

2 PFAS Actions Highlight Expanding Regulation of ‘Forever Chemicals’

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A pair of recent actions involving PFAS highlight the increasing governmental regulation of these substances and heightened judicial review of such regulation.

PFAS (per- and polyfluoroalkyl substances) are a family of chemicals with a unique resistance to oil, water and heat. Accordingly, PFAS have been used for decades in countless products ranging from food packaging to cosmetics to nonstick cookware to firefighting foams. A growing body of research indicates that PFAS are resistant to breaking down in both the environment and in humans, leading them to be dubbed “forever chemicals.”¹

Recently, the U.S. Food and Drug Administration has taken steps to increase its surveillance of foods that may be contaminated by PFAS or other chemical contaminants. Specifically, FDA recently issued an Import Alert for food products with “detectable levels of chemical contaminants that may present a safety concern to human health,” including PFAS.²

EPA has also recently proposed new analytical tests for PFAS detection, begun requiring PFAS reporting for companies, and issued orders prohibiting chemical companies from manufacturing PFAS-containing products.

EPA Stop-Manufacturing Orders Vacated by Fifth Circuit

In late March 2024, a unanimous three-judge panel on the Fifth Circuit vacated two EPA orders issued under the Toxic Substances Control Act (TSCA) prohibiting a Texas company from manufacturing plastic containers that created PFAS as a byproduct.³ The EPA orders were issued after the Agency discovered that the company, Inhance Technologies, used a fluorination process that created PFAS compounds when reinforcing its manufactured plastic packaging. Section 5 of TSCA allows EPA to regulate new chemical substances and “significant new uses” of existing chemical substances.⁴

The Fifth Circuit panel found that EPA had exceeded its statutory authority under Section 5 because Inhance’s fluorination process had been used for decades and therefore was not a “significant new use” of existing chemical substances as required under TSCA.⁵ This decision sheds light on how courts may handle EPA’s recent, more aggressive action to regulate PFAS.

FDA Import Alert Issued to Prevent Import of PFAS-Contaminated Food Products

Also in March 2024, FDA issued an Import Alert for food products containing PFAS or other chemical contaminants. The FDA issues Import Alerts to FDA staff and publishes such alerts to the public at large to provide notice that FDA has evidence allowing it to detain imported products that appear to violate FDA regulations.⁶ Import Alert 99-48, *Detention without Physical Examination of*

Foods Due to Chemical Contamination, was issued by FDA following a targeted survey for PFAS by FDA in 81 seafood samples collected at retail in 2022. FDA determined that the estimated exposure to perfluorooctanoic acid (PFOA), a type of PFAS, from certain samples of canned claims from China is a likely health concern. The FDA also plans an additional targeted survey of molluscan shellfish in 2024 and may use the Import Alert to refuse entry of foods with chemical contaminants, including seafood contaminated with PFAS.⁷

Import Alerts are one of FDA's stronger enforcement mechanisms given the authority that the federal Food, Drug, and Cosmetic Act provides to FDA under Section 801 to refuse the admission of shipments merely on the basis that, after examination by FDA, the products appear to be adulterated or otherwise violative of the Act. Once a firm is added to the "Red List" of an Import Alert, getting off of that list—and avoiding the refusal of shipments—is challenging. Import Alert 99-48 provides guidance to secure release of an individual shipment subject to detention without physical examination under the alert. Specifically, the FDA must receive a private laboratory analysis of a representative sample of the shipment that demonstrates the product does not bear or contain levels of chemical contaminants that may render it injurious to health. In order to remove a firm from the Red List, the firm must adequately demonstrate that it has resolved the conditions that gave rise to the appearance of the violation. Typically, this will take at least five consecutive demonstrably non-violative shipments (as demonstrated by private laboratory analysis conducted and submitted in accordance with FDA's guidance), as well as demonstrated corrective actions. To avoid such consequences, importers will want to be mindful of assessing whether there is a risk of PFAS or other chemical contaminants with respect to foods intended for import.

¹ *PFAS Explained*, EPA, <https://www.epa.gov/pfas/pfas-explained> (Oct. 25, 2023).

² *FDA Issues Import Alert for Food Products with Chemical Contaminants Including PFAS*, FDA (Mar. 20, 2024), <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-import-alert-food-products-chemical-contaminants-including-pfas>.

³ *Inhance Technologies, L.L.C. v. EPA*, No. 23-60620, 2024 WL 1208967 at *1 (5th Cir. Mar 21, 2024).

⁴ *Id.* at *2.

⁵ *Id.* at *4–6.

⁶ *Import Alert 99-48*, FDA (Mar. 19, 2024), https://www.accessdata.fda.gov/cms_ia/importalert_1180.html.

⁷ *Id.*