



August 5, 2021

Dear Manufacturers, Distributors, and Users of Fluorinated Polyethylene Food Contact Articles:

The U.S. Food and Drug Administration (FDA) is directing this letter to manufacturers, distributors, and food manufacturers that use fluorinated polyethylene food contact articles as a reminder that only certain fluorinated polyethylene containers are authorized for food contact use. Specifically, FDA's regulation authorizing the use of fluorinated polyethylene in contact with food is listed in Title 21 of the Code of Federal Regulations Part 177.1615 (21 CFR 177.1615).<sup>1</sup> This regulation stipulates that fluorinated polyethylene containers for food contact use may only be manufactured by modifying the surface of the molded container using fluorine gas in combination with gaseous nitrogen as an inert diluent. The regulation does not authorize fluorination in the presence of water, oxygen, or gases other than nitrogen.

Available information indicates that some manufacturers of fluorinated polyethylene produce articles via alternative manufacturing methods from that stipulated in FDA's regulation. For example, fluorination of polyethylene for non-food uses may occur during the fabrication or molding of the container<sup>2</sup> or involve the use of fluorine gas in combination with other inert diluents such as carbon dioxide, helium, or argon.<sup>3,4</sup> Oxygen can also be incorporated into the fluorinating mixture to modify the properties of the final container.<sup>3,5</sup> These alternative processes for fluorination of polyethylene are not compliant with 21 CFR 177.1615, and are not lawful for use in food contact articles. It is the responsibility of food packaging manufacturers and distributors to only market fluorinated polyethylene containers that are manufactured in compliance with FDA's regulations.

Recently, based on testing performed by the Environmental Protection Agency (EPA),<sup>6</sup> FDA has become aware that certain per- and polyfluoroalkyl substances (PFAS) can form and migrate from some fluorinated high-density polyethylene (HDPE – a type of polyethylene) containers.<sup>7</sup> EPA's testing was conducted on containers that are not regulated by FDA (containers intended to hold mosquito-controlling pesticides not approved for direct use on food crops). However, we are concerned that such containers could also be used in contact with food. The specific PFAS detected in EPA's testing are perfluoroalkyl carboxylic acids (PFCAs). Several of these PFCAs are either known or suspected to

---

1 Title 21 Code of Federal Regulations (CFR) Part 177.1615 *Polyethylene, Fluorinated* [https://www.ecfr.gov/cgi-bin/text-idx?SID=344ecfb48f994e11f8fccd039875cceb&mc=true&node=se21.3.177\\_11615&rgn=div8](https://www.ecfr.gov/cgi-bin/text-idx?SID=344ecfb48f994e11f8fccd039875cceb&mc=true&node=se21.3.177_11615&rgn=div8)

2 A.P. Kharitonov, Practical applications of the direct fluorination of polymers. *Journal of Fluorine Chemistry*, 2000, 103, 123-127.

3 A.P. Kharitonov, R. Taeye, G. Ferrier, N.P. Piven, The kinetics and mechanism of the direct fluorination of polyethylenes. *Surface Coatings International Part B: Coatings Transactions*, 2005, 88 (B3), 157-230

4 A.W. Hawkins, M.J. O'Hara, F. P. Gortsema, E. Hedaya, U.S. Patent 3,988,180, December 21, 1976.

5 J.P. Hobbs, J. F. Dei Tos, M. Anand, U.S. Patent 5,770,135, June 23, 1998.

6 U.S. EPA's Analytical Chemistry Branch PFAS Testing of Selected Fluorinated and Non-Fluorinated HDPE

Containers [https://www.epa.gov/sites/production/files/2021-03/documents/results-of-rinsates-samples\\_03042021.pdf](https://www.epa.gov/sites/production/files/2021-03/documents/results-of-rinsates-samples_03042021.pdf)

7 Per- and Polyfluoroalkyl Substances (PFAS) in Pesticide Packaging <https://www.epa.gov/pesticides/pfas-packaging>

biopersist in humans and are associated with adverse health effects.<sup>8, 9, 10</sup> Analytical studies find that PFCAs can form when the fluorination of HDPE occurs in the presence of oxygen or water, but not in the presence of nitrogen.<sup>11</sup> As noted above, FDA's regulation does not authorize fluorination of polyethylene containers in the presence of water, oxygen, or gases other than nitrogen.

Substances that are reasonably expected to become a component of food under their intended conditions of use are food additives (section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) if they are not prior sanctioned or generally recognized as safe (GRAS) for their use. All food additives are required to undergo FDA premarket approval in accordance with section 409 of the FD&C Act. Fluorinated polyethylene food containers that are not manufactured in compliance with 21 CFR 177.1615 are adulterated within the meaning of section 402(q)(2)(C) of the FD&C Act. Manufacturers and distributors should also note that 21 CFR 174.5(a)(2) requires that any substance used in contact with food shall be of a purity suitable for its intended use. Food producers, distributors, and manufacturers are responsible for complying with all aspects of the FD&C Act.

As always, manufacturers and distributors are encouraged to consult with FDA regarding the regulatory status of any substances used in contact with food, including processes used during the manufacturing of the final food contact container.

If you have any questions concerning this matter, please do not hesitate to contact us at [premarkt@fda.hhs.gov](mailto:premarkt@fda.hhs.gov).

Sincerely,

Dennis M. Keefe, Ph.D.  
Director  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition

---

8 EFSA (2020) Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA J., 10.2903/j.efsa.2020.6223.

9 Rice, P. (2019) Human health risk assessment of perfluorinated chemicals. *In* Environmental and Occupational Health Series—Perfluoroalkyl Substances in the Environment: Theory, Practice, and Innovation, D.M. Kempisty, Y. Xing, and L. Racz, eds., CRC Press, Boca Raton, FL., 521 p.

10 Rice, Penelope, Bandele, Omari, and Honigfort, Paul (2014), Perfluorinated compounds in food contact materials. *In* Toxicants in Food Packaging and Household Plastics, S.M. Snedeker. ed., Humana Press, New York, NY, 310 p.

11 A. A. Rand, S. A. Mabury, Perfluorinated Carboxylic Acids in Directly Fluorinated High-Density Polyethylene Material. *Environmental Science & Technology*, 2011, 45, 8053-8059.