February 13, 2023

Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency Mail Code 7101M
1200 Pennsylvania Avenue NW
Washington DC 20460

Re: EPA Review of LCPFAC SNUNs Submitted by Inhance Technologies

Dear Assistant Administrator Freedhoff:

We are writing to express deep concern about nine pending significant new use notices[1] ("SNUNs") that test EPA's commitment to preventing exposure to unsafe per- and polyfluoroalkyl substances ("PFAS") under the Toxic Substances Control Act ("TSCA").

These SNUNs were submitted in late 2022 by Inhance Technologies LLC ("Inhance"), the principal U.S. provider of post-mold "fluorination" services to distributors and users of plastic containers. Extensive testing shows that the fluorination process results in the formation of several long-chain perfluoroalkyl carboxylate ("LCPFAC") substances subject to the Agency's July 2020 significant new use rule ("SNUR") under TSCA. Inhance has been producing these LCPFACs in violation of the SNUR since it took effect. It belatedly filed SNUNs only after EPA repeatedly informed the company that it was failing to comply with the law. Despite filing SNUNs, Inhance continues to manufacture and process LCPFACs. Separate suits have been filed by PEER and CEH and by EPA to stop this unlawful conduct and protect the public from unsafe exposure to illegally produced LCPFACs.

The nine SNUNs and the LPCFACs they cover are as follows:

SNUN #	CAS #	PFAS	"Species"[2]
SN-23-0002	335-67-1	Perfluorooctanoic acid (PFOA)	1
SN-23-0003	307-55-1	Perfluorododecanoic acid (PFDoA)	5
SN-23-0004	375-95-1	Perfluorononanoic acid (PFNA)	2
SN-23-0005	335-76-2	Perfluorodecanoic acid (PFDA)	3
SN-23-0006	2058-94-8	Perfluoroundecanoic acid (PFuDA)	4
SN-23-0008	376-06-7	Perfluorotetradecanoic acid (PFteDA)	7
SN-23-0009	72629-94-8	Perfluorotridecanoic acid (PFtrDA)	6
SN-23-0010	67905-19-5	Perfluorohexadecanoic acid (PDHxDA)	8
SN-23-0011	16517-11-6	Perfluorooctadecanoic acid (PFODA)	9

According to the ChemView database, the SNUNs were received on December 30, 2022, and the

[2] "Species" is an Inhance identifier.

review period is now underway.

Prohibiting Formation of LCPFACs under TSCA Section 5(f)

With the filing of the SNUNs, section 5(a) of TSCA requires EPA to review the health and environmental impacts of the fluorination process and make determinations of safety for LCPFACs manufactured, processed and distributed in commerce by Inhance. Under the 2016 TSCA amendments, these determinations must be made "without consideration of costs or other nonrisk factors." EPA can only take into account protection of people and the environment.

As addressed below, the only legally and scientifically defensible outcome of EPA's SNUN reviews is a determination that LCPFACs formed during fluorination "present an unreasonable risk of injury to health or the environment" under TSCA section 5(a)(3)(A). This determination must result in issuance of an order under section 5(f)(3)(A) prohibiting Inhance from conducting any fluorination activities that form LCPFACs.

Disallowing Unjustified CBI Claims

We also call upon EPA to immediately review and reject Inhance's all-encompassing claims of Confidential Business Information ("CBI") for the SNUNs. Almost all the information in the SNUNs has been redacted, including extensive health and safety data[3] that must be disclosed under section 14(b)(2) of TSCA. Lack of access to these data denies the public vital information about the risks of LCPFACs produced by Inhance to workers, consumers and communities and prevents public interest groups like ours from providing informed comments during the SNUN review process. Consistent with section 14(g) of TSCA, EPA must accept or reject Inhance's CBI claims within 90 days and extend the completion of its SNUN review period so that the public has the opportunity to review and comment on information that has been unlawfully withheld.

Our review of the redacted SNUNs has identified several documents that, as described, fall within EPA's broad definition of health and safety study[4] and should be prioritized for immediate disclosure without redaction because they contain critical information on exposure and risk.[5] We look forward to receiving these unredacted documents from EPA as soon as possible.

Basis for the 2020 SNUR

Since the early 2000s, EPA has used its SNUR authority under TSCA to codify the phaseout of PFAS of concern by imposing rigorous notice and review requirements on companies that seek to reintroduce these PFAS in commerce. The 2022 LCPFAC SNUR is a prominent example of this approach. 85 Fed. Reg. 45109 (July 27, 2020). The basis for the SNUR is the 2010-2015 PFOA

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[4] 40 CFR § 716.3 states that the term "health and safety study … is intended [to] be interpreted broadly," and includes a wide array of formal or informal compilations of data on human, environmental, and workplace exposure, and environmental fate and transport.

[5] At a minimum, for each of the nine SNUNs, EPA should immediately unredact Attachments: 3A and 3B (Risk Assessments), 10 (Diagram …and Worker Activities Associated with Production Steps), 13 (Illinois Wastewater Industrial Pretreatment Program, Industrial User Discharge Permit), 24 (Environmental Release and Disposal), 26 (Occupational Exposure), and 4 through 9 (various Reports of Analysis and Analytical Reports). These documents are within the scope of PEER and CEH's January 5, 2023 Freedom of Information Act request (EPA-2023-001593).

Stewardship Program, under which the principal manufacturers and processors of LCPFACs voluntarily agreed to cease their production as of December 31, 2015. The SNUR assures that manufacturing of LCPFACs cannot resume without notification to and careful review by EPA. As a result of the SNUR, EPA "expects the presence of LCPFAC chemical substances in humans and the environment to decline over time as has been observed in the past when production and use of other persistent chemicals have ceased." 85 Fed. Reg. 45113.

Risk Profile of PFOA and Other LCPFACs

Allowing *any* manufacture and processing of LCPFACs in response to the Inhance SNUNs would undermine the Agency's goal of reducing exposure to these substances and add to the risks of harm that now exist. This would undo the progress EPA is making under its PFAS Action Plan in preventing the further accumulation of LCPFACs in people and the environment.

According to the SNUR, perfluorooctanoic acid ("PFOA") and its salts "have been a primary focus of studies related to the LCPFAC class of chemical substances." 85 Fed. Reg. 45113. It is well-established that PFOA presents a serious risk of injury to people and the environment because of the combination of pervasive exposure and serious adverse health effects at near-zero concentrations. Although less extensively studied, other LCPFACs likely have similar exposure and toxicity profiles to PFOA. As with other hazardous substances, exposure and risk are greatest for environmental justice communities (communities of color and low-income populations).

Like most PFAS, PFOA is persistent and has a half-life in humans of 2.3–3.8 years. Id. PFOA has been found in the blood of 98 percent of the U.S. population, "indicating that exposure to these chemical substances is widespread." Id. PFOA is linked to "adverse effects in laboratory animals, including cancer and developmental and systemic toxicity," and "[h]uman epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia and cancer (testicular and kidney)." Id.

In its latest toxicity assessment of PFOA, EPA underscored that "new published peer-reviewed data and draft EPA analyses indicate that the levels at which negative health outcomes could occur are much lower than previously understood." As a result, the Agency set a new interim drinking water health advisory for PFOA of 0.004 ppt, reflecting its conclusion "that some negative health effects may occur with concentrations of PFOA . . . in water that are near zero and below EPA's ability to detect at this time."

Increased Risks from LCPFAC Exposure Due to Fluorination

Given the extraordinarily low levels of PFOA capable of harming health, any increase in exposure from the formation of PFOA and other LCPFACs during fluorination would represent an unacceptable increase in risk. The limited information available publicly provides alarming evidence that fluorination may be a significant contributor to overall exposure to PFOA and other PFAS:

- The LCPFACs identified by Inhance in fluorinated containers consist of PFOA, PFDoA, PFNA, PFDA, PFuDA, PFTeDA, PFtrDA, PDHxDA and PFODA .
- Short-chain PFAS are also consistently detected in these containers.
- Aggregate levels of PFAS found in containers are in the parts per billion (ppb). These levels are observed to increase if the container is heated, solvents are present, or samples are taken over time.

- It is estimated that Inhance fluorinates over 140 million containers per year.
- Fluorinated containers have diverse applications across the economy, including for home cleaning products, paint removers, automotive products, fuel tanks and totes, lawn and garden products, bulk industrial containers, lubes and greasers, solvents, agricultural chemicals, foods, and craft and hobby materials.
- There are significant pathways of human exposure at every level in the distribution chain, including by:
    - Workers directly engaged in fluorination at Inhance's 11 U.S. treatment facilities;
    - Workers who handle fluorinated containers when filling them with products, preparing them for shipment to downstream users or accessing their contents during end-use;
    - Workers in container recycling and disposal operations; and
    - Consumers who purchase or otherwise use fluorinated containers and may be exposed to PFAS when handling or transporting containers and their contents.
- Routes of exposure may include dermal contact, inhalation and ingestion.
- Environmental releases provide additional pathways of exposure and include:
    - Stack and fugitive emissions and wastewater discharges containing LCPFACs from Inhance treatment facilities or sites where fluorinated containers are processed and used;
    - Releases of LCPFACs from wastewater treatment operations;
    - Releases of LCPFACs to the environment from recycling or landfilling of used containers;
    - Spills of LCPFAC-containing fuels, chemicals or other products during transport and use.

In analyzing the significance of these pathways, it is important to recognize that many workers and consumers likely have multiple exposure events because they handle and use one or more fluorinated containers repeatedly over a period or weeks or months. In such cases, exposure will be ongoing and significant. Ongoing and significant exposure is also likely from water and air releases by Inhance's 11 US facilities. These releases could have substantial environmental justice impacts, given that residential areas in closest proximity to industry are often predominantly low-income communities and communities of color disproportionately burdened by toxic chemicals. Moreover, these worker, consumer, and EJ populations will have preexisting levels of PFOA and other PFAS in their blood. The PFAS in fluorinated containers will be additive to this ongoing body burden and therefore magnify the risk that already exists. Given EPA's determination that even trace levels of PFOA likely have harmful effects, any incremental risk from fluorinated containers would be "unreasonable" under TSCA.

<u>Assuring that Inhance Risk Analyses Use Realistic Data and Sound Methodologies</u>

The redacted SNUNs indicate that Inhance has submitted risk analyses for various exposure pathways to EPA. However, the methodologies and inputs for these analyses cannot be reviewed because of Inhance's expansive CBI claims. This makes it impossible to identify flaws and underestimations in Inhance's calculations of exposure and risk. It is uncertain, for example, whether these calculations are based on EPA's latest health effects findings for PFOA and how they account for the hazards of other LPCFACs that lack data but should be assumed to be comparable in toxicity to PFOA. It is also unclear whether Inhance's calculations underestimate risks by evaluating exposure to each LCPFAC in isolation or assess the aggregate risks of the nine LCPFACs and short-chain PFAS formed during fluorination in combination. Further, consistent with Biden EPA policies for evaluating new and existing chemicals, worker exposure should be determined without assuming the use of personal protective equipment ("PPE").

Moreover, as a recent Greenwire article describes in detail, Inhance has a history of violations of pollution control requirements and excess emissions and releases. This history should prompt careful scrutiny of the exposure and release scenarios in the SNUNs to make sure they account for unplanned discharges and other worst-case but plausible exposure scenarios. Public review of the SNUNs can add greatly to this scrutiny but will be impossible unless EPA acts quickly to reject CBI claims for health and safety information that is ineligible for confidential treatment under TSCA.

In conclusion, the Inhance SNUNs present a critical test of whether EPA will adhere to its commitment to stop the buildup of PFAS in people and the environment by preventing new sources of exposure and release. Here, this commitment requires EPA to prohibit the formation of PFOA and other LCPFACs during the fluorination of plastic containers by Inhance.

EPA must also disallow Inhance's CBI claims for health and safety data that must be disclosed to the public under section 14(b) of TSCA.

PEER and CEH look forward to providing additional input to EPA as its review of the SNUNs proceeds.

Please contact CEH counsel Bob Sussman bobsussman1@comcast.net with any questions.

Respectfully submitted,

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