ALERT

ENVIRONMENTAL

New to Whom? The Fifth Circuit strikes down EPA's attempt to regulate ongoing uses of PFAS under TSCA's "significant new use" provision.

March 27, 2024

Pittsburgh, PA and Washington, DC

Environmental Alert

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On March 21, 2024, the U.S. Court of Appeals for the Fifth Circuit issued an opinion in *Inhance Technologies, L.L.C. v. U.S. Environmental Protection Agency*, No. 23-60620 (5th Cir. Mar. 21, 2024) that confirmed the obvious: a company that has a 40-year history of using perfluoroalkyl substances (PFAS) in its fluorination manufacturing process is not engaged in a "significant new use" under the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-2697. While not preventing the U.S. Environmental Protection Agency (EPA) from regulating existing uses of PFAS under other TSCA provisions, this common-sense conclusion provides industry with much-needed clarity and predictability.

TSCA Background

TSCA was enacted in 1976 to regulate chemicals that "present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2601. EPA may do so in one of two ways. Under TSCA § 5, EPA may regulate the use of "new chemical substance[s]" and any "significant new use" of chemical substances. 15 U.S.C. § 2604. To determine whether use of a chemical substance is a significant new use, EPA considers four factors:

> (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). If the use is a significant new use, EPA issues a Significant New Use Rule (SNUR) for public notice and comment. *Id.* Industry wishing to engage in the significant new use then must submit a Significant New Use Notice (SNUN) at least 90 days in advance of manufacture or processing. *Id.* at § 2604(a)(1)(B)(i). EPA must review that SNUN and make one of three findings: "[1] the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment … [2] the information available …is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use … or [3] the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment." *Id.* at § 2604(a)(3). If EPA finds that there is an unreasonable risk or insufficient information to evaluate the risk, then it must issue an order prohibiting or limiting the chemical substance's manufacture. *Id.* at § 2604(e), (f).

Alternatively, under TSCA § 6, EPA may regulate any chemical substance—not just new chemical substances or significant new uses. *Id.* at § 2605. The broader authority conferred under TSCA § 6, however, is balanced by a more rigorous rulemaking process that requires EPA to perform, among other things, a cost-benefit analysis supporting the new regulation. *Id.* at § 2605(c)(2)(A)-(C).

In 2020, EPA invoked its authority under TSCA § 5 to finalize a SNUR designating as a significant new use any manufacture or processing of certain PFAS that would not be ongoing after December 31, 2015 or for which there

currently was no ongoing use (the "PFAS SNUR"). *Inhance Tech.*, No. 23-60620, at *5-6. EPA stated in the proposed PFAS SNUR that it would not designate ongoing uses as significant new uses, but it required companies seeking protection under this safe harbor to submit their prior manufacture and use of PFAS for approval. *Id.* at *11. EPA then excluded only the submitted ongoing uses from coverage under the final SNUR. *Id.* Notably, in the proposed PFAS SNUR, EPA included a non-exhaustive list of industries as potentially affected by the proposed rule, but did not include the fluorination industry on this list.

EPA orders Inhance to cease manufacturing or process PFAS

Inhance fluorinates plastic containers to create a barrier that prevents the containers' contents from leaching out and outside substances from permeating in. *Id.* at *2. Neither Inhance nor EPA was aware during the rulemaking process for the PFAS SNUR that fluorination involved the manufacture or processing of PFAS. *Id.* at *11. Because EPA had not identified the fluorination industry as one of the industries potentially subject to the PFAS SNUR Inhance did not submit a SNUN during the rulemaking process to invoke the safe harbor for ongoing uses. *Id.*

Two years after finalizing the PFAS SNUR, EPA learned that Inhance's fluorination process resulted in the creation of PFAS. *Id.* at *2. Relying on the PFAS SNUR, EPA issued Inhance a notice of violation ordering Inhance to either change its fluorination process to stop creating PFAS or temporarily cease fluorination resulting in the creation of PFAS. *Id.* Rather than complying with the notice of violation, however, Inhance submitted SNUNs for its fluorination process to EPA for review. *Id.*at *2-3. EPA completed its review by issuing orders prohibiting Inhance from manufacturing or processing PFAS through its fluorination process, and Inhance petitioned the Fifth Circuit for review. *Id.* at *3.

The Fifth Circuit considers what qualifies as a significant new use

At the heart of Inhance's petition for review was whether the creation of PFAS through its fluorination process was an ongoing use, which EPA could regulate only under TSCA § 6, or a significant new use, which EPA could regulate under TSCA § 5. TSCA does not define "significant new use" or "new," and the parties proposed very different definitions. EPA argued that a significant new use is any use "not previously known to EPA," *id.* at *9, whereas Inhance argued that a significant new use is a use "having recently come into existence" or "not previously existing," *id.* at *8. Inhance's fluorination process would qualify as a significant new use under EPA's definition, since its creation of PFAS was not known to EPA until 2022, but would not so qualify under Inhance's definition, since the process had been in place for decades.

The Fifth Circuit found Inhance's definition to be more persuasive for two reasons.

First, Inhance's definition better aligned with the TSCA's text, structure, and purpose. TSCA § 5 creates forward-looking requirements—requiring notice *before* manufacture and processing and requiring EPA to consider *projected* volumes and *reasonably anticipated* manners and methods of manufacturing. *Id.* at *9. The cost-benefit analysis required under TSCA § 6 also indicates that Congress intended a more careful balancing for processes that had previously existed. *Id.* at *10. And, at bottom, the idea that an existing use becomes "new" when discovered by EPA runs counter to common sense. *Id.*

Second, Inhance's definition avoids constitutional issues that would arise under EPA's definition. Because Inhance did not know that its fluorination process created PFAS during the PFAS SNUR rulemaking, it had no reason to know that it would be subject to the regulation or that it would need to submit a SNUN to take advantage of the regulation's safe harbor. EPA's definition thus would require Inhance—and companies in a similar position—to be clairvoyant in identifying their regulatory obligations. *Id.* at *11-12.

What it all means

The Fifth Circuit was careful to note in conclusion that its decision only prohibits EPA from invoking its TSCA § 5 authority to regulate ongoing uses of PFAS. EPA may continue to invoke its TSCA § 6 authority. As the Fifth Circuit acknowledged, though, the regulatory process under TSCA § 6 is more rigorous and requires a cost-benefit analysis that

is absent from the TSCA § 5 process. Given the difficulties some industries have faced in finding effective PFAS replacements, it is thus possible that ongoing uses that would have been prohibited or limited under TSCA § 5 will survive due to the cost-benefit analysis required under TSCA § 6. Though time will tell, this might prove to be the most significant consequence of the Fifth Circuit's decision.

As the federal and state governments continue to take action to address PFAS across many program areas, Babst Calland attorneys continue to track these developments and are available to assist you with PFAS-related matters. For more information on this development and other remediation matters, please contact Joseph V. Schaeffer at (412) 394-5499 or **jschaeffer@babstcalland.com**, Sloane Anders Wildman at (202) 853-3457 or **swildman@babstcalland.com**, or any of our other **environmental attorneys**.