No. 23-60620

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

INHANCE TECHNOLOGIES L.L.C.,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review of Orders of the Environmental Protection Agency

BRIEF *AMICUS CURIAE* FOR THE AMERICAN CHEMISTRY COUNCIL, THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, CROPLIFE AMERICA, THE HOUSEHOLD & COMMERCIAL PRODUCTS ASSOCIATION, AND THE OUTDOOR POWER EQUIPMENT INSTITUTE IN SUPPORT OF PETITIONER

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CERTIFICATE OF INTERESTED PERSONS

Case No. 23-60620

Inhance Technologies L.L.C. v. United States Environmental Protection Agency; Michael S. Regan, Administrator, United States Environmental Protection Agency

The undersigned counsel of record certifies that, in addition to the persons and entities identified in the certificates of Petitioner and *amicus* the Coalition for Responsible TSCA Implementation, the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 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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The American Chemistry Council

The Chamber of Commerce of the United States of America

CropLife America

The Household & Commercial Products Association

The Outdoor Power Equipment Institute

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INTERESTS OF *AMICI CURIAE* [1]

Amici are trade associations whose members have serious concerns about the interpretation of the Toxic Substances Control Act ("TSCA") advanced and applied here by the Environmental Protection Agency ("EPA"), and about the manner in which EPA has chosen to announce and enforce this interpretation.

The American Chemistry Council ("ACC") represents the leading companies engaged in the business of chemistry, which is a $639 billion enterprise and a key element of the nation's economy. ACC participates on behalf of its members in administrative proceedings and in litigation arising from those proceedings.

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. The Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

CropLife America is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

pesticides for agriculture and pest management. Member companies produce, sell, and distribute virtually all the pesticide products used by American farmers, professional users, and consumers. Members have invested billions of dollars in research and testing to ensure those products' safety to humans and the environment.

The Household & Commercial Products Association ("HCPA") is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution, and sale of more than $180 billion annually of familiar consumer products. HCPA represents a range of home and commercial products used every day, including disinfectants, deodorizers, and a host of pest management, cleaning, aerosol, and other products.

The Outdoor Power Equipment Institute ("OPEI") is an international trade association representing manufacturers and suppliers of non-road gasoline powered engines, personal transport and utility vehicles, golf carts, and consumer and commercial outdoor power equipment ("OPE"). OPE includes lawnmowers, garden tractors, trimmers, edgers, chain saws, snow throwers, tillers, leaf blowers and related products. OPEI member companies and their suppliers contribute approximately $18 billion to U.S. GDP each year.

Amici write to share their perspective about the legal defects and negative implications of EPA's interpretation of TSCA and the adverse impact it threatens to have on *amici*'s members and other businesses across the country.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case concerns the lawfulness of orders EPA issued under TSCA against a company engaged in the business of fluorination, a process that creates a chemical barrier on the surface of plastic articles, like high-density polyethylene ("HDPE") containers, that enables them to safely, legally, and reliably transport and store products such as chemicals, pesticides, and fuels. But this case's ramifications go well beyond Petitioner Inhance Technologies LLC ("Inhance") and its fluorination process. To be sure, the EPA orders at issue do pose immediate practical consequences for the many businesses and customers that rely on fluorinated containers. Even more troubling, however, is the unfounded claim of regulatory authority underlying EPA's orders—and the alarming manner in which EPA elected to assert it. The Court should reject EPA's flawed interpretation of TSCA and set aside its orders as unlawful.

The basic components of the relevant regulatory scheme bear repeating. TSCA provides EPA with the authority to regulate the manufacture, import, and processing of commercial chemical substances for uses that EPA determines to be "significant new uses." 15 U.S.C. § 2604(a)(1)(A)(ii). EPA determines "significant new uses" via rulemakings called Significant New Use Rules, which require persons who want to manufacture, import or process a chemical for a "significant new use," as established by the rule, to submit a Significant New Use Notice to EPA at least

90 days prior to manufacture, import, or processing of the substance for that new use. 15 U.S.C. § 2604(a)(1)(B). EPA then determines whether the significant new use presents an "unreasonable risk of injury to health or the environment" and takes appropriate actions based on this risk determination. 15 U.S.C. § 2604(a)(3).

EPA warped that process here. In July 2020, it issued a Significant New Use Rule (the "Rule") for the manufacture, import, or processing of certain long-chain perfluoroalkyl carboxylates ("LCPFACs").[2] Nearly two years later, in March 2022, EPA asserted for the first time that the Rule applies to the fluorination industry. It issued Petitioner a Notice of Violation asserting that certain LCPFAC substances produced in trace amounts in Petitioner's fluorination process are subject to the Rule,[3] and that, because Petitioner had not previously submitted a Significant New Use Notice, Petitioner's fluorination activity (which had been ongoing for 40 years) violates the Rule.[4] Under protest, Petitioner submitted Significant New Use Notices

[2] *Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule*, 85 Fed. Reg. 45,109 (July 27, 2020) (codified at 40 C.F.R. § 721.10536).

[3] Annually, Petitioner incidentally produces only 2,212 grams total of LCPFAC across the millions of containers it fluorinates. *See* EPA, *TSCA Section 5 Order for a Significant New Use of Certain Chemical Substances* (Dec. 1, 2023) ("Section 5(f) Order") at 38, http://tinyurl.com/meeamk6a.

[4] The Department of Justice later brought suit against Petitioner alleging TSCA violations. That action remains pending. *See United States v. Inhance Techs. LLC*, Civ. No. 5:22-CV-05055-JFM (E.D. Pa.).

to EPA for nine LCPFAC compounds, maintaining that no such Notices were required. In response, EPA issued two orders under TSCA Section 5 prohibiting Petitioner from manufacturing the compounds.[5] Asserting that EPA's orders "will shut down [its] fluorination business and bankrupt the company,"[6] Petitioner brought this action challenging their validity.

Against this background, *amici* make two overarching points.

First, EPA's orders are unlawful. They subject Petitioner's unintentional production of trace amounts of LCPFACs to a regulatory regime that expressly applies to significant new uses of substances, not to previously existing uses of substances that also are impurities. EPA's determination that Petitioner's ongoing use is actually a "new" use exceeds its authority under TSCA—as does its asserted application of a Significant New Use Rule to impurities, which are exempt from such a rule's requirements. The orders also contradict EPA's established interpretation

[5] One order, under Section 5(f), prohibited Petitioner from manufacturing, processing, distributing in commerce, using, or disposing of three LCPFAC compounds. *See* Section 5(f) Order. Another order, under Section 5(e), prohibited Petitioner from manufacturing six LCPFAC compounds until extensive testing is completed (at which point EPA may or may not permit manufacture in the future). *See* EPA, *TSCA Section 5 Order for a Significant New Use of Certain Chemical Substances* (Dec. 1, 2023), http://tinyurl.com/4mhzdnjj.

[6] Opening Br. for Pet'r Inhance Techs. LLC ("Opening Br.") [Dkt. 56-1] at 14; *see also* Inhance's Mot. for Exped. Briefing & Arg. & for Stay Pending Appeal ("Mot. to Stay") [Dkt. 6-1] at 15 (citing evidence). The Court granted Inhance's unopposed motion to stay EPA's orders pending issuance of the mandate in this appeal. Dkt. 23-2.

and violate due process because EPA failed to provide fair notice that it was adopting, much less planning to enforce, such an expansive application of the Rule.

Second, if allowed to stand, EPA's orders will have severe consequences for businesses across the country. The administrative record contains evidence tending to show that the practical impact would be disruptive and devastating. Without readily available substitutes, commercial and consumer users of fluorinated containers across the country would suddenly lack a mechanism to safely, legally, and reliably transport and store a variety of critical products. Furthermore, the potential legal impact of EPA's orders would reach far beyond the fluorination industry and those who rely upon it. The sweeping and unwarranted assertion of regulatory authority underlying EPA's orders poses a threat to all businesses whose activities are subject to TSCA.

This Court should grant the petition and set aside EPA's orders.

ARGUMENT

I. EPA's orders are unlawful.

EPA's orders are premised on EPA's incorrect conclusion that the Rule applies to the LCPFAC impurities that are unintentionally present with the container-surface treatments produced in Petitioner's fluorination process.[7] EPA's

[7] EPA, *Press Release: EPA Takes Action to Protect People from PFAS that Leach from Plastic Containers into Pesticides and Other Products* (Dec. 1, 2023) ("EPA Press Release"), https://tinyurl.com/5n7j9tz2.

approach is unlawful for at least three independent reasons: (1) Petitioner is not engaged in a "new use" of a substance and, thus, is not subject to the Rule; (2) Petitioner unintentionally produces only trace amounts of LCPFACs that are impurities and, thus, are exempt from the Rule; and (3) EPA failed to provide adequate notice to the regulated community that it would treat (through an enforcement action) such impurities as subject to the Rule at all. Each reason is a sufficient basis to set aside the orders.

A. EPA's orders exceed its authority under TSCA by purporting to subject ongoing uses to Significant New Use Rules.

Under TSCA, no person may "manufacture or process any chemical substance for a use which [EPA] has determined . . . is a significant new use" without first submitting a Significant New Use Notice to EPA at least 90 days prior to manufacture (which includes import) or processing of the substance for the significant new use. 15 U.S.C. § 2604(a)(1)(A)–(B). As the text of this provision makes clear, and as EPA has previously acknowledged, this regulatory framework applies only to significant *new* uses of substances. In the Rule, EPA defined "new uses" as those "arising after the publication of the proposed rule," as contrasted with "ongoing uses" that already "exist at publication of the proposed rule." 85 Fed. Reg. at 45,111. The Rule specifically states that "[o]ngoing uses cannot be subject to a [Significant New Use Rule]." *Id.* at 45,115.

When the proposed rule was published in 2015, Petitioner had been fluorinating containers for about forty years. Mot. to Stay [Dkt. 6-1] at 9. Under EPA's own definition in the Rule, this squarely qualifies as an ongoing use. But EPA declined to follow its established interpretation and, if needed, to exercise its separate authority under TSCA Section 6, 15 U.S.C. § 2605, governing *existing* chemicals and uses. Instead, EPA improperly characterized Petitioner's decades-old use as a significant "new" use. Because this determination exceeds EPA's statutory authority and contradicts previous Significant New Use Rules, it should be set aside. *See, e.g.*, *Chamber of Com. of United States of Am. v. U.S. Dep't of Labor*, 885 F.3d 360, 379 (5th Cir. 2018) (agency "lacked statutory authority to promulgate" rule containing "overreaching definition" of key term); *Nat'l Envtl. Dev. Ass'ns Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("[A]gency action may be set aside as arbitrary and capricious if the agency fails to comply with its own regulations.") (internal citations omitted).

1. Ongoing uses are not subject to Significant New Use Rules.

A Significant New Use Rule's clear and limited application is to "new" uses of substances. *See Kornman & Assocs., Inc. v. United States*, 527 F.3d 443, 451 (5th Cir. 2008) (courts give undefined statutory terms their plain, ordinary meaning). Because EPA's orders are premised on its incorrect determination that Petitioner's ongoing use of LCPFACs is "new," they exceed EPA's authority under TSCA.

EPA does not have unfettered discretion to determine whether use of a substance constitutes a significant new use. TSCA delineates specific factors that EPA must consider, including (1) "the projected volume of manufacturing and processing of a chemical substance"; (2) "the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance"; (3) "the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance"; and (4) "the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance." 15 U.S.C. § 2604(a)(2).

The plain language contemplates the regulation only of new uses of substances. *See Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 583 U.S. 109, 131 (2018) (an agency cannot "obscure what the statutory language makes clear"). This is evident in the above-cited factors, such as the "*projected* volume" of the substance and the "*anticipated* manner" of manufacturing the substance. 15 U.S.C. § 2604(a)(2) (emphasis added). It also is apparent from TSCA's requirement that a company provide EPA notice "before" beginning "manufacturing or processing" of a substance for a significant new use. *Id.* § 2604(a)(1)(B)(ii). In contrast, under TSCA Section 6, which regulates *existing* uses of chemicals, EPA evaluates a chemical for prioritization (the step required before risk evaluation) based on consideration of

factors stemming from the chemical's past, existing and ongoing uses, *see id.* § 2605(b)(1)(A)—not its "projected" or "anticipated" new uses.

Interpreting TSCA to allow ongoing uses to be considered "new" would not just render words like "projected," "anticipated," and "before" superfluous. *See Corley v. United States*, 556 U.S. 303, 314 (2009) (a "statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous") (citations omitted). That reading directly contradicts the statutory language. EPA's determination that Petitioner's ongoing fluorination operations constitutes a "new" use exceeds its authority under, and is contrary to, the statute.

2. EPA's determination contradicts previous Significant New Use Rules, which make clear that ongoing uses are not subject to such rules.

"One of the most well-known limitations on agency action is the longstanding prohibition on agency determinations that contradict the agency's own regulations." *HealthAlliance Hosps., Inc. v. Azar*, 346 F. Supp. 3d 43, 55 (D.D.C. 2018). In targeting Petitioner's pre-existing, ongoing use through the Rule, EPA disregarded that limitation.

As EPA correctly stated in the Rule, "[o]ngoing uses cannot be subject to a [Significant New Use Rule]." 85 Fed. Reg. at 45,115. That reflects the agency's longstanding position, regularly reiterated in preambles to final Significant New Use Rules, that "[t]o establish a significant new use, EPA must determine that the use is

not ongoing." *See, e.g.*, 88 Fed. Reg. 21,480, 21,482 (Apr. 11, 2023); 88 Fed. Reg. 13,696, 13,698 (Mar. 6, 2023); 87 Fed. Reg. 73,941, 73,944 (Dec. 2, 2022); 87 Fed. Reg. 58,999, 59,001 (Sept. 29, 2022); 87 Fed. Reg. 37,999, 38,001 (June 27, 2022). Through proposed Significant New Use Rules, EPA seeks to identify ongoing uses so they can be excluded from the rules' requirements. EPA does so by soliciting public comments, in which regulated entities can identify ongoing uses,[8] or reviewing reasonably available information about the manufacture, processing, and use of the substance.[9]

EPA may not be able to identify all ongoing uses through research and comments, however. Some manufacturers may not even become aware that they have an ongoing use until after a rule is finalized (the scenario here, according to Petitioner, *see* Opening Br. at 32–33; Mot. to Stay at 12–13). It would dramatically expand EPA's authority under TSCA if it could lawfully treat an ongoing use as a

[8] *See, e.g.*, 88 Fed. Reg. 40,728, 40,729 (June 22, 2023) (proposed Significant New Use Rule inviting public comment on ongoing uses of certain flame retardants). EPA plans to issue Significant New Use Rules for uses of certain phthalates, solvents, and other substances undergoing TSCA Section 6 risk evaluations where the uses are no longer ongoing. *See* EPA Fall 2023 Unified Regulatory Agenda, http://tinyurl.com/4fcyysvv.

[9] "EPA will not determine that a use is a 'significant new use' if information reasonably available to the Agency, including that received during the period for public comment, establishes that the use is ongoing at the time the proposed rule is published in the Federal Register." 88 Fed. Reg. at 40,728.

"new" use in such circumstances. That assertion, which EPA advances here, is contrary not only to the statutory text—which expressly refers to "new" uses (not, for example, to "newly known" or "newly disclosed" uses)—but also to EPA's established practice. *See Army & Air Force Exch. Svc. v. Sheehan*, 456 U.S. 728, 733 (1982) (describing as "well-established" the "legal principle that a federal agency must comply with its own regulations"). The Court should reject it.

B. EPA's orders would unlawfully subject impurities to Significant New Use Rules.

1. Impurities are exempt from Significant New Use Rule requirements.

EPA is also wrong about a second issue of importance extending far beyond this case—the distinction between impurities and byproducts in EPA's TSCA regulations.

Petitioner maintains that the substances unintentionally created in its fluorination process are impurities and therefore exempt from the Rule. EPA contends that these substances are byproducts subject to the Rule. The distinction is important because significant new use regulations provide a full exemption when a "person manufactures or processes the substance only as an impurity." 40 C.F.R. § 721.45(d).[10] On the other hand, persons who manufacture or process byproducts

[10] Impurities are also exempt from other TSCA requirements, such as those regarding premanufacture notices, 40 C.F.R. § 720.30(h)(1); general reporting, *id.* §

are subject to Significant New Use Rules, unless the "person manufactures or processes the substance only as a byproduct which is used only by public or private organizations that (1) burn it as fuel, (2) dispose of it as a waste . . . or (3) extract component chemical substances from it for commercial purposes." *Id.* § 721.45(e).

EPA defines the terms "impurity" and "byproduct" in 40 C.F.R. § 720.3.[11] An impurity is "a chemical substance which is unintentionally present with another chemical substance." *Id.* § 720.3(m). A byproduct is "a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical or mixture." *Id.* § 720.3(d). These definitions can and often do overlap. For instance, a substance that is incidentally produced during the manufacture of another substance without a separate commercial intent (which would make it a byproduct) can also remain part of the other substance without being separated from it (which would make it an impurity). The determinative feature that makes a substance an impurity is that it *unintentionally remains present* with another substance and is not separated from it.

Therefore, substances that are impurities—meaning, they *remain part of the substance*—are exempt. Substances that are *separated from* the host substance and,

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704.5(c); chemical data reporting, *id.*§ 711.10(c); and inclusion on the TSCA Inventory, *id.* § 710.4(d).

[11] 40 C.F.R. § 721.3 states that the definitions contained in 40 C.F.R. § 720.3 apply to significant new use regulations.

therefore, do not qualify as impurities, are byproducts not exempt from the significant new use regulatory process (unless used in one of the three ways specified in 40 C.F.R. § 721.45(e)).

2. EPA's position that unintentionally produced substances are not impurities contradicts previous TSCA rules.

EPA's determination that the impurities Petitioner produces are subject to the Rule directly contradicts the Rule itself and prior rules regarding impurities. *See Army & Air Force Exch. Svc.*, 456 U.S. at 733 ("a federal agency must comply with its own regulations"). EPA clarified in the Rule's preamble that substances unintentionally present with another chemical substance are exempt impurities. In providing that guidance, EPA anticipated a scenario analogous to Petitioner's:

> One commenter stated that their imported article contained residual LCPFAC from the use of polytetrafluoroethylene (PTFE) production, outside the US. . . . To the extent the chemical substance subject to the [Significant New Use Rule] is only "unintentionally present" at the point of foreign manufacture, *it is already exempt from reporting by the importer as an imported impurity*. See 40 CFR 721.45(d). As such, importers are not required to submit a [Significant New Use Notice] for or report on a substance based simply on that substance's presence as an impurity (*i.e.,* a chemical substance is unintentionally present with another chemical substance, 40 CFR 720.3(m)). Additionally, the impurity exemption at 40 CFR 721.45(d) *includes domestic manufacture and processing.*

85 Fed. Reg. at 45,121 (emphasis added). This language demonstrates EPA's clear intention to exempt impurities produced in the manufacturing process.

In addition, in EPA's health and safety study reporting rule, which likewise exempts impurities from reporting and defines these terms the same as the Significant New Use Rule regulations, EPA explained that byproducts that are also impurities meet the impurities exemption and are exempt from reporting: "Other substances that are produced as byproducts, *but not separated from the product, are impurities* of the product and are thus not covered in the present rule." 47 Fed. Reg. 38,780, 38,781 (Sept. 2, 1982) (emphasis added). EPA thereby expressed its understanding that the definitions of byproduct and impurity can overlap—and, when they do, that the substance is understood to be an impurity because it remains part of the product and not separated from it.

In connection with the TSCA Chemical Data Reporting Rule ("CDR"), which also exempts impurities from reporting, *see* 40 C.F.R. § 711.10(c), EPA has clarified that substances produced as byproducts that also are impurities are exempt from CDR reporting under the impurities exemption. EPA has provided the following guidance:

> **10.23. Chemical X is formed unintentionally, without any separate commercial purpose, during the manufacture of another chemical, Chemical Y. Furthermore, Chemical X is not separated from Chemical Y. Would it be accurate to describe substance Chemical X as an impurity with no reporting obligation?**
>
> Chemical X could be described as an impurity because it is unintentionally present with Chemical Y, but it would be more accurate to describe it as a byproduct because it is manufactured

> without a separate commercial purpose. *The manufacture of this byproduct/impurity is not reportable for CDR purposes*. See 40 CFR 711.10(c) and 40 CFR 720.30(h)(1) [citing to the impurities exemption] . . . .[12]

Here again, EPA acknowledged that when a substance (Chemical X) is both an impurity and a byproduct, the substance is exempt from CDR reporting under the impurities exemption, because it is *not separated from* the manufactured product (Chemical Y).

C. EPA's orders violate due process.

It is a fundamental principle that "agencies should provide regulated parties fair warning of the conduct a regulation prohibits or requires." *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158 (2012) (internal citations omitted). This "requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). In issuing the Rule on which its two orders are premised, however, EPA violated this requirement. It failed to give fair notice to Petitioner and other businesses in the fluorination industry that they would be subject to the Rule.

[12] EPA, *Determining the Chemical Substances Subject to the CDR Rule*, (emphasis added), http://tinyurl.com/26pv3uc5.

In the Rule, EPA enumerated a list of potentially impacted industries—including chemical manufacturing, petroleum refining, carpet and upholstery cleaning, electronic products and appliances, fiber mills, and home furnishing. 85 Fed. Reg. at 45,110.[13] Container fluorination was absent from that list, *see id.,* despite EPA's awareness of fluorination technology.[14] No wonder "EPA's violation notice came as a surprise to" Petitioner. Opening Br. at 1. Due process demands more:

> It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.

Christopher, 567 U.S. at 158–59; *see also Diamond Roofing Co. v. Occupational Safety & Health Review Comm'n*, 528 F.2d 645, 649 (5th Cir. 1976) ("[A] regulation cannot be construed to mean what an agency intended but did not adequately express.").

[13] EPA also included a vague catch-all of "other types of entities not listed in this unit," which is insufficient notice to affected industries. 86 Fed. Reg. at 45,110.

[14] EPA has discussed fluorination in other rulemakings, such as final rules for emission standards for highway motorcycles, 69 Fed. Reg. 2398, 2426 (Jan. 15, 2004), and for nonroad spark-ignition engines, 73 Fed. Reg. 59,034, 59,125 (Oct. 5, 2008).

Petitioner also lacked fair notice that it was subject to the Rule because it was not engaged in a new use and it produced the substance only as an exempt impurity. *See* Parts I.A–B *supra*. Given that EPA's established interpretation exempts both ongoing uses and impurities, Petitioner had no reason to expect that its fluorination process would be subject to the Rule. *See* 85 Fed. Reg. at 45,115 ("[o]ngoing uses cannot be subject to a [Significant New Use Rule]"); 40 C.F.R. § 721.45(d) (exempting impurities from significant new use requirements). "To keep things fair," EPA was required to give notice of what conduct was prohibited, *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 189 (5th Cir. 2023), but it failed to do so here.

II. Unless rejected, EPA's novel approach poses severe harms to industry.

EPA's interpretation of TSCA is not only unsupported and unlawful, it threatens immediate and direct harms. Petitioner's brief makes clear that the potential harms to users of fluorinated containers (including some of amici's members) if EPA's interpretation stands are significant and compelling and could cascade through the supply chain. But of even greater concern to *amici* is the uncertainty that EPA's sweeping interpretation creates and the burdensome impact it would impose on companies that manufacture, import, or process products containing trace impurities.

A. EPA's orders could debilitate numerous supply chains that depend on fluorinated containers for the safe, legal, and reliable storage and transport of chemicals, fuels, and other essential products.

If left undisturbed, EPA's orders here could have a serious, adverse impact on the many businesses and customers who depend on the safety and reliability of fluorinated containers to transport and store products. By effectively shuttering a major fluorination provider,[15] the orders threaten to disrupt the supply chains that rely heavily on these containers. The orders thus flout Congress's instruction that EPA consider the "economic[] and social impact of any action the Administrator takes or proposes" under TSCA. 15 U.S.C. § 2601(c).

1. Fluorinated containers are critical to industry.

To appreciate the threat posed by EPA's orders, it is necessary to understand the pervasive use and necessary reliance on fluorinated containers by businesses and customers across the country. Fluorinated containers are critical in a variety of supply chains—including agricultural products, lawn and garden chemicals, biomedical and pharmaceutical products, vaccines, cosmetics, household products, toys, electronics, paints and coatings, industrial and sanitary supplies, aerospace and defense applications, and automobiles. Millions of fluorinated fuel tanks are

[15] Petitioner states that it fluorinates "over a hundred million containers a year." Opening Br. at 13; *see also* Section 5(f) Order at 41 (referencing the "121 to 200 million plastic containers that are fluorinated annually by the Company").

installed annually in power equipment, including lawnmowers, grass trimmers, hedge trimmers, leaf blowers, and utility vehicles.[16]

Fluorinated containers are widespread because fluorination technology addresses a range of critical packaging and environmental problems, in compliance with applicable EPA and U.S. Department of Transportation ("DOT") requirements. By creating a barrier that prevents the molecules of packaged products from permeating the walls of plastic containers, fluorination prevents cracks, container distortion and failure, and a loss of product integrity.[17] The process increases shelf life and reduces product loss, odor, odor absorption, and loss of quality. Fluorinated barrier protection greatly increases the utility of plastic containers in place of glass and metal containers that are heavier and costlier to transport.

Fluorination can be particularly critical when containers hold ingredients that are corrosive, solvent-based, or prone to rancidity—such as fragrances, essential oils, kerosene, gasoline, paint thinners, insecticides, hydrocarbon solvents, acetone, and many other essential chemistries and ingredients. The barrier created by fluorination prevents the emission of products that may be harmful to the

[16] Petitioner alone fluorinates 5.5 million HDPE fuel tanks for small spark-ignited engines each year. *See* Daniel J. Mustico (OPEI), Ltr. to Michal Freedhoff (EPA) (Aug. 7, 2023) ("OPEI Letter") [Dkt. 6-12] at 1.

[17] *See* A.P. Kharitonov, *Practical applications of the direct fluorination of polymers*, 103 J. FLUORINE CHEM. 123, 124 (2000).

environment if not properly packaged and handled. Indeed, fluorination enables a variety of critical products to satisfy EPA standards. For example, it provides the barrier treatment necessary to line the surface of fuel tanks used in gas-powered outdoor power equipment, by forcing fluorine gas into every crevice and thereby improving the barrier's reliability and durability. 73 Fed. Reg. at 59,125. Fluorination is a particularly effective technology for complying with EPA's small engine evaporative emissions standards, which limit releases of volatile organic compounds into the environment,[18] and for equipment whose tank size, shape, or configuration limits production and material options. *See* OPEI Letter at 1.

Pesticides are another critical set of products that use fluorinated containers. Society depends on the public health benefits of pesticides, which mitigate bacteria, viruses, and other pathogens and control disease vectors such as mosquitoes and rodents. Crop protection pesticides also allow farmers to reliably produce abundant and affordable food, fiber, and fuel. A shortage of fluorinated containers would have profound impacts on distribution channels, as many concentrated pesticides are transported in fluorinated packaging before being diluted by the final manufacturer.

[18] 40 C.F.R. Chapter I, Subchapter U ("Air Pollution Controls"). In particular, 40 C.F.R. Part 1060 sets permeation standards for fuel tanks used in most outdoor power equipment. *See* 40 C.F.R. § 1054.110 (handheld spark-ignition engines); *id.* § 1054.112 (non-handheld spark-ignition engines).

There could be severe disruptions for manufacturers, farmers, consumers, and others who require dependable access to a range of pesticide products.

The importance of fluorinated containers—and, therefore, the potential economic, environmental, and practical impacts of sidelining a major provider of them—are significant. As *amicus* OPEI previously informed EPA, "the unavailability of fluorination would have dramatic, cascading effects on the supply chain that would result in the closure of multiple production facilities and laying off of thousands of employees." OPEI Letter at 3. Petitioner has provided evidence from NERA Economic Consulting ("NERA") that approximately 80% of agricultural chemical packaging in North America that requires barrier protection is treated with post-mold fluorination and that, if deprived of access to Petitioner's process, the pesticide and other agricultural chemical manufacturing sectors would experience estimated total output losses of $13.3 billion and job losses of 32,600 full-time equivalents.[19] Petitioner's evidence is similar with respect to lawn and garden equipment: the unavailability of Petitioner's post-mold fluorination for the fuel systems integral to manufacturing equipment would lead to output impact losses of $8.5 billion and job losses of 25,600. Carey Decl. at 6–7 ¶ 17. In total, NERA has estimated that the national economy would face a total annual output loss of

[19] Decl. of Julie M. Carey in Supp. of Pet'r's Mot. for Expedited Briefing & Arg. & for Stay Pending Appeal at 6 ¶ 16 (Dec. 7, 2023) ("Carey Decl.") [Dkt. 6-3].

approximately $39.8 billion from industries and sectors across the supply chain that touch Petitioner's business. *Id.* at 5 ¶ 12. NERA also estimated job losses of approximately 112,100 in the absence of Petitioner's technology, 84% of which are associated with original equipment manufacturers and distributers (including some of *amici*'s members). *Id.* at 5 ¶ 13.

2. Adequate, available substitutes could be years away.

The potential impacts described above would be softened if customers had ready and proven substitutes for fluorinated containers that comply with regulatory requirements. But, as even EPA appears to concede, not all "sectors" will be able "to continue to provide products with the necessary protective packaging," *see* EPA Press Release, and the timeline for developing ready and approved alternatives in those sectors would be lengthy. Manufacturers (some operating with limited resources) would need to order new equipment, alter their manufacturing processes, and iteratively test and retest until alternatives are developed and approved that adequately store chemicals while protecting humans and the environment in compliance with legal and regulatory requirements. In the meantime, manufacturers and their customers could suffer serious consequences.

Take again the example of fuel tanks. It is illegal to sell outdoor power equipment with fuel tanks that do not meet EPA's evaporative emission standards, and "Inhance has been virtually the only domestic supplier of fluorination services

used to make HDPE fuel tanks impermeable to meet the EPA standards." OPEI Letter at 2. It likely would be years before new alternative technologies could be identified, tested, and validated for efficacy, safety, and satisfaction of applicable evaporative emissions standards. The need for such a long testing period is to be expected, given the potentially hazardous context: fuel tanks are subject to extreme temperature cycles due to their close proximity to engines, and tank designs and materials need to be lab- and field-tested to assure durability and to satisfy the regulatory requirements of both EPA and the Consumer Product Safety Commission. New technologies may require manufacturers to redesign equipment to accommodate new fuel tank shapes, causing further delay in bringing outdoor power equipment to the market. "This could result in billions of dollars in lost production and sales while consumers would be adversely affected." *Id.* at 3.

The same is true in the pesticides sector—there too, the operative regulatory regime constrains producers' ability to quickly substitute new containers. Before a pesticide product can be placed on the market in the United States, it must be registered with EPA under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. This is a time-consuming and resource-intensive process. A company seeking to register a pesticide product must provide EPA detailed information about the product's chemical composition, labeling, and, of

relevance in this case, packaging (including containers).[20] Registration applications must be supported by extensive scientific data, including "storage stability data" showing that, during its storage life, a pesticide product's packaging will maintain its integrity, active ingredients will remain within an acceptable range, and no significant changes to the product will occur that could interfere with its usefulness or safe handling.[21] Pesticide containers must comply with the construction and performance standards set forth in 40 C.F.R. Part 165, including any applicable DOT requirements. If EPA is satisfied that the submitted data support the proposed uses of the pesticide, EPA may issue a registration allowing the product to be distributed in commerce with its approved composition, labeling, and packaging. *See* 40 C.F.R. § 152.112. Once a registration is issued, changes to the pesticide product—including to its packaging—"must be approved by the Agency before the product, as modified, may legally be distributed or sold."[22] EPA can take many months to review amendment applications, and capacity constraints and other policy priorities could reasonably extend that period to a year or more.

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[20] *See* 40 C.F.R. § 152.50; Application for Pesticide Registration/Amendment, EPA Form 8570-1, http://tinyurl.com/3d55sj85.

[21] *See* 40 C.F.R. § 158.310; USEPA, Product Properties Test Guidelines: OPPTS 830.6317 Storage Stability, http://tinyurl.com/2vyurd5z.

[22] 40 C.F.R. § 152.44; *see also id.* § 152.46 (allowing for registration amendment via streamlined "notification" process for certain minor changes in product labeling and packaging).

The consequence of these requirements is a long lead time for replacing the fluorinated containers affected by EPA's orders. Even after a pesticide registrant identifies and qualifies suitable alternative containers with adequate barrier protection for all registered pesticides, substantial additional time would be needed to comply with FIFRA regulations before the alternatives could be deployed. These delays could cause severe disruptions for both pesticide manufacturers and end users, particularly members of the agricultural community who depend on having access to necessary crop protection tools.

In short, if the containers treated by Petitioner suddenly become unavailable, the ripple effects could be devastating for the many sectors of the economy that depend on them.

B. EPA's interpretation of TSCA threatens harm far beyond this case.

The implications of EPA's orders transcend the fluorinated container industry and the particular substances at issue here. EPA's drastic change to its approach to interpreting "significant new uses" creates broad uncertainty and threatens to set a dangerous precedent for TSCA regulation and enforcement.

Consider EPA's flawed interpretation, described in Part I.B *supra*, that substances that are unintentionally produced in the manufacture of another substance and remain present with the substance are not impurities and are not exempt from Significant New Use Rule requirements. The logic of this interpretation sweeps

broadly: it would capture not merely the substances unintentionally produced in Petitioner's fluorination process, but potentially *any* substance that is the subject of a Significant New Use Rule that is unintentionally produced in the manufacture of another substance and remains part of the substance. This would include impurities present in imported products, which are not typically known to importers and would require testing. Given the hundreds of chemicals subject to Significant New Use Rules, *see* 40 C.F.R. 721 Subpart E, the implications are significant: the reach of *all* such rules would expand to apply to impurities.

If EPA's reading of TSCA's impurity exemption is upheld, thousands of manufacturers, importers, and processors suddenly could face the potential threat of enforcement under TSCA for manufacturing, importing or processing previously exempted impurities. They could be required, unnecessarily, to undertake the effort of trying to identify or test for these trace impurities and file onerous Significant New Use Notices for these kinds of unintentionally generated substances and wait for EPA approval. This burden would be compounded if EPA requires that, contrary to TSCA, not only new uses but certain ongoing uses of substances are subject to Significant New Use Rules. EPA would need to expend its already limited resources reviewing a flood of Significant New Use Notices for uses of substances of very little concern to the agency. In the meantime, given the existing backlog of such Notices and EPA's notorious delays in reviewing them (often years beyond the

statutory 90-day review period),[23] it is unlikely that companies would be able to manufacture, import, or process these substances anytime soon.

In sum, *amici* are concerned that the harms threatened in this case could be visited upon thousands of companies if EPA is not forced to course-correct. Today it is Petitioner whose operations are the target; tomorrow it could be any other business whose activities are subject to TSCA. The Court should reject EPA's novel, illegal interpretation of the governing statutory and regulatory provisions.

CONCLUSION

The Court should grant the petition and set aside EPA's orders.

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Respectfully submitted,

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[23] EPA currently has over 400 active new chemical notices, including significant new use notice cases. *See* EPA, *Statistics for the New Chemicals Review Program Under TSCA*, http://tinyurl.com/2jkdfath.

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CERTIFICATE OF SERVICE

I hereby certify that, on December 29, 2023, I electronically filed this brief with the Clerk of this Court by using the appellate CM/ECF system. 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

This document 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 6,428 words according to Microsoft Word's word-count function.

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