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EPA Puts Industry on Notice of Potential TSCA Violations for PFAS Contamination in Plastic Containers

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Does your company manufacture, process, distribute, use, or dispose of fluorinated high-density polyethylene (HDPE) containers and similar plastics? If so, it may be time for supply chain and process reviews aimed at identifying and eliminating possible per- and polyfluoroalkyl substance (PFAS) contamination.

In a <u>March 16, 2022 open letter</u> to HDPE manufacturers and users, EPA announced that the versatile plastic commonly used for storing and transporting pesticides, food products, personal care products, and a wide range of other products may be contaminated with PFAS—and that companies may be violating the Toxic Substances Control Act (TSCA). Because TSCA civil penalties can be assessed up to \$43,611 for each day a violation occurs, potentially affected companies should carefully consider EPA's letter.

In the letter, EPA explained that fluorination—the process creating the high-performance barrier designed to reduce permeation through container walls and protect against degradation—could result in the unintentional manufacture of PFAS. The presence in HDPE containers (or any other products) of long-chain PFAS identified in EPA's 2020 long-chain perfluoroalkyl carboxylate (LCPFAC) Significant New Use Rule (SNUR) may be violations under TSCA. Although the LCPFAC SNUR contains a limited exemption for long-chain PFAS present only as byproducts, the exemption applies only to byproducts used as fuel, disposed of as waste, or from which component chemical substances are extracted for commercial purposes.

Accordingly, any company whose process results in the manufacture of a long-chain PFAS identified in the LCPFAC SNUR that does not meet the byproduct exemption criteria must notify EPA 90 days prior to commencing manufacture (including import) or processing of the substance and wait for EPA's review and approval. Advance notification requirements also apply to any company that plans to import a product containing certain LCPFAC chemicals as part of a surface coating on the product. Given EPA's current stance on PFAS, it is highly unlikely that any approval would be granted, meaning that the LCPFAC SNUR operates effectively as a ban, including for HDPE processes that result in the manufacture of PFAS that remains in the finished HDPE container (or otherwise does not meet the byproduct exemption criteria for SNURs). And in the absence of specific EPA approval, the presence of long-chain PFAS in HDPE containers could subject companies to significant and costly TSCA penalties.

EPA has been investigating PFAS contamination in HDPE containers since at least September 2020, when it was alerted (through "citizen science testing") to potential PFAS contamination of a mosquito control pesticide product. In March 2021, EPA <u>announced</u> that testing had determined that an HDPE container used to store and transport a mosquito control pesticide contained PFAS compounds that leached into the pesticide. EPA's March 16, 2022 letter discloses that EPA has continued to investigate the scope of potential PFAS contamination in HDPE containers, even beyond pesticide products.

EPA is not the only agency concerned about PFAS contamination in HDPE containers. As we previously reported, in August 2021, the Food and Drug Administration (FDA) issued an open letter to manufacturers, distributors, and users of fluorinated polyethylene food contact articles warning of the possible unintended manufacture of PFAS during fluorination. FDA reminded stakeholders that fluorinated polyethylene containers for food contact use may be manufactured only in accordance with <u>21 C.F.R. § 177.1615</u>, which specifies that only gaseous nitrogen may be used in combination with fluorine gas during fluorination. In its March 16, 2022 letter, EPA likewise directed the HDPE industry to gaseous nitrogen as a possible alternative to fluorination processes that may lead to the manufacture of PFAS (e.g., the use of oxygen).

EPA's letter to the HDPE community is just the latest in a series of aggressive actions taken by the agency in support of its <u>PFAS Strategic Roadmap</u>. Given these warning shots EPA has recently fired with respect to PFAS, companies that manufacture or use HDPE containers would be well advised to undertake careful reviews of their supply chains and processes—and make swift changes if needed—to ensure that there is no risk of PFAS formation during manufacture.

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