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FDA REACHES VOLUNTARY AGREEMENT WITH MANUFACTURERS TO PHASE OUT CERTAIN SHORT-CHAIN PFAS IN FOOD PACKAGING

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The U.S. Food and Drug Administration has announced that manufacturers of certain per- and polyfluoroalkyl substances (PFAS) used for grease proofing in paper and paperboard for food packaging (for example, as coatings on some fast food wrappers, to-go boxes, and pizza boxes) have voluntarily agreed to phase out sales of these substances for use as food contact substances in the United States, following new analyses of data raising questions about potential human health risks from chronic dietary exposure.

Starting in January 2021, three manufacturers will begin a three-year phase out of their sales of certain substances that contain 6:2 FTOH for use as food contact substances in the U.S. marketplace. It may take up to 18 months after the phase-out period to exhaust existing stocks of paper and paperboard products containing these food contact substances from the market. A fourth manufacturer informed the FDA in 2019 that they have stopped sales of their short-chain PFAS products in the U.S. market.

According to the FDA, this phase out balances uncertainty about the potential for public health risks with minimizing potential market disruptions to food packaging supply chains during the COVID-19 public health emergency. Earlier this year, FDA scientists published their analyses of studies on certain PFAS used in food packaging. Their analyses of data from rodent studies raised questions about a subset of short-chain PFAS that contain 6:2 fluorotelomer alcohol (6:2 FTOH) because of evidence of biopersistence.

The four manufacturers of these short-chain grease-proofing agents previously obtained authorization for the use in food contact paper packaging applications through the FDA's Food Contact Notification (FCN) process, whichexamines whether food contact substances (FCSs) are safe for their intended use. Following analysis of the recent studies, the FDA engaged the manufacturers in discussions concerning the voluntary phase out. The manufacturers' voluntary phase-out commitments will be noted in the FDA's Inventory of Effective Food Contact Substance Notifications, which is how the FDA informs both the public and industry of substances authorized through the FCN program.

In addition to monitoring data regarding food contact applications, including reviewing the limited authorized uses of certain PFAS in food contact applications, the FDA continues to assess foods for possible PFAS contamination, with the goal of monitoring levels in the food supply.

What Does This Mean for Businesses in the Food Packaging Industry

- This is a voluntary cessation of sales by the chemical manufacturers, so no action is required by downstream users.
- · However, downstream users of these products should identify alternatives that meet their quality and performance standards to avoid disruption in their supply chain.
- · Chemical manufacturers, and downstream chemical users in the food packaging space should consider an evaluation of the PFAS concentration in their products to minimize disruption from future regulatory action.

BCLP's PFAs Team has been closely monitoring regulation of PFAs, and has published "PFAs 101" explaining what PFAs are, where they are found, and risk mitigation strategies. For questions or more information, please contact the authors or a member of the PFAs Team.

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