UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-60620

Inhance Technologies, L.L.C.,
Petitioner,

versus

United States Environmental Protection Agency; Michael S. Regan, *Administrator, United States Environmental Protection Agency*,
Respondents.

Petition for Review from an Order of the Environmental Protection Agency

Agency No. SN-23-0002

Agency No. SN-23-0004 Agency No. SN-23-0005 Agency No. SN-23-0003
Agency No. SN-23-0006 Agency No. SN-23-0008 Agency No. SN-23-0009
Agency No. SN-23-0010 Agency No. SN-23-0011

BRIEF OF *AMICI CURIAE* CENTER FOR ENVIRONMENTAL HEALTH, PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY, AND JAY DE LA ROSA IN SUPPORT OF RESPONDENT UNITED STATES EPA

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.1.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Federal Register

INTERESTS OF *AMICI CURIAE*

Amici Center for Environmental Health (CEH) and Public Employees for Environmental Responsibility (PEER) are non-profit organizations whose purposes include protecting the public from harmful per- and polyfluoroalkyl substances (PFAS). Amicus Jay De La Rosa, a Los Angeles furniture maker and do-it-yourself car mechanic, is concerned about his ongoing exposure to PFAS from plastic containers that he uses on a daily basis.

Amici have strongly advocated protecting consumers and workers from the dangers of PFAS-contaminated plastic containers fluorinated by petitioner Inhance Technologies. They contend that the Environmental Protection Agency (EPA) orders challenged by Inhance are essential to protect public health from this dire threat and that an unfavorable decision by this Court would seriously compromise safeguards against unsafe exposure to PFAS, an overriding concern of the federal government, states, and communities across the United States. Amici are also concerned that acceptance of Inhance's arguments would have far-reaching and unintended consequences for EPA's overall ability to address chemical risks under the Toxic Substances Control Act (TSCA).

Amici state that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person – other than the amicus curiae, its members, or

its counsel – contributed money that was intended to fund preparing or submitting the brief.

INTRODUCTION AND SUMMARY

EPA's PFAS Roadmap recognizes that PFAS "are an urgent public health and environmental issue facing communities across the United States." AR0021239. Due to their strong carbon-fluorine bonds, many PFAS can be very persistent in the environment and the human body and can take a decade to clear from the body. Doc. 57-1 at 8-9. PFAS are often called "forever chemicals" and accumulate in the tissues and blood of many species, including people. 88 Fed. Reg. 18638, 18642 (Mar. 29, 2023).

PFAS have been detected in the blood of 98 percent of the general U.S. population. 88 Fed. Reg. 18643. They are linked to "cancer and effects on the liver (*e.g.,* liver cell death), growth and development (*e.g.,* low birth weight), hormone levels, kidney, immune system, lipid levels (*e.g.,* high cholesterol), the nervous system, and reproduction." *Id.*

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 perfluorooctanoic acid (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. *Id.* 4511; 88 Fed. Reg. 18639; Doc. 57-1 at 8.

Inhance's fluorination process forms nine LCPFACs subject to the SNUR. Thus, once the SNUR took effect on September 24, 2020, TSCA required Inhance to cease production and submit significant new use notices (SNUNs). However, it chose to continue fluorinating containers in violation of TSCA's express prohibition on manufacturing SNUR substances without meeting the statutory requirements. On December 30, 2022, nine months after EPA had issued a notice of violation (NOV) demanding that Inhance cease LCPFAC production, it finally submitted SNUNs for the nine LCPFACs. 88 Fed. Reg. 10320 (Feb. 17, 2023). Even then, Inhance continued to unlawfully produce LCPFACs. Since Inhance fluorinates approximately 120-200 million containers per year, the PFAS it produces are found in nearly every sector of the economy.

EPA's December 1, 2023 orders prohibit Inhance from manufacturing, processing, distributing in commerce, using, or disposing of the nine LCPFACs. AR0020577, AR0020629; Docs. 57-1 and 57-2. EPA's decision to impose these restrictions was based on a comprehensive risk assessment concluding 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" tens of millions of consumer and industrial products. AR001389; Doc. 57-1 at 8-10. The orders thus conclude that that EPA "cannot control potential exposures to the SNUN Chemical Substances through means other than a prohibition on the manufacture of these substances." *Id.* at 11.

Inhance's challenge to the orders is really an attack on the 2020 SNUR and is time-barred because Inhance did not meet the 60-day statutory deadline for seeking judicial review. On the merits, Inhance's arguments must be rejected because they depart from the plain language of TSCA and EPA regulations. Inhance's attack on the orders also misrepresents EPA's risk assessment and ignores the compelling scientific justification for concluding that only a ban on producing LCPFACs during fluorination can protect the millions of citizens exposed to these dangerous substances.

ARGUMENT

I. APPLICATION OF THE SNUR TO INHANCE'S FLUORINATION PROCESS CANNOT BE CHALLENGED IN THIS APPEAL AND IN ANY EVENT COMPLIES WITH TSCA

Inhance claims that the EPA orders are unlawful because EPA lacked authority under section 5(a) of TSCA to apply SNUR requirements to uses of chemicals that are not "new." However, the orders do not define the scope of EPA's SNUR authority but merely implement the review process EPA must follow upon receiving SNUNs under TSCA Section 5(a)(1)(B)(i). It is the SNUR that defines when LCPFAC production comprises a "significant new use" and obligates companies to submit SNUNs.

Thus, Inhance's quarrel is not with the orders but with the SNUR. The remedy it seeks – a decision rejecting EPA's authority to treat fluorination as a significant new use – can only be imposed if the Court declares the SNUR invalid.

Inhance faces two insurmountable obstacles in challenging the SNUR. First, the 60-day deadline for seeking judicial review of the SNUR under section 19(a)(1)(A) of TSCA has long since passed, even if it might have been tolled for a brief period. Second, TSCA provides authority to treat preexisting uses as "new" where, as here, industry did not bring these uses to the Agency's attention during the SNUR rulemaking and it had no basis for exempting them from the SNUR.

A. The SNUR Defines All Non-Exempt Uses of LCPFACs as Significant New Uses

The scope of the SNUR is defined in 40 C.F.R. § 721.10536. Subsection (b) identifies "the chemical substances and significant new uses subject to reporting." Paragraphs (b)(1)-(3) describe the defining characteristics of substances which fall within the LCPFAC class. Paragraph (b)(4) then defines the activities which constitute "significant new uses" of these LCPFACs. Most relevant here, subparagraph (b)(4)(ii) states that "[m]anufacture (including import) or processing *for any use after December 31, 2015*" is a "significant new use" (emphasis added).

The only exceptions to this expansive definition are thirteen specific uses of LCPFACs listed in paragraph (b)(5), which "shall not be considered as a significant new use subject to reporting under this section." The preamble to the final rule explains that "[s]everal commenters claimed ongoing uses [of LCPFACs]" and "requested that EPA modify the proposed SNUR to [exempt] ... ongoing activities that do not appear to have been previously identified by the Agency." 85 Fed. Reg. 45118. In the final rule, EPA "recognized and excluded from the definition of 'significant new use'" ongoing use activities that it or these commenters had substantiated. *Id.*

Manufacture of LCPFACs during the fluorination of plastic containers is *not* among these excluded activities because no commenter had brought it to EPA's attention and the Agency had not identified and confirmed the use on its own.

Thus, under the plain language of subparagraph (b)(4)(ii), the Inhance fluorination process is a "significant new use."

Both the initial 2015 SNUR proposal (80 Fed. Reg. 2885, 2894 (Jan. 21, 2015)) and March 3, 2020 re-proposal (85 Fed. Reg. 12479, 12481) urged industry to identify uses of LCPFACs underway before January 21, 2015 so they could be exempted from the SNUR. The preamble to the final rule made clear that ongoing uses that "were unable to be substantiated" would not be "recognized and excluded from the definition of 'significant new uses.'" 85 Fed. Reg. at 45118. Moreover, the Agency twice sought public comment on whether to "include a safe harbor provision for [firms] that can demonstrate their use was ongoing prior to the effective date of this rule" but did not "realize the subject chemical substance was in [their] product[s]." 85 Fed. Reg. 45120. Rejecting this option, the preamble pointed to EPA's extensive efforts to notify industry of the SNUR in 2015 and 2020 and expressed concern that a safe harbor would encourage firms to ignore EPA's rulemaking and retroactively claim exemptions from the SNUR. *Id*.

In short, while EPA granted exemptions for ongoing uses that were documented, the final SNUR defines all unknown uses as "significant new uses." Thus, the designation of Inhance's process as a "new use" that Inhance contests stems from the SNUR itself and not the challenged orders.

B. Inhance's Challenge to the SNUR is Time-barred under TSCA's Judicial Review Provisions

Under section 19(a)(1)(A) of TSCA, petitions for review of a SNUR must be filed in a court of appeals "not later than 60 days after the date on which [the] rule is promulgated under this subchapter." The LCPFAC SNUR was published in the Federal Register on July 27, 2020 and, under 40 C.F.R. § 23.5, "promulgated" for judicial review purposes two weeks later on August 10, 2020. A petition for review was therefore required by October 9, 2020, more than three years ago.

Judicial review deadlines in EPA-administered laws have been determined to be "jurisdictional, and may not be enlarged or altered by the courts." *Edison Elec. Inst. v. EPA*, 996 F.2d 326, 331 (D.C. Cir. 1993). According to this Court, "[s]tatutory time limits on petitions for review of agency actions are jurisdictional in nature such that if the challenge is brought after the statutory time limit, we are powerless to review the agency's action ...." *Texas Municipal Power Agency v. EPA*, 836 F.2d 1482, 1484 (5th Cir. 1988) (quoting *Texas Municipal Power Agency v. EPA*, 799 F.2d 173, 174 (5th Cir. 1986)).

C. Inhance Has Not Met the Stringent Criteria For Tolling TSCA's Judicial Review Deadline

Even if TSCA's judicial review provisions were not jurisdictional, equitable tolling of their deadlines would be warranted only when, "due to circumstances external to the party's own conduct, it would be unconscionable to enforce the

limitation period against the party and gross injustice would result." *Robinson v. Dep't of Homeland Sec.*, 71 F.4th 51, 58 (D.C. Cir. 2023) (quotation omitted). Thus, the Supreme Court has held that a party seeking equitable tolling must satisfy two elements: (1) it has been pursuing its rights diligently; and (2) some extraordinary circumstance stood in its way. *Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005).

Inhance has insisted that, when the SNUR was promulgated, it "had no idea ... that its fluorination process produced PFAS." Br. at 33. But even if this is true, Inhance's ignorance begs the question of whether a reasonably diligent company in its position *should have known* of the formation of PFAS during fluorination. A 2011 scientific publication by Rand and Mabury of the University of Toronto reported testing fluorinated and unfluorinated containers and finding that concentrations of PFAS were significantly higher in fluorinated containers. The source of the fluorinated containers used in this study was Fluoro-Seal, which was renamed Inhance in 2013. AR0021328 As the source of the tested containers and the only US practitioner of in-mold fluorination, Inhance knew or should have known of the Rand and Mabury findings. At the very least, once EPA proposed the SNUR in 2015, these findings should have prompted it to conduct further testing to confirm or disprove the formation of PFAS during fluorination.

It is unlikely that any technically savvy company whose dominant business was based on fluorine chemistry would have been ignorant of the highly publicized PFAS issue during the SNUR rulemaking. Starting in March 2000, companies like 3M made high-profile announcements that they were stopping manufacture of PFOA and other long-chain PFAS.[1] In response, EPA initiated a voluntary stewardship program in 2006 for long-chain PFAS, leading to their phaseout by major producers in 2015. 80 Fed. Reg. 2890.

Inhance not only knew about the dangers of PFAS but tried to profit from them. In 2019, it filed a patent application for a fluorination-based process to remove PFOA from fluoropolymer particles.[2] The application discussed at length the chemistry of PFAS and described PFOA's health effects as including "kidney cancer, testicular cancer, ulcerative colitis, thyroid disease, and hypertension."

Inhance's sophisticated understanding of the chemistry of fluorination and the harmful properties of PFAS makes it hard to believe that it did not know that the reaction between the carboxylic acids in HDPE plastic and free fluorine would

[1] EPA and 3M Announce Phase Out of PFOS, Https://Www.Epa.Gov/Archive/Epapages/Newsroom_Archive/newsreleases/33aa946e6cb11f35852568e1005246b4.html.

[2] US11014999B2 - SYSTEMS AND METHODS FOR PROCESSING FLUOROPOLYMER MATERIALS AND RELATED WORKPIECES - GOOGLE PATENTS

create PFAS and trigger application of the proposed SNUR. If Inhance was really ignorant about its formation of PFAS, that only demonstrates its egregious lack of diligence and disqualifies it from the extraordinary remedy of tolling the judicial review deadline for the SNUR.

In any case, Inhance's claimed ignorance was short-lived. In early September 2020, EPA became aware of testing performed for PEER showing the presence of PFAS in the Anvil 10+10® mosquito control pesticide packaged in containers fluorinated by Inhance. EPA received unused fluorinated containers from the distributor of Anvil 10+10® and, through its own testing, detected several PFAS subject to the SNUR. On January 14, 2021, two months after the judicial review deadline for the SNUR, EPA issued a lengthy press release recounting these events and announcing EPA testing "that shows PFAS contamination from fluorinated containers."[3] On the same day, EPA issued a subpoena under TSCA seeking information concerning Inhance's fluorination processes. Doc. 6-6.

These developments plainly alerted Inhance that its fluorination process produced PFAS subject to the SNUR. They should have spurred it to examine whether the SNUR exceeded EPA's authority under TSCA and to petition for judicial review of the SNUR. However, Inhance did nothing.

[3] https://www.epa.gov/newsreleases/epa-takes-action-investigate-pfas-contamination.

The Agency's March 1, 2022 NOV confirmed that EPA had "determined" that Inhance's fluorination process created long-chain PFAS and was a "significant new use under the LCPFAC SNUR." Doc. 6-7 at 1. In an open letter to industry on March 16, 2022, EPA reiterated that "long-chain PFAS as defined in EPA's 2020 [SNUR] ... that are found to be present in or on fluorinated polyolefins ... [are] a significant new use under TSCA." AR0012883. But again Inhance did not challenge the SNUR.

In sum, Inhance's claim that EPA exceeded its authority under TSCA by treating fluorination as a new use is barred as an untimely challenge to the SNUR.

D. If Properly Before the Court, Inhance's Claim that Fluorination was not a "New Use" is Without Merit

For its "new use" argument, Inhance relies on dictionary definitions of "new" to mean "having recently come into existence" and "not previously existing." Br. at 21. However, the Supreme Court has cautioned that "[w]hether a statutory term is unambiguous ... does not turn solely on dictionary definitions of its component words." *Yates v. United States*, 574 U.S. 528, 537-38 (2015). Rather, the meaning of statutory language must be determined by "the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson* v. *Shell Oil Co.*, 519 U.S. 337, 341 (1997).

TSCA does not define "new use." Nor does it state that a use that existed before a SNUR was proposed can never be "new." Instead, Congress left these

questions of interpretation to EPA. Thus, section 5(a)(1)(A)(ii) prohibits manufacture or processing of a substance for a "use *which the Administrator has determined* ... is a significant new use" (emphasis added). Under section 5(a)(2), the Administrator shall make this "determination" in a rulemaking "after a consideration of *all relevant factors*" (emphasis added). Thus, Congress looked to EPA to weigh the practical and policy considerations bearing on the scope of its SNUR authority.

In general, EPA has recognized that uses that are ongoing when a SNUR is proposed are not "new" and "would be free to continue without submitting a SNUN." 80 Fed. Reg. at 2887. However, applying this broad principle in practice has posed challenges. For example, EPA has issued numerous SNURs for discontinued uses of chemicals even though these uses had existed for many years and could not be considered "new" in a literal sense. E.g. 77 Fed. Reg. 19862 (April 2, 2012) (Polybrominated Diphenylethers). Similarly, exempting existing uses from SNURs has been hampered by the practical difficulty of identifying all such uses during the rulemaking process. Thus, in the absence of knowing what other ongoing uses might exist, EPA's practice has been to treat all unidentified uses of SNUR substances as "significant new uses." E.g. 84 Fed. Reg. 17345 (April 25, 2019) (asbestos).

Inhance has offered no feasible alternative that would enable EPA to grandfather all unidentified uses yet define the scope of SNUR requirements with precision and clarity. As noted above, during the LCPFAC rulemaking, EPA considered the option of creating a "safe harbor" mechanism for retroactively exempting ongoing uses first identified after the SNUR took effect. However, the Agency rejected this option because it would "provide incentives for importers to not submit comments to EPA during the public comment period regarding ongoing uses" and later "use the safe harbor to challenge the rule." 85 Fed. Reg. 45120-21. Thus, EPA put the burden on manufacturers to identify ongoing uses during the SNUR rulemaking and required compliance with the SNUR for uses that had not been identified. This choice was plainly within EPA's authority under TSCA.

II. INHANCE'S CLAIM IT LACKED "FAIR NOTICE" IS BOTH TIME-BARRED AND UNPERSUASIVE

A. Inhance's Fair Notice Claim Should be Rejected as an Untimely and Inapplicable Challenge to the SNUR

Inhance claims it lacked "fair notice" because EPA failed to identify the fluorination process when proposing and finalizing the LCPFAC SNUR: "[a]t no point during its lengthy rulemaking process did EPA ever identify the fluorination industry as potentially impacted by the rule." Br. at 31.

These are not claimed deficiencies of EPA's orders but of the SNUR, and should have been raised in a timely challenge to the SNUR under TSCA section

19(a)(1). Even if Inhance was correct that EPA should have identified its fluorination process in the SNUR, any lack of notice was remedied two months later when, as discussed above, EPA released test data identifying PFAS in containers fluorinated by Inhance and issued a subpoena under TSCA. Inhance should have then filed a petition for review of the SNUR and sought to toll the 60-day filing deadline during the two months before LCPFACs were detected in fluorinated containers. Having failed to do so, Inhance's fair notice claims are time-barred.

Moreover, the fair notice doctrine provides that "[a]conviction or punishment fails to comply with due process if the statute or regulation under which it is obtained fails to provide a person of ordinary intelligence fair notice of what is prohibited …" *FCC v. Fox TV Stations, Inc.*, 567 U.S. 239, 253 (2012) (internal quotation marks and citations omitted). Here, Inhance has not been subject to any sanction or punishment for violating the SNUR stemming from lack of notice of what it covered. In fact, it filed SNUNs after EPA reiterated that fluorination was a covered new use.

Instead, Inhance apparently claims that if the proposed SNUR had explicitly covered fluorination, it would have notified EPA that it was an ongoing use and would not have needed to file SNUNs, and therefore would not have been subject to the challenged orders (which, in any event are not sanctions for violating the

SNUR). This speculative and attenuated causal chain does not rise to the constitutional due process violation to which the fair notice doctrine applies.

B. Application of the SNUR to Fluorination Could Have Been Determined with Ascertainable Certainty from the Text of the Rule Itself

Inhance's claims fare no better on the merits. The premise of these claims is that a complex rule that applies to hundreds of discrete substances must identify all potential uses of these chemicals so that the regulated community is on notice of each specific use subject to the rule. This would have been a monumental task for LCPFACs, which include several well-established chemicals that had numerous uses before they were voluntarily phased out by their producers. There's no reason why EPA – an agency that works on hundreds of rules, orders, and permits– should alone undertake this laborious process while companies with deep knowledge of their technology sit on their hands.

This Circuit has held that, when addressing fair notice claims, the "relevant inquiry is whether the agency's interpretation of [its] regulations could have been understood with 'ascertainable certainty'" from the regulations themselves. *ExxonMobil Pipeline Co. v. U.S. Dep't of Transp.*, 867 F.3d 564, 578-79 (5th Cir. 2017). In the widely-cited formulation of the DC Circuit:

> [The test is] whether the regulated party received, or should have received, notice of the agency's interpretation in the most obvious way of all: by reading the regulations. If, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with "ascertainable certainty," the standards with which the agency

> expects parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation.

General Elec. Co. v. EPA, 53 F.3d 1324, 1329 (D.C. Cir. 1995). A regulated party is not "entitled, as a matter of due process, to personal notice of all existing regulatory requirements that might affect its application; rather, the burden was upon [the party] to read and to comply with the agency's published regulations." *Lakeshore Broadcasting, Inc. v. FCC*, 199 F.3d 468, 475 (D.C. Cir. 1999).

Thus, EPA had no responsibility to call attention to fluorination when a knowledgeable reader could have determined with "ascertainable certainty" that it was within the universe of activities to which the SNUR applied. Moreover, Inhance cannot claim that it carefully analyzed the SNUR and honestly concluded that it did not apply to fluorination. There is no evidence that it even knew of the SNUR. Moreover, had it been aware of the SNUR, Inhance would have undoubtedly ignored it, since it says it had no idea that fluorination formed LCPFACs during EPA's rulemaking. In short, Inhance's claimed lack of notice of the SNUR's application to fluorination had no cause other than its own ignorance and lack of diligence.

III. THE LCPFACs FORMED DURING FLUORINATION ARE BYPRODUCTS SUBJECT TO THE SNUR

Under the plain meaning of EPA regulations, the LCPFACs are "byproducts," not exempt "impurities." EPA guidance confirms that the LCPFACs are covered byproducts and this authoritative interpretation of its regulations should receive deference under *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019).

A. Byproducts as Defined in EPA Regulations Are Subject to SNURs and Do Not Fall within the Impurity Exemption

EPA's 1988 Part 721 regulations establish the basic framework for the SNUR process. 40 CFR § 721.5(a)(1) requires notification by any "person who intends to manufacture or process for commercial purposes a chemical substance" subject to a SNUR and "to engage in a significant new use." Byproducts are subject to SNUR notification requirements under 40 C.F.R. § 721.45(e) except where burned as a fuel, disposed of as a waste or used to extract component chemical substances for commercial purposes. 40 CFR § 720.3(d) defines "byproducts" as chemicals "produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture."

EPA defines an "impurity" as "a chemical substance which is unintentionally present with another chemical substance." 40 C.F.R. § 720.3(m). Impurities are exempt from SNURs under 40 C.F.R. § 721.45(d). However, 40

C.F.R. § 721.45(d) limits this exemption to "a person [who] manufactures or processes the substance *only as an impurity"* (emphasis added). Thus, a substance that is "unintentionally present" with another substance but is also "produced coincidentally during a chemical reaction to form" another chemical is a "byproduct" subject to the SNUR.

B. LCPFACs Formed During Fluorination Meet the Definition of Byproduct under EPA Regulations

As described in the Inhance SNUNs, fluorination is a chemical process in which molded High Density Polyethylene (HDPE) is exposed to fluorine gas (F2). AR0010890 Two chemical reactions occur during this process. First, "[t]he HDPE reacts with the fluorine to form a layer of fluoropolymer, which acts as the barrier needed to prevent permeation of [the container contents]." At the same time, "the carboxylic acids [present in the HDPE] react with the fluorine to form LCPFACs." This makes the LCPFACs "byproducts" as defined in 40 C.F.R. § 720.3(d) since they are "produced without a separate commercial intent during the manufacture. . . of another chemical substance or mixture." Because the LCPFACs produced during fluorination do not fall within the narrow "byproduct" exemption in 40 C.F.R. § 721.45(e),[4] they are subject to the LCPFAC SNUR.

[4] Oddly, Inhance argues that the difference between byproducts and impurities is "whether the chemical substance remains 'present with'—or is instead separated from—the intended end product." Br. at 26. But there is no language in the

And since the LCPFACs are not "only" impurities, the impurity exemption does not apply.

C. EPA Has Reasonably Interpreted Its Regulations to Define LCPFACs Formed During Fluorination as Byproducts and Not Impurities

Even if EPA's regulations did not speak for themselves, the Court should defer to EPA guidance interpreting these regulations.

1. *EPA Guidance Consistently Treats LCPFACs Formed During Fluorination as Byproducts and not Impurities*

In its March 1, 2022 NOV, EPA "determined that regulated LCPFAC substances are produced as a byproduct during the fluorination process and do not have a separate commercial intent" and are therefore subject to the SNUR. EPA explained that it did not consider the LCPFACs exempt impurities because

> An impurity is a substance that is introduced unintentionally as part of one of the raw materials used as an input to a process that remains unreacted. The information you submitted indicates that the LCPFAC substances detected in the fluorinated containers were manufactured during the fluorination process. *Because the LCPFAC substances were manufactured during the fluorination process rather than present as an input to the fluorination process, the LCPFAC substances are not impurities under 40 C.F.R. Part 721.*

Doc.6-7 at 3 (emphasis added, footnotes omitted).

Two weeks later, EPA issued an "open letter" to industry reiterating that "the LCPFACs formed during fluorination process" would be subject to the

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definition of byproduct that requires it to be separated from the substance with which it was produced.

SNUR as "byproducts of the manufacturing process [that were] produced during the manufacture of the fluorinated polyolefins and do not have a separate commercial intent." AR0012883

The NOV referenced longstanding EPA guidance for its 2011 Chemical Data Reporting (CDR) rule.[5] As the guidance explained, "chemical substances that are produced as byproducts during the manufacture, processing, use, or disposal of another chemical substance or mixture, like any other manufactured chemical substance, are subject to CDR reporting . . ." By contrast, the impurity definition would only apply to "a substance that was introduced as an impurity *as part of one of the raw materials used as an input to the process"* (emphasis added). Here, the LCPFACs were not preexisting components of the plastic or fluorine raw materials for fluorination but were formed during fluorination itself.

2. *EPA's Interpretation of its Regulations Meets the Kisor Criteria for Deference*

Kisor reaffirms that courts should defer to agency interpretations of regulations where they "reflect an agency's authoritative, expertise-based, 'fair[, or] considered judgment.'" 139 S. Ct. at 2414. Here, EPA met these criteria.

[5] https://www.epa.gov/sites/default/files/2020-11/documents/cdr_frequent_questions_final_11.2.2020_updated_submission_period_closure_clean.pdf.

United States v. Vargas, 74 F.4th 673, 690-97 (5th Cir. 2023) (en banc) (applying *Kisor* test for deference).

First, EPA's interpretation of its definition of "byproduct' and "impurity" is "reasonable" in light of the "text, structure [and] history" of TSCA and the applicable regulations. *Kisor,* 139 S. Ct. at 2416. Second, since notices of violation, guidance letters to industry, and question-and-answer documents are all well-established tools for explaining the meaning of regulations, EPA's interpretation is "authoritative," i.e. "emanate[d] from those actors, using those vehicles, understood to make authoritative policy in the relevant context." *Id.* Third, because it addressed the nuances of chemical manufacturing under a specialized regulatory scheme, EPA's interpretation drew on its "[a]dministrative knowledge and experience" and "implicate[d] its substantive expertise." *Id.* at 2417. And finally, because its rationale was fully explained and drew on long-standing agency guidance, EPA's interpretation reflected "fair and considered judgment" and was not a "convenient litigating position" or "*post hoc* rationalization." *Id*.

The Court should thus defer to EPA's conclusion that the LCPFACs formed during fluorination are "byproducts" subject to the SNUR even if it concludes that EPA's regulations do not unambiguously compel that conclusion.

IV. EPA WAS NOT REQUIRED TO RESTATE ITS LEGAL POSITION IN THE ORDERS

Inhance claims the EPA orders were arbitrary and capricious because they "failed to consider and address Inhance's argument that its fluorination process is not subject to its SNUR." Br. at 37-39. As explained above, the proper forum for this argument was a timely challenge to the SNUR, not a challenge to the orders.

In any case, EPA's positions on these issues were clearly and repeatedly communicated to Inhance. For example, the SNUR specified that *any* LCPFAC use that was not explicitly exempted in the rule was a significant new use. By defining the universe of LCPFACs subject to the rule, the SNUR also provided fair notice to Inhance. Similarly, the plain language of EPA's SNUR regulations demonstrated that LCPFACs formed during fluorination were byproducts covered by the SNUR. Inhance could have challenged the SNUR at least by early 2021 when EPA issued a press release about the discovery of PFAS in Inhance's containers, and EPA's byproduct interpretation by mid-2022 when EPA issued the NOV and the open letter to industry, but failed to do so.

Accordingly, it would have been redundant and meaningless for EPA to restate its legal positions in the orders. Moreover, TSCA nowhere requires EPA to address its authority when reviewing SNUNs and issuing orders. As prescribed by section 5(a)(1)(B)(ii), EPA's responsibilities are solely to review the SNUN, make determinations of unreasonable risk under section 5(a)(3), and issue the

orders associated with these determinations under sections 5(e) and 5(f). EPA plainly met these responsibilities. TSCA did not require EPA to go further and explain why the SNUNs and orders were authorized by the applicable SNUR given that these issues could have been settled in a timely legal challenge to the SNUR itself.[6] Accordingly, EPA's failure to reiterate its legal position in the orders was not arbitrary and capricious.

V. INHANCE'S CHALLENGES TO THE SCIENTIFIC BASIS FOR PROHIBITING LCPFAC PRODUCTION ARE UNTENABLE

A. EPA's Prohibition of LCPFAC Formation During Fluorination Did Not Constitute Differential Treatment of Similar Entities and Was Supported by the Record

The level of risk EPA identifies during its SNUN review determines whether it takes regulatory action and what restrictions are "necessary to protect against such risk" under sections 5(e) and 5(f). Reflecting the wide range of concerns presented by chemicals, section 5(a)(3) of TSCA allows EPA to choose among a range of risk determinations, including a conclusion that a chemical is "unlikely to present an unreasonable risk" and a determination that it "may present" or does "present" an unreasonable risk. Where EPA makes a finding of

[6] Tellingly, while preserving Inhance's legal position, the SNUNs did not seek a determination by EPA that their submission was unwarranted under TSCA and they should be withdrawn. Plainly, Inhance *wanted* EPA to review the SNUNs because it expected EPA to exonerate its fluorination process.

"unreasonable risk," section 5(f)(2) authorizes it to impose a "requirement prohibiting the manufacture ... of such substance for a particular use." [7] EPA's determination to do so here was not unprecedented. EPA has prohibited commercialization of new or SNUN substances 13 times since 2016.[8] Since EPA has received only 145 SNUNs since enactment of TSCA in 1976, such prohibitions hardly represent a "once in a blue moon step," as Inhance asserts.

Inhance cannot point to a single PFAS that EPA allowed to be produced for SNUN-proposed uses. Thus, Inhance has not identified a "similarly situated" PFAS that it was "treated differently" from.

Equally important, EPA's assessment and orders demonstrate the uniquely harmful aspects of the LCPFACs formed during fluorination and explain why any remedy short of a ban on manufacture would not protect the public:

> [E]xposures will occur and be widespread due to the extremely large number of containers that lnhance fluorinates annually (i.e., approximately 121 million containers . . . in 2021).
>
> Such exposures, due to the persistent, bioaccumulative and toxic (PBT) nature of the nine SNUN substances, will contribute to the burden of PFAS that currently exist in people and the environment and will continue to accumulate over time.
>
> Because all nine SNUN substances are long-chain PFAS, a class of chemicals with extensive data indicating they bioaccumulate in humans and

[7] Section 5(f))(2) incorporates the remedies provided in section 6(a)(2) of TSCA, which include a prohibition on manufacture for a specific use.
[8] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

> fish tissue, all are expected to bioaccumulate and . . . none of the nine SNUN substances are expected to degrade under normal environmental conditions.
>
> Identified human health hazards include systemic, reproductive, developmental and carcinogenic effects . . . 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.
>
> Based on the current fluorination process and the diverse uses of the millions of fluorinated containers , . . releases to the environment of the SNUN substances produced as byproducts during Inhance's fluorination process are expected to be unavoidable and [there are] . . . numerous and diverse pathways for exposure to these SNUN substances – especially to consumers.
>
> There is also expected to be an additive hazard and exposure concern because the nine SNUN substances co-exist. Additionally. . . there is evidence that other potentially hazardous PFAS are formed during the fluorination . . . Due to the additive and compounding exposures, there is added concern for . . . the release and potential exposure of PFAS to human health and the environment.

AR0013896.

In view of these findings, the orders conclude that "[t]he 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." AR0020577. As EPA elaborated, "[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, EPA cannot realistically set limits on releases to water, air, and/or land, or mitigate worker, consumer, and general population exposures . . [and] prevent the PFOA contamination . . . other

than prohibiting the PFOA from being manufactured in the first place." AR0020577, Docs. 57-1 and 57-2.

In sum, EPA's prohibition on PFAS formation was neither discriminatory nor arbitrary and capricious.

B. EPA Separately Analyzed Inhance's DuraBloc and Enkase Treatment Technologies and Justified Prohibiting LCPFAC Formation for Both

Inhance's SNUNs addressed two lines of fluorination treatment -- DuraBloc, used for fuel tanks and portable fuel containers, and Enkase, used for other forms of plastic packaging. Both technologies form the same 9 LCPFACs. However, because some aspects of these treatment methods differ, EPA's risk assessment conducted separate analyses of each. Drawing on use information in the SNUNs, the assessment presents detailed breakdowns of the worker, general population, consumer, and environmental exposure scenarios for both DuraBloc and Enkase-fluorinated packaging applications. AR0013896 The assessment also documents that consumers and workers often use both container types concurrently, maximizing their overall exposure to LCPFACs. *Id.*

For each technology, the assessment concludes that the "the wide variety of potential uses of the plastic containers fluorinated by Inhance" results in "many and different releases and exposures for the nine SNUN substances." *Id.* Thus, EPA determined that a prohibition on PFAS formation during fluorination was needed, regardless of the fluorination treatment type.

Inhance argues the DuraBloc process generates more LCPFACs than he Enkase process (Br. at 45), but EPA's assessment emphasizes that, regardless of the LCPFAC levels present, "the nine SNUN substances leach or are released into the contents of the fluorinated containers over time through regular use of the containers" and this "results in releases and exposures." AR0013896 As EPA underscored, "even 'small' amounts of PFAS can have a disproportionate amount of risk" and "based on the known persistence, bioaccumulation, toxicity of PFOA, there is risk from even the smallest exposure." AR0020577. These well-documented findings amply justified EPA's decision to prohibit PFAS formation during both treatment technologies.

C. EPA Strongly Supported its Decision to Conduct a Qualitative Risk Assessment on the LCPFACs

Inhance questions EPA's decision to conduct a qualitative rather than a quantitative risk assessment on the LCPFACs formed during fluorination. Br. at 45-46. However, EPA went to great lengths to explain why "risks to human health and the environment [would] be underestimated by conventional, quantitative risk assessment methods:"

> 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.

AR0020577. EPA also conducted 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." Eighty percent of the calculations in the sensitivity analysis showed risk, confirming that likely levels of LCPFAC exposure from fluorinated containers would have harmful effects on a large segment of the population. Finally, EPA rejected Inhance's own quantitative risk assessment as greatly underestimating risk and having numerous methodological flaws. *Id.*

Although described by Inhance as "largely a non-specific literature review." Br. at 47, the EPA assessment provides detailed analyses of release and exposure pathways for the many products packaged in fluorinated containers, rigorously demonstrates why the 9 LCPFACs are potent PBT substances, and describes their well-documented health effects. It also emphasizes that these risks are magnified by the large volume of fluorinated containers produced, the existing LCPFAC body burden in the human population, the contribution of fluorinated containers to further long-term PFAS buildup in people, and the simultaneous exposure of container users to multiple long- and short-chain PFAS with compounding health effects. AR0013896. Clearly, the assessment was supported by substantial evidence.

CONCLUSION

The petition for review should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I electronically filed this brief using the appellate CM/ECF system on January 24, 2024. The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT, TYPE FACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

I hereby certify that this brief complies with the type-volume limit of Local Rule 29.3 and Federal Rule of Appellate Procedure 29(a)(5) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f), it contains 6,486 words according to Microsoft Word's word-count function. This document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

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