April 11, 2024

Michael S. Regan, Administrator
U.S. Environmental Protection Agency
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VIA EMAIL AND CERTIFIED U.S. MAIL RETURN RECEIPT REQUESTED

Re: Citizen Petition under TSCA Section 21 to Regulate PFOA, PFNA, and PFDA Manufactured during Plastic Fluorination

Dear Administrator Regan:

On behalf of Center for Environmental Health, Public Employees for Environmental Responsibility, Alaska Community Action on Toxics, Clean Cape Fear, Clean Water Action, Delaware Riverkeeper, and Merrimack Citizens for Clean Water, we hereby petition the U.S. Environmental Protection Agency ("EPA") under Section 21 of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2620, to establish regulations pursuant to Section 6 of TSCA, 15 U.S.C. § 2605, prohibiting the manufacturing, processing, use, distribution in commerce, and disposal of three per- and polyfluoroalkyl substances ("PFAS")—perfluorooctanoic acid (CASRN 335-67-1) ("PFOA"), perfluorononanoic acid (CASRN 375-95-1) ("PFNA"), and perfluorodecanoic acid (CASRN 335-76-2) ("PFDA")—formed during the fluorination of plastic containers.[1]

Each year, hundreds of millions of plastic containers are fluorinated using a process that creates a suite of toxic PFAS, including PFOA, PFNA, and PFDA.[2] These PFAS are highly toxic, extremely persistent in the environment, and bioaccumulate in the human body.[3] The fluorination process and the subsequent leaching of PFAS into products stored in these

[1] At issue in this petition is the post-mold fluorination process that EPA has already found to generate PFAS—other fluorination processes not addressed in the EPA risk assessment are outside the scope of this petition.
[2] *See* Memorandum from Risk Assessment Branches/Industrial Chemistry Branch, New Chems. Div., Off. of Pollution Prevention and Toxics to Geraldine Hilton, Risk Mgmt. Branch 1, New Chems. Division, Off. of Pollution Prevention and Toxics, Re: Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002–0006 and SN-23-0008–0011 at 22 (Nov. 30, 2023) ("EPA Risk Assessment") (attached as **Exhibit 1**) (noting that Inhance Technologies, LLC ("Inhance"), a producer of fluorinated containers, "fluorinated approximated 121 million containers in 2021" and, in August 2023, "state[d] that it fluorinates over 200 million containers annually"); *see also id.* at 12 (stating that nine long-chain PFAS—including PFOA, PFNA, and PFDA—are formed during the coating via fluorination of high-density polyethylene storage containers and other shorter chain PFAS are likely to be formed during fluorination as well).
[3] *See id.* at 16, 18–22.

containers expose workers, consumers, and the general public to these harmful substances.[4] Critically, just last year EPA determined that the manufacture, processing, distribution in commerce, use, or disposal of PFOA, PFNA, and PFDA—when manufactured or processed during the process of fluorinating plastic containers—presents an unreasonable risk of injury to health or the environment.[5] EPA has the power to regulate the fluorination process that creates these toxic PFAS under Section 6 of TSCA, as the U.S. Court of Appeals for the Fifth Circuit recently recognized.[6] TSCA Section 6(a) provides that when EPA determines that a chemical "presents an unreasonable risk of injury to health or the environment," EPA "shall" regulate the chemical "to the extent necessary so that [it] no longer presents such risk."[7] Having already made that precise unreasonable risk determination under Section 5 for the chemicals and uses at issue in this petition, EPA is obligated to grant the petition and initiate a rulemaking under TSCA Section 6(a) to eliminate the unreasonable risks caused by the production and processing of PFOA, PFNA, and PFDA during plastic fluorination and by the use, distribution in commerce, and disposal of fluorinated containers.

EPA has already concluded that it "cannot control potential exposures to [these three PFAS] through means other than a prohibition on the manufacture of these substances."[8] Thus, a prohibition of PFAS production during fluorination of plastic containers is necessary to eliminate the unreasonable risks presented by PFOA, PFNA, and PFDA created during that process. In order to eliminate the unreasonable risk posed by these PFAS created during plastic fluorination, EPA must "promptly commence" a rulemaking under TSCA Section 6(a) and ensure that its rule takes effect "as soon as practicable."[9] We further urge EPA to adopt any such rule promptly and to make it immediately effective upon proposal in order to address the widespread risk of harm posed by these PFAS and plastic fluorination.[10]

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[4] *See id.* at 29–31.

[5] *See* EPA, TSCA Section 5 Order for a Significant New Use of Certain Chemical Substances, Significant New Use Notice Numbers: SN-23-0002, SN-23-0004 and SN-23-0005 at 3 (Dec. 1, 2023) ("EPA 5(f) Order") (attached as **Exhibit 2**).

[6] *See* Opinion at 13, *Inhance Techs., LLC v. EPA*, No. 23-60620 (5th Cir. Mar. 21, 2024), ECF No. 186-1 ("Inhance Opinion"). As described below, the Inhance Opinion did not question or overturn the findings of the EPA Risk Assessment. Nothing in this petition should be interpreted as endorsing the Inhance Opinion or in any way affecting the pending suit brought by EPA and petitioners PEER and CEH in the District Court for the Eastern District of Pennsylvania. *See United States v. Inhance Techs. LLC*, 5:22-cv-05055 (E.D. Pa.)

[7] 15 U.S.C. § 2605(a).

[8] EPA 5(f) Order at 6.

[9] 15 U.S.C. §§ 2620(b)(3), 2605(d)(1)(A).

[10] *Id.* § 2605(d)(3)(A) (allowing EPA to declare a Section 6(a) proposed rule to be effective "upon publication in the Federal Register of the proposed rule" if it determines that "the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance . . . is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors; and . . . making such proposed rule so effective is necessary to protect the public interest").

I. Background

A. TSCA Section 21 permits the public to petition EPA to regulate chemicals that present unreasonable risks.

Section 21(a) of TSCA permits "[a]ny person" to petition EPA to initiate a proceeding for the issuance of a rule under TSCA Section 6.[11] A Section 21 petition must "set forth the facts which it is claimed establish that it is necessary to issue" such a rule.[12] Within 90 days of the filing of a Section 21 petition, EPA must either grant or deny the petition; if EPA grants it, EPA "shall promptly commence an appropriate proceeding" in accordance with the section under which the action is sought.[13]

Section 6(a), in turn, directs EPA to regulate a chemical substance by rule that it has determined "presents an unreasonable risk of injury to health or the environment" and to impose restrictions "to the extent necessary so that the chemical substance . . . no longer presents such risk."[14] A rulemaking initiated by a Section 21 petition does not require EPA to conduct a risk evaluation or list the substance as a high-priority chemical. Nor can EPA base its determinations of unreasonable risk on a balancing of costs and benefits, an element of EPA's decision-making process under the original law that Congress explicitly eliminated when it amended TSCA in 2016.[15] Rather, a petitioner is entitled to relief if it shows that a chemical substance presents an unreasonable risk under one or more conditions of use such that a Section 6(a) rule is necessary.[16] As EPA has explained, "[a] TSCA Section 21 citizen petitioner need only present

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[11] *Id.* § 2620(a).
[12] *Id.* § 2620(b)(1).
[13] *Id.* § 2620(b)(3).
[14] *Id.* § 2605(a).
[15] *See id.* § 2605(b)(4)(A). Under the amended Section 6, if EPA determines that a chemical presents unreasonable risk, EPA must regulate the chemical "to the extent necessary so that [it] no longer presents such risk." 15 U.S.C. § 2605(a). Only after EPA has made an unreasonable risk determination and initiated a Section 6(a) rulemaking process can EPA consider, among other factors, "the costs and benefits of the proposed and final regulatory action." *Id.* § 2605(c)(2)(A)(iv)(II). Even then, EPA's overriding obligation is to eliminate unreasonable risk, such that EPA's consideration of costs and other non-risk factors can only influence the choice between risk management measures that would eliminate the unreasonable risk.
[16] *See* Letter from Michal Freedhoff, Assistant Adm'r for Chem. Safety and Pollution Prevention, EPA to Elizabeth Forsyth and Katherine O'Brien, Earthjustice Re: Petition ID No. 001845: Toxic Substances Control Act Section 21 Petition Regarding N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediaine (CASRN 793-24-8, aka 6PPD) in Tires – Final EPA Response to Petition at 2 (Nov. 2, 2023) ("EPA 6PPD Response") (granting petition seeking risk management rule for a chemical without a TSCA risk evaluation and agreeing to commence a rulemaking proceeding under TSCA Section 6(a)); *Food & Water Watch, Inc. v. EPA*, 291 F. Supp. 3d 1033, 1046 (N.D. Cal. 2017) ("[T]here are three different pathways to a Section 6(a) rule. The predicate for a rule is a finding of unreasonable risk. Section 6(b) governs two processes that may result in an

facts demonstrating that a chemical substance poses an unreasonable risk due to one or more conditions of use, not all conditions of use."[17]

B. EPA has found that PFOA, PFNA, and PFDA produced during the fluorination of plastic containers present unreasonable risk.

As EPA has acknowledged, "[f]or far too long, communities across the United States have been suffering from exposure to PFAS pollution."[18] While they do not occur naturally and a century ago they did not exist, today PFAS contaminate "[a]t least 45% of the nation's tap water" and the blood of more than 98% of people tested in the United States.[19] PFAS are often called "forever chemicals," and "[d]ue to their widespread use, physicochemical properties, and prolonged persistence, many PFAS co-occur in exposure media (*e.g.,* air, water, ice, sediment), and bioaccumulate in tissues and blood of aquatic as well as terrestrial organisms, including humans."[20] PFAS generally are associated with "significant and diverse" adverse health effects that "include (but are not limited to): cancer and effects on the liver (*e.g.,* liver cell death), growth and development (*e.g.,* low birth weight), hormone levels, kidney, immune system, lipid levels (*e.g.,* high cholesterol), the nervous system, and reproduction."[21]

EPA has already determined that the PFOA, PFNA, and PFDA formed during the fluorination of plastic present unreasonable risk. Indeed, as EPA has recognized, those PFAS are associated with a range of serious adverse health effects, including cancer, reproductive and developmental harm, immune system toxicity, and other harms.[22] EPA has also found that at least

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unreasonable risk finding: risk evaluations based on EPA's *sua sponte* designation of a 'high priority' chemical[] and risk evaluations at the request of a manufacturer. Section 21 governs the third pathway, one that appears to be independent of the Section 6(b) risk evaluation process. Indeed, the TSCA explicitly requires a Section 6(b) 'risk evaluation' to be performed for 'high priority' chemicals and in response to manufacture requests, but does not state that the same requirement applies to citizen petitions.").

[17] EPA 6PPD Response at 2; *see also Food & Water Watch, Inc.*, 291 F. Supp. 3d at 1048–49 ("[T]he text, structure, and purpose of the TSCA clearly demonstrate that a Section 21 petition does not need to address all conditions of use.").

[18] EPA, *PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024* at 1 (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

[19] News Release, U.S. Geological Survey, Tap Water Study Detected PFAS Forever Chemicals Across U.S. (July 5, 2023), https://www.usgs.gov/news/national-news-release/tap-water-study-detects-pfas-forever-chemicals-across-us; Antonia M. Calafat et al., *Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000*, 115 Env't Health Persps. 1596 (2007), https://doi.org/10.1289/ehp.10598.

[20] PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638, 18,642 (Mar. 29, 2023).

[21] *Id.* at 18,643.

[22] *See* Part II.A, *infra.*

two of those three PFAS—PFOA and PFDA—present health risks at exposure levels below detectable levels.[23]

In 2020, to "stop products containing PFAS from entering or reentering the marketplace without [EPA's] explicit permission," EPA finalized a significant new use rule ("SNUR") under Section 5(a) of TSCA, requiring companies to notify EPA before commencing any significant new uses of long-chain carboxylate PFAS.[24] Upon receipt of a significant new use notice ("SNUN"), EPA generally must evaluate the risks associated with the use; determine whether the use is "not likely to present," "may present," or "presents" unreasonable risk; and issue orders under Section 5(e) or 5(f) associated with unreasonable risk determinations that prohibit or restrict the use "to the extent necessary to protect against" such risk.[25]

In 2022, Inhance Technologies, LLC ("Inhance"), a company that fluorinates plastic containers and produces long-chain PFAS subject to the 2020 SNUR during its fluorination process, submitted multiple consolidated SNUNs to EPA for Inhance's production of nine such PFAS.[26] In response to these SNUNs, EPA conducted a risk assessment and determined that the manufacture, processing, distribution in commerce, use, or disposal of PFOA, PFNA, and PFDA—when manufactured or processed for the fluorination of plastic containers—presents an unreasonable risk of injury to health or the environment. EPA made this determination pursuant to Section 5(a)(3)(A) and (f)(1) of TSCA,[27] which contain substantively identical language to the unreasonable risk determination called for in Section 6. In either case, EPA is directed to consider whether a chemical "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use."[28] Given that "identical words used in different parts of the same statute are generally presumed to have the same meaning," the "unreasonable risk"

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[23] 88 Fed. Reg. at 18,669 ("The level at which no known or anticipated adverse effects on the health of persons would occur is well below current analytical quantitation level for PFOA . . ."); EPA 5(f) Order at 27 (adopting lower reference dose for PFDA than that of PFOA).

[24] Press Release, EPA, EPA Takes Action to Stop Use of Certain PFAS in Products and Protect American Consumers (June 22, 2020), https://www.epa.gov/newsreleases/epa-takes-action-stop-use-certain-pfas-products-and-protect-american-consumers; *see also* Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 85 Fed. Reg. 45,109 (July 27, 2020).

[25] 15 U.S.C. § 2604(a)(3), (e), (f). As explained below, the Fifth Circuit recently vacated Section 5 orders EPA issued pursuant to this 2020 SNUR. It ruled that since fluorination by Inhance Technologies, LLC was ongoing throughout and after the SNUR rulemaking, EPA could not treat it as a "new use" of long-chain PFAS. Petitioners PEER and CEH, *amici curiae* in that litigation, believe that this holding misinterpreted the language and intent of TSCA.

[26] *See* Certain New Chemicals; Receipt and Status Information for January 2023, 88 Fed. Reg. 10,320, 10,323–24 (Feb. 17, 2023).

[27] EPA 5(f) Order at 3.

[28] 15 U.S.C. § 2604(a)(3)(A), (f)(1); *see also id.* § 2605(b)(4)(A).

standard in sections 5 and 6 should be interpreted identically.[29] EPA has acknowledged as much: At oral argument before the 5th Circuit, counsel for EPA explained that "Section 6 has the exact same language about making risk determinations" as in Section 5 and that there are "three steps in Section 6, and only the third step is different between Section 6 and 5."[30] EPA's counsel proceeded to explain that the first two steps that are the same in Sections 5 and 6 are: (1) "determin[ing] whether" a chemical substance or use "presents or may present unreasonable risk," and (2) deciding "what's necessary to prevent that risk—what are the measures?"[31]

This is reinforced by the structure of TSCA. If EPA finds, pursuant to Section 5, that a chemical substance poses an unreasonable risk, it must issue either a Section 5(f) order to "prohibit or limit" the manufacture of a chemical substance or a Section 6(a) rule otherwise regulating those activities.[32] That is, TSCA contemplates that both a Section 5(f) order and a Section 6(a) rule follow the same triggering finding—that a chemical substance poses an unreasonable risk of injury to health or the environment. As EPA has explained, its "Section 5 responsibilities complement its Section 6 responsibilities. . . . [O]nce EPA becomes aware through a Section 5 review that a chemical substance or use presents unreasonable risk, EPA may also take action under Section 6."[33]

In finding that these PFAS present unreasonable risk, EPA explained that PFOA, PFNA, and PFDA—like the other long-chain PFAS produced by fluorination—are persistent, bioaccumulative, and toxic chemicals ("PBTs"),[34] such that "[s]mall releases to the environment can have a significant long-term contribution to exposure and risk."[35] EPA elaborated that PFOA, PFNA, and PFDA contain "multiple C-F bonds, which are extremely stable, and each is anticipated to be extremely persistent."[36] As "long-chain PFAS, a class of chemicals with extensive data indicating they bioaccumulate in humans and fish tissue, all are expected to bioaccumulate."[37] And none "are expected to degrade under normal environmental

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[29] *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005) (noting the "normal rule of statutory interpretation that identical words used in different parts of the same statute are generally presumed to have the same meaning.").
[30] *See* Oral Argument at 19:45–50, 19:56–20:02, *Inhance Techs. LLC v. EPA*, Case No. 23-60620 (5th Cir. Feb. 5, 2024).
[31] *Id.* at 20:04–13. Counsel for EPA continued: "Third, what happens . . . is if you need to decide between multiple measures that both adequately prevent risk, then you do an analysis of effects to the economy or costs to the regulated entity. But . . . what EPA still needs to do is decide what will actually prevent the risk, and that's in Section 6 as well." *Id.* at 20:14–33.
[32] 15 U.S.C. § 2604(f)(1)–(3).
[33] *See* EPA Response Br. at 10 n.1, *Inhance Techs., LLC v. EPA*, No. 23-60620 (5th Cir. Jan. 22, 2024), ECF No. 88.
[34] EPA Risk Assessment at 14–22.
[35] *Id.* at 6; EPA 5(f) Order at 14; *see also* EPA 5(f) Order 20 ("Because these SNUN Chemical Substances are PBTs, they are expected to accumulate over time.").
[36] EPA Risk Assessment at 30.
[37] *Id.*

conditions."[38] EPA further highlighted that "PFOA, PFNA, and PFDA are extremely toxic and have been detected in US human serum samples,"[39] and explained that, due to the severe adverse health effects associated with PFOA, "there is currently no safe level of exposure."[40] EPA noted that the long-chain PFAS produced by fluorination, including PFOA, PFNA, and PFDA, "do, without a doubt, leach from the fluorinated containers" into the products stored therein and that "over time and due to their persistent and bioaccumulative nature, the amount of these . . . PFAS in the environment will grow with each successive manufacture of fluorinated containers."[41] EPA also outlined the various ways that humans and organisms come into contact with the PFAS created by plastic fluorination.[42]

Based on its unreasonable risk determination and as required by TSCA, on December 1, 2023, EPA issued a Section 5(f) order to Inhance, prohibiting it from manufacturing, processing, distributing in commerce, using, or disposing of PFOA, PFNA, or PFDA for its "significant new use"—its fluorination of plastic containers. In its 5(f) order, EPA explained that "[a] prohibition on the manufacture of [PFOA, PFNA, and PFDA] is required because the risk cannot otherwise be adequately mitigated."[43]

After EPA issued orders under Section 5 to protect the public from the risks posed by the production of PFAS during the fluorination of plastic containers,[44] Inhance petitioned for judicial review of the orders in the U.S. Court of Appeals for the Fifth Circuit. Inhance asserted that EPA's orders were unlawful because, among other things, its fluorination technology is not a "new" use and thus could not be regulated under TSCA Section 5. On March 21, 2024, the Fifth Circuit vacated the orders, agreeing with Inhance that its fluorination process was not a "significant new use" within the meaning of TSCA Section 5.[45] In so ruling, the Fifth Circuit expressly declined to reach the merits of Inhance's other arguments, including its challenge to EPA's underlying risk assessments, and did not cast any doubt on the validity of EPA's

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[38] *Id.*
[39] EPA 5(f) Order at 20.
[40] *Id.* at 38; *see also id.* at 37.
[41] *Id.* at 39.
[42] *Id.* at 30–36.
[43] *Id.* at 5.
[44] In addition to the Section 5(f) order, on December 1, 2023, EPA also issued an order under Section 5(e) of TSCA prohibiting the manufacture, processing, distribution in commerce, use, or disposal of the six other long-chain PFAS manufactured by Inhance during plastic fluorination for that use. EPA, *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 (Dec. 1, 2023). This order was based on EPA's determination that Inhance's production of these six other long-chain PFAS may present an unreasonable risk of injury to health or the environment. *Id.* at 3. This petition does not seek regulation of the long-chain PFAS subject to EPA's 5(e) order.
[45] *See* Inhance Opinion at 12–13. As noted above, by submitting this petition, Petitioners are not endorsing the logic or outcome of the Inhance Opinion, which we believe misinterpreted EPA's Section 5 authority.

unreasonable risk determination.[46] Indeed, the court "hasten[ed] to add" that EPA could "properly proceed" to regulate the process under Section 6 of TSCA.[47]

II. EPA Correctly Determined That PFOA, PFNA, and PFDA Produced During the Fluorination of Plastic Containers Present an Unreasonable Risk to Health or the Environment

As EPA has found—considering the best available science and following a comprehensive review of the relevant evidence[48]—the manufacturing, processing, distribution in commerce, use, or disposal of PFOA, PFNA, and PFDA produced during the fluorination of plastic containers pose an unreasonable risk to health or the environment. EPA must therefore issue a Section 6(a) rule assuring that these PFAS "no longer present[] such risk."[49]

Since the same "unreasonable risk" standard applies under TSCA Section 5 and Section 6, EPA's determination made in support of its 5(f) order requires rulemaking under Section 6(a) and compels a grant of this petition. EPA's unreasonable risk determination is also well supported by EPA's reasoning and comprehensive analysis of the SNUNs, as well as by the weight of the scientific evidence.[50] Indeed, as EPA recently explained in its brief to the Fifth Circuit, allowing an entity that fluorinates plastic containers "to continue to manufacture any detectable amount of [l]ong-[c]hain PFAS," including the three PFAS subject to the 5(f) order, "would go against the best available science and EPA's stated policies."[51]

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[46] *See id.* at 8 n.8.

[47] *Id.* at 13. While the Fifth Circuit referenced a cost-benefit analysis in its opinion, that analysis is not relevant to EPA's determination of whether a chemical substance poses an unreasonable risk. Nor can EPA's consideration of economic factors during risk management under Section 6(c) override EPA's obligation to apply risk management measures "to the extent necessary so that the chemical substance . . . no longer presents such risk." 15 U.S.C. § 2605(a). That is, EPA can factor in costs and benefits associated with a measure only to choose among regulatory options that will eliminate unreasonable risk, not to compromise the level of protection EPA must afford in its rule.

[48] *See* 15 U.S.C. § 2625(h) ("In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science . . . .").

[49] *Id.* § 2605(a).

[50] *Cf. id.* § 2625(i) ("The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence.").

[51] *See* EPA Response Br. at 36*, Inhance Techs., LLC v. EPA*, No. 23-60620 (5th Cir. Jan. 22, 2024), ECF No. 88.

A. PFOA, PFNA, and PFDA are hazardous to human health and the environment at extremely low levels.

The human health risks associated with PFAS are well established and have been widely recognized by international scientific organizations,[52] federal and state regulatory agencies,[53] and other leading scientific bodies.[54] As EPA explained following its review of relevant literature in its risk assessment, the three long-chain PFAS for which petitioners seek a Section 6(a) rule "are well studied PFAS that are known to be extremely toxic."[55] They are associated with cancer (PFOA, PFNA),[56] developmental harm (PFOA, PFNA, PFDA), reproductive harm (PFOA, PFNA, PFDA), immune system toxicity (PFOA, PFNA, PFDA), liver toxicity (PFOA, PFNA, PFDA), thyroid toxicity (PFOA), and kidney toxicity (PFOA), among other adverse effects.[57]

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[52] *See* United Nations Env't Programme, *Report of the Persistent Organic Pollutants Review Committee on the Work of Its Twelfth Meeting Addendum,* UNEP/POPS/POPRC.12/11/Add.2, at 24–26 (Oct. 2016) (Risk Profile on Pentadecafluorooctanoic Acid (PFOA, Perfluorooctanoic Acid), its Salts and PFOA-related Compounds), http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.12-11-Add.2.English.PDF.

[53] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Perfluoroalkyls,* at 4–21, 26–29 (May 2021), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf; Cal. Env't Protection Agency, *Public Health Goals*: *Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water (First Public Review Draft),* Off. of Env't Health Hazard Assessment, at 62–166 (July 2021), https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf.

[54] Nat'l Acad. of Sci., Eng'g, & Med., *Guidance on PFAS Exposure, Testing, and Clinical Follow-Up,* at 6–8 (2022), https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up (click "Download Free PDF"); *see also* Arlene Blum et al., *The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)*, 123 Env't Health Persp. A107 (2015), https://ehp.niehs.nih.gov/doi/epdf/10.1289/ehp.1509934 (statement of more than 250 scientists expressing "concern[] about the production and release into the environment of an increasing number of [PFAS]").

[55] EPA Risk Assessment at 2; *see also id.* at 18–21.

[56] The International Agency for Research on Cancer ("IARC") has recently classified PFOA as "carcinogenic to humans." *See* WHO, IARC Monographs *Evaluate The Carcinogenicity of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid* (PFOS) (Dec. 1, 2023), https://www.iarc.who.int/news-events/iarc-monographs-evaluate-the-carcinogenicity-of-perfluorooctanoic-acid-pfoa-and-perfluorooctanesulfonic-acid-pfos/. And, as EPA recently explained, "[a]n epidemiological study has . . . indicated increased risk of renal cell carcinoma with exposure to PFNA, especially within African-Americans." Listing of Specific PFAS as Hazardous Constituents, 89 Fed. Reg. 8606, 8614 (Feb. 8, 2024).

[57] *See* 88 Fed. Reg. at 18,646–47, 18,656–63, 18,704, 18,718; EPA, *IRIS Toxicological Review of Perfluorodecanoic Acid [PFDA, CASRN 335-76-2] and Related Salts (External Review Draft),* Doc. No. EPA/635/R-23/056a at xvi (Apr. 2023), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=546623; *see also* EPA Risk Assessment at 2 (noting that PFOA, PFNA, and PFDA "are well studied PFAS that are known to be extremely toxic").

And adverse health effects can occur at extremely low levels of exposure;[58] as EPA has recently explained, "there is no dose below which" one of the PFAS at issue here, PFOA, "is considered safe."[59]

PFOA, PFNA, and PFDA also harm the environment. As EPA recognizes in its risk assessment of the long-chain PFAS produced during plastic fluorination, PFOA is toxic to aquatic organisms.[60] Research confirms that exposure to PFOA, PFNA, and PFDA has adverse effects on aquatic organisms, including certain bivalves and bacteria.[61]

The danger associated with exposure to PFOA, PFNA, and PFDA is heightened by the fact that multiple other PFAS are produced during fluorination,[62] and people are exposed to these in combination. As EPA explained in its risk assessment, six other long-chain carboxylate PFAS are present in fluorinated containers, and other shorter-chain PFAS are likely to exist as byproducts formed during fluorination.[63] Like many PFAS, PFOA, PFNA, and PFDA have common health effects, and people who are exposed to multiple PFAS—like those who face exposures to all of the PFAS co-produced during fluorination processes—face greater risks of

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[58] *See* EPA Risk Assessment at 21. EPA permissibly chose to conduct a qualitative risk assessment, explaining in detail why "risks to human health and the environment [could] be[] underestimated by conventional, quantitative risk assessment methods." *Id.* at 5. It did, however, perform a sensitivity analysis calculating risk for PFOA and PFDA using EPA's human health hazard information and Inhance-submitted exposure calculations; eighty percent of the calculations performed in the sensitivity analysis showed risk. *Id.* at 8 n.11. EPA also correctly found that Inhance's quantitative risk assessment was unsupported and, in key respects, inaccurate. *Id.* at 11–12. As EPA explains, EPA's interim or draft reference doses for PFOA and PFDA are extremely low—thousands of times lower than the values that Inhance selected to support its position that its fluorination process presents no unreasonable risk. *See id.* With the use of EPA's scientifically supported toxicity values, Inhance's own risk assessment supports EPA's finding of unreasonable risk. *Id.*

[59] 88 Fed. Reg. at 18,639; *see also id.* (explaining that, for PFOA, "the level at which no known or anticipated adverse effects on the health of persons is expected to occur is well below current analytical quantitation levels").

[60] *See* EPA Risk Assessment at 18.

[61] *See* Tinting Ma et al., *Toxicity of Per- and Polyfluoroalkyl Substances to Aquatic Invertebrates, Planktons, and Microorganisms*, 19 Int'l J. of Env't Rsch. & Pub. Health Art. No. 16729 (Dec. 2022), doi: 10.3390/ijerph192416729/.

[62] Six other long-chain PFAS are produced during Inhance's fluorination process and are present in fluorinated containers alongside PFOA, PFNA, and PFDA. EPA Risk Assessment at 12. In addition, there are likely to be "other, shorter-chain PFAS formed as byproducts during fluorination" present in fluorinated containers. *Id.*; *see also id.* at 31 ("[T]here is evidence that other potentially hazardous PFAS are formed during the fluorination process.").

[63] *Id.* These other long-chain PFAS are: perfluoroundecanoic acid (CASRN 2058-94-8) ("PFuDA"), perfluorododecanoic acid (CASRN 307-55-1) ("PFDoA"), perfluorotridecanoic acid (CASRN 72629-94-8) ("PFTrDA"), perfluorotetradecanoic acid (CASRN 376-06-7) ("PFTeDA"), perfluorodexadecanoic acid (CASRN 67905-19-5) ("PFHxDA"), and perfluorostearic acid (CASRN 16517-11-6) ("PFODA"). *Id.* at 4, 12.

harm from co-exposure than they would from exposure to any of these PFAS individually. Studies have shown that exposure to PFAS mixtures, including mixtures with PFOA, PFNA, and PFDA, alters critical biological processes in children and young adults that are associated with an increased risk of developmental disorders, cardiovascular disease, and many types of cancer.[64] Recent human birth cohort studies also reported associations between exposures to multiple PFAS during pregnancy—including PFOA, PFNA, and PFDA—and adverse health outcomes, including an increased risk of gestational diabetes and altered glucose levels during pregnancy, altered levels of thyroid hormones in pregnant people and newborns, and liver injury in children.[65] As EPA has explained, "PFAS have dose additive impacts,"[66] and failing to account for the "growing body of evidence on the dose additive effects for mixtures of PFAS . . . will result in underestimating risk."[67]

These additive exposures exacerbate the risks associated with the co-production of PFOA, PFNA, and PFDA during plastic fluorination. TSCA requires EPA to regulate to protect against unreasonable risks, which include unreasonable risks to any "potentially exposed or susceptible subpopulation."[68] This category includes overburdened communities, such as groups that face greater risks because of their aggregate or additive chemical exposures.[69] And people who are exposed to multiple chemicals that cause the same health effects, or to non-chemical

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[64] Jesse A. Goodrich et al., *Metabolic Signatures of Youth Exposure to Mixtures of Per- and Polyfluoroalkyl Substances: A Multi-Cohort Study*, 131 Env't Health Persp. Art. No. 27005 (2023), https://ehp.niehs.nih.gov/doi/epdf/10.1289/EHP11372.

[65] Guoqi Yu et al., *Environmental Exposure to Perfluoroalkyl Substances in Early Pregnancy, Maternal Glucose Homeostasis and the Risk of Gestational Diabetes: A Prospective Cohort Study*, 156 Env't Int'l Art. No. 106621 (2021), doi:10.1016/j.envint.2021.106621; Blanca Sarzo et al., *Maternal Perfluoroalkyl Substances, Thyroid Hormones, and* DIO *Genes: A Spanish Cross-sectional Study*, 55 Env't Sci. Tech. 11144 (2021), https://pubs.acs.org/doi/10.1021/acs.est.1c01452; Arash Derakhshan et al., *Association of Per- and Polyfluoroalkyl Substances with Thyroid Homeostasis During Pregnancy in the SELMA Study*, 167 Env't Int'l Art. No. 107420 (2022), doi:10.1016/j.envint.2022.107420; Richard Christian Jensen et al., *Higher Free Thyroxine Associated with PFAS Exposure in First Trimester. The Odense Child Cohort*, 212 Env't Rsch. Art. No. 113492 (2022), doi:10.1016/j.envres.2022.113492; Jianqiu Guo et al., *Umbilical Cord Serum Perfluoroalkyl Substance Mixtures in Relation to Thyroid Function of Newborns: Findings From Sheyang Mini Birth Cohort Study,* 273 Chemosphere Art. No. 129664 (2021), doi:10.1016/j.chemosphere.2021.129664; Nikos Stratakis et al., *Prenatal Exposure to Perfluoroalkyl Substances Associated With Increased Susceptibility to Liver Injury in Children*, 72 Hepatology 1758, 1758–70 (2020), doi:10.1002/hep.31483.

[66] 88 Fed. Reg. at 18,649–50.

[67] EPA Risk Assessment at 12.

[68] 15 U.S.C. § 2605(b)(4)(A).

[69] *See id.* § 2602(12) (defining "potentially exposed or susceptible subpopulation" as a "group of individuals . . . who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture"); *see also* Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74,292, 74,305 (Oct. 30, 2023).

stressors that worsen the impacts of chemical exposures, are more likely to experience harm than they would be without those additive exposures and thus have "greater susceptibility" to the effects of each chemical.[70]

B. The fluorination of plastic containers exposes people and other organisms to PFOA, PFNA, and PFDA.

It is well established, including from EPA's own studies, that PFAS formed during the fluorination process leach from fluorinated plastic containers into the products stored in them.[71] As a result, exposure to toxic PFOA, PFNA, PFDA and other PFAS can occur at all stages of the lifecycles of these containers, including their manufacturing, processing, distribution, use, and disposal.

In its 5(f) order, EPA listed the myriad ways that humans and other organisms are exposed to the long-chain PFAS created by plastic fluorination, including through: dermal absorption from handling fluorinated containers and their contents; consuming contaminated drinking water and fish; groundwater contamination from landfill leachate; inhaling contaminated air;[72] PFAS releases to surface water;[73] and contaminated pesticide spray drift and runoff.[74] These exposures occur throughout the fluorinated containers' lifecycles: The workers who fluorinate containers at manufacturing facilities are exposed to PFAS, as are the communities surrounding the facilities where fluorination occurs.[75] Users of products in

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[70] 15 U.S.C. § 2602(12); *see also* Nat'l Rsch. Council, *Science and Decisions: Advancing Risk Assessment*, at 214 (2009), https://nap.nationalacademies.org/catalog/12209/science-and-decisions-advancing-risk-assessment (click "Download Free PDF") ("Ignoring numerous agents or stressors that affect the same toxic process as the chemical of interest and omitting background processes could lead to risk assessments that, for example, assume population thresholds in circumstances where such thresholds may not exist."); *see also* Kristi P. Fedinick, et al., *A Cumulative Framework for Identifying Overburdened Populations under the Toxic Substances Control Act: Formaldehyde Case Study*, 18 Int'l J. of Env't Rsch. & Pub. Health Art. No. 6002 (2021), https://doi.org/10.3390/ijerph18116002; EPA, *Framework for Cumulative Risk Assessment,* Doc. No. EPA/630/P-02/001F, at 51 (May 2003), https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf.

[71] *See, e.g.*, Memorandum from Thuy Nguyen, Chief, Analytical Chem. Branch, EPA to Anne Overstreet, Acting Dir., Biological & Econ. Analysis Div., EPA Off. of Pesticide Programs Re: Results of EPA's Analytical Chemistry Branch Laboratory Study of PFAS Leaching from Fluorinated HDPE Containers - ACB Project B21-02 (Aug. 12, 2022), https://www.epa.gov/system/files/documents/2022-09/EPA%20PFAS%20Container%20Leaching%20Study%2008122022_0.pdf (finding "clear" evidence "of the migration (leaching) of PFAS from container walls to the liquid solutions in the container"); EPA Risk Assessment at 10.

[72] EPA 5(f) Order at 32–36.

[73] *Id.* at 32–33, 35–36.

[74] *Id.* at 35.

[75] EPA Risk Assessment at 23, 25–28.

fluorinated containers are exposed to PFAS by multiple exposure pathways when they handle those containers and their contents,[76] which may be any of a wide array of products, including fuel, pesticides, automotive products, and consumer goods.[77] PFAS can leach from fluorinated plastic containers into water and food, further exposing consumers, and the amount of PFAS that leach into the contents of the containers generally increases over time.[78] Human exposure can occur by inhalation, ingestion, or dermal contact.[79]

When products stored in fluorinated containers are used, PFAS can be released to the environment, where they can contaminate soil and travel to groundwater and surface water, exposing humans and aquatic organisms.[80] And with hundreds of millions of fluorinated plastic containers produced each year, the disposal of those containers into landfills can further spread PFAS through landfill leachate.[81] As EPA noted in its risk assessment, long-chain PFAS "are known to be present in leachate from municipal solid waste landfills," indicating that leaching of the PFAS produced during plastic fluorination "can occur and they are expected to migrate through soil, and eventually to groundwater."[82] Exposure can also occur when plastic containers are recycled at the ends of their useful lives or at end-of-life incineration.[83]

The breadth of these exposures is troubling on its own, but the exposures are particularly concerning in light of the persistence of these PFAS. Because of this persistence, there is "potential for long-lasting environmental and human exposure . . . that is difficult to control and

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[76] *Id.* at 24, 26, 28.
[77] EPA 5(f) Order at 5, 10, 37.
[78] Heather D. Whitehead and Graham F. Peaslee, *Directly Fluorinated Containers as a Source of Perfluoroalkyl Carboxylic Acids*, 10 Env't. Sci. & Tech. Letter 350 (2023), https://pubs.acs.org/doi/10.1021/acs.estlett.3c00083; Tom Perkins, *Toxic 'Forever Chemicals' are Contaminating Plastic Food Containers*, The Guardian (July 9, 2021), https://www.theguardian.com/environment/2021/jul/09/toxic-forever-chemicals-plastic-food-containers ("A 2011 University of Toronto study also suggests that the chemicals can leach from plastic containers at high volumes. PFAS levels in water that was left in a fluorinated container for a year measured at a startling 188,000 parts per trillion (ppt).").
[79] EPA 5(f) Order at 32–36.
[80] EPA Risk Assessment at 24–29; *see also* EPA, Effluent Guidelines Program Plan 15 at 6-13 (Jan. 2023), https://www.epa.gov/system/files/documents/2023-01/11143_ELG%20Plan%2015_508.pdf ("EPA evaluated discharge data from over 200 landfills across the country and found PFAS present in the leachate at over 95 percent of the landfills. PFAS detections included 63 different PFAS . . . .").
[81] *See* EPA Risk Assessment at 17, 24–28; Jason Masoner et al., *Landfill Leachate Contributes Per-/Poly-Fluoroalkul Substances (PFAS) and Pharmaceuticals to Municipal Wastewater*, 6 Env't Sci.: Water Rsch. Tech. 1300 (2020), https://doi.org/10.1039/D0EW00045K ("Our study indicates that disposal of landfill leachate into WWTPs contributes substantially to concentrations of numerous PFAS (*e.g.*, PFOA, PFOS, perfluorodecanoic acid (PFDA), PFHxA . . .).").
[82] EPA Risk Assessment at 17.
[83] EPA 5(f) Order at 32–34.

reverse."[84] With hundreds of millions of fluorinated plastic containers produced each year and introduced into commerce, the release of PFAS they contain can contaminate the environment and people's bodies for years to come.

C. The widespread exposure to toxic PFAS from plastic fluorination presents unreasonable risk.

As EPA's 5(f) order makes clear, PFOA, PFNA, and PFDA are extremely toxic at very low levels of exposure.[85] They also already exist in the environment, are extremely persistent in environmental media and in people's bodies, and bioaccumulate. And they have additive effects, such that exposure to the three PFAS can cause more harm than exposure to one would. As EPA explained in its 5(f) order, "even 'small' amounts of PFAS can have a disproportionate amount of risk" and "over time and due to their persistent and bioaccumulative nature, the amount of [fluorination-generated PFAS] in the environment will grow with each successive manufacture of fluorinated containers."[86]

This risk is particularly grave where a condition of use results in widespread and simultaneous exposures to multiple toxic PFAS through multiple pathways. The fluorination of some two hundred million plastic containers and subsequent leaching of toxic PFAS into the products stored therein does just that—it puts individuals around the country in contact with multiple sources of the extremely hazardous PFOA, PFNA, and PFDA through multiple exposure pathways and routes. Indeed, individuals may be exposed to PFAS by using multiple fluorinated containers storing different products, as well as to PFAS released to the environment during fluorination and from the downstream use and disposal of fluorinated containers. EPA was thus correct to find that the persistent, bioaccumulative, and toxic PFOA, PFNA, and PFDA generated during plastic fluorination present an unreasonable risk of injury to human health or the environment.

III. A Section 6(a) Rule is Necessary to Address the Unreasonable Risks Presented by the Three PFAS

As explained above, and as EPA has already found, there is unreasonable risk presented by the manufacturing, processing, distribution in commerce, use, or disposal of PFOA, PFNA, and PFDA resulting from the fluorination of plastic containers. Because EPA has already made an unreasonable risk determination, TSCA Section 6(a) directs that EPA "shall by rule" require risk management measures "to the extent necessary" to ensure that these PFAS "no longer present[] such risk."[87]

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[84] Ian T. Cousins et al., *Why is High Persistence Alone a Major Cause of Concern?*, 21 Env't Sci. Processes & Impacts 781 (2019), https://doi.org/10.1039/C8EM00515J.
[85] *See* EPA 5(f) Order at 27 (listing reference doses for PFOA, PFNA, and PFDA of 1.5 x 10^{-9} mg/kg-bw/day, 3 x 10^{-6} mg/kg-bw/day, and 4 x 10^{-10} mg/kg-bw/day, respectively).
[86] *Id.* at 39.
[87] 15 U.S.C. § 2605(A).

All substances and mixtures, new and existing, are within EPA's authority under Section 6. Here, regulation under Section 6 is a vital tool with which EPA can protect against the unreasonable risk it has determined is presented by the formation of PFOA, PFNA, and PFDA during fluorination. That risk is not now being addressed under TSCA as a result of the Fifth Circuit decision vacating EPA's order under Section 5(f) prohibiting the production of the three PFAS during fluorination.[88] Because of this ruling, the sole U.S. producer of PFAS during fluorination of plastic containers can continue to create these toxic substances without restriction and evade regulation under TSCA. But as the Fifth Circuit acknowledged, EPA can protect against the resulting threat to health by using its authority to regulate PFAS creation during Inhance's fluorination process under Section 6, and EPA must do so to address the unreasonable risk posed by the PFAS created by that process.[89]

Here, EPA has not only determined that PFOA, PFNA, and PFDA present unreasonable risk, but it has also determined the regulation that is necessary to eliminate such risks. According to EPA, "a prohibition on the manufacture of" PFOA, PFNA, and PFDA in plastic fluorination "is required because the risk cannot otherwise be adequately mitigated."[90] EPA's risk assessment and Section 5 orders comprehensively explain why a ban on production of these PFAS during plastic fluorination is necessary to protect the public, highlighting that the large number of containers that are fluorinated will lead to "widespread exposure" to the long-chain PFAS created during fluorination.[91] In light of the extreme toxicity, persistence, and bioaccumulative tendencies of the PFAS at issue, the background burden of PFAS in the human body and the environment, and the widespread production and use of fluorinated containers, EPA correctly determined that "it cannot control potential exposures to" the long-chain PFAS created by plastic fluorination "through means other than a prohibition on the manufacture of these substances."[92] As EPA points out, "[g]iven 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, . . . there is no mitigation measure that EPA could have put into place to prevent the [PFAS] contamination . . . other than prohibiting the [PFAS] from being manufactured in the first place."[93]

Therefore, in order to comply with TSCA Section 6(a)'s directive to regulate "to the extent necessary so that" a chemical "no longer presents [unreasonable] risk,"[94] EPA must ban

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[88] Petitioners PEER and CEH, *amici curiae* in the Fifth Circuit litigation, believe this decision was incorrect and should be reconsidered or reversed.
[89] *See* Inhance Opinion at 13.
[90] EPA 5(f) Order at 5; *see also id.* at 6 ("Based on concerns for persistence, bioaccumulation, and hazards identified in the assessment of the SNUN Chemical Substances, prohibiting manufacture is necessary to ensure that the order is protective against an unreasonable risk of injury to health or the environment.").
[91] EPA Risk Assessment at 9; *see also id.* at 31; EPA 5(f) Order at 38, 41.
[92] EPA 5(f) Order at 6.
[93] *Id.* at 41.
[94] 15 U.S.C. § 2605(a).

the manufacture, processing, and distribution of PFOA, PFNA, and PFDA in connection with plastic fluorination and prohibit the distribution in commerce, use, and disposal of fluorinated containers in which these PFAS are present. We urge EPA to promptly propose and finalize these bans. With every day of delay, additional sources of these highly toxic and persistent PFAS will enter the stream of commerce and continue to expose people and the environment.[95]

IV. EPA Should Make its Rule Immediately Effective at the Time of Proposal

Petitioners further urge EPA to use the authority granted to it under TSCA to make the Section 6(a) rule it proposes in response to this petition immediately effective upon publication in the Federal Register. Making the proposed rule effective upon publication will ensure that the unreasonable risk of immediate and widespread injury posed by PFOA, PFNA, and PFDA produced during the fluorination of hundreds of millions of plastic containers is swiftly addressed.

TSCA Section 6(d)(3)(A) provides that EPA "may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule."[96] It may do so upon determining that: (1) "the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors," and (2) "making such proposed rule so effective is necessary to protect the public interest."[97, 98]

EPA's comprehensive risk assessment for PFOA, PFNA, and PFDA provides ample support for determining that these factors are met. As EPA has explained, and as reviewed above, because of their strong persistence and bioaccumulative properties, these PFAS build up

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[95] EPA must "promptly commence" the Section 6 rulemaking process and must ensure that its rule takes effect "as soon as practicable." *Id.* §§ 2605(d)(1)(A), 2620(b)(3).

[96] *Id.* § 2605(d)(3)(A).

[97] *Id.*

[98] Section 6(d)(3)(A)(ii) further requires that "in the case of a proposed rule to prohibit the manufacture, processing, or distribution *of a chemical substance or mixture* because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture." *Id.* § 2605(d)(3)(A)(ii) (emphasis added). This requirement is inapplicable here because it applies only to proposed rules that seek to prohibit the manufacture, processing, or distribution of a chemical substance as a whole. Here, the rule sought by petitioners is limited to a specific condition of use—the fluorination of plastic containers using a process that creates PFOA, PFNA, or PFDA—and would not impose an across-the-board prohibition on the manufacture, processing, or distribution of these PFAS. Indeed, Section 6(a) of TSCA differentiates between total prohibitions on manufacture, processing, and distribution of a chemical—restrictions authorized by Section 6(a)(1)—and prohibitions of these activities for "a particular use"—restrictions authorized by Section 6(a)(2). *See id*. §§ 2605(a)(1), (a)(2).

in the human body and new exposures add to their long-term presence in people from previous exposures. Because PFAS have additive effects and are associated with similar adverse health effects at low levels, the additional exposures to these three PFAS produced during plastic fluorination increase the risk of injury to health. These risks are further magnified by co-exposure to other PFAS that are also formed during fluorination and the widespread distribution and large volume of plastic containers fluorinated using PFAS-producing fluorination processes.

Allowing the manufacture of PFOA, PFNA, and PFDA during the plastic fluorination process to continue for years would present an "unreasonable risk of serious or widespread injury."[99] To "protect the public interest,"[100] EPA should make immediately effective any rule it proposes following its grant of this petition.[101]

* * *

EPA has already determined that the manufacture, processing, distribution in commerce, use, or disposal of PFOA, PFNA, and PFDA made during the fluorination of plastic containers presents an unreasonable risk of injury to health or the environment. Petitioners request, pursuant to TSCA Section 21, that EPA use its Section 6(a) authority to protect against such risk by prohibiting the manufacture, processing, and distribution in commerce of PFOA, PFNA, and PFDA produced during plastic fluorination. Given the scope and severity of the risks, Petitioners look forward to EPA's response to this petition as soon as possible, and no later than 90 days from the filing of the petition.[102]

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[99] *Id.* § 2605(d)(3)(A)(i)(I).

[100] *Id.* § 2605(d)(3)(A)(i)(II).

[101] Section 6(c)(2)(C) requires EPA, to the extent practicable, to consider the availability of technically and economically feasible alternatives when imposing significant restrictions on a particular condition of use. *See id.* § 2605(c)(2)(C). While this analysis cannot override EPA's obligation to eliminate the unreasonable risk, it is noteworthy that the Agency has recognized that several feasible alternatives to the PFAS-producing fluorination process exist that impart effective barrier protection to plastic containers. For example, in reviewing the acceptability of container types in connection with pesticide registrations, EPA has found that it is "unlikely that the use of non-fluorinated containers including Baritainer (Kortrax®) would contribute to the contamination of PFAS in products stored in these containers." Letter from Elizabeth Fertich, Office of Pesticide Programs, EPA to Jan Brill, Bayer US LLC re: PRIA Amendment – Updating Container Type (Sept. 28, 2021), https://www3.epa.gov/pesticides/chem_search/ppls/000432-01132-20210928.pdf; Letter from Jacquelyn Herrick, Office of Pesticide Programs, EPA to Karen Larson, Clarke re: PRIA Amendment – Updating Container Type (Apr. 12, 2021), https://www3.epa.gov/pesticides/chem_search/ppls/008329-00062-20210412.pdf.

[102] 15 U.S.C. § 2620(b)(3) ("Within 90 days after filing of a [Section 21] petition . . . the Administrator shall either grant or deny the petition.").

Sincerely,

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Exhibit 1

[redacted]

CJ 12/01/23
DSB 12/1/23
GH 12/4/23
RJA 12/4/23

United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

November 30, 2023

MEMORANDUM

SUBJECT: Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011

FROM: Risk Assessment Branches/Industrial Chemistry Branch
New Chemicals Division
Office of Pollution Prevention and Toxics

TO: Geraldine Hilton
Risk Management Branch 1
New Chemicals Division
Office of Pollution Prevention and Toxics

This memo presents the New Chemicals Program's risk assessment [1] of the per- and polyfluoroalkyl substances (PFAS) in SN-23-0002 through 0006 and SN-23-0008 through 0011. This assessment considers the persistence, bioaccumulation and toxicity (PBT); expected degradation, hydrolysis and incineration products; and exposure pathways resulting in potential or expected[2] exposure to workers, environmental receptors, consumers and the general population for the nine substances in the Significant New Use Notices (SNUNs).

The New Chemicals Program's conclusions regarding the risks posed by the per- and polyfluoroalkyl substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011 are based on an evaluation of these substances under the New Chemical Program's *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (hereafter referred to as the *PBT policy* (US EPA, 1999) and the *Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use*

[1] Determination of risk is a function of hazard and exposure. Generally, numerical values are assigned to the hazard and exposure components of the risk equation to arrive at a numeric risk value. This quantitative method is used by the New Chemicals Program whenever possible. As explained throughout this document, the inability to precisely quantify hazard and exposure for the class of substances known as PFAS (per- and polyfluoroalkyl substances) requires the New Chemicals Program to qualitatively assess risk. In this case, we document the existence of a hazard concern that will increase over time due to sustained and widespread exposures, leading to a buildup (bioaccumulation) of the SNUN substances in people and the environment leading to risks of concern.

[2] Throughout this document, the terms "potential" or "expected," when referring to exposure, mean that, depending on the individual SNUN 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 (See Section 4 for additional details).

[redacted]

Notices (SNUNs) (hereafter referred to as the *PFAS Framework;* US EPA, 2023a). The New Chemicals Program's conclusions further take into consideration the risk assessments (and other information) submitted by Inhance Technologies, LLC (hereafter referred to as Inhance) for SN-23-0002-0006 and SN-23-0008-0011, the *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024* (US EPA, 2021a) with commitments to action on PFAS in the environment, 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.

The New Chemicals Program concludes that each of the nine Significant New Use Notice (SNUN) substances in the two Inhance consolidated submissions are persistent, bioaccumulative, and toxic chemicals (PBTs). Three of the SNUN substances (SN-23-0002 [PFOA], SN-23-0004 [PFNA], and SN-23-0005 [PFDA]) are well studied PFAS that are known to be extremely toxic. PFOA and PFDA have EPA-reviewed toxicity assessments that have been made public. PFNA has been reviewed by the Agency for Toxic Disease Registry (ATSDR), the EPA Office of Water has a proposed Maximum Contaminant Level (MCL) that addresses PFNA, made public in a March 2023 proposed rule, and EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024 [3]. The toxicity of the other six SNUN substances do not yet have EPA-developed, public toxicity assessments. In addition, there are potential or expected environmental releases of the nine SNUN substances and these releases are expected to result in human exposures and exposures to aquatic life, based on the manufacture, processing, distribution, use and disposal associated with the significant new use of these nine SNUN substances. Further, as described more fully in Section 1.2.2, data already show the presence of seven of the nine SNUN substances in the human body (exceptions are SN-23-0010 [PFHxDA] and SN-23-0011 [PFODA]) widespread across the U.S. population. In fact, nearly 100% of people sampled in the U.S. have been exposed to at least one PFAS (NAS, 2022). Thus, the New Chemicals Program concludes there is risk of concern from the manufacture, distribution, use, and disposal of the nine SNUN substances for the significant new use identified in Inhance's Significant New Use Notices. Finally, data gaps are identified, where appropriate, for the SNUN substances.

1 Background

1.1 Significant New Use Notices (SNUN) Submissions from Inhance

Inhance submitted two consolidated SNUNs for a total of nine substances (see Table 1). The nine substances are formed as byproducts during the surface coating (via fluorination) of high density polyethylene (HDPE) fuel and non-fuel storage containers, and remain in or on the walls of the container and migrate into any liquid subsequently stored in the container (see Section 2.1). Seven of the nine substances are existing chemicals and are included on the TSCA Inventory; the exceptions are SN-23-0006 [PFuDA] and SN-23-0009 [PFTrDA].

[3] The ATSDR Minimum Risk Level (MRL) for PFNA was used by Inhance in their risk assessment. The proposed EPA's Office of Water proposed PFAS National Primary Drinking Water Regulation rulemaking incorporating final MCLs for several PFAS is scheduled to be finalized in 2024 (88 FR 18638; March 29, 2023).

[redacted]

EPA has determined that the nine substances are PFAS (per- and polyfluoroalkyl substances), as defined in the *PFAS Framework*, containing the structure R-(CF_2)-CF(R')R", where both the CF_2 and CF moieties are saturated carbons (US EPA, 2023a). Specifically, the nine substances are perfluorocarboxylic acids containing fluorinated carbon chain lengths of 8-18 carbons.

The Inhance submission included 83 attachments with the first consolidated submission (SN-23-0002-0006) and 70 attachments with the second consolidated submission (SN-23-0008-0011). Two risk assessments were submitted by Inhance. Both state that they consider risks associated with all nine PFAS substances covered by the SNUNs. The 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 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 risk assessments submitted by Inhance.

In addition, EPA acknowledges receipt and review of the following information on September 29, 2023, discussed further throughout this document:

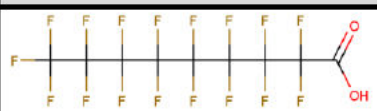
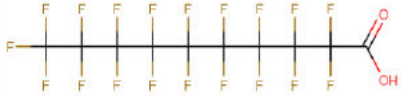
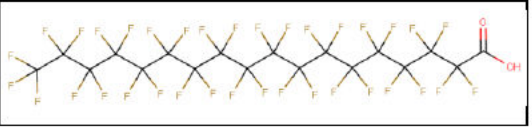
- Cover letter
- Report entitled – "Use of Drinking Water Standards"
- PDF of a 25-slide presentation summarizing the newly submitted information
- Results of sampling fuel containers for the nine SNUN substances (collected from October, 2022 to May, 2023)
- Results of sampling packaging containers for the nine SNUN substances (collected from October, 2022 to May, 2023)
- The analytical method used to measure the nine SNUN substances in the containers
- Customer/sector information for fuel containers
- Customer/sector information for packaging containers
- An economic impact assessment on the loss of the Inhance fluorination technology on the fuel/packaging systems

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.

Table 1: Substances in the Two Consolidated SNUNs

Chemical Substance (Abbrev., No. of Carbons)	CASRN	SNUN Number	PV[1](kg/yr)	Structure
Perfluorooctanoic acid (PFOA, 8)	335-67-1	SN-23-0002	0.337	

[redacted]

Chemical Substance (Abbrev., No. of Carbons)	CASRN	SNUN Number	PV[1](kg/yr)	Structure
Perfluorononanoic acid (PFNA, 9)	375-95-1	SN-23-0004	0.212	
Perfluorodecanoic acid (PFDA, 10)	335-76-2	SN-23-0005	0.213	
Perfluoroundecanoic acid (PFuDA, 11)	2058-94-8	SN-23-0006*	0.223	
Perfluorododecanoic acid (PFDoA, 12)	307-55-1	SN-23-0003	0.202	
Perfluorotridecanoic acid (PFTrDA, 13)	72629-94-8	SN-23-0009*	0.21	
Perfluorotetradecanoic acid (PFTeDA, 14)	376-06-7	SN-23-0008	0.211	
Perfluorohexadecanoic acid (PFHxDA, 16)	67905-19-5	SN-23-0010	0.371	
Perfluorostearic acid (PFODA, 18)	16517-11-6	SN-23-0011	0.233	

*Not on TSCA inventory

[1] Taken from the SNUN submissions, representing the maximum estimated annual production volume (PV) by Inhance for each SNUN substance formed as a byproduct from the fluorination process and represents both fuel and non-fuel container production

1.2 Review Process for PFAS in the New Chemicals Program

1.2.1 Background

Harmful per-and poly-fluoroalkyl substances (PFAS) are an urgent public health and environmental issue facing communities across the United States. PFAS have been manufactured and used in a variety of industries in the United States and around the globe since the 1940s, and they are still being used today. Because of the duration and breadth of use, PFAS can be found in surface water, groundwater, soil, and air – from remote rural areas to densely-populated urban centers. A growing body of scientific evidence shows that exposure at certain levels to specific PFAS can adversely impact human health and other living things. Despite these concerns, PFAS are still used in a wide range of consumer products and industrial applications.[4]

[4] EPA's *PFAS Strategic Roadmap* (p. 5).

[redacted]

In October of 2021, EPA released both the *PFAS Strategic Roadmap* (US EPA, 2021a) with commitments to a 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 precisely quantifying the exposures and risks associated with PBTs, as reflected in the New Chemicals Program PBT policy, especially PBT PFAS (see section 1.2.2), 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.

1.2.2 Challenges to Precisely Quantifying Risk for PBT PFAS Including the Nine SNUN Substances

Precisely quantifying the risk posed by PBT PFAS, including the nine SNUN substances, is complicated by: (1) the lack of robust toxicity information on most of the thousands of PFAS (exceptions include some of the SNUN substances, for example, PFOA, PFNA and PFDA, and other PFAS not covered by the 9 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 this section.

First, only one (PFOA) of the nine SNUN substances has robust toxicity information *for <u>both</u>* human health and environmental organisms. Thus, for the other eight SNUN substances, information is lacking (for either human health or environmental organisms, or both) which does not allow for the completion of precise estimates of the risk posed by the SNUN substance of interest. In order to precisely quantify risk[5], an accurate hazard identification value that reflects some level of certainty needs to be identified for the substance of interest. Use of a close analogue is often used in place of hazard information for a given chemical, but this does introduce uncertainty.[6] Thus, hazard information on the substance of interest should be used whenever possible. This leads to the second complicating factor: the available information on a limited number of more well-studied PFAS (such as PFOA, PFNA and PFDA) indicates that they are extremely toxic, and understanding the toxicity of each of the nine SNUN substances would

[5] In this risk assessment, the New Chemicals Program did not quantify risk. Thus, for 8 of 9 SNUN substances available human health hazard information was sufficient to identify hazard concerns for PBT classification purposes (the exception was PFTrDA). For the environmental organisms, PFOA was used as an analogue for the eight other SNUN substances.

[6] For example, lack of toxicity information led both EPA and Inhance (in the Inhance-submitted risk assessment) to use analogues for either or both human health and environmental organisms where there was no available hazard information for certain of the SNUN substances.

[redacted]

be necessary to precisely understand the hazard of all of the SNUN substances. Due to the uncertainty with the use of analogues and the possible spectrum of toxicity among PFAS, some PFAS may be more or less toxic than expected or predicted by use of an analogue.

Third, the nine SNUN substances co-exist as byproducts from the fluorination process and so to properly quantify risk, their additive effects need to be considered. However, conducting a risk assessment to quantify the additive effects poses a challenge. EPA is working to develop methodologies to evaluate mixtures and risk in other contexts and programs[7] but a standard, widely accepted method and approach for PFAS is not yet available. Fourth, it has been established that the carbon-fluorine bond is extremely stable and persists in the environment. When a chemical substance is both present and persistent in the environment, it is difficult to quantify exposure using traditional methods that only capture exposures associated with a release at a particular point in time.

Fifth, PFAS have been shown to bioaccumulate in the environment, humans and environmental organisms. Importantly, bioaccumulation of PFAS can be significantly higher in humans compared to rodents, which are typically used to determine the points of departure for use in quantitative human health risk assessment (ITRC, 2023). PFOA has a reported half-life in humans of 2.3-3.8 years (as reviewed in Seals et al. (2011) and recently confirmed in Li et al. [2018]. This means it would take the body more than a decade[8] to rid itself of PFOA residing in the body assuming there is no further exposure. Any new or additional exposure would result in an increase in the time it would take for the body to rid itself of PFOA. Sixth, due to their persistence and bioaccumulative nature, PFAS have been widely detected in the environment around the globe, thus showing widespread exposures. Small releases to the environment can have a significant long-term contribution to exposure and risk. Current risk assessment methods used in the two Inhance risk assessments do not account for chemical substance accumulation over time in environmental media, environmental organisms and humans.[9]

And finally, the persistence, bioaccumulation and toxicity of many PFAS has resulted in an existing burden in humans, environmental organisms, and the environment that is not accounted for in the New Chemicals Program's traditional quantitative methodologies or in Inhance's risk assessments. The National Academy of Sciences recently provided an overview of the extent and magnitude of PFAS contamination, stating "(D)ata from the National Health and Nutrition Examination survey [NHANES] 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 five of the SNUN substances (PFOA, PFNA, PFDA, PFuDA and PFDoA), but the incidence and concentrations are highest for PFOA and PFDA. There are other biomonitoring data showing the presence of

[7] For example, see risk assessment for mixtures guidance at the Office of Research and Development (epa.gov/ and search for 1986 Guidelines for the Health Risk Assessment of Chemical Mixtures).

[8] On average, it takes 5-7 half-lives to eliminate a chemical from the body. For example, if the half-life is 3 years, at the end of 3 years, half (i.e., 50%) of the chemical is still present. After the "second half-life", there would be 25% of the original concentration. At the end of 5 half-lives, approximately 3% would still be present (15 years later). See National Institute of Health, National Library of Medicine (www.ncbi.nom.nih.gov)

[9] The two Inhance risk assessments use conventional methods for quantifying risk that do not account for bioaccumulation. See Sections 2 and 3 for details and more discussion.

[redacted]

two of the other SNUN substances in human serum in US samples (PFTeDA and PFTrDA).[10] 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 and precisely quantify the risk from additional, incremental exposures to the nine SNUN substances.

Notably, many of the SNUN 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 2020a). 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 several of the SNUN substances (SN-23-0003, -0004, -0005, -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 Substances in Freshwater Fish Tissue (2013-2014 NRSA and 2015 NCCA)

SNUN 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-23-0004 (PFNA)	39	78
SN-23-0005 (PFDA)	84	88
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 described, there is uncertainty in determining the amount of the nine SNUN substances that are actually manufactured as byproducts during the fluorination process. This uncertainty makes it difficult to accurately quantify exposures (see section 2.2 for discussion of potential underestimation of production volume in the risk assessment submitted by Inhance). Available data also show that other PFAS (not covered by the Long Chain PFAS Significant New Use Rule [SNUR]), in addition to the nine SNUN substances, are also byproducts from fluorinating containers. The possible contribution of these other PFAS to the bioaccumulation and toxicity potential of the nine SNUN substances is unknown at this time.

[10] 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.

[redacted]

Based on these considerations, and as outlined further in the *PFAS Framework*, EPA generally expects to evaluate risk for PBT PFAS qualitatively. Thus, EPA's risk assessment for these PFAS SNUN substances is qualitative.[11]

1.2.3 Overview of the *PFAS Framework*

The New Chemicals Program generally follows the PBT Policy (US EPA, 1999) in assessing and managing PMNs and SNUNs that involve PBTs. This longstanding policy is used to identify substances that meet the criteria for persistence, bioaccumulation and toxicity and warrant appropriate risk mitigation efforts (see Section 3 for further information).

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 substances in light of significant health and environmental concerns associated with, widespread environmental exposure to, and environmental persistence of 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 metabolites, a PBT determination is 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. 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.

The New Chemicals Program's evaluation of whether the nine SNUN Substances are PBTs under the PBT Policy is consistent with the PFAS Framework. Then, because the New Chemicals

[11] 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 this Section (1.2.2) and elsewhere in this document, 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 Inhance. EPA's human health hazard information (i.e., PODs) for PFOA and PFDA are different from the ones used by Inhance 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 Inhance-derived exposure values" as part of the administrative record for this action). Inhance's risk assessment utilized the ATSDR MRL as the human health hazard POD for PFNA and, using that POD, did not show risk for any scenario in their quantitative assessment. EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. In addition, there were deficiencies, unrelated to the PODs, in Inhance's quantitative risk assessment, discussed further in section 2.6.

[redacted]

Program has determined these substances to be PBTs that are formed during the fluorination process leading to widespread exposure – especially to consumers (as pointed out in Section 4) - and consistent with the PFAS Framework, it has qualitatively assessed the risk of the nine SNUN substances.

The considerations outlined in the *PFAS Framework* are also applied in the review of the risk assessments submitted by Inhance in the next section.

2 Review of the Risk Assessments and Other Information Submitted by Inhance

Two risk assessments were included in the Inhance submissions – one to evaluate the nine SNUN substances formed in fuel storage containers and one to evaluate the nine SNUN substances formed in non-fuel storage containers (see section 1.1). As outlined in the *PFAS Framework* and in section 1.2.2, 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 Inhance risk assessments (though bioaccumulation was acknowledged as an uncertainty by Inhance). The following sections present EPA's review of important information in the submitted risk assessments regarding the presence of long-chain PFAS in fluorinated HDPE containers, the uncertainty in the amount of PFAS being produced as byproducts, as well as environmental and human health risk assessment concerns.

Since the submission of the SNUNs on December 30, 2022, EPA has received more detailed information from Inhance regarding the optimization of Inhance'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 were received on September 29, 2023. While these data do indicate that Inhance has adapted its process with respect to certain types of containers to reduce the amount of long-chain perfluoroalkyl carboxylate (LCPFAC) formed—stating that over 98% of the samples have non-detectable levels for the 9-18 carbon LCPFACs—for the 8-carbon PFOA, the non-detect frequency dropped to 84%. This shows at a minimum that of the nine SNUN substances, the one that is currently known to be the most toxic (i.e., PFOA) is still being produced as a byproduct during Inhance's fluorination process. In addition, the detection limit used in these studies provided by Inhance (~300 ppt in extracts from the plastic container coupons) is much higher than other comparable methods. For example, EPA Office of Pesticide Program's Biological and Economic Analysis Division (BEAD) has validated a method in the laboratory that is much more sensitive than the one employed for these measurements by Inhance. 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).

2.1 Presence of Long-Chain PFAS in Fluorinated HDPE Containers

The risk assessments conducted by Inhance did not consider that the nine SNUN substances co-exist when formed as byproducts from the fluorination process. Inhance 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

[redacted]

assessments and again provided more evidence in their September 29, 2023 submission of additional information (see Section 1.1). Because the nine SNUN substances co-exist and are chemically similar, they will likely interact with each other. Considering exposure and hazard for each SNUN substance separately does not account for the additive[12] exposure and the likely hazard/toxicity interaction (whether it be additive, 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 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 Inhance's fluorination process and co-exist with the LCPFAC. For instance, testing conducted by the BEAD Laboratory within EPA's Office of Pesticide Programs 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 (see section 2.4). The possible contribution of these other PFAS to the exposure, bioaccumulation and toxicity potential of the nine SNUN substances may affect the estimation of risk for the nine SNUN substances.

2.2 Production Volume Uncertainty

In order to accurately and precisely quantify risk, it is important to have confidence in the estimates of the amount of the nine SNUN substances formed from Inhance's fluorination process. For the substances that were considered in the Inhance-submitted risk assessments, Inhance provided estimates of production volume which claim that the nine SNUN substances are produced at levels below 400 grams per year for each one. 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 Inhance.

2.3 Dermal Exposure

Inhance developed conceptual exposure models for both the fuel and non-fuel uses of their fluorinated containers. In both models, they recognize that dermal exposure occurs, but they dismiss the possibility of the SNUN substances being absorbed across the skin layer because they

[12] Additivity means that it is likely that the SNUN substances interact so that both hazard and exposure could be additive as they are present as a mixture. This additivity could be either due to dose additivity or response additivity (see epa.gov/risk and search for 1986 *Guidelines for the Health Risk Assessment of Chemical Mixtures*).

[redacted]

believe the SNUN substances are too large. While this may be an uncertainty for most of the SNUN substances, there is information showing dermal exposure/absorption occurs for PFOA (Fasano et al. 2005. Fairley et al., 2007, and Franko et al. 2012). Again, PFOA is recognized as one of the highly toxic PFAS substances. Similar information documenting absorption through the skin layer for the other eight SNUN substances is not readily available and therefore is an uncertainty and may underestimate risk.

2.4 Toxicity to Aquatic Organisms

The aquatic toxicity analysis in the risk assessment performed by Li et al 2021 was referenced and used in the Inhance risk assessments. Li et al. estimated an aquatic life chronic predicted no-effect concentration (PNEC; 0.0067 mg/L) based on a species sensitivity distribution (SSD) approach using test data for PFOA (SN-23-0002). Inhance also applied the estimated PNEC for PFOA using read-across for the remaining eight SNUN substances to evaluate hazards. EPA agrees with this approach to evaluate the environmental hazard of the nine SNUN substances. The actual hazard value used to derive the PNEC was an HC_5[13] value of 0.033 mg/L, which meets the EPA criteria for chronic toxicity concern for aquatic organisms (or, a T score of 2 for the PBT score).[14]

2.5 Toxicity to Human Health

The human health toxicity values proposed in the Inhance-submitted risk assessments are based on hazards that support a human health toxicity score of 2, consistent with EPA's approach (Table 2; section 3.3.2; US EPA, 2023a). EPA has qualitatively evaluated risk for these cases per the *PFAS Framework* and for the reasons explained in section 1.2.2 concluded that it is challenging to quantitatively and precisely assess risk from PBT PFAS, including the nine SNUN substances. Further, EPA identified a number of deficiencies in the Inhance-submitted quantitative risk assessments, with key concerns briefly described in this section.

While EPA is qualitatively evaluating risk for the nine SNUN substances, and therefore not selecting hazard points of departures (PODs) for a quantitative risk assessment, EPA notes that Inhance did not use EPA-developed, publicly available, risk assessments/PODs for PFOA and PFDA, and did not address why they chose the ones they did use. For example, PODs have been used by the EPA in other contexts to develop reference doses for PFOA and PFDA that are substantially different from the values used in the Inhance risk assessments. For PFOA, the interim reference dose published by EPA's Office of Water of 1.5×10^{-9} mg/kg-bw/day (US EPA, 2022), is 2000-fold lower than the Inhance-selected value of 3×10^{-6} mg/kg-bw/day (ATSDR, 2021). For PFDA, EPA's IRIS Program developed a draft reference dose of 4×10^{-10} mg/kg-bw/day (US EPA, 2023b), 37,500-fold lower than Inhance-selected value of 1.5×10^{-5} mg/kg-bw/day (TCEQ, 2016). Use of either of the EPA PFOA or PFDA PODs—or any other PODs for any of the SNUN substances—by Inhance would change the risk results for these two SNUN substances. For example, if Inhance had used EPA's

[13] An HC_5 is the logarithm of the fifth percentile of the distribution of chronic toxicity values for PFOA from 24 species representing eight taxonomic groups.

[14] See Section 3 for the details of scoring attribution for the P, B, and T for a PBT assignation.

[redacted]

PODs for PFOA and PFDA, Inhance would have identified risks of concern for 80% of the scenarios calculated.[15]

In the Inhance risk assessments, the risk for each SNUN substance was considered individually. EPA notes that Inhance provided data that show there is a mixture of PFAS (i.e., the nine SNUN substances) present in the fluorinated containers, indicating a need to carefully consider how the PFAS may act in concert to elicit adverse human health effects. Additionally, as described in section 2.1, present in the fluorinated containers are both the nine SNUN substances—which are all perfluorocarboxylic acids, with variation only in fluorinated carbon chain length, from 8-18 carbons (Table 1)—and the likely existence of other, shorter-chain PFAS formed as byproducts during fluorination (US EPA, 2021 and 2022; Whitehead and Peaslee, 2023; Vitale et al., 2022). Considering the similarity in structure across the PFAS present in the fluorinated containers, along with the known overlap in toxicities of both short- and long-chain PFAS, it is reasonable to expect the potential for additive effects among the PFAS that would likely affect the overall bioaccumulation and risk posed by the nine SNUN substances (US EPA, 2023c, Fenton et al., 2021). There is a growing body of evidence on the dose additive effects for mixtures of PFAS (for example, see Addicks et al., 2023; Dale et al., 2022; Marques et al., 2021) which, if not accounted for, will result in underestimating risk.

As noted in the Inhance risk assessments (Section 6 in both), there is uncertainty associated with not quantifying the bioaccumulative effects that are expected to occur with these PFAS substances which also, if not accounted for, will result in underestimating risk.

Finally, Exhibit 11 in the September 29, 2023 submission by Inhance is a document entitled: *Use of Drinking Water Standards.* This 10-page document points out that, even though the units are the same, concentrations of a substance in a container matrix or fluid is not the same as the concentrations of that same substance in a drinking water standard. EPA agrees and this does not change this assessment as we are not applying drinking water standards – nor are we quantifying risk – in this qualitative risk assessment.

Despite this non-exhaustive list of unaccounted for toxicity considerations, as well as differences in the identification of relevant human health toxicity information in the Inhance risk assessments, the Inhance risk assessments provide toxicity information supporting a human health toxicity score of 2 for each of the SNUN substances (see Table 3).

[15] 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 this Section (1.2.2) and elsewhere in this document, 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 Inhance. Eighty percent of the calculations performed in the sensitivity analysis showed risk and 20% did not (See "Sensitivity Analysis: Calculating risk using EPA-derived toxicity values with Inhance-derived exposure values" as part of the administrative record for this action). Inhance's risk assessment utilized the ATSDR MRL as the human health hazard POD for PFNA and, using that POD, did not show risk for any scenario in their quantitative assessment. EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. In addition, there were deficiencies, unrelated to the PODs, in Inhance's quantitative risk assessment, discussed further in section 2.6.

[redacted]

Table 3. Human Health Toxicity Values Used in the Inhance Risk Assessments

Case Number (Chemical, Abbr., No. of Carbons)	*Toxicity Value*	*Basis*	*Reference*
SN-23-0002 (PFOA, 8)	3×10^{-6} mg/kg-bw/day	Skeletal effects in mice	Koskela et al, 2016 as cited in ATSDR, 2021
SN-23-0004 (PFNA, 9)	3×10^{-6} mg/kg-bw/day	Liver weight increases in pregnant mice in a developmental toxicity study. This was coupled with measured serum and liver PFNA levels in pregnant mice. In addition, offspring showed decreased body weight, developmental delays, increased liver weight, and PFNA in liver and serum up to PND 70	Das et al., 2015, as cited in ATSDR, 2021
SN-23-0005 (PFDA, 10)	1.5×10^{-5} mg/kg-bw/day	Decreases in fetal body weight in a mouse developmental study (LOAEL = 0.1 mg/kg-bw/day)	Harris and Birnbaum 1989 as cited in TCEQ 2016
SN-23-0006 (PFuDA, 11)	PFDoA as analogue		
SN-23-0003 (PFDoA, 12)	1.2×10^{-5} mg/kg-bw/day	Twenty-five percent reduction in body weight in 14-day oral rat study at 5 mg/kg-bw/day; with a NOAEL of 1 mg/kg-bw/day	Shi et al. as cited in TCEQ, 2016
SN-23-0009 (PFTrDA, 13)	PFDoA as analogue		
SN-23-0008 (PFTeDA, 14)			
SN-23-00010 (PFHxDA, 16)	PFOA as analogue		
SN-23-0011 (PFODA, 18)			

2.6 EPA's Summary of the Deficiencies in the Inhance Risk Assessments

EPA does not agree with the Inhance risk assessment conclusion that there are no risks to either human health or environmental organisms from exposure to the nine SNUN substances. Not taken into consideration in the Inhance risk assessments are the: 1) persistence and bioaccumulation of the nine SNUN 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 *National Health and Nutrition Examination Survey,* or NHANES[16] data documenting the presence of five of the SNUN substances (PFuDA, PFDoA and the highly toxic PFOA, PFNA, and PFDA) in human serum, information on the presence of two (PFTeDA and PFTrDA)

[16] As cited in NAS, 2022 but all data are available at – cdc.gov/exposurereport/data_tables.html (and searching for individual chemicals).

[redacted]

of the remaining SNUN substances in US human serum samples[17], and the EPA National Aquatic Resource Survey data supporting widespread presence in freshwater fish tissue in U.S. rivers and Great Lakes for, PFuDA, PFDoA, and the highly toxic PFNA and PFDA, which affects the ability to estimate exposure to, and hazard and risk for, the nine SNUN substances (US EPA 2020a); and 3) the co-existence and likely interaction of the nine SNUN substances with the possible contributions from other PFAS which may affect the hazard/exposure estimates for the nine SNUN substances. Furthermore, although the estimated production volumes provided by Inhance for the nine SNUN substances are uncertain, the exposure calculations and estimates made by Inhance in their risk assessments demonstrate that the nine SNUN substances are formed as byproducts from the fluorination process and would be released to the environment (if use is permitted).

3 Evaluation of the SNUNs for Potential to be Persistent, Bioaccumulative and Toxic (PBT)

3.1 The New Chemicals Program's PBT Policy

In 1999, EPA issued a policy statement identifying PBT chemicals 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 in reviews. 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 (US EPA, 2018).

Table 4: Persistence and Bioaccumulation Score Criteria

Persistence[1]	**Low Persistence (P1)**	**Persistent (P2)**	**Very Persistent (P3)**
Water, soil, sediment	< 60 days	≥ 60 days	>180 days
Air	<2 days	>2 days	
Bioaccumulation[1]	**Low Bioaccumulation (B1)**	**Bioaccumulative (B2)**	**Very Bioaccumulative (B3)**
Fish BCF or BAF	<1000	≥1000	≥5000
[1] Note, qualitative estimates based on modeling and/or physical-chemical properties are also used to inform the P and B score. BCF = bioconcentration factor, BAF = bioaccumulation factor.			

Traditional metrics like bioconcentration factor (BCF) and bioaccumulation factor (BAF) may not fully characterize the potential for PFAS to accumulate via dietary exposure (Evich et al. 2022). These metrics are most relevant for chemicals that bioaccumulate via lipophilic partitioning, whereas PFAS typically accumulate by proteinophilic partitioning or other mechanisms. There are

17 "Report on comparison of cell-based bioactivity concentrations and human population blood concentrations for selected PFAS compounds" in the administrative record for this action.

[redacted]

also differences in clearance mechanisms and rates between gill- and air-breathing animals, potentially leading to substantially higher bioaccumulation in the latter (De Silva et al. 2021). Food web-based metrics like biomagnification factors and trophic magnification factors are sometimes considered more robust predictors of bioaccumulation in humans, yet even these are subject to significant uncertainty when measured for PFAS (Franklin 2016; Miranda et al. 2022). Apart from these considerations, it is important to note that human exposure to certain PFAS such as PFOA and PFOS (perfluorooctanesulfonic acid) may occur primarily through drinking water, so even an accurate estimate of bioconcentration in fish harvested for food underestimates potential human exposure (McLachlan et al. 2017).

In addition, EPA considers the known presence and persistence of many PFAS in human serum (half-lives ranging from weeks to years) to be direct evidence of their bioaccumulation potential in humans (Fenton et al., 2021; Li et al. 2018). Thus, since 2018, EPA has evaluated most PFAS in the New Chemicals Program by assigning a bioaccumulation potential rating (B) of B*high. Similarly, a persistence (P) rating of P3 is assigned to most PFAS based on their observed persistence in the environment and the stability of the C-F bond. 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.

The scores for toxicity are based on the following criteria (from p. 15 of the *Points to Consider* document) and EPA uses this same approach for PFAS:

> "*The T score (in the overall PBT score) is based on developmental/reproductive and/or chronic hazards to the general population and/or to chronic hazards to aquatic organisms...; it is not designated for acute toxicity (i.e., mammalian or aquatic organisms) and is not typically used for hazards identified by the dermal or inhalation routes of exposure, as these types of toxicity and exposure routes are not typically associated with P and B chemicals*."[18]

3.2 Persistence and Bioaccumulation Scores for the SNUNs

All nine Inhance SNUN substances are Class 1 chemicals (i.e., their compositions can be represented with definite structural diagrams[19]). They are fully fluorinated alkyl carboxylic acids ranging in chain length from 8 (PFOA) 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 all nine SNUN substances to reflect the possibility of incomplete combustion in municipal solid waste incinerators, TFA is not driving the PBT determination for these SNUN substances.

[18] The phrase …"not typically used for hazards identified by the dermal and inhalation routes of exposure…" relates to portal of entry (i.e., site of contact effects such as skin and respiratory irritation) and not systemic effects (i.e., absorbed into the blood and distributed throughout the body). For chemicals that are absorbed via dermal and inhalation exposures, and that are persistent, bioaccumulative and toxic, these exposure pathways are important.

[19] 83 FR 52694.

[redacted]

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 nine SNUN substances is 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 nine SNUN substances is 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 are expected to bioaccumulate. References to chemical-specific field data are included in Table 5. Based on these considerations, each of the nine SNUN substances is rated B*high.

Table 5 presents the P and B scores for the nine SNUN substances.

Table 5: Persistence and Bioaccumulation Scores for the Nine SNUN Substances

SNUN Substance, Abbrev., No. of Carbons	P Score*	B Score	B Score Basis**
SN-23-0002 (PFOA, 8)	P3	B*high	Dai and Zeng (2019); Furdui et al. (2007); Vierke et al. (2012); analogy to other PFAS
SN-23-0004 (PFNA, 9)	P3	B*high	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS
SN-23-0005 (PFDA, 10)	P3	B*high	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS
SN-23-0006 (PFuDA, 11)	P3	B*high	De Silva et al. (2011); Gebbink et al. (2016); Khairy et al. (2019); Murakami et al. (2011); analogy to other PFAS
SN-23-0003 (PFDoA, 12)	P3	B*high	Khairy et al. (2019); Lin et al. (2014); analogy to other PFAS
SN-23-0009 (PFTrDA, 13)	P3	B*high	Zhang et al. (2018); Pan et al. (2017); analogy to other PFAS
SN-23-0008 (PFTeDA, 14)	P3	B*high	Pan et al. (2017); analogy to other PFAS
SN-23-00010 (PFHxDA, 16)	P3	B*high	analogy to other PFAS
SN-23-0011 (PFODA, 18)	P3	B*high	analogy to other PFAS

*The basis of the P scores for all nine SNUN substances is the presence of numerous, highly stable C-F bonds combined with the observed environmental persistence of PFAS as a class.

**In addition to the references listed in the table, the observed bioaccumulation of PFAS in humans and other air-breathing animals is used to support the B scores for all nine SNUN substances.

3.3 Other Fate Considerations for the SNUNs

Manufacture, distribution, use and disposal of the nine SNUN substances results in potential or expected releases to the environment. In understanding the environmental fate of the nine SNUN 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 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 subsurfaces 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; 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 Inhance's claim that landfill leachate would result in "very small incremental releases, if any," (Attachment 12 at 25), leaching of the nine SNUN substances can occur and they are expected to migrate through soil, and eventually to groundwater[20].

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 nine SNUN 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.

[20] As pointed out in the next section (Section 4), Inhance produces more than 200 million fluorinated containers a year.

[redacted]

3.4 Toxicity

As noted earlier, the T score in PBT can be based on either chronic toxicity concerns to aquatic organisms or developmental, reproductive or chronic toxicity concerns for human health.

3.4.1 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 nine SNUN substances), with most of the other SNUN substances lacking experimental test data/information applicable to this assessment. Modeled data are not incorporated into the environmental hazard assessment for the eight SNUN 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 eight of the nine SNUN substances, the exception being PFOA, for which an HC_5 value of 0.033 mg/L was reported in Li et al. (2021). This value was used by Inhance in their risk assessment and has been accepted by the EPA's New Chemicals Program to represent the hazard concerns for this qualitative assessment of the nine SNUN substances. PFOA (SN-23-0002) is considered a concern for chronic toxicity to aquatic organisms based on the high environmental hazard observed in the submitted data (Table 6); the environmental toxicity "T" score for SN-23-0002 is T2. For the eight other SNUNs, the environmental toxicity score is considered unknown and thus the PFOA data are used as read-across for EPA's 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 Inhance (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.

Table 6: Aquatic Toxicity Profile for the Nine SNUN Chemical Substances

SNUN Substance, Abbrev, No. of Carbons	Hazard Value for Chronic Aquatic Toxicity
SN-23-0002 (PFOA, 8)	HC_5 value of 0.033 mg/L from the Species Sensitivity Distribution (SSD) Reported by Li et al. (2021) and used by Inhance

[redacted]

SNUN Substance, Abbrev, No. of Carbons	Hazard Value for Chronic Aquatic Toxicity
SN-23-0004 (PFNA, 9)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0005 (PFDA, 10)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0006 (PFuDA, 11)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0003 (PFDoA, 12)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0009 (PFTrDA, 13)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0008 (PFTeDA, 14)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-00010 (PFHxDA, 16)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0011 (PFODA, 18)	Unknown, using HC_5 value of 0.033 mg/L as Read Across

3.4.2 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 EPA New Chemicals Program assessed toxicity to human health for the nine SNUN substances based on available toxicological information for eight of the nine SNUN substances and an analogous substance for one of the SNUN substances (PFTrDA). EPA primarily relied on available human health toxicity information from EPA assessments and the ITRC website (ITRC, 2023) for five of the SNUN substances. For three SNUN substances, EPA identified animal studies in the literature (Hirata-Koizumi et al., 2012, 2015) with relevant human health toxicity information. See the following paragraphs and Table 7 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). PFOA and PFDA have EPA-reviewed toxicity assessments that have been made public. PFNA has been reviewed by the Agency for Toxic Disease Registry (ATSDR), the EPA Office of Water (publicly in a proposed rule), and is currently under review with the EPA IRIS program.

[redacted]

For PFOA, EPA relied on the extensive review of the data available in the interim drinking water health advisory document from EPA's Office of Water (US EPA, 2022a). PFNA is reviewed extensively in ATSDR, 2021, as well as in a health-based maximum contaminant level support document from the New Jersey Drinking Water Quality Institute (NJ DWQI, 2015). In addition, EPA has issued a preliminary regulatory determination to regulate PFNA as a contaminant under the Safe Drinking Water Act (PFAS National Primary Drinking Water Regulation Rulemaking, 2023), with a health-based water concentration also based on the ATSDR findings (ATSDR, 2021, as cited in US EPA, 2023d). Finally, for PFNA, EPA is currently developing a draft IRIS toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. [21] For PFDA, there is a draft EPA IRIS toxicological review containing an extensive literature review that has been released for public comment (US EPA 2023b).

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 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 substance are listed in Table 7. EPA notes that the evidence provided is sufficient for a T score of 2, however additional hazard evidence for each SNUN substance is available in the cited documents. While EPA performed a qualitative assessment, some POD values identified by EPA are presented in Table 7 to illustrate the potency of the toxicity for the three well-studied SNUN substances (i.e., PFOA, PFNA and PFDA). However, the PODs were not used to determine a T-score nor for quantitative purposes in this assessment

In addition to the hazards identified for each SNUN substance individually, EPA notes the nine SNUN 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. As described in section 2.4, some dose additive effects are expected based on similarity 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, see Addicks et al., 2023; Dale et al., 2022; Marques et al.,

[21] The ATSDR Minimum Risk Level (MRL) for PFNA was used by Inhance in their risk assessment. The proposed EPA's Office of Water proposed PFAS National Primary Drinking Water Regulation rulemaking incorporating final MCLs for several PFAS is scheduled to be finalized in 2024 (88 FR 18638; March 29, 2023).

[redacted]

2021). The T scores for each of the SNUN substances do not account for potential dose additive effects.

Table 7: 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-23-0002 (PFOA, 8)	***Developmental immune effect*** in children (Grandjean et al., 2012, and Budtz-Jørgensen and Grandjean, 2018, as cited in US EPA, 2022), the basis for Office of Water's interim reference dose (RfD) of 1.5×10^{-9} mg/kg-bw/day	T2
SN-23-0004 (PFNA, 9)	***Decreased body weight and developmental delays*** (Das et al., 2015, as cited in ATSDR, 2021) are the basis for ATSDR's minimal risk level of 3×10^{-6} mg/kg-bw/day (this is the toxicity value used by Inhance, see section 2.5, and used in the EPA Office of Water proposed rule (US EPA, 2023d)).	T2
SN-23-0005 (PFDA, 10)	***Developmental immune effect and decreased birth weight in children*** (Grandjean et al., 2012, Budtz-Jørgensen and Grandjean, 2018, and Wikström et al., 2020, as cited in US EPA 2023b), the basis for the proposed IRIS developmental RfD of 4×10^{-10} mg/kg-bw/day	T2
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

3.5 Final PBT Score for Each of the Nine SNUN Substances

Based on the analysis presented in Sections 3.1 through 3.4, the New Chemicals Program considers the nine SNUN substances identified in the SNUNs submitted by Inhance to be persistent, bioaccumulative and toxic (PBT) (Table 8).

[redacted]

Table 8: PBT Scores for the Nine SNUN Substances

SNUN Substance, Abbrev., No. of Carbons	Persistence Score	Bioaccumulation Score	Toxicity Score	Total PBT Score
SN-23-0002 (PFOA, 8)	P3	B*-high	T2	P3B*HT2
SN-23-0004 (PFNA, 9)	P3	B*-high	T2	P3B*HT2
SN-23-0005 (PFDA, 10)	P3	B*-high	T2	P3B*HT2
SN-23-0006 (PFuDA, 11)	P3	B*-high	T2	P3B*HT2
SN-23-0003 (PFDoA, 12)	P3	B*-high	T2	P3B*HT2
SN-23-0009 (PFTrDA, 13)	P3	B*-high	T2	P3B*HT2
SN-23-0008 (PFTeDA, 14)	P3	B*-high	T2	P3B*HT2
SN-23-00010 (PFHxDA, 16)	P3	B*-high	T2	P3B*HT2
SN-23-0011 (PFODA, 18)	P3	B*-high	T2	P3B*HT2

4 Environmental Release, Exposure Pathways and Environmental and Human Health Receptors

In the New Chemicals Program, the engineering assessment 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, as was noted in footnote 2 on page 1 (partially reproduced here[22]), use of "potential or expected" for environmental releases and exposures is a phrase used throughout this risk assessment document. This is to reflect that there is exposure to the nine SNUN substances from the manufacture, processing, use and/or disposal of Inhance fluorinated containers; it is only a matter of degree and level of certainty with respect to each individual SNUN substance, life cycle stage, exposure pathway, and receptor. As was done by Inhance in their risk assessments, there are many exposure scenarios to document and that is done in separate EPA reports (Engineering Reports and Exposure Reports available in the administrative record for this action).

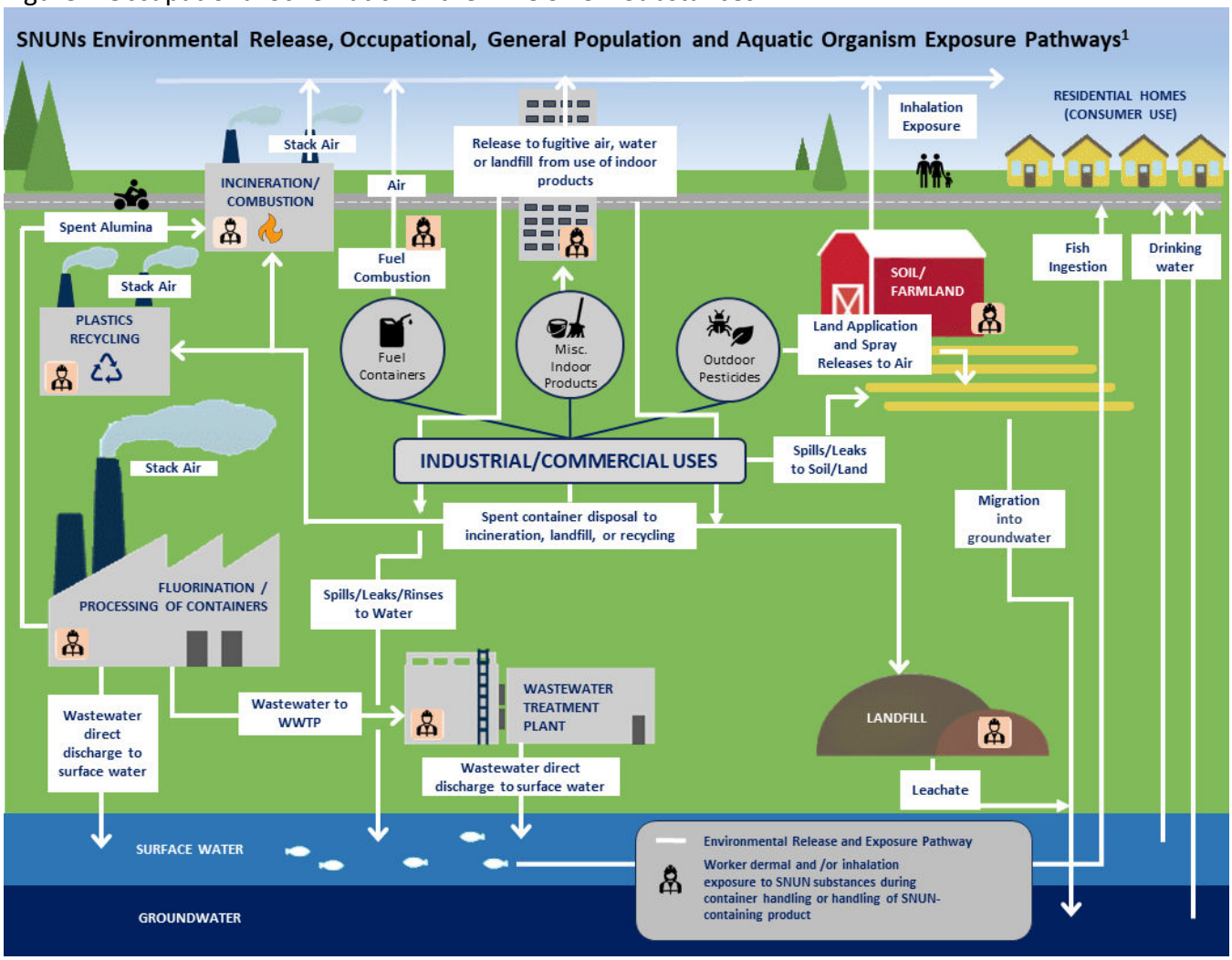
In addition, according to slide #8 in Exhibit 9 submitted by Inhance on September 29, 2023, Inhance fluorinated approximately 121 million containers in 2021. This resulted in an estimated 75 million gallons of container contents and 25 million pounds of plastic. Assuming this is a normal year, it means that over 120 million containers are fluorinated each year and are available for distribution, use and disposal. EPA notes that Inhance's own press release from August 2023 states that it fluorinates over 200 million containers annually (Inhance 2023).

[22] Throughout this document, the terms "potential" or "expected," when referring to exposure, mean that, depending on the individual SNUN 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 available in the administrative record for this action.

[redacted]

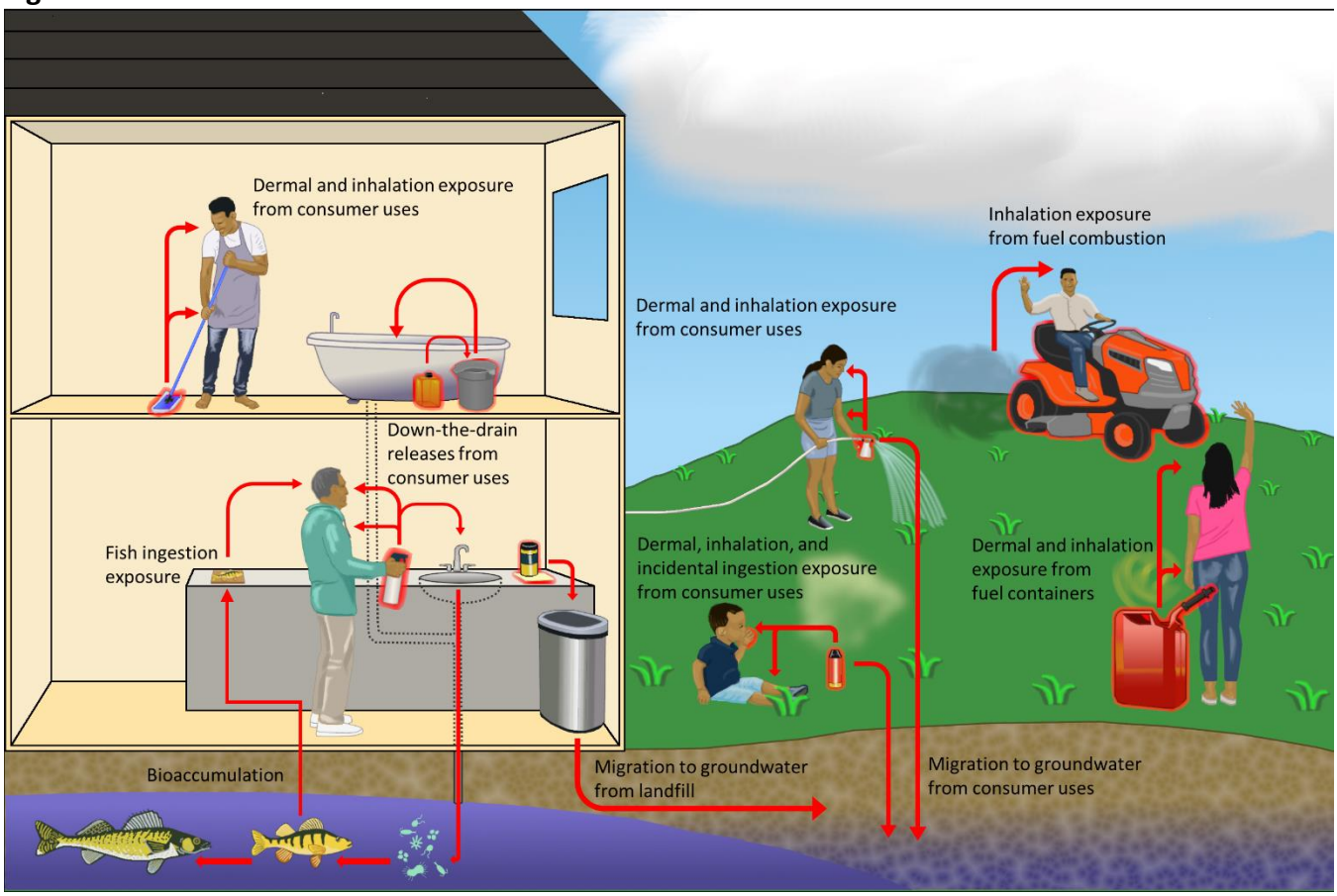
Two conceptual, schematic diagrams are provided in this section; one for environmental releases and occupational, general population, and aquatic organism exposure pathways (Figure 1) and the other for consumer exposures (Figure 2). These figures show many and different releases and exposures for the nine SNUN 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 Inhance, these schematics do not represent all of the potential or expected releases and exposure pathways from all the applications for the nine SNUN substances.

Figure 1 Occupational Schematic for the Nine SNUN 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 Nine SNUN Substances



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

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 precisely and accurately reflect the overall environmental and human health risk posed by these chemicals that bioaccumulate over time (see section 1.2.2). This section identifies the environmental media of release and potential or expected exposures to human (workers, the general population and consumers) and ecological receptors of concern.

All of the SNUN substances are PFAS substances that are expected to be formed during the fluorination process of HDPE containers. Potential or expected releases and exposure occur during manufacture, processing, use and disposal (of the containers or its contents). In addition, as pointed out in Sections 2 and 3, EPA also expects other PFAS besides the nine SNUN substances to be formed during the fluorination process. The tables in this section provide an overview of the media of environmental release and exposure (including exposure pathways, and human and environmental receptors) (see Tables 9 and 10 for the fuel storage container use; Tables 11 and 12 for the other (non-fuel) storage container uses).

[redacted]

4.1 Fuel Storage Container Use

Based on a qualitative engineering assessment performed using information provided in the Inhance submission and the physical and chemical properties of the nine SNUN substances, EPA determined that there are potential or expected environmental releases from manufacturing (to air, water, incineration[23]), processing (to air and water), use (to air, water, combustion in engines, land), and end of life disposal (to air, incineration and landfill) of fuel storage containers and tanks where the nine SNUN substances are present as byproducts (Table 9). There is also potential or expected dermal exposure for workers to the nine SNUN substances from fluorinated portable fuel containers, or liquid fuel containing SNUN substances, and for inhalation exposure to workers (Table 9).

Table 9: 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] Inhance sites)	The nine SNUN 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 Inhance submission and the physical and chemical properties of the SNUN substances, EPA determined that there is potential or expected human health exposures to the general population via drinking

[23] See Table 9, Media of Release column for a more detailed description of whether a release is from incineration, combustion, or fugitive.

[redacted]

water, fish ingestion, groundwater impacted by landfill leachate, and inhalation of air impacted by fugitive emissions and stack emissions[24], including emissions from incinerators (Table 10). EPA also determined that there are potential or expected exposures to environmental receptors (aquatic organisms) via releases to surface water (Table 10). In addition, there is potential or expected consumer exposures via dermal and inhalation pathways from the use of fluorinated storage containers and fuel tanks where the nine SNUN substances are present (Table 10). Exposure to the general population and aquatic organisms resulting from Down the Drain disposal is not expected related to fuel storage container use.

Table 10: 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 nine SNUN 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), Land	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.

[24] Stack air emissions are point source or directed air streams (i.e., coming out of a stack). Fugitive emissions are non-directed air streams (such as valve leaks, evaporation loss from tanks, etc.).

[redacted]

4.2 Non-Fuel Storage Container Use

Based on a qualitative engineering assessment performed using information provided in the Inhance submission and the physical and chemical properties of the nine SNUN 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 landfill) and from end of life disposal (to air, incineration and landfill) of storage containers used in miscellaneous applications where the nine SNUN substances are present as byproducts (Table 11). Depending on the process/lifecycle stage and physicochemical properties, there is potential or expected worker exposure to the nine SNUN substances, via dermal pathways from fluorinated product containers, or from liquid products containing SNUN substances, and via inhalation pathways as vapor and mist (Table 11).

Table 11: Environmental Release and Occupational Exposures (Non-Fuel Storage Container Use)[a]

Potential or Expected Environmental Release Media and Occupational Exposure[b,c]			
Operation	**Use Description**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Worker Exposure Pathway (Inhalation, Dermal)**
Manufacturing (at [redacted] Inhance sites, [redacted] specifically identified)	The nine SNUN substances are byproducts of the fluorination of storage containers used in various applications: household [redacted], trigger-spray pesticides and [redacted], commercial pesticides, and [redacted].	Air (stack and fugitive), Incineration	Inhalation, Dermal
Processing (no details on the operations of Inhance 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 the detail in the engineering report.

Based on the qualitative exposure assessment performed using information from the Inhance submission and the physical and chemical properties of the SNUN 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. In addition, exposure to the

[redacted]

general population is expected via indirect dermal contact and incidental ingestion from pesticide spray applications (Table 12). 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 12). 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 nine SNUN substances are present (Table 12). 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 12: 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] Inhance sites, [redacted] specifically identified)	The nine SNUN substances are byproducts of the fluorination of storage containers used in various applications, household [redacted], trigger-spray pesticides and [redacted], commercial pesticides, and [redacted]	General Population	Air (stack and fugitive*), Incineration	Inhalation*
Processing (no details on the operations of Inhance customers)		General Population	Air (fugitive*)	Inhalation*
Commercial USE 1A, Indoor		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

[redacted]

Potential or Expected General Population, Consumer, and Environmental Exposure Pathways[a]				
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.

5 Conclusions

Inhance submitted two consolidated SNUNs for a total of nine chemical substances formed as byproducts from the fluorination of plastic containers (fuel and non-fuel containers). Seven of the nine substances are existing chemicals included on the TSCA Inventory (the exceptions are SN-23-0006 and SN-23-0009). All of the nine SNUN substances are long-chain perfluoroalkyl carboxylic acids ranging from 8-18 carbons long. The nine SNUN substances co-exist on the surface of the container walls, embedded within the container wall, and (via leaching or migration) in the liquid contents of the fluorinated container.

In their submitted risk assessments, Inhance claims - using conventional risk assessment methods – that there are no risks to workers, the general population, or environmental organisms from the fluorination of their HDPE containers. This is based on Inhance identifying hazard values from various sources as points of departure (PODs) and providing estimates (with some measured data) for exposure values for a number of scenarios. There are different interpretations regarding the most appropriate PODs to be used to develop hazard values/reference doses for certain PFAS—for example, in other contexts, EPA has identified PODs for PFOA and PFDA that are 2,000- and 37,500-fold lower, respectively, than the PODs used in Inhance's risk assessments. Inhance's risk assessments did not address why its chosen PODs are the most appropriate. Use of EPA's PODs for PFOA and PFDA in Inhance's risk assessment methodology rather than those used by Inhance results in 80% of evaluated scenarios for the SNUN substances showing risks of concern (see narrative and footnotes in Sections 1.2.2 and 2.5).

Irrespective of the hazard values used, the fact remains that exposures will occur and be widespread due to the extremely large number of containers that Inhance fluorinates annually (i.e., approximately 121 million containers that Inhance fluorinated in 2021 (Exhibit 9, Inhance submission on 9/29/23) up to "more than 200 million plastic articles annually" (as described in Inhance August 2023 press release)) and which were distributed, used and disposed of. Although there is uncertainty in the amount of the nine SNUN substances that are manufactured as byproducts during the fluorination process, the fact is that they are formed and do exist. Such exposures, due to the persistent, bioaccumulative and toxic (PBT) nature of the nine SNUN substances, will contribute to the burden of

[redacted]

PFAS that currently exist in people and the environment and will continue to accumulate over time. There is ample evidence for this accumulation in the existence of seven of the SNUN substances (especially the highly toxic PFOA, PFNA, and PFDA) in human serum (see NHANES and other data, Sections 1.2.2 and 2.6) and for several of the SNUN substances in fish tissue (see fish tissue data, Section 1.2.2).

The available evidence shows that all nine SNUN substances are persistent, bioaccumulative, and toxic (PBT) using the scoring system explained in Section 3 (see section 3.5 for scores). Each of the nine SNUN substances contains multiple C-F bonds, which are extremely stable, and each is anticipated to be extremely persistent and rated P3 (see Section 3.1). Because all nine SNUN substances are long-chain PFAS, a class of chemicals with extensive data indicating they bioaccumulate in humans and fish tissue, all are expected to bioaccumulate and are rated B*high (Section 3.2). Based on their chemical structures, none of the nine SNUN substances are expected to degrade under normal environmental conditions.

Ecological hazards were identified in a species sensitivity distribution (SSD) analysis for chronic effects from PFOA exposure to 24 species from 8 taxonomic groups, including primary producers, fishes, amphibians, crustaceans, rotifers, mollusks, insects, and other invertebrates. The SSD was submitted by Inhance and EPA accepted it. Both Inhance and EPA found the PFOA data would be an acceptable analogue for the other eight SNUN substances and all of the SNUN substances are considered toxic to aquatic life. Based on the EPA criteria for chronic toxicity concern for aquatic organisms, all nine are rated T2 for ecological hazard (see Section 3.4.1). However, the appropriate and available environmental organism toxicity data are on only one of the nine SNUN substances (PFOA); showing a lack of robust environmental toxicity information for the other eight SNUN substances.

Identified human health hazards include systemic, reproductive, developmental and carcinogenic effects. Based on the best available information, including information submitted by Inhance, toxicity information supports a human health toxicity score of T2 for each of the nine SNUN substances (see Section 3.4.2). In fact, one of the SNUN substances (PFOA) has long been the focus of studies related to PFAS and is extremely toxic and persistent, with a half-life in humans of approximately 2-3 years. The other two SNUN substances with substantial available data (PFNA and PFDA) are also highly toxic. Although some toxicity data are available for five of the other SNUN substances (PFTrDA lacks toxicity data), collectively there is a lack of the appropriate toxicity information for this group of PFAS to inform hazard and possible dose-response/bioaccumulation information in humans. This overall lack of sufficient information – coupled with the available information on some PFAS - is indicative of the general concern for PFAS and their unique toxicity characteristics in terms of potency, persistence and bioaccumulation.

In line with the EPA New Chemicals Program PBT Policy (US EPA, 1999) and consistent with the recently released US EPA PFAS Framework (US EPA, 2023a), the New Chemicals program concludes that each of the nine SNUN substances are PBT substances, which means they are expected to accumulate over time in the environment, humans and environmental organisms.

The nine SNUN substances leach or are released into the contents of the fluorinated containers over time through regular use of the containers, including use of the containers for storage. The existence of

these nine SNUN substances on and/or in the fluorinated plastic containers – and the eventual leaching into the contents of the fluorinated containers – results in releases and exposures. Exposure to the nine SNUN substances is expected during the manufacture, processing, distribution, use and disposal of the fluorinated containers that contain these nine SNUN substances. Based on the current fluorination process and the diverse uses of the millions of fluorinated containers, and consistent with the PFAS Framework, releases to the environment of the SNUN substances produced as byproducts during Inhance's fluorination process are expected to be unavoidable and, because of the numerous and diverse pathways for exposure to these SNUN substances – especially to consumers - exposure will occur to these persistent, bioaccumulative and toxic chemicals.

There is also expected to be an additive hazard and exposure concern because the nine SNUN substances co-exist. Additionally, though the SNUNs and this analysis are limited to the nine SNUN substances, there is evidence that other potentially hazardous PFAS are formed during the fluorination process (see Section 1.2.2.). Due to the additive and compounding exposures, there is added concern for this type of byproduct formation and the release and potential exposure of PFAS to human health and the environment.

Consistent with the recently released PFAS Framework, the New Chemicals Program concludes there is risk from the manufacture, distribution, use, and disposal of the nine SNUN substances based on the PBT nature of the nine SNUN substances and the potential or expected exposures to workers, the general population, consumers and environmental organisms. Because these nine SNUN substances are PBTs, they are expected to accumulate over time. Three of the SNUN substances, PFOA, PFNA and PFDA, are extremely toxic. Seven of the SNUNs have been detected in US human serum samples (PFOA, PFNA, PFDA, PFuDA, PFDoA, PFTrDA, and PFTeDA). 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 risk assessments submitted by Inhance. Thus, Inhance's quantitative risk assessment underestimates the risk due to the unquantified buildup of the nine SNUN substances (for both toxicity and exposure) over time. In addition, as noted in Section 2.4 of this document, 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 additive effects from exposures to the nine SNUN substances together.

6 Potentially Useful Information

"Potentially useful information" is a term used to describe those data gaps that, if filled with case-specific information, may reduce uncertainty and provide a more accurate PBT assessment for a premanufacture notice or significant new use notice. The case-specific information refers to information on both compound and components of interest considered in an assessment, which may include expected degradation, hydrolysis and incineration products. The goal of testing requirements for the New Chemical Program is to obtain empirical data with case-specific information, which can be used to remove uncertainties in the risk assessment and better inform the risk management approach.

A tiered testing approach is used to facilitate evaluation of PFAS substances in the New Chemicals Program, in alignment with the PFAS Framework (US EPA, 2023a) and the National PFAS Testing Strategy (US EPA, 2021b). There are two tiers - with Tier 1 testing aimed at collecting information on

[redacted]

physical chemical properties, genetic toxicity and toxicokinetics; and in some cases in vitro dermal absorption studies. Tier 2 includes testing to provide additional information on bioaccumulation potential and repeat dose testing. Tier 1 physical chemical properties and toxicokinetics testing will also inform the choice and design of toxicity studies. The potentially useful information for SN -23-0002-0006 and SN-23-0008-0011, based on this risk assessment, is outlined in Table 13 in this section, based on the tiered testing approach.

In Appendix A, the purpose of each study is identified to guide higher tier testing and to inform the risk management approach. Where sufficient information are available, including where information submitted by Inhance was sufficient, testing is noted as *not applicable* in these appendix tables.

[redacted]

Table 13: Summary of Potentially Useful Information for Each SNUN Substance (a full outline of Potentially Useful Information, including descriptions of dependencies and the purpose of each study is provided in Appendix A)

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)
SN-23-0002 perfluorooctanoic acid (PFOA) CASRN 335-67-1	• 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)	• Avian reproduction (OCSPP 850.2300)

SN-23-0004
perfluorononanoic acid (PFNA)
CASRN 375-95-1
	• Water solubility (OECD TG 105)
	• K_{ow} (OECD TG 107)
	• Boiling Point (OECD 103)
	• 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)
	• Henry's Law Constant (Ji C, et al. 2007, and Sander R, et al. 2022)
	• 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)
	• Dermal absorption (in vitro) (OECD TG 428)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) ((using mice)
		• 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-23-0005 perfluorodecanoic acid (PFDA) CASRN 335-76-2	• Kow (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)	• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) • Chronic study for sediment dwelling organisms (OECD 233) • Avian reproduction (OCSPP 850.2300)
SN-23-0006 perfluoroundecanoic acid (PFuDA)	• K_{ow} (OECD TG 107) • Boiling Point (OECD 103) • Melting Point (OECD TG 102)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening

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

CASRN 2058-94-8	• 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)
	• 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)
		test (OECD TG 422) (Dependent on OECD TG 417 study)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201)
		• 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 perfluorotridecanoic acid (PFTrDA) CASRN 72629-94-8	• Water solubility (OECD 105) • K_{ow} (OECD TG 107) • Vapor Pressure (OECD TG 104) • Boiling Point (OECD 103)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)

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

	• 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)
	• 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 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-23-0008
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 perfluorohexadecanoic acid (PFHxDA)	• 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

[redacted]

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

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)

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8 Appendix A

Table A1. Tier 1 Potentially Useful Information for SN-23-0002 (perfluorooctanoic acid (PFOA), CASRN 335-67-1)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Measured (4.34 g/L)	• *Not applicable, sufficient test data available*
K_{ow} (OECD TG 107)	Measured (3.15)	
Vapor Pressure (OECD TG 104)	Measured (0.0316 Torr)	
Boiling Point (OECD 103)	Measured (189°C)	
Melting Point (OECD TG 102)	Measured (55°C)	
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C*
Bacterial Reverse Mutation Test (OECD TG 471)	ATSDR, 2021	• *Not applicable, sufficient test data available*
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)	ATSDR, 2021	

[redacted]

Table A2. Tier 2 Potentially Useful Information for SN-23-0002 (perfluorooctanoic acid (PFOA), CASRN 335-67-1)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	ATSDR, 2021	• *Not applicable, sufficient data available*
Other bioaccumulation studies	Dai and Zeng (2019); Furdui et al. (2007); Vierke et al. (2012); analogy to other PFAS	
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201)	HC5 value of 0.033 mg/L from the Species Sensitivity Distribution (SSD) for PFOA Reported by Li et al. (2021) and used by Inhance	
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A3. Tier 1 Potentially Useful Information for SN-23-0004 (perfluorononanoic acid (PFNA), CASRN 375-95-1)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	Estimation	
Vapor Pressure (OECD TG 104)	Measured (0.00977 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Melting Point (OECD TG 102)	Measured (69-71°C)	• *Not applicable, sufficient test data available*
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
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)	None	
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Toxicokinetics in rats and mice (OECD TG 417)	Tatum-Gibbs et al (2011) and Ohmori et al. (2003)	• *Not applicable, sufficient test data available information suggests PFNA has a longer half-life in mice*

[redacted]

Table A4. Tier 2 Potentially Useful Information for SN-23-0004 (perfluorononanoic acid (PFNA), CASRN 375-95-1)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Das et al., 2015 2015; Feng et al., 2009; and Feng et al., 2010 as cited in NJ DWQI	• To address lack of substance-specific in vivo mammalian guideline hazard data to better inform the human health T score, and therefore risk to workers the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). • Mice should be used (based on Tier 1 toxicokinetics study)
Other bioaccumulation studies	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue, PFOA, is considered a sufficiently similar analogue for PFNA, differing in structure by a single fully fluorinated carbon; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity "T" score and therefore, risk to the environment
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A5. Tier 1 Potentially Useful Information for SN-23-0005 (perfluorodecanoic acid (PFDA), CASRN 335-76-2)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Measured (5.13E-6 g/L)	• *Not applicable, sufficient test data available*
K_{ow} (OECD TG 107)	Estimated	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Vapor Pressure (OECD TG 104)	Measured (0.00174 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Measured (218°C),	
Melting Point (OECD TG 102)	Measured (77.2-78.9°C)	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25*°C and WS < 0.5 mg/L
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	US EPA, 2023b	• *Not applicable, sufficient test data available*
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)	US EPA, 2023b	• *Not applicable, sufficient test data available*

[redacted]

Table A6. Tier 2 Potentially Useful Information for SN-23-0005 (perfluorodecanoic acid (PFDA), CASRN 335-76-2)

Tier 2 Studies (Test Guideline) for	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	US EPA, 2023b	• *Not applicable, sufficient data available*
Other bioaccumulation studies	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS	
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered sufficiently similar to PFDA, differing in structure by two fewer fully fluorinated carbons • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A7. Tier 1 Potentially Useful Information for SN-23-0006 (perfluoroundecanoic acid (PFuDA) CASRN 2058-94-8)

Tier 1 Studies (Test Guideline) for	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Measured (0.056 g/L)	• *Not applicable, sufficient test data available*
K_{ow} (OECD TG 107)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Vapor Pressure (OECD TG 104)	Measured (7.41E-4 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Melting Point (OECD TG 102)	None	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
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)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population and consumers

[redacted]

Table A8. Tier 2 Potentially Useful Information for SN-23-0006 (perfluoroundecanoic acid (PFuDA) CASRN 2058-94-8)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Takahashi et al., 2014 (rats)	• In Takahashi et al, rats were tested; however, if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD TG 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population and consumer and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	De Silva et al. (2011); Gebbink et al. (2016); Khairy et al. (2019); Murakami et al. (2011); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in the assessment, PFOA, is considered a sufficiently similar analogue for PFuDA, PFOA contains seven fully fluorinated carbons compared to the ten for PFuDA. • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A9. Tier 1 Potentially Useful Information for SN-23-0003 (perfluorododecanoic acid (PFDoA), CASRN 307-55-1)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	Estimation	
Vapor Pressure (OECD TG 104)	Measured (6.17E-5 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Measured (249°C)	
Melting Point (OECD TG 102)	Measured (112-114 °C)	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C*
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
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)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population, and consumers

[redacted]

Table A10. Tier 2 Potentially Useful Information for SN-23-0003 (perfluorododecanoic acid (PFDoA), CASRN 307-55-1)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Kato et al., 2015a (rats)	• In the Kato et al. study, rats were tested; however, if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). • Mice should be used (based on Tier 1 toxicokinetics study).
Other bioaccumulation studies	Khairy et al. (2019); Lin et al. (2014); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue to PFDoA; PFOA contains seven fully fluorinated carbons compared to the eleven in PFDoA. • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A11. Tier 1 Potentially Useful Information for SN-23-0009 (perfluorotridecanoic acid (PFTrDA), CASRN 72629-94-8)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Melting Point (OECD TG 102)	Measured (112-123 °C)	• *Not applicable, sufficient test data available*
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
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)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
		• To better inform risk to workers, the general population and consumers

Table A12. Tier 2 Potentially Useful Information for SN-23-0009 (perfluorotridecanoic acid (PFTrDA), CASRN 72629-94-8)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Analogue (PFOA, PFDoA, PFTeDA, PFHxDA, PFODA (see Table 6))	• To address lack of substance-specific in vivo mammalian hazard data to better inform the human health T score, and therefore risk to workers the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). • Mice should be used (based on Tier 1 toxicokinetics study). • PFOA was used as an analogue based on structure and substantial availability of data; PFDoA, PFTeDA, PFHxDA, PFODA were also used as analogues based on closer structural similarity and the availability of some data; substance-specific data in the species with the longer half-life (identified in the toxicokinetics study previously) would be prioritized for identifying hazards
Other bioaccumulation studies	Zhang et al. (2018); Pan et al. (2017); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue for PFTrDA; PFOA differs in structure by five fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A13. Tier 1 Potentially Useful Information for SN-23-0008 (perfluorotetradecanoic acid (PFTeDA), CASRN 376-06-7)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Measured (270°C)	• *Not applicable, sufficient test data available*
Melting Point (OECD TG 102)	Measured (130-135°C)	
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C* • To address lack of substance-specific data
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
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)	None	• To address lack of substance-specific bioaccumulation information

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
		• Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population, and consumers

Table A14. Tier 2 Potentially Useful Information for SN-23-0008 (perfluorotetradecanoic acid (PFTeDA), CASRN 376-06-7)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Hirata-Koizumi et al., 2015 (rats)	• In the Hirata-Koizumi et al., study, rats were tested; however if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	Pan et al. (2017); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue for PFTeDA; PFOA differs in structure by six fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A15. Tier 1 Potentially Useful Information for SN-23-0010 (perfluorohexadecanoic acid (PFHxDA), CASRN 67905-19-5)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Measured (211°C)	• *Not applicable, sufficient test data available*
Melting Point (OECD TG 102)	Measured (153-155°C)	
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP* > 25°C
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
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)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population, and consumers

[redacted]

Table A16. Tier 2 Potentially Useful Information for SN-23-0010 (perfluorohexadecanoic acid (PFHxDA), CASRN 67905-19-5)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Hirata-Koizumi et al., 2015 (rats)	• In the Hirata-Koizumi et al., study, rats were tested; however if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue for PHHxDA; PFOA differs in structure by eight fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
If there is concern for bioaccumulation: Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A17. Tier 1 Potentially Useful Information for SN-23-0011 (perfluorostearic acid (PFODA), CASRN 16517-11-6)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Measured (235°C)	• *Not applicable, sufficient test data available*
Melting Point (OECD TG 102)	Measured (162-172°C)	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C*
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• to address lack of substance-specific genetic toxicity information
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)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population and consumers

[redacted]

Table A18. Tier 2 Potentially Useful Information for SN-23-0011 (perfluorostearic acid (PFODA), CASRN 16517-11-6)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Hirata-Koizumi et al., 2012	• In the Hirata-Koizumi et al. study, rats were tested, however, if in the OECD TG 417 study listed previously mice are determined to be the species with the longer half-life, the OECD TG 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	Analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue to PFODA; PFOA differs in structure by ten fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
If there is concern for bioaccumulation: Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

Exhibit 2

EPA Sanitized

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-23-0002, SN-23-0004 and SN-23-0005
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(f) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2604(f),

Inhance Technologies, LLC

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

DENISE KEEHNER

Digitally signed by DENISE KEEHNER
DN: c=US, o=U.S. Government, ou=Environmental Protection Agency, cn=DENISE KEEHNER, 0.9.2342.19200300.100.1.1=68001004465783
Date: 2023.12.01 10:24:49 -05'00'

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(f) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. § 2604(f)), 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):

- Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA) (CASRN 335-67-1) (SN-23-0002),

- Nonanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-heptadecafluoro- (PFNA) (CASRN 375-95-1, SN-23-0004), and

- Decanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluoro- (PFDA) (CASRN 335-76-2, SN-23-0005).

The Company submitted SNUNs for nine chemical substances. As indicated earlier, this Order addresses the SNUNs for three of these chemical substances. The SNUNs for the other six chemical substances are addressed in a separate Order. 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 (Significant New Use), the administrative record, and determinations made herein, the Company 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.

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 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 presents a substantial risk of injury to health or the environment, as required under Section 8(e) of TSCA, 15 U.S.C. § 2607(e). The notice should reference the appropriate SNUN identification number(s) for the substance(s) and contain a statement that the Significant New Use of the SNUN Chemical Substance(s) 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)(A)

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 § 5(f) of TSCA, 15 U.S.C. § 2604(f):

EPA has determined, pursuant to Sections 5(a)(3)(A) and 5(f)(1) of TSCA, 15 U.S.C. § 2604(a)(3)(A), (f)(1), that the manufacture, processing, distribution in commerce, use, or disposal of the SNUN Chemical Substances when manufactured or processed for the Significant New Use presents an unreasonable risk of injury to health or the environment.

EPA has determined that each of the SNUN Chemical Substances are PBTs and there are expected environmental releases and exposures to humans and to environmental organisms based on the expected 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 presents an unreasonable risk is based on the following significant and influencing factors:

- The SNUN Chemical 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.
- 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 states that human epidemiological and animal toxicity studies showed the identified hazards of PFOA are so significant that there are no safe levels of exposure. Based on EPA's latest science related to PFDA, EPA has developed a proposed toxicity assessment that shows that it is

highly toxic. PFNA has been reviewed by the Agency for Toxic Disease Registry (ATSDR), the EPA Office of Water has recently proposed a Maximum Contaminant Level (MCL) that addresses PFNA, and EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment [1].

- The persistence, bioaccumulation and toxicity of the SNUN Chemical Substances has resulted in an existing burden in humans, environmental organisms, and the environment. For example, as described in section 1.2.2 of EPA's Risk Assessment[2], data from the CDC's National Health and Nutrition Examination Survey (NHANES) "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 PFOA, PFNA, and PFDA. This includes >99-100% of samples for PFOA above the level of detection in human serum. Similarly, data from EPA's National Aquatic Resource Surveys show that 84% and 88% of fish tissue samples in the nation's rivers and Great Lakes, respectively, have PFDA above the method detection limit. PFNA also shows significant percent of samples above the method detection limit (see Table 1 of Appendix 2). The SNUN Chemical Substances have been shown to bioaccumulate in the environment, humans and environmental organisms. For example, PFOA has a reported half-life in humans of 2.3-3.8 years (as reviewed in Seals et al. (2011) and recently confirmed in Li et al. [2018]). This means it would take the body more than a decade to rid itself of PFOA residing in the body assuming there is no further exposure. Any new or additional exposure would result in an increase in the time it would take for the body to rid itself of PFOA.
- Under the New Chemicals Program, the SNUN Chemical Substances are rated as persistent, bioaccumulative and toxic to human health and the environment (they are rated P3B*(high)T2) (See section 3 of EPA's Risk Assessment for detailed discussion on

[1] The ATSDR Minimum Risk Level (MRL) for PFNA was used by the Company in their risk assessment. The proposed EPA's Office of Water proposed PFAS National Primary Drinking Water Regulation rulemaking (88 FR 18638; March 29, 2023), incorporating final MCLs for several PFAS, is scheduled to be finalized in 2024.
[2] Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011 (November 2023)

the PBT rating of the SNUN Chemical Substances). Consistent with the PBT Policy, EPA interprets this to mean that even small exposures to the SNUN Chemical Substances over time pose a risk (see also Appendix 3 to this order).

- The Significant New Use of the SNUN Chemical Substances will result in releases of PFOA, PFNA, and PFDA and additional human and environmental exposures to PFOA, PFNA, and PFDA will occur as a result of these uses. (See section 1.2.2 of EPA's Risk Assessment document for detailed information on evidence 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 (which involve direct application in the environment), 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.
- EPA has performed a sensitivity analysis to understand the impact of using toxicity values based on the latest science for PFOA and PFDA (the values derived by EPA scientists through the systematic review of the available toxicity studies) in the risk assessment performed by the Company. As described in more detail in the Technical Support Document entitled "Sensitivity Analysis: Calculating risk using EPA-derived toxicity values with the Company-derived exposure values" in the administrative record for this order, there are risks of concern associated with PFOA and PFDA in containers, even without accounting for existing body burden and the full extent and duration of exposure associated with these persistent and bioaccumulative compounds.

A prohibition on the manufacture of the SNUN Chemical Substances is required because the risk cannot otherwise be adequately mitigated. As discussed in Appendix 3: (1) even small

releases of PBT PFAS into the environment over time can contribute to considerable exposure and potential risk; (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. Based on concerns for persistence, bioaccumulation, and hazards identified in the assessment of the SNUN Chemical Substances, prohibiting manufacture is necessary to ensure that the order is protective against an unreasonable risk of injury to health or the environment. 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 SNUN Chemical Substances for the Significant New Use as described in this Order:

- Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA) CASRN 335-67-1) (SN-23-0002),

- Nonanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-heptadecafluoro- (PFNA) (CASRN 375-95-1, SN-23-0004), and

- Decanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluoro- (PFDA) (CASRN 335-76-2, SN-23-0005), by the Company, as follows:

I. 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 LCPFAC 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)).

II. 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 II.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.

III. Modification and Revocation of the Order

EPA may modify or revoke provisions of this Order if EPA determines, upon consideration of information or data submitted to EPA, 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.

IV. 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.

V. 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 present 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.

VI. 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").

VII. 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.

VIII. 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.

"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 a 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:

- Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA) (CASRN 335-67-1) (SN-23-0002),
- Nonanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-heptadecafluoro- (PFNA) (CASRN 375-95-1, SN-23-0004), and
- Decanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluoro- (PFDA) (CASRN 335-76-2, SN-23-0005)

Appendix 2: Basis for EPA's Determination

Chemical Name:

- Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro- (PFOA) (CASRN 335-67-1, SN-23-0002),

- Nonanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-heptadecafluoro- (PFNA) (CASRN 375-95-1, SN-23-0004), and,

- Decanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluoro- (PFDA) (CASRN 335-76-2, SN-23-0005).

Conditions of Use (intended, known, or reasonably foreseen)[3]:

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]), [redacted]), aerial/ground fogger pesticides, and [redacted].

Known conditions of use: Applying such factors as described in footnote 3, 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.

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[3] 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 submission that the submitter omits in a revised PMN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN 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.

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)(A) (15 U.S.C. § 2604(a)(3)(A), EPA has determined that the manufacture, processing, distribution in commerce, use, or disposal of the SNUN Chemical Substances for the Significant New Use presents 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 of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011 (November 2023). A summary of EPA's Risk Assessment is provided next in this section.

The New Chemicals Program's 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 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. The New Chemicals Program concludes that each of the SNUN Chemical Substances is a PBT. In addition, there are potential environmental releases and exposures to human and the environmental receptors based on the manufacture, processing, distribution and use of these SNUN Chemical Substances.

Background

The SNUN Chemical Substances are formed during fluorination of the high density polyethylene (HDPE) fuel and non-fuel storage containers.

The Company provided information in two consolidated sets. The Company's risk assessments considered risks associated with the three SNUN Chemical Substances addressed in this Order and six 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 SNUN Chemical Substances and six 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 SNUN Chemical Substances and six 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 SNUN Chemical Substances and six 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.[4]

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 a 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

[4] 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 nonrisk 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 nonrisk 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.

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 such as the SNUN Chemical Substances, is complicated by: (1) the exceptionally high toxicity of well-studied PFAS, including the SNUN Chemical Substances (2) the likely additive impacts of exposure to multiple PFAS; (3) the persistence of PFAS; (4) the bioaccumulative properties of PFAS; (5) the widespread occurrence of PFAS in the environment; and (6) 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 complicating factors is further explained in EPA's Risk Assessment in section 1.2.2 and summarized in this document.

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 do not account for chemical substance accumulation over time in environmental media, environmental organisms and humans.[5] Second, there is an undetermined number 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. This is important because in order to attempt to quantify added risks from exposure to the SNUN Chemical Substances, background risk must be known. The National Academy of Sciences 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…" (NAS,

[5] 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.

2022, p. xi) also referred to as NHANES data). These data showing PFAS in human serum include the presence of PFOA, PFNA, and PFDA. 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 SNUN Chemical Substances.

Notably, two of the SNUN Chemical Substances (PFNA and PFDA) have been shown to be widespread in fish tissue in U.S. waters (Table 1). Fish are time-integrating indicators of persistent pollutants, and contaminant bioaccumulation in fish tissue has important human health implications (EPA 2020a). 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-23-0004 and SN-23-0005) at high frequencies of detection in its statistical surveys of the nation's rivers and the Great Lakes (see Table 1).

Table 1: Detection Frequency of PFDA and PFNA 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-23-0004 (PFNA)	39	78
SN-23-0005 (PFDA)	84	88

[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 these 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 in 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 six 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 on the bioaccumulation and toxicity potential of the SNUN Chemical Substances is unknown at this time.

Based on these considerations, and as outlined further in 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 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 that document, 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 the Company-derived exposure values" as part of the administrative record for this action). The Company's risk assessment utilized the ATSDR MRL as the human health hazard POD for PFNA and, using that POD, did not show risk for any scenario in their quantitative assessment. EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. In addition, there were deficiencies, unrelated to the PODs, in the Company's quantitative risk assessment, discussed further in section 2.6 of the risk assessment.

metabolites, a PBT determination is 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, but that for the 8-carbon PFOA, the non-detect frequency only dropped to 84%. These data therefore 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).

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 additive[7] exposure and the likely hazard/toxicity interaction (whether it be additive or 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,

[7] Additivity means that it is likely that the SNUN Chemical Substances interact so that both hazard and exposure could be additive as they are present as a mixture. This additivity could be either due to dose additivity or response additivity (see epa.gov/risk and search for 1986 *Guidelines for the Health Risk Assessment of Chemical Mixtures*).

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 assessment for the SNUN Chemical Substances.

In order to accurately and precisely quantify risk, it is important to have confidence in the estimates 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[8] data documenting the presence of PFOA, PFNA, and PFDA in human serum, and the EPA National Aquatic Resource Survey data supporting widespread presence in freshwater fish tissue in U.S. rivers and Great Lakes for PFNA and PFDA, which affects the ability to estimate exposure to, and hazard and risk for the SNUN Chemical Substances; 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. PFOA, PFNA, and PFDA are extremely toxic and have been detected in US human serum samples. There are substantial scientific challenges with 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) over time. Additional risks may be associated with existing levels of PFAS in both the environment and human serum (i.e., background levels of

[8] As cited in NAS, 2022 but all data are available at – cdc.gov/exposurereport/data_tables.html (and searching for individual chemicals).

PFAS) and possible interaction from exposures to the SNUN Chemical Substances together and with other PFAS formed during the Company's fluorination process.

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.

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 8 (PFOA) to 10 (PFDA) 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 these 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, the SNUN Chemical Substances are not 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 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.). The SNUN Chemical Substances are not anticipated to degrade under environmental conditions. They are long-chain PFAS, a class of chemicals which extensive data indicate can bioaccumulate in humans. As such, they 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 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, PFAS, including the SNUN Chemical Substances, would be expected to be released to receiving/surface waters used as

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

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 EPA's Risk Assessment, the majority of available PFAS aquatic toxicity test data are only for PFOA (SN-23-0002), with PFNA (SN-23-0004) and PFDA (SN-23-0005) lacking experimental test data/information applicable to the assessment. Modeled data are not incorporated into the environmental hazard assessment for PFNA or PFDA because aquatic toxicity models based on lipophilic partitioning (e.g., ECOSAR) are unreliable for PFAS.

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 EPA's qualitative assessment of the SNUN Chemical Substances. PFOA is considered a concern for chronic toxicity to aquatic organisms based on the high environmental hazard observed in the submitted data (see Table 6 of EPA's Risk Assessment); the environmental toxicity "T" score for SN-23-0002 (PFOA) is T2. For SN-23-0004 (PFNA) and SN-23-0005 (PFDA), the environmental toxicity score is considered unknown and thus the PFOA data are used as read-across for EPA's 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 the SNUN Chemical Substances and five of the PFAS covered by SNUNs that are addressed in a separate order, and an analogous substance for one of PFAS covered by a SNUN that is addressed in a separate Order (PFTrDA). EPA primarily relied on available human health toxicity information from EPA assessments and the ITRC website (ITRC, 2023) for the SNUN Chemical Substances. See Table 2 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). PFNA has

been reviewed by the Agency for Toxic Disease Registry (ATSDR), the EPA Office of Water (publicly in a proposed rule), and is currently under review with the EPA IRIS program.

For PFOA, EPA relied on the extensive review of the data available in the interim drinking water health advisory document from EPA's Office of Water (US EPA, 2022a). PFNA is reviewed extensively in ATSDR, 2021, as well as in a health-based maximum contaminant level support document from the New Jersey Drinking Water Quality Institute (NJ DWQI, 2015). In addition, EPA has issued a preliminary regulatory determination to regulate PFNA as a contaminant under the Safe Drinking Water Act (PFAS National Primary Drinking Water Regulation Rulemaking, 2023), with a health-based water concentration also based on the ATSDR findings (ATSDR, 2021, as cited in US EPA, 2023d). For PFNA, EPA is currently developing a draft IRIS toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. [10] Finally, for PFDA, there is a draft EPA IRIS toxicological review containing an extensive literature review that has been released for public comment (US EPA 2023b).

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 2 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. While EPA performed a qualitative assessment, POD values identified by EPA are presented in Table 2 to illustrate the potency of the toxicity for the three SNUN Chemical Substances (i.e., PFOA, PFNA and PFDA). However, the PODs were not used to determine a T-score nor for quantitative purposes in EPA's Risk Assessment.

[10] The ATSDR Minimum Risk Level (MRL) for PFNA was used by the Company in their risk assessment. The proposed EPA's Office of Water proposed PFAS National Primary Drinking Water Regulation rulemaking (88 FR 18638; March 29, 2023) incorporating final MCLs for several PFAS is scheduled to be finalized in 2024.

In addition to the hazards identified for each SNUN Chemical Substance individually, EPA notes the SNUN Chemical Substances are present together and with other PFAS (covered by a separate order) formed during the Company's fluorination process (i.e., co-exist), 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. As described in section 2.4 of the 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 2: 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-23-0002 (PFOA, 8)	***Developmental immune effect*** in children (Grandjean et al., 2012, and Budtz-Jørgensen and Grandjean, 2018, as cited in US EPA, 2022), the basis for Office of Water's interim reference dose (RfD) of 1.5 x 10^{-9} mg/kg-bw/day.	T2
SN-23-0004 (PFNA, 9)	***Decreased body weight and developmental delays*** (Das et al., 2015, as cited in ATSDR, 2021) are the basis for ATSDR's minimal risk level of 3 x 10^{-6} mg/kg-bw/day (this is the toxicity value used by the Company, see section 2.5, and used in the EPA Office of Water proposed rule (US EPA, 2023d)).	T2
SN-23-0005 (PFDA, 10)	***Developmental immune effect and decreased birth weight in children*** (Grandjean et al., 2012, Budtz-Jørgensen and Grandjean, 2018, and Wikström et al., 2020, as cited in US EPA 2023b), the basis for the proposed IRIS developmental RfD of 4 x 10^{-10} mg/kg-bw/day	T2

Environmental Release, Exposure Pathways and Environmental and Human Health Receptors

In the New Chemicals Program, the engineering assessments evaluate 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[11], 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 disposal of 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).

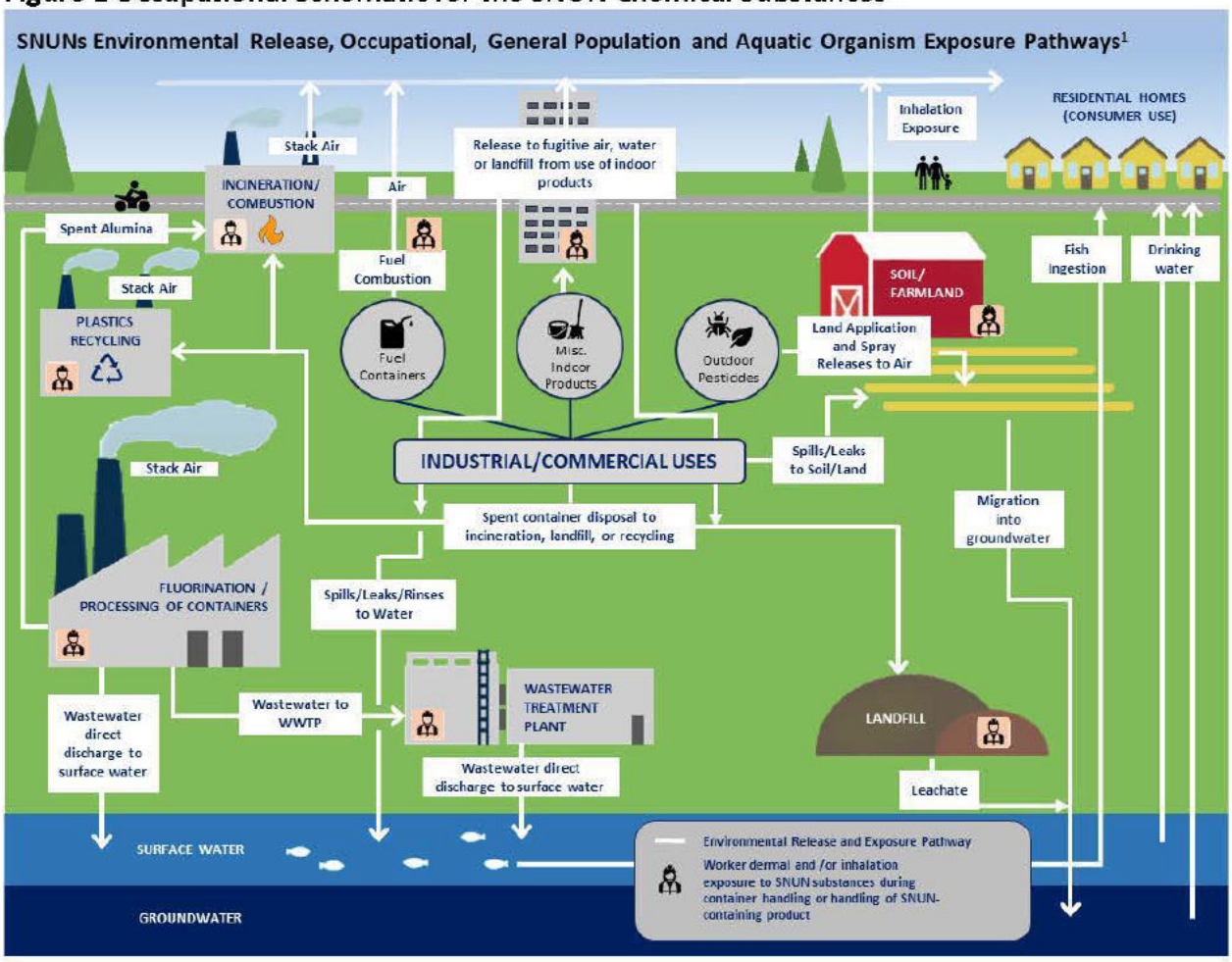
Consistent with the PFAS Framework, the New Chemicals Program will not be quantifying risk (exposure and hazard) for PBT PFAS due to the likelihood that a quantitative risk assessment would underestimate risk and thus not be protective of human health and the environment. A quantitative assessment would 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.

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 exposures occur

[11] 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.

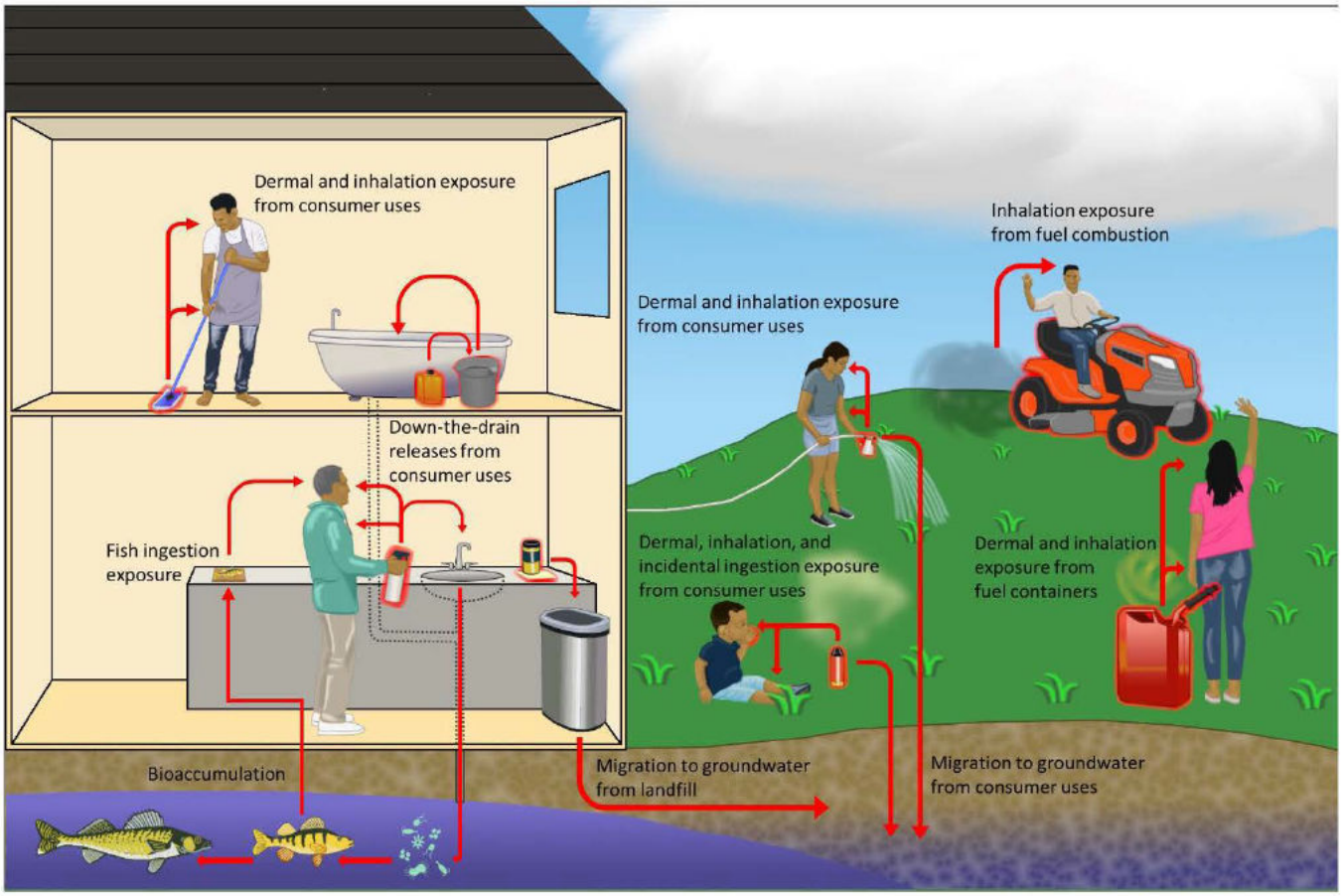
during manufacture, processing, use and disposal (of the containers or its contents). EPA also expects other PFAS besides the SNUN Chemical Substances to be formed during the fluorination process, including the six other PFAS substances which are the subject of additional SNUNs, have been identified by 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 potential (including exposure pathways, and human and environmental receptors) (see Tables 3 and 4 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 environmental releases from manufacturing (to air, water, incineration[12]), processing (to air and water), commercial use (to air, water, combustion in engines, land), and end of life disposal (to air, incineration and landfill)

[12] See Table 3 Media of Release column for more detailed description of whether a release is from incineration, combustion, or fugitive.

of fuel storage containers and tanks where the SNUN Chemical Substances are present as byproducts (Table 3). There is also potential for 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 3).

Table 3: Environmental Release and Occupational Exposures (Fuel Storage Container Use)[a]

Potential or Expected Environmental Release Media and Occupational Exposure Pathways			
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[b]), 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 submission and the physical and chemical properties of the SNUN Chemical Substances, EPA determined that there is potential for human health exposure to the general population via drinking water, fish ingestion, groundwater impacted by landfill leachate, and inhalation of air impacted by emissions and stack air 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 4). 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 4). Exposure to the general population and aquatic organisms resulting from Down the Drain disposal is not expected for the fuel storage container use.

Table 4. 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), Land	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 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 5). Depending on the process/lifecycle stage and physicochemical properties, there is a 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 5).

Table 5: 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: household [redacted] trigger-spray pesticides [redacted], commercial pesticides, and [redacted]	Air (stack and fugitive), Incineration	Inhalation, Dermal
Processing (no details on the operations of 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's 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. In addition, exposure to the general population is expected via indirect dermal contact and incidental ingestion from pesticide spray applications (Table 6). 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 6). In addition, there is potential or expected consumer exposure via dermal and inhalation pathways from using various household products contained in the non-fuel storage containers where SNUN Chemical Substances are present (Table 6). Releases to water from 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 6: General Population, Consumer, and Environmental Exposures (Non-Fuel Storage Container Use)

Potential General Population, Consumer, and Environmental Exposure Pathways for SN-23-0002 and SN-23-0005				
Operation	**General Population, Consumer, and Environmental Receptors**			
	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 storage containers used in various applications, household [redacted]	General Population	Air (stack and fugitive*), Incineration	Inhalation*
Processing		General Population	Air (fugitive*)	Inhalation*
Consumer Use 1A; Indoor		General Population, Environmental Receptors	Air (fugitive*), Water, Land	Inhalation*, Ingestion, Aquatic Organisms
Consumer Use 1B; Outdoor	[redacted] trigger-spray pesticides and [redacted]	General Population, Environmental Receptors	Air (fugitive/spray drift), Land, Water (spray drift and runoff)	Inhalation, Dermal, Ingestion, Aquatic Organisms

End of Life	commercial pesticides, and [redacted]	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: 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[13], which was discovered through citizen science testing of the pesticide.

EPA's Risk Assessment used Inhance's total reported 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.[14]

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

[13] 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.

[14] 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 4: 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.

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