



## MEMORANDUM

**SUBJECT:** Notes from Meeting with the United States Food and Drug Administration

**FROM:** Engineering and Analysis Division  
Office of Water  
United States Environmental Protection Agency

**FOR:** Effluent Limitations Guidelines and Standards Planning Record

**DATE:** July 7, 2022

On April 25, 2022, the United States Environmental Protection Agency (EPA) met with representatives from the United States Food and Drug Administration (FDA) to discuss use of per- and polyfluoroalkyl substances (PFAS) in food contact substances. See Table 1 for a list of meeting attendees, along with professional affiliation and contact information.

**Table 1. Meeting Attendees**

Name	Affiliation	Email
Sharon Koh-Fallet	FDA, Office of Food Additive Safety	<a href="mailto:Sharon.Koh-Fallet@fda.hhs.gov">Sharon.Koh-Fallet@fda.hhs.gov</a>
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Paul Honigfort	FDA, Office of Food Additive Safety	<a href="mailto:Paul.Honigfort@fda.hhs.gov">Paul.Honigfort@fda.hhs.gov</a>
Paul South	FDA, Office of Food Additive Safety	<a href="mailto:Paul.South@fda.hhs.gov">Paul.South@fda.hhs.gov</a>
Alix Heard	FDA, Executive Office	
Doruntinë Rexhepi	EPA, ELG Planning Lead	<a href="mailto:Rexhepi.Doruntine@epa.gov">Rexhepi.Doruntine@epa.gov</a>
Ryan Novak	ERG (EPA contractor)	<a href="mailto:Ryan.Novak@erg.com">Ryan.Novak@erg.com</a>

Below is a summary of the topics discussed during the meeting. A presentation provided by EPA during the meeting is included in these notes as Attachment 1.

### Meeting Background

In September 2021, EPA published its [Preliminary Effluent Guidelines Program Plan 15](#), announcing several efforts to address industrial discharges of PFAS, including rulemakings for the Organic Chemicals, Plastics, Synthetics, and Fibers (OCPSF) and Metal Finishing point source categories and detailed studies for the Landfills and Textile Mills point source categories. Preliminary Effluent Guidelines Program Plan 15 and a supporting report, [Multi-Industry PFAS Study – 2021 Preliminary Report](#), also summarize EPA's collection and review of available information and data concerning PFAS discharges from the Pulp, Paper, and Paperboard point source category. While EPA announced it was not prioritizing a rulemaking for the Pulp, Paper, and Paperboard category at this time, the Agency stated it would continue to study pulp and paper mill PFAS use and potential for PFAS wastewater discharges. See Attachment 1 for additional

discussion of EPA's findings for the Pulp, Paper, and Paperboard category and the effluent guidelines program.

PFAS are primarily used by Pulp, Paper, and Paperboard facilities that manufacture food contact papers and packaging (e.g., fast food wrappers, take-out containers, bakery bags, popcorn bags, pizza box liners), but also have limited applications for specialty paper products (e.g., carbonless forms, masking paper). Chemicals used in food contact applications are regulated by the FDA because of their potential to migrate to food. As part of the Multi-Industry PFAS Study, EPA determined that certain PFAS are approved for use in food contact applications including nonstick cookware, food processing equipment, processing aids, and food contact paper and packaging for their non-stick and grease, oil, and water-resistant properties. EPA requested this meeting with the FDA to discuss historical and ongoing use of PFAS in food contact applications, with a focus on food contact paper and packaging, and the FDA's review of these chemicals.

### **Discussion of PFAS Use in Food Contact Paper and Packaging**

All food contact substances (FCS) must be authorized by the FDA prior to marketing and typically come through the Food Contact Substance Notification (FCN) Program, under which the FDA will review available migration, exposure, and human health risk data to ensure a FCS is safe for its intended use prior to approving it for use in market. Manufacturers of chemicals authorized to be used as a FCS are permitted to market and sell these chemicals to food contact paper and packaging producers who will use them in their products sold into food contact applications.

Since the 1960s, the FDA has authorized several PFAS for use as FCS including certain long-chain PFAS<sup>1</sup> and more recently short-chain fluorotelomer PFAS and polyfluorinated polymers (e.g., six-carbon side-chain fluorinated polymers, perfluoropolyethers). When the FDA identifies potential safety concerns with a FCS, the agency may work with industry to obtain voluntary market phase-out agreements or revoke food contact authorizations. In 2011, the FDA worked with three manufacturers (DuPont, Clariant Corporation, and BASF Corporation) to voluntarily end sales of several FCS containing long-chain PFAS for food contact applications. In 2016, the FDA revoked authorizations for the remaining uses of FCS containing long-chain PFAS and these chemicals are no longer approved for use in food contact applications in the United States. In July 2020, the FDA announced that four manufacturers will voluntarily phase-out the use of PFAS FCS containing or degrading to 6:2 FTOH in food contact paper and packaging. The market phase-out is a response to FDA research that raised questions about human health risks for 6:2 FTOH. The four manufacturers (AGC, Chemours, Daikin, and Archroma) hold FCNs for approximately 11 PFAS FCS containing or degrading to 6:2 FTOH. AGC, Daikin, and Archroma agreed to a complete market phase-out of PFAS containing 6:2 FTOH by December 31, 2023; Chemours has already stopped sales of 6:2 FTOH-containing products in the United States. The FDA stated that it expects the remaining three manufacturers will complete the phase-out according to the agreed upon schedule. Additional information on authorized uses of PFAS in food contact applications and this voluntary phase-out is available on the FDA's website at <https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications>.

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<sup>1</sup> While the FDA has authorized several long-chain PFAS for use as FCS, the FDA has never authorized perfluorooctanoic acid (PFOA) or perfluorooctane sulfonic acid (PFOS). Although PFOA and PFOS were not authorized by the FDA for food contact use, these chemicals were used in the manufacture of previously authorized substances and may have been present as a residual impurity or by result of degradation of a long-chain PFAS.

As part of the Multi-Industry PFAS Study, EPA identified eight facilities operated by five companies that used PFAS in the manufacture of grease-resistant food contact papers and packaging in calendar year 2020. EPA asked the FDA if they were aware of any additional facilities or companies using PFAS. The FDA responded that it does not have information on specific facilities or companies using PFAS in the manufacture of food contact paper or packaging. The FDA requires food contact paper and packaging manufacturers use only approved FCS but does not collect information on which approved FCS companies/facilities are actually using.

EPA asked the FDA whether manufacturers are substituting revoked or voluntarily phased out PFAS with alternative PFAS or nonfluorinated substances. The FDA stated that one manufacturer, Daikin, is seeking to replace 6:2 FTOH with a nonfluorinated chemical that is also authorized by the FDA; however, the FDA does not have any additional information on the industry's plan to replace these chemicals. While manufacturers are free to submit FCN applications to use other PFAS in food contact paper and packaging, the FDA expects that its review of available data to determine if that data demonstrate a reasonable certainty of no harm for its intended use would be highly scrutinized. The FDA noted that public pressure and consumer demand for PFAS-free products may encourage manufacturers to seek nonfluorinated replacements.