presence in the environment, and the tendency to bioaccumulate (Brendel et al. 2018, Scheurer and Nödler 2021, Evich et al. 2022). In laboratory animal studies, PFAS have been shown to lead to reproductive, developmental, liver, kidney and immunological toxicity, as well as cancer (ITRC, 2023). Humans can be more sensitive to PFAS compared to rodents as health effects are observed in humans at doses below those eliciting adverse effects in animal toxicology studies (ITRC, 2023). PFAS exposure has been associated with human health outcomes including increased cholesterol levels as well as evidence for decreased infant and fetal growth, decreased immune response, cancer and thyroid hormone disruption (US EPA 2016a; NAS, 2022; US EPA,2016b). In addition, some PFAS have been shown to cause adverse respiratory effects following acute inhalation exposure (PubChem, 2022).

The New Chemicals Program assessed toxicity to human health for the SNUN Chemical Substances based on available toxicological information for five of the SNUN Chemical Substances and three PFAS covered by SNUNs that are addressed in a separate order, and an analogous substance for one of the SNUN Chemical Substances (PFTrDA). EPA primarily relied on the ITRC website (ITRC, 2023) and EPA assessments for the identification of human health toxicity information for five of the SNUN Chemical Substances and an analogue for one of the SNUN Chemical Substances. For three SNUN Chemical Substances, EPA identified animal studies in the literature with relevant human health toxicity information. See Table 3 of this document for details.

The available data on perfluorocarboxylic acids (PFCAs) are largely limited to PFOA (8 carbons, SN-23-0002), PFNA (9 carbons, SN-23-0004), and PFDA (10 carbons, SN-23-0005). There are

limited data available on PFuDA (11 carbons, SN-23-0006), PFDoA (12 carbons, SN-23-0003), PFTeDA (14 carbons, SN-23-0008), PFHxDA (16 carbons, SN-23-0010) and PFODA (18 carbons, SN-23-0011). There are no data available for PFTrDA (13 carbons, SN-23-0009). For SN-23-0009, EPA selected analogues based on both availability of data and structural similarity. PFDoA (12 carbons) and PFTeDA (14 carbons) represent good, primary analogues as they bracket the carbon chain length of PFTrDA (13 carbons). Also, the available information on the remaining six SNUN Chemical Substances provides evidence of concerns for developmental, reproductive, and/or chronic toxicity to substantiate a T2 score for PFTrDA.

The criteria for determining a human health T score of 2 is the identification of developmental, reproductive and/or chronic hazards, typically using human data or animal studies, and can be based on the submitted chemical substance and/or analogues. Key hazards identified by the New Chemicals Program as the basis for a T score of 2 for each SNUN Chemical Substance are listed in Table 3 of this document. EPA notes that the evidence provided is sufficient for a T score of 2, however additional hazard evidence for each SNUN Chemical Substance is available in the cited documents.

In addition to the hazards identified for each SNUN Chemical Substance individually, EPA notes the SNUN Chemical Substances are present together (i.e., co-exist) both within the matrix of the HDPE container as well as in the contents of the container as part of a PFAS mixture that also likely includes short-chain PFAS coproducts, and PFOA, PFNA, and PFDA, which are the subject of additional SNUNs submitted by the Company. As described in section 2.4 of EPA's Risk Assessment, some dose additive effects are expected based on similarly in structure and known overlap in toxicities of both short- and long-chain PFAS present in the fluorinated containers (US EPA, 2023c, Fenton et al., 2021; for examples of dose additive effects, please see Addicks et al., 2023; Dale et al., 2022; Marques et al., 2021). The T score for each SNUN Chemical Substance does not account for potential dose additive effects.

Table 3: Basis for Human Health Toxicity Score for PBT Designation

Case Number (Chemical, Abbr., No. of Carbons)	***Primary Basis for Human Health T score*** and associated point of departure	Human Health T Score
SN-23-0006 (PFuDA, 11)	***Decrease in neonatal weight and a decrease in postnatal weight gain*** observed in a developmental toxicity study in rats (Takahashi et al., 2014 as cited in ITRC Table 17-8).	T2
SN-23-0003 (PFDoA, 12)	***Full litter resorptions, decreased litter size, decreased number of live pups at birth and other effects*** observed in a rat developmental toxicity study (Kato et al., 2015a in Table 17-8 in ITRC).	T2
SN-23-0009 (PFTrDA, 13)	The New Chemicals Program used ***PFOA*** as an analogue based on structure and substantial availability of data; PFDoA, ***PFTeDA, PFHxDA, PFODA*** are also used as analogues based on closer structural and the availability of some data. Collectively, these data provide evidence for the T2 call.	T2
SN-23-0008 (PFTeDA, 14)	***Liver effects (increased liver weight, centrilobular hepatocyte hypertrophy and microgranulomas), thyroid effects (decreased thyroid weight and follicular cell hypertrophy) and decreased pup weight gain, as well as decreased absolute seminal vesicle weight in males and decreased pituitary gland weight*** observed in a repeated dose reproductive/developmental toxicity study (Hirata-Koizumi et al., 2015).	T2
SN-23-0010 (PFHxDA, 16)	***Liver effects (increased liver weight, centrilobular hepatocyte hypertrophy and fatty change), thyroid effects (increased thyroid weight, decreased T3 and T4), decreased adrenal weight and decreased pup weight gain*** observed in a repeated dose reproductive/developmental toxicity study (Hirata-Koizumi et al., 2015).	T2
SN-23-0011 (PFODA, 18)	***Liver effects (centrilobular hepatocyte hypertrophy and necrosis), reproductive/developmental effects (decrease in number of corpora lutea, implantation, total number of live pups and decreased pup weight)*** observed in a repeated dose reproductive/developmental toxicity study (Hirata-Koizumi et al., 2012).	T2

Environmental Release, Exposure Pathways and Environmental Human Receptors

In the New Chemicals Program, the engineering assessments evaluates industrial/commercial releases to the environment and workplace (occupational) exposures. The exposure assessment covers exposure to the general population, consumers and aquatic species.

In this summary[10], use of the phrase potential or expected for environmental releases and exposures occurs throughout. This is to reflect that there is exposure to the SNUN Chemical Substances from the manufacture, processing, use and/or disposal of the Company's fluorinated containers; it is only a matter of degree and level of certainty with respect to each individual SNUN Chemical Substance, life cycle stage, exposure pathway, and receptor. As was done by the Company in their risk assessments, there are many exposure scenarios to document and that is done in separate EPA reports (See the Engineering and Exposure Assessments in the administrative record for this action).

In addition, according to information submitted by the Company on September 29, 2023, they fluorinated approximately 121 million containers in 2021. This resulted in an estimated 75 million gallons of container contents and 25 million pounds of plastic. Assuming this is a normal year, it means that over 120 million containers are fluorinated each year and are available for distribution, use and disposal. EPA notes that the Company's own press release from August 2023 states that it fluorinates over 200 million containers annually (Inhance 2023).

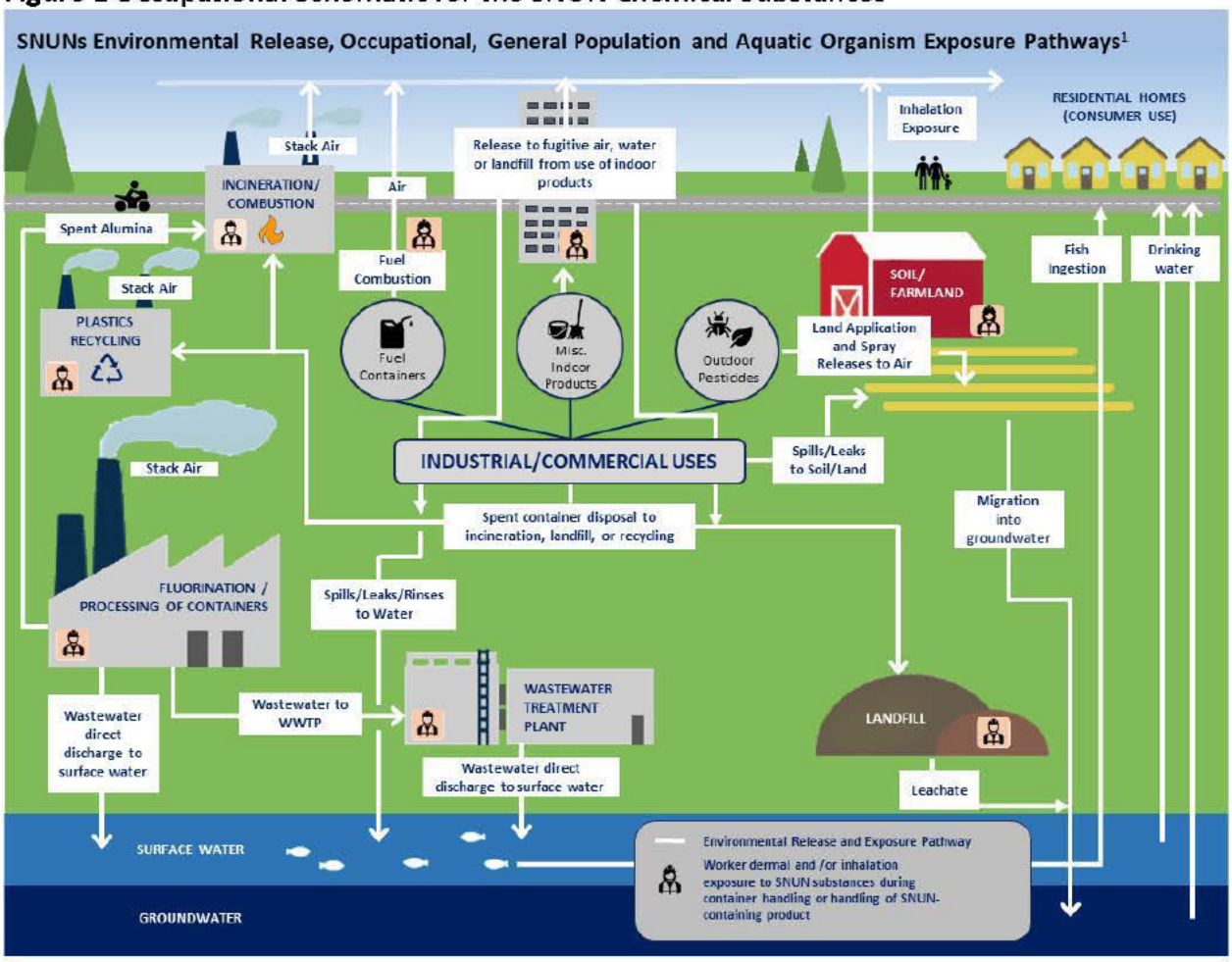
Consistent with the PFAS Framework, the New Chemicals Program will not be quantifying risk (exposure and hazard) for PBT PFAS due to the likelihood that a quantitative risk assessment would underestimate risk and thus not be protective of human health and the environment. A quantitative assessment would provide only a "snapshot" of the exposure at one point in time and would not accurately reflect the overall environmental and human health risk posed by these chemicals that bioaccumulate over time. This section identifies the environmental media of release and potential or expected exposures to human and ecological receptors of concern.

All of the SNUN Chemical Substances are PFAS substances that are expected to be formed during the fluorination process of HDPE containers. Potential or expected releases and

[10] Throughout this summary of EPA's risk assessment, the terms "potential" or "expected," when referring to exposure, mean that, depending on the individual SNUN Chemical Substance, life cycle stage (manufacture, distribution, use and disposal), exposure pathway, or receptor (humans or environmental organisms) there is either more or less uncertainty about exposure. Importantly, the use of either term means there is exposure, but it is a matter of the level of uncertainty in that finding. Details for each exposure scenario are in separate reports.

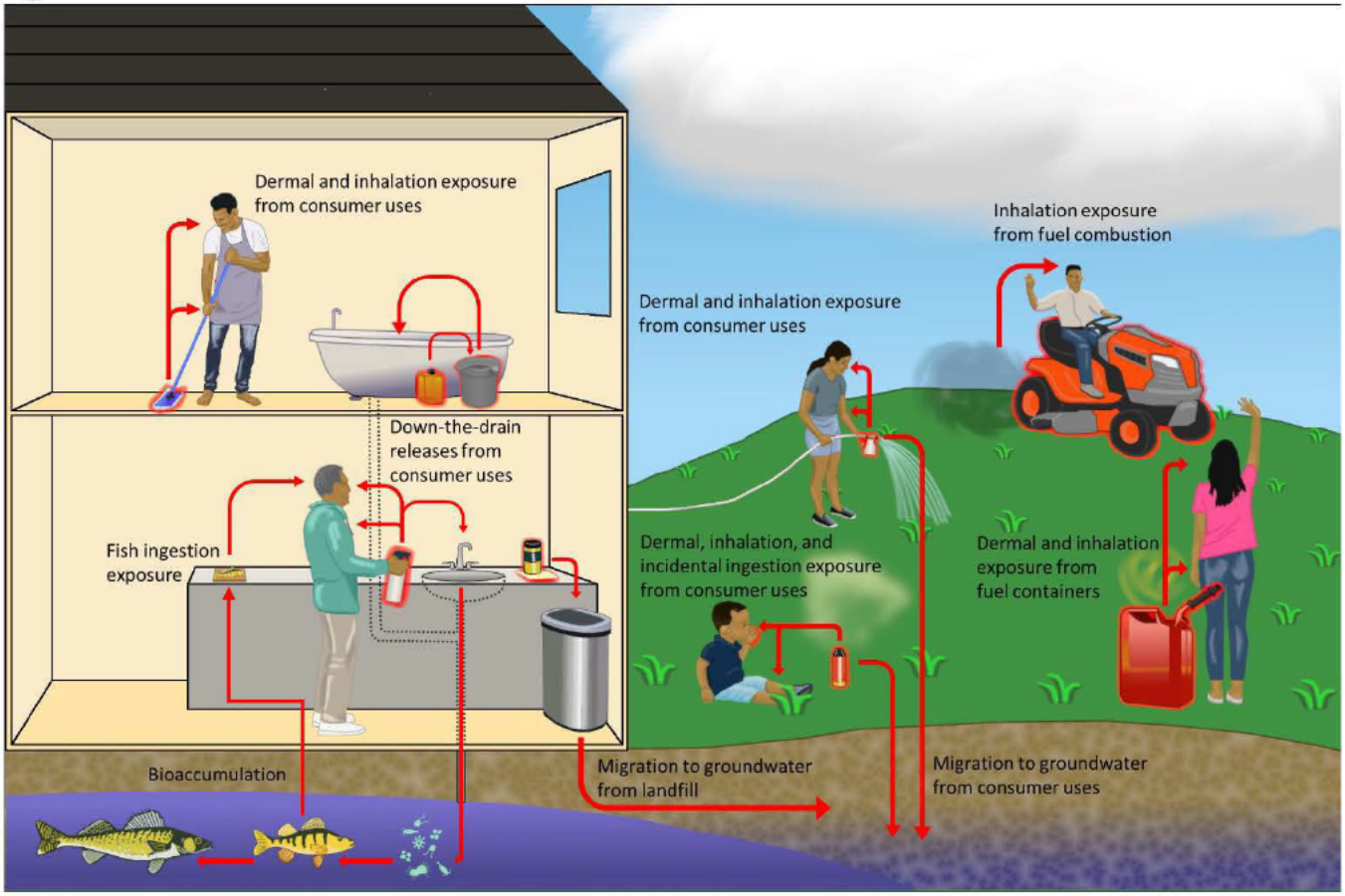
exposures occur during manufacture, processing, use and disposal (of the containers or its contents). EPA also expects other PFAS besides the SNUN Chemical Substances to be formed during the fluorination process, including PFOA, PFNA, and PFDA which are the subject of additional SNUNs, have been identified the Company as being formed during the fluorination process and are subject to a separate order. The tables in this section of the document provide an overview of the media of environmental release and exposure (including exposure pathways, and human and environmental receptors) (see Tables 4 and 5 for the fuel storage container use; Tables 5 and 6 for the other (non-fuel) storage container uses). See also Figures 1 and 2 which are two conceptual, schematic diagrams: one for environmental releases and occupational, general population, and aquatic organism exposure pathways (Figure 1) and the other for consumer exposures (Figure 2). These figures show many and different releases and exposures for the SNUN Chemical Substances. The fluorinated containers are used in various commercial and consumer applications (fuel and non-fuel). Based on the wide variety of potential uses of the plastic containers fluorinated by the Company, these schematics do not represent all of the potential or expected releases and exposure pathways from all the applications for the SNUN Chemical Substances.

Figure 1 Occupational Schematic for the SNUN Chemical Substances[1]



[1] Not all the release sources and exposure activities from all uses are shown on the diagram. Details of the specific release points and exposure activities are described in the Engineering and Exposure Reports for these chemicals provided under the respective releases and exposures summary table later in this section. Graphics adapted from: PFAS Water Cycle. United States Environmental Protection Agency. October 2022. https://www.epa.gov/system/files/documents/2022-10/pfas-water-cycle-508-friendly_0.pdf

Figure 2 Consumer Schematic for the SNUN Chemical Substances



Based on the wide variety of potential uses of the plastic containers fluorinated by the Company, this schematic does not represent all of the potential exposure pathways for the SNUN Chemical Substances from the containers fluorinated by the Company.

Fuel Storage Container Use:

Based on a qualitative engineering assessment performed using information provided in the Company's submission and the physical and chemical properties of the SNUN Chemical Substances, EPA determined that there are potential or expected environmental releases from manufacturing (to air, water, incineration[11]), processing (to air and water), commercial use (to air, water, combustion in engines, land), and end of life disposal (to air, incineration and landfill)

[11] See Table 4 Media of Release column for more detailed description of whether a release is from incineration, combustion, or fugitive air.

of fuel storage containers and tanks where the SNUN Chemical Substances are present as byproducts (Table 4). There is also potential or expected dermal exposure for workers to the SNUN Chemical Substances from fluorinated portable fuel containers, or liquid fuel containing SNUN Chemical Substances, and for inhalation exposure (Table 4).

Table 4: Environmental Release and Occupational Exposures (Fuel Storage Container Use)[a]

Potential or Expected Environmental Release Media and Occupational Exposure Pathways[b]			
Operation	**Use Description**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Worker Exposure Pathway (Inhalation, Dermal)**
Manufacturing (at [redacted] Company sites)	The SNUN Chemical Substances are byproducts of the fluorination of fuel storage containers and fuel tanks used in small combustion engines, ground-supported small engines, small motorsport engines, and marine engines.	Air (stack and fugitive), Water from Pressure/Leak testing (via WWTP[c]), Incineration	Inhalation, Dermal
Processing (Unknown Sites, number not specified)		Air (fugitive only), Water (from pressure/leak testing)	
Commercial Use		Air (fugitive), Water (spills and leaks), Incineration (from combustion of fuel), Land/Soil (from spills and leaks)	
End of Life		Air, Incineration, Landfill – all from handling, recycling, process and disposal	

[a] Based on the engineering report – see "Engineering Assessment for Fuel Storage Containers and Fuel Tanks Uses" in the administrative record for this action.
[b] For the SNUN substances that are not considered volatile by the EPA, releases to fugitive air and resultant exposure during manufacturing and processing are not expected. See details in the engineering report.
[c] WWTP – wastewater treatment plant.

Based on the qualitative exposure assessment performed using information from the Company's submission and the physical and chemical properties of the SNUN Chemical Substances, EPA determined that there is potential or expected human health exposure to the general population via drinking water, fish ingestion, groundwater impacted by landfill leachate, and inhalation of air impacted by fugitive emissions and stack emissions, including emissions from incinerators (Table 4). EPA also determined that there are potential or expected exposures to environmental receptors (aquatic organisms) via releases to surface water (Table 5). In addition, there is potential or expected consumer exposure via dermal

and inhalation pathways from the use of fluorinated storage containers and fuel tanks where the SNUN Chemical Substances are present (Table 5). Exposure to the general population and aquatic organisms resulting from Down the Drain disposal is not expected related to the fuel storage container use.

Table 5. General Population, Consumer, and Environmental Exposures (Fuel Storage Container Use)

Potential or Expected General Population, Consumer and Environmental Exposure Pathways[a]				
Operation	**Use Description**	**Exposure Group**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Exposure Pathway (Inhalation, Ingestion, Dermal) and Environmental Receptors (Aquatic Organisms)**
Manufacturing	The SNUN Chemical Substances are byproducts of the fluorination of fuel storage containers and fuel tanks used in small combustion engines, ground-supported small engines, small motorsport engines, and marine engines.	General Population, Environmental Receptors	Air (stack and fugitive*), Water, Incineration	Inhalation*, Ingestion, Aquatic Organisms
Processing (On others site)		General Population, Environmental Receptors	Air (fugitive*), Water	Inhalation*, Ingestion, Aquatic Organisms
Commercial Use 1a		General Population, Environmental Receptors	Air (fugitive), Water, Incineration (from fuel combustion), Landfill	Inhalation, Ingestion, Aquatic Organisms
End of Life		General Population	Air (fugitive), Incineration, Landfill	Inhalation, Ingestion
Consumer Use		Consumer	Air, Incineration (from fuel combustion)	Inhalation, Dermal

[a] Based on the exposure report – see "Exposure Assessment for Fuel Storage Containers and Fuel Tank Uses" in the administrative record for this action.
*For the SNUN substances that are not considered volatile by the EPA, fugitive air emissions and resultant inhalation exposures are not expected during Manufacturing or Processing. See the engineering and exposure assessments for more detail.

Non-Fuel Storage Container Use:

Based on a qualitative engineering assessment performed using information provided in the Company's submission and the physical and chemical properties of the SNUN Chemical Substances, EPA determined that there are potential or expected environmental releases from manufacturing (to air and incineration), from processing (to air), from commercial use (to air, water, land) and from end of life disposal (to air, incineration and landfill) of storage containers used in miscellaneous applications where the SNUN Chemical Substances are present as byproducts (Table 6). Depending on the process/lifecycle stage and physicochemical properties, there is potential or expected worker exposure to the SNUN Chemical Substances, via dermal pathways from fluorinated product containers, or from liquid products containing SNUN Chemical Substances, and via inhalation pathways as vapor and mist (Table 6).

Table 6: Environmental Release and Occupational Exposures (Non-Fuel Storage Container Use)[a]

Potential or Expected Environmental Release Media and Occupational Exposure Pathways[b,c]			
Operation	**Use Description**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Worker Exposure Pathway (Inhalation, Dermal)**
Manufacturing (at [redacted] Company sites, [redacted] specifically identified)	The SNUN Chemical Substances are byproducts of the fluorination of storage containers used in various applications: [redacted], trigger-spray pesticides and [redacted] commercial pesticides, and [redacted].	Air (stack and fugitive), Incineration	Inhalation, Dermal
Processing (no details on the operations of the Company customers)		Air (fugitive only)	
Commercial Use 1A, Indoor		Air, Water, Landfill	
Commercial Use 1B, Outdoor		Air, Land	
End of Life		Air, Incineration, Landfill – all from handling, recycling process and disposal	

[a] There was no information in the submission for industrial chemical storage application.
[b] Based on the engineering report – see "Engineering Assessment for Containers Used in Various Commercial-Industrial Applications" in the administrative record for this action.
[c] For the SNUN substances that are not considered volatile by the EPA, releases to fugitive air and resultant exposure during manufacturing and processing are not expected. See details in the engineering report.

Based on the qualitative exposure assessment performed using information from the Company submission and the physical and chemical properties of the SNUN Chemical Substances, EPA determined that there is potential or expected exposure to the general population via drinking water, fish ingestion, groundwater impacted by land/landfill leachate, and via inhalation from air impacted by fugitive emissions and stack emissions, including emissions from incinerators (Table 7). In addition, exposure to the general population is expected via indirect dermal contact and incidental ingestion from pesticide spray applications (Table 7). EPA also determined that there are potential or expected exposures to environmental receptors (aquatic organisms) via releases to surface water and as a result of pesticide spray drift and runoff (Table 7). In addition, there is potential or expected consumer exposure via dermal and inhalation pathways from container handling and using various household products contained in the non-fuel storage containers where the SNUN Chemical Substances are present (Table 7). Releases to water from Down the Drain disposal of consumer products (e.g., [redacted] etc.) into household wastewater are expected, which is in alignment with the conceptual exposure model provided by the submitter (Figure 3, page 39, Attachment 012). Therefore, the general population is expected to be exposed via drinking water and fish ingestion, and environmental exposure to aquatic organisms is expected.

Table 7: General Population, Consumer, and Environmental Exposures (Non-Fuel Storage Container Use)

Potential or Expected General Population, Consumer, and Environmental Exposure Pathways[a]				
Operation	**Use Description**	**Exposure Group**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Exposure Pathway (Inhalation, Ingestion, Dermal) and Environmental Receptors (Aquatic Organisms)**
Manufacturing (at [redacted] Company sites, [redacted] specifically identified)	The SNUN Chemical Substances are byproducts of the fluorination of storage containers used in various applications, [redacted]	General Population	Air (stack and fugitive*), Incineration	Inhalation*
Processing (no details on the operations of the Company customers)		General Population	Air (fugitive*)	Inhalation*

Commercial USE 1A, Indoor	[redacted] trigger-spray pesticides and [redacted], commercial pesticides, and [redacted]	General Population, Environmental Receptors	Air (fugitive*), Water, Landfill	Inhalation*, Ingestion, Aquatic Organisms
Commercial USE 1B, Outdoor		General Population, Environmental Receptors	Air (fugitive/spray drift), Land, Water (spray drift and runoff)	Inhalation, Dermal, Ingestion, Aquatic Organisms
End of Life		General Population	Air (fugitive), Incineration, Landfill	Inhalation, Ingestion
Consumer Use		Consumer, General Population, Environmental Receptors	Air, Land, Water	Inhalation, Dermal, Ingestion, Aquatic Organisms
Down the Drain		General Population, Environmental Receptors	Water	Ingestion, Aquatic Organisms

[a] Based on the exposure report – see "Exposure Assessment for Containers Used in Various Commercial-Industrial and Consumer Applications" in the administrative record for this action.

*For the SNUN substances that are not considered volatile by the EPA, fugitive air emissions and resultant inhalation exposures are not expected during Manufacturing, Processing, or Commercial Use1A. See the engineering and exposure assessments for more detail.

Appendix 3: Testing Provisions

I. Notice of Test Scheduling

A. The Company must notify EPA's Monitoring Assistance and Media Programs Division, in writing, with the following information within 10 days of scheduling any study or within 15 days after the effective date of this Order, whichever is later:

1. The date when the study is scheduled to commence;
2. The name and address of the laboratory conducting the study;
3. The name and contact information (telephone number, email) of a person at the Company or laboratory whom EPA may contact regarding the study; and,
4. The SNUN identification number for each substance and a statement that the substance is subject to this Order.

B. The written notice should be submitted to EPA/OECA as follows:

Postal Mail Address

U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
Room 7117B
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

C. Concurrently, the Company must submit a copy of the information as a support document for the SNUNs, using the procedures set out in 40 C.F.R. § 720.40.

II. Good Laboratory Practice Standards

Each test performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 C.F.R. part 792.

III. Modified Test Protocols

A. Prior to initiating any test that will use a modified version of a test protocol required by this Order, the Company must first submit the test protocol to EPA and receive EPA's approval.

B. Test protocols must be submitted as a support document, using the procedures set out in 40 C.F.R. § 720.40.

C. EPA's acceptance of a test protocol does not constitute pre-acceptance of any future test results.

IV. Submission of Test Reports and Underlying Data

A. The Company must submit the final report (Public and CBI versions in accordance with 40 C.F.R. § 703.5) and all underlying data, within 90 days of the conclusion of the test.

B. The final report must contain the contents specified in 40 C.F.R. § 792.185.

V. Raw Data

A. EPA may, at its discretion, require the Company to submit raw data, such as slides and laboratory notebooks.

B. The Company must provide raw data to EPA within 30 days of EPA's initial request for such data.

VI. Interim Results

A. EPA may require the Company to submit the results of an interim phase of a test.

B. The Company must provide interim results to EPA within 30 days of EPA's initial request for such results.

VII. Submission of Information

All test information must be submitted as a support document for the SNUNs, using the procedures set out in 40 C.F.R. § 720.40.

VIII. Effect of Equivocal Results

A. If EPA determines that the results are scientifically equivocal, the testing requirements or test protocols may be modified to generate results that EPA believes will not be equivocal, by written notification by the EPA to the Company.

IX. Determination of Invalid Data

A. If the Company finds that data is scientifically invalid, the Company must:
   1. Notify EPA, in writing, within 2 weeks of first finding or becoming aware that data generated by a test is scientifically invalid.
   2. Explain in detail, the circumstances which have caused, or will cause, development of scientifically invalid data within 2 weeks of providing the notice of Invalid Data to EPA.

B. If EPA determines that data is scientifically invalid, EPA:
   1. Will notify the Company, in writing
   2. May modify the testing requirements or test protocols by an amendment to this Order.
   3. May require the Company to reconduct the testing and submit the final report and underlying data.

C. Refuting EPA's Determination
   1. The Company may refute EPA's determination of invalid data by submitting a written report to EPA

2. The report must be submitted within 4 weeks of receiving the determination of invalid data from EPA.

NOTE: Any required testing described in the Order was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the SNUN Chemical Substances. Further, any such testing/information identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. Pursuant to TSCA section 4(h), 15 U.S.C. § 2603(h) which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the required testing.

Appendix 4: Understanding the Risk and Management of the Company's Manufacture of PFOA and Related PFAS

Per- and polyfluoroalkyl substances (PFAS) have strong, stable carbon-fluorine (C-F) bonds, making them resistant to hydrolysis, photolysis, microbial degradation, and metabolism (Ahrens, 2011; Beach et al., 2006; Buck et al., 2011). These properties are what make PFAS useful for commercial and industrial applications and purposes. However, these are also what make some PFAS extremely persistent in the human body and the environment (Calafat et al., 2007, 2019).

Long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances, a subset of PFAS, 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 (3M, 1999; EPA, 2009). Perfluorooctanoic acid (PFOA) and its salts, which are LCPFAC chemical substances, have been a primary focus of studies related to the LCPFAC class of chemical substances. 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 (Butt et al., 2010; Calafat et al., 2007; EPA, 2009; Houde et al., 2006; Lau et al., 2007). Human epidemiology data report associations between PFOA exposure and high cholesterol, increases in markers of liver damage, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney) (EPA 2016). Multiple pathways of exposure, including through drinking water, food, house dust, and release from articles, are possible (Strynar and Lindstrom, 2008).

In December 2022, the Company submitted to EPA nine significant new use notices (SNUNs) for LCPFAC chemical substances, one of which is PFOA. The nine chemical substances are produced in the process of fluorinating plastic containers. The SNUNs submitted by the Company identified fluorinated plastic used in a wide range of applications, including in fuel tanks, fuel storage containers, consumer product containers, and pesticide containers. The PFAS leach from the plastic containers into contents stored in the containers. This was first observed when

PFAS was found to have leached from a fluorinated plastic container into a pesticide that was then sprayed into the environment[12], which was discovered through citizen science testing of the pesticide.

EPA's risk assessment used the Company's reported total annual production volume of PFOA of 337 g and the total annual production of all nine substances, including PFOA, of 2,212 g (2.2 kg). This manufacture of PFOA and the other eight substances is distributed across 121 to 200 million plastic containers that are fluorinated annually by the Company. If you divide the total annual volume of PFOA or all nine PFAS across the upper range of the number of containers the Company fluorinates each year, that comes to an average projected 0.16 mg of PFOA per container and 1.1 mg of all nine PFAS per container. To some, this may seem like a small amount of PFOA, but based on the known persistence, bioaccumulation, toxicity of PFOA, there is risk from even the smallest exposure.

In March 2023, based upon a consideration of the best available peer reviewed science and a consideration of an adequate margin of safety, EPA's Office of Water proposed a health-based Maximum Contaminant Level Goal (MCLG) of **zero** for PFOA in drinking water (88 FR 18638, March 29, 2023). An 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. Based on a systematic review of available human epidemiological and animal toxicity studies, EPA found that the identified hazards of PFOA (e.g., carcinogenicity) are so great that there is currently no safe level of exposure.[13]

In the same March 2023 proposal, EPA proposed an individual maximum contaminant level (MCL) of 4.0 nanograms per liter (ng/L) or 4.0 parts per trillion (ppt) for PFOA. The MCL is the

[12] Deprez, Esmé E. Plastic Bottles With No. 2 Recycle Symbol May Have Toxic Problem. Bloomberg News. Sept. 28, 2023. Accessed at https://news.bloomberglaw.com/environment-and-energy/plastic-bottles-with-no-2-recycle-symbol-may-have-toxic-problem.

[13] EPA establishes MCLGs of zero for carcinogens classified as *Carcinogenic to Humans* or *Likely to be Carcinogenic to Humans* where there is insufficient information to determine that a carcinogen has a threshold dose below which no carcinogenic effects have been observed. In addition to carcinogenicity, EPA has also determined that the evidence indicates that PFOA exposure is associated with adverse hepatic effects, immunological effects, developmental effects, and cardiovascular effects.

maximum level allowed of a contaminant in water which is delivered to any user of a public water system, which is an enforceable standard. The PFOA MCL considers feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water; as well as the costs and public health benefits, while the PFOA MCLG considers only public health and not the limits of detection, limits of quantification, and treatment technology effectiveness or costs. EPA anticipates finalizing the regulation by the end of 2023. If finalized as proposed, the MCL for PFOA would be the second lowest MCL ever established by EPA —lower than the MCLs for mercury and PCBs.

If you take the 2.2kg of the 9 PFAS formed during the Company's annual fluorination of containers, it would take 145 billion gallons of water annually to dilute the Company's annual production of the 9 PFAS from the fluorination of containers to a level below the proposed EPA drinking water MCL for PFOA of 4 ng/L (or 4 ppt). To put 145 billion gallons of water into context, it is equivalent to 967 days' or 2.6 years' worth of water use by New Orleans, based on the city's roughly 150 million gallons of water used a day—no amount of water could dilute 2.2kg to the health-based MCLG of zero.

While EPA does not expect the total volume of the 9 PFAS to enter drinking water, this example is illustrative of the fact that even "small" amounts of PFAS can have a disproportionate amount of risk. The 9 PFAS, however, do, without a doubt, leach from the fluorinated containers. Furthermore, looking at the annual production volume of the 9 PFAS does not paint a complete picture of the amount of PFAS from these containers that may be present in the environment at any one time because of the persistence and bioaccumulative nature of these substances. The 9 PFAS will likely not leach all at once, but over time and due to their persistent and bioaccumulative nature, the amount of these 9 PFAS in the environment will grow with each successive manufacture of fluorinated containers.

The leaching of and exposure to PFOA and the other 8 LCPFAC substances, is not theoretical. As noted previously, the leaching of PFAS from fluorinated plastic was first observed in a pesticide product. As described in a September 2023 article from Bloomberg News, the drinking water in the town of Easton, Massachusetts tested positive for PFOA, and the PFAS contamination was

later linked to the spraying of the pesticide Anvil 10+10 to manage mosquitoes (Deprez 2023). The pesticide was stored in fluorinated plastic containers. Unfortunately, PFOA contamination is increasingly being identified across the U.S., often linked to chemical manufacturing, firefighting training facilities, military bases, or airports. The contamination in Easton, MA, however, has clear linkages to plastic containers fluorinated by the Company.

Exposure to PFOA and other LCPFAC chemical substances from fluorinated containers can occur at any point during the lifecycle of the container, from manufacture to disposal. For example, in Henderson, KY, PFAS contamination was discovered at a plastics recycling company. As reported by Louisville Public Media, "scientists discovered PFAS chemicals outside of Shamrock's facilities, in the soil and groundwater nearby, as well as in a creek that flows into the Ohio River, a drinking water source for millions of people." (Van Velzer, 2021). Due to the persistent, bioaccumulative, and toxic (PBT) nature of PFOA, there is potential risk not only to those who directly use the chemical substance but also to the general population because PFOA builds up in the environment over time. Due to their persistence in the environment and bioaccumulation potential, small releases of PBT PFAS into the environment over time can contribute to considerable exposure and potential risk.

A SNUN provides EPA with the opportunity to evaluate any intended significant new use of the regulated chemical substances and, if necessary, an opportunity to protect against potential unreasonable risks. In order to manage unreasonable risk, the New Chemicals Program may impose requirements such as the use of worker personal protective equipment, exposure limits for workers, restrictions for certain uses (e.g., no consumer use), limits on releases to water, air, and/or land, or prohibit manufacture. The only way to manage the risk of PFOA and the other 8 LCPFAC chemical substances, based on the conditions of use in fluorinated plastic containers, is to prohibit manufacture. Once made, these chemical substances will be released from the fluorinated plastic containers and there is no other way to mitigate their release other than preventing their manufacture in the first place. Other than prohibiting manufacture, all other risk management options would fail to manage the unreasonable risk.

When thinking of chemical manufacturing, we typically picture chemicals produced in a contained reaction vessel where the chemical is localized and then moves through identifiable steps where potential releases and exposures can be mapped out and often quantified.

When mapped out and quantified, risk managers are able to apply specific controls such as HEPA filtration to capture fugitive emissions, to set water release limits, or to require respirator use. These risk management requirements reduce identified risk to the chemical substance. The Company's manufacture of the 9 PFAS substances, however, is different. The 9 PFAS substances are manufactured on the surface of 121 to 200 million different fluorinated containers each year—equivalent to one fluorinated container for every U.S. household. Given the diverse uses of the products contained in these fluorinated containers, and the fact that leaching can occur throughout the lifecycle of the fluorinated containers, EPA cannot realistically set limits on releases to water, air, and/or land, or mitigate worker, consumer, and general population exposures. Returning to the real-world example of the PFAS that leached from the fluorinated container into the pesticide product that was then sprayed into the environment, there is no mitigation measure that EPA could have put in place to prevent the PFOA contamination there other than prohibiting the PFOA from being manufactured in the first place.

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Appendix 5: Potential Compliance Approach Guidance

EPA may consider any evidence to assess compliance with the prohibition on manufacture of the SNUN Chemical Substances contained in this order, including evidence in support of either of the following two approaches.

Approach 1:

Evidence that the company does not fluorinate HDPE containers or articles.

Approach 2:

Evidence that the company's fluorination processes do not manufacture the SNUN Chemical Substances. Such evidence might include testing that demonstrates that the SNUN Chemical Substances are not being produced at or above detectable levels conducted using a method approved for use by EPA's Office of Chemical Safety and Pollution Prevention, such as the EPA Container Coupon Method for PFAS Determination.

Nothing in this appendix limits or otherwise impacts the Agency's ability to consider any evidence to evaluate compliance with the terms of this order.

Appendix 6: References

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