May 17, 2024

Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Re: Notice of Intent to File Suit to Compel Performance of a Non-discretionary Duty under Section 20(a)(2) of TSCA

Dear Administrator Regan:

This notice of intent to sue to compel the Environmental Protection Agency ("EPA") to perform non-discretionary duties under section 20(a)(2) of the Toxic Substances Control Act ("TSCA") is submitted by the Center for Environmental Health ("CEH") and Public Employees for Environmental Responsibility ("PEER").

CEH and PEER are non-profit organizations headquartered in Oakland, California, and Silver Spring, Maryland, respectively, who are dedicated to protecting the public from environmental and health hazards and promoting a high standard of environmental ethics, scientific integrity, and legal accountability.

It is the position of CEH and PEER that EPA has failed to perform its non-discretionary duty under section 4(f) of TSCA, 15 U.S.C. § 2603(f), to initiate applicable action under section 5, 6 or 7 to prevent or reduce the risk posed by perfluorooctanoic acid ("PFOA") formed in the process of fluorinating plastic containers. This obligation arose within 180-days of EPA's receipt of information indicating that there may be a reasonable basis to conclude that, when present in such containers, PFOA presents a significant risk of serious or widespread harm to human beings.

EPA received information triggering section 4(f) by March 29, 2023, if not earlier. As of that date, EPA possessed conclusive data on the carcinogenicity of PFOA to humans together with extensive documentation of the formation of PFOA and other harmful Per- and Polyfluoroalkyl substances ("PFAS") during the fluorination of tens of millions of plastic containers distributed and used throughout the economy.

March 29, 2023 was a critical milestone in EPA's understanding of the risks of fluorination because, on that date, EPA proposed its National Primary Drinking Water Regulation for PFOA

and five other PFAS under the Safe Drinking Water Act ("SDWA"). Consistent with previous EPA findings, the proposal stated, "Following a systematic review of available human epidemiological and animal toxicity studies, EPA has determined that PFOA … [is] likely to cause cancer (*e.g.,* kidney and liver cancer) and that there is no dose below which … [it] is considered safe."[1] EPA also concluded that PFOA has been "detected in up to 98 percent of human serum samples taken in biomonitoring studies that are representative of the U.S. general population,"[2] and that there is "widespread occurrence of PFOA …in multiple geographic locations."[3] Due to the widespread occurrence of PFOA, its presence in virtually every American's blood, and its carcinogenicity, EPA proposed to set the health-based value, or the Maximum Contaminant Level Goal ("MCLG"), at zero.[4]

As detailed below, by March 29, 2023, as a result of a thorough investigation starting in late 2020, EPA also had received comprehensive data demonstrating that the fluorination process conducted by Inhance Technologies LLC ("Inhance") produced PFOA at levels of concern in up to 200 million plastic containers annually. EPA further understood that this PFOA was not only present in the container walls, but also was leaching into the contents of those containers. Thus, the Agency knew that fluorination was causing PFOA contamination of pesticides, fuels, and a variety of other products extensively used by workers and consumers, resulting in widespread human exposure and environmental release.

In short, by March 29, 2023, EPA had compelling evidence of PFOA cancer risk at all dose levels and widespread PFOA exposure from the extensive distribution and use of fluorinated packaging. This information demonstrated conclusively that PFOA formed in the fluorination process presented a significant risk of serious or widespread harm to humans. Because section 4(f) was triggered on or before that date, EPA should have initiated action to "prevent or reduce [the risk] to a sufficient extent" within 180 days, or by no later than **September 25, 2023**. This non-discretionary duty has not yet been performed.

To our knowledge, no other chemical currently produced in the United States has an MCLG of zero, is a Group 1 carcinogen, is present in virtually all Americans' blood, is persistent and bio-accumulative, has been found in food, water, soil and house dust, and is widely distributed in and released from tens of millions of products packaged in fluorinated containers. This convergence of several alarming risk factors presents a compelling case for invoking section 4(f). If section 4(f) is not triggered under these circumstances, it is hard to imagine any chemical to which it would apply.

On December 1, 2023, EPA issued an order and risk assessment under section 5(f) of TSCA determining that harmful PFAS produced during fluorination of plastic containers present an unreasonable risk of injury to health. The order was directed to Inhance as the sole company conducting post-mold fluorination of plastic containers in the US. The order and supporting risk assessment were the outgrowth of EPA's intensive examination of the risks of fluorination after

[1] 88 Federal Register 18638, 18639 (March 29, 2023).
[2] Id at 18643
[3] Id at 18648
[4] Id at 18639.

receiving significant new use notices ("SNUNs") from Inhance in late 2022. Thus, they confirmed information EPA already possessed on or before March 29, 2023 demonstrating that PFOA formed during fluorination posed a "significant" and "serious or widespread" risk to health triggering section 4(f).

EPA's December 1, 2023 orders under Section 5(f) prohibited Inhance from producing PFOA and other PFAS during its fluorination process,[5] and could be considered the initiation of an action to "prevent or reduce the risk" as required by Section 4(f). However, because its section 5(f) order was stayed by the Court of Appeals for the Fifth Circuit and never took effect, EPA has not yet met its obligations under section 4(f). We request that EPA comply with section 4(f) by issuing an immediately effective rule under section 6 prohibiting production of PFOA during fluorination as soon as possible. If the rule is not made immediately effective, EPA must file an imminent hazard suit seeking this relief against Inhance under TSCA section 7.

As required by 40 C.F.R. § 702.62(b), the basis for compelling EPA to perform this non-discretionary duty is as follows:

Applicable Provisions of TSCA

Section 20(a)(2) of TSCA authorizes "any person" to commence a civil action against EPA "to compel [it] to perform any act or duty under this Act which is not discretionary." Section 20(b)(2) provides that no suit can be filed until 60 days from plaintiff's notification of EPA, except that suit can be filed 10 days after giving notice of EPA's failure to commence an imminent hazard action under section 7.

Section 4(f) of TSCA is triggered when EPA receives information "which indicates to [the Agency] that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings." Upon acquiring such information, EPA "shall . . . initiate applicable action under section [5, 6 or 7] to prevent or reduce such risk to a sufficient extent" or determine that the risk is "not unreasonable." EPA must discharge this obligation "within the 180-day period beginning on the date of the receipt of the information."

Background

The Fluorination Process. Fluorination is a process by which fluorine gas is applied to high-density polyethylene ("HDPE") and other plastic containers under high temperatures to impart barrier protection to these containers. Inhance, a Texas company, is the only provider of post-mold fluorination services to U.S. manufacturers, distributors, and users of plastic packaging. At eleven U.S. facilities, it fluorinates approximately 200 million containers and other items each year. Starting in late 2020, EPA obtained extensive evidence that several PFAS, including PFOA, are formed during the Inhance fluorination process and are present in both the walls of containers and their contents.

[5] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-orders-issued-inhance

The LCPFAC SNUR. On July 27, 2020, EPA issued a significant new use rule ("SNUR") under section 5(a) of TSCA for long-chain perfluoroalkyl carboxylates ("LCPFACs"). 85 Fed. Reg. 45109 (July 27, 2020). A particularly dangerous subset of PFAS, these substances include the highly toxic PFOA, which EPA has determined has no safe level of exposure and was phased out in 2015 after causing widespread environmental contamination and serious health impacts to exposed communities. 85 Fed. Reg. at 45113**;** 88 Fed. Reg. 18638 Shortly after the SNUR took effect, testing conducted by PEER and EPA showed the presence of PFOA and eight other LCPFACs in containers fluorinated by Inhance; these findings were subsequently confirmed in further studies by EPA, independent laboratories, and Inhance itself.

Submission of SNUNs. Once the SNUR took effect on September 24, 2020, TSCA required Inhance to cease production of the nine LCPFACs and submit SNUNs under section 5(a) of TSCA. However, it refused to cease fluorinating containers as the law required. On December 30, 2022, nine months after EPA had issued a notice of violation ("NOV") demanding that Inhance cease LCPFAC production, Inhance finally submitted SNUNs for the nine LCPFACs. 88 Fed. Reg. 10320 (Feb. 17, 2023). Even then, Inhance continued to unlawfully produce LCPFACs and is doing so today.

EPA's Section 5(e) and 5(f) Orders. Throughout 2023, EPA reviewed the Inhance SNUNs and additional information about the nine LCPFACs and assessed the risks to health from exposure to these PFAS during the processing, use, distribution in commerce, and disposal of fluorinated containers. The findings and conclusions of EPA's assessment were embodied in its December 1, 2023 orders and supporting risk assessment under TSCA sections 5(e) and 5(f). The orders prohibited the manufacture of the nine LCPFACs during fluorination and the processing, distribution in commerce, use, or disposal of fluorinated containers.

The first order applies to three LCPFACs – PFOA, perfluorononanoic acid (CASRN 375-95- 1) ("PFNA") and perfluorodecanoic acid (CAS RN 335-76-2) ("PFDA"). It determines under TSCA section 5(a)(3)(A) that their "manufacture, processing, distribution in commerce, use, and disposal . . . presents an unreasonable risk of injury to health or the environment." 5(f) order at 3. This determination obligated EPA to issue an order under section 5(f)(1) of TSCA, 15 U.S.C. § 2604(f)(1), which directs the Agency to prohibit or restrict SNUN substances presenting an unreasonable risk "to the extent necessary to protect against such risk." The order that EPA issued prohibited production of the three PFAS during fluorination and processing, distribution in commerce, use and disposal of fluorinated containers in which the PFAS were present.

The second order addressed the other six LCPFACs for which Inhance submitted SNUNs.[6] It determined under TSCA section 5(a)(3)(B)(ii)(I) that "in the absence of sufficient information to permit EPA to make a reasoned evaluation of the health and

[6] 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").

environmental effects of the" SNUN substances, they "may present an unreasonable risk of injury to health or the environment." 5(e) Order at 3. As a result of this determination, EPA was obligated to issue an order under section 5(e) of TSCA, 15 U.S.C. §2604(e), which requires restrictions on manufacture and other activities where substances "may present" an unreasonable risk but available information on the risk is insufficient. EPA's order requires Inhance to conduct testing on the six LCPFACs but directs that "manufacture of the SNUN Chemical Substances [may not] commence while testing is being conducted [b]ased on concerns for persistence, bioaccumulation, and hazards." *Id*. at 5.[7]

Rationale for the Orders. The comprehensive EPA risk assessment supporting the orders concludes that: "[b]ecause 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;" "the identified hazards of PFOA are so significant that there are no safe levels of exposure;" and extensive exposure and environmental release are the inevitable "result of leaching or migration of [LCPFACs] from fluorinated, plastic storage containers over time into" numerous consumer and industrial products. Thus, the orders conclude that EPA "cannot control potential exposures to the SNUN Chemical Substances through means other than a prohibition on the manufacture of these substances."

Fifth Circuit Decision Staying the EPA Orders. The EPA orders were set to become effective on February 28, 2023 but were stayed by the Fifth Circuit Court of Appeals on December 12, 2023 and then vacated in its March 21 decision.[8] As a result, the orders never took effect. In its decision, the Court concluded that EPA lacked authority to issue the orders because the Inhance fluorination process, which predated the SNUR and continued after it was promulgated, could not be deemed a "significant new use" within the meaning of TSCA.[9] The Court took as a given the presence of harmful LCPFACs in fluorinated containers and their contents. It also did not question the scientific justification for the orders and the seriousness of the health threat they sought to remedy. At no point did the decision suggest that EPA's risk findings could not be invoked to support action under other provisions of TSCA; indeed, the Court expressly recognized that EPA could restrict PFAS formation during fluorination under section 6.

Application of Section 4(f) to PFOA Formed during the Fluorination of Plastic Containers

To trigger section 4(f), EPA must have information that a chemical substance presents a "significant risk" of harm to human health that is "serious or widespread." This information need not be definitive or conclusive. Rather, if there "may be a reasonable basis to conclude"

[7] Because the second order is based on a "may present" finding and requires further testing of the six LCPFACs, it does not at this time trigger a 4(f) finding although the six LCPFACs add to the risk from exposure to PFOA, PFNA and PFDA because all nine LCPFACs co-occur in fluorinated containers.
[8] *Inhance Technologies, LLC v. US Environmental Protection Agency,* 96 F.4th 888 (5th Cir. 2024).
[9] The signatories to this notice believe that the Fifth Circuit's interpretation of TSCA was incorrect and the decision should be reconsidered.

that the substance meets the 4(f) risk threshold, that starts the clock for initiating action to address the risk.

In this case, as shown above, EPA had information meeting the section 4(f) risk threshold for PFOA in fluorinated containers at least as early as March 2023. The Agency understood the significance of this information, as reflected in its proposed drinking water standards for PFAS and its intensive assessment throughout 2023 of Inhance's December 2022 significant new use notices ("SNUNs"). EPA's determination of unreasonable risk in its December 1, 2023 orders and risk assessment confirmed that PFOA not only met the section 5(f) standard, but also the section 4(f) standard, as described below.

The Risks to Health of the LCPFACs Subject to the 5(f) Order are Serious and Significant. Following its review of relevant literature, EPA's risk assessment found that PFOA, PFNA and PFDA "are well studied PFAS that are known to be extremely toxic."[10] PFOA in particular has long been recognized as among the most harmful PFAS. As EPA has stated on numerous occasions, scientific evidence links PFOA to cancer, developmental harm, reproductive harm, immune system toxicity, liver toxicity, thyroid toxicity and kidney toxicity.[11] The International Agency for Research on Cancer ("IARC") has recently classified PFOA as "carcinogenic to humans."[12] In its recent drinking water standards for PFOA and five other PFAS, EPA also determined that PFOA is "Likely to be Carcinogenic to Humans based on sufficient evidence of carcinogenicity in humans and animals" and "concluded that there is no known threshold for carcinogenicity." For this reason, EPA finalized a Maximum Contaminant Level Goal ("MCLG") for PFOA in drinking water of zero, determining that there is no level of exposure at which "known or anticipated adverse effects on the health of persons" do not occur and allow for an adequate margin of safety.[13]

Indeed, over *twenty years ago*, on September 27, 2002, the then-Director of the Office of Pollution Prevention and Toxics wrote a memo stating that, "The reproductive/developmental toxicity data, the carcinogenicity data, and the blood monitoring data reviewed in the interim revised hazard assessment raise the possibility that PFOA might meet the criteria for action under section 4(f) of the Toxic Substances Control Act."[14] This concern was reiterated in a 2003 Federal Register Notice.[15] In the intervening 21 years, any uncertainties regarding the toxicity of PFOA have been resolved and, as EPA has confirmed in its proposed and final drinking water

---

[10] EPA Risk Assessment at 2; *see also id.* at 18–21.
[11] E.g., 88 Fed. Reg. 18638, 18,646–47, 18,656–63, 18,704. 18,718 (Mar. 29, 2023) (proposed drinking water standards for PFOA and five other PFAS).
[12] *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/.
[13] https://www.epa.gov/system/files/documents/2024-04/pfas-npdwr_prepubfederalregisternotice_4.8.24.pdf (final drinking water standards).
[14] https://static.ewg.org/files/226-1127.pdf
[15] https://www.federalregister.gov/documents/2003/04/16/03-9418/perfluorooctanoic-acid-pfoa-fluorinated-telomers-request-for-comment-solicitation-of-interested

standards, the evidence conclusively demonstrates multiple adverse effects at extremely low levels of exposure and no safe level of exposure for carcinogenicity.

Magnifying the seriousness of these toxic effects are the persistence and bioaccumulation of LCPFACs in general and PFOA in particular. Because of these characteristics, "[s]mall releases to the environment can have a significant long-term contribution to exposure and risk."[16] According to EPA's risk assessment, PFOA and other long-chain PFAS contain "multiple C-F bonds, which are extremely stable, and each is anticipated to be extremely persistent."[17] Accordingly, "long-chain PFAS, a class of chemicals with extensive data indicating they bioaccumulate in humans and fish tissue, all are expected to bioaccumulate."[18] For example, PFOA has been detected in human serum samples for 98 percent of the US population."[19]

Adding further to the risk, six other long-chain carboxylate PFAS are formed during fluorination that "may present an unreasonable risk" according to EPA's section 5(e) order, along with four short-chain PFAS that raise toxicity concerns.[20] Because they have common health effects, people who are exposed to multiple PFAS—like those who face exposures to the 13 PFAS co-produced during fluorination processes—face greater risks of harm from co-exposure than they would from exposure to any of these PFAS individually. As EPA has explained, "PFAS have dose additive impacts,"[21] and failing to account for the "growing body of evidence on the dose additive effects for mixtures of PFAS . . . will result in underestimating risk."[22]

The Risks to Health of LCPFACs Found in Fluorinated Containers are Widespread. With approximately 200 million fluorinated containers entering commerce each year, the risks to health presented by PFOA and other PFAS are also extremely widespread, extending across multiple sectors of the economy and impacting millions of workers and consumers.

It is well established, including from studies conducted by EPA as early as December 2020, that PFAS formed during the fluorination process leach from fluorinated plastic containers into the many different types of products stored in them.[23] As a result, exposure to PFOA and other

---

[16] Risk Assessment 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.").
[17] Risk Assessment at 30.
[18] *Id.*
[19] 88 Fed. Reg. at 18643.
[20] EPA 5(f) Order at 27.
[21] 88 Fed. Reg. at 18649–50.
[22] EPA Risk Assessment at 12.
[23] *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"

PFAS produced during fluorination can occur at all stages of the lifecycles of these containers, including production of PFAS during fluorination and processing, distribution, use, and disposal of fluorinated containers.

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;[24] PFAS releases to surface water;[25] and contaminated pesticide spray drift and runoff.[26] 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.[27] Users of products in fluorinated containers are exposed to PFAS by multiple exposure pathways when they handle those containers and their contents,[28] which may be any of a wide array of products, including fuel, pesticides, automotive products, and household cleaning products.[29] PFAS have been demonstrated to leach from fluorinated plastic containers to their contents, further exposing consumers, and the amount of PFAS that leach into the contents of the containers generally increases over time.[30] Human exposure can occur by inhalation, ingestion, or dermal contact.[31]

During the use of products packaged in fluorinated containers, PFAS can also be released to the environment, where they can contaminate soil, groundwater and surface water, exposing humans and aquatic organisms.[32] The disposal of those containers into landfills can further distribute

---

evidence "of the migration (leaching) of PFAS from container walls to the liquid solutions in the container"); EPA Risk Assessment at 10.

[24] EPA 5(f) Order at 32–36.

[25] *Id.* at 32–33, 35–36.

[26] *Id.* at 35.

[27] Risk Assessment at 23, 25–28.

[28] *Id.* at 24, 26, 28.

[29] EPA 5(f) Order at 5, 10, 37.

[30] 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).").

[31] EPA 5(f) Order at 32–36.

[32] 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 . . . .").

PFAS through landfill leachate.[33] 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."[34] Exposure can also occur when plastic containers are recycled at the ends of their useful lives or at end-of-life incineration.[35]

The breadth of these exposures is magnified by 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 reverse."[36] With 200 million fluorinated plastic containers produced each year and introduced into commerce, the release of the PFAS they contain can contaminate the environment and peoples' bodies for years to come. Plainly, the risk from exposure to PFOA and other PFAS produced during fluorination is *widespread* as well as *significant* and *serious.*

EPA's Obligation to Take Action under Section 4(f)

The findings and conclusions reflected in EPA's March 2023 drinking water proposal and assessment of the Inhance SNUNs throughout 2023 provided a "reasonable basis" to conclude that PFOA produced during fluorination met the section 4(f) risk threshold. Thus, EPA received information triggering the 180-day deadline to "initiate applicable action under section [5, 6 or 7]" at least by March 2023 and likely earlier. While the 5(f) order itself might have satisfied EPA's obligation to "initiate applicable action" under section 4(f), it was stayed by the Fifth Circuit Court of Appeals before it took effect. Thus, EPA's duty to take action in response to information triggering section 4(f) has not yet been discharged. To meet this obligation, EPA must initiate rulemaking under section 6 and file an imminent hazard action against Inhance under section 7 if it does not make its proposed rule immediately effective. These steps must be taken as soon as possible given that the 180 day period to take action established in section 4(f) expired in September 2023.

While we believe that all three PFAS subject to the 5(f) order met the 4(f) criteria, we urge EPA to focus its follow-up actions on PFOA as the one LCPFAC which has been determined to lack a threshold for carcinogenicity and have no safe level of exposure, and for which EPA had information supporting a 4(f) determination more than 180 days ago. A prohibition on PFOA formation during fluorination will prevent Inhance from producing other PFAS since PFOA is a

---

[33] *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 . . .).").

[34] Risk Assessment at 17.

[35] EPA 5(f) Order at 32–34.

[36] 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.

necessary byproduct of the chemical reactions that occur when HDPE plastic is treated with fluorine. If limited to PFOA, EPA's response to its 4(f) designation will be more efficient and expeditious while providing full protection against the risks of multiple PFAS formed during fluorination, including PFNA and PFDA.[37]

Under section 4(f), the action that EPA must take within 180-days is required to "prevent or reduce [the risk] to a sufficient extent" – i.e. to undertake risk management. This comports with the policy goal of section 4(f): assuring that EPA affords immediate protection of public health for chemicals documented to present unusually serious or widespread risks. Accordingly, EPA could not satisfy its obligation to "initiate applicable action" under section 6 by merely commencing a risk evaluation under section 6(b) but would need to initiate a rulemaking to reduce or eliminate the risk under section 6(a).

In prior 4(f) situations, EPA has initiated action under section 6(a) by publishing advance notices of proposed rulemaking ("ANPRs") seeking comment on how the Agency should follow-up on its 4(f) determination. In this instance, however, the extensive information collection and analysis EPA has already conducted under SDWA and section 5 of TSCA define the nature, severity and extent of the risk presented by PFOA formed during fluorination. Thus, an ANPR is unnecessary and would only delay measures to address a serious and urgent threat that is already well-understood.

Similarly, there is no need for further work to determine the risk management measures necessary to eliminate the unreasonable risk; EPA has already found that it can only be effectively addressed by prohibiting fluorination that produces PFAS. Thus, EPA should meet the180-day deadline under section 4(f) by proposing a section 6(a) rule that, like its section 5(f) order, prohibits the manufacture of PFOA during fluorination and the processing, distribution in commerce, use, or disposal of fluorinated containers in which this PFAS is present. As discussed in our section 21 petition, EPA should use its authority under TSCA section 6(d) to make the proposed rule immediately effective on publication so that the serious and widespread risks created by PFAS formation during fluorination do not continue for the duration of the rulemaking process.

Section 7 Imminent Hazard Authority

If EPA does not declare its proposed rule immediately effective, it must file an action in district court against Inhance using the imminent hazard authority of section 7. Section 7(f) defines an "imminently hazardous chemical substance or mixture" as --

> "a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other nonrisk factors. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use,

[37] However, we would also support an EPA choice to propose a section 6(a) rule for all three PFAS, as requested in the April 11, 2024 section 21 petition.

> or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk."

The information that triggered section 4(f) and EPA's section 5(f) order demonstrates that the production of PFOA during fluorination "presents an imminent and unreasonable risk of serious or widespread injury to health . . ., without consideration of costs or other nonrisk factors" and "the risk is likely to result in such injury to health or the environment before a final rule" is promulgated. Section 7(a)(2) directs that, where "the Administrator has not made a [section 6(a)] rule . . . immediately effective . . . with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence" an imminent hazard action in district court. EPA must perform this non-discretionary duty if its proposed section 6(a) rule is not made immediately effective.

Citizen and Legal Counsel Giving Notice

The citizens giving notice are:

Center for Environmental Health
2201 Broadway, Suite 508
Oakland, CA 94612
510-655-3900

Public Employees for Environmental Responsibility
762 Wayne Avenue, Suite 610
Silver Spring, MD 20910
202-265-7337

CEH is represented by:

Robert M. Sussman
Sussman and Associates
3101 Garfield St, NW
Washington DC 20008
bobsussman1@comcast.net
202-716-0118

PEER is represented by:

Paula Dinerstein
General Counsel
Laura Dumais
Staff Counsel
Colleen Teubner
Staff Litigation and Policy Attorney
Public Employees for Environmental Responsibility

762 Wayne Avenue, Suite 610
Silver Spring, MD 20910
202-265-7337
pdinerstein@peer.org ldumais@peer.org
cteubner@peer.org

Please contact Mr. Sussman directly with your response to this notice.

Conclusion

PFOA and other PFAS produced during the fluorination of plastic containers raise serious health and environmental concerns because of their persistence, mobility, accumulation in people and the bio-sphere, and serious toxicity. Fluorinated plastic containers are also widely distributed in commerce and come into contact with large numbers of workers and consumers, resulting in extensive exposure and release. EPA received information that the presence of PFOA in these containers poses a significant risk of serious and widespread harm to human health by March 29, 2023, if not earlier. Therefore, it was obligated under section 4(f) of TSCA to initiate action under sections 5, 6 or 7 to address this risk within 180 days – or by no later than September 25, 2023**.** EPA has not yet discharged this non-discretionary duty. By this notice, we therefore request that EPA take action as soon as possible under TSCA sections 6 and/or 7 requiring that Inhance immediately cease all PFOA production during fluorination of plastic containers. We would be pleased to consult with EPA about the steps that must be taken in accordance with TSCA.

Sincerely yours,

Timothy Whitehouse
Executive Director, PEER

Kizzy Charles-Guzman
CEO, CEH

cc: Dr. Michal Freedhoff
Dr. Elissa Reaves
Mark Hartman