ENVIRONMENTAL DEFENSE FUND, BREAST CANCER PREVENTION PARTNERS, CENTER FOR FOOD SAFETY AND ENVIRONMENTAL WORKING GROUP

September 18, 2023

Dr. Kristi Muldoon-Jacobs
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
5100 Campus Drive
College Park, MD 20740-3835

Re: Food additive petition asking FDA to revoke its approvals of fluorinated plastic pursuant to 21 U.S.C. § 348

Dear Dr. Muldoon-Jacobs:

We submit this food additive petition pursuant to section 409(b) of Federal Food, Drug, and Cosmetic Act requesting that the Food and Drug Administration (FDA) remove its approval of the use of fluorinated polyethylene as an indirect food additive at 21 C.F.R. § 177.1615. Recent scientific studies raise serious questions about the safety of fluorinated polyethylene's use in contact with food such that the use no longer meets the applicable standard of safety. The applicable safety standard is that there must be "reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use" after considering:

- "The probable consumption of the substance and any substance formed in or on food because of its use,"
- "The cumulative effect of substance in the diet, taking into account any chemically or pharmacologically related substance or substances in the diet."
- "Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate." 21 C.F.R. § 170.3(i).

The fluorinated polyethylene manufactured consistent with § 177.1615 produces ***polymeric*** per- and poly-fluorinated alkyl substances (PFAS) by replacing some or all of the hydrogens on the carbon alkyl chains in the polyethylene.[1] Because fluorine is so reactive, it may also break the covalent bonds joining some of the carbons together in the polymer. If this occurs in the presence of oxygen or water, the fluorination process is likely to form harmful ***short-chain and long-chain***[2] PFAS known as perfluoroalkyl carboxylic acids (PFCA).[3]

These substances are commonly known as "forever chemicals" because they do not degrade in the environment. According to the White House, some "'forever chemicals,' are a set of human-made chemicals that can cause cancer and other severe health problems. Found in air, drinking water, and our

[1] FDA, Letter to Manufacturers, Distributors, and Users of Fluorinated Polyethylene Food Contact Articles, August 5, 2021, at https://www.fda.gov/media/151326/download.
[2] Short chains have seven or less carbons in an alkyl chain. Long-chains have eight or more carbons in an alkyl chain. See FDA, Authorized Uses of PFAS in Food Contact Applications, accessed on June 23, 2023 at https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications.
[3] FDA, Letter to Manufacturers, Distributors, and Users of Fluorinated Polyethylene Food Contact Articles, August 5, 2021, at https://www.fda.gov/media/151326/download.

food supply, PFAS pollution disproportionately affects disadvantaged communities, and poses a serious threat across rural, suburban, and urban areas."[4]

Without regard to the risks of generating harmful short- and long-chain PFAS[5], we are concerned that fluorinated polyethylene food contact materials present potentially significant risks to both the workers at and the communities around the facilities that either produce the materials or incinerate, landfill, or recycle them. In light of the many other food contact materials that have similar or better performance and do not involve PFAS,[6] pursuant to the National Environmental Policy Act (NEPA),[7] we determined that the only ethical and legal option would be to stop all polyethylene fluorination treatment.

For these reasons, as explained in more detail below, we maintain that FDA should take the necessary steps to protect the public by removing its approval of the use of fluorinated polyethylene as an indirect food additive at § 177.1615.

I. Sources of oxygen and water that contribute to forming short-and long-chain PFAS

Oxygen is essential to forming short- and long-chain PFCA. Section 177.1615 allows a mixture of only nitrogen and fluorine gas to be present. Oxygen gas is not allowed to be intentionally used. However, oxygen may be present from any of these three sources:

1. As a contaminant in nitrogen gas that is blended with fluorine gas;
2. Saturated in the polyethylene when the pellets or other articles are manufactured; and
3. Ambient air around the polyethylene when it is molded into pellets, films, containers, or other articles.

In addition, short- and long-chain PFAS may also be formed when the fluorine reacts with the carbon alkyl chain attached to oxidation products such as alcohols, ketones, aldehydes, acids, and esters. These substances are formed on the surface of the polyethylene when it is extruded, heated, or otherwise processed into articles in the presence of oxygen.[8]

The greater the amount of oxygen and oxidative products present during the fluorination, the greater amounts of short- and long-chain PFAS generated.

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[4] White House, FACT SHEET: Biden-Harris Administration Takes New Action to Protect Communities from PFAS Pollution," March 14, 2023 at https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/14/fact-sheet-biden-harris-administration-takes-new-action-to-protect-communities-from-pfas-pollution/.

[5] FDA, Indirect Food Additives: Paper and Paperboard Components, Final Rule, 81 *Federal Register* 5, January 4, 2016. See https://www.federalregister.gov/documents/2016/11/22/2016-28116/indirect-food-additives-paper-and-paperboard-components.

[6] In the food additive petition that resulted in § 177.1615, the petitioner, Union Carbide, identified polyethylene terephthalate, metal cans, and glass as alternatives that would serve the same function as fluorinated polyethylene. See FDA, Response to FOI Request No. 2021-3366, July 30, 2021 (FOIA Response) at page 12 of 235 at https://www.edf.org/sites/default/files/2023-08/FDA_FOIA_Response_2021-3366_on_7-30-21_for_Fluorinated_Polyethylene_FAP8B3394-redacted.pdf. In addition, food contact materials often use multilayer laminates to meet the performance measures as an alternative to fluorinated polyethylene. For example, see Baritainer at https://baritainer.com/news/hello-world-2/.

[7] Pub.L. 91–190, 83 Stat. 852.

[8] Ceretti, D.V.A.; Edeleva, M.; Cardon, L.; D'hooge, D.R., Molecular Pathways for Polymer Degradation during Conventional Processing, Additive Manufacturing, and Mechanical Recycling. Molecules 2023, 28, 2344. https://doi.org/10.3390/molecules28052344.

In processes where the fluorination occurs while polyethylene is molded into a container or flexible film (known as "in-mold"), oxygen is present from the first two sources. In addition, oxidative products are likely to be generated from the extrusion process to make polyethylene pellets.

In processes where the fluorination occurs from exposure to a nitrogen/fluorine gas mixture after the container is molded (known as "post-mold"), all three sources of oxygen are present as well as oxidative products. Thus, it is likely that the amount of oxygen present in "post-mold" fluorination processes is greater than in the "in-mold" processing. As a result, greater levels of short- and long-chain PFAS are likely to be generated.

The "post-mold" process has been demonstrated to produce substantial amounts of a wide range of harmful short-chain and long-chain PFAS. The levels are significant enough that Public Employee for Environmental Responsibility (PEER) and Center for Environmental Health (CEH) as well as the Environmental Protection Agency (EPA) have filed lawsuits against Inhance Technologies LLC, a company conducting "post-mold" fluorination of polyethylene containers, for failing to comply with EPA's Significant New Use Rule[9] promulgated pursuant to the Toxic Substance Control Act.[10] In follow-up filings, the company acknowledged that nine long-chain PFAS, including perfluorooctanoic acid (PFOA), are routinely generated as an "unavoidable aspect" from Inhance's fluorination process.[11] The litigation is pending as of the filing of this petition.

At the time of this petition, there is limited information about the levels of PFAS generated by "in-mold" fluorination of polyethylene articles.

II. FDA's 1983 approval of fluorinated polyethylene

In 1983, FDA approved the use of fluorinated polyethylene in response to a 1978 food additive petition by Union Carbide.[12] The approval, promulgated as 21 C.F.R. § 177.1615, states that:

> "Fluorinated polyethylene, identified in paragraph (a) of this section, may be safely used as food-contact articles in accordance with the following prescribed conditions:
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> (a) Fluorinated polyethylene food-contact articles are produced by modifying the surface of polyethylene articles through action of **fluorine gas in combination with gaseous nitrogen as an inert diluent**. Such modification affects only the surface of the polymer, leaving the interior unchanged. Fluorinated polyethylene articles are manufactured from basic resins containing not less than 85 weight-percent of polymer units derived from ethylene and identified in § 177.1520 (a)(2) and (3)(i).
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> (b) Fluorinated polyethylene articles conform to the specifications and use limitations of § 177.1520(c), items 2.1 and 3.1.

[9] EPA, Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 85 *Federal Register* 45109 (July 27, 2020).
[10] United States v. Inhance Technologies LLC, 5:22-cv-5055 (E.D.Pa. Dec. 19, 2022). Public Employees for Environmental Responsibility, Center for Environmental Health, and Jay De La Rosa have intervened in the case per April 26, 2023 order of the court.
[11] PEER and CEH, Comments on 18 Inhance Technologies, LLC (Inhance) Significant New Use Notifications (SNUNs), EPA–HQ–OPPT–2023–0061, May 22, 2023. See https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0061-0002.
[12] FDA, Final Rule, Indirect Food Additives; Polymers, 48 *Federal Register* 39057, August 29, 1983. See https://archives.federalregister.gov/issue_slice/1983/8/29/39054-39058.pdf#page=4.

(c) The **finished food-contact article, when extracted with the solvent or solvents** characterizing the type of food and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, **yields fluoride ion not to exceed 5 parts per million** calculated on the basis of the volume of food held by the food-contact article." *[Emphasis added]*

In May 2021, EDF submitted a Freedom of Information Act (FOIA) request to FDA asking for all documents related to that decision. It received the agency's response on July 30, 2021 and combined the documents into a single PDF at https://www.edf.org/sites/default/files/2023-08/FDA_FOIA_Response_2021-3366_on_7-30-21_for_Fluorinated_Polyethylene_FAP8B3394-redacted.pdf.[13]

In a November 9, 1978 memo, FDA's toxicologists told the person within the agency in charge of the petition that they were concerned the process would release organic fluoride and about the lack of toxicity data.[14] They recommended that the petition not be filed because no toxicity data has been submitted. They asked specifically if the substances that migrated from the fluorinated polyethylene was "fluoride ion free or organic, such as ethylene fluoride of the low molecular weight fraction (LMWF).[15]

Union Carbide responded to these and other questions in an August 25, 1982 letter that prompted FDA to agree to file the petition on September 28, 1982.[16] In the FOIA, FDA redacted the company's response to the questions raised by its toxicologists.[17]

FDA's toxicologists remained concerned. In a November 4, 1982 memo evaluating the safety of the product, the food additives evaluation team stated that:

> We are concerned, however, with the possible formation and migration of small amounts [REDACTED] and of other possibly toxic low molecular weight fluoridated organic compounds. [REDACTED] the possibilities discussed above. In the absence of such information we would require petitioner to conduct toxicity studies on aqueous extracts of the fluoridated polymer.[18]

In the memo, the toxicologists acknowledged that the FDA chemists claimed that the aqueous extracts "are composed of fluoride ion with trace amounts of low molecular weight oligomers of polyethylene, which are found after extraction of non-fluoridated polyethylene." The toxicologists' memo concludes by advising that "we ask the chemists to address the question of possible formation of [REDACTED]. In the

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[13] FDA, Response to FOI Request No. 2021-3366, July 30, 2021 (FOIA Response). See https://www.edf.org/sites/default/files/2023-08/FDA_FOIA_Response_2021-3366_on_7-30-21_for_Fluorinated_Polyethylene_FAP8B3394-redacted.pdf.

[14] FDA Memorandum from Judy C. Edwards/T.R. Carson in Division of Toxicology, HFF-185 to J. Smith in Petitions Control Branch, HFF 334 regarding pre-file review of food additive petition no. 8B-3394, November 9, 1978. See FDA FOIA Response page 125 of 235.

[15] *Id.*

[16] Letter from FDA's Julius Smith to Union Carbide's Reginald Pender on September 28, 1982. See FDA FOIA Response page 167 of 235.

[17] *Id. page 4 and 5.* See FDA FOIA Response page 150-151 of 235.

[18] FDA Memorandum, Marvin J. Bleiberg, Food Additives Evaluation Branch (HFF-156) to Julius Smith, Petitions Control Branch (HFF-334) on November 4, 1982. Safety Evaluation of Fluorinated Polyethylene for Food and/or Drug Contact Use Applications; Chemistry Memo, 10-6-82; Submission of August 25, 1982. Page 3. See FDA FOIA Response page 172 of 235.

absence of such information we would require petitioner to conduct toxic studies on extracts of the fluoridated polymer."[19]

FDA's chemists replied to the toxicologists' request in a December 21, 1982 memo.[20] The memo opens by explaining that the Office of Toxicology has asked the Office of Chemist to "address the question of possible formation of [EXTENSIVE REDACTIONS]. **Our general conclusion is that low molecular weight fluorocarbon-oxygen compounds should not be present in significant quantities**."[21] *[Emphasis added]* Due to the redactions, we are unable to discern the precise questions considered or the chemists' reasoning for its conclusion. However, we can reasonably conclude that FDA's chemists agreed organic fluorinated compounds were present.

There is no record of further discussion of the issue. On May 5, 1983, FDA provided Union Carbide with a preliminary draft of the regulation.[22] Apparently, either the chemists' response addressed the toxicologists concerns or FDA's management sided with the chemists over the toxicologists without additional investigation or toxicity testing and moved forward with approving the petition.

We note four additional items from our review of FDA's FOIA Response:

- FDA chose to extensively redact significant portions of memos by its scientists evaluating the safety of the product claiming they were "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4). Exemption 4 of FOIA. It is disturbing that the agency would withhold health and safety information generated by its own scientists in a memo written in 1982. Health and safety information clearly does not constitute confidential business information (CBI). To the extent that a business could articulate a CBI claim over health and safety information, such an interest would be greatly outweighed by the public interest in disclosure especially 40 years later.
- Union Carbide makes clear that the process normally treats both sides of the polyethylene. It states that "In the normal operation of such manufacturing process both the internal and external surfaces of the polymer article are treated."[23]
- While not explicitly required in its approval, FDA expected that the fluorinated polyethylene would be washed with water prior to food use. Specifically, FDA's chemist said "[f]or food contact use we would consider [Good Manufacturing Practice] to always include water washing the treated article."[24] After washing, PFAS made could contaminate the wastewater and be released into the environment.[25]

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[19] *Id.*
[20] FDA Memorandum from Michael Flood in Food Additive & Animal Drug Chemistry Evaluation Branch, HFF-458 to J. Smith in Petitions Control Branch, HFF-334, December 21, 1982 regarding FAP8B3394 – Union Carbide Corp. OT's request for information dated 11-4-82. See FDA FOIA Response, page 197 of 235 in PDF.
[21] *Id.*
[22] Letter from FDA's Julius Smith to Union Carbide's Reginald Pender on May 5, 1983. See FDA FOIA Response page 217 of 235.
[23] Letter from Union Carbide's R.S. Pender to FDA's Julius Smith dated September 14, 1978. See FDA FOIA Response page 82 of 235.
[24] FDA Memorandum from Michael Flood in Food Additive & Animal Drug Chemistry Evaluation Branch, HFF-458 to J. Smith in Petitions Control Branch, HFF-334, December 21, 1982 regarding FAP8B3394 – Union Carbide Corp. OT's request for information dated 11-4-82. See FDA FOIA Response, page 198 of 235 in PDF.
[25] EPA's Thuy Nguyen, Chief of Analytical Chemistry Branch to EPA's Anne Overstreet, Acting Director, Biological and Economic Analysis Division regarding Results of EPA's Analytical Chemistry Branch Laboratory Study of PFAS Leaching from Fluorinated HDPE Containers (ACB Project B21-02), dated August 12, 2022. See https://www.epa.gov/system/files/documents/2022-09/EPA%20PFAS%20Container%20Leaching%20Study%2008122022_0.pdf.

- In reviewing the documents, we found no evidence that Union Carbide or FDA considered the levels of oxygen or moisture contaminants in the nitrogen gas used in its studies that formed the basis of its food additive petition.

III. Levels of PFAS that FDA considered insignificant 40 years ago are not safe

When FDA approved the fluorine/nitrogen gas treatment of polyethylene, the agency essentially acknowledged that low-molecular weight fluorocarbon-oxygen compounds (which could include PFOA) would be present, but it concluded that they should not be present in significant quantities. They did not define what they meant by significant.

In the intervening forty years, what was believed to be insignificant then is now known to be a serious health risk requiring action by FDA, EPA, Agency for Toxic Substances and Disease Registry (ATSDR), and other federal agencies to protect public health.[26]

The threat that PFAS poses to human health even at very low levels of exposure is now widely recognized. For example, FDA has revoked approval of long-chain PFAS such a PFOA in 2016 stating that:

> In the early 2000s, new scientific studies raised safety questions with the types of PFAS that contain 8 or more carbon atoms in length, commonly referred to as "C8 compounds" or "long-chain" compounds. The most common types are perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). The studies indicated that these C8 compounds persist in the environment and animal tissue and have toxic effects on humans and animals.
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> In 2016, the FDA revoked the regulations authorizing the remaining uses of these long-chain PFAS in food packaging (see 81 FR 5, January 4, 2016 and 81 FR 83672, November 22, 2016). As of November 2016, long-chain PFAS are no longer authorized to be used in food contact applications sold in the United States.[27]

FDA also has prompted industry to voluntarily phase-out the use of 6:2 fluorotelomer alcohol, a chemical that the agency included in the class of short-chain PFAS, stating that:

> In the spring of 2020, the FDA published findings from our scientific review and analysis of newly available data on short-chain PFAS that contain 6:2 fluorotelomer alcohol (6:2 FTOH). Our findings raised safety questions for exposure to 6:2 (FTOH) from some authorized uses of short-chain PFAS. Four manufacturers hold 15 Food Contact Notifications (FCNs) for 11 short-chain PFAS compounds that may contain 6:2 fluorotelomer alcohol (6:2 FTOH).[28]

More recently, EPA proposed Maximum Contaminant Level Goals (MCLGs) and maximum contaminant levels (MCLs)[29] for six forms of PFAS including PFOA and PFNA, both of which have been found in

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[26] White House, FACT SHEET: Biden-Harris Administration Launches Plan to Combat PFAS Pollution, October 18, 2021 at https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/18/fact-sheet-biden-harris-administration-launches-plan-to-combat-pfas-pollution/.

[27] FDA, Authorized Uses of PFAS in Food Contact Applications, accessed on May 22, 2023 at https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications.

[28] *Id.*

[29] EPA, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, 81 *Federal Register* 18638, March 29, 2023. See https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027.

fluorinated plastic containers.[30] The proposed MCLG for PFOA is "zero" based on EPA's determination that it is a carcinogen with no safe level of exposure. The proposed MCL for PFOA of four nanograms per liter (ng/L or parts per trillion) or 0.004 parts per billion (ppb) is the level closest to the MCLG that could be reliably measured in drinking water.

EPA also determined that the non-cancer Reference Dose (RfD) for PFOA should be 3×10^{-5} µg/kg body weight/day to protect against adverse immune, developmental, and cardiovascular outcomes. The RfD, equivalent to the Acceptable Daily Intake (ADI) used by FDA, is extraordinarily low. For a 60 kg adult, this RfD would translate to an ADI of 0.0018 µg/person/day, more than 800 times lower than the 1.5 µg/person/day ADI that FDA assumes is safe in its Threshold of Regulation at § 170.39.

EPA also announced it is making preliminary regulatory determinations for PFNA, PFHxS, PFBS, and HFPO-Dimer Acid (commonly referred to as GenX Chemicals), and mixtures of these four PFAS in accordance with the Safe Drinking Water Act regulatory development process. EPA proposed to regulate PFNA, GenX Chemicals, PFHxS, and PFBS using a Hazard Index (HI) formula. HI is a tool used to evaluate potential health risks from exposure to chemical mixtures based on an assumption of dose additivity. To establish the proposed Health Based Water Concentrations (HBWCs) for PFHxS, PFNA, GenX Chemicals, and PFBS, which is the level below which no health effects are expected for that PFAS, EPA assessed the best available peer reviewed science with final toxicity values for noncancer health effects associated with oral exposure. EPA derived the PFNA HBWC from an ATSDR Intermediate-Duration Oral MRL (minimal risk level) 3×10^{-3} µg/kg/d, which was based on decreased birth weight, delayed developmental milestones and decreased survival in mice.

As a reminder, FDA's rule allows 5,000 ppb of total fluorine in a container's food. If only a portion of the 5,000 ppb is PFOA as FDA's toxicologists thought in 1983, it would result in extremely high levels of exposure for consumers. For example, if one percent of the fluorine were PFOA, the current rule would allow up to 73 ppb[31] of PFOA in the food which means an adult consuming one-liter of contaminated beverage each day would be exposed to:

- more than 300 times the Minimal Risk Level[32] that FDA and ATSDR have established for intermediate-duration exposures of PFOA;[33]
- 600,000 times more than the reference dose EPA used in its proposed MCL for the substance.

We also point out that even if there was a single exposure to PFOA, the chemical is biopersistent and remains in the body for years, continuing to exert toxicity in target organs. People are exposed to multiple PFAS chemicals and mixtures which result in a cumulative effect on human health. Fenceline communities, communities of color, and low-income communities are more likely to be

[30] The others are perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS).

[31] 7264 µg/kg of food (ppb) = (5000 µg F / kg of food) * (1 µmol F / 19 µg F) * (1 µmol PFOA / 15 µmol F) * (414.07 µg PFOA / µmol PFOA) * 1%.

[32] Agency for Toxic Substances and Disease Registry. Oral Intermediate Minimal Risk Level (MRL) is 3×10-6 milligrams of PFOA per kilogram of body weight per day established by ATSDRin May 2021 Toxicological Profile for Perfluoroalkyls. See Table 1-2 and 1-3. FDA adopted the MRLs in June 2021. An Intermediate MRL is based on 15 to 364 days of exposure.

[33] FDA, Authorized Uses of PFAS in Food Contact Applications, accessed on May 22, 2023 at https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications stating that "Recently, the agency began using the finalized minimal risk levels (MRLs) from the ATSDR's May 2021 Toxicological Profile for Perfluoroalkyls" at https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

disproportionately exposed to PFAS. Lastly, FDA identified PFOA as a carcinogen more than a decade ago.[34]

IV. Fluorinated polyethylene results in PFAS migration into food at levels likely to be harmful

Already in the 1990s, scientists have explained in detail how the presence of oxygen drives the formation of fluorinated organics later defined as perfluorinated carboxylic acid.[35, 36] We used PubMed and Google Scholar to perform a literature search for studies conducted on directly fluorinated polyethylene with no date limits. We used the following search terms:

- Food AND fluorinated plastic AND PFAS, OR extraction, OR migration. It excluded: -paper, -board, -turf, -water, -soil, -fabric
- Fluorinated polyethylene AND food AND PFAS. It excluded -paper, -board.

We also searched the Food Packaging Forum FCCmigex database dashboard using the following filters:

- Chemical: PFAS
- Food contact material: Plastics
- Type of food contact material: Single-use
- Type of experiment performed: Extraction, migration into food, migration into food simulants
- Whether the chemical was detected: Yes

The search in the FCCmigex database produced 10 references, none of which were relevant to polyethylene or fluorinated plastic. The date of the publications included in the database range from 1976 to 2022.

From the literature search, we identified three studies that examine the generation of PFAS from the fluorination process and their potential migration into the contents of the container. Additionally, we examine the two studies conducted by the EPA, one study conducted by Eurofins that was included in the ongoing lawsuit to Inhance and unpublished data from a doctoral thesis.

In general, these studies showed that:

- short and long-chain PFAS have been extracted from fluorinated polyethylene containers;
- short and long-chain PFAS migrated from fluorinated polyethylene containers into water and food in quantities that vary with temperature and duration in contact with the container;
- differences in PFAS concentrations may also depend on the type of fluorination process used (i.e., "post-mold" or "in-mold") and whether the containers were rinsed after fluorination took place.

[34] Memorandum from FDA Toxicology Group 1 Penelope Rice to Regulatory Group 2 Paul Honigfort, Critical review of studies conducted with ≥ C8 perfluorinated compounds concerning selected endpoints. [Redacted] September 30, 2010.
[35] A.P. Kharitonov and Y.L. Moskvin. Direct fluorination of polystyrene films. *J. Fluorine Chem.* 1998, 91:87-93
[36] A.P. Kharitonov and L.N. Kharitonova. Surface modification of polymers by direct fluorination: A convenient approach to improve commercial properties of polymeric articles. *Pure Appl. Chem.* 2009, 81:451-471. https://doi.org/10.1351/PAC-CON-08-06-02.

Among the extracted and migrating chemicals are PFOA and other long-chain PFAS FDA has already effectively banned from uses in contact with food.[37] The results of studies by Rand and Mabury[38], EPA, Whitehead and Peaslee[39], Vitale et al.[40], and Eurofins[41] indicate that the process of post-mold fluorination of polyethylene plastic generates PFAS that easily migrate into water and food. We examine the studies below.

1. Rand and Mabury, 2011 study[42]

The investigators purchased 20 one-liter fluorinated high-density polyethylene (HDPE) bottles from two separate firms: Fluoro-Seal International (now Inhance Technologies), which produced bottles with five degrees of fluorination[43]; and Air Products and Chemicals/Airopak which made bottles with only the first level of fluorination and notes that that the fluorination was only on the inside of the container. They extracted the samples with methanol at high temperatures for two hours. They tested for nine PFAS with fully fluorinated carbon chain lengths between one and ten. The bottles with higher degrees of fluorination (called F5) had the highest total PFAS concentration, 70 ppb and contain all nine perfluorocarboxylic acids (PFCA) tested including PFOA, PFNA, and PFDA. The authors showed that long-chain PFAS were more commonly found in the bottles with higher degree of fluorination.

They also stored water for one year in bottles with a F3 degree of fluorination at room temperature and then tested samples of the water for the same PFAS. The average total PFAS was 188 ppb and the PFAS were predominantly short-chain. The authors concluded that "[i]t is possible the fluorinated HDPE bottles, over the course of the year-long period, continued to undergo auto-oxidation and chain scission leading to further production of PFCAs."

Petitioners' assessment: The study provides a detailed assessment of the type and amounts of PFAS released from polyethylene containers with various degrees of fluorination. It also provides a rationale for the presence of PFAS in methanol extracts, their leaching into water, and their leaching over time. It

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[37] FDA, Indirect Food Additives: Paper and Paperboard Components, Final Rule, 81 *Federal Register* 5, January 4, 2016. See https://www.federalregister.gov/documents/2016/11/22/2016-28116/indirect-food-additives-paper-and-paperboard-components. See also FDA, Authorized Uses of PFAS in Food Contact Applications, accessed on November 27, 2022 at https://cacmap.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications where FDA states "As of November 2016, long-chain PFAS are no longer used in food contact applications sold in the United States."

[38] A. Rand and S. Mabury. Perfluorinated Carboxylic Acids in Directly Fluorinated High-Density Polyethylene Material. *Environ. Sci. Technol.* 2011, 45, 19, 8053–8059, https://doi.org/10.1021/es1043968.

[39] H.D. Whitehead and G.F. Peaslee. Directly fluorinated containers as a source of perfluoroalkyl carboxylic acids. *Environ. Sci. Technol. Letters* 2023, 10, 4, 350–355, https://doi.org/10.1021/acs.estlett.3c00083. Although the authors did not explicitly indicate that the bottles tested were produced using post-mold fluorination process, their results were similar to those obtained by EPA from fluorinated polyethylene plastic produced using post-mold technology.

[40] R.J. Vitale, J.K. Acker, S.E. Somerville. An assessment of the potential for leaching of per- and polyfluoroalkyl substances from fluorinated and non-fluorinated high-density polyethylene containers. *Environmental Advances* 2022, 9, 100309, https://doi.org/10.1016/j.envadv.2022.100309.

[41] Eurofins Replication of Peaslee and Whitehead (2023). Page 153 of 203. In comments submitted to EPA on 18 significant new use notifications by Inhance Technologies, LLC, CEH and PEER provided results from recent testing of fluorinated and non-fluorinated HDPE containers conducted by Eurofins Lancaster Laboratories Environment Testing, LLC.(2023)

[42] A. Rand and S. Mabury, Perfluorinated Carboxylic Acids in Directly Fluorinated High-Density Polyethylene Material, *Environmental Science & Technology* **2011** *45* (19), 8053-8059, DOI: 10.1021/es1043968. See https://pubs.acs.org/doi/10.1021/es1043968.

[43] Degree of fluorination is a measure of how much of the polyethylene was fluorinated.

agrees with the 1982 memo by FDA's chemists regarding the presence of organic fluorinated compounds in aqueous extracts of fluorinated polyethylene.

2. EPA 2021 study[44]

In 2021 EPA showed that rinsing fluorinated HDPE plastic for approximately 1 minute with methanol extracted eight PFAS including the long-chain PFOA, PFNA, PFDA and PFUnA. The total level of all PFAS ranged from 20-50 ppb. The tested containers were supplied by the producer of the pesticide product that had been flagged to EPA for PFAS contamination.

Petitioners' assessment: Although EPA used methanol for the extraction, the study results agree with the 1982 memo by FDA's chemists regarding the presence of organic fluorinated compounds in aqueous extracts of fluorinated polyethylene.

3. EPA 2022 study[45]

In 2022, EPA conducted a more nuanced study that included different types of liquid and length of time the liquids were in contact with the fluorinated containers (up to 20 weeks). Results showed that "in all fluorinated containers tested, higher levels of total PFAS were found in the methanol (up to ~ 15 ppb) and water (up to ~3 ppb) leachates compared to that from non-fluorinated container leachate, whereas the highest total level of PFAS found is about 0.04 ppb, which is similar to the laboratory background levels commonly encountered." EPA tested three different brands of fluorinated polyethylene containers purchased from the open market. EPA identified the same eight PFAS as in the previous test. The concentration of PFAS in water increased with the storage time (from 0.092 ppb after one day to 2.888 ppb after 20 weeks) likely due to ongoing releases as explained by Rand and Mabury.

Petitioners' assessment: In this study, EPA used both water and methanol to extract PFAS. The study adds more evidence of the presence of PFAS and agrees with the 1982 memo by FDA's chemists regarding the presence of organic fluorinated compounds in aqueous extracts of fluorinated polyethylene.

4. Vitale et al., 2022 study[46]

The investigators evaluated fluorinated HDPE containers made from three fluorination technologies which they described as: 1) "advanced in-mold fluorination;" 2) "post-mold fluorination;" and 3) "post-mold plasma fluorination," and compared them to non-fluorinated containers.[47] The authors indicated that IPACKCHEM fluorinated containers were included in the testing. Regarding the sources of the other

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[44] EPA's Thuy Nguyen, Chief of Analytical Chemistry Branch to EPA's Kimberly Nesci, Director, Biological and Economic Analysis Division regarding EPA's Analytical Chemistry Branch PFAS Testing Rinses from Selected Fluorinated and Non-Fluorinated HDPE Containers, dated March 4, 2021. See https://www.epa.gov/sites/default/files/2021-03/documents/results-of-rinsates-samples_03042021.pdf.

[45] EPA's Thuy Nguyen, Chief of Analytical Chemistry Branch to EPA's Anne Overstreet, Acting Director, Biological and Economic Analysis Division regarding Results of EPA's Analytical Chemistry Branch Laboratory Study of PFAS Leaching from Fluorinated HDPE Containers (ACB Project B21-02), dated August 12, 2022. See https://www.epa.gov/system/files/documents/2022-09/EPA%20PFAS%20Container%20Leaching%20Study%2008122022_0.pdf.

[46] R.J. Vitale, J.K. Acker, S.E. Somerville., An assessment of the potential for leaching of per- and polyfluoroalkyl substances from fluorinated and non-fluorinated high-density polyethylene containers, Environmental Advances, Volume 9, 2022, p. 2666-7657, https://doi.org/10.1016/j.envadv.2022.100309.

[47] *Id.*

containers, the authors only stated that they "were packed and shipped under formal Chain-of-Custody to the laboratory."

The authors describe advanced in-mold fluorination as a process that "occurs under positive (above atmospheric) pressure, typically around 8 bar. The plastic (parison) used for the article exits the extruder at around 160 °C, and the compressed air used during 'conventional' container blowing is replaced with a fluorine in nitrogen gas mixture to blow the parison against the mold sidewalls."

The containers were filled with 1L of methanol and aliquots were measured at 1, 4, 8, and 12-weeks post-filling. Nineteen PFAS were measured including carboxylic (11 substances from C4-C14) and sulfonic acids (7 substances, C4-C10) and GenX (HFPO-DA).

The authors report that for the advanced in-mold fluorination "none of the target PFAS compounds were detected at or above the laboratory-reported [limit of quantification] LOQ," and that "other fluorination technologies (post-mold fluorinated HDPE containers and post-mold plasma-fluorinated HDPE containers) yielded multiple detections of multiple target PFAS compounds."[48] They also stated that PFAS levels found in post-mold fluorinated and plasma-fluorinated HDPE "were generally consistent" with EPA's testing results. This study was funded by IPACKCHEM Group, a multinational company that manufactures advanced in-mold fluorinated plastic packaging and has opened a manufacturing facility in Murray, Kentucky.

Petitioner's Assessment: There are several concerns with this study including:

- *The company evaluated its own products raising questions about the independence of the study and the credibility of its conclusions.*[49]
- *There is no disclosure of the source of the containers either fluorinated or not;*
- *The methodology lacks specificity;*
- *There are substantial differences in the results of the same set of three containers for the same PFCA. For example,*
    - *in week 8 the levels of PFPeA for samples ID 3-2-A, 3-2-B and 3-2-C were 2100, 490 and 1200 ppt, respectively.*
    - *In week 12, the levels of PFPeA for the same ID numbers were 230, 980, and 220 ppt, respectively.*

  The authors explained the disparity in the results between A, B and C bottles from both sets 3 (post-mold fluorination) and set 5 (plasma fluorination) as "significant variability between individual containers" and that "leaching of PFAS is not uniform." Importantly, the authors acknowledged that the data from these two sets "resulted in higher degrees of quantitative uncertainty" due to recovery issues with its labelled extracted internal standard.

The study funded by IPACKCHEM, a manufacturer of "advanced in-mold fluorination concluded that PFAS did not leach at or above their LOQ using its technology. However, there is low confidence in the overall conclusions due to the lack of details in the methodology, unknown sources of tested samples and financial conflicts of interest. It also showed that results for the polyethylene containers fluorinated using

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[48] *Id.*

[49] Murray Ledger Times, IPACKCHEM acquires TPG Plastics LLC, October 6, 2022. See https://www.murrayledger.com/news/local/ipackchem-acquires-tpg-plastics-llc/article_d8ec65bc-4502-11ed-b3fd-2fa460b1ea70.html. The article says "IPACKCHEM Group ("IPACKCHEM") announced it has acquired a majority stake in TPG Plastics LLC ("TPG"), a leading manufacturer of engineered plastic blow molded products, to bring IPACKCHEM's Advanced In-Mold Fluorination technology ("Advanced IMF") to North America, with an initial focus on the crop protection market for the 2023-24 growing season."

post-mold and plasma fluorination technology are similar to those published by others and agree with the 1982 memo by FDA's chemists regarding the presence of organic fluorinated compounds in aqueous extracts of fluorinated polyethylene.

5. Whitehead and Peaslee, 2023 study[50]

The study was designed to measure the mobility of PFCAs from containers into the products they can contain. The investigators purchased 12 containers of fluorinated HDPE (EW-62500-10) and nonfluorinated HDPE (EW-62150-20) from Cole-Parmer (Vernon Hills, IL). Segments of the fluorinated and non-fluorinated HDPE plastics were exposed to water, methanol, and acetone for one week at room temperature. They measured 21 PFAS ranging from C4 to C18 carbon chain length. The average sum of PFAS (ng/g plastic) was 0.99, 69.72 and 50.13 for water, methanol, and acetone, respectively. In water, the shortest-chain PFAS was a C5 and the longest was C14; in methanol the shortest was C4 and longest C11; in acetone the shortest was a C4 and longest C12. PFOA was quantified in water and acetone extracts.

Samples of fluorinated polyethylene were also exposed to store-bought olive oil, ketchup, and mayonnaise for one week either at room temperature or 50°C. They also exposed the plastic samples to water at 50°C for the same duration. Extraction of the containers and of food matrices was performed using FDA's modified-QuEChERS method.

The average sum of PFAS (ng/g plastic) substantially increased with higher temperatures:

	Average sum of PFAS (ng/g plastic)	
Food	Room temperature	50°C
Olive oil	2.66	5.63
Ketchup	5.95	55.25
Mayonnaise	7.19	31.52
Water	0.99	26.88

C4-C14 PFAS were quantified in foods in contact with fluorinated plastic at room temperature while C4-C12 were quantified in food in contact with fluorinated plastic after exposure at 50°C for the same 1-week duration.

Petitioners' assessment: The study showed the migration of short- and long-chain PFAS, including PFOA, from fluorinated HDPE to food and water. Long- and short-chain PFAS were also extracted from the plastic with solvents. The results are similar to those published by others and agree with the 1982 memo by FDA's chemists regarding the presence of organic fluorinated compounds in aqueous extracts of fluorinated polyethylene.

6. Eurofins Replication of Peaslee and Whitehead 2023 study

In comments submitted to EPA on 18 significant new use notifications by Inhance Technologies, LLC,[51] CEH and PEER provided results from recent testing of fluorinated and non-fluorinated HDPE containers conducted by Eurofins Lancaster Laboratories Environment Testing, LLC – a third-party accredited

[50] H.D. Whitehead and G.F. Peaslee, Directly Fluorinated Containers as a Source of Perfluoroalkyl Carboxylic Acids, *Environmental Science & Technology Letters* **2023** *10* (4), 350-355
DOI: 10.1021/acs.estlett.3c00083. See https://pubs.acs.org/doi/abs/10.1021/acs.estlett.3c00083.
[51] PEER and CEH, Certain New Chemicals; Receipt and Status Information for January 2023, EPA–HQ–OPPT–2023–0061, May 22, 2023 at https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0061-0013.

analytical laboratory – to corroborate the results of Whitehead and Peaslee's (2023) study. PEER provided the fluorinated and non-fluorinated HDPE containers to the lab.

Seven-day leaching experiments were conducted with water, methanol, and acetone to determine whether PFCAs leached from fluorinated containers into the contents. Eurofins result show that eight different PFCAs were detected in the leachate, including five long-chain PFCAs. The highest concentrations of PFCAs were detected in the acetone followed by the methanol solvent. PFOA was detected in all three replicate samples of methanol and acetone at an average concentration of 4.07 ± 0.96 ppb and 4.93 ± 0.50 ppb, respectively.

Petitioners' assessment: The study showed that short- and long-chain PFAS, including PFOA, can be extracted from fluorinated HDPE using solvents, The results are similar to those published by others and agree with the 1982 memo by FDA's chemists regarding the presence of organic fluorinated compounds in aqueous extracts of fluorinated polyethylene.

7. Unpublished Work by Whitehead 2023

In comments submitted to EPA on 18 significant new use notifications by Inhance Technologies, LLC,[52] CEH and PEER included a summary of Whitehead's unpublished evaluation of in-mold fluorinated HDPE containers for the presence of PFCAs by performing targeted analyte extracts of these containers. As summarized by Dr. Diaz Leiva, "[i]n line with the findings of Vitale et al. (2022), Whitehead found that none of the target analytes measured above their limit of quantitation in the extracts from in-mold fluorinated containers. Only one short-chain PFCA, perfluoro-heptanoic acid (PFHpA), was measured just above the limit of quantitation in this level 3 in-mold fluorinated container."

Petitioners' assessment: The conclusions of this evaluation were made by CEH' science director who (may) have had access to the unpublished data. Petitioners rely on the conclusions presented in the legal filing. However, questions remain about the source of the containers, the rationale for only testing level 3 fluorinated containers and the methodology.

V. Claims suggesting that some methods to make fluorinated polyethylene are safe

We have identified four claims that suggest that fluorinated polyethylene might be made safely.

1. FDA's 2021 statement about its 1983 approval[53]

On August 5, 2021, FDA published an open letter addressing the manufacturers, distributors, and users of fluorinated polyethylene food contact articles, warning them that "available information indicates that some manufacturers of fluorinated polyethylene produce articles via alternative manufacturing methods from that stipulated in FDA's regulation."[54] The letter explains that "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." And that "**FDA's regulation does not authorize fluorination of polyethylene containers in the presence of water, oxygen, or gases other than nitrogen**." *[Emphasis added]*

[52] *Id.*
[53] FDA, Dear Manufacturers, Distributors, and Users of Fluorinated Polyethylene Food Contact Articles Letter, August 5, 2021. See https://www.fda.gov/media/151326/download.
[54] *Id.*

Unfortunately, FDA's statement makes little sense: all nitrogen gas contains water and oxygen as impurities because the nitrogen is extracted from the atmosphere. Water and oxygen cannot be realistically eliminated. For example:

- Food grade nitrogen gas allows as much as 10,000 ppm of oxygen and 300 ppm of water;[55]
- High-purity nitrogen gas allows as much as 0.5 ppm of oxygen and 3 ppm of water;[56]
- Ultra-high purity nitrogen gas allows as much as 2 ppm of oxygen and 1 ppm of water;[57] and
- Oxygen-free nitrogen as much as 0.5 ppm of oxygen.[58]

If FDA is serious about its claim that no oxygen or water may be present in the nitrogen gas, then the agency has effectively determined that the 1983 approval should be revoked. Our petition, then, simply asks for the agency to formalize that decision.

Note that we investigated what grade of nitrogen gas Union Carbide used in its food additive petition that resulted in FDA's 1983 approval. In our review of FDA's July 30, 2021 FOIA response,[59] we found no information regarding the purity of the nitrogen used by Union Carbide in its studies that formed the basis of its food additive petition. It appears that FDA did not consider oxygen or moisture content in the nitrogen gas.

2. Law firm's comments to FDA on behalf of unnamed client[60]

Keller and Heckman LLP submitted a comment on behalf of an unnamed client, a provider of fluorination services for almost 40 years. It claims containers "fluorinate[d] for food-contact applications are limited to HDPE containers mostly for packaging flavoring and fragrance concentrates."[61] The law firm acknowledged the facility is not fully aware of the customers intended use for the packaging.

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1 [redacted] is a provider of fluorination services to customers that provide containers for treatment. Consequently, [redacted] is not always aware of the customer's intended uses for their containers. Nevertheless, [redacted] provides a letter to customers regarding the requirements for compliance with federal food additive regulations when packaging food in fluorinated containers.

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The law firm's description of the technology used by its client explains that already-molded containers "are placed in a temperature-controlled chamber that is then sealed and evacuated to remove air. A

[55] NiGen, What is Food-Grade Nitrogen?, accessed on May 15, 2023 at https://nigen.com/food-grade-nitrogen-generator-gas-suppliers/.
[56] NiGen, Nitrogen Gas Purity Grades for Different Industry Uses, accessed on May 15, 2023 at https://nigen.com/nitrogen-gas-purity-grade-specification-industrial-medical-food/.
[57] *Id.*
[58] *Id.*
[59] FDA, Response to FOIA Request No. 2021-3366, July 30, 2021 (FOIA Response). See FDA's July 30, 2021 FOIA response.
[60] Devon Hill of Keller and Heckman, Re: Fluorinated Polyethylene Containers for Food Contact Use; Request for Information; Docket No. FDA-2022-N-1526, October 17, 2022 posted in the docket at https://www.regulations.gov/comment/FDA-2022-N-1526-0013.
[61] Keller and Heckman, Fluorinated Polyethylene Containers for Food Contact Use; Request for Information; Docket No. FDA-2022-N-1526, October 17, 2022. See https://www.regulations.gov/comment/FDA-2022-N-1526-0013.

prescribed amount of a mixture of fluorine and nitrogen gas are then added to the chamber and allowed to react with the container surface."[62] The description is of a post-mold fluorination process.

The law firm claims that it "has performed analytical testing for thirteen perfluorinated carboxylic acids in fluorinated HDPE containers and conducted an assessment of potential dietary exposures based on the results of this testing. This analysis demonstrates that the dietary exposure to PFAS that could result from the use of fluorinated HDPE containers in food-contact applications is below a level that is of toxicological significance."

Unfortunately, the description of the method and the results are entirely redacted. As a result, we are unable to evaluate the claims. However, the reference to "toxicological significance" suggests that it is using the 1.5 µg/person/day that FDA assumes is safe in its Threshold of Regulation at § 170.39. This threshold is based on assumptions that are not applicable to PFAS because many of the PFAS released from fluorinated containers biopersist in the body, therefore the common assumption used in toxicity testing, namely, a chemical is quickly eliminated from the body, does not apply. Additionally, we have better science-based methods to establish an Acceptable Daily Intake (ADI). The ADI is essentially the Reference Dose (RfD).

As discussed in Section II, the ADIs or RfDs for PFAS that have been established are extraordinarily low. When it comes to a safe level of PFAS in drinking water, EPA determined that the Maximum Contaminant Level Goal (MCLG) for PFOA should be zero to protect against carcinogenicity and the Reference Dose (RfD) should be 3 × 10–5 µg/kg/day to protect against immune, developmental, and cardiovascular outcomes. For a 60 kg adult, this ADI would be 0.0018 µg/person/day, more than 800 times lower than the 1.5 µg/person/day that FDA assumed was safe when it promulgated its Threshold of Regulation at § 170.39. It should no longer be used as a basis of comparison given the available scientific evidence.

VI. Companies producing fluorinated polyethylene

Since EPA released the first results of its investigation in 2021, we have learned from marketing materials and industry sources the disturbing fact that the fluorination of plastic is commonly used to treat hundreds of millions of polyethylene containers each year.[63] Uses range from packaged food and consumer products that individuals buy to larger containers used by retailers such as restaurants to even larger drums used by manufacturers to store and transport fluids.[64]

On October 18, 2022, EDF submitted comments on FDA's request for information on fluorinated polyethylene containers for food contact use[65] providing marketing information from seven companies in the United States offering either fluorination services, fluorinated products, or both.

From this list, we identified two companies that appear to be producing fluorinated polyethylene: Inhance Technologies, which is using the post-mold process, and Pretium Packaging, which appears to be using

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[62] *Id at 3.*
[63] Rand and Mabury, 2011. See also PEER and CEH, Certain New Chemicals; Receipt and Status Information for January 2023, EPA–HQ–OPPT–2023–0061, May 22, 2023 at https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0061-0013.
[64] *Id.*
[65] EDF, Comments on Fluorinated Polyethylene Containers for Food Contact Use; Request for Information, October 18, 2022. See https://www.regulations.gov/comment/FDA-2022-N-1526-0012.

the in-mold process. In addition, as noted in Section 3, a local media outlet reported in October 2022 that IPACKCHEM is planning to launch production in Murray, Kentucky. [66]

We do not have information on fluorinated polyethylene containers made outside the United States and imported into the country.

1. Inhance Technologies LLC

Inhance Technologies,[67] formerly known as Fluoro-Seal, advertises a barrier packaging called "Enkase" (formerly Fluoro-Seal™) described as "fluorination barrier technology."[68] Inhance Technologies states that Enkase[69] works best on polyolefins such as high-density polyethylene (HDPE), polypropylene, and copolymers. The company uses the post-mold fluorination process and claims this treatment is better than conventional plastics for formulations that contain solvents, flavors, fragrances, organic active ingredients, and fuel mixtures. It described the product as enhancing the quality of the shelf life of the product and is fully recyclable in HDPE collection streams. In a 2017 interview,[70] Michael Koma, chief operating officer at Inhance Technologies, claimed Inhance was the sole fluorination provider worldwide. Its patented fluorination technology is applied "to prevent staining of plastics used for food packaging and storage."[71]

Inhance Technologies has a subsidiary known as Advanced Research Chemicals, Inc.[72] and has partnered with Basco.[73] In marketing materials, Basco states that "Inhance's fluorination process is FDA compliant but remember: You must choose FDA-approved containers for food products."[74]

Basco appears to have partnered with the Cary Company[75] because they use the same graphics.

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[66] Murray Ledger Times, IPACKCHEM acquires TPG Plastics LLC, October 6, 2022. See https://www.murrayledger.com/news/local/ipackchem-acquires-tpg-plastics-llc/article_d8ec65bc-4502-11ed-b3fd-2fa460b1ea70.html. The article says "IPACKCHEM Group ("IPACKCHEM") announced it has acquired a majority stake in TPG Plastics LLC ("TPG"), a leading manufacturer of engineered plastic blow molded products, to bring IPACKCHEM's Advanced In-Mold Fluorination technology ("Advanced IMF") to North America, with an initial focus on the crop protection market for the 2023-24 growing season."

[67] https://www.inhancetechnologies.com/, accessed on October 18, 2022. See Attachment A of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.

[68] Enkase™ - Fluorination barrier technology by Inhance Technologies approved by RecyClass. See https://recyclass.eu/news/enkase-fluorination-barrier-technology-by-inhance-technologies-approved-by-recyclass, accessed on October 18, 2022. See Attachment A of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.

[69] https://www.inhancetechnologies.com/brands-and-products/barrier-packaging?hsLang=en, accessed on October 18, 2022. See Attachment A of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.

[70] AgroPages: Inhance Technologies: Extending its barrier technology to the agrichemical packaging market in Latin America, https://news.agropages.com/News/NewsDetail---22899.htm, accessed on August 31, 2023.

[71] *Id.*

[72] Advance Research Chemicals, Inc. An Enhance Technologies company, https://www.fluoridearc.com/ accessed on August 31, 2023.

[73] Basco surface fluorination services, https://bascousa.com/plastic-container-surface-fluorination-services-by-basco/, accessed on October 18, 2022. See Attachment B of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.

[74] *Id.*

[75] The Cary Company, https://www.thecarycompany.com/ accessed on October 18, 2022. See Attachment D of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.

and descriptions to portray the fluorination offerings. The Cary Company says its products include food packaging,[76] beverage packaging,[77] and personal care products.[78]

Inhance's compliance with the Toxic Substance Control Act (TSCA) regarding its fluorinated products has reached the courts. In December 2022, PEER and CEH and the US. Department of Justice (DOJ), acting on behalf of EPA, filed lawsuits against Inhance Technologies claiming that the company is producing long-chain PFAS without complying with TSCA.[79] Note that the lawsuits are focused on a wide array of consumer and commercial applications for fluorinated containers but do not directly address foods, which are not subject to TSCA.

On May 16, 2023, the DOJ filed a Memorandum in Support of a Motion for Partial Summary Judgment, stating that Inhance Technologies continues to generate PFAS on its fluorinated containers. Specifically, it alleges that:

- Inhance "[h]as fluorinated containers in multiple locations since the effective date of the Final Rule, including Allentown, Pennsylvania; Forest Park, Georgia; Homerville, Georgia; Centerville, Iowa; Mt. Pleasant, Iowa; West Chicago, Illinois; Columbus, Ohio; Houston, Texas; St. Louis, Missouri; Yuma, Arizona; and Troy, Alabama."[80]
- "Inhance's fluorination processes produce, as byproducts, nine species of PFAS that are subject to the Long-Chain PFAS Rule."[81]

In the Appendix to the May 16, 2023 Memorandum, the DOJ provided extensive lab reports from two different labs showing PFAS migrated from the fluorinated polyethylene container into the simulant.

2. *Pretium Packaging in Manchester, Pennsylvania is likely treating polyethylene with fluorine/nitrogen gas*

Pretium Packaging[82] offers a patented in-mold fluorination process[83] that allows "the interior, unpigmented virgin high-density polyethylene (HDPE) resin surface to be treated with fluorine while the external layer is unaffected." The company says it produced nearly 800 million containers[84] in FY 2021

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[76] The Cary Company, https://www.thecarycompany.com/industries/food-packaging, accessed on October 18, 2022. See Attachment D of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.
[77] The Cary Company, https://www.thecarycompany.com/industries/beverage, accessed on October 18, 2022. See Attachment D of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.
[78] The Cary Company, https://www.thecarycompany.com/industries/personal-care, accessed on October 18, 2022. See Attachment D of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.
[79] United States v. Inhance Technologies LLC, 5:22-cv-5055 (E.D.Pa. Dec. 19, 2022). Public Employees for Environmental Responsibility, Center for Environmental Health, and Jay De La Rosa have intervened in the case per April 26, 2023 order of the court.
[80] U.S. Department of Justice Memorandum, Motion for Partial Summary Judgment; page 8. May 16, 2023
[81] *Id.*.
[82] Pretium. https://www.pretiumpkg.com/, accessed on October 18, 2022. See Attachment E of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.
[83] Pretium. https://www.pretiumpkg.com/capabilities/, accessed on October 18, 2022. See Attachment E of EDF's comments to FDA in Docket No. FDA-2022-N-1526-0012 at https://www.regulations.gov/comment/FDA-2022-N-1526-0012.
[84] EDF. Comments on Fluorinated Polyethylene Containers for Food Contact Use; Request for Information. October 19, 2022. https://www.regulations.gov/comment/FDA-2022-N-1526-0012. See also https://www.pretiumpkg.com/products/.

for Food & Specialty Beverage applications. Products include containers for condiments, dressings, flavorings, oils, sauces, snack foods, spices, syrups, juices, liquor & wines, and mixers. A sales representative, via email, stated the company sends plastics to a third-party which is not available in their system.[85] However, we found evidence that a Manchester, PA facility performs in-line fluorination after reviewing their Clean Air Act's Risk Management Plan required for companies with more than 1,000 pounds of fluorine at their facilities.

On October 14, 2022, the Environmental Defense Fund viewed in EPA's reading room a copy of the risk management plan for Pretium Packaging's Manchester PA facility. In the plan, we learned that the facility's main activity is the production of blow-molded, in-line fluorinated high-density polyethylene (HDPE) containers. The facility blends fluorine gas and nitrogen gas to produce a mixture of 1.0% fluorine and 99% nitrogen. This mixture is used during the blowing process when producing the containers.

The facility reported to EPA that their worst-case scenario is a fluorine gas release of 23.4 pounds per minute for 10 minutes. Under this scenario, the gas would reach 3.9 miles and risk exposing 31,094 residents. The area includes schools, residences, public recreation, and commercial/industrial zones.

Beyond the worst-case scenario posed by a fluorine gas release, Pretium Packaging's facility may be releasing PFAS into the community and environment around the facility as a result of the treatment. For example, the facility discharges wastewater to the Northeastern York County Sewer Authority, a municipal treatment plant that has a National Pollutant Discharge Elimination System (NPDES) permit from the state of Pennsylvania to discharge to the Susquehanna River and land apply biosolids.[86] If the wastewater from the Pretium Packaging facility is contaminated with PFAS due to likely rinsing of the fluorinated plastic containers, [87] the PFAS is likely to pass through in the municipal treatment plant and be discharged to surface water through the NPDES permitted outfall or to the land through the biosolids.

3. IPACKCHEM manufactures in-mold fluorinated plastic containers

As described in Section III, a local media outlet reported in October 2022 that IPACKCHEM is planning to launch production in Murray, Kentucky. [88]

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[85] EDF. Comments on Fluorinated Polyethylene Containers for Food Contact Use; Request for Information. October 19, 2022. https://www.regulations.gov/comment/FDA-2022-N-1526-0012. Attachment E provides an email with a Pretium Packaging representative on September 16, 2022.

[86] Pennsylvania Department of Environmental Protection, NPDES Permit Fact Sheet Individual Discharge, NPDES Permit No. PA0023744, May 26, 2022. See https://files.dep.state.pa.us/water/wastewater%20management/EDMRPortalFiles/Permits/PA0023744_FACT_SHEET_20220526_DRAFT_V3.pdf.

[87] Barrier Plastics, Inc. "PFAS in the Environment and Packaging," May 17, 2021 at https://baritainer.com/news/pfas-in-the-environment-and-packaging/. It states that "Technology has been developed to remove or minimize PFAS compounds on fluorinated HDPE (fHDPE) but it is expensive and does not account for the safe disposal of the resultant rinse water which contains the PFAS compounds."

[88] Murray Ledger Times, IPACKCHEM acquires TPG Plastics LLC, October 6, 2022. See https://www.murrayledger.com/news/local/ipackchem-acquires-tpg-plastics-llc/article_d8ec65bc-4502-11ed-b3fd-2fa460b1ea70.html. The article says "IPACKCHEM Group ("IPACKCHEM") announced it has acquired a majority stake in TPG Plastics LLC ("TPG"), a leading manufacturer of engineered plastic blow molded products, to bring IPACKCHEM's Advanced In-Mold Fluorination technology ("Advanced IMF") to North America, with an initial focus on the crop protection market for the 2023-24 growing season."

VII. Environmental Review

In the food additive petition that resulted in FDA issuing § 177.1615, Union Carbide identified polyethylene terephthalate, metal cans, and glass as alternatives that would serve the same function as fluorinated polyethylene.[89]

While there appears to be differences between the amount of PFAS generated with the various fluorine/nitrogen gas treatments, all operations pose:

- A risk of exposure to even very low levels of PFAS, especially perfluorooctanoic act (PFOA), poses potentially significant health risks to human health;
- A potentially significant risk to both the workers at and to the communities around the facilities that produce the fluorinated containers; and
- Potentially significant risks at and around the facilities that process, recycle, use, or dispose of pre- and post-consumer fluorinated plastic waste.

Given the information available, pursuant to the National Environmental Policy Act (NEPA),[90] we determined that the only ethical and legal option would be to stop all polyethylene fluorination treatment and petition FDA to revoke § 177.1615.

Summary

We have submitted this food additive petition electronically. Appendix 1 provides our responses to elements required by § 171.1, including proposed amendments to the rule.

Should FDA file the petition, we request that the agency include the petition and appendices in the docket and request public comment.

If you have questions or comments, please contact Tom Neltner at tneltner@edf.org and Dr. Maricel Maffini at drmvma@gmail.com on all responses.

Sincerely,

Tom Neltner

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[89] Union Carbide Food Additive Petition. See FDA FOIA Response at page 12 of 235.
[90] Pub.L. 91–190, 83 Stat. 852.

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Index to Appendices:

Appendix I
Responses to elements required by 21 CFR § 171.1

Per 21 CFR § 171.1, we provide responses to the requested elements of a food additive petition.

The petitioners incorporate by reference the letter to Dr. Muldoon-Jacobs preceding this page and Appendix II.

I.A. Name and Pertinent Information Concerning Food Additive

The identity of the food additive is as follows:

1. Name: Fluorinated Polyethylene
2. Chemical formula: Not applicable
3. Formula weight: Not applicable
4. Chemical Abstract Service No.: 977149-41-9
5. INS No.: Not applicable
6. UNI No.: Not applicable

In its "Inventory of Food Contact Substances Listed in 21 CFR,"[91] FDA lists the following other names for Fluorinated Polyethylene.

- POLYETHYLENE, FLUORINATED (SURFACE)
- FLUORINATED POLYETHYLENE (SURFACE)
- POLYETHYLENE, SURFACE FLUORINATED

I.B. Directions, Recommendations, and Suggestions Regarding Proposed Use

We are asking FDA to revoke its approval of fluorinated polyethylene at 21 C.F.R. § 177.1615 to prevent generating per- and poly-fluorinated alkyl substances (PFAS) as a byproduct that can migrate into the container's contents. There will be no proposed use.

I.C. Data establishing that food additive will have intended physical or other technical effect.

We are asking FDA to revoke its approval of fluorinated polyethylene at 21 C.F.R. § 177.1615 to prevent generating per- and poly-fluorinated alkyl substances (PFAS) as a byproduct that can migrate into the container's contents. There will be no proposed use.

[91] FDA, Inventory of Food Contact Substances Listed in 21 CFR" with search for "fluorinated," accessed on August 29, 2022 at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives&id=POLYETHYLENEFLUORINATEDSURFACE.

I.D. Description of practicable methods to determine the amount of the food additive in the food

We are asking FDA to revoke its approval of fluorinated polyethylene at 21 C.F.R. § 177.1615 to prevent generating per- and poly-fluorinated alkyl substances (PFAS) as a byproduct that can migrate into the container's contents. There will be no proposed use.

I.E. Full reports of investigations made with respect to the safety of the food additive

See Appendix II.

I.F. Proposed tolerances for the food additive

We are asking FDA to revoke its approval of fluorinated polyethylene at 21 C.F.R. § 177.1615 to prevent generating per- and polyfluoroalkyl substances (PFAS) as a byproduct that can migrate into the container's contents. There will be no proposed use, and no tolerance will be needed.

I.G. Full information on each proposed change to the original regulation

We are asking FDA to revoke its approval of fluorinated polyethylene at 21 C.F.R. § 177.1615 to prevent generating per- and polyfluoroalkyl substances (PFAS) as a byproduct that can migrate into the container's contents as follows.

~~Sec. 177.1615 Polyethylene, fluorinated.~~
~~Fluorinated polyethylene, identified in paragraph (a) of this section, may be safely used as food-contact articles in accordance with the following prescribed conditions:~~

~~(a) Fluorinated polyethylene food-contact articles are produced by modifying the surface of polyethylene articles through action of fluorine gas in combination with gaseous nitrogen as an inert diluent. Such modification affects only the surface of the polymer, leaving the interior unchanged. Fluorinated polyethylene articles are manufactured from basic resins containing not less than 85 weight-percent of polymer units derived from ethylene and identified in § 177.1520 (a)(2) and (3)(i).~~

~~(b) Fluorinated polyethylene articles conform to the specifications and use limitations of § 177.1520(c), items 2.1 and 3.1.~~

~~(c) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields fluoride ion not to exceed 5 parts per million calculated on the basis of the volume of food held by the food-contact article.~~

I.H. Environmental review component

The proposed changes requested in this food additive petition comply with the categorical exclusion criterion at 21 CFR § 25.32(m) for an "action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics." We have identified no extraordinary circumstances as defined at 21 CFR § 25.21 for the actions requested in this petition which would require the submission of

an Environmental Assessment.

By requesting the prohibition on the use of fluorinated polyethylene for food contact uses, this change would virtually eliminate the risk of generating PFAS that may contaminate food or, when the container is emptied, the environmental contamination impact or the impact on the recycled polyethylene. To the extent that it reduces production of fluorinated polyethylene containers at the facility, it would likely reduce workers' exposure and reduce potential risk of environmental contamination from wastewater discharged to municipal sewage treatment plants or the environment.

Appendix II
List of reports concerning the hazards of PFAS

We incorporate by reference the following EPA and ATSDR reports as the most recent and comprehensive review and summary of the hazards of the PFAS.

1. **Environmental Protection Agency. Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. March 29, 2023**[92]

EPA issued a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS as contaminants under the Safe Drinking Water Act.

EPA is also proposing a National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for these four PFAS and their mixtures as well as for PFOA and PFOS.

EPA is proposing to set the health-based value, the MCLG, for PFOA and PFOS at zero. Considering feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water, EPA is proposing individual MCLs of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS. EPA is proposing to use a Hazard Index (HI)approach to protecting public health from mixtures of PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS because of their known and additive toxic effects and occurrence and likely co-occurrence in drinking water. EPA is proposing an HI of 1.0 as the MCLGs for these four PFAS and any mixture containing one or more of them because it represents a level at which no known or anticipated adverse effects on the health of persons is expected to occur and which allows for an adequate margin of safety. EPA has determined it is also feasible to set the MCLs for these four PFAS and for a mixture containing one or more of PFHxS, HFPO-DA and its ammonium salt, PFNA, PFBS as an HI of unitless 1.0.

2. **Agency for Toxic Substances and Disease Registry. Toxicological Profile for Perfluoroalkyls. May 2021**[93]

ATSDR established the following intermediate minimal risk levels:

- PFOA: $3x10^{-6}$ mg/kg/day based on skeletal effects in mice;
- PFOS: $2x10^{-6}$ mg/kg/day based on delayed eye opening and decreased pup weight in rats;
- PFHxS: $2x10^{-5}$ mg/kg/day based on thyroid follicular epithelial hypertrophy/hyperplasia in rats; and
- PFNA: $3x10^{-6}$ mg/kg/day based on decreased body weight and developmental delays in rats. .

Excerpts from the report regarding effects of PFAS in humans:

Perfluoroalkyls have been detected in the serum of workers, residents living near perfluoroalkyl facilities, and the general population. A large number of epidemiological studies have evaluated possible associations between perfluoroalkyl exposure and a wide range of adverse health outcomes. However, most of the studies have focused on PFOA and/or PFOS; fewer studies have evaluated a smaller number

[92] EPA's PFAS National Primary Drinking Water Regulation Rulemaking. Docket EPA–HQ–OW–2022–0114; FRL 8543–01–OW. FR 88 18638. March 29, 2023. https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfas-national-primary-drinking-water-regulation-rulemaking.

[93] Toxicological Profile for Perfluoroalkyls. Agency for Toxic Substances and Disease Registry. 2021.

of potential health outcomes for the remaining 10 perfluoroalkyls included in this toxicological profile. Most of the epidemiological studies lack exposure monitoring data, and there is a potential for multiple routes of exposure (inhalation and oral); however, most of the studies used serum perfluoroalkyl level as a biomarker of exposure. The three primary sources of this information are occupational exposure studies, studies of communities living near a PFOA manufacturing facility with high levels of PFOA in the drinking water, and studies of populations exposed to background levels of perfluoroalkyls (referred to as general population studies). In the studies examined, workers have the highest potential exposure to a specific perfluoroalkyl, followed by the highly-exposed residents such as residents in the Mid-Ohio Valley who have elevated levels of PFOA and background levels of other perfluoroalkyls, and then the general population. In one study of workers at the Washington Works facility in West Virginia, the arithmetic mean serum PFOA level in 2001–2004 was 1,000 ng/mL (Sakr et al. 2007a); the arithmetic mean PFOA level in highly-exposed residents (without occupational exposure) near this facility was 423 ng/mL in 2004–2005 (Emmett et al. 2006a). By comparison, the arithmetic mean concentration of PFOA in the U.S. population was 4.91 ng/mL in 2005–2006 (calculated by ATSDR from NHANES data reported in CDC 2013). Although a large number of epidemiological studies have examined the potential of perfluoroalkyls to induce adverse health effects, most of the studies are cross-sectional in design and do not establish causality. Based on a number of factors (described in Section 2.1), the available epidemiological studies suggest associations between perfluoroalkyl exposure and several health outcomes; however, cause-and-effect relationships have not been established for these outcomes:

- Pregnancy-induced hypertension/pre-eclampsia (PFOA, PFOS)
- Increases in serum hepatic enzymes, particularly alanine aminotransferase (ALT), and decreases in serum bilirubin levels (PFOA, PFOS, PFHxS)
- Increases in serum lipids, particularly total cholesterol and low-density lipoprotein (LDL) cholesterol (PFOA, PFOS, PFNA, PFDA)
- Decreased antibody response to vaccines (PFOA, PFOS, PFHxS, PFDA)
- Small (<20-g or 0.7-ounce decrease in birth weight per 1 ng/mL increase in either PFOA or PFOS blood level) decreases in birth weight (PFOA, PFOS)

The International Agency for Research on Cancer (IARC 2017) concluded that PFOA is possibly carcinogenic to humans (Group 2B), and EPA (2016e, 2016f) concluded that there was suggestive evidence of the carcinogenic potential of PFOA and PFOS in humans. Increases in testicular and kidney cancer have been observed in highly exposed humans.

There is also some suggestive evidence for associations between perfluoroalkyls and additional health outcomes; there is less certainty in these associations due to inconsistencies across studies and/or a smaller number of studies examining a specific outcome. These health outcomes include osteoarthritis in women under 50 years of age (PFOA, PFOS) and decreased antibody response to vaccines (PFNA, PFUnA, PFDoDA). Additionally, associations between serum PFOA and PFOS and decreases in glomerular filtration rate and increases in serum uric acid levels and between serum PFOA, PFOS, PFHxS, and PFNA and increased risk of early menopause have been observed; these effects may be due to reverse causation, where the effect (disease) causes the change in serum perfluoroalkyl levels (exposure).

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ENVIRONMENTAL DEFENSE FUND, BREAST CANCER PREVENTION PARTNERS, CENTER FOR FOOD SAFETY, ENVIRONMENTAL WORKING GROUP, AND TOM NELTNER

January 22, 2024

Sharon Koh-Fallet, Ph.D.
Chief, Regulatory Review Branch
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Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

Re: Food Additive Petition (FAP) No. 3B4837

Dear Dr. Koh-Fallet:

We appreciate meeting with Dr. Muldoon-Jacobs and you on November 13, 2023 to discuss FDA's decision not to file Food Additive Petition (FAP) No. 3B4837 made five days earlier. The petition asks the agency to remove its approval of the use of fluorinated polyethylene as an indirect food additive at 21 C.F.R. § 177.1615 because new evidence indicates the food contact material can no longer be considered safe under 21 C.F.R. § 170.3(i).

You suggested that the petition would be more appropriate as a citizen petition instead of a food additive petition. As explained in more detail below, we disagree for three reasons:

1. Our food additive petition fully meets the filing requirements of the FFDCA and FDA's implementing rules.
2. The Federal Food Drug and Cosmetic Act (FFDCA) and FDA's implementing rules do not support use of a citizen petition to approve, amend, or revoke a food additive regulation.
3. FDA's rules do not authorize the agency to impose additional requirements for filing such as those described in its decision not to file our petition.

For these reasons, with this letter, we supplement our petition pursuant to 21 C.F.R. § 171.3(i)(1) to address the issues FDA raised. If FDA still maintains FAP No. 3B4837 is deficient for the reasons outlined in your November 8, 2023 letter, the proper course would be for FDA to file the petition, conduct the review required by the FFDCA and implementing regulations, and determine whether to grant or deny the petition consistent with the statutory deadline.

1. **Our food additive petition fully meets the filing requirements of the FFDCA and FDA's implementing rules.**

Paragraph (b) of 21 C.F.R. § 171.130, describes what a petition to amend or revoke a food additive regulation shall contain:

> Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are

> available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions.

In essence, the petition must demonstrate **one of the following criterion**:

1. New information exists with respect to the food additive;
2. New uses have been developed or old uses abandoned;
3. New data are available as to toxicity of the chemical; or
4. Experience with the existing regulation or exemption may justify its amendment or repeal.

In our petition, we demonstrated not just one but three of the four criteria.

For the first criterion, we provided information that short- and long-chain PFAS are likely to be generated by the treatment of polyethylene with fluorine/nitrogen gas mixture. We explained that FDA's scientists recognized in its evaluation of the original Union Carbide food additive petition that the treatment may be generating organic fluorine molecules that appeared to be found in the food simulant.

The agency's scientists were concerned about the potential risks from those organic fluorine molecules but lacked the analytical tools to identify and quantify them at levels currently of concern. Forty years later, we now have those tools, and by using them, we know that short- and long-chain PFAS are a byproduct of the treatment and that they leach from the food contact materials at levels that raise serious concerns about the safety of the approved food additive uses.

We also demonstrated the third criterion by presenting new data that indicate that short- and long-chain PFAS are generated during fluorination and may pose a risk. In addition, the new data indicate that the environmental consequences of these PFAS are significant because they do not degrade when fluorinated polyethylene containers are reused, recycled, or disposed. As determined by EPA in its risk assessment supporting the TSCA [Toxic Substances Control Act] Section 5(e) and 5(f) orders to Inhance: "[b]ecause of the persistent and bioaccumulative nature of these PFAS [long-chain perfluoroalkyl carboxylates (LCPFACs)], exposure to each SNUN [Significant New Use Notice] Chemical Substance will continue over time, long after the immediate exposure associated with their use.[1]" The agency also stated that "the identified hazards of PFOA are so significant that there are no safe levels of exposure;" and extensive exposure and environmental release are the inevitable "result of leaching or migration of [LCPFACs] from fluorinated, plastic storage containers over time into" numerous consumer and industrial products. Thus, the orders conclude that EPA "cannot control potential exposures to the SNUN Chemical Substances through means other than a prohibition on the manufacture of these substances."

Finally, we demonstrated the fourth criterion regarding experience with the existing regulation that warrants its amendment or repeal. In the petition, we explained that all

[1] EPA. Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011. https://www.epa.gov/system/files/documents/2023-12/11-30-23-final-clean-inhance-risk-assessment-of-9-pfas-snuns_marked_redacted.pdf

commercial grades of nitrogen gas contain some oxygen or moisture and, however low, that oxygen or moisture can generate some amount of PFAS. Since nitrogen is made from ambient air, it is impossible to have absolutely no oxygen or moisture.

Unfortunately, the original Union Carbide food additive petition did not consider the presence of oxygen or moisture in the nitrogen gas. As a result, FDA did not specify a grade of nitrogen or set a limit for oxygen and moisture contamination in 21 C.F.R. § 177.1615. Therefore, it is critical that FDA address the omission now through rulemaking.

2. The FFDCA and FDA's implementing rules do not support use of a citizen petition to approve, amend, or revoke a food additive regulation.

Section 409 of the FFDCA, codified at 21 U.S.C. § 348, establishes the requirements a person must follow to file a food additive petition with FDA. Subparagraph (b)(1) states that "[a]ny person may, with respect to any intended use of a food additive, file with the Secretary a petition[2] proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used."

Where a food additive regulation has already been promulgated by FDA, paragraph (i) directs FDA to promulgate a rule to "prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such **procedure shall conform to the procedure provided in this section for the promulgation of such [food additive] regulations**." (emphasis added).

Therefore, any procedure to amend or repeal a food additive regulation shall be consistent with the requirements of Section 409 of the FFDCA. Those requirements include:

- Approving or denying a food additive petition by an order within 180 days of filing;
- Publishing the order and providing 30 days for adversely affected parties to file objections and request a public hearing; and
- If there is an actual controversy regarding the validity of an order issued pursuant to the objections, allowing adversely affected parties to obtain judicial review by the U.S. Court of Appeals.

Pursuant to paragraph (i), FDA promulgated regulations at 21 C.F.R. § 171.130 establishing procedures for petitions to amend or repeal a food additive regulation. Specifically, paragraph (a) of that rule states that:

> The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter,[3] may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

[2] This petition is a food additive petition.
[3] Chapter refers to Chapter I of Title 21 of the C.F.R. It consists of FDA's rules implementing the FFDCA.

Part 10 governs submission of petitions to FDA. Section 10.25(a) states that:

> An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either:
> (1) in the form specified in other applicable FDA regulations, *e.g.,* the form for a color additive petition in § 71.1, **for a food additive petition in § 171.1** or § 571.1, for a new drug application in § 314.50, for a request to establish or amend an import tolerance in § 510.205, for a new animal drug application in § 514.1, or
> (2) in the form for a citizen petition in § 10.30. (emphasis added).

Section 10.30 describes the requirements for a citizen petition. Paragraph (a) states that:

> This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) **except to the extent that other sections of this chapter apply different requirements to a particular matter**. (emphasis added).

While Section 10.25 appears to allow a citizen petition to amend or revoke a regulation, Section 10.30(a) would preclude that option for food additive regulations because other regulations – specifically Section 171.30 – apply. In addition, the procedures by which FDA evaluates citizen petitions do not conform to those in Section 409 of the FFDCA.

Therefore, since 21 C.F.R. § 177.1615 is a food additive regulation, our only mechanism to ask the agency to amend or revoke the rule is through a food additive petition. A citizen petition is not an option allowed by the law.

3. FDA's rules do not authorize the agency to impose additional requirements for filing such as those described in its decision not to file our petition.

First, in our prenotice consultation submission to FDA, we presented two options for rulemaking:

- Revoke the rule because the approved use can no longer be considered safe; or
- Amend the rule to ensure through periodic testing that there was no measurable leaching of PFAS from fluorinated polyethylene.

For each option, we provided a proposed regulation consistent with 21 C.F.R. § 172.3(c)(F), which states that "[a] petitioner **may** include a proposed regulation." (emphasis added).

In response, FDA told us that we must choose between a revocation or an amendment; we were not permitted to present two alternatives to address the issue. We disagreed but chose not to challenge FDA's unjustified interpretation of its rules. As a result, we chose to call for FDA to revoke the food additive regulation since it would be best means to protect public health.

Second, FDA appears to demand that our petition demonstrate that the use is occurring or estimate the actual consumption from this approved use. The rules contain no such requirement.

Despite the absence of a requirement, we provided in our petition multiple marketing materials from companies conducting either in-mold or post-mold treatment indicating that their fluorinated polyethylene was used as food contact materials. As of January 7, 2024, Inhance Technologies' website states that:

> Following several stories inaccurately linking Inhance Technologies' operations to food packaging, we can confirm that the HDPE containers fluorinated by Inhance Technologies are not used as packaging for consumer food and less than 1% of those HDPE containers are used by the food industry for additives or similar products.[4]

While less than 1% may seem small, it represents as many as 1.2 million containers used by the food industry.[5]

Third, in its letter declining to file our petition, FDA made the following claims. We provide our responses below:

FDA claims that our petition contained:	Our response to FDA's claims.
No information demonstrating that this data [the presence of PFAS in the content of fluorinated polyethylene containers] was collected on containers intended for food-contact use and the petition does not address whether the cited PFAS formation would also be present in food-contact containers.	The additive in question is fluorinated polyethylene. We provided full reports of investigations showing that long- and short-chain PFAS leach out of fluorinated polyethylene containers into the content. FDA has already established that the same long-chain PFAS are unsafe for human consumption. We now include additional evidence provided by Inhance, a producer of fluorinated polyethylene, to EPA. Inhance stated that **as many as 1.2 million fluorinated containers are used by the food industry for additives or similar products**. As long as the fluorination of polyethylene is carried out in the presence of oxygen or water, PFAS will be formed regardless of

[4] Inhance Technologies, Inhance Technologies Statement on Regulatory Compliance, accessed on January 6, 2024 at http://web.archive.org/web/20230104022119/https://www.inhancetechnologies.com/news/inhance-technologies-statement-on-regulatory-compliance.

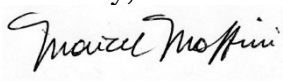
[5] The company reported to the Environmental Protection Agency (EPA) that it produced 121 million containers in 2021 according to EPA's 2023 order to stop production. U.S. Environmental Protection Agency. TSCA Section 5 Order for a Significant New Use of Certain Chemical Substances. https://www.epa.gov/system/files/documents/2023-12/sn-23-0002-0004-0005_order-signature-copy_12-01-2023_marked_redacted.pdf

	what the content of the container would be. The evidence we submitted clearly showed that PFAS present in fluorinated plastic transfer to water. And it continues over time. From the available evidence, the fluorination processes are the same regardless of whether fluorinated plastic will hold food or other products. Lastly, when foods packaged in non-fluorinated containers were put in contact with fluorinated polyethylene for a week at room temperature, PFAS transferred from the plastic to the food and the transfer was greater at higher temperature. It does not make sense that food held in fluorinated polyethylene containers manufactured in the same manner will be free from PFAS.
No information demonstrating that PFAS would form in fluorinated polyethylene containers manufactured in accordance with 21 CFR 177.1615.	The petition from Union Carbide showed the presence of organic fluorine compounds. FDA acknowledged that but concluded the amounts were irrelevant in terms of safety considerations. The rule allows up to 5000 parts per billion fluoride ion. If only 1% is in the form of organic fluorine compounds it would account for 50 parts per billion of PFAS in food. We now know that, at least for long-chain PFAS there is no safe level of exposure. FDA did not provide any specifications on the purity of the nitrogen, the maximum levels of oxygen or moisture allowed in the gases or in the polyethylene plastic itself even though the agency acknowledged the presence of organic fluorine compounds. From the above, the logical conclusion is that there is PFAS formation in the fluorinated polyethylene containers.
No information demonstrating that these cited levels are applicable to any exposure that results from the food contact uses authorized in 21 CFR 177.1615.	The testing data from EPA indicate that PFAS leach from the fluorinated containers into water at room temperature conditions and this leaching continues over time. There is reason to believe the same PFAS

	will transfer to food. Whitehead and Peaslee have quantified PFAS in food after being in contact with fluorinated plastic for a week and that the transfer accelerated at high temperature.
No primary data which would serve as a basis for dietary exposure to PFAS or other impurities from the food contact uses authorized in 21 CFR 177.1615.	We provided testing reports by the Environmental Protection Agency. These tests are reasonably applicable to show that unsafe PFAS are leaching from fluorinated polyethylene. We also provide the manufacturer's statement that as many as 1.2 million fluorinated containers are used by the food industry for additives or similar products.
No toxicological study reports addressing the dietary exposures from this use.	FDA deemed long-chain PFAS unsafe in 2016 and removed their approvals. Although the agency did not remove the authorization of food contact substance notifications (FCN) for long-chain PFAS used in food contact materials, it is noted in the Inventory of Effective FCNs. For other PFAS we provided toxicity assessments carried out by peer agencies Agency for Toxic Substances and Disease Registry and EPA.

With this supplemental information, we ask that FDA file our petition within the 15 business days allowed in its rules.

Sincerely,



Maricel Maffini, Ph.D.