2022

FDA-Approved: How PFAS-laden Food Contact Materials are Poisoning Consumers and What to do About it

Katya S. Cronin

The Business, Entrepreneurship & Tax Law Review

Volume 6 | Issue 1 Article 9

FDA-Approved: How PFAS-laden Food Contact Materials are Poisoning Consumers and What to do About it

Katya S. Cronin

FDA-Approved: How PFAS-laden Food Contact Materials are Poisoning Consumers and What to do About it

Katya S. Cronin[*]

ABSTRACT

Nearly every person in the United States currently has in their body dangerous amounts of chemicals proven to cause cancer, endocrine disruptions, liver and kidney failures, infertility, developmental difficulties, learning disorders, and immunodeficiencies. These chemicals are known collectively as "PFAS"—per- and poly-fluoroalkyl substances—and they were designed for heavily industrial applications. However, over the last two decades, they have surreptitiously and successfully migrated from heavy machinery and building sites onto the many items that consumers use to cook, serve, or store their food. With the FDA's blessing, PFAS are now ubiquitous in food contact materials, from where they leach directly into food. In fact, in the last 24 hours alone, many people likely ingested more of these same chemicals by the simple act of putting butter on their toast, drinking orange juice or milk, grabbing take-out food, eating baked goods, ordering pizza, making microwave popcorn, or having wrapped candy. Once ingested, PFAS stay in the human body for years, wreaking havoc in the meantime.

This article addresses the health, legal, and socioeconomic implications of PFAS in food contact materials and argues for comprehensive regulation. First, it examines the scientific evidence for the public health dangers posed by PFAS in food contact materials and the current regulatory shortcomings that allow these chemicals to make their way into our bloodstream unimpeded. Second, it surveys available remedies—including litigation, market pressures, and state and local legislation—and proposes that the most effective, efficient, and prompt solution to this public health crisis is a systematic regulatory approach. Specifically, the article calls on the FDA to: (1) rescind all current authorizations for fluorinated substances in food contact materials, (2) provide a more robust framework for processing future premarket authorization requests for these substances, and (3) impose strict and enforceable labeling requirements. Lastly, the article engages in a cost-benefit analysis and concludes that any costs associated with the proposed actions could be effectively mitigated. More importantly, these costs are worthwhile to prevent PFAS in food contact materials from continuing to deteriorate our nation's health, damage consumers' economic security, and deepen socioeconomic and racial inequalities.

---

* Associate Professor of Law, Fundamentals of Lawyering Program, George Washington University Law School. I would like to thank William Dawson for excellent research assistance, and Iselin Gambert and Matthew Cronin for the inspiration and invaluable feedback. Thanks to the faculty at Georgetown Law for the many helpful comments and suggestions and to Sichang Chen for her thoughts on earlier drafts. Thanks also to the Future of Food Symposium at the University of Missouri Law School for the opportunity to present a draft of this paper and receive valuable feedback.

I. INTRODUCTION

More than 98% of Americans have unsafe levels of dangerous chemicals in their blood that have been slowly poisoning them for decades.[1] These are chemicals that few have heard of, and likely even fewer can pronounce: per- and polyfluoroalkyl substances (commonly referred to as, "PFAS").

PFAS have long been a staple in heavy industrial applications and certain household items, such as carpets, upholstery, and outerwear. Troublingly, within the last few decades, manufacturers began routinely using PFAS as coating on food wrappers, cookware, and myriad other items that people use to cook, store, and consume food. Scientists have proven that PFAS in these food contact materials ("FCMs") can leach into food, resulting in dietary exposure.[2] PFAS also can remain

1. Ryan C. Lewis et al., *Serum Biomarkers of Exposure to Perfluoroalkyl Substances in Relation to Serum Ttestosterone and Measures of Thyroid Function Among Adults and Adolescents from NHANES 2011–2012*, 12 INT'L J. ENV'T RSCH. PUB. HEALTH 6098, 6103–06 (2015); *See generally* CENTERS FOR DISEASE CONTROL AND PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (Feb. 2015); Antonia.M. Calafat, et al, *Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000*, 115 ENV'T HEALTH PERSP. 1596, 1596 (2007).

2. Overall, 6 papers address the occurrence of PFAS on plastics and twenty-eight papers to date report the occurrence and migration of PFAS from FCMs. *See* Mohamed Ateia et al., *Sorption Behavior of Real Microplastics (MPs): Insights for Organic Micropollutants Adsorption on a Large Set of Well-Characterized MPs*, 720 SCI. TOTAL ENV'T 137634, 137634 (2020); Adil Bakir, Steven J. Rowland & Richard C. Thompson, *Enhanced Desorption of Persistent Organic Pollutants from Microplastics Under Simulated Physiological Conditions*, 185 ENV'T POLLUTION 16, 16–23 (2014); Yao. Cheng et al.,, *Occurrence and Abundance of Poly- and Perfluoroalkyl Substances (PFASs) on Microplastics (MPs) in Pearl River Estuary (PRE) Region: Spatial and Temporal Variations*, 281 ENV'T POLLUTION 117025, 117025 (2021); Marta Llorca et al., *Levels and Fate of Perfluoroalkyl Substances in Beached Plastic Pellets and Sediments Collected From Greece*, 87 MARINE POLLUTION BULL. 286, 286–91 (2014); Fei Wang, Kai Min Shih, Xiao Yan Li, *The Partition Behavior of Perfluorooctanesulfonate (PFOS) and Perfluorooctanesulfonamide (FOSA) on Microplastics*, 119 CHEMOSPHERE 841, 841–47 (2015). Ana Lorena Monge Brenes et al., *PFOA and PFOS Levels in Microwave Paper Packaging Between 2005 and 2018*, 12 FOOD ADDITIVE CONTAMINATION PART B SURVEILLANCE 191,191–98 (2019); Sridhar Chinthakindi, Hongkai Zhu & Kurunthachalam Kannan, *An Exploratory Analysis of Poly- and Per-Fluoroalkyl Substances in Pet Food Packaging from the United States*, 21 ENV'T TECH. INNOVATION 101247, 101247 (2021); Heeju Choi et al., *Perfluorinated Compounds in Food Simulants After Migration from Fluorocarbon Resin-coated Frying Pans, Baking Utensils and Non-stick Baking Papers on the Korean Market*, 11 FOOD ADDITIVE CONTAMINATION B 264, 264–72 (2018); Sebastiann Dolman & Mathias Pelzing, *An Optimized Method for the Determination of Perfluorooctanoic Acid, Perfluorooctane Sulfonate and Other Perfluorochemicals in Different Matrices Using Liquid Chromatography/Ion-trap Mass Spectrometry*, 879 J. CHROMATOGRAPHY B 2043, 2043–50 (2011); Maria P. Elizalde, Sonia Gómez-Lavín & Ane M. Urtiaga, *Migration of Perfluorinated Compounds from Paperbag to Tenax and Lyophilised Milk at Different Temperatures*, 98 INT. J. ENV'T ANALYTICAL CHEMISTRY 1423, 1423–33 (2018); Romy Fengler et al., *Migration of Fluorinated Telomer Alcohols (FTOH) from Food Contact Materials into Food at Elevated Temperatures*, 71 ORGANOHALOGEN COMPOUNDS 939, 939–42 (2011); Hector Gallart-Ayala, Oscar Núñez & Paolo Lucci, *Recent Advances in LC–MS Analysis of Food Packaging Contaminants*, 42 TRENDS ANALYTICAL CHEMISTRY 99, 110 (2013); Wouter A. Gebbink et al., *Polyfluoroalkyl Phosphate Esters and Perfluoroalkyl Carboxylic Acids in Target Food Samples and Packaging—Method Development and Screening*, 20 ENV'T SCI. POLLUTION RSCH. INT'L 7949, 7949–58 (2013); Matthias Kotthoff et al., *Perfluoroalkyl and Polyfluoroalkyl Substances in Consumer Products*, 22 ENV'T SCI. POLLUTION. RSCH. 14546, 14546 (2015); Xiaoyu Liu et al., *Determination of Fluorotelomer Alcohols in Selected Consumer Products and Preliminary Investigation of Their Fate in the Indoor Environment*, 129 CHEMOSPHERE 81, 81–86 (2015); Maria P. Martinez-Moral & Maria T. Tena, *Determination of Perfluorocompounds in Popcorn Packaging by Pressurised Liquid Extraction and Ultra-Performance Liquid Chromatography Tandem Mass Spectrometry*, 101 TALANTA 104, 104 (2012); Kenneth Marsh & Betty Bugusu, *Food Packaging—Roles, Materials, and Environmental Issues*, 72 J. FOOD SCI. R39, R41−R43 (2007); Cristina Moreta & Maria T. Tena, *Fast*

in the human body for years.[3] And they cause irreversible damage to humans and animals. PFAS increase the risk of cancer, hypertension, liver damage, thyroid disease, and asthma.[4] They affect growth, learning, and behavior of infants and children, decrease immune response, interfere with fertility, and complicate pregnancy outcomes.[5]

Yet, despite the overwhelming scientific evidence of PFAS' detrimental effects on human health, the federal government currently does little to prevent these chemicals from poisoning our society through ingestion. The dire reality is that, without regulatory intervention, most consumers—and especially those from disadvantaged backgrounds—will continue to be heavily exposed to PFAS through food contact materials. Relying solely on consumer engagement and market forces is a slow and insufficient solution, as the information is complex, seldom public, and requires significant scientific literacy. The current scheme of occasional voluntary phase-

---

Determination of Perfluorocompounds in Packaging by Focused Ultrasound Solid–Liquid Extraction and Liquid Chromatography Coupled to Quadrupole-Time of Flight Mass Spectrometry, 1302 J. CHROMATOGRAPHY A 88, 88–94 (2013); Somrutai Poothong, Suwanna K. Boontanon & Narin Boontanon, *Determination of Perfluorooctane Sulfonate and Perfluorooctanoic Acid in Food Packaging Using Liquid Chromatography Coupled with Tandem Mass Spectrometry*, 205-06 J. HAZARD MATERIALS 139, 139–43 (2012); Evelyn E. Ritter et al., *PIGE as a Screening Tool for Per- and Polyfluorinated Substances in Papers and Textiles*, 407 NUCLEAR INSTRUMENTS & METHODS IN PHYSICS RSCH. SECTION B: BEAM INTERACTION WITH MATERIALS AND ATOMS 47, 47–54 (2017); Alix E. Robel et al., *Closing the Mass Balance on Fluorine on Papers and Textiles*, 51 ENV'T SCI. TECH. 9022, 9022–32 (2017); Laurel A. Schaider et al., *Fluorinated Compounds in U.S. Fast Food Packaging*, 4 ENV'T SCI. TECH. LETTERS 105, 105–11 (2017); Martin Schlummer et al, *Emission of Perfluoroalkyl Carboxylic Acids (PFCA) from Heated Surfaces Made of Polytetrafluoroethylene (PTFE) Ppplied in Food Contact Materials and Consumer Products*, 129 CHEMOSPHERE 46, 46–53 (2015); Tamer Shoeib et al., *Poly- and Perfluoroalkyl Substances (PFASs) in Indoor Dust and Food Packaging Materials in Egypt: Trends in Developed and Developing Countries*, 144 CHEMOSPHERE 1573, 1573–81 (2016); Mona Still et al., *Impact of Industrial Production and Packaging Processes on the Concentration of Per- and Polyfluorinated Compounds in Milk and Dairy Products*, 61 J. AGRIC. FOOD CHEMISTRY 9052, 9052–62 (2013); Magdalena Surma et al., *Determination of Selected Perfluorinated Acids (PFCAs) and Perfluorinated Sulfonates (PFASs) in Food Contact Materials Using LC-MS/MS*, 28 PACKAGING TECH. & SCI. 789, 790 (2015); Xenia Trier, Kit Granby & Jan H. Christensen, *Polyfluorinated Surfactants (PFS) in Paper and Board Coatings for Food Packaging*, 18 ENV'T SCI. POLLUTION RSCH. 1108, 1108–20 (2011); Y Xu et al., *Migration of Perfluoroalkyl Acids from Food Packaging to Food Simulants*, 30 FOOD ADDITIVES AND CONTAMINANTS - PART A CHEMISTRY, ANALYSIS, CONTROL, EXPOSURE AND RISK ASSESSMENT 899, 899–908 (2013); Guanxiang Yuan et al., *Ubiquitous Occurrence of Fluorotelomer Alcohols in Eco-Friendly Paper-Made Food-Contact Materials and Their Implication for Human Exposure*, 50 ENV'T SCI. TECH. 942, 942 –50 (2016); Effrosyni Zafeiraki et al., *Determination of Perfluorinated Compounds (PFCs) in Various Foodstuff Packaging Materials Used in the Greek Market*, 94 CHEMOSPHERE 169, 169–76 (2014); Itsaso Zabaleta et al., *Fast and Simple Determination of Perfluorinated Compounds and Their Potential Precursors in Different Packaging Materials*, 152 TALANTA 353, 362 (2016); Itsaso Zabaleta et al., *Screening and Identification of Per- and Polyfluoroalkyl Substances in Microwave Popcorn Bags*, 230 FOOD CHEMISTRY 498, 497–506 (2017); Itsaso Zabaleta et al., *Occurrence of Per- and Polyfluorinated Compounds in Paper and Board Packaging Materials and Migration to Food Simulants and Foodstuffs*, 321 FOOD CHEMISTRY 126746, 126746 (2020).

3. *See Toxicological Profile for Perfluoroalkyls*, AGENCY FOR TOXIC SUBSTANCES AND DISEASE RSCH., https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf, (last visited April 10, 2022) [hereinafter ATSDR Toxicological Profiles].

4. *See Emerging Issues in Food Waste Management Persistent Chemical Contaminants*, EPA 4 (Aug. 2021), https://www.epa.gov/system/files/documents/2021-08/emerging-issues-in-food-waste-management-persistent-chemical-contaminants.pdf [hereinafter *EPA Emerging Issues*].

5. *See* IRAC MONOGRAPHS, SOME CHEMICALS USED AS SOLVENTS AND IN POLYMER MANUFACTURE 47 (2017); Philippe Grandjean et al., *Severity of COVID-19 at Elevated Exposure to Perfluorinated Alkylates*, 12 PLOS ONE 1, 2 (2020).

outs by industry and piecemeal state legislation likewise makes little difference for most consumers.

Fortunately, the Food and Drug Administration ("FDA") can comprehensively regulate this toxicological ticking time bomb. This article explains why and how it should do so using its existing authority. The argument proceeds in five parts. Part I examines the health implications of PFAS in food contact materials. Part II provides an overview of the global and U.S. regulation of PFAS, identifying shortcomings of the current system. Part III surveys the patchwork of remedies that currently exist to address this public health crisis—including state and local regulatory efforts, private and public litigation, and market-driven change—and discusses their limitations. Part IV explains that the FDA is the only actor that can fully address this crisis in the U.S. Specifically, this section posits that the FDA should use its existing authority to: (1) rescind all current authorizations for PFAS in food contact materials, giving industry a two-year phase-out period, (2) route any future authorization requests through an in-depth petition review, and (3) institute strict labeling and enforcement requirements. Part V considers the larger implications of the proposed solution, including possible costs to various stakeholders. It demonstrates that non-PFAS alternatives are readily available and in use in places like Denmark, California, Washington, and even the U.S. military, without compromising either quality or profitability. It also explains that the central question in this analysis is not *whether* there are costs involved but *who* bears them. Currently, the chemical industry pushes the significant cost of PFAS exposure onto consumers, the healthcare system, and society, as the long-term impacts of these chemicals slowly deepen socioeconomic and racial inequalities and degrade our nation's health. That is a fundamentally unjust result that requires a systemic regulatory remedy.

II. PFAS BELONG TO "THE MOST TOXIC AND POLLUTING GROUP OF CHEMICALS ON THE PLANET"

Within the last 80 years, chemists discovered how to bond halogens to carbon, thus producing molecules with nearly indestructible bonds.[6] While these molecules possess useful properties on a commercial scale, they also strongly resist the natural process of biodegradation.[7] This environmental staying power, combined with their high level of toxicity and evidence that they bio-persist in living organisms, has earned them the reputation of "the most toxic and polluting group of chemicals on

6. Joe Ackerman, Meg Sears & David McRobert, *PFAS on Food Contact Materials: Consequences for Human Health, Compost, and the Food Chain and Prospects for Regulatory Action in Canada and Beyond* 1, https://preventcancernow.ca/wp-content/uploads/2021/12/PFAS-on-food-contact-materials-consequences-for-compost-and-the-food-chain_Ackerman_Sears_McRobert_2020-12-08.pdf (last visited Apr. 2022).

7. *See id.* at 2; Lena Vierke et al., *Perfluorooctanoic Acid (PFOA)-Main Concerns and Regulatory Developments in Europe from an Environmental Point of View*, 23 ENV'T SCI. EUR. 1, 6 (2012).

the planet."[8] Among these halogenated carbons are the infamous DDT, PCBs, dioxins, furans, and PFAS.[9]

PFAS are formed by substituting fluorine atoms for hydrogens on a carbon chain.[10] These compounds can subsequently be polymerized, producing coatings resistant to heat and almost all solvents, or can be turned into surfactants that repel oil, water, stains, and fire.[11] The resulting carbon-fluorine bond in PFAS is the strongest bond in organic chemistry and is virtually indestructible in nature.[12] Thus, PFAS are highly persistent and widespread in the environment, including in air, water, soil, sediments, wildlife, animals, and humans.[13]

There are many families and sub-families of PFAS.[14] There are currently over 4,700 PFAS compounds in use on the global market.[15] The chemical structure of many of these substances is proprietary, and new PFAS may be synthesized at any point, making compound by compound analysis exceedingly difficult.[16] One common classification is to divide PFAS into long-chain compounds (8 or more carbon

8. Elsie M. Sunderland, et al., *A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health* Effects, 29 J. OF EXPOSURE SCI. & ENV'T EPIDEMIOLOGY 131, 14–15 (2019); *See also See also* NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH AND HUM. SERVS., NTP MONOGRAPH ON IMMUNOTOXICITY ASSOCIATED WITH EXPOSURE TO PERFLUOROOCTANOIC ACID (PFOA) OR PERFLUOROOCTANE SULFONATE (PFOS) 1 (Sept. 2016), https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf; JOSEPH THORNTON, PANDORA'S POISON (2000); Zhineng Wu et al., *Exposure Pathways, Levels and Toxicity of Polybrominated Diphenyl Ethers in Humans: A Review*, 187 ENV'T RSCH. 109531, 109531 (2020); Susan D. Richardson et al., *Occurrence, Genotoxicity, and Carcinogenicity of Regulated and Emerging Disinfection By-Products in Drinking Water: A Review and Roadmap for Research*, 636 MUTATION RSCH. 178, 226 (2007).

9. Ackerman et al., *supra* note 6, at 2.

10. *Id.*; *See also EPA Emerging Issues*, *supra* note 4 (citing R. Lazcano, et al., *Per- and Polyfluoroalkyl Substances in Commercially Available Biosolid-Based Products: The Effect of Treatment Processes*, 91 WATER ENV'T RSCH. 1669–77 (2019)).

See IRAC MONOGRAPHS, SOME CHEMICALS USED AS SOLVENTS AND IN POLYMER MANUFACTURE 41 (2017); *See* Trier et al., *supra* note 2 at 1108–20.

12. Ackerman et al., *supra* note 6, at 2.

13. *See* Marie P. Krafft & Jean G. Riess, *Per- and Polyfluorinated Substances (PFASs): Environmental Challenges*, 20 CURRENT OP. IN COLLOID & INTERFACE SCI. 192, 192–212 (2015); Marie P. Krafft & Jean G. Riess,

Selected Physicochemical Aspects of Poly- and Perfluoroalkylated Substances Relevant to Performance, Environment and Sustainability—Part One, 129 CHEMOSPHERE 4, 4–19 (2015); *see also* Schaider, *supra* note 2, at 2; WORLD HEALTH ORG., MICROPLASTICS IN DRINKING-WATER 61 (2019); Jimmy Seow, Haluk Alper & Paul Callaghan, *PFAS – the "Forever Chemical"*, INT;L FILTRATION NEWS (Feb. 6, 2020), https://www.filtnews.com/pfas-the-forever-chemical; DANIEL HITCHOCK, ET AL., PFAS IN EGGS OF ARCTIC BREEDING GEESE, 9 (n.d.); Poster presentation. Svalbard Sci. Conference, Oslo. 06-08 (Nov. 2017); *Polluntants and Energy Brought from Afar in Artic* Geese, FRAM FORUM, 2018 at 111, https://issuu.com/framcentre/docs/framforum-2018-issuu.

14. *See* Ackerman et al., *supra* note 6, at 2.

15. *See* Ksenia J. Groh et al., *Overview of Intentionally Used Food Contact Chemicals and Their Hazards*, 150 ENV'T INT'L 106225, 106225 (2021); Ian T. Cousins et al., *Strategies for Grouping Per- and Polyfluoroalkyl Substances (PFAS) to Protect Human and Environmental Health*, 22 ENV'T SCI. PROCESSES IMPACTS 1444, 1460 (2020); *See also* ORGANIZATION ON ECONOMIC COOPERATION AND DEVELOPMENT, TOWARD A NEW COMPREHENSIVE GLOBAL DATABASE OF PER- AND POLYFLUOROALKYL SUBSTANCES (PFASS): SUMMARY REPORT ON UPDATING THE OECD 2007 LIST OF PER- AND POLYFLUOROALKYL SUBSTANCES (PFASS) 7 (2018) [hereinafter OECD].

16. *See* Zhanyun Wang et al., *Fluorinated Alternatives to Long-Chain Per Fluoroalkyl Carboxylic Acids (PFCAs), Per Fluoroalkane Sulfonic Acids (PFSAs) and Their Potential Precursors* 60 ENV;T INT'L 242, 243 (2013); Trier et al., *supra* note 2, at 1108–20; Badreddine Barhoumi, Sylvia G. Sander & Imma Tolosa, *A Review on P- and Polyfluorinated Alkyl Substances (PFASs) in Microplastic and Food-Contact Materials*, 206 ENV'T RSCH. 112595, 112595 (2022).

atoms) and short-chain compounds (7 or less carbon atoms).[17] Long-chain compounds—also known as "legacy PFAS"—came on the scene first, and some of the most notorious substances from this class (notably, PFOS and PFOA), have since been subject to partial voluntary phase-outs due to their proven detrimental health and environmental effects.[18] In response, the chemical industry created short-chain PFAS as an allegedly safer alternative.[19] These newer compounds have a shorter carbon-fluorine bond, which the chemical industry touts as evidence of greater biodegradation, and favor water rather than lipids, which proponents say means they get excreted from living tissues faster.[20] These short-chain compounds, however, are analogous in form, structure, stability, and function to their long-chain counterparts,[21] and, in many ways, have proven an even bigger cause for concern.[22]

A. PFAS are Found in an Increasing Number of Food Contact Materials

PFAS possess "efficient water and oil repellency, non-flammability, high capacity to dissolve gases, high stability, extremely low reactivity, good heat conductivity, ability to generate strong acids, [and] resistance to hydrolysis, photolysis and microbial degradation, among others."[23] These properties make them extremely valuable in industrial applications.[24] To date, over 300 uses for PFAS have been recorded, including paints, insecticide formulations, fire-fighting foams, turbine-engine lubricants, production of caustic soda, heavy metal plating, coal-based power plants, bearings in uranium enrichment plants, and chemical driven oil production.[25]

---

17. *See* Ackerman et al., *supra* note 6, at 2.

18. *See* Sunderland et al., *supra* note 8, at 1.

19. Alexis Temkin, *The New Generation of 'Forever Chemicals' – Toxicity, Exposure, Contamination and Regulation*, Env't Working Grp. (May 17, 2021), https://www.ewg.org/news-insights/news/new-generation-forever-chemicals-toxicity-exposure-contamination-and-regulation (Some of the most widely used short-chained PFAS today include GenX, PFBA, PFBS, PFHpA, PFPeA, PFPeS, 6:2 FTSA, 6:2 FTOH, and PFHxA.); *See* Ackerman, *supra* note 6, at 5.

20. *See* Anthony L. Luz, et al., *Perfluorohexanoic Acid Toxicity, Part I: Development of a Chronic Human Health Toxicity Value for Use in Risk Assessment*, 103 REGUL.TOXICOLOGY AND PHARMACOLOGY 41, 42 (2019); Janet K. Anderson, et al., *Perfluorohexanoic Acid Toxicity, Part II: Application of Human Health Toxicity Value for Risk Characterization*, 103 REGUL. TOXICOLOGY AND PHARMACOLOGY 10,10 (2019).

21. *See Per- and Poly-Fluorinated Substances (PFAS)*, KEMI SWEDISH CHEM. AGENCY, https://www.kemi.se/en/chemical-substances-and-materials/highly-fluorinated-substances (last visited Apr. 18, 2022).

22. *See* U.S. ENV'T PROT. AGENCY, HUMAN HEALTH TOXICITY VALUES FOR PERFLUOROBUTANE SULFONIC ACID AND RELATED COMPOUND POTASSIUM PERFLUOROBUTANE SULFONATE 54–55 (2021) (finding that short-chain PFAS, including GenX, PFBS and PFHxA, have similar toxicity as their predecessors PFOA and PFOS).

23. *See* Barhoumi, *supra* note 16. *See also* Juliane Glüge et al., *An Overview of the Uses of Per- and Polyfluoroalkyl Substances (PFAS)*, 22 ENV'T SCI.: PROCESSES IMPACTS 2345–73 (2020); Konstantinos Prevedouros et al., *Sources, Fate and Transport of Perfluorocarboxylates*, 40 ENV'T SCI. TECH., 32–44 (2006); Chad D. Vecitis et al., *Treatment Technologies for Aqueous Perfluorooctanesulfonate (PFOS) and Perfluorooctanoate (PFOA)*, FRONTIERS OF ENV'T SCI. & ENG'G IN CHINA 129, 129–51 (2009).

24. *See* Glüge et al., *supra* note 23, at 2.

25. *See* Dorte Herzke, Elizabeth Olsson & Stefan Posner, *Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs) in Consumer Products in Norwaye—a Pilot Study*, 88 CHEMOSPHERE 980, 980–87 (2012); *See also* Prevedouros, *supra* note 24, at 32; Schaider et al., *supra* note 2, 2.

In recent years, PFAS have also seen increased usage in food contact materials.[26] FCMs, as their name suggests, are materials used for the production, cooking, or storage of food, which make direct contact with food surfaces.[27] Examples of PFAS-laden FCMs include non-stick and glazed pans, griddles, waffle makers, storage containers, gaskets, burger and sandwich wrap paper, bakery contact paper, muffin cups liners, take-out containers, pizza boxes, chocolate and candy wrappers, food bags, disposable dishes, butter wrappers, microwavable popcorn bags, pet food bags, infant formula boxes, take out cups, ice cream tubs, and numerous other paper and plastic food storage containers.[28] The FDA broadly groups PFAS use in FCMs in four categories: (1) non-stick cookware; (2) food processing equipment parts; (3) processing aids; and (4) paper/paperboard food packaging.[29] A fifth use of PFAS in FCMs, which does not appear in FDA's summary, is fluorine gas applied to the surface of plastic containers.[30]

Quantifying the levels of PFAS in FCMs has proven difficult. Because PFAS compositions are often proprietary and undisclosed, most researchers test only for specific PFAS.[31] Slight variations in chemical composition can thus cause a "not detected" result on a test looking for a specific substance, despite the presence of other chemically equivalent compounds in the product, and thus can lead to serious underreporting.[32] Other researchers test for the total fluorine levels as an indication of total PFAS, which does not allow for the identification and study of the specific substances.[33]

Despite these limitations and inherent underreporting, PFAS have been detected in significant quantities and in an increasing number of FCMs on the U.S. market. Testing in 2014 of more than 400 samples of fast-food packaging in larger cities in the USA found fluorine in 56 percent of dessert and bread wrappers, in 38 percent of burger-contact papers, and in 20 percent of paperboard samples.[34] The researchers identified 27 different PFAS, including both long- and short-chain compounds. Concentrations ranged from 1000 to 100,000 parts per billion (ppb)[35] for

26. *See* Barhoumi, *supra* note 16.

27. *Id*.

28. *See EPA Emerging* Issues, supra note 4, at 17*; See also* Trier et al., *supra* note 2, at 1008-20; Gebbink, *supra* note 2; Zafeiraki, *supra* note 2; Zabaleta (2016), *supra* note 2, at 354; Zabaleta (2017), *supra* note 2, at 498; ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT ("OECD"), PFAS AND ALTERNATIVES IN FOOD PACKAGING (PAPER AND PAPERBOARD): REPORT ON THE COMMERCIAL AVAILABILITY AND CURRENT USES 15 (2020).

29. *See* Food and Drug Administration, *Authorized Uses of PFAS in Food Contact Applications* (Oct. 10, 2020) https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications [hereinafter FDA]; *See also* Ackerman et al., *supra* note 6, at 1; Glüge, *supra* note 23.

30. 21 C.F.R. § 177.1615 (2022); *See also* Tom Neltner, *Beyond Paper: PFAS Linked to Common Plastic Packaging Used for Food, Cosmetics, and Much More*, ENV'T DEFENSE FUND HEALTH BLOG (July 7, 2021), http://blogs.edf.org/health/2021/07/07/beyond-paper-pfas/#_ftn1 (Although this process was once thought to affects only the surface of the polyethylene and to leave the interior of the plastic unchanged, recently, studies by the EPA demonstrated that the fluorine gas substitutes the hydrogen molecules on the plastic's surface with fluorine, thus creating high amounts of PFAS, which in turn migrate into the food); *See* Vihaan Nagal, *A Comprehensive Study on Fluorination of HDPE Container*, PACKAGING GURUJI (June 10, 2020), https://packagingguruji.com/plastic-fluorination-process.

31. *See* Ackerman et al., *supra* note 6, at 2.

32. *See* Wang et al., *supra* note 16, at 243.

33. *See* Schaider et al., *supra* note 2, at 1.

34. *Id.* at 5.

35. Various studies report their findings in different units, including parts per million (ppm), parts per billion (ppb), parts per trillion (ppt), µg/kg-bw/day, µg/kg, ng/g, ng, and others. For clarity, consistency, and easy comparison, the author has converted all values to parts per billion (ppb).

surface coating and from 600,000 to 9,000,000 ppb for PFAS added to paper pulp.[36] Importantly, the authors cautioned that the method they used may not be sensitive enough to identify all samples with intentionally added PFAS.[37]

Recent studies show similar findings, with an increasing number of take-out containers, bakery or deli paper, paper bags, and disposable bowls and trays testing above the threshold level.[38] In 2022, Consumer Reports tested 118 products across 24 retailers in Connecticut, Mississippi, New Jersey, New York, and Texas and found that "[a]lmost a third—37 products—had organic fluorine levels above 20 ppm, and 22 were above 100 ppm."[39] Importantly, the testing targeted specifically those retailers that have claimed to have phased out or reduced PFAS in their packaging.[40] The list included Cava, Chipotle, Panera Bread, Sweetgreen, Arby's, Burger King, McDonalds, Taco Bell, and Whole Foods Market.[41] Consumer Reports also tested the products with the highest organic fluorine readings for specific PFAS compounds and found that the most identified PFAS is a recent substitute of some phased-out legacy PFAS, underscoring the fact that "[t]rying to ban individual PFAS is an impossible game of whack-a-mole."[42] More disturbingly, consistent with previous studies, the 30 specific compounds that the testing identified accounted for only 1% of the total fluorine, demonstrating that many more PFAS compounds are in active use than labs are equipped to test for or even know exist.[43] Lastly, the results demonstrated that, despite being phased out of production in the U.S., the two main legacy PFAS that have since been inextricably linked to devastating health consequences—PFOS and PFOA—still show up in a significant number of imported products that make their way to the U.S. market.[44]

FCMs made outside the U.S. fare no better. In a 2016 study of food contact materials in China, 90% of the products tested positive for at least one PFAS.[45] In a similar study in Thailand, the long-chain PFOA and PFOS were detected in over 30 (out of 34) samples from instant food cups, fast-food and dessert containers, baking paper, beverage cups, and microwave popcorn bags. PFAS have also been measured in food contact materials in developed countries.[46] Most recently, a May 2021 survey of FCMs in six European countries found PFAS in 32 out of 42 samples tested, in levels that were up to 60 times higher than the indicator values set by the respective Food Administrations.[47] As was the case with the Consumer Reports study in the U.S., here too, only about 1% of the PFAS detected in these samples

36. Schaider et al., *supra* note 2, at 7; *See also* Ackerman et al., *supra* note 6, at 4.
37. Schaider et al., *supra* note 2, at 7.
38. ZHISHI GUO ET AL., PERFLUOROCARBOXYLIC ACID CONTENT IN 116 ARTICLES OF COMMERCE IN U.S. ENVIRONMENTAL PROTECTION AGENCY 2 (2009); *See* Yuan et al., *supra* note 2, at 942–50.
39. CONSUMER REPS., *Dangerous PFAS Chemicals are in Your Food Packaging* (March 24, 2022) https://www.consumerreports.org/pfas-food-packaging/dangerous-pfas-chemicals-are-in-your-food-packaging-a3786252074/#allResults.
40. *Id.*
41. *Id.*
42. *Id.*
43. *Id.*
44. *Id.*
45. Yuan et al., *supra* note 2, at 242–50..
46. XENIA TRIER ET AL., PFAS IN PAPER AND BOARD FOR FOOD CONTACT: OPTIONS FOR RISK MANAGEMENT OF POLY- AND PERFLUORINATED SUBSTANCES 111 (2017); *See also* Trier et al., *supra* note 2., at 1108–20.
47. JITKA STRAKOVA, ET AL., THROWAWAY PACKAGING, FOREVER CHEMICALS 7 (2021).

could be individually identified, underscoring scientists' fears that many PFAS in FCMs avoid detection depending on the testing methods of individual labs.[48]

B. PFAS Migrate from FCMs to Humans

PFAS migrate from consumer product to humans. A study found that nearly 98% of Americans have PFAS in their blood.[49] Recently released short-chain replacement chemicals are also already in up to 22.6 percent of the U.S. population.[50] Short-chain PFAS have also been detected in human organs, including the lung and the brain,[51] as well as in a majority of breast milk samples.[52]

Although drinking contaminated water, eating contaminated food, or working directly with PFAS are all potential sources of human contact with these chemicals,[53] an often overlooked but significant path of exposure is the direct migration of PFAS from FCMs into food and, through consumption, into the human body.[54] While a relatively new field of study, independent scientists have established PFAS migration into food from PFAS-infused plastics,[55] microwave popcorn bags,[56] baking papers,[57] paper bowls,[58] paperboard,[59] butter wrappers,[60] and compostable

48. *Id.*

49. Lewis et al., *supra* note 1, at 6103–06; CENTER FOR DISEASE CONTROL, s*upra* note 1; Calafat et al., *supra* note 1, at 1596.

50. Antonia.M. Calafat et al., *Legacy and Alternative Per- and Polyfluoroalkyl Substances in the U.S. General Population: Paired Serum-Urine Data From the 2013-2014 National Health and Nutrition Examination Survey*, 131 *ENV'T INT'L* 105048, 105048 (2019) (finding PFHxA, PFBA, GenX and PFHpA in 22.6, 13.3, 1.2 and 1.1 percent of the general U.S. population, respectively).

51. Francisca Perez et al., *Accumulation of Perfluoroalkyl Ssubstances in Human Tissues*, 59 *ENV'T INT'L 354*, 354–62 (2013).

52. Guomao Zheng et al., *Per- and Polyfluoroalkyl Substances (PFAS) in Breast Milk: Concerning Trends for Current-Use PFAS*, 55 *ENV'T SCI. TECH.* 7510, 7510–20 (2021).

53. *EPA Emerging Issues*, *supra* note 4; DHHS Toxicological Profiles, *supra* note 3.

54. DHHS Toxicological Profiles, *supra* note 3; *See also* Hebert P. Susmann et al., *Dietary Habits Related to Food Packaging and Population Exposure to PFASs*, 127 ENV'T HEALTH PERSPS. 107003-1, 107003-1–10 (2019).

55. Commission Regulation (EU) No 10/2011 of Jan. 14, 2011 on Plastic Materials and Articles Intended to Come into Contact with Food, 2011 O.J. (L 12) 1.

56. Timothy H. Begley et al., *Perfluorochemicals: Potential Sources of and Migration from Food Packaging*, 22 FOOD ADDITIVES & CONTAMINANTS PART A 25, 384 (2008) (studied the migration of PFOA from microwave popcorn bags into a food oil (Mygliol) and the migration of other fluorotelomers into the water, vinegar, ethanol, butter and oil); Karsten Müller, et al., *Studies on the Migration of Per- and Polyfluorinated Compounds from Paper Based Packaging into Real Food and Food Simulants*, FRAUNHOFER (2012), https://www.ivv.fraunhofer.de/content/dam/ivv/en/documents/Forschungsfelder/Produktsicherheit-und-analytik/Migration_of_per_and_polyfluorinated_compounds.pdf.

57. Romy Fengler et al., *Data on Migration of Poly- and Perfluorinated Compounds from Food Control Materials into Food and Food Simulants*, FRAUNHOFER (2012), https://www.researchgate.net/profile/Romy-Fengler/publication/234056037_Data_on_migration_of_poly-_and_perfluorinated_compounds_from_Food_Contact_Materials_into_Food_and_Food_simulants/links/53ce68b60cf2b8e35d1483fa/Data-on-migration-of-poly-and-perfluorinated-compounds-from-Food-Contact-Materials-into-Food-and-Food-simulants.pdf; Fengler, *supra* note 2, at 939–42 (demonstrating migration of PFBA, PFHxA and PFOA as well as of several FTOHs at varying temperatures).

58. Yuan et al., *supra* note 2, at 242–50.

59. Trier et al., *supra* note 2, at 1108–20.

60. Schlummer et al., *supra* note 2, at 46–53.

containers,[61] with transfer rates anywhere between 4.8 and 100 percent.[62] Migration of PFAS from a single microwavable popcorn bag, for example, has been measured at up to 39 ppb.[63] (For reference, the Environmental Protection Agency ("EPA") had established that it is unsafe to drink water containing *0.07 ppb* of the two most common PFAS contaminants, PFOS and PFOA.[64] In light of recent evidence that PFAS causes significant health damage at much lower levels than previously thought,[65] however, the EPA decreased these limits more than a thousandfold to *0.02 ppt* and *0.004 ppt* respectively (1 ppb equals 1,000,000 ppt).[66]) Likewise, the concentration of PFAS in butter stored for 45 days at 5°C increased nearly eight-fold over that time.[67] Further, the EPA recently discovered that plastic containers treated with fluorine—used to store orange juice, milk, yogurt, butter, cream cheese, and other food items[68]—leached significant quantities of both short- and long-chain PFAS into the product they were storing after only 1 minute of exposure. [69]

The degree of migration depends on many factors, including the characteristics of the food, and the duration and temperature of exposure.[70] Therefore, test conditions can vastly affect the results.[71] Importantly, researchers have noted that the most common food simulants used in industry-sponsored PFAS migration testing "do not provide an accurate measure of the PFASs quantity that actually migrate into food" and result in "significant underestimations."[72] Despite these challenges, researchers have found that PFAS from FCMs leach into food at all temperatures

---

61. Joe Fassler, *The Bowls at Chipotle and Sweetgreen are Supposed to be Compostable. They Contain Cancer-Linked "Forever Chemicals"*, THE COUNTER (Aug. 05, 2019), https://thecounter.org/pfas-forever-chemicals-sweetgreen-chipotle-compostable-biodegradable-bowls (findings showed average fluorine levels of 1,740 ppm on the outside and 1,599 ppm on the food-contact side—these levels are 2.2 million times the Federal limit on PFOA in drinking water).

62. Xu et al., *supra* note 2, at 899–908.

63. Xu et al., *supra* note 2, at 899-908; Susmann, et al., *supra* note 54, at 107003-1–10.

64. *Drinking Water Health Advisories for PFOS and PFOA*, U.S. ENV'T PROTECTION AGENCY (2016), https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos#:~:text=To%20provide%20Americans%2C%20including%20the,at%2070%20parts%20per%20trillion.

65. *EPA Advances Science to Protect the Public from PFOA and PFOS in Drinking Water*, U.S. ENV'T PROTECTION AGENCY (Nov. 16, 2021), https://www.epa.gov/newsreleases/epa-advances-science-protect-public-pfoa-and-pfos-drinking-water.

66. *Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances*, U.S. ENV'T PROTECTION AGENCY (June 15, 2022), https://www.govinfo.gov/content/pkg/FR-2022-06-21/pdf/2022-13158.pdf; *Drinking Water Health Advisories for PFOS and PFOA*, U.S. ENV'T PROTECTION AGENCY (2016), https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos#:~:text=To%20provide%20Americans%2C%20including%20the,at%2070%20parts%20per%20trillion.

67. Schlummer et al., *supra* note 2, at 46–53.

68. Amy A. Rand & Scott A. Mulbery, *Perfluorinated Carboxylic Acids in Directly Fluorinated High-Density Polyethylene Material*, 45 ENV'T SCI. TECH. 8053, 8053–59 (2011).

69. *EPA Takes Action to Investigate PFAS Contamination*, U.S. ENV'T PROTECTION AGENCY (Jan. 14, 2021), https://www.epa.gov/newsreleases/epa-takes-action-investigate-pfas-contamination?eType=EmailBlastContent&eId=a4352a0c-61ac-48a3-b7fd-b5ae008cba57; *See also* Rand, *supra* note 68, at 8053–59; Commission Regulation, *supra* note 55.

70. Elizalde et al., *supra* note 2 at 1423–33; *See also* Trier et al., *supra* note 2, at 1108–20; Xu et al., *supra* note 2, at 899–908; Yuan et al, *supra* note 2, at 242–50; Zabaleta et al. (2020), *supra* note 2 at 126756; Fengler et al., *supra* note 2, at 939–42; Schlummer et al., *supra* note 2, at 46–53.

71. Elizalde et al., *supra* note 2, at 1423–33(finding that the increase of temperature in the range 80–160°C gave rise to the migration of the PFCAs).

72. Begley et al., *supra* note 56 at 384; *See also* Zabaleta (2020) et all, *supra* note 2 at 126756.

tested (5°C to 220°C).[73] They also discovered a "PFAS-factory" effect—additional PFAS can spontaneously generate from precursors—at typical baking temperatures.[74] Contrary to claims that the newer compounds are safe, several studies have found that shorter-chain compounds migrate into food to a greater extent than long-chain PFAS, especially when heated or in the presence of emulsifiers.[75] Prolonged storage in PFAS-laden FCMs likewise increased migration.

PFAS migration amounts to significant consumer exposure. Research in Canada, for example, has estimated that coated food paper alone contributes more than 50% of the total daily exposure to PFAS for Canadian citizens.[76] Studies also show that while the levels of legacy PFAS have remained constant in the environment, the blood serum levels of these substances has steadily decreased since their phase-out from FCMs.[77] This strongly suggests that direct ingestion through food contact was once a significant source of exposure.[78] Unfortunately, the same is true for the newer, short-chain compounds, which are already a large—and growing—source of exposure.[79]

C. PFAS Bio-Persist and Impact Human Health

Upon migrating into the human body, PFAS bio-persist (i.e., stays for a long time) in the body,[80] and cause significant harm. Despite industry claims to the contrary, both short and long-chain PFAS bio-persist.[81] While some short-chain PFAS have half-lives of 32 days in the human body, others have upward of 35 years.[82] FDA's own scientists recently confirmed that the industry dramatically underestimated the bio-persistence of certain short-chain PFAS.[83] More importantly, the cumulative harm from chronic exposure and short-chain PFAS' unique ability to

73. Craig M. Butt, Derek C.G. Muir & Scott A. Mabury, *Biotransformation Pathways of Fluorotelomer-Based Polyfluoroalkyl Substances: a Review*, 33 ENV'T TOXICOLOGY AND CHEM. 243–67 (2013); Müller et al., *supra* note 56.

74. Butt, *supra* note 71, at 243–67; Fengler et al., *supra* note 2, at 939–42.

75. Schlummer et al., *supra* note 2, at 46–53; Yuan et al., *supra* note 2, at 242–50.

76. Sheryl A. Tittlemier, et al., *Dietary Exposure of Canadians to Perfluorinated Carboxylates and Perfluorooctane Sulfonate via Consumption of Meat, Fish, Fast Foods, and Food Items Prepared in Their Packaging*, 55 J. OF AGRIC. AND FOOD CHEM. 3203, 3203–3210 (2007).

77. Sunderland et al., *supra* note 8.

78. *Id.*

79. *Id; See also* Leo W. Y. Yeung, et al., *Perfluorinated Compounds and Total and Extractable Organic Fluorine in Human Blood Samples from China*, 42 ENV'T SCI. TECH. 8140, 8140–45 (2008).

80. Shruti V. Kabadi, et al., *Internal Exposure-Based Pharmacokinetic Evaluation of Potential for Biopersistence of 6:2 Fluorotelomer Alcohol (FTOH) and its Metabolites*, 112 FOOD AND CHEM.TOXICOLOGY 375, 375–82 (2018). (Some studies use the terms bio-persistence and bioaccumulation interchangeably. In others, however, bioaccumulation refers to PFAS' ability to accumulate up the food chain in increasing concentrations. To distinguish the two effects, this article will only use the term bio-persistence to refer to PFAS' staying power inside living tissues.).

81. *See* DHHS Toxicological Profiles, *supra* note 3.

82. *Id.*

83. Penelope A. Rice, *C6-Perfluorinated Compounds: The New Greaseproofing Agents in Food Packaging*, 2 CURRENT ENV'T HEALTH REPS. 33, 33–40 (2015); Shruti V. Kabadi, et al., *Characterizing Biopersistence Potential of the Metabolite 5:3 Fluorotelomer Carboxylic Acid After Repeated Oral Exposure to the 6:2 Fluorotelomer Alcohol*, 388 TOXICOLOGY AND APPLIED PHARMACOLOGY 1, 1–9 (2020); Penelope A. Rice, et al., *Comparative Analysis of the Toxicological Databases for 6:2 Fluorotelomer Alcohol (6:2 FTOH) and Perfluorohexanoic Acid (PFHxA)*, 138 FOOD AND CHEM. TOXICOLOGY 1, 1–16 (2020). *See also* Kabadi et al., *supra* note 80.

easily enter internal organs allows even the least bio-persistent substance sufficient time to significantly harm the human body.[84]

PFAS' health implications are well-established. Epidemiological studies have reported associations between exposure to PFOA and/or PFOS—the two most widely studied long-chain PFAS substances to date—with testicular and kidney cancer, low birth weight, pregnancy complications, hypothyroidism, high cholesterol, ulcerative colitis, and decreased semen quality.[85] PFAS have proven mutagenic and carcinogenic properties, increase cholesterol, increase uric acid, reduce kidney function, and disrupt thyroid and sex hormone levels.[86] They alter immune functions, cause immunological toxicity, and reduce antibody production.[87] A large study by the U.S. National Toxicology Program[88] revealed an association between greater severity of COVID-19 infection and higher plasma-PFAS concentrations.[89] Children appear even more vulnerable to PFAS exposure, with a particular increase in cases of high cholesterol, impaired renal function, endocrinal disruptions, and immunotoxicity.[90]

Studies on new-generation PFAS have concluded that they are as potent in their toxicity as legacy PFAS.[91] Laboratory studies link exposure to short-chain PFAS to developmental delays, disrupted reproductive cycles, higher incidence of pregnancy loss, increased liver and kidney weight, liver lesions, kidney degeneration, damaged liver function and changes to liver parameters, convulsions, tremors,

84. Jimmy Seow et al., *PFAS—A Better Way*, INT'L FILTRATION NEWS (Apr. 30, 2020), https://www.filtnews.com/pfas-a-better-way; Robert J. Letcher, et al., *Legacy and New Halogenated Persistent Organic Pollutants in Polar Bears from a Contamination Hotspot in the Arctic*, 610–611 SCI. OF THE TOTAL ENV'T, SUPPLEMENT C 121, 121–36 (2018); Marianne Haukås, et al., *Bioaccumulation of Per- and Polyfluorinated Alkyl Substances (PFAS) in Selected Species from the Barents Sea Food Web*. 148 ENV'T POLLUTION 360, 360–71 (2007) (Short-chain PFAS also have a proven greater "bioaccumulation factor," so, once they are released from a human body, they become part of the contaminated environment, which in turn exposes humans to cyclical and increasing contamination.); *See* Andrea. C. Blaine, et al., *Uptake of Perfluoroalkyl Acids into Edible Crops Via Land Applied Biosolids: Field and Greenhouse Studies*, 47 ENV'T SCI. AND TECH. 14062,14062–14069 (2013) (C8 had a bioaccumulation factor of 1.6, C6 of 4.2, C5 of 20, and C4 of 56); *Poly- and perfluoroalkyl substances (PFAS)*, EUR. COMM'N (Oct. 14, 2020) https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf'; *see also* Wang et al., *supra* note 16, at 243; Grohet al., *supra* note 16, 106225.

85. *See EPA Emerging Issues*, *supra* note 4; Vaughn Barry, Andrea Winquist & Kyle Steenland, *Perfluorooctanoic Acid (PFOA) Exposures and Incident Cancers Among Adults Living Near a Chemical Plant*, 121ENV'T HEALTH PERSPECT. 1313, 1313–18 (2013); Maria-Jose Lopez-Espinosa, et al., *Thyroid Function and Perfluoroalkyl Acids in Children Living Near a Chemical Plant*, 120 ENV'T HEALTH PERSPECT. 1036, 1036–41 (2012); Kyle. Steenland, et al., *Ulcerative Colitis and Perfluorooctanoic Acid (PFOA) in a Highly Exposed Population of Community Residents and Workers in the Mid-Ohio Valley*, 121 ENV'T HEALTH PERSPECT. 900, 900–06 (2013); Lyndsey A. Darrow, Cheryl R. Stein & Kyle Steenland , *Serum Perfluorooctanoic Acid and Perfluorooctane Sulfonate Concentrations in Relation to Birth Outcomes in the Mid-Ohio Valley, 2005–2010*, 121 ENV'T HEALTH PERSPECT. 1207, 1207–14 (2013).

86. Seow et al., *supra* note 13.

87. IARC Publications, *supra* note 4; Sunderland et al., *supra* note 8.

88. National Toxicology Program, *supra* note 9.

89. Phillipe. Grandjean, et al., *Severity of COVID-19 at Elevated Exposure to Perfluorinated Alkylates*, 15 PLOS ONE 1, 1–12 (Dec.31, 2020).

90. Kristen M. Rappazzo, Evan Coffman, & Erin P. Hines, *Exposure to Perfluorinated Alkyl Substances and Health Outcomes in Children: A Systematic Review of the Epidemiologic Literature*, 691 INT'L J. ENV'T RSCH. PUB. HEALTH 1, 1–22 (2017); Phillipe Grandjean, et al., *Serum Vaccine Antibody Concentrations in Children Exposed to Perfluorinated Compounds*, 125 ENV'T HELATH PERSP. 1, 1–7; Phillipe Grandjean, et al., *Estimated Exposures to Perfluorinated Compounds in Infancy Predict Attenuated Vaccine Antibody Concentrations at Age 5-Years*, 14 J. IMMUNOTOXICOLOGY 188, 188–95 (2017).

91. Melissa I. Gomis et al, *Comparing the Toxic Potency in Vivo of Long-Chain Perfluoroalkyl Acids and Fluorinated Alternatives*. 113 ENV'T INT'L 1, 1-9 (2018).

labored breathing, disrupted thyroid signaling, estrogenic activity, and disrupted lipid metabolism.[92] Moreover, short-chain PFAS may cause yet-undiscovered health concerns.[93] Current research indicates that these smaller-molecule compounds have a greater likelihood of interacting with cellular function.[94] Short-chain PFAS are also proven to cross the placental barrier more easily, thus impacting fetal development to a higher degree.[95]

III. CURRENT PFAS REGULATION

Despite PFAS' established health and environmental harm, consistent regulation is markedly lacking. Although more than 150 countries have committed to controlling the production, use, and disposal of select PFAS, very few have delivered on that promise and, even then, only with limited results.

A. *Global Regulation*

The main international instrument dealing with PFAS is the Stockholm Convention, which introduced an international restriction regime for persistent organic

92. *See, e.g.*, Xuejiao Feng, et al., *Exposure of Pregnant Mice to Perfluorobutanesulfonate Causes Hypothyroxinemia and Developmental Abnormalities in Female Offspring*, 155 TOXICOLOGY SCIS. 409, 409–19 (2017); Scott Korzeiowski, et al., *Toxicological Evaluation of Sodium Perfluorohexanoate*, 264 TOXICOLOGY 32, 32–44 (2009); Pushkor Mukerji, et al., *Oral Repeated-Dose Systemic and Reproductive Toxicity of 6:2 Fluorotelomer Alcohol in Mice*, 2 TOXICOLOGY REPS. 130, 130–43 (2015); James E. Klaunig, et al., *Evaluation of the Chronic Toxicity and Carcinogenicity of Perflurohexanoic Acid (PFHxA) in Sprague-Dawley Rats*, 43 TOXICOLOGIC PATHOLGOY 209, 209–20 (2015); Christopher P. Chengelis, et al., *A 90-Day Repeated Dose Oral (Gavage) Toxicity Study of Perfluorohexanoic Acid (PFHxA) in Rats (with Functional Observational Battery and Motor Activity Determinations)*, 27 REPROD. TOXICOLOGY 342, 342–51 (2009); *Perfluorohexanoic Acid (CAS #307 24-4) GreenScreen for Safer Chemicals (GreenScreen®) Assessment*, TOXIC-FREE FUTURE (2016), https://cswab.org/wp-content/uploads/2019/11/GenX-Toxicity-of-New-Next-Generation-PFAS-GenX-Toxic-Free-Future-Jan-2018.pdf; Yangjie Li, et al., *Perfluorinated Alkyl Substances in Serum of the Southern Chinese General Population and Potential Impact on Thyroid Hormones*, 7 SCI. REPS. 1, 1–7 (2017); Surabhi Shah-Kulkarni, et al., *Prenatal Exposure to Perfluorinated Compounds Affects Thyroid Hormone Levels in Newborn Girls*, 94 ENV'T INT'L 607, 607–613 (2016), Viengtha Vongphachan, et al., *Effects of Perfluoroalkyl Compounds on mRNA Expression Levels of Thyroid Hormoneresponsive Genes in Primary Cultures of Avian Neuronal Cells*, 120 TOXICOLOGICAL SCIS., 392–402 (2011); Lopez-Espinosa et al., *supra* note 85; A. K. Rosenmai, et al., *Fluorinated Alkyl Substances and Technical Mixtures Used in Food Paper-Packaging Exhibit Endocrine-Related Activity in Vitro*, 4 ANDROLOGY 662, 662–72 (2016); Hiroshi Ishibashi, Eun-Young Kim, & Hisato Iwata, *Transactivation Potencies of the Baikal Seal (Pusa sibirica) Peroxisome Proliferator-Activated Receptor α by Perfluoroalkyl Carboxylates and Sulfonates: Estimation of PFOA Iinduction Equivalency Factors*, 45 ENV'T SCI. TECH. 3123, 3123–30 (2011); Cynthia J. Wolf, et al., *Activation of Mouse and Human Peroxisome Proliferator-Activated Receptor-Alpha (PPARα) by Perfluoroalkyl Acids (PFAAs): Further Investigation of C4-C12 Compounds*, 33 REPROD. TOXICOLOGY 546, 546 (2012); Hiroshi Ishibashi, et al., *Fluorotelomer Alcohols Induce Hepatic Vitellogenin Through Activation of the Estrogen Receptor in Male Medaka* (Oryzias Latipes), 71 CHEMOSPHERE 1853, 1853 (2008); Marleen Maras, et al., *Estrogen-Like Properties of Fluorotelomer Alcohols as Revealed by MCF-7 Breast Cancer Cell Proliferation*, 114 ENV'T HEALTH PERSP. 100, 100 (2016).

93. *See* Eur. Comm'n, *supra* note 84, at 6.

94. *See* Butt, *supra* note 73, at 263.

95. *See* DANISH MINISTRY OF THE ENV'T, SHORT-CHAIN POLYFLUOROALKYL SUBSTANCES (PFAS), (2015), https://www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-15-5.pdf.

pollutants.[96] PFOS was added to the list of pollutants in 2009;[97] PFOA in 2019.[98] The Convention provides that its signatories (152 countries to date) shall prohibit the production, use, import, and export of listed substances.[99] Unfortunately, the Convention's provision on non-compliance does not provide for any real penalties,[100] allowing most signatories to simply pay lip service or entirely disregard their commitments.

Compliance with the Convention varies. A number of signatories have entirely failed to regulate the production and use of PFAS.[101] Others, notably Japan,[102] Korea,[103] and China[104]— some of the biggest importers of consumer goods into the U.S. market[105]—have on paper enacted legislation designating a handful of PFAS as chemicals of concern. However, in practice, these countries remain heavily involved in the manufacture of PFAS and PFAS-infused FCMs.[106] Still others, like Canada and Australia, have taken regulatory steps to reduce the risk of certain long-chain PFAS but remain largely reliant on voluntary actions by manufacturers.[107]

The European Union has the most extensive PFAS regulations, having enforced the Stockholm Convention and designated many short- and long-chain PFAS as chemicals of concern through their REACH Regulation.[108] Norway, Sweden, Germany, Denmark, and the Netherlands are working on EU legislation that would

---

96. *See* Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 2256 U.N.T.C. 119 [hereinafter Stockholm Convention].

97. *See Portal on Per- and Poly-Fluorinated Chemicals—European Union*, OECD, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/european-union.htm.

98. *See PFOA Added to Stockholm Convention POP List*, CHEMANGER (May 27, 2019), https://www.chemanager-online.com/en/news/pfoa-added-stockholm-convention-pop-list.

99. *See* Stockholm Convention, *supra* note 96, at 3, 14–15 (contemplating research, development, and monitoring of the listed pollutants, including their release into the environment, presence and levels in humans, effects on human health, socio-economic and cultural impacts, and other measures).

100. *See* Stockholm Convention, *supra* note 96, at 19.

101. *See, e.g.*, Int'l Pollutants Elimination Network, *PFAS: Bangladesh Situation Report*, (2019) [hereinafter IPEN]; IPEN, *Egypt PFAS Situation Report*, (April 2019); IPEN, *India PFAS Situation Report, (2019)*; IPEN, *Indonesia PFAS Situation Repo*rt, (April 2019); IPEN, *Malaysia PFAS Situation Report*, (March 2019); IPEN, *Lebanon PFAS Situation Report*, (April 2019); IPEN, *Nepal PFAS Situation Report*, (March 2019); IPEN, *Sri Lanka PFAS Situation Report*, (2019*); IPEN, Thailand PFAS Situation Report*, (March 2019).

102. *See* IPEN, *Japan PFAS Situation Report*, at 1 (April 2019); *Portal on Per- and Poly-Fluorinated Chemicals—Japan*, OECD, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/japan.htm.

103. *See Portal on Per- and Poly-Fluorinated Chemicals—Korea, OECD,* https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/korea.htm.

104. *See Portal on Per- and Poly-Fluorinated Chemicals—China*, OECD, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/china.htm.

105. *See* Nordic Council of Ministers, *PFAS in Paper and Board for Food Contact: Options for Risk Management of Poly- and Perfluorinated Substances* (2018), https://backend.orbit.dtu.dk/ws/portalfiles/portal/149769110/Rapport_PFAS_in_paper_and_b oard_for_food_contact_Options_for_risk_management_of_poly_and_perfluorina.pdf.

106. *See* IPEN *supra* note 102; *Japan*, *supra* note 102; *Korea*, *supra* note 103; *China*, *supra* note 104.

107. *See Portal on Per- and Poly-Fluorinated Chemicals—Canada*, OECD, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/canada.htm; *Portal on Per- and Poly-Flurinated Chemicals—Australia*, OECD https://www.oecd.org/chemicalsafety/portal-perfluorinatedchemicals/countryinformation/australia.htm.

108. *See* Council Regulation 1907/2006 of Dec. 18, 2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), J.O. (L 396) 1, 80–87 (seeking to improve the protection of human health and the environment from the risks that can be posed by chemicals and to promote alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.).

ban all PFAS through REACH.[109] A handful of EU countries have enacted further national bans and drinking-water thresholds for PFOS and PFOA.[110] Most notably, in July 2020, Denmark enacted a national ban on the use of all short- and long-chain PFAS in food contact paper products.[111]

B. *The General U.S. Regulatory Landscape*

The United States lags significantly behind the European Union in its approach to regulating PFAS. On the environmental side, the EPA has historically relied on voluntary action, consultation, and cooperation.[112] As part of EPA's 2010/2015 PFOA Stewardship Program, eight major manufacturers worked toward a phase-out of PFOA by the end of 2015.[113] Several regulations also require notifications prior to manufacturing, importing, or processing of certain long-chain PFAS.[114]

Under the Biden Administration, the EPA has taken more concrete steps in addressing the threat PFAS pose to the environment and human health, though active regulation is still lacking. In February 2021, EPA published a final determination to regulate PFOA and PFOS and began work on obtaining "new data on 29 PFAS that are critically needed to improve EPA's understanding of PFAS impacts on community drinking water."[115] In April 2021, the EPA announced that it will no longer be approving Low Volume Exemptions for PFAS and would instead be conducting more thorough review through the pre-manufacture notice review process.[116] In October, 2021, the EPA published its toxicity study for GenX, recognizing that this group of short-chain PFAS can be highly toxic and detrimental to humans at significantly lower doses of exposure than previously assumed.[117] In November 2021, the EPA began review of recent scientific data indicating that PFOA and PFOS are dangerous at "much lower levels of exposure [] than previously understood and that PFOA is a likely carcinogen"—which ultimately culminated in

109. *See PFAS Restriction Proposal*, NAT'L INST. FOR PUB. HEALTH AND THE ENV'T, *PFAS restriction proposal* (2020), https://www.rivm.nl/en/pfas/pfas-restriction-proposal; *Registry of Restriction Intention Until Outcome*, EUR. CHEMS. AGENCY (2018), https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d; *Chemicals Strategy for Sustainability*, EUR. COMM'N https://ec.europa.eu/environment/strategy/chemicals-strategy_en (citing the European Commission's commitment to phase out all non-essential uses of PFAS).

110. *See, e.g., Portal on Per- and Poly-Fluorinated Chemicals—Germany*,OECD https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/germany.htm; *Portal on Per- and Poly-Fluorinated Chemicals—Sweden*, OECD, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/sweden.htm.

111. *See Opinion of the European Commision on the "Order on Food Contact Materials and on Provisions for Penalties for Breaches of Related EU Legislation*," 2019 O.J. 520 DK.

112. *See* Ackerman et al., *supra* note 6.

113. *See PFOA Stewardhip* Program, ENV'T PROT. AGENCY (Jan. 25, 2006), Docket No. EPA-HQ-OPPT-2006-0621, https://www.regulations.gov/docket/EPA-HQ-OPPT-2006-0621; *Per- and Poly-Fluorinated Chemicals—United States*, OECD, https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/united-states.htm.

114. *See* 40 C.F.R. § 721.9582 (2020); 40 C.F.R. § 721.10536 (2020).

115. *See EPA Actions to Address PFAS*, ENV'T PROT. AGENCY, https://www.epa.gov/pfas/epa-actions-address-pfas (last modified June 15, 2020).

116. *See EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market*, ENV'T PROT. AGENCY (Apr. 27, 2021), https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market.

117. *See Human Health Toxicity Assessments for GenX Chemicals*, ENV'T PROT. AGENCY (Jan. 13, 2022), https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals.

an August 2022 proposal to designate these two substances as hazardous under CERCLA.[118]

The growing public concern over PFAS environmental contamination likewise spurred a proposed bill in Congress to designate PFOS and PFOA as "persistent, bioaccumulative, and toxic substances," and as hazardous under CERCLA and the CAA.[119] HR 117-2467, which recently passed in the House, also contemplates further investigation into GenX contamination and would require the EPA to determine whether to designate all PFAS as hazardous under CERCLA and as toxic under the TSCA.[120] The Act would further establish national standards for PFAS quantities, promulgate label standards for PFAS-free products, prohibit unsafe PFAS waste incineration, and require the EPA in consultation with the FAA to minimize fire-fighting foam and other equipment containing PFAS.[121]

Congress and the Department of Defense have also partially addressed the use of PFAS in the military in the National Defense Authorization Act. Of note, the 2019-2022 NDAAs have prohibited the use of PFAS in meals ready-to-eat packaging delivered to the military,[122] restricted DOD procurement of products containing PFAS,[123] and commissioned further health and safety studies of PFAS, among other PFAS-limiting provisions.[124]

C. *Regulation of PFAS in Food Contact Materials*

Notwithstanding ample authority to address this crisis, the FDA's regulation of PFAS in food contact materials is anemic at best.

1. *The FDA's Authority to Regulate Food Contact Materials*

Congress expanded the FDA's ability to regulate substances like PFAS in several rounds. The 1938 Food, Drug, and Cosmetics Act ("FDCA") gave the FDA

118. *See EPA Advances Science to Protect the Public from PFOA and PFOS in Drinking Water*, ENV'T PROT. AGENCY (Nov. 16, 2021), https://www.epa.gov/newsreleases/epa-advances-science-protect-public-pfoa-and-pfos-drinking-water; *Proposed Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, ENV'T PROT. AGENCY (SEPT. 8, 2022), https://www.epa.gov/superfund/proposed-designation-perfluorooctanoic-acid-pfoa-and-perfluorooctanesulfonic-acid-pfos. EPA's review resulted in lowering the health advisory limits for PFOS and PFOA more than a thousandfold . *See supra* n. 66. The EPA has also promised a first-of-its-kind proposed PFAS National Drinking Water Regulation in the Fall of 2022. *Id.*

119. *See* PFAS Action Act of 2021, H.R. 2467, 117th Cong. §2 (as passed by House, July 21, 2021).

120. *Id.*

121. *Id.*; 14 C.F.R. § 139.317(h), (j) (2022 (Because PFAS are heavily used in fire-fighter foam at airports, for example, the FAA has promulgated several regulations attempting to curtail that practice.); Fed. Aviation Admin., National Part 139 Cert Alert No. 21–05 (Oct. 4, 2021). Unfortunately, to date, these efforts have not made a significant difference. *See* Liz Hitchcock, *FAA Must End the Use of Polluting PFAS Firefighting Foam* (Oct. 5, 2021), https://saferchemicals.org/2021/10/05/faa-must-end-the-use-of-polluting-pfas-firefighting-foam. *See also* Qualified Products Database https://qpldocs.dla.mil/search/parts.aspx?qpl=1910&param=QPL-24385&type=256 (listing Fire Extinguishing Agent, Aqueous Film-Forming Foam (AFFF) Liquid Concentrate, for Fresh and Sea Water).

122. *See* S. Res. 1790, 116th Cong. (2019) (enacted).

123. *See* H.R. Res. 6395, 116th Cong. (2021) (enacted).

124. *See* National Defense Authorization Act for Fiscal Year 2022, S. 1605, 117th Cong. (2021).

authority to oversee the safety of food.[125] The 1958 Food Additives Amendment expanded that authority to "food additives"—any substance that may become "a component or otherwise affect[] the characteristics of any food."[126] The newly added section, titled "Unsafe Food Additives," stated that the FDA can regulate a food additive by (1) expressly listing it as safe,[127] (2) exempting it from regulation,[128] or (3) granting market approval for a specific use through a petition process.[129]

The 1997 Food and Drug Modernization Act added a specific reference to "food contact substances"—substances "intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food"—as a subset of food additives.[130] Section 409(h) also provided for a new, more passive premarket authorization scheme for food contact substances, whereby a manufacturer submits a food contact notification (FCN) to the FDA for each new chemical and, if the FDA does not object within 120 days, the substance gains automatic market approval.[131] Under the amendment, all food contact substances are routed through the FCN program, unless the Secretary decides that a petition "is necessary to provide adequate assurance of safety."[132] Because PFAS are neither listed as safe nor exempt from regulation, and the Secretary has not routed them through a petition process, all PFAS in food contact materials currently gain market approval through the filing of an FCN.[133]

2. *The Current FDA Procedures for PFAS in Food Contact Materials are Deficient*

The FDA claims to conduct rigorous review of the scientific data supporting each FCN and to only "authorize[]" a substance if "sufficient scientific information" demonstrates that the substance "is safe for the intended use"[134]—defined as a "reasonable certainty in the minds of competent scientists that a substance is not harmful under the intended conditions of use."[135] The FDA further claims that, even after

125. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75–717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301–99(i)).
126. Food Additives Amendment of 1958, Pub. L. No. 85–929, 72 Stat. 1785 (codified at 21 U.S.C. § 348).
127. 21 C.F.R. § 172.5 (2022); 21 C.F.R. § 174.5 (2022).
128. 21 C.F.R. § 170.39 (2022).
129. Food Additive Amendment, *supra* note 126.
130. 21 U.S.C. § 348(h)(6).
131. 21 U.S.C. § 348(h)(2)(A).
132. 21 U.S.C. § 348(h)(3).
133. 21 U.S.C. § 348(h).
134. *See Authorized Uses of PFAS in Food Contact Applications*, FOOD AND DRUG ADMIN., https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications (last modified Feb. 24, 2022); *Preparation of Food Contact Substance Notifications (Administrative): Guidance for Industry*, FOOD AND DRUG ADMIN. (Oct. 2021), https://www.fda.gov/media/153218/download.
135. 21 C.F.R. § 170.3(i)(2002). (In prior iterations of its regulation, the FDA has defined safe in less strict terms—requiring instead merely "no significant risk of harm," (21 C.F.R. § 121.1(i) (1972)), or "convincing evidence that establishes with reasonable certainty that no harm will result."); 21 C.F.R. § 121.1(i) (1970); *see also Food Additives*: *Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong., 456 (1957) (reasoning "We do not want to feed chemically treated food to our children if the only assurance we have is that it is reasonably probable that the added

market approval, it "reviews new scientific information on the authorized uses of food contact substances to ensure that these uses continue to be safe." [136] It also may revoke an FCN if there is no longer a reasonable certainty of no harm from the authorized use.[137]

This process, however, plays out differently in practice. First, under the FCN program, the FDA does not actually "authorize" substances for market use. Because an FCN becomes automatically effective within 120 days, and because the FDA has no obligation to communicate its approval to the manufacturer,[138] the fact that an FCN is currently effective does not by itself demonstrate affirmative review or determination of safety.[139]

Second, the type of data the FDA currently requires for an FCN does not allow for meaningful review. According to FDA's guidance to industry, "the level of data required to support the safety of a food contact substance depends on the estimated daily intake of the [substance]."[140] The Agency currently leaves this important determination to the notifying party, asking it to conduct its own migration testing and estimation.[141] Different testing conditions, however, can produce vastly different values, and often result in industry greatly underestimating migration.[142] The FDA not only does not require strict testing conditions but it permits industry to use methods that FDA's own scientists have established result in underreporting PFAS migration into food.[143] The FDA even advises notifying parties on how to avoid potential *over*estimation.[144]

---

chemicals will not cause harm. We want to know that it has been established convincingly . . . ." The current version is arguably the strictest—contemplating not only affirmative reasonable certainty of safety (rather than passive lack of data on harm), but also looking to the opinions held by the scientific community at large, rather than just FDA's own reviewers.); 21C.F.R. § 170.3(i) (2022); *see also* Cyclamate Commissioner's Decision,45 Fed. Reg. 61,474, 61,477 (proposed Sept. 16,1980) (discussing the general safety standard in the course of affirming the decision to reject the food additive petition for cyclamate); *Marshall Minerals, Inc. v. FDA*, 661 F.2d 409, 419 (5th Cir. 1981) (noting that the FDA "assert[ed] that this later definition is taken from the legislative history of the Act," but resolving the dispute concerning gentian violet without regard to which of the two standards applied).

136. *See* Food and Drug Admin., *supra* note 134.

137. *Id.*

138. Action on a premarket notification for a food contact substance (FCN), 21 C.F.R. § 170.104 (2022).

139. 21 U.S.C. § 348(h)(2)(A).

140. *See Regulatory Report: Assessing the Safety of Food Contact Substances*, FOOD AND DRUG ADMIN. (Sept. 2007), http://wayback.archive-it.org/7993/20171114191242/https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ucm064166.htm.

141. *See Guidance for Industry: Preparation of Food Contact Substance Notifications (Toxicology Recommendations)*, FOOD AND DRUG ADMIN (Oct. 2021), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-substance-notifications-toxicology-recommendations; *See also Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations)*, FOOD AND DRUG ADMIN. (2007), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-premarket-submissions-food-contact-substances-chemistry.

142. *See* Elizalde et al. (2018), *supra* note 2, at 10–11 (finding that the increase of temperature in the range 80–160°C gave rise to the migration of the PFCAs.); Begley et al., *supra* note 58, at 1028.

142. *See* Zabaleta et al. (2020), *supra* note 2, at 8.

143. *See* Begley et al., *supra* note 56.

144. *See* Food and Drug Admin. (Chemistry Recommendations), *supra* note 141, at 5 (For example, in its guidance on testing FCMs used with infant formula, the FDA explicitly permits the use of the testing simulant Tenax, which has been discredit by scientists as consistently underreporting migration especially for milk powders, (*see* Zabaleta et al. (2020), *supra* note 2, at 1), all the while cautioning industry on how to avoid *over*reporting.).

Aided by these permissive guidelines, a manufacturer can self-determine estimated exposure to their substance and may thus submit minimal safety data.[145] For a substance with expected dietary exposure equal to or less than 0.5 ppb, the FDA requires no toxicity studies.[146] If the expected exposure falls between 0.5 ppb and 50 ppb, the FDA "recommends," but does not require, short-term genetic toxicity tests to evaluate carcinogenic potential.[147] The manufacturer has no obligation, however, to evaluate a substance's other health effects.[148] Indeed, the FDA would request studies on neurotoxicity, immunotoxicity, teratogenicity, and reproductive toxicity only for very high estimated exposure and, even then, only if there are any "troubling findings" in the original submission.[149] Unsurprisingly, under this self-reporting system, 85% of the chemicals subject to FCNs have claimed dietary exposure below 50 ppb, even though independent testing shows that actual levels are several magnitudes higher.[150] Thus, as the FDA itself acknowledged, "for the majority of FCSs and their impurities, the safety decision is based primarily on [] short-term genotoxicity testing," without taking into account other potential health impacts.[151]

Third, the FDA's claim that it routinely examines new data on prior approvals is suspect given FDA's proven failure to uncover pertinent health information for years after it has become publicly available.[152] As one of many examples, in 2010, the FDA allowed several FCNs for certain short-chain PFAS (6:2 FTOH) to become effective despite the fact that one of the applicants, Daikin, had already conducted a study revealing the chemical's high toxicity to lab rats' kidneys and livers.[153] The company repeated the study in 2014 and confirmed the same toxicity results.[154] Both of these studies were publicly available on the company website until December 2017.[155] Likewise, in 2012, another manufacturer, DuPont, conducted a study that showed these compounds bio-persist.[156] This study too is published and available.[157] Had the FDA engaged in the type of post-authorization review that it claims to routinely conduct, it should have been alerted to the fact that 6:2 FTOH are anything but "safe" for human consumption years ago. Indeed, FDA's own scientists

145. *See* Food and Drug Admin. (Toxicology Recommendations), *supra* note 141, at 8.
146. *Id.*
147. *Id.*
148. *Id.*
149. *Id.*
150. *See* Food and Drug Admin., *supra* note 141.
151. *Id.*
152. *Agriculture, Rural Development, Food And Drug Administration, And Related Agencies Appropriations For 2020*, Hearings on Appropriations H. of Rep., 116th Cong. 355–56 (2019) (statement by Dr. Gottlieb) (in response to a question about whether "the FDA consider[s] new scientific information once an indirect food additive has been approved," stating that the FDA "would evaluate the food contact materials in the same way we would evaluate other food additives. […] If there are historical compounds still in use that your specific question is about, I would be happy to take that back and take a look at what the process was that they went through and whether or not there was updated scientific information that we have taken into consideration.").
153. *See* Tom Perkins, *Chemical Giants Hid Dangers of 'Forever Chemicals' in Food Packaging*, THE GUARDIAN (May 2021), https://www.theguardian.com/environment/2021/may/12/chemical-giants-hid-dangers-pfas-forever-chemicals-food-packaging-dupont.
154. *See Activities for Environmental Issues*, DAIKIN INDUST, LTD., (2017),
155. *Id.*
156. *See* Shawn A. Gannon, et al., *Toxicokinetic Evaluation of 6:2 Fluorotelomer Alcohol and Metabolites in Rats Following 90-days of Oral Exposure*, 126 TOXICOLOGY OFF. J. SOC. TOXICOLOGY 319, 319-28 (2012).
157. *Id.*

published a comprehensive review of the available literature in 2015,[158] followed by a study in 2018,[159] and two published studies in early 2020,[160] all concluding that 6:2 FTOH and its metabolites bio-persist in living tissue and have much higher toxicity than originally assumed.

Finally, the FDA's claim that it would revoke authorizations when the science no longer supports reasonable certainty of safety likewise does not play out in practice. Since the 1960s, the FDA has allowed the use in food packaging of 83 different PFAS compounds—19 of which since 2002.[161] It has also authorized the use of four types of PFAS to make plastic food packaging, one as recently as 2016.[162] To date, the FDA has not issued ***any*** proactive bans or revocations on the use of PFAS in food contact materials. News outlets sometimes refer to a handful of long-chain PFAS as "banned,"[163] but that is imprecise. In response to growing public pressure, by 2002, the main global manufacturer of PFAS (3M) voluntarily discontinued the chemical used to produce PFOS and its precursors.[164] Pursuant to EPA's Stewardship Program, eight manufacturers also phased out production of PFOA by 2010. Thus, by 2016, when the FDA removed its authorization of three long-chain PFAS in response to a public interest petition,[165] these chemicals had already been phased out voluntarily for over five years.[166] In 2016, 3M notified the FDA that the use of two other long-chain PFAS "has been completely and permanently abandoned by industry in the U.S. market."[167] In response, the FDA rescinded its market authorization for these chemical compounds as well.[168] Importantly, the FDA noted that "amending this regulation is not based on a safety evaluation; rather, it is based on the abandonment of these uses."[169]

Indeed, even when faced with hard evidence that certain PFAS pose a serious risk of harm to consumers, the FDA has refused to take decisive actions. After

158. *See* Rice et al., *supra* note 83.
159. *See* Kabadi et al., *supra* note 80.
160. *See* Kabadi et al., *supra* note 83; Rice et al., *supra* note 80.
161. *See Inventory of Effective Food Contact Substance (FCS) Notifications*, FOOD AND DRUG ADMIN. (Jan. 25, 2022), https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications; Food and Drug Admin. (2012), *supra* note 132; *FOIA Requests to FDA*, ENV'T DEF. FUND (Oct. 2017), http://blogs.edf.org/health/files/2018/05/EDF-PFAS-FDA-FCN-Environmental-Assessments-Full-5-17-18.pdf.
162. *See Beyond Paper, Part 2: PFAS Intentionally Used to Make Plastic Food Packaging*, ENV'T DEF. FUND (Aug. 2021), http://blogs.edf.org/health/2021/08/12/beyond-paper-part-2-pfas-intentionally-used-to-make-plastic-food-packaging.
163. *See, e.g.*, Carolyn Heneghan, *FDA Bans Long-Chain PFCs Used in Food Packaging, Citing Safety Concerns*, FOODDIVE (Jan. 6, 2016), https://www.fooddive.com/news/fda-bans-long-chain-pfcs-used-in-food-packaging-citing-safety-concerns/411598.
164. *See* Mangus Land, et al., *What is the Effect of Phasing Out Long-Chain Per- and Polyfluoroalkyl Substances on the Concentrations of Perfluoroalkyl Acids and Their Precursors in the Environment? A Systematic Review Protocol*, 4 ENV'T EVID. 1, 1–13 (2015).
165. *See* Indirect Food Additives: Paper and Paperboard Components Final Rule, 81 Fed. Reg. 83672 (Proposed Jan. 04, 2016)(to be codified at 21 C.F.R. Part 176).
166. *See FDA Bans Three Toxic Chemicals From Food Wrapping – Too Little, Too Late*, ENV'T WORKING GRP. (Jan. 4, 2016), https://www.ewg.org/news-insights/news-release/fda-bans-three-toxic-chemicals-food-wrapping-too-little-too-late.
167. *See FDA Removes Approval for the Use of PFCs in Food Packaging Based on the Abandonment*, FOOD AND DRUG ADMIN. (Nov. 21, 2016) https://www.fda.gov/food/cfsan-constituent-updates/fda-removes-approval-use-pfcs-food-packaging-based-abandonment; *see also* Indirect Food Additives: Paper and Paperboard Components Final Rule, 81 Fed. Reg. at 83672.
168. *See* Indirect Food Additives: Paper and Paperboard Components Final Rule, 81 Fed. Reg. at 83672.
169. *Id.*

learning that Daikin and DuPont hid damaging evidence, and in response to Dr. Rice's findings that 6:2 FTOH bioaccumulate, bio-persist, and are toxic, for example,[170] the FDA merely sent out soft inquiry letters.[171] Five years later, the Agency allowed the manufacturers to voluntarily phase out these substances on their own timeline (and to replace them with new PFAS in due time).[172] Likewise, following the EPA's August 2021 announcement that PFAS can form and migrate from some fluorinated plastic containers in high quantities,[173] the FDA merely issued "a letter reminding industry that only certain fluorinated polyethylene containers are authorized for food contact use" and asked manufacturers to consult "FDA's regulation."[174]

Tepid admonitions, limited phase-outs, self-professed "bans," and promises for future action notwithstanding, 61 PFAS chemicals continue to be used in bottles, bags, paperboard, other food packaging, nonstick cookware, and plastic containers.[175] Moreover, although the phased-out PFAS are no longer used in the U.S., the majority of them are technically still authorized for use, so they may be imported in finished food-contact products arriving from countries, such as China, where both long- and short-chain PFAS remain unregulated.[176]

To make matters worse, not only are PFAS getting to the U.S. market almost by default and lingering long after they have been proven harmful by scientists, but they could also entirely sneak under FDA's—and the public's—radar by being self-certified as "generally recognized as safe" ("GRAS"). Congress recognized that certain substances, such as salt, pepper, sugar, and vinegar, while technically "food additives," have been so widely recognized as safe that they needed to be excepted from regulation.[177] The FDA therefore has authority to grant GRAS status to certain

170. *See, e.g.*, Kabadi et al., *supra* note 80; Rice et al., *supra* note 83.

171. *See, e.g.*, Office of Food Additive Safety Center for Food Safety and Applied Nutrition, Opinion Letter on Use of Food Additives on Paper and Paperboard to Keller & Heckman LLP (Oct. 01, 2019). *Cf.* 21 C.F.R. § 170.105.

172. *See, e.g.*, Office of Food Additive Safety Center for Food Safety and Applied Nutrition, Opinion Letter Regarding FCN Nos. 820, 827, 888, 933, 1044, 1360, and 1451 (July 29, 2020). (Five years after learning that 6:2 FTOH are bio-persistent and toxic to humans, on July 31, 2020, the FDA announced that, starting in January 2021, three manufacturers will begin a voluntary 3-year phase-out of their sales of certain substances that contain 6:2 FTOH for use as food contact substances in the U.S. marketplace. A fourth manufacturer had begun a voluntary phase-out of their short-chain 6:2 FTOH products in the U.S. market in 2019.); *FDA Announces Voluntary Agreement with Manufacturers to Phase Out Certain Short-Chain PFAS Used in Food Packaging*, FOOD AND DRUG ADMIN. (July 31, 2020) https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-agreement-manufacturers-phase-out-certain-short-chain-pfas-used-food.

173. *See EPA Takes Action to Investigate PFAS Contamination*, ENV'T PROT. AGENCY (Jan 14. 2021), https://www.epa.gov/newsreleases/epa-takes-action-investigate-pfas-contamination.

174. *See FDA Issues Letter to Industry on Fluorinated Polyethylene Food Contact Containers*, FOOD AND DRUG ADMIN. (Aug. 5, 2021), https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-letter-industry-fluorinated-polyethylene-food-contact-containers.

175. *See* Tom Neltner & Marciel Maffini, *FDA Must Abandon Its Flawed Assumptions when Reviewing Safety of Approved PFAS Uses in Food*, ENV'T DEF. FUND (Aug. 5, 2019), http://blogs.edf.org/health/2019/08/05/fda-must-abandon-flawed-assumptions-reviewing-safety-pfas/?utm_source=gmail&utm_campaign=edf-health_none_upd_hlth&utm_medium=email&utm_id=1565024364.

176. *See* Nordic Council, *supra* note 105; *see also* Food and Drug Admin. (2002), *supra* note 161.

177. *See* 1957 Hearings, *supra* note 135, at 461–62, 64 (statement of George P. Larrick, Commissioner of Food and Drugs providing that "There are literally thousands of substances in that category." One witness read the GRAS exception to mean that "this amendment would not apply to normally safe food additives of agricultural and farm origin; it would principally apply to food chemical additives in an industrial sense.").

substances under prescribed conditions.[178] Under its GRAS Rule, however, the FDA also allows parties to make private determinations that a substance qualifies as GRAS, and to either voluntarily notify the Agency or use the substance without notice and regulatory oversight.[179]

Currently, the FDA database of all voluntarily filed GRAS notices lists at least one fluorinated carbon compound to be used as a food additive in "the production of food flavors and flavorings as an extraction solvent"—refrigerator freon.[180] The notice was filed in 2001 and the FDA had "no questions" concerning this GRAS determination.[181] An untold number of other fluorinated substances may well be in use without a voluntary notice,[182] because FDA's inaction on PFAS telegraphs to the industry the Agency's implicit agreement that these substances are safe for use as food additives.

IV. CURRENT APPROACHES TO THE CRISIS OF PFAS IN FCMS

FDA's lack of meaningful regulation over PFAS in FCMs has prompted a patchwork of different approaches from stakeholders, including Congress, individual states and cities, private litigants, and retailers and food establishments. These approaches are instructive on possible paths to resolving this public health emergency but so far have had limited effect.

Congressional action on PFAS in FCMs has been sparse. Members of Congress have introduced bills such as "Keep Food Containers Safe from PFAS"—two as recently as November 2021—but they have never gone past the subcommittee stage.[183] The only context, in which Congress has been willing to act on PFAS, has been the military. Due in part to the military's role in proliferating PFAS into the

178. *See* Food Additive Amendment, *supra* note 126. (Substances that are determined as GRAS by the FDA are listed in 21 C.F.R. § Parts 170, 184, 186, and 570).

179. 81 FR 54960 (In 2010, the Government Accountability Office conducted a review of FDA's GRAS procedures); *see* U.S. Government Accountability Office, *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)*, GAO-10-246, https://www.gao.gov/products/gao-10-246 [hereinafter GAO Report] (the report concluded that "FDA's oversight process does not help ensure the safety of all new GRAS determinations."); *Id.*(It noted that the "FDA only reviews those GRAS determinations that companies submit to the agency's voluntary notification program—the agency generally does not have information about other GRAS determinations companies have made because companies are not required to inform FDA of them."); *Id.* (Even more problematically, the agency "has not issued guidance to companies on how to document their GRAS determinations or monitored companies to ensure that they have conducted GRAS determinations appropriately."); *Id.* (These flaws, the GAO concluded, "detract[] from the program's credibility" because "the agency has not systematically reconsidered GRAS substances since the 1980s."); *Id.* (Nor does the FDA know "to what extent, or even whether, companies track evolving scientific information about their GRAS substances."); *Id.* (On the basis of these and other concerns, the GAO recommended significant changes in the GRAS procedures); *Id.* (However, despite enacting the latest GRAS Rule after the GAO report issued, the FDA has largely failed to address any of these recommendations in a meaningful way, leaving a potential and significant loophole in its food additive and food contact substances regulations); *Id.*

180. *See* FDA, *GRAS Notices Database*, GRN 82, https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&sort=GRN_No&order=DESC&startrow=1&type=basic&search=fluor.

181. *Id.*

182. *See* GAO Report, *supra* note 179.

183. *See* Keep Food Containers Safe from PFAS Act of 2019, H.R. 2827, 116th Cong. (2019); Keep Food Containers Safe from PFAS Act of 2021, H.R. 6026, 117th Cong. (2021); Keep Food Containers Safe from PFAS Act of 2021, S.3169, 117th Cong. (2021).

environment, Congress has allotted significant funds to researching the environmental and health implications of PFAS on and around military bases and has slowly phased out PFAS in various military applications.[184] Most notably, "to protect our servicemembers from ever being exposed to harmful PFAS chemicals in MREs, Meal, Ready-to-Eat,"[185] the 2020 NDAA prohibited the use of PFAS in food packaging for MREs effective October 1, 2021 through a bipartisan amendment.[186]

Given the federal vacuum, several states have taken proactive measures to ban PFAS in FCMs. In 2019, Maine banned PFAS in food packaging, if the state environmental agency determines that safer alternatives exist.[187] In November 2021, California implemented a broad ban on the use of PFAS in a range of products, including food packaging and cookware.[188] New York State likewise enacted a broad ban on the sale and distribution of food packaging with intentionally added PFAS as of December 31, 2022.[189] Starting in February 2023, Washington will restrict the use of PFAS in four types of food packaging, for which the Legislature has determined safer alternatives exist.[190] Vermont[191] and Connecticut[192] also enacted a ban on PFAS in food packaging effective in 2023. Lastly, Minnesota banned all businesses from "knowingly" selling or distributing food packaging containing PFAS as of January 2024.[193] Ten other states are presently considering increased restrictions or bans on PFAS in food packaging.[194] Individual cities, like New York

184. *See, e.g.*, John S. McCain National Defense Authorization Act for Fiscal Year 2019, PUB. L. 115-232 § 323 (2018); William M. (Mac) Thornberry National Defense Authorization Act, PUB. L. NO. 116-6395 § 333 (2021); National Defense Authorization Act for Fiscal Year 2022, PUB. L. 117-81 (2021) (135 Stat. 1541).

185. H. Rept. 116-333 (NDAA 2020); 116 Cong. Rec. H5648, 2019 (statement of Rep. Debbie Dingell).

186. *See* National Defense Authorization Act for Fiscal Year 2020, PUB. L. 116-92 § 329 (2019).

187. *See* State of Maine, *An Act To Protect the Environment and Public Health by Further Reducing Toxic Chemicals in Packaging*, H.P. 1043 - L.D. 1433 (2019), https://www.maine.gov/dep/safechem/packaging/LD1433-PL277.pdf.

188. Rick McNeil, *No Treats, Too Many Tricks, For PFAS This Halloween*, CROWELL (Nov. 17, 2021) https://www.retailconsumerproductslaw.com/2021/11/no-treats-too-many-tricks-for-pfas-this-halloween/.

189. State of New York, *Relates to The Use of Perfluoroalkyl and Polyfluoroalkyl Substances in Food Packaging*, Senate Bill S8817 (2019-2020 Legislative Session) https://www.nysenate.gov/legislation/bills/2019/s8817.

190. Washington State, *Packages Containing Metals and Toxic Chemicals*, 70A.222 RCW https://apps.leg.wa.gov/rcw/default.aspx?cite=70A.222; Washington State Department of Ecology and Health, *PFAS in Food Packaging Alternatives Assessment* https://www.ezview.wa.gov/site/alias__1962/37610/pfas_in_food_packaging_alternatives_assessment.aspx.

191. State of Vermont, *No. 36 An Act Relating to Restrictions on Perfluoroalkyl and Polyfluoroalkyl Substances and Other Chemicals of Concern in Consumer Products* (May 19, 2021) https://legislature.vermont.gov/Documents/2022/Docs/ACTS/ACT036/ACT036%20As%20Enacted.pdf.

192. State of Connecticut, *An Act Concerning the Presence of PFAS in Certain Consumer Packaging* (June 9, 2021). https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=SB00926&which_year=2021.

193. *See* State of Minnesota, *Omnibus Environment, Natural Resources, and Tourism Bill* (June 2021) https://www.revisor.mn.gov/bills/bill.php?b=House&f=SF20&ssn=1&y=2021.

194. *See, e.g.*, Arizona, *Food Packaging; Prohibitions*, HB2095 (2021), https://apps.azleg.gov/BillStatus/BillOverview/74483; Iowa, *An Act Relating to The Control of Certain Chemicals in Public Drinking Water Supply Systems and Consumer Products*, House File 293, https://www.legis.iowa.gov/legislation/BillBook?ba=HF293&ga=89; Massachusetts, An *Act Relative to Chemicals in Food Packaging*, Bill S1494, https://malegislature.gov/Bills/192/S1494; Maryland Senate Bill 195, https://legiscan.com/MD/bill/HB22/2021; Michigan, HB5250 (2021), http://www.legislature.mi.gov/(S(y142ukzdhagqmpmqegnvyag1))/mileg.aspx?page=GetObject&objectname=2021-HB-5250; Oregon, HB2365 Relating to Food Service Ware,

City[195] and San Francisco[196] have also banned the use of foam or single-use plastic containers and PFAS on food-contact papers. While these measures are encouraging, they fall short of delivering the type of uniform and decisive action needed to address this national crisis.

Litigation efforts offer another potential solution in the long-term but can do little to protect consumers today. There are several multi-district and class action lawsuits related to harm that PFAS has caused through environmental exposure (e.g., firefighting foams and groundwater contamination).[197] While meritorious litigation can be a powerful force for societal change, it often takes years before it shifts industry practice. More needs to be done in the interim to protect public health.

Market-based solutions can be an optimal driver of change if the market is properly informed and engaged in the issue. Environmental and consumer protection groups' efforts have helped educate a subset of consumers about the dangers of PFAS. These consumers have in turn created market pressure that prompted some fast-food retailers and grocery chains to phase out the use of PFAS-laden food packaging and paper products. Public commitments have come from Cava, Chipotle, Freshii, McDonald's, Panera Bread, Sweetgreen, Taco Bell, Wendy's, Trader Joe's, Burger King, Chick-fil-A, Whole Foods Market, and Amazon.[198] These promises, while encouraging, are limited in scope and impact.[199] Even assuming every one of these entities lives up to their commitment without regulatory pressure, many other retailers and manufacturers are unwilling or unable to do so on their own. Moreover, without better testing protocols and strict labeling requirements, consumers and retailers alike easily fall prey to "green-washing"—manufacturers claiming their products are "PFAS-free" because they do not contain PFOS and PFOA, even though they contain numerous lesser-known PFAS that are equally harmful to human health.[200] Lastly, market pressure is an effective catalyst

---

https://olis.oregonlegislature.gov/liz/2021R1/Measures/Overview/HB2365; Pennsylvania HB1965, https://www.legis.state.pa.us/cfdocs/billinfo/BillInfo.cfm?syear=2021&sind=0&body=H&type=B&bn=1965; Rhode Island S110, https://legiscan.com/RI/bill/S0110/2021; Virginia HB1712 https://lis.virginia.gov/cgi-bin/legp604.exe?211+ful+HB1712+hil; Wisconsin S361 https://docs.legis.wisconsin.gov/2021/proposals/reg/sen/bill/sb361.

195. City of New York City, Foam Ban (2019), https://www1.nyc.gov/assets/dsny/site/resources/recycling-and-garbage-laws/collection-setout-laws-for-business/foam-ban.

196. City of San Francisco, *Environment Code- Single-Use Food Ware Plastics, Toxics, and Litter Reduction*, 1 (2018), https://sfgov.legistar.com/View.ashx?M=F&ID=6440747&GUID=CB06903B-B172-4E84-A653-732D73DD982B.

197. *See*, e.g., *Aqueous Film-Forming Foams (AFFF) Products Liability Litigation*, MDL No. 2873 (S.D. SC); *In re:* E. I. du Pont de Nemours and Company C-8 Personal Injury Litigation, 2:13-md-02433-EAS-EPD (S.D. Oh); *see also* Sullivan et al. v. Saint-Gobain Performance Plastics Corporation, 5:16-cv-00125-gwc (Filed May 6, 2016; Settlement Finalized by Court Jan. 6, 2022 (S.D. Ver.); Johns et al v. Wolverine World Wide, Inc. et al., 1:18-cv-01302-JTN-SJB (W.D. Mich.); New Jersey Department Of Environmental Protection et al. v. E.I. Du Pont De Nemours And Company et al., 3:19-cv-14767-ZNQ-JBC (D. N.J.); Giovanni et al. v. United States Department of the Navy, 2:16-cv-04873-GJP (E.D. Penn.).

198. *See* Toxic-Free Future, *Get the Facts: PFAS*, https://saferchemicals.org/get-the-facts/toxic-chemicals/pfas-per-and-polyfluoroalkyl-substances/; *see also Amazon Restricts 17 Chemicals in FCMs*, FOOD PACKAGING FORUM (Dec. 2020), https://www.foodpackagingforum.org/news/amazon-restricts-17-chemicals-in-fcms; *see also* CONSUMER REPS., *supra* note 39.

199. CONSUMER REPS., *supra* note 39.

200. *See* Courtney Lindwall & Molly M. Ginty, *"Forever Chemicals" Called PFAS Show Up in Your Food, Clothes, and Home*, NRDC (Jan. 07, 2020), https://www.nrdc.org/stories/forever-chemicals-called-pfas-show-your-food-clothes-and-home; *see also* Jeff Gearhart, *Undisclosed PFAS Coatings*

for change but requires time to shift behavior.[201] Given that PFAS are a ticking bomb, time is of the essence.

IV. PROPOSED SOLUTION

PFAS have all the markers of a public health crisis. They are ubiquitous in food contact materials, readily migrate into food, bioaccumulate and bio-persist in human tissues, and have proven detrimental health effects. Yet, FDA's current response is anemic to nonexistent. This is not the first time that the FDA has allowed a slow-moving crisis to unfold while it fails to act. Consider the fight against tobacco manufacturers,[202] DDT's use in agriculture,[203] and lead contamination.[204] In all these scenarios, while numerous stakeholders played an instrumental role in bringing about awareness and change, only a sweeping regulatory overhaul—belated though it may have been—ultimately addressed the root cause of the crisis. The same is true with PFAS.

While solutions outside of federal regulation are essential, the FDA is best suited to address the catastrophic consequences of PFAS in our food. It has both the authority and duty to do so. Therefore, this article argues that the most direct approach is for the FDA to regulate PFAS as a class,[205] and to (1) rescind all current

Common on Cookware, Research Shows, ECOLOGY CTR. (Dec. 15, 2020), https://www.ecocenter.org/undisclosed-pfas-coatings-common-cookware-research-shows; Lela Nargi, *Teflon Pan Safety: What You Need to Know About Nonstick Pans*, FOODPRINT (May 26, 2020), https://foodprint.org/blog/teflon-pan-safety/; *PFAS Coatings Continue to be Found on Cookware*, ECOLOGY CTR. (Oct. 6, 2021), https://www.ecocenter.org/our-work/healthy-stuff-lab/reports-landing-page/whats-cooking-2021-update/pfas-coatings-continue.

201. *See* U.S. Department of Agriculture, Economic Research Service, *ERS Charts of Note* https://www.ers.usda.gov/data-products/charts-of-note/charts-of-note/?topicId=f575ba4b-a80b-4786-ad83-bf5af5c0aa2d (Despite "double-digit growth for most years since 2000," for example, the organic food market still accounts for just over 5% of the total U.S. market.).

202. *See, e.g.*, R., *A Look Back at the Evolution of the Family Smoking Prevention and Tobacco Control Act and the Present-Day Impact on "Overlooked and Belated Issues"-Electronic Nicotine Delivery Systems (Ends) and the Youth Epidemic*, Ment, 17 IND. HEALTH L. REV. 107, 108 (2020) (Smoking raised health concerns as early as the 1960s, yet it took Congress and the FDA until 2009 to pass any meaningful regulation.).

203. *See* S. Banks, *The "Erin Brockovich Effect": How Media Shapes Toxics Policy*, Environs Envtl. L. & Pol'y J., 219, 222-223 (Spring 2003) (Despite scientists raising concerns about the use of DDT as early as the mid-40s, the EPA did not ban the pesticide until 1972.).

204. *See, e.g.*, K Reiss, *Federal Regulation of Lead in Drinking Water*, 11 VA. ENVTL. L.J. 285, 294 (1992) (Despite Congressional action in the early 70s to limit lead in drinking water (and despite lead being a known contaminant since the time of the Roman Empire), the EPA did not begin to effectively regulate lead contamination until the 1990s.).

205. *See* EDF, et al., *Citizens Petition Requesting That the Agency Take More Aggressive Action to Protect Consumers From Per- and Poly-fluoroalkyl Substances (PFAS) by Banning All Forms that Biopersist in the Human Body* (June 3, 2021), http://blogs.edf.org/health/files/2021/06/PFAS-Petition-to-FDA-FINAL-6-1-21.pdf (Several public interest and consumer protection organizations asked the FDA to do just that in June 2021); *See* FDA, *Food Additives: Food Contact Substance Notification That Is No Longer Effective*, 87 FR 3949 (2022) https://www.govinfo.gov/content/pkg/FR-2022-01-26/pdf/2022-01527.pdf (As of the date of this writing and despite a 180-day deadline to respond (21 C.F.R. § 10.30(e)(2)), the FDA has neither acted nor addressed their petition. Instead, on January 26, 2022, the FDA issued a proposed rule "to amend its regulations relating to the procedures by which [it] determine[s] that a premarket notification for a food contact substance (FCN) is no longer effective."); (If adopted, this rule would allow the FDA to rescind currently effective FCNs for reasons *other than* safety and would afford manufacturers or suppliers additional opportunities "to provide input before [the FDA] could determine that an FCN is no longer effective.") (In other words, rather than re-examining current science and rescinding notices on the grounds of valid and well-supported safety concerns, the FDA is

PFAS authorizations, (2) route any future requests through a petition process, and (3) institute strict labeling and enforcement requirements.

A. The FDA Has Both Authority and a Duty to Ban PFAS in FCMs

Despite its reluctance to act decisively, the agency has the authority to take all proposed steps without the need for additional Congressional authorization. Both the FDCA and the implementing regulations give the FDA authority to amend or repeal a food additive authorization, including a currently effective FCN, where new data "demonstrate that the intended use of the food contact substance is no longer safe."[206] The Act also allows the FDA to promulgate regulations describing the circumstances in which a food additive petition would be required prior to marketing a food contact substance.[207] In making this determination, the FDA should consider probable consumption and potential toxicity.[208] If the FDA approves a petition for a food contact substance, it also has the authority to impose any labeling or packaging requirements it deems necessary to ensure consumer safety.[209]

The FDA also has every reason to act. Historically, the FDA has resisted calls to ban the use of PFAS in FCMs by noting that it does not have sufficient data on specific PFAS substances to quantify their migration, bio-persistence, and health implications, and "more studies are needed to draw concrete conclusions about [individual substances'] safety."[210] These assertions fundamentally misunderstand the applicable burden of proof for establishing safety. Neither the FDA nor the public need to demonstrate definitive lack of safety. To the contrary, the FDCA requires that food additives are *presumed unsafe*,[211] and the burden of proof for demonstrating safety lies entirely with the manufacturer. [212] The manufacturer must establish with reasonable certainty that the substance it intends to use in FCMs does not migrate or expose consumers, does not bio-persist, and does not carry negative health consequences. Lack of data or certainty on any of these points is a reason to deny—or rescind—an FCN, not to keep it effective for longer.

But in the context of PFAS, neither data nor certainty is lacking. The current, near-unanimous,[213] scientific findings demonstrate that both long-[214] and short-chain[215] PFAS migrate from FCMs onto food, bioaccumulate up the food chain, bio-persist in living tissues, and have devastating health effects. Neither group can

actively paving the way for more industry-friendly collaboration and an even softer tack to current PFAS market authorizations).

206. 21 U.S.C. § 348(i); 21 C.F.R. § 171.130(a); 21 C.F.R. §170.105.
207. 21 U.S.C. § 348(h)(3)(B).
208. 21 U.S.C. § 348(h)(3)(B).
209. 21 U.S.C. § 348(c)(1)(A).
210. *See* Perkins, *supra* note 153.
211. 21 U.S.C. § 348(a).
212. 21 C.F.R. § 170.3(i).
213. *See, e.g.*, Anderson, *supra* note 18 (the only studies that conclude otherwise are sponsored by the FluoroCouncil and industry participants).
214. *See* FDA, *Reference 3 FDA Memorandum from P. Rice to P. Honigfort, September 30, 2010 re: Indirect Food Additives: Paper and Paperboard Components* (Jan 7, 2016), https://www.regulations.gov/document/FDA-2015-F-0714-0015.
215. *See* Rice, *supra* note 83; Kabadi, *supra* note 81*; see also FDA Letter to Daikin*, *supra* note 171.

plausibly satisfy the definition of a "safe" food contact substance.[216] Therefore, under any burden of proof, the FDA has enough data, and a legal obligation, to act.

B. A Blueprint to Banning PFAS in FCMs

The FDA should address the use of PFAS in FCMs in three stages: (1) withdrawing current authorizations, (2) routing future requests through a petition process, and (3) enforcing strict labeling requirements.

1. Withdrawal of Current PFAS Authorizations with a Two-Year Phase Out Period

First, the FDA should withdraw all current authorizations for fluorinated substances, including currently effective FCNs, authorizations for the use of fluorine gas in the production of plastic, and any GRAS determinations for fluorinated carbon compounds.

To rescind all currently effective FCNs for PFAS,[217] the agency must notify each company that the intended use of its substance is no longer safe and must then give the company an opportunity to respond.[218] If, based on the response, the FDA affirms its conclusion, it must post a notice in the Federal Register that the specific FCN is no longer effective.[219] The FDA's determination is "a final agency action subject to judicial review."[220]

The FDA should also revoke its 1983 authorization for the use of fluorine gas in the manufacture of polyethylene FCMs.[221] Studies confirm that this treatment method results in high concentrations of PFAS in plastic containers, which in turn migrate in large quantities onto the food or liquid stored inside.[222] Lastly, the FDA should examine its food additive regulations, and should withdraw any approvals for a member of the PFAS family through a simple notice-and-comment process.[223] It should also issue final guidance to industry that no PFAS should be self-certified as GRAS in the future.[224]

Concurrent to these withdrawals, the FDA should conduct a study to determine whether some of these products constitute "an imminent hazard to public health" and must therefore be immediately recalled from the market.[225] Where a product does not fit the regulatory definition for such hazard, the FDA should issue a two-

---

216. 21 C.F.R. § 170.3(i).
217. *See* FDA, *Inventory of Effective Food Contact Substance (FCS) Notifications*, *supra* note 161 (there are currently 69 FCNs for PFAS in FCMs, 8 of which are scheduled for a voluntary phase-out in the near future).
218. 21 C.F.R. § 170.105.
219. *Id.*
220. *Id.*
221. 21 C.F.R. § 177.1615 (2022).
222. *See* EPA, *Rinses from Selected Fluorinated and Non-Fluorinated HDPE Containers* (2021), https://www.epa.gov/pesticides/rinses-selected-fluorinated-and-non-fluorinated-hdpe-containers; *see also* Rand, *supra* note 68.
223. 21 C.F.R. § 170.30(l) (2022) (cross-referencing 21 C.F.R. § 170.38); *see, e.g.*, 36 FED. REG. 12,109, 12,110 (1971) (proposing to revoke saccharin's GRAS status and substitute a provisional food additive regulation); 34 FED. REG. 17,063 (1969) (revoking cyclamate's GRAS status).
224. *See, e.g.*, FDA, CFSAN Level 2 Guidance FDA-2016-D-4484.
225. 21 C.F.R. § 2.5 (2022).

year phase-out period. This phase-out period is intentionally short to minimize public exposure to these substances while permitting manufacturers of FCMs to effectively and economically replace PFAS in their products with safer alternatives, many of which already exist and are in wide use.[226]

2. Routing Future PFAS Premarket Authorizations through a Food Additive Petition

Second, the FDA should promulgate regulations that route any future PFAS authorization requests through a petition.[227] Currently, the FDA requires the submission of a petition when (1) the use of a food contact substance will increase the total dietary consumer exposure to 1000+ ppb for a non-biocide substance or 200+ ppb for biocides,[228] or (2) when existing data is not clearly negative for carcinogenicity.[229] PFAS currently do not satisfy either prong because the FDA calculates PFAS exposure on a substance-per-substance basis. The FDA tolerates as safe a single substance exposure of 50 ppb, [230] and does not require carcinogenicity data below that threshold.

Determining toxicity for bio-accumulating and bio-persistent chemicals like PFAS on a substance-per-substance basis is akin to determining whether tobacco can cause cancer on a cigarette-by-cigarette basis. PFAS substances do not exist in vacuum and the FDA should start evaluating them as a class rather than as unrelated additives. In 2018, the FDA recognized in the context of heavy metal contamination that it had to look "at all the metals across all foods rather than one contaminant, one food at a time" because "[e]ven though the levels of a metal in any particular food is low, our overall exposure adds up because many of the foods we eat contain them in small amounts."[231] The same holds true for PFAS. With several thousand individual substances and with multiple dietary (and many non-dietary) sources of PFAS contamination in our daily lives, the overall consumer exposure adds up, even if individual products contribute limited amounts. Indeed, FDA's own regulations reflect this understanding and instruct the agency to consider a food additive's safety by looking at "[t]he cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet."[232] Therefore, the FDA should quantify total exposure from PFAS as a class from all dietary sources and use that figure as a reference value. Given that a single microwave popcorn bag contributes 39 ppb to a consumer's daily exposure,[233] and liquid stored in fluorine-treated plastic can alone contain 70 ppb of

226. *See* OECD (2020), *supra* note 27.
227. 21 U.S.C. § 348(h)(3)(B) (2018).
228. *See* European Commission, *Poly- and perfluoroalkyl substances (PFAS)* (2020), https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf.
229. 21 C.F.R. § 170.100(c) (2022).
230. *See* FDA, *Letter re: FCN 1493* (Dec. 17, 2014), http://blogs.edf.org/health/files/2019/10/Archroma-FCN-1493-Toxicology-memo.pdf.
231. *See* FDA, *What FDA is Doing to Protect Consumers from Toxic Metals in Foods* (2018), https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods.
232. 21 C.F.R. § 170.3(i) (2022).
233. *See* Begley, *supra* note 56.

various PFAS,[234] the total potential exposure for consumers can easily surpass even FDA's current 50 ppb limit and thus trigger the need for carcinogenicity studies.

In addition, the FDA's current tolerable threshold for PFAS is thousands of times higher than those of the EPA and the Agency for Toxic Substances and Disease Registry.[235] Because of PFAS' outsized propensity to bioaccumulation and bio-persistence, the FDA should require carcinogenicity studies for any substance with a possible cumulative exposure over 0.5 ppb. That alone would guarantee that all PFAS premarket authorizations only happen through a petition rather than an FCN, because the available data on carcinogenicity for both short- and long-chain PFAS is anything but "clearly negative."[236]

Switching PFAS authorizations to a petition process would ensure these substances receive rigorous review. The FDA notes that "the safety standard is the same for all food additives, whether subject to the petition process or the FCN process," implying that the processes are interchangeable.[237] Not so. For one, a petition ensures that no substance gets automatic market approval, even if the agency needs longer than 120 days to complete review.[238] Additionally, unlike an FCN, a petition is statutorily required to include "full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations."[239] Moreover, under what is known as the Delaney clause, a petition cannot issue if the substance "is found to induce cancer when ingested by man or animal, or if it is found, [] to induce cancer in man or animal."[240] Although the Act's general safety standard already encompasses potential cancer risks,[241] both the formulation and application of the

234. *See* Rand & Mulbery, *supra* note 68.

235. *See Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances*, *supra* note 66; *see also* Nordic Council of Ministers, *supra* note 105 (noting in 2018, the Agency for Toxic Substances and Disease Registry concluded that EPA's values should be 10 times lower); *Toxicological Profile for Perfluoroalkyls*, *supra* note 5.

236. 21 C.F.R. § 170.100(c) (2022).

237. *See* FDA, *Preparation of Food Contact Substance Notifications (Administrative): Guidance for Industry (2021)* https://www.fda.gov/media/153218/download.

238. *Compare* 21 U.S.C § 348(c)(2) (2018) (allowing Commissioner to issue order 180 days after the filing of a petition) *with* 21 U.S.C. § 348(h)(2)(A) (stating that FCN automatically effective after 120 days); *see also* 21 C.F.R. § 171.1(j) (2022) ("The date used for computing the 90-day limit . . . shall be moved forward 1 day for each day after the mailing date of the [FDA] request taken by the petitioner to submit the sample."); *Id.* § 171.6 (2022) ("[I]f the Commissioner determines that the additional information or data amount to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew."); *Id.* § 171.7 (2022) (If a petition is withdrawn and then refiled, "the time limitation will begin to run anew.").

239. 21 U.S.C. § 348(b)(2)(E).

240. *Id.* § 348(c)(3)(A).

241. *See* 104 CONG. REC. 17,420 (1958) (statement of Hon. James J. Delaney); *see* 1957 Hearings, *supra* note 135, at 168-69 (statement of Hon. James J. Delaney) (explaining his introduction of a new bill revised only to add the anti-cancer clause)*; see also* 104 CONG, REC. 17,414 (1958) (statement of Hon. Oren Harris) ("While the Committee felt that the bill as reported by the committee includes the matter covered by the Delaney amendment in the general language contained in the bill, there was no objection to the addition of the amendment suggested by Mr. Delaney."); 104 CONG. REC. 17,415 (1958) (letter from Elliot L. Richardson, Assistant Secretary of HEW) ("To single out one class of diseases for special mention would be anomalous and could be misinterpreted. . . . At the same time, if it would serve to allay any lingering apprehension on the part of those who desire an explicit statutory mandate on this point, the Department would interpose no objection to appropriate mention of cancer in food additives legislation."); *cf*. H.R. REP. No. 2284, 85th Cong., 2d Sess. 5 (1958) ("Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with

Delaney clause have provided a more stringent threshold for carcinogenic food additives, requiring that they be disapproved without regard to the (potentially low) level of risk or exposure.[242] Because PFAS have been inextricably linked with cancer risk,[243] application of the Delaney clause through the petition process should, at least in theory, result in few, if any, PFAS compounds approved.

Beyond cancer-specific risks, as part of its petition review, the FDA should issue guidance to industry to require that all PFAS manufacturers, regardless of estimated migration and exposure levels, conduct studies and include data on genetic toxicity, neurotoxicity, immunotoxicity, teratogenicity, reproductive toxicity, and any other health markers suggested by current medical studies. To prevent intentional concealment of post-market safety information, the obligation to provide this type of data should be ongoing.[244] The FDA should also proactively look for new information on its own and should institute systematic post-market reassessment of safety decisions to bring its findings in line with current science in a timely manner.[245]

3. *Instituting Strict Labeling Requirements and Enforcement Procedures*

Lastly, reviewing PFAS through a petition process would allow the FDA to impose appropriate labeling requirements.[246] The FDA relies heavily on consumer warnings for many products in its purview.[247] Currently, there is no expectation that PFAS should be labeled as an ingredient of FCMs. Neither customers nor retailers, therefore, have any way of knowing whether the products they purchase contain these deadly chemicals, short of testing each individual product for total fluorine content. Worse yet, many manufacturers have taken advantage of the lack of regulation in this space and have labeled their products "PFAS-free," when in fact, they are anything but.[248] The omission of the most well-known compounds, such as PFOA and PFOS, ostensibly gives these manufacturers sufficient grounds to make fraudulent and dangerous claims of safety. The FDA must put a stop to this practice.

---

respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count.").

242. *See, e.g.*, Institute of Medicine (US) Food Forum, *Enhancing the Regulatory Decision-Making Approval Process for Direct Food Ingredient Technologies: Workshop Summary*, WASHINGTON (DC): NATIONAL ACADEMIES PRESS, APPENDIX A, LEGAL ASPECTS OF THE FOOD ADDITIVE APPROVAL PROCESS (1999), https://www.ncbi.nlm.nih.gov/books/NBK224037/ ("Although the Delaney clause may trigger disapproval of a carcinogenic food additive without regard to risk, the general safety standard applicable to food additives provides greater flexibility.").

243. *See, e.g.*, *PFAS Exposure and Risk of Cancer*, NATIONAL CANCER INSTITUTE, https://dceg.cancer.gov/research/what-we-study/pfas.

244. *See* Gannon, *supra* note 154 (DuPont's scientists published the key 2012 study that FDA relied on to determine that 6:2 FTOH bioaccumulated in humans).

245. 21 U.S.C § 348(d) (2018).

246. *Id.*. § 348(c)(1)(A).

247. *See generally* Lars Noah, *The Imperative to Warn*: *Disentangling The* "*Right to Know*" *from the* "*Need to Know*" *About Consumer Product Hazards*, 11 YALE J. ON REG. 293 (1994); *see also* 21 C.F.R. § 109.16(b) (regarding labeling of lead and heavy metals); *Id.* § 70.25 (color additive labeling requirements); *Id.* § 1141 (reagarding tobacco consumer warnings).

248. *See* Ginty, *supra* note 200.

To the extent that any PFAS remain authorized for use—either temporarily during a phase-out period or as authorized through a petition—the FDA should require that any product containing intentionally added PFAS be clearly labeled as such.[249] The FDA should then test both for authorized PFAS and for total fluorine levels to ensure that any amount of PFAS, whether individually identifiable or not, would be detected. If a product contains PFAS levels over the tolerable limit (which should ideally be set at cumulative dietary exposure of 0.5 ppb), the FDA should consider the product adulterated and subject to an enforcement action,[250] including seizure and destruction,[251] and potential debarment.[252] Further, if the product contains any amount of PFAS but is not properly labeled, it should be subject to an enforcement action for false or misleading label,[253] failure to label a health threat,[254] and for failure to reveal a material fact.[255] Lastly, the FDA should prohibit the labeling of any product containing intentionally added PFAS as either "Recyclable" or "Compostable," to stop these substances from re-entering the food chain after disposal.[256]

The combined effect of all three steps would likely be the effective ban of PFAS as a class from use in food contact materials. In the unlikely event that any substance gains authorization, it would have done so under strict review commensurate with current science and would be subject to continuous monitoring and strict labeling. Taking these steps is the only way for the FDA to fulfil its statutory obligations under the FDCA, to get in step with current science, instead of lagging decades behind, and to effectively protect the health and safety not only of current consumers, but of generations to come.

V. LARGER IMPLICATIONS

The solution outlined in this article is a simple, if not an easy, one. It requires no Congressional action or coordinated steps with other agencies, branches of government, or additional actors. Like any action worth doing, it does come with certain costs. The costs of inaction, however, are far greater.

A. Potential Administrative and Financial Burdens of the Proposed Solution

First, it imposes administrative burdens on the FDA. The simultaneous revocation of 61 FCNs, as well as examining FDA's regulations and GRAS designations to close potential loopholes would impose an increased workload on agency personnel. [257] Evaluating voluminous health and safety data for each new substance

249. 21 U.S.C. § 342(c)(1)(A) (2005).
250. *Id.* § 342(a)(2)(C).
251. 21 U.S.C. § 334 (2014).
252. *Id.* § 335.
253. 21 U.S.C. 343(a)(1) (2010).
254. *Id.* 343(v)(2).
255. 21 C.F.R. § 1.21(a) (2022).
256. *See, e.g.*, Cal. SB 343 (2021); Cal. AB 1201 (2021).
257. *See* FDA, History of the GRAS List and SCOGS Reviews https://www.fda.gov/food/gras-substances-scogs-database/history-gras-list-and-scogs-reviews (the last time the FDA re-evaluated systematically the safety of already approved GRAS substances, it did so on the order of President Nixon in

under the more rigorous and time-consuming petition process would likewise require additional agency resources.[258] Contrary to industry's claims,[259] however, this burden would be limited to FDA's Center for Food Safety and Applied Nutrition ("CFSAN") and would not impact other areas of FDA's work.[260] Indeed, FDA's budget for Fiscal Year 2022 contemplates the burdens of increased involvement by CFSAN's staff in the management of PFAS—requesting a total of $19.7 million earmarked for emerging chemical and toxicological issues, including "ensur[ing] premarket safety evaluations," recruiting "additional experts such as toxicologists and environmental scientists," and "expand[ing] scientific review capacity" to assess PFAS' impact.[261] Moreover, the actions proposed in this paper are not subject to statutory deadlines and require a simple notice-and-comment process.[262] And while routing PFAS through a petition could lead to bottlenecks and delays in approvals, in the case of PFAS—where industry is requesting permission to place substances with proven high toxicity and bio-persistence into consumers' food—these delays are a feature, not a bug. In the end, the statutory scheme contemplates these

1969. In response, the FDA tasked a Select Committee on GRAS Substances (SCOGS) comprised of Life Sciences Research Office scientists to do the actual study. Ten years later, SCOGS delivered 151 detailed reports covering over 400 substances and the FDA took over 15 more years to actually review and implement the recommendations in these reports.); *see also* Institute of Medicine (US) Food Forum, *supra* note 242 (the task proposed in this article, however, is magnitudes more modest by that required by Nixon's presidential order).

258. *See, e.g.*, Institute of Medicine (US) Food Forum, *supra* note 242 (documenting the backlog of food additive petitions at the FDA prior to Congress instituting the FCN program in through the 1997 Modernization Act).

259. *See, e.g.*, *State & Federal Officials Move To Regulate & Even Ban PFAS Chemicals*, FORBES (2022) https://www.forbes.com/sites/patrickgleason/2022/02/14/state--federal-officials-concurrently-move-to-regulate--even-ban-an-entire-category-of-chemicals-but-many-wonder-whether-that-makes-sense/?sh=164a4913536f.

260. *See* FDA, Center for Food Safety and Applied Nutrition (CFSAN) https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan.

261. *Justification of Estimates for Appropriations Committees*, DEPT. OF HEALTH AND HUMAN SERVS. (2022) (the budget also requests an additional increase of $44.8 million (for a total of $51.9 million) for FDA's New Era of Smarter Food Safety initiative, which likewise contemplated CFSAN engaging with food safety, including food additive safety, and an increase of $18 million (for a total of $22 million) to address CFSAN staff review capacity and allow for more regulatory actions for toxic elements and safety concerns in infant and children's products; *Id.*

262. *See* 21 C.F.R. § 170.105 (2022); 21 C.F.R. § 170.30(l) (2022); *compare* 21 U.S. Code § 348(c)(2) (2018) (allowing Commissioner to issue order 180 days after the filing of a petition) *with* 21 USC § 348(h)(2)(A) (2018) (instructing that FCN is automatically effective after 120 days)*; see also* 21 C.F.R. § 171.1(j) (2022) ("The date used for computing the 90-day limit . . . shall be moved forward 1 day for each day after the mailing date of the [FDA] request taken by the petitioner to submit the sample."); *Id*. § 171.6 ("[I]f the Commissioner determines that the additional information or data amount to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew."); *Id*. § 171.7 (If a petition is withdrawn and then refiled, "the time limitation will begin to run anew.").

administrative burdens,[263] and they represent the reality of an agency doing its job and protecting public health.[264]

The solution also would impose a financial burden on PFAS manufacturers, like 3M and DuPont, who would need to spend more time and resources studying the health and safety implications of their products before applying for premarket authorization. Moreover, the immediate revocation of all currently effective FCNs and GRAS determinations, coupled with short phase-out periods of two years, would introduce some uncertainty into these manufacturers' business models. Given that PFAS is a small part of these companies' revenue streams, however, and PFAS in FCMs an even smaller segment still,[265] the proposed solution would not cause significant financial tremors in the chemical sector. In fact, the reduced revenue may be offset by reducing future liability for PFAS contamination, which in 2020 alone were estimated to be more than $6.5 billion for just the three largest manufacturers.[266] Besides, balancing the need to protect consumers from health-endangering products has to take priority.[267] A recent study of the health impacts of PFAS in Europe estimated annual direct healthcare expenditures of €52−84 billion.[268] Adjusting for population size, in the U.S., these costs amount to $37−59 billion annually, currently paid for by consumers, insurance companies, and taxpayers.[269] These numbers do not account for lost wages, reduced quality or duration of life, and many other less tangible (but no less real) impacts on individuals, families, and communities.[270] PFAS manufacturers' business practices over the last 73 years—including contaminating the environment and our drinking water sources,[271] exposing their workers to life-threatening levels of these chemicals,[272] and

263. *See, e.g.,* Alan Rulis & Laura Tarantino, *The Food Additive Petition Process*: *Recent Data*, 48 FOOD & DRUG L.J. 137, 138-39 & 145 (1993) (Dr. Rulis, then the Chief of the FDA's Regulatory Food Chemistry Branch and the manager of the food additives program noted that agency review "must be rigorous enough to ensure with reasonable certainty that additives are safe for consumption by the consumers."); *see also* Buc v. Food & Drug Admin., 762 F. Supp. 2d 62 (D.D.C. 2011), as amended (Feb. 24, 2011) (noting, in the context of FOIA requests, that, to establish "exceptional circumstances" required to extend the period for Agency response, the "agency must show both (1) that it is deluged with volume of requests vastly in excess of that anticipated by Congress, and (2) that existing resources are inadequate to deal with volume of such requests within statutorily prescribed time limits.").

264. *See Portal on Per- and Poly-Fluorinated Chemicals—European Union*, *supra* note 97 (As one of the two leading food safety agencies in the world (the other being the German BfR), the FDA's decision to permit the use of a substance carries huge implications not only for U.S. consumers, but for the entire world market of food contact materials).

265. *See, e.g.*, DUPONT DE NEMOURS INC., SEC Form 10-K (Dec. 31, 2020) https://s23.q4cdn.com/116192123/files/doc_financials/2020/ar/DuPont-2020-10-K-(Final).pdf.

266. *See Chemours settles PFAS dispute with DuPont, Corteva*, C&EN (Jan. 2021), https://cen.acs.org/policy/litigation/Chemours-settles-PFAS-dispute-DuPont/99/web/2021/01#:~:text=Morningstar%20financial%20analyst%20Seth%20Goldstein,%241.3%20billion%20is%20cleanup%20costs.

267. *See* OECD, *Economic Assessments and Valuations of Environmental and Health Impacts Caused by Perfluorooctanoic Acid (PFOA) and Its Salts*, ENVIRONMENT WORKING PAPER No.128 (2018), https://www.oecd.org/officialdocuments/publicdisplaydocument-pdf/?cote=ENV/WKP(2018)2&docLanguage=En.

268. *See* Gretta Goldenman, et al., *Cost of Inaction: A Socio-Economic Analysis of Environmental and Health Impacts Linked to Exposure to PFAS*; *see* Nordic Council of Ministers, *supra* note 105.

269. *See* Alissa Cordner, et al., *The True Cost of PFAS and the Benefits of Acting Now*, 55 (14) ENV'T. SCI. TECH. 9630–33 (2021).

270. *Id.*

271. *See supra* note 115.

272. *See* Jared Hayes, *For Decades, Polluters Knew PFAS Chemicals Were Dangerous But Hid Risks From Public*, ENVIRONMENTAL WORKING GROUP https://www.ewg.org/pfastimeline/.

knowingly concealing from regulators and the public internal evidence of PFAS' devastating effects on human health[273]—have demonstrated that the only way to protect consumer health and to decrease societal costs associated with PFAS is through strict and unwavering regulation.

Manufacturers and retailers of FCMs would also be impacted financially by the need to find safer alternatives to PFAS in their products. Fortunately, such alternatives already exist. Food contact materials utilizing natural greaseproof paper, other cellulose-based structures, vegetable parchment, Polylactic Acid (PLA), clay, or bio-wax have all proven to provide similar physical properties.[274] When required to do so, manufacturers and retailers are already using these alternatives to successfully replace the use of PFAS in EU countries, Canada, and individual U.S. States.[275] For instance, in the last year, the Department of Defense has successfully banned the use of PFAS in ready-to-eat meals delivered to the military, requiring an industrywide change in practices for military-based contracts and services.[276] To be sure, non-PFAS alternatives cost more—an estimated markup of 12% to 32%, depending on the product used.[277] For an industry that exceeds $80 billion in sales,[278] absorbing this additional cost should not pose an existential threat. Indeed, the use of PFAS itself adds roughly 12% to the cost basis of the untreated paper product[279]—a markup that the industry has readily accepted. Moreover, as regulatory and market changes force more producers to switch to these safer alternatives, further innovation and economies of scale would dramatically reduce these costs. Studies also suggest that switching to safer alternatives in turn decreases other current costs, such as the cost of buying coating, protecting and educating workers, disposing of chemical waste, and fighting negative publicity.[280] Lastly, even if the cost increase was passed directly to the consumer in its entirety (and it should not be), the marginal increase would only be an estimated $0.005 per product for the replacement.[281]

B. Potential Societal Costs of Inaction

The costs of the proposed solution pale by comparison to the costs of not addressing this public health crisis. PFAS affect everyone, but not equally. Most

273. *See* Lauren Richter, et al., *Non-Stick Science: Sixty Years of Research and Iin)action on Fluorinated Compounds*, 48 SOCIAL STUDIES OF SCI. 691−714 (2018); *see* Perkins, *supra* note 153.

274. *See* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT ("OECD"), PFAS AND ALTERNATIVES IN FOOD PACKAGING (PAPER AND PAPERBOARD): REPORT ON THE COMMERCIAL AVAILABILITY AND CURRENT USES 15, *supra* note 27.

275. *Id. See also* Nordic Council of Ministers, *supra* note 105.

276. *See* 2020 NDAA, *supra* note 185.

277. *See* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT ("OECD"), PFAS AND ALTERNATIVES IN FOOD PACKAGING (PAPER AND PAPERBOARD): REPORT ON THE COMMERCIAL AVAILABILITY AND CURRENT USES 15, *supra* note 27.

278. *See* Nordic Council of Ministers, *supra* note 105.

279. *See* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT ("OECD"), PFAS AND ALTERNATIVES IN FOOD PACKAGING (PAPER AND PAPERBOARD): REPORT ON THE COMMERCIAL AVAILABILITY AND CURRENT USES 15, *supra* note 27.

280. *See* Nordic Council of Ministers, *supra* note 105 (stating that after a chemical from printing inks used on FCM was found in baby milk in 2005, Nestlé estimated that they lost 600 million Euros in two days); *see id.*

281. *See* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT ("OECD"), PFAS AND ALTERNATIVES IN FOOD PACKAGING (PAPER AND PAPERBOARD): REPORT ON THE COMMERCIAL AVAILABILITY AND CURRENT USES 15, *supra* note 27.

troublingly, the societal cost of PFAS in FCMs falls disproportionately on disadvantaged communities. Few studies have been done to date on PFAS concentration in specific populations, but they all bear out this unfortunate pattern. A study of the blood serum levels of 6 PFAS in 178 middle-aged U.S. women, for example, showed higher levels of four PFAS in African American women as compared to all other study participants.[282] Other, more widely studied, toxic contaminants in food show similar trends and help explain these findings. Phthalates, for example, have been proven to "disproportionately harm people of color, people of low wealth, and babies and young children undergoing critical periods of growth and development."[283] Likewise, BPA, found in the lining of many lower cost, canned, and prepackaged foods, has significantly higher concentrations in non-Hispanic Blacks, females, and those of lower socioeconomic status.[284] A large 2020 study of 143 chemical biomarkers across 38,080 U.S. women revealed that, compared to non-Hispanic White women, non-Hispanic Black, Mexican American, other Hispanic, and multiracial women had significantly higher levels of metals, pesticides, and chemicals from consumer products.[285] The same is true for children.[286]

Some of this disproportionate impact is linked to socioeconomic factors. Racial or ethnic minority groups and low-income communities are frequently exposed to social stressors, poverty, and lack of food security.[287] They also live in food deserts with no access to fresh produce and healthy food options.[288] As a result, people of lower income levels are forced to frequent fast-food establishments [289] and consume pre-packed food.[290] But these disparities transcend income levels. Data of women in the U.S., for example, suggests that "women of color have higher levels of certain endocrine-disrupting chemicals, such as phthalates and parabens, in their bodies compared with white women and that these racial/ethnic differences are not explained by socioeconomic status."[291] Some scholars have suggested that

---

282. *See* Katharine Boronow, et al., *Serum Concentrations of PFASs and Exposure-Related Behaviors in African American and Non-Hispanic White Women*, 29(2) J. EXPO SCI ENVIRON EPIDEMIOL. 206–217 (2019).

283. *See Groups Sue to Force FDA Decision on Petitions to Ban Phthalates in Food*, EARTHJUSTICE (Dec. 7, 2021) https://earthjustice.org/news/press/2021/groups-sue-to-force-fda-decision-on-petitions-to-ban-phthalates-in-food.

284. *See, e.g.*, A.M. Calafat, et al., *Exposure of the U.S. Population to Bisphenol A and 4-Tertiary-Cctylphenol: 2003–2004*, 116 ENV'T HEALTH PERSPECT 39-44 (2008); Jessica W. Nelson, et al., *Social Disparities in Exposures to Bisphenol A and Polyfluoroalkyl Chemicals: A Cross-Sectional Study Within NHANES 2003–2006*, 11 ENV'T HEALTH 10 (2012).

285. *See* Vy Kim Nguyen, et al., *A Comprehensive Analysis of Racial Disparities in Chemical Biomarker Concentrations in United States Women, 1999–2014*, 137 ENV'T INT'L 105496 (2020).

286. *See* Manori J. Silva, *Improved Quantitative Detection of 11 Urinary Phthalate Metabolites in Humans Using Liquid Chromatography–Atmospheric Pressure Chemical Ionization Tandem Mass Spectrometry*, J. CHROMATOGR. B ANAL. TECHNOL. BIOMED. LIFE SCI. (2003).

287. *See, e.g.*, Rachel Morello-Frosch, et al., *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30 HEALTH AFF (MILLWOOD) 879-87 (2011).

288. *See, e.g.*, Renee E. Walker, et al., *Disparities and Access to Healthy Food in the United States: A Review of Food Deserts Literature*, 16(5) HEALTH PLACE 876-84 (2010).

289. *See, e.g.*, Peter James, et al., *Do Minority and Poor Neighborhoods Have Higher Access to Fast-Food Restaurants in the United States?*, 29 HEALTH & PLACE 10-17 (2014).

290. *See, e.g.*, Lisa M. Powell, et al., *The Availability of Fast-Food and Full-Service Restaurants in the United States: Associations with Neighborhood Characteristics*, 33 (4 Supp.) AM. J. PREV. MED. 240-5 (2007).

291. *See, e.g.*, Ami Zota, et al., *The Environmental Injustice of Beauty: Framing Chemical Exposures from Beauty Products as a Health Disparities Concern*, 217(4) VIEWPOINT (2017); Roni W. Kobrosly,

"[t]argeted racial/ethnic marketing can influence product use and related health inequities" independent of socioeconomic status.[292] Examining the different causes for these socioeconomic inequalities goes beyond the scope of this article. Given the public health concern of continued PFAS use, further study is needed to tease out the various contributing factors and to better understand the full scope of these disparities. For present purposes, suffice it to say that the continued use of PFAS in FCMs deepens racial and socioeconomic inequalities by disproportionately affecting the wellbeing, learning outcomes, reproductive health, financial stability, working capacity, and life expectancy of communities of color and people from other disadvantaged backgrounds. The proposed solution, therefore, is compelled not only by FDA's statutory obligation to protect the nation's health, but also by a basic notion of justice and equity.

VI. CONCLUSION

PFAS may have a place in our society, but they do not have a place in our food and bodies. Exposure to PFAS through food contact materials has ushered in a silent public health crisis. The science is clear on the harm. The law is clear on the remedy. All that is left is the will to act. The FDA is under a legal, policy, and equitable obligation to implement prompt measures to protect the wellbeing of all citizens. The fact these measures may involve time, effort, and money cannot—and must not—serve as an excuse for institutional inertia.

et al., *Socioeconomic Factors and Phthalate Metabolite Concentrations Among United States Women of Reproductive Age*, 115 ENV'T RSCH. 11-17 (2012).

292. *See* Zota, *supra* note 291; *see also* N. Craig Smith, et al., *Ethics and Target Marketing: The Role of Product Harm and Consumer Vulnerability*, 61 J. OF MARKETING 1-20 (1997); Sonya A. Grier, et al., *The Context for Choice: Health Implications of Targeted Food and Beverage Marketing to African Americans*, 98 AM. J. OF PUB. HEALTH 1616–29 (2008).