Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

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Mr. Thomas Groeneveld
Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania, Ave. NW
Washington, DC 20460-0001
Groenveld.thomas@epa.gov

Re: Inhance Technologies' Comments on Certain Per- and Polyfluoroalkyl Substances (PFAS) Risk Management Under the Toxic Substances Control Act (TSCA) (EPA Docket ID: EPA-HQ-OPPT-2024-0131)

Dear Mr. Groeneveld:

Inhance Technologies, LLC ("Inhance") submits the following comments in response to the United States Environmental Protection Agency's ("EPA") September 30, 2024 notice seeking information regarding the manufacture of certain per- and polyfluoroalkyl substances ("PFAS"), including perfluorooctanoic acid ("PFOA"), perfluorononanoic acid ("PFNA"), and perfluorodecanoic acid ("PFDA"), during the fluorination of high-density polyethylene ("HDPE") and other plastic containers.[1] Inhance has been providing post-mold fluorination services to customers in multiple sectors across the United States since 1983. As such, Inhance has a uniquely relevant perspective on the fluorination process and its importance to the domestic economy.

EPA explains that information is requested "to inform the Agency's path forward with respect to regulation of . . . PFAS formed during fluorination of plastic containers under [the Toxic Substances Control Act] section 6."[2] To support its assessment, EPA specifically requests information on: (1) the number, location, and uses of fluorinated containers in the United States, including any uses critical to the national economy, national security, or critical infrastructure (which may include uses in medical devices); (2) alternatives to the fluorination process; and (3) measures to address the alleged risk from PFOA, PFNA, and PFDA formed during the fluorination of plastic containers.

In this comment letter, Inhance provides information responsive to the topics identified in EPA's September 30, 2024 notice. Specifically, Inhance: (1) provides information describing the importance of fluorination to the United States economy; (2) explains why there are not viable alternative technologies to fluorination; and (3) describes available measures to minimize the potential for the unintentional

[1] 89 Fed. Reg. 79581 (Sept. 30, 2024).
[2] *Id.*

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

generation of PFOA, PFNA, and PFDA as impurities during fluorination. This comment letter also addresses the various legal requirements EPA must meet to promulgate a rule under Section 6(a) of the Toxic Substances Control Act ("TSCA").

I. Fluorinated Containers are Essential to the United States Economy.

a. Fluorination is a well-known process that has been approved by the Government.

Fluorination is an important technology that modifies the surface of containers made from HDPE and other plastics (e.g., polyolefins) by imparting barrier protection properties. During the fluorination process, fluorine atoms replace a portion of the hydrogen atoms on the exposed surface of the plastic articles, thereby significantly reducing their permeability. Because fluorination causes a chemical change in the treated plastic, the fluorocarbon barrier is highly robust and cannot be peeled or scratched off. Fluorination can be deployed to treat a wide variety of polyolefin plastic containers of varying designs, sizes, and irregular shapes.

Fluorination can occur either during (via in-mold fluorination) or after (via post-mold fluorination) the manufacturing process for plastic articles.[3] In either process, the plastic is exposed to fluorine and nitrogen gas mixtures under controlled conditions, including time, temperature, pressure, and level of fluorine.

Notably, fluorination is recognized as an approved regulatory use for the treatment of fuel tanks and certain food purposes. Indeed, EPA has long acknowledged the robust barrier protection benefits that fluorination provides. As early as 1994, EPA recognized fluorination as a viable technology for fuel tanks to meet evaporative emission standards under the Clean Air Act.[4] In its final rule setting forth evaporative emissions standards for large spark-ignition engines, EPA describes the fluorination process and notes that fluorination could result in a "more than a 95-percent reduction in permeation emissions from new fuel tanks . . . ."[5] EPA describes and reiterates the benefits of fluorination technology in subsequent rulemakings, including in a 2004 final rule adopting new permeation evaporative emission standards for highway motorcycles,[6] and a 2008 final rule regulating new non-road spark-ignition engines.[7]

The Food and Drug Administration ("FDA") has also promulgated regulations permitting the use of fluorination for food-contact articles.[8]

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[3] Although EPA seeks information regarding fluorination generally, Inhance engages in post-mold fluorination. As a result, Inhance's comments generally pertain to this particular method of fluorination.
[4] 59 Fed. Reg. 55930, 55974 (Nov. 9, 1994).
[5] *Id.*
[6] 69 Fed. Reg. 2398, 2426 (Jan. 15, 2004).
[7] 73 Fed. Reg. 59034, 59125 (Oct. 8, 2008).
[8] 21 C.F.R. § 177.1615.

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22008 North Berwick Drive
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T: +1.281.578.1440 F: +1.877.701.5097
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b. Fluorination has multiple critical uses across various sectors.

Fluorinated containers play a crucial role in the production, storage, and distribution of many essential products and goods used throughout, and vital to, the United States economy. Given the number of products that require packaging with barrier protection, many industries—including in the agricultural, chemical manufacturing, healthcare, and transportation sectors—rely on fluorinated packaging. Products that require fluorinated containers include vaccines, prescription medications, surgical products, and solvent-based chemicals used for crop production.

For instance, in the healthcare sector, fluorination is used to treat packaging that stores chemistries used for diagnostic testing and pharmaceuticals. Fluorination is also needed for cold chain packaging to prevent spoliation when storing and transporting vaccines. Importantly, packaging that undergoes the fluorination process has improved temperature stability, which improves shelf life and ensures the integrity and efficacy of temperature-sensitive medication, including vaccines.

Fluorination is also widely used to treat fuel tanks that are integrated into various vehicles and equipment, including boats, off-road vehicles, motorcycles, and outdoor power equipment. Due to the complex configurations of these types of products, the fuel tanks often have unique designs, sizes, and shapes. Because post-mold fluorination occurs after the molding process and is not constrained by shape, size, or design, it is the preferred barrier protection technology for fuel system molders. For instance, the Outdoor Power Equipment Institute ("OPEI")[9] explains that "[f]luorination is necessary for many HDPE fuel tanks to meet design configurations . . . and [to] comply with EPA evaporative emission standards."[10]

c. A prohibition on fluorination would have significant detrimental impacts on the United States economy.

In the simplest terms, a ban on fluorination technology would be highly disruptive to numerous supply chains and detrimental to the larger domestic economy. Inhance is the predominant post-mold fluorination company in the United States. In 2023, Inhance commissioned an independent firm—NERA Economic Consulting ("NERA")—to assess the economic impact the absence of Inhance's fluorination

[9] OPEI is an international trade association representing the manufacturers and suppliers of non-road gasoline powered engines, personal transport and utility vehicles, golf carts, and consumer and commercial outdoor power equipment. OPEI member companies and their suppliers contribute approximately $18 billion to the United States Gross Domestic Product each year.

[10] Letter from Daniel J. Mustico, Senior Vice President, Government & Market Affairs, OPEI to Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, EPA, *Inhance Technologies, Fluorinated Fuel Tanks, and the Outdoor Power Equipment Industry* (Aug. 7, 2023) (attached as Ex. 1).

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
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technology would have on the economy.[11] Based on its analysis, NERA concluded that the United States economy would face an estimated economic output loss of approximately $39.8 billion. This includes a direct loss of approximately $15 billion to original equipment manufacturers ("OEMs"), distributors, and plastic molders who would be unable to sell their various products (e.g., pesticides, auto care products, vaccines, lawn and garden equipment, outdoor power equipment) without fluorinated containers and fuel tanks.

NERA also estimated that a prohibition of fluorination by EPA would result in a loss of approximately 112,100 jobs. Approximately 16 percent of the job losses would come from plastic molders and Inhance, while 84 percent of lost jobs would come from OEMs (i.e., product manufacturers) and the distributors selling these products. Specifically, OEMs and distributors in the following industries are projected to face the greatest amount of job losses if fluorination is prohibited: agricultural chemical manufacturing (NAICS 325320), lawn and garden equipment manufacturing (NAICS 333112), petroleum lubricating oil and grease manufacturing (NAICS 324191), chemical product and preparation manufacturing (NAICS 325998), and surgical and medical instrument manufacturing (NAICS 339112).

While significant, the estimates of the economic impacts described above should be considered conservative as NERA's analysis only considers economic costs associated with the absence of Inhance's fluorination technology. A Section 6 rule that widely prohibits or otherwise imposes limitations on the entire fluorination industry would be even more damaging because it would go far beyond just impacting Inhance, its customers, and downstream supply chains. Such regulation would also harm Inhance's competitors (i.e., other fluorination companies), importers of fluorinated containers, and all related customers and supply chains. Thus, the NERA analysis is merely a starting point for the harmful economic consequences that would result from a Section 6 rule banning fluorination.

II. Alternatives to Fluorination are Inadequate.

a. There are no viable alternatives to fluorination available.

Currently, there are no viable alternative barrier technologies that can match the efficacy, flexibility, and scalability that fluorination provides. Industry itself has made this point undeniably and abundantly clear. In an *amici* brief to the United States Court for the Fifth Circuit of Appeals, a coalition of trade associations representing hundreds of companies across various industries said in no uncertain terms that there are no available alternatives to fluorination.[12]

Despite this recognition from industry, at least one company—BP Polymers—has repeatedly touted itself as viable alternative to Inhance. In reality, this technology suffers from serious technical

[11] This report contains confidential business information ("CBI") and is being provided to EPA through Central Data Exchange consistent with the procedures set out 40 C.F.R. Part 703.
[12] *See Inhance Techs. LLC v.* EPA, No. 23-60620 (5th Cir. Dec. 29, 2023), ECF No. 66-1 at 23-26 (attached as Ex. 2).

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

limitations that impact performance, and even if it did not, this technology—by BP Polymers own admission—cannot be scaled to a production level that would be needed if fluorination were no longer available. BP Polymers offers what it describes as a "proprietary barrier resin" that can be blended with HDPE during the container molding process. BP Polymer claims that this additive imbues containers with necessary barrier protection. However, testing conducted by Inhance and others has shown that this additive technology is inferior to fluorination from a performance perspective and sparingly works in only certain niche applications. The BP Polymers additives form discontinuous lamellar structures, which allow for solvents and other hydrocarbon-based formulations to continue to permeate the plastic container and be available to the environment. Moreover, unlike fluorinated containers, where the presence and degree of fluorination can be easily and readily verified, the uniformity of the distribution of the lamellar layers created by BP Polymers' proprietary barrier resin (and thus the barrier efficacy) cannot be authenticated. Given these inherent flaws, other companies including DuPont and LG have previously tried and subsequently abandoned the development and commercialization of barrier resins.

Additionally, the BP Polymers additive presents significant process challenges for the extruders and molding machines used to mold plastic containers. The additive often requires specialized modifications to the extruder and significant capital investments to be able to process the material. Due to the difficulty in molding the modified resin, especially at higher additive loading levels, there are often quality-related issues, which makes the containers with this additive unreliable. In most instances, the addition of this additive results in significant embrittlement of the container, which compromises the drop strength required by the United States Department of Transportation, therefore limiting the technology's use in commerce. To offset this embrittlement, the addition of these additives has to be counteracted by thicker container walls, which increases the weight of the container, making the container both less sustainable and more expensive. In addition, unlike fluorination, which can be applied to any container size, shape, or design, BP Polymers' lamellar barrier technology can only be practiced with standard container shapes and sizes.

For these reasons, Inhance's customers continue to use fluorinated containers for their packaging needs despite the availability of BP Polymers' additive. Indeed, several customers have informed Inhance that they have unsuccessfully attempted to use BP Polymers' additive as an alternative to fluorination. In many cases, the customer has reverted back to using fluorinated containers as it is the only viable option for reliable barrier packaging.

It is clear that BP Polymers' barrier technology is an insufficient solution to meet market and regulatory demands, but even if the substantial technical limitations could be overlooked, BP Polymers' technology has not been scaled to the level required to replace the need for fluorinated containers. At a recent Society of Plastics Engineers ("SPE") conference held on October 29-30, 2024,[13] CKS Packaging, a molder using BP Polymers' additive, claimed it could sell up to two million containers using the additive in 2025—i.e., less than 2 percent of the fluorinated containers used in the United States annually.

[13] *See* SPE Conference: Per- and Polyflouroalkyl Substances (PFAS) in the Plastics Industry 2024 | SPE.

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Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
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Other traditional alternatives to fluorinated containers also have major inherent limitations, making them inadequate to replace fluorination. And, despite what some commentors have claimed, there is no readily available alternative to fluorination, nor is there any indication that an alternative, with equivalent technical specifications and economic characteristics, is achievable in the near future. Fluorination, therefore, continues to perform a critical role in multiple sectors because of the lack of viable alternatives. For example:

- Multilayer, or coextruded containers may be suitable for certain applications that require barrier protection, but only if the containers are a standard shape and size. There is no multilayer capacity available for many of the unique container shapes and sizes that Inhance treats because multilayer coextrusion requires a high capital investment for each container mold. Moreover, multilayer containers with complex shapes typically yield significantly inferior barrier performance due to the "thin-walling" that occurs at the corners and edges of such containers. As a result, multilayer containers have demonstrated intermittent barrier failures in the field over the last several decades.

- Ionkraft's plasma coating technology is still in its infancy and under development. The technology is not currently available, nor has it been proven effective at production volumes.

- Centro's RotoLoPerm™ process for rotomolded fuel tanks involves significantly more processing time (as compared to fluorination) due to the multilayer construction. The process also experiences considerable yield losses, which has limited its adoption to date. Fluorination, on the other hand, provides a barrier solution that significantly simplifies the process of producing compliant rotomolded fuel tanks by using a monolayer construction that reduces cycle times and eliminates yield losses. These process advantages make fluorination of monolayer rotomolded fuel tanks a more reliable solution. In addition, fluorinated rotomolded fuel tanks are significantly lighter than Centro's RotoLoPerm fuel tanks, making them more sustainable.

- Glass and steel are also not feasible replacements for fluorinated plastic containers. While these materials could provide adequate barrier protection, they are significantly heavier than plastic, making it more difficult for products to be transported, stored, handled, and disposed. In certain situations, the use of a heavier material would be detrimental to overall performance (e.g., fuel tanks for outdoor vehicles or marine vessels). Additionally, glass is more brittle than plastic, making it a dangerous packaging substitute for certain products (e.g., pesticides).

III. Fluorination Does Not Pose an Elevated Risk to Human Health or the Environment.

a. Containers fluorinated by Inhance meet all applicable PFAS regulations.

To date, EPA has not promulgated any regulations limiting concentrations of PFAS in articles, including fluorinated containers. The European Union ("EU"), however, has set threshold limits on PFAS

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

in articles. Specifically, the European Chemicals Agency ("ECHA") requires that articles have 25 parts per billion ("ppb") or less for any singular PFAS compound and 250 ppb for all PFAS species in articles. Inhance has global operations, including in the EU, and ensures that all its fluorinated containers are compliant with all relevant regulations for PFAS in articles, including Substance of Very High Concern ("SVH"); Registrations, Evaluation, Authorization, and Restrictions of Chemicals ("REACH"); and Restrictions for Hazardous Substances ("RoHS") regulations.

b. The amounts of PFOA, PFNA, and PFDA that could be unintentionally formed during fluorination are insignificant.

The total amount of these PFAS compounds unintentionally generated as impurities during fluorination pales in comparison to amounts generated from other sources. As previously noted, to the extent that any PFOA, PFNA, or PFDA is generated during fluorination, such amounts are unintentionally formed at very low concentrations and are impurities that serve no commercial purpose. The amount of these very low concentrations of specific PFAS compounds unintentionally generated during fluorination amount to an infinitesimal fraction of the total amount of PFAS found in commerce.

Based on available data, Inhance has estimated the amount of PFAS in commerce from the sale of various products in the United States in 2023. These estimates were derived from a literature review of studies reporting detectable levels of PFAS in products. Importantly, Inhance did not attempt to quantify PFAS releases from industrial sources. As a result, its estimates of the amounts of the relevant PFAS species are highly conservative. Product categories considered as part of Inhance's estimates include: dental floss, non-stick cookware, lens wipes, manicure products, mascara, paints, plastics, sunscreen, food contact materials, textiles, textile finishing agents, thread sealant tapes, waterproofing products, automotive wax and polish, lip products, bike lubricants, dishwasher liquids, floor wax and sealants, electronic products, bowls, plastics, lids, utensils, trays, boots, foundation, bandages, and apparel. Inhance estimates that the following amounts of the relevant PFAS compounds were distributed in commerce from these categories in 2023:

- PFOA: Between 5,500 kilograms (5,500,000 grams) and 55,000 kilograms (55,000,000 grams)
- PFNA: Between 150 kilograms (150,000 grams) and 1,500 kilograms (1,500,000 grams)
- PFDA: Between 160 kilograms (160,000 grams) and 1,600 kilograms (1,600,000 grams)

By comparison, based on data collected from May 2024 through August 2024, Inhance estimates that less than *one gram cumulatively* of PFOA, PFNA, and PFDA are unintentionally formed as impurities in its barrier packaging across 25 million pounds of plastic articles treated annually.

EPA is aware of the continued use of PFAS in commerce and, as recently as June 2020, concluded that such uses do not present an unacceptable risk demanding a Section 6 rulemaking. The potential contribution of PFAS from fluorination, as compared to other continuing uses of PFAS

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

compounds, is minuscule. As such, there is no basis for EPA to find that a Section 6 rulemaking is needed to address fluorination, when it has already determined that a rulemaking was unnecessary to address a much broader range of uses across the economy.

In a June 2020 response to comments document, the agency noted that the "semiconductor and small electronic component manufacturing industries represent the largest portion of stakeholders with ongoing uses. Additionally, there continue to be uses of LCPFAC and PFAS chemical substances in firefighting foams, coatings, automotive articles, waterproofing emulsions, and other uses as noted in the final SNUR."[14] EPA was aware of these continuing uses and received comments during its Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use rulemaking asking for initiation of a Section 6 rule restricting the continued use of PFAS compounds already in commerce. Nonetheless, EPA affirmatively concluded that a Section 6 rule was unnecessary. In fact, EPA concluded "that a rule under TSCA section 5(a)(2), in conjunction with the 2010/2015 PFOA Stewardship Program, is an effective method to protect human health and the environment from any risks posed by LCPFAC and perfluoroalkyl sulfonate chemical substances."[15]

c. Inhance has shown that it can successfully reduce the unintentional formation of PFOA, PFNA, and PFDA to minute levels.

The results described above show that fluorination can be conducted in a manner that generates minimal amounts of PFOA, PFNA, and PFDA and does not present an unreasonable risk to human health or the environment. Over the last four years, Inhance has developed and implemented an extensive research and development ("R&D") program to address the issue of unintentional PFAS formation. As part of its R&D program, Inhance has performed extensive sampling and testing to optimize its fluorination process to prevent the unintentional formation of PFAS.

These R&D efforts have led to significant improvements in Inhance's fluorination process. Specifically, the company has modified its fluorination parameters (e.g., duration, temperature, pressure, fluorine concentration) and significantly upgraded its process equipment (e.g., installation of manifolds and upgrades of programmable logic controllers ("PLCs") at its facilities), all of which have been at Inhance's sole expense. Since implementing its R&D program, Inhance has reduced the unintentional formation of PFAS in fluorinated packaging by more than 90 percent. While the amount of PFAS unintentionally generated during fluorination is minuscule and insignificant, Inhance is continuing its R&D program to refine its processes to further suppress PFAS formation.

[14] *Response to Public Comments, Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule* (RIN 2080-AJ99) (June 2020) at 8 (hereinafter "Long-Chain PFAS SNUR RTC").
[15] *Id.* at 10.

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

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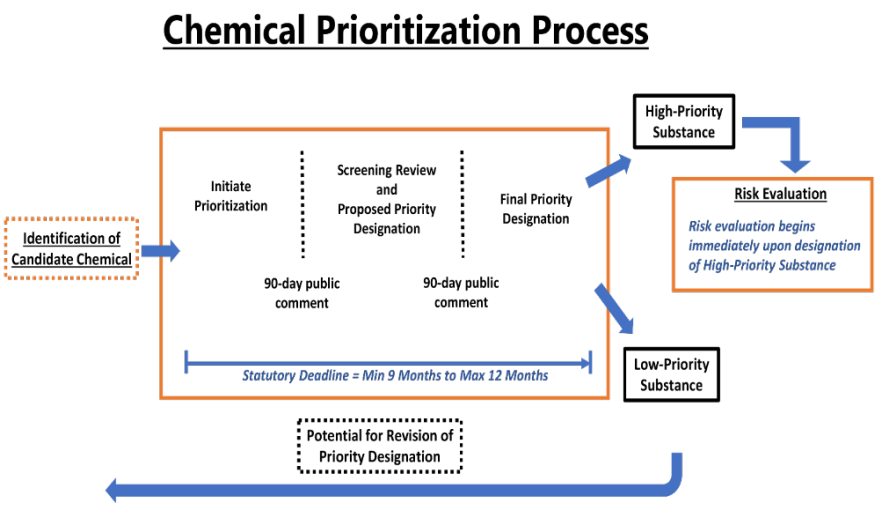
IV. EPA Must Adhere to Statutory and Regulatory Requirements if the Agency Intends to Undertake a Section 6 Rulemaking

a. EPA cannot skirt the prioritization process and immediately propose a Section 6 rule targeting "fluorination."

When promulgating a rule under TSCA Section 6, EPA must prioritize the chemicals that will undergo risk evaluations by designating them "high-priority" substances.[16] Once designated, EPA must initiate a risk evaluation to determine whether the chemical "presents an unreasonable risk of injury to health or the environment."[17] Under Section 6(h) of TSCA, EPA must forgo this typical process and take expedited action to complete Section 6(a) rules on certain persistent, bioaccumulative, and toxic ("PBT") chemicals. Specifically, chemicals identified under Section 6(h) do not need to undergo the prioritization process nor a risk evaluation.[18] Chemicals subject to Section 6(h) were identified in the 2014 update to the TSCA Work Plan for Chemical Assessments.[19] PFOA, PFNA, and PFDA were not included in the 2014 TSCA Work Plan. Therefore, regulation of these chemical substances must undergo the typical prioritization process. *See* Figure 1.

Figure 1. EPA Prioritization Process Under Section 6.



[16] 15 U.S.C. § 2605(b)(1)(A).
[17] *See, e.g.*, 88 Fed. Reg. 87423 (Dec. 18, 2023) (initiating prioritization process for acetaldehyde, acrylonitrile, benzamine, vinyl chloride, and 4,4-Methylene bis(2-chloroaniline)).
[18] 15 U.S.C. §§ 2605(h)(1), (2).
[19] U.S. EPA, *TSCA Work Plan for Chemical Assessments: 2014 Update* (Oct. 2014), available at https://www.epa.gov/sites/default/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

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22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

Section 6 requires EPA to consider the following factors when determining whether a chemical substance is a high or low priority for a risk evaluation: (1) hazard and exposure potential of the chemical substance; (2) persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage near significant sources of drinking water; (5) the conditions of use or significant changes in the conditions of use of the chemical substance; (6) the volume or significant changes in the volume of the chemical substance; and (7) other risk-based criteria that EPA determines to be relevant.[20]

At this stage, EPA lacks critical information to determine whether PFOA, PFNA, and PFDA under their current conditions of use should be considered a high priority for a risk evaluation. EPA's efforts to solicit information regarding fluorination—i.e., a single condition of use—cannot remedy this issue. Instead, to proceed with a Section 6 rule, EPA would need to issue a broader request for information soliciting comments on all uses of these PFAS compounds in all various scenarios and applications. EPA can only initiate the prioritization process after it collects the relevant information.

b. If EPA does designate PFOA, PFNA, and PFDA as "High-Priority Substances," the agency must conduct a new risk evaluation.

As noted above, once a chemical substance is deemed a "high-priority," EPA will conduct a risk evaluation "to determine whether a chemical substance present an unreasonable risk of injury to health or the environment."[21] Thus, EPA must prepare a risk evaluation consistent with Section 6(b)(4)(A) before issuing a proposed Section 6 rule. EPA recently confirmed this interpretation in its response to public comments received on its amendments to the agency's risk evaluation procedures under Section 6(b). In that document, EPA confirmed that "[b]y law, the Agency begins the process of determining appropriate risk management actions under TSCA section 6(a) *only after a determination of unreasonable risk is made in the risk evaluation.*"[22]

EPA previously considered Inhance's fluorination of containers and fuel tanks in connection with its review of significant new use notices ("SNUNs") that Inhance submitted to EPA under Section 5 of TSCA. As part of that review, EPA prepared engineering assessments, exposure assessments, and a so-called qualitative "risk assessment." Inhance maintains that EPA cannot rely on these analyses as a basis to engage in rulemaking under an entirely separate section of TSCA—and particularly under TSCA Section 6.[23] Furthermore, the information that was submitted by Inhance only provides risk information

[20] 15 U.S.C. § 2605(b)(1)(A).
[21] 15 U.S.C. § 2605(b)(4).
[22] U.S. EPA, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) EPA-HQ-OPPT-2023-0496: EPA Response to Comments, at § 1.2, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0496-0431 (emphasis added).
[23] EPA has recognized that risk characterizations under Section 5 of TSCA are qualitative, at best. For example, in its Long-Chain PFAS SNUR RTC, EPA notes that its "decision to finalize a SNUR for a particular chemical substance *is not based on an extensive evaluation of the hazard, exposure, or potential risk* associated with that chemical substance."

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

relevant to Inhance's fluorination technology and does not provide any data about the full spectrum of fluorination, which would include companies practicing all types of fluorination technologies in the United States, as well as any companies importing fluorinated articles.

Furthermore, EPA's qualitative "risk assessment," generated in connection with Inhance's SNUNs, is fundamentally flawed for numerous reasons. Among other things, EPA's assessment was not prepared consistent with industry standards. Instead, the assessment reads as a non-specific literature review that made broad, categorical conclusions (in many instances based on factually inaccurate statements) about potential exposure pathways without quantifying what, if any, risk may actually be present.

c. A Section 6 Rule Targeting "Fluorination" is Inconsistent with EPA's "Whole Chemical" Approach Under Section 6.

EPA has determined that Section 6 of TSCA requires it to consider *all* conditions of use when conducting a risk evaluation for a chemical substance. In May 2024, EPA amended its procedural framework rule for conducting risk evaluations to codify this requirement.[24] EPA explains that it "lacks authority to exclude conditions of use from the scope of the risk evaluation."[25] EPA states that "[t]he plain language of TSCA section 6(b)(4)(A) specifies that EPA must determine in a risk evaluation whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.'"[26] EPA further cautions that if it did not consider all conditions of use of a chemical, "the existence of unevaluated uses and exposures would perpetuate uncertainties as to the safety of existing chemicals in the marketplace—the very problem Congress sought to address through its reform efforts."[27]

EPA's failure to adhere to its own Section 6 regulations and policies would be a textbook example of a challengeable arbitrary and capricious action.[28] To proceed with a Section 6 rulemaking, EPA must evaluate whether PFOA, PFNA, and PFDA—under all of their conditions of use (i.e., not just as they relate to fluorination)—present an unreasonable risk; EPA cannot pursue a Section 6 rule selectively targeting fluorination.

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Long-Chain PFAS SNUR RTC at 16 (emphasis added). Such an evaluation is patently insufficient for decision-making under Section 6 of TSCA.

[24] 89 Fed. Reg. 37208 (May 3, 2024), codified at 40 C.F.R. Part 702, Subpart B.

[25] *Id.* at 37031.

[26] *Id.*

[27] *Id.*

[28] *See, e.g.*, *Mine Reclamation Corp. v. FERC,* 30 F.3d 1519, 1525 (D.C. Cir. 1994) ("[I]t is a well settled rule that an agency's failure to follow its own regulations is fatal to the deviant action.") (internal quotation marks and citation omitted).

Inhance Technologies
22008 North Berwick Drive
Houston, TX 77095
T: +1.281.578.1440 F: +1.877.701.5097
inhancetechnologies.com

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Inhance remains committed to working with EPA to ensure that any potential regulatory actions applicable to the fluorination industry are protective of human health and the environment, without causing any unnecessary disruption to supply chains critical to the United States economy.

Prakash Iyer
Chief Executive Officer
Inhance Technologies, LLC