



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dear Manufacturers, Processors, Distributors, Users, and Those that Dispose of Fluorinated Polyolefin Containers:

The U.S. Environmental Protection Agency (EPA) is directing this information to manufacturers (including importers), processors, distributors, users, and those that dispose of fluorinated high-density polyethylene (HDPE) containers and similar plastics (i.e., fluorinated polyolefins). EPA was made aware of and determined via testing that certain per- and polyfluoroalkyl substances (PFAS) have formed and migrated from these fluorinated polyolefins.¹ The contamination was first noted in HDPE containers used to store and transport a pesticide product.² As the Agency continues to determine the potential scope of the use of this fluorination process outside of its use for pesticide storage containers, EPA is issuing this letter to: (1) remind industry of this issue to help prevent unintended PFAS formation and contamination and (2) emphasize the requirement under the Toxic Substances Control Act (TSCA) as it relates to PFAS and fluorinated polyolefins. These efforts are in line with EPA's recently released PFAS Strategic Roadmap, which includes ambitious steps to further the science and research to restrict these PFAS from impacting human health and the environment.³

Fluorinated Polyolefins Containers and PFAS Formation. The process of fluorinating polyolefins involves the modification of certain types of polymers (plastics), using fluorine to create a high-performance barrier that is meant to mitigate permeation through container walls, as well as protect against environmental weathering and degradation of the plastic. Fluorination can occur before or after the shaping process of the HDPE containers or similar plastic and the fluorinated containers can be used to store and transport a variety of products.

It is during certain types of fluorination (e.g., the presence of oxygen) that the manufacture of PFAS has occurred. Manufacturers (including importers), processors, distributors, users, and those that dispose of fluorinated HDPE containers should be reminded of this potential for manufacturing PFAS and comply with any applicable regulations under TSCA, as described in the next section.

EPA is aware of alternative fluorination processes that use fluorine gas in the presence of gaseous inert (e.g., nitrogen) without the presence of oxygen that could reduce the potential for unintentional manufacture of PFAS. These alternative processes for fluorination of polyethylene are highlighted in the U.S. Food and Drug Administration's (FDA) August 2021 letter on this issue as it relates to food contact articles.⁴

¹ U.S. EPA's Analytical Chemistry Branch PFAS Testing of Selected Fluorinated and Non-Fluorinated HDPE Containers, https://www.epa.gov/sites/default/files/2021-03/documents/results-of-rinsates-samples_03042021.pdf

² <https://www.epa.gov/newsreleases/epa-takes-action-investigate-pfas-contamination>

³ https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

⁴ U.S. Food and Drug Administration's August 2021 Letter: <https://www.fda.gov/media/151326/download>

Requirements under TSCA PFAS Significant New Use Rules. Certain PFAS, including long-chain PFAS as defined in EPA’s 2020 long-chain perfluoroalkyl carboxylate (LCPFAC) Significant New Use Rule (SNUR) (40 CFR § 721.10536), that are found to be present in or on fluorinated polyolefins may be subject to TSCA regulations and enforcement. EPA considers the manufacturing of certain PFAS from the fluorination of polyolefins to be a significant new use under TSCA. LCPFAC chemical substances present in polyolefins due to the fluorination process would be considered byproducts of the manufacturing process because they are produced during the manufacture of the fluorinated polyolefins and do not have a separate commercial intent (40 CFR § 720.3(d)). LCPFAC chemical substances that are byproducts of the manufacturing process for fluorinated polyolefins do not meet the requirements of the byproducts exemption at 40 CFR § 721.45(e)⁵ and are subject to significant new use notice requirements. Significant new use rules require industry to notify EPA at least 90 days before commencing the manufacture (including import) or processing of subject chemical substances for a significant new use. The required significant new use notification (SNUN) initiates EPA’s evaluation of the conditions of use associated with the significant new use. Entities may not commence manufacturing (including import) or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. [Learn more about filing a SNUN.](#)

EPA encourages manufacturers to assess their processes to ensure they are complying with existing EPA regulations, as well as to review the full requirements in the EPA regulations at 40 CFR part 721.

If regulated entities have any questions concerning this subject, they are encouraged to contact the Existing Chemicals Risk Management Division in the Office of Pollution Prevention and Toxics at TSCA_PFAS@epa.gov.

Sincerely,

Tala R. Henry, Ph.D.
Deputy Director
Office of Pollution Prevention & Toxics

⁵ “(e) The person manufactures, imports, or processes the substance only as a byproduct which is used only by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes.” (40 CFR § 721.45(e))