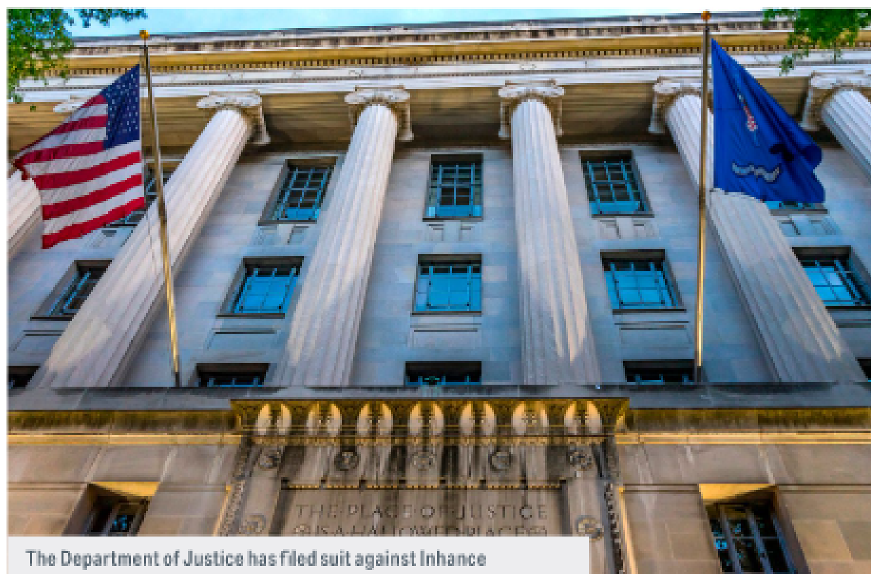
TSCA litigation: The case to watch

Lynn L. Bergeson of **Bergeson & Campbell** discusses some ongoing legal cases with big implications for chemical regulation in the US

The implementation of the game-changing 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act, amending the Toxic Substances Control Act (TSCA), is now a hotbed of legal dispute. Lawsuits challenging key aspects of the law's implementation are piling up. While all are legally noteworthy, one citizen enforcement case in particular merits attention.

As discussed below, two recent cases have raised novel issues pertinent to the scope of the Environmental Protection Agency's (EPA) Significant New Use Rule (SNUR) authority under TSCA Section 5 and a more general challenge to the agency's right to pre-empt citizen actions if the government is 'diligently prosecuting' the act a citizen plaintiff wishes to restrain. The resolution of these cases and both issues will have important implications, making these cases worth watching.



The Department of Justice has filed suit against Inhance

Background

On 19 December 2022, the Deparrment of Justice (DOJ) filed suit in the US District Court for the US Eastern District of Pennsylvania against Inhance Technologies USA to prevent Inhance from generating certain per- and polyfluoroalkyl substances (PFAS) when fluorinating plastic containers.

Only eight few days later, the Center for Environmental Health (CEH) and Public Employees for Environmental Responsibility (PEER), both citizen plaintiffs, filed a lawsuit in the US District Court for the District of Columbia (DC), also against Inhance, essentially for the same reasons. Why would citizen plaintiffs file suit under TSCA's citizen suit provision if DOJ had already brought an action alleging the same violations of TSCA? In short, it's complicated.

According to CEH and PEER, testing found PFAS chemicals on the inner and outer surfaces of fluorinated containers, and in the contents of the containers. These, according to the plaintiffs, probably resulted from chemical reactions that occur during Inhance's fluorination process.

The EPA had previously issued a Notice of Violation (NOV) to Inhance in March 2022 alleging that its fluorination process produces PFAS compounds in violation of the long-chain PFAS SNUR, which prohibits entities from producing perfluorooctanoic acid (PFOA) and other PFAS until the EPA is able to determine under TSCA Section 5 whether the proposed uses might present an unreasonable risk to health.

Late last year, Inhance filed 'under protest' SNUR notices for the uses in dispute. The EPA's review of these notices is ongoing. CEH and PEER are now seeking a court order restraining the company from continued manufacture of the PFAS and distribution of the fluorinated containers, and directing it to inform recipients of the containers that their activities constitute unlawful processing of the PFAS under the SNUR that must cease until the significant new use notice (SNUN) review process has been completed.

The fact that the DOJ had had filed its action in Pennsylvania, alleging substantially similar TSCA violations to those filed days later in CEH and PEER's suit in DC, begs two questions: why did the citizen plaintiffs file suit and is their case barred by TSCA Section 20(b)(1)(B), which precludes a legal action if the EPA is 'diligently prosecuting a proceeding' to issue an order under TSCA Section 16?

Inhance has filed a motion to dismiss the citizen suit on the grounds that the plaintiff failed to meet this statutory bar. Additionally, in its amicus brief, the DOJ states that it is diligently prosecuting the case against Inhance and similarly argues that the citizen plaintiffs' suit is barred on that basis. Aside from this procedural anomaly, the cases raise fascinating substantive issues testing the EPA's SNUR authority.

Discussion

These cases raise two key issues. The first involves what constitutes 'diligent' prosecution. While this issue has been raised and litigated in other contexts, this question appears to be a first under TSCA. At issue here is whether the government's actions to date are sufficiently 'diligent' to meet the standard.

Paragraph 35 of the citizens' complaint suggests the citizen plaintiffs are concerned with the government's diligence. It reads: "Because of the many redactions in the Complaint and the lengthy two-year delay between EPA's initiation of discussions with Enhance [*sic*] and the filing of its suit, plaintiffs are concerned that EPA will not 'diligently prosecute' its action in the Eastern District of Pennsylvania, removing a possible bar to plaintiffs' suit in this Court under TSCA section 20(b)(1)(B) and enabling plaintiffs to seek all relief authorized by law in this action."

In that there have been relatively few Section 20 citizen actions to compel a person or company to come into TSCA compliance, this case is one to watch. Regardless of Inhance's motion to dismiss, the citizens' lawsuit has turned up the heat on the government and highlighted what the citizens implicitly assert has been EPA's 'slow walking' its enforcement action against the company.

The second issue is whether EPA has exceeded its statutory authority under TSCA by asserting that Inhance's manufacturing activities identified in the complaint are 'new' uses subject to the SNUR. Inhance argues that the uses were pre-existing and ongoing well before the SNUR was issued.

Additionally, Inhance asserts that it had no reason to expect that the agency would require notification. It points to the EPA's 'open letter to industry' issued on 16 March 2022, after the NOV was sent to Inhance, explaining publicly for the first time that the agency was interpreting its SNUR to cover fluorination of containers.

Another interesting twist is whether the manufacture of the SNUR chemicals, both as a by-product of the fluorination process and also as impurities with no commercial purpose in the products being processed and distributed, is exempt from the SNUR notification requirements. Although the by-product exemption in the SNUR regulation itself, i.e. 40 CFR Section 721.45(e), appears not to cover the activity, the pre-manufacture notice (PMN) regulations exempt under 40 CFR Section 720.30(h)(2) any by-product "which is not used for commercial purposes".

This would appear to cover the by-products relevant here, especially when read in the context of the chapeau to 40 CFR Section 720.30(h) and 40 CFR Section 721.1(c) of the SNUR regulations, which states: "The provisions of part 720 of this chapter apply to this part 721. For purposes of this part 721, wherever the phrase 'new chemical substance' appears in part 720 of this chapter, it shall mean the chemical substance subject to this part 721. In the event of a conflict between the provisions of part 720 of this chapter and the provisions of this part 721, the provisions of this part 721 shall govern."

Arguably, there is no conflict between the SNUR regulation and the PMN regulations regarding the applicability of the exemption at 40 CFR Section 720.30(h)(2) to SNURs. In the absence of a provision making the exemption not applicable in specific SNURs, it would appear applicable. That the SNUR regulation exemptions duplicate certain PMN exemptions but exclude certain others should not necessarily be read to mean those excluded exemptions are not applicable, given the language in 40 CFR Section 721.1(c), as noted above.

Another interesting question that appears relevant is whether the manufacture of a substance as a by-product that is also an impurity in a product that is processed and distributed in commerce is not subject to the SNUR because the substance is not being manufactured 'for a use' within the meaning of TSCA Section 5(a)(1)(A)(ii) or, similarly, 'for any use' within the meaning of the SNUR, but is inadvertently produced and remains unintentionally present (as impurities) in the final product.

The EPA may be of the view that a by-product cannot also be an impurity if it is unintentionally present with another substance. This interpretation would be a dramatic departure from over 40 years of TSCA history.

Conclusion

Even if the citizen suit is dismissed on the grounds that the plaintiffs failed to show that the DOJ was not diligently prosecuting its case against Inhance, the court's decision (if articulated) will help define the degree of prosecution that is sufficiently 'diligent' to preclude a citizen suit. A resolution of the issues here around the scope of the EPA's Section 5 authority to regulate significant new uses of chemicals will be consequential and is much anticipated.

While the EPA can be expected to assert broad authority to regulate the generation of PFAS, their status here as by-products and/or impurities, and in the context of longstanding fluorination processes that were announced as subject to the SNUR years after the long-chain PFAS SNUR was issued, raises fundamental questions of fair notice and due process.

In short, stay tuned. These cases and the EPA's administrative deliberations on the SNURs will probably progress slowly but they will be worth the wait. •

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