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Bystanders to a Public Health Crisis: The Failures of the U.S. Multi-Agency Regulatory Approach to Food Safety in the Face of Persistent Organic Pollutants

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Abstract

Per- and polyfluoroalkyl substances ("PFAS") are devastating our food systems and our health. Recent studies link even small exposure to PFAS to a host of adverse health outcomes, including cancer, autoimmune diseases, thyroid disease, liver damage, childhood obesity, infertility, and birth defects.

Food consumption is a primary route of PFAS exposure. PFAS are omnipresent at dangerous levels in our marine and agricultural environments, including in water, soil, fertilizers, compost, and air. From there, they can find their way into virtually every plant, fish, animal, and animal product, and ultimately (in the greatest concentration) into the consumer. In addition, PFAS-laden food processing equipment, disposable dishes, and containers leach dangerous levels of these chemicals into processed food products, further infusing our every meal with PFAS. It is no surprise then that everything from chocolate cake and microwave popcorn to free range eggs, wild caught fish, organic milk, and organic kale can harbor staggering quantities of these toxic substances.

Despite this widespread presence and strong scientific evidence of PFAS's harmful impact on humans, federal regulation of PFAS in food is currently nonexistent. At least fifteen agencies have a mandate to ensure the safety of our food supply in one form or another. More is not always better. In the case of regulatory agencies, it can lead to fragmented demand for attention, diffusion of responsibility, and bureaucratic bystander apathy. This story has played out time and again with other toxic contaminants like polychlorinated biphenyls ("PCBs") and pesticides. Despite our country's devastating experience with past contaminants and the unprecedented scientific progress of our time, however, the federal response to new food safety threats has only become more sluggish and inadequate.

This article lays a pathway for change, taking the issue of PFAS food contamination as a case study for the broader dysfunction in the food safety regulatory system. Part I reviews the

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history of federal food regulation and explores the role that each federal actor in the field plays in ensuring the safety of the food supply. It analyzes the agencies' jurisdictional limits, institutional constraints, and funding challenges, revealing a divided and dysfunctional bureaucracy that has failed consumers repeatedly. Part II provides background on the chemical and toxicological profile of PFAS and their widespread presence in the environment in general and food supply in particular. It also surveys the current state of PFAS regulation in the United States and the additional regulatory challenges posed by these substances. Part III examines possible approaches to more effective regulation of environmental contaminants in food and proposes a readily available but currently overlooked mechanism for combatting the current public health crisis of PFAS in food. Lastly, Part IV catalogues the expected benefits of the solution and addresses anticipated skepticism. It concludes that the approach proposed in this article is likely to withstand both legal and policy challenges and can effectively protect consumers from PFAS in food today, while simultaneously garnering much needed data to usher in a more permanent solution in the future.

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INTRODUCTION

> *"In food, excellent medicine can be found; in food, bad medicine can be found."* – Hippocrates[2]

Just about every other day, a scary news title warns us of the dangers of toxic "forever chemicals." "PFAS 'forever chemicals' linked to higher thyroid cancer risk, study finds."[3] "PFAS exposure linked to decreased bone health in adolescents and young

[2] Diana Cardenas, *Let not thy food be confused with thy medicine: The Hippocratic misquotation*, EUROPEAN SOC'Y FOR CLINICAL NUTRITION AND METABOLISM 1, 2 (2013) (quoting/translating THE HIPPOCRATIC CORPUS).

adults."[4] "Exposure to 'forever chemicals' during pregnancy linked to increased risk of obesity in kids."[5] "Common PFAS Chemicals Linked to Cancers in Women."[6] On and on goes the daily parade of horribles. And just about every other month, a new report tells us that PFAS are also in our daily food and drink. "PFAS Found in Eggs Laid by Hens that are Fed Contaminated Feed."[7] "U.S. Kale Contains 'Disturbing' Amounts of 'Forever Chemicals,' Research Finds."[8] "New Study Finds PFAS in Bottled Water."[9] "PFAS chemical found in chocolate cake."[10] Amid this grim news cycle, one would be justified to ask: How is this possible? Where are the regulators in charge of food safety and what are they doing about this? Could anything even be done to stop this public health catastrophe?

This article aims to answer these questions by offering (1) a comprehensive overview of the federal food safety regulatory system, (2) a helpful analytical framework for examining possible approaches to emerging food safety threats, and (3) a readily available, workable, and, so far, overlooked regulatory mechanism that can help stem the tide of widespread PFAS contamination in food. The article proceeds in four parts.

Part I explores the current federal food safety system by first looking at its history and its sources of fragmentation and friction. It then analyzes the present state of the system and its many actors, zeroing in on the jurisdictional limits, institutional advantages, and structural handicaps of each of the major players. Finally, this section posits that although the fragmented nature of the food regulatory system results in many ills, the most relevant failing with respect to emerging food safety threats is the issue of regulatory bystander apathy.

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[3] Bob Curley, *PFAS 'forever chemicals' linked to higher thyroid cancer risk, study finds*, MEDICAL NEWS TODAY (Oct. 25, 2023), https://www.medicalnewstoday.com/articles/pfas-forever-chemicals-linked-to-higher-thyroid-cancer-risk.

[4] Keck School of Medicine of USC, *PFAS exposure linked to decreased bone health in adolescents and young adults*, MEDICAL PRESS (Dec. 6, 2023), https://medicalxpress.com/news/2023-12-pfas-exposure-linked-decreased-bone.html.

[5] Corrie Pikuk, *Exposure to 'forever chemicals' during pregnancy linked to increased risk of obesity in kids*, BROWN UNIVERSITY (June 7, 2023), https://www.brown.edu/news/2023-06-07/pfas-obesity.

[6]Denise Mann, *Common PFAS Chemicals Linked to Cancers in Women*, U.S. NEWS (Sept. 19, 2023. 11:13 AM), https://www.usnews.com/news/health-news/articles/2023-09-19/common-pfas-chemicals-linked-to-cancers-in-women.

[7] *PFAS Found in Eggs Laid by Hens that are Fed Contaminated Feed*, FOOD SAFETY MAGAZINE (Feb. 2, 2023), https://www.food-safety.com/articles/8318-pfas-found-in-eggs-laid-by-hens-that-are-fed-contaminated-feed.

[8] Eva Hagan, *U.S. Kale Contains "Disturbing" Amounts of "Forever Chemicals," Research Finds*, GREEN MATTERS (July 21, 2023, 3:57 PM), https://www.greenmatters.com/health-and-wellness/pfas-kale.

[9] Ryan Felton, *New Study Finds PFAS in Bottled Water, as Lawmakers Call for Federal Limits*, CONSUMER REPORTS (June 17, 2021), https://www.consumerreports.org/health/bottled-water/pfas-in-bottled-water-new-study-finds-a1111233122/.

[10] Britt E. Erickson, *PFAS chemical found in chocolate* cake, CHEMICAL AND ENGINEERING NEWS (June 7, 2019), https://cen.acs.org/environment/persistent-pollutants/PFAS-chemical-found-chocolate-cake/97/i23#:~:text=PFPeA%20is%20one%20of%20many,chocolate%20milk%20at%20154%20ppt.

Part II introduces the problem of PFAS contamination in food as a case study of bystander apathy. It provides background on the chemical and biological profile of these substances, traces their routes to food products, and surveys the current dearth of regulatory efforts to combat their widespread and devastating consequences. The section also analyzes the peculiar hurdles that this group of chemicals presents, which any proposed regulatory fix would have to overcome.

Part III searches for a feasible solution. It first grapples with the most commonly proposed solution to the overall dysfunction plaguing the food safety system—a massive regulatory overhaul resulting in a unified, single-agency scheme. It concludes that such a step is practically infeasible and cannot effectively address a pressing public health concern like PFAS in food in a timely manner. Next, the article explores the possibility of PFAS-specific legislation or FDA-driven regulation. While increased public attention on PFAS may eventually lead to such actions, the current political climate, intense lobbying efforts, and the food agencies' skepticism of PFAS are likely to delay such a fix for far too long. The article thus proposes a solution that bridges the gap between the present state of crisis and a potential long-term action on PFAS. The proposed approach relies on EPA's current regulatory authority over pesticides. It urges the EPA—the only federal agency that has so far shown willingness to deal with PFAS contamination—to ban the use of PFAS in pesticides, monitor PFAS occurrence in food systematically, and enforce low tolerances for PFAS residue on food products.

Lastly, Part IV examines the advantages of this proposal and addresses some anticipated concerns, including a potential major questions doctrine challenge, the politically precarious nature of agency-level actions, and the need to rely on limited testing and enforcement capabilities. This section argues that, while not without its challenges, the proposed action would protect consumers from repeated exposure to toxic substances, while establishing ground truth about the real degree of PFAS contamination in food, enabling remediation of contaminated environments, and ushering in longer-term legislative reform.

I. A Regulatory System in Disarray

> *"Question: 'What is more scrambled than an egg?' Answer: 'The federal food inspection system.'"* – Rep. Jon C. Porter[11]

It is an indisputable fact that the U.S. food regulatory system is "often duplicative, sometimes contradictory, undeniably costly, and unduly complex."[12] With a system of cumbersome and antiquated food safety laws and at least thirteen agencies having a stake in the game,[13] this criticism is hardly surprising. This section traces the historical origins

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[11] *Question: What is More Scrambled Than an Egg? Answer: The Federal Food Inspection System:, Hearing before the Subcomm. on the Fed. Workforce and Agency Org.*, 109th Congress, 109–47 (2005).
[12] STAFF OF S. COMM. ON GOV'T AFF., 95TH CONG., FOOD REGUL.: A CASE STUDY OF USDA AND FDA 113 (Comm. Print 1977).
[13] Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 127 (2000).

of this fragmentation, surveys the present state of jurisdictional divisions and limitations, and explores the many challenges posed by the current regulatory system.

A. History of Fragmented Regulation

Although societies have dealt with food safety issues for most of human history,[14] in the United States, food safety regulation has a relatively short, yet sordid, record. In 1862, the thirty-seventh Congress established the United States Department of Agriculture, with an Act signed by President Lincoln.[15] The enabling statute charged the Department to "acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture in the most general and comprehensive sense of that word, and to procure, propagate, and distribute among the people new and valuable seeds and plants."[16] At the beginning, the Department's mission lacked a food safety focus.

Routine adulteration of food through unsanitary processing practices, impurities, and additives, however, eventually led Congress to pass the first federal food safety law—An Act to Prevent the Importation of Adulterated and Spurious Tea—in 1882.[17] Just over three years later, another law, the Oleomargarine Act of 1886, sought to regulate the sale of domestic margarine marketed as butter.[18] Due to the prevalence of chemical adulteration of foods, the USDA's Division of Chemistry—which up until that point had been largely concerned with studying soil composition—was redesignated the "Bureau of Chemistry" and was tasked with studying the effects and safety of chemical additives to food.[19] This was the beginning of the ideological division of responsibilities in the federal food regulatory system—with the Bureau of Chemistry focused on consumer safety while other agencies within USDA focused on promoting and supporting agriculture and food producers.[20] These two missions within the Department were often at odds with each other and caused considerable personal and political friction.[21]

A major victory for the food safety side of the Department came in 1906. The tireless efforts of the Bureau's Chief Chemist, Dr. Harvey Wiley, along with the publication of Upton Sinclair's *The Jungle*,[22] prompted President Theodore Roosevelt to

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[14] *See* Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 5(1984) (detailing food safety codes from biblical times).

[15] Act to Establish a Department of Agriculture, ch. 72, 12 Stat. 387 (1862) (codified as amended at 7 U.S.C. § 2201).

[16] *Id.*

[17] An Act to Prevent the Importation of Adulterated and Spurious Tea, H.R. No. 7486, 47th Cong. 40 (1982).

[18] *See* NEAL D. FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 4 (2d ed., 2017).

[19] *Milestones in U.S. Food and Drug Law History*, FDA (last updated Jan. 30, 2023), https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law.

[20] *See generally* DEBORAH BLUM, THE POISON SQUAD: ONE CHEMIST'S SINGLE-MINDED CRUSADE FOR FOOD SAFETY AT THE TURN OF THE TWENTIETH CENTURY (1st ed., 2018) (detailing the history of the Bureau of Chemistry and the ideological conflicts between Harvey Wiley and his superiors at USDA).

[21] *Id.*

sign into law two acts of Congress on the same day—the Pure Food and Drug Law ("PFDA")[23] and the Meat Inspection Act ("MIA")[24]. Curiously, Congress vested the USDA (and its Bureau of Animal Industry) with sole responsibilities for the inspection and seizure of adulterated meat under the MIA, but split the implementation of the PFDA between "the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce," with the Bureau of Chemistry serving all three in promulgating rules.[25] This allocation of responsibility, along with many philosophical and personal disagreements inside USDA over the degree of regulation needed to ensure pure food, further exacerbated the already-entrenched conflicts between the Bureau of Chemistry and the Department at large.[26]

These clashes eventually led to a formal division of the Department of Agriculture. In 1907, the Secretary of Agriculture created a new Board of Food and Drug Inspection, which was designed to serve as a counterbalance to the Bureau of Chemistry's approach to food purity.[27] In 1927, Congress spun out the Bureau's enforcement role into a separate agency, still housed within the Department—the Food, Drug, and Insecticide Administration.[28] In 1930, the USDA renamed it the Food and Drug Administration ("FDA").[29] The passage of the 1938 Food, Drugs, and Cosmetics Act ("FDCA") significantly augmented the food safety authority of the FDA—which now extended to creating food quality standards, establishing tolerance limits for unavoidable poisons, inspecting food production facilities, and regulating food labeling.[30] In 1939, pursuant to the Reorganization Act, Congress created a new unit within the executive branch—the Federal Security Authority (the predecessor to the modern-day Department of Health and Human Services).[31] And, in 1940, President Franklin Roosevelt announced that "[t]he Food and Drug Administration in the Department of Agriculture and its functions, except those functions relating to the administration of the Insecticide Act of 1910 and the Naval

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[22] *See generally* UPTON SINCLAIR, THE JUNGLE (1906) (which detailed the abhorrent conditions of meat processing in the United States).
[23] Act of June 30, 1906, ch. 3915, 34 Stat. 768, repealed by Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §392(a) (1938).
[24] Act of Mar. 4, 1907, ch. 2907, 34 Stat. 1260, amended by Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584 (1967).
[25] 21 U.S.C. §3 (1906), repealed by Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 392(a) (1938), (1938).
[26] *See generally* Blum, *supra* note 19.
[27] Merrill & Francer, *supra* note 12, at 82.
[28] *Id.*
[29] *Id.*
[30] Act of June 25, 1938, ch. 676, 52 Stat. 1060 (codified at 29 U.S.C. §§201-219 (West Supp. 1999)). *See also* 21 U.S.C. §341 (1994) (authorizing FDA to promulgate food quality standards to promote "honesty and fair dealing"); *id.* §346 (directing FDA to promulgate tolerances for substances that "cannot be avoided" in food production); *id.* §374 (providing FDA with inspection authority of food production facilities).
[31] Act of Apr. 3, 1939, ch. 36, 53 Stat. 561, amended by Reorganization Act of 1966, Pub. L. 89-554, 80 Stat. 394 (codified at 5 U.S.C. §901).

Stores Act, are transferred to the Federal Security Agency."[32] Importantly, USDA fought for and retained its authority over meat products.

The formal separation of the USDA and the FDA did not put an end to the jurisdictional infighting, however. Not only did the agencies inherit jurisdictional overlaps, but newly passed laws continued to split responsibilities between the two, thus perpetuating the problem. For example, in 1947, Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), pursuant to which the USDA oversaw approving pesticides for shipping and use on food crops, while the FDA was responsible for setting and enforcing permissible residue on food products.[33]

Although the history of the USDA and the FDA most prominently depicts the rifts in the federal food regulatory system, these were far from the only relevant actors. Tracing back to the allocation of responsibilities under the PFDA, the Department of the Treasury levied taxes on imitation or adulterated products, while the FTC took over the regulation of food advertisement.[34] The Department of Commerce was also responsible for regulating seafood.[35] In 1970, following the publication of Rachel Carson's *Silent Spring*[36]—which shined a spotlight on the irresponsible use of herbicides and insecticides in the U.S.—President Nixon transferred the responsibility over pesticide regulation from the USDA to the newly-created Environmental Protection Agency.[37] The EPA also took on FDA's authority to set and enforce pesticide tolerances on food.[38] New and evolving threats to food safety also required increased research efforts, which were shared between the Agricultural Research Service housed in the USDA, the Center for Disease Control and Prevention, and the National Institute of Health.[39] The chaotic diffusion of regulatory responsibility over food safety only increased from there.

B. The Present State of Chaos

With the ever-increasing complexity of consumer behaviors, food processing capabilities, and new threats to safety, the food regulatory system has only gotten more cumbersome, compound, and crippled over the last century. Currently, at least fifteen different agencies, housed within five Departments, have some authority over food safety.[40] This section focuses on the three main agencies in the field—the Food and Drug Administration, the Food Safety and Inspection Service, and the Environmental Protection Agency. It analyzes their jurisdictional reach, institutional strengths, and

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[32] *See* Reorganization Plan No. IV 12, reprinted in 54 Stat. 1237 (1940).
[33] Act of Oct. 30, 1947, ch. 125, 61 Stat. 163.
[34] *See* U.S. COMM'N ON ORG. OF THE EXEC. BRANCH OF THE GOV'T, THE HOOVER COMMISSION REPORT 250–51 (McGraw-Hill eds., 1949).
[35] *Id.*
[36] *See generally* RACHEL CARSON, SILENT SPRING (1962).
[37] See Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15, 623 (1970), reprinted in 42 U.S.C. §4321 (establishing the EPA). *See also* 21 U.S.C. §346(a).
[38] *Id.*
[39] Merrill & Francer, *supra* note 12, at 82.
[40] Emily M. Broad Leib & Margot J. Pollans, *The New Food Safety*, 107 CALIF. L. REV. 1173, 1175 (2019).

regulatory challenge in responding to emerging food safety threats, like those posed by environmental contaminants.

The Food and Drug Administration

The Food and Drug Administration, housed within the Department of Health and Human Services, is the main player in the field of food safety regulation. The FDA's mission with respect to food safety requires the agency to "protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled."[41] Specifically, FDA's Center for Food Safety and Applied Nutrition ("CFSAN") establishes safety standards for processed and other non-meat foods (including produce, seafood, fish, and shellfish).[42] The Agency is also solely in charge of pre-market authorization of any food additives to food or food-adjacent products, and for testing and controlling for any non-pesticide environmental or chemical contaminants.[43] FDA's field force of inspectors and laboratories, in turn, monitors and inspects food and ensures that CFSAN's standards are met.[44] The main enabling food statutes for the agency are the Federal Food, Drug and Cosmetic Act (FDCA),[45] the 1958 Food Additives Amendment to the FDCA, and the Food Safety and Modernization Act (FSMA).[46]

The agency also implements portions of many other statutes, over which it shares jurisdiction with USDA.[47] FDA shares jurisdiction with the Department of Commerce over regulating fish and seafood, where the FDA has implemented a voluntary compliance program under the Hazard Analysis and Critical Control Points (HACCP) system that provides process control to prevent food safety problems.[48] FDA is also charged with enforcing EPA's tolerance limits for pesticide residue in the foods under its jurisdiction.[49]

Due to its strong rulemaking and enforcement authority under the FDCA and FSMA and the fact that it regulates over 80% of all food, the FDA is often considered "the" food safety agency. Despite these advantages, however, the FDA has been slow to respond effectively to new and emerging food safety threats due to a variety of challenges. First, to a degree, the FDA is subject to a dual mandate to protect both food producers and food consumers.[50] When faced with multiple contradictory goals, agencies

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[41] 21 U.S.C. § 393(b)(2).
[42] *Id.* at §§ 348, 374.
[43] *Id.* § 331(b) (defining food additives as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food").
[44] *See Office of Regulatory Affairs,* FDA (last updated May 11, 2023), https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs (noting that the Office of Regulatory Affairs is the lead office for all agency field activities, including inspections of regulated products).
[45] 21 U.S.C. §§ 321–399.
[46] *Id.* § 350(g).
[47] Merrill & Francer, *supra* note 12, at 82, n. 195.
[48] See Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,095 (Dec. 18, 1995) (to be codified at 21 C.F.R. pts. 123, 1240).
[49] 21 U.S.C. §§ 321–399.

"frequently resolve . . . interstatutory conflicts by prioritizing their primary mission and letting their secondary obligations fall by the wayside.[51] And because the FDA is subject to intense industry lobbying by "Big Food," it often defaults to working *with* industry, rather than enforcing standards *against* industry.[52]

Beyond that, the FDA's effectiveness on food safety issues is often impeded by its structure. Although the FDA has oversized responsibilities for food safety, food in general, and safety in particular, are only a minor component of the agency's mission, workforce, and funding. CFSAN's budget for food safety is a mere 1.8% of FDA's total budget—or only $128.2 million for 2023.[53] Even accounting for all food activities beyond CFSAN (such as field inspections), the total food budget still only amounts to a mere 18% of the agency's overall funding.[54] It is an open secret in Washington that "regulating food is simply not a high priority at the agency," and that, as the former acting commissioner of FDA put it, "[t]he food program is on the back burner."[55] FDA has jurisdiction over more than "53,000 establishments that produce, process, and store food," and over another "750,000 restaurants, grocery stores, and other retail" businesses,[56] while CFSAN currently has less than 900 employees in total, and only a handful of them are field inspectors.[57] As a result, where USDA inspects production facilities under its jurisdiction daily, FDA can only inspect a limited number of facilities on a once-every-three-to-five-years schedule.[58] FDA inspections therefore cover only a fraction of domestic products on the market and an even smaller share of imports.

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[50] Gabriela Steier, *Dead People Don't Eat: Food Governmentenomics and Conflicts-of-Interest in the USDA and FDA*, 7 PITT. J. ENVTL. PUB. HEALTH L. 1, 32 (2012).
[51] J.R. DeShazo & Jody Freeman, *Public Agencies as Lobbyists*, 105 Colum. L. Rev. 2217, 2220 (2005).
[52] Kelly D. Brownell & Kenneth E. Warner, *The Perils of Ignoring History Big Tobacco Played Dirty and Millions Died. How Similar is Big Food?*, 87 THE MILBANK Q. 259, 276 (2009) (recounting several clashed between FDA and "Big Food" lobbying efforts); Daniel G. Aaron, *The Fall of FDA Review*, 22 YALE J. HEALTH POL'Y L. & ETHICS 95, 157 (2023) ("It is hard to think of a system more favorable to industry than self-affirmed GRAS, at least in the short-term.").
[53] *See FDA Seeks $7.2 Billion to Protect and Advance Public Health by Enhancing Food Safety and Advancing Medical Product Availability*, FDA (Mar. 9, 2023), https://www.fda.gov/news-events/press-announcements/fda-seeks-72-billion-protect-and-advance-public-health-enhancing-food-safety-and-advancing-medical *See also FY 2023 FDA Budget Summary*, FDA (2023), https://www.fda.gov/media/157193/download?attachment.
[54] Mark Von Eisenburg, Christina Badaracco & Kelly L. George, *Amid Growing Safety Issues in America's Food Supply, the FDA's Proposal for a New Human Foods Program Presents Opportunities for Stakeholders to Act*, AVALERE(Feb. 23, 2023), https://avalere.com/insights/fda-human-foods-program-redesign-would-centralize-food-safety-efforts#:~:text=(While%20food%20regulation%20relies%20solely,drug%20and%20device%20user%20fees.
[55] Helena Bottemiller Evich, *The FDA's Food Failure*, POLITICO (Apr. 8, 2022, 5:00 AM), https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/.
[56] Michael R. Taylor, *Preparing America's Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD DRUG L.J. 13, 16 (1997).
[57] A. MILLER & T. NORDENBERG, ENCYCLOPEDIA OF FOOD SCIENCES AND NUTRITION, 2504 (Benjamin Caballero ed., 2nd ed. 2003).
[58] Taylor, *supra* note 55, at 16.

Due to all these impediments, instead of direct enforcement, the Agency often relies on self-monitoring and good faith compliance by industry.[59] It has implemented numerous voluntary programs, pursuant to which food producers may, but do not have to, consult the Agency on compliance issues and can instead self-certify compliance with the applicable standards and regulations.[60] Even when the FDA learns of violations, its most frequent response is to issue a non-enforceable opinion letter and to work with the food producer on voluntary recalls.[61] Lastly, in the unlikely event that the FDA decides to act on new food safety issues (or new information about a food safety issue), its rule-making process is slow and cumbersome—"not your run-of-the-mill slow-churning Washington bureaucracy" but "so slow, it's practically in its own league."[62]

In short, "[t]here is a remarkable level of consensus that the agency is simply not working," and both "[c]urrent and former officials and industry professionals use[] terms like 'ridiculous,' 'impossible,' 'broken,' 'byzantine' and 'a joke' to describe the state of food regulation at FDA."[63] Despite its perceived status as the main food regulatory body, therefore, the FDA is not capable of responding to new food contaminants and addressing safety concerns in any meaningful way.

Food Safety and Inspection Service

The Food Safety and Inspection Service ("FSIS") is one of USDA's 18 agencies. Established by the Secretary of Agriculture in 1981,[64] FSIS is charged with regulating meat (including Siluriformes fish, commonly known as catfish), poultry, and eggs through the inspection of processing operations and the approval of product labels under the Federal Meat Inspection Act ("FMIA"), the Poultry Products Inspection Act ("PPIA"), and the Egg Products Inspection Act ("EPIA").[65] Under this authority, FSIS inspects slaughterhouses, meat, poultry, and egg processors, and other food processors

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[59] *Id.*

[60] *See, e.g.*, U.S. Dept. of Health and Hum. Serv., *Guidance for Industry: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, 209 FDA GUIDANCE DOCUMENTS 1, 3 (2012), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf (discussing the FDA voluntary plan to phase out the use of antibiotics in food production). *See also* Katya S. Cronin, *FDA-Approved: How PFAS-laden Food Contact Materials are Poisoning Consumers and What to do About it*, 6 BUS. ENTREPRENEURSHIP & TAX L. REV. 117, 137 (2022) (discussing the problem of industry certifying its food additive ingredients as "generally recognized as safe" without any FDA oversight).

[61] *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); 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).

[62] POLITICO, *supra* note 54. *See also* Jonathan A. Havens, *What Happens When FDA Delays a Rule? Menu Labeling as a Case Study,* FOOD AND DRUG LAW INSTITUTE UPDATE MAGAZINE (Nov./Dec. 2017) (discussing FDA's four-year delay in finalizing a menu labeling rule, followed by another four years of delaying its implementation).

[63] POLITICO, *supra* note 54.

[64] *See* 5 U.S.C. § 301; Reorganization Plan No. 2 of 1953, 18 Fed. Reg. 3219, reprinted in 5 U.S.C. § 901.

[65] 21 U.S.C. §§ 601, 453, 1031.

whose products contain a certain percentage of meat as an ingredient.[66] FSIS is required to inspect every single animal carcass intended for food sale within the United States and any product subject to FSIS jurisdiction that has not undergone inspection is per se adulterated and subject to seizure.[67] In addition to this continuous inspection mandate, the FSIS is charged with pre-market approval and labeling for most meat and poultry products.[68] FSIS shares jurisdiction over egg products and processed food containing meat as an ingredient with the FDA.[69]

Although the main concern for FSIS inspectors is biological contamination—which they address by a combination of visual inspections and microbial testing—FSIS also inspects food products under its jurisdiction for chemical hazards, such as natural toxins, unapproved food or color additives, or drug residues.[70] FSIS also enforces the pesticide residue tolerances set by the EPA through its National Residue Program, which tests and monitors for the occurrence of pesticide residue in domestic and imported meat, poultry, and egg products, and through its enforcement mechanism, which permits it to seize non-compliant products.[71]

In some respects, FSIS is well-positioned to serve as an effective check on food safety. For one, FSIS's budget is large—nearly $1.5 billion for 2023—and over 80% of it is spent on salary and benefits for inspection personnel.[72] USDA employs more than 6500 full-time inspectors to conduct these inspections in about 6200 plants.[73] FSIS has large laboratory capabilities and conducts testing in both federal and non-federal labs through its Accredited Laboratory Program.[74] FSIS also benefits from the research work of other USDA agencies and has the advantage that its entire department is focused on food and agriculture. Lastly, FSIS has at its disposal a wide array of enforcement mechanisms, including issuing noncompliance records, prompting voluntary recalls, condemning diseased animals, detaining adulterated misbranded, or otherwise violative food products under its jurisdiction, initiating administrative control actions, withholdings, and suspensions, or engaging in civil seizures.[75]

FSIS's work, however, has also been subject to considerable criticism. Most importantly, scholars point out that the agency is susceptible to severe regulatory

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[66] *Id.*
[67] 21 U.S.C. § 604.
[68] 21 C.F.R. 317.4.
[69] 21 U.S.C. §§ 1033(f), 1034(a), 1052(c)).
[70] 9 C.F.R. 417.2(b)(1).
[71] FSIS Directive 8410.1 Rev. 6, Detention and Seizure (U.S.D.A. 2014); 9 C.F.R. 309.16.
[72] *See* U.S. Dep't of Agric., *USDA FY 2023 Budget Summary*, at 65-8, https://www.usda.gov/sites/default/files/documents/2023-usda-budget-summary.pdf.
[73] *See* U.S. Dep't of Agric., *Food Inspector*, FOOD SAFETY AND INSPECTION SERV. (2024), https://www.fsis.usda.gov/careers/career-profiles/food-inspector. *See also* Taylor, *supra* note 55, at 16.
[74] *See* U.S. Dep't of Agric., *Laboratories & Procedures*, FOOD SAFETY AND INSPECTION SERV. (2024), https://www.fsis.usda.gov/science-data/laboratories-procedures.
[75] *See* U.S. Dep't of Agric., *Quarterly Enforcement Reports*, FOOD SAFETY AND INSPECTION SERV. (2024), https://www.fsis.usda.gov/inspection/regulatory-enforcement/quarterly-enforcement-reports. *See also* 9 C.F.R. § 500.1.

capture—the process by which "organized interest groups successfully act to vindicate their goals through government policy at the expense of the public interest."[76] For one, USDA's overall institutional mission, which trickles down to FSIS, focuses on the promotion of meat, dairy, and egg production and consumption, and this goal can often be at odds with safety regulation and policing violations.[77] More troublingly, there is a well-established "revolving door" practice, under which former food industry lobbyists and executives are hired by the agency in key positions but continue to maintain their old ties and allegiances to industry in the hopes of future lucrative employment after their government tenure.[78] Investigations have described FSIS as "[a]n old boys club with a revolving door 'between the USDA and FSIS, and the captains of the meat industry,'" which often results in "large meat producers […being] given a 'pass' thanks to their high-paid lobbyists."[79] For example, the former head of FSIS, Al Almanza, permitted JBS rotten beef to be imported into the United States in 2017 and took 90 days to act on the issue.[80] In July 2017, he left FSIS to work for JBS.[81] Similarly, an investigation revealed that Rebeckah Adcock—a former pesticide lobbyist—continued working on behalf of the pesticide industry as a senior advisor to the Secretary of Agriculture focusing on regulatory policy.[82] The former head of FSIS, Michael Taylor, also spent years working in high-ranking positions in Monsanto.[83] As a result of these deficiencies, for decades, FSIS has been satisfied with entering into voluntary agreements with industry, rather than countering emerging threats to food safety proactively and forcefully.

The Environmental Protection Agency

Housed within the Department of the Interior, the EPA is a fairly recent addition to the Executive Branch and one whose mission is "to protect human health and the environment."[84] There are two main programs within EPA that touch upon food safety—water regulation and pesticide regulation.

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[76] Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1340 (2013).
[77] Zoe A. Bernstein, *The Fight over Frankenmeat*: *The FDA as the Proper Agency to Regulate Cell-Based "Clean Meat*," 86 BROOKLYN L. REV. 593, 601 (2021).
[78] *See, e.g.,* Alex Kotch, *Revolving Door: Food Industry Lobbyists Swarm USDA to Shape Welfare, Visa Policies*, TYT NETWORK (Mar. 22, 2018), https://legacy.tyt.com/2018/03/22/revolving-door-food-industry-lobbyists-swarm-usda-to-shape-welfare-visa-policies/.
[79] *Captured: How Agribusiness Controls Regulatory Agencies and Harms Producers and Consumers*, ORGANIZATION FOR COMPETITIVE MARKTES (Aug. 24, 2020), https://competitivemarkets.com/wp-content/uploads/2020/08/Regulatory-Capture-Paper_Final.pdf (describing conversations with FSIS officials, who confirmed these troubling trends).
[80] *Id.*
[81] *Id.*
[82] Alexander Rony, *Here's What Our Supporters Found in Former Lobbyist's Emails at the USDA*, SIERRA CLUB (Aug. 26, 2020), https://www.sierraclub.org/articles/2020/08/heres-what-our-supporters-found-former-lobbyists-emails-usda
[83] MARION NESTLE, FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH 91-115 (2007).
[84] *Our Mission and What We Do*, EPA, https://www.epa.gov/aboutepa/our-mission-and-what-we-do.

The EPA regulates water pollution under the Clean Water Act, which, as relevant to food production, includes the regulation of wastewater management and the discharge of animal waste from some concentrated animal feed operations.[85] Additionally, the EPA has special jurisdiction over drinking water under the Safe Drinking Water Act of 1974.[86] The Act requires EPA to set and enforce standards for public drinking water for over 90 contaminants, known as the National Primary Drinking Water Regulations ("NPDWR").[87] Notably, regulation of bottled water falls outside EPA's jurisdiction and is instead in FDA's purview.[88]

The Office of Pesticide Programs ("OPP") is charged with overseeing the registration of pesticides and setting pesticide tolerance limits for residue found on food.[89] The EPA derives its authority over pesticides from FIFRA, the FDCA, and the Food Quality Protection Act of 1996 ("FQPA").[90] Under FIFRA, no pesticide may be placed in interstate commerce unless the OPP has issued a preauthorization.[91] OPP also sets tolerances of pesticide residue left on food under the FDCA and FQPA.[92] In doing so, OPP must evaluate a pesticide's potential for harm to human health by taking into consideration all known sources of exposure and the special susceptibilities of infants and children.[93] FSIS and FDA must enforce EPA's tolerance limits in the foods over which each agency otherwise has jurisdiction and, if a food is found to exceed the tolerance set by the EPA, the commodity is subject to seizure.[94]

EPA has several institutional advantages over FSIS and FDA in its ability to manage emerging threats. First, EPA's budget is magnitudes larger than that of both FSIS and CFSAN—totaling at $10 billion for 2023.[95] And while not all of these funds go to food-specific initiatives, both the Pesticide Program and the Safe Drinking Water Initiative are top priorities for the agency and receive a significant share of the budget appropriations.[96] EPA also has a sizable workforce—15,115 people—and built-in

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[85] *Animal Feeding Operations (AFOs)*, EPA (2023), https://www.epa.gov/npdes/animal-feeding-operations-afos.
[86] 42 U.S.C. § 300(f).
[87] *Id.*
[88] 21 C.F.R. 165.110.
[89] *Setting Tolerances for Pesticide Residues in Food*, EPA (2023), https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#:~:text=To%20ensure%20the%20safety%20of,in%20foods%20and%20animal%20feeds.
[90] 21 U.S.C. §§ 301, 321, 331, 333, 342, 346a, 348.
[91] 7 U.S.C. § 136a(c)(5)(D).
[92] 21 U.S.C. § 346a(b)(2)(A)(ii).
[93] 21 U.S.C. § 30.
[94] *Summary of the Federal Food, Drug, and Cosmetic Act*, EPA (2023), https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act.
[95] *See EPA's Budget and Spending*, EPA (2024), https://www.epa.gov/planandbudget/budget.
[96] *See, e.g., Safe Drinking Water Act*, EPA (2024) https://www.epa.gov/sdwa#:~:text=Protecting%20America's%20drinking%20water%20is,that%20strengthen%20public%20health%20protection (listing safe drinking water as a "top priority" for EPA); *EPA Budget in Brief*, EPA (2023), https://www.epa.gov/system/files/documents/2022-03/fy-2023-epa-bib.pdf (requesting an additional $25.6 million for Pesticide Enforcement, $14 million for Pesticide Program

synergies between its various components and programs.[97] And it has an accumulated knowledge bank and decades of experience addressing toxic environmental contaminants. Importantly, the agency's mission is focused entirely on the protection of the public, rather than the prosperity of its regulated industries, which creates fewer opportunities for conflict of interest and divided loyalties. Further, because EPA's focus is not on food safety, the agency is less likely to become subject to regulatory capture by food industry players (though it is still susceptible to regulatory capture by the chemical industry).[98]

On the other side, because its focus is not on food safety, the EPA is only able to regulate food to the degree that it has explicit jurisdiction over specific issues. Therefore, it has historically needed grants of augmented authority by an Act of Congress before it can take the lead in addressing emerging food safety threats.[99]

Other Agency Actors

Numerous other agencies have a stake in a specific corner of the food safety system. Most have no regulatory function and focus primarily on research. The Center for Disease Control and Prevention, for example, which is housed in the Department of Health and Human Services, systematically investigates foodborne illnesses, including those caused by pathogens, chemicals, and other contaminants.[100] HHS's National Institute of Health conducts food safety research.[101] USDA's Agricultural Research Service develops tests and processes to keep the food supply safe and to reduce and control pathogens and toxins in agricultural products.[102] The National Institute of Food and Agriculture researches issues of nutrition and foodborne illnesses,[103] the Food Nutrition Service provides food assistance and conducts food safety research with a focus on schools,[104] and the Animal and Plant Health Inspection Service conducts research into pest control, soil quality, and plant health.[105]

Some agencies do have a limited stake in regulation and enforcement. Within the Department of Agriculture, the Agricultural Marketing Service operates a voluntary inspection system for the grading of eggs,[106] while the Grain Inspection, Packers, and Stockyards Administration inspects grain for safety and quality.[107] The National Marine

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Implementation grants, and $4.9 million for enabling the Pesticide Program to integrate ESA requirements in conducting risk assessments).

[97] *See EPA's Budget and Spending*, EPA (2023), https://www.epa.gov/planandbudget/budget.

[98] *See, e.g.,* Lindsey Dillon, et al., *The Environmental Protection Agency in the Early Trump Administration: Prelude to Regulatory Capture*, 108 AJPH PERSPECTIVES S89 (2018).

[99] *See* Part I.C *infra.*

[100] *See Mission, Role, and Pledge*, CDC (2024), https://www.cdc.gov/about/organization/mission.htm.

[101] *Division of Occupational Health and Safety*, NIH (2024), https://ors.od.nih.gov/sr/dohs/safety/food_water/Pages/food_safety.aspx

[102] *About ARS*, USDA (2024), https://www.ars.usda.gov/about-ars/.

[103] Food, Conservation, and Energy Act of 2008, Pub. L. 110–234, 122 Stat. 936, codified as 7 U.S.C. § 2011.

[104] 7 C.F.R. 210.13.

[105] *Animal and Plant Health Inspection Service*, USDA (2024), https://www.aphis.usda.gov/aphis/home/.

[106] 7 C.F.R. 2.79.

Fisheries Service under the auspices of the Commerce Department continues to co-regulate fisheries and seafood jointly with the FDA,[108] the Federal Trade Commission (under the Department of Labor) regulates food advertising,[109] the U.S. Customs and Border Patrol (under the Department of Homeland Security) enforces inspections and seizures of imports under USDA and FDA regulations,[110] and the Consumer Product Safety Commission has overlapping jurisdiction with the FDA over regulating the chemical safety of products that come in direct contact with food.[111] Because these agencies' functions are confined to discrete issues, none of these actors is able to take major steps towards addressing the issue of emerging food contaminants.

C. More Is Not Always Better

The failures of the current federal food safety system—all stemming from the fractured and overpopulated regulatory scheme—are numerous and well-documented.

First, although theoretically working toward the same goal of consumer safety, each individual agency has unique interests and focus, which often leads to agency infighting and jurisdictional posturing.[112] As a recent example, both the FDA and USDA asserted exclusive jurisdiction over the regulation of genetically engineered and cultured cell "meat."[113] This type of turf claiming could in turn lead to overregulation (in the form of multiple requirements that industry has to meet),[114] uneven regulation (with one agency enforcing a standard more frequently or zealously than another),[115] or inconsistent regulation (with mutually incompatible expectations).[116] It at a minimum leads to "myopic risk management," where each agency looks at a particular problem through the lens of a

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[107] 7 C.F.R. 2.81.

[108] Magnuson–Stevens Fishery Conservation and Management Act of 2006, Pub. L. 117-328, 120 Stat. 3575, codified as 16 U.S. Code Ch. 38.

[109] 15 U.S.C. §§ 52-55.

[110] 19 C.F.R. §§ 12.110 - 12.117.

[111] Consumer Safety Protection Act of 2008, Pub. L. 110–314, 86 Stat. 1207, as codified in 15 U.S.C. § 2051.

[112] *See, e.g.,* Diane E. Hoffmann, *The Biotechnology Revolution and Its Regulatory Evolution,* 38 DRAKE L. REV. 471, 543 (1988) (describing the fight between FDA and USDA over genetically modified products).

[113] Sarah Luther, *From Un-Coordinated to Efficient: A Proposal for Regulating GE Products in a Way that Meets the Needs of Consumers, Producers, and Innovators,* 20 VT. J. ENVTL. L. 32, 50-51 (2019); Jaden Atkins, *Regulating the Impending Transformation of the Meat Industry: "Cultured Meat*," 24 J. TECH. L. & POL'Y 1, 3 (2020).

[114] *See generally* Stephanie Neitzel, *One Size Fits All: A Federal Approach to Accurate Labeling of Consumer Products*, 23 J. HEALTH CARE L. & POL'Y 87, 103 (2020) (arguing that food labeling requirements "under the current system [lead to] businesses [being] needlessly burdened by overregulation and consumers are left utterly confused or even misled.")

[115] George Kimbrell, *Cutting Edge Issues in 21st Century Animal Food Product Labeling*, 27 DRAKE J. AGRIC. L. 179, 182 (2022) (discussing the variable and uneven requirements applied to different food manufacturers under the current system of fragmented and decentralized food regulation).

[116] *See* STAFF OF S. COMM. ON GOV'T AFF., 95th Cong., STUDY ON FEDERAL REGULATION: REGULATORY ORGANIZATION 113 (Comm. Print 1977) (concluding that the U.S. food safety system is "often duplicative, sometimes contradictory, undeniably costly, and unduly complex.")

specific policy priority and often misses the big picture of how various risks and aspects associated with a problem interact with each other.[117]

Second, the antiquated system of food safety legislation creates absurd divisions and inefficient overlaps in authority. For example, the CDC has primary jurisdiction over investigating outbreaks of foodborne illness, but FDA and USDA have jurisdiction to order a recall of the contaminated foods.[118] While USDA regulates red meat and poultry, the FDA regulates "game" species like deer, buffalo, ostrich, and pheasant.[119] While USDA regulates cattle, the FDA regulates milk. FDA has jurisdiction over plants producing cheese pizza, while FSIS has jurisdiction over plants making pepperoni pizza.[120] The jurisdiction over eggs is even more inexplicable—with FDA having jurisdiction over in-shell eggs, AMS having jurisdiction over grading the quality of in-shell eggs, while FSIS having jurisdiction over egg products, and FDA having jurisdiction over products made with eggs.[121] These and many other jurisdictional absurdities have necessitated the use of hundreds of costly and cumbersome interagency Memoranda of Understanding, which attempt to outline the basic division of responsibilities and rules of engagement and cooperation.[122]

Third, and most relevant in the case of emerging food safety threats, the highly populated food safety field often results in *less* action, not more, due to the phenomenon psychologists call the "bystander effect" or "bystander apathy."[123] The theory of bystander apathy was developed in the aftermath of the horrific murder of Kitty Genovese in 1964.[124] According to reports at the time (which may have been apocryphal), 38 of Ms.

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[117] Broad Leib & Pollans, *supra* note 39, at 1177.
[118] RENEE JOHNSON, CONG. RSCH. SERV., R42885, FOOD SAFETY ISSUES FOR THE 114TH CONGRESS 1, 3 (2015).
[119] Taylor, *supra* note 55, at 16.
[120] *Id.* at 18.
[121] *Id.*
[122] *See, e.g.,* Memorandum of Understanding Between FSIS and CDC (Jan. 24, 24 2014), https://www.fsis.usda.gov/sites/default/files/media_file/2020-11/MOU-FSIS-CDC-ATSDR.pdf (detailing agencies collaboration on foodborne illness investigations, including food tracebacks, assessments of FSIS-regulated establishments, food recalls and alerts to consumers); Memorandum of Understanding Between the FSIS and FDA, (Mar. 24, 2015), https://www.fsis.usda.gov/sites/default/files/media_file/2020-11/Memorandum%20of%20Understanding%20betwee &n%20FSIS%20and%20FDA.pdf (outlining rules for cooperation and collaboration "on the review of submissions each Participant receives regarding the use of food ingredients used in the production of or on a meat, poultry, or egg product."). *See also* Memorandum of Understanding Between the FDA and EPA (May 5, 2022), https://www.fda.gov/about-fda/domestic-mous/mou-225-05-2001 (Environmental Contaminants in Fish and Shellfish); Memorandum of Understanding Between the USDA and FDA, (July 13, 2018), https://www.fda.gov/about-fda/domestic-mous/mou-225-72-2009 (Inspection of Food Products and Establishments); Memorandum of Understanding Between the EPA and CDC (July 28, 2000), https://www.epa.gov/sites/default/files/2015-09/documents/epacdc-mou.pdf (Pesticides and Food Safety); Pamela Starke-Reed, *Closer to Zero: Partnership to Protect Our Food*, USDA. (Jan. 21, 2022), https://www.usda.gov/media/blog/2022/01/21/closer-zero-partnership-protect-our-food (Closer to Zero Initiative on the presence of heavy metals in food).
[123] Bibb Latane & John M. Darley, *Bystander "Apathy,"* 57 AM. SCIENTIST 244, 244 (1969).

Genovese's neighbors watched and listened as she was being killed over a half hour, yet did not help or even call the police.[125] Examining the perplexing nature of such inaction, the theory of bystander apathy poses that an emergency presents a high-risk, low-reward situation that requires instant and decisive action, but that prompts bystanders to ignore what is happening by distorting their perceptions to underestimate their responsibilities for coping with it.[126] This effect is magnified when there are multiple bystanders present, which further diffuses the sense of responsibility and the desire to act outside one's routine.[127]

In the world of administrative law, a similar phenomenon of diffused responsibility is captured by the term "regulatory commons." According to the theory of regulatory commons, "when social ills match no particular political-legal regime or jurisdiction, but instead encounter fragmented political-legal structures, predictable incentives arise for potential regulators to opt against investing in such regulatory opportunities."[128] In the food space, one example of regulatory commons problem occurs with aquaculture, where many regulators—the EPA, the National Marines and Fisheries Service, the FDA, and the United States Army Corp of Engineers—all arguably have jurisdiction.[129] Thus, "[n]o single regulator [] is perceived as the regulatory leader and hence looked to for creation of regimes to deal with transboundary or ecosystem aquaculture risks, nor is any particular regulator likely to be blamed for harms that could result from aquaculture," and so the field is heavily underregulated.[130] Regulatory commons exist not just in a defined regulatory area, but also when regulators are faced with a novel yet diffused problem.[131] The issue of environmental contaminants in food is just such a problem. Because of the interconnectedness between the environment, natural resources, food production, food safety, and public health, the problem lies at the intersection of many agencies' jurisdictions and squarely within no one's. Issues of toxic contamination of food are also usually of the high-profile, high-complexity, and low-reward variety, making them vastly unattractive for any one agency to step out of its jurisdictional wheelhouse to take the lead.

Past examples of toxic contaminants in food illustrate this difficulty. Polychlorinated biphenyls (or PCBs) are a group of chemicals widely used in both industrial and consumer products from 1929 to 1979.[132] As early as 1939, there were

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[124] *Id.*
[125] *Id.*
[126] *Id.* at 246.
[127] *Id.* at 244.
[128] William Buzbee, *Recognizing the Regulatory Commons: A Theory of Regulatory Gaps*, 89 IOWA L. REV. 1, 6 (2003-2004).
[129] *Id.* at 9.
[130] *Id.*
[131] *See id.* at 13 (describing global warming as a regulatory commons problem).

widely publicized studies that linked PCBs to devastating human health consequences.[133] By the 1950's, health authorities and industry alike were warning the public of likely contamination of food by PCBs.[134] In the 1960s, research demonstrated that there were traces of PCBs globally in even the most remote areas of the Arctic.[135] Yet, in the face of mounting chemical manufacturers' opposition and the overall complexity and ubiquity of the problem, no federal agency took any actions to regulate or restrict the use of PCBs or their spread in the food supply, until Congress voted on Aug 23, 1976, to ban within 3 years the manufacture of PCBs and to give additional powers to the EPA to regulate these hazardous chemicals.[136] Subsequently, the EPA took up the task of "bring[ing] under control the vast majority of PCBs still in use, [which] will help prevent further contamination of our air, water and food supplies from a toxic and very persistent man-made chemical."[137] This effort continues to this day.

A remarkably similar story can be told about another group of chemicals—Dichlorodiphenyltrichloroethane ("DDT") and other chlorinated hydrocarbon compounds, like dieldrin, aldrin, and endrin. Manufactured in 1874, these chemicals' effectiveness as insecticides was discovered in 1939 and, shortly thereafter, they were produced in copious amounts and were sprayed on agricultural lands, over public spaces, and in private residences alike.[138] By 1940, DDT in particular and chlorinated hydrocarbons in general were already demonstrated to be carcinogenic and to cause a slew of other health issues, and by the 1950s, these substances were heavily present in the U.S. food supply.[139] In 1953, a medical researcher warned that "[e]xposure

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[132] *Learn about Polychlorinated Biphenyls*, EPA (2023), https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls#:~:text=PCBs%20were%20domestically%20manufactured%20from,yellow%20or%20black%20waxy%20solids.

[133] Cecil Drinker, *Further Observations on the Possible Systemic Toxicity of Certain of the Chlorinated Hydrocarbons with Suggestions for Permissible Concentrations in the Air of Workrooms*, 21 J. IND. HYG. TOXICOL. 155 (1939).

[134] Gerald Markowitz, *From Industrial Toxins to Worldwide Pollutants: A Brief History of Polychlorinated Biphenyls*, 133 PUB. HEALTH REPORTS 721, 723 (2018).

[135] *What are PCBs?*, NOAA (last updated Jan. 20, 2023), https://oceanservice.noaa.gov/facts/pcbs.html#:~:text=PCBs%2C%20or%20polychlorinated%20biphenyls%2C%20are%20industrial%20products%20or%20chemicals.&text=PCB%20chemicals%20were%20banned%20in,harm%20human%20and%20environmental%20health.

[136] Richard D. Lyons, *House Votes Ban on Output of PCB's Within 3 Years*, NY TIMES (Aug. 24, 1976), https://www.nytimes.com/1976/08/24/archives/new-jersey-pages-house-votes-ban-on-output-of-pcbs-within-3-years.html

[137] *EPA Bans PCB Manufacture; Phase Out Uses*, EPA Archive (April 19, 1979), https://www.epa.gov/archive/epa/aboutepa/epa-bans-pcb-manufacture-phases-out-uses.html

[138] EPA, *DDT Regulatory History: A Brief Survey (to 1975)*, EPA REPORT (JULY 1975), https://www.epa.gov/archive/epa/aboutepa/ddt-regulatory-history-brief-survey-1975.html#:~:text=DDT%20(Dichloro%2Ddiphenyl%2Dtrichloroethane,was%20only%20discovered%20in%201939.

[139] Gerald Markowitz, *From Industrial Toxins to Worldwide Pollutants: A Brief History of Polychlorinated Biphenyls*, 133 PUB. HEALTH REPORTS 721, 722 (2018).

to this whole group of compounds is now universal in the United States, and it appears that few persons escape storage of these toxic agents in the body fat."[140] Despite having authority to regulate insecticides under FIFRA, neither the USDA nor the FDA took any meaningful steps to curtail the use of these substances. Indeed, the USDA itself was one of the main "consumers" of insecticides.[141] Over the course of thirteen years, from 1957 to 1970, the USDA began very slowly phasing out only certain uses of DDT in limited settings.[142] Like with PCBs, it took an Act of Congress—several, in fact—to first transfer regulatory authority over pesticides to the newly-created EPA and then to augment EPA's authority under FIFRA, before the agency could take meaningful action in banning all DDT formulations and directing the FDA and USDA to monitor food products for DDT and other chlorinated hydrocarbon residues.[143]

II. Regulating PFAS: A Case Study in Dysfunction and Diffused Responsibility

> *"Can anyone believe it is possible to lay down such a barrage of poisons on the surface of the earth without making it unfit for all life?"* – Rachel Carson[144]

Yet another, nearly identical story to the failures of the past is being written today—the tale of per- and polyfluoroalkyl substances, or PFAS. This section provides a brief overview of these substances and their presence in our food supply, reviews current PFAS regulation, and analyzes the unique regulatory challenges that these contaminants pose.

A. Background on PFAS

Per- and polyfluoroalkyl substances—also known as PFAS for short—are a class of thousands of synthetic chemicals that have been in use since the 1940s.[145] Notably, these chemicals contain a carbon-fluorine bond—the strongest bond known in organic

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[140] Morton S. Biskind, *Public Health Aspects of the New Insecticides*, 20 AM. J. DIG. DIS. 331 (1953).
[141] EPA, *DDT Regulatory History: A Brief Survey (to 1975)*, EPA REPORT (JULY 1975), https://www.epa.gov/archive/epa/aboutepa/ddt-regulatory-history-brief-survey-1975.html#:~:text=DDT%20(Dichloro%2Ddiphenyl%2Dtrichloroethane,was%20only%20discovered%20in%201939.
[142] EPA, *DDT Regulatory History: A Brief Survey (to 1975)*, EPA REPORT (JULY 1975), https://www.epa.gov/archive/epa/aboutepa/ddt-regulatory-history-brief-survey-1975.html#:~:text=DDT%20(Dichloro%2Ddiphenyl%2Dtrichloroethane,was%20only%20discovered%20in%201939.
[143] *Id. See also Determination of Chlorinated Hydrocarbons (CHCs) and Chlorinated Organophosphate Hydrocarbons (COPs) with Gel Permeation Chromatography (GPC)*, FSIS (2004), https://www.fsis.usda.gov/sites/default/files/media_file/2020-09/CLG_CHC_3_04.pdf (setting standards for testing food products for the presence of chlorinated hydrocarbons).
[144] Carson, *supra* note 35.
[145] *See* Cronin, *supra* note 59.

chemistry—making them virtually indestructible and impervious to extreme conditions such as heat, water erosion, and even radiation.[146] These qualities make PFAS highly desirable in industrial and commercial applications, because they make products water-, oil-, and dirt-resistant.[147] As a result, these chemicals are used in anything from firefighting foam, to water-repellant clothing, cosmetics, and food contact materials, such as non-stick pans.[148]

PFAS' indestructible bond has a darker side, however. It not only survives artificially created extreme conditions but also resists the natural processes of degradation.[149] For this reason, these chemicals are classified as highly persistent and have been dubbed "forever chemicals"—absent an intentional action to filter or destroy them from a medium, they will likely stay there forever. Their widespread use in industrial and commercial applications, coupled with their ability to travel long distances in various environments, has further made these chemicals ubiquitous. PFAS are now present in the air, soil, water, wildlife, and 98% of humans, including in fetuses in utero.[150] They have been found not only near sites of heavy industrial activity but also in otherwise pristine and remote locations, like the Arctic and atop Mt. Everest.[151]

PFAS are detrimental to human health. The two most widely used substances—PFOS and PFOA—have been proven to cause wide range of health issues, including kidney, testicular, and thyroid cancer, reproductive and pregnancy complications, negative birth outcomes, high cholesterol, endocrinal disruptions, and immunotoxicity.[152] The newer generation (or short-chain) PFAS, like GenX, are likewise linked to developmental delays, pregnancy loss and disrupted reproductive cycles, liver and kidney damage, hormonal and metabolic disruptions, and many others.[153] Because these chemicals bioaccumulate in human tissue and could persist in the body for years, even small doses of them can prove fatal with chronic exposure.[154]

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[146] *Id.* at 121.
[147] *Id.*
[148] *See, e.g.,* Juliane Glüge et al., *An Overview of the Uses of Per- and Polyfluoroalkyl Substances (PFAS)*, 12 ENV'T SCI.: PROCESSES AND IMPACTS (2020).
[149] *See, e.g.,* 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).
[150] 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).
[151] 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); Murray Carpenter, *"Forever Chemicals,' Other Pollutants Found Around the Summit of Everest*, WASH. POST (Apr. 17, 2021), https://www.washingtonpost.com/science/mt-everest-pollution/2021/04/16/7b341ff0-909f-11eb-bb49-5cb2a95f4cec_story.html.
[152] Cronin, *supra* n. 59, at 128.
[153] *Id.* at 128-129. *See also* Laura Anderko & Emma Pennea, *Exposures to per-and polyfluoroalkyl substances (PFAS): Potential risks to reproductive and children's health*, 50(2) CURRENT PROBS. IN PEDIATRIC & ADOLESCENT HEALTH CARE 100760 (2020); Francesca Coperchini, *Thyroid Disrupting Effects of Old and New Generation PFAS*, 11 FRONTIERS IN ENDOCRINOLOGY 612320 (2021).

D. PFAS in Our Food Supply

One of the main routes of human exposure to PFAS is through ingestion of either contaminated drinking water or contaminated food.[155] PFAS find their way into drinking water through direct discharge in water sources or through air and water dispersion from contaminated sites to more remote locations.[156] A recent U.S. Geological Survey found PFAS present at detectable levels in nearly half of the nation's tap water.[157]

PFAS end up in food through numerous routes. One is the migration of PFAS from food contact materials—such as paper wrappers and containers, non-stick cookware, or food processing equipment—onto the food itself.[158] Another is through contaminated soil, which may contain PFAS due to present-day or historic application of PFAS-contaminated biosolid fertilizers, spraying of PFAS-containing pesticides and biocides, use of PFAS-contaminated compost, or irrigation with PFAS-contaminated water.[159] From the soil, PFAS get taken up by plants, thus contaminating fresh produce and processed food made from such produce.[160] Or they migrate further into animals—such as cows, pigs, and chickens—who eat contaminated plants, like grass or grain, and drink contaminated water.[161] These animals in turn produce milk, eggs, or other products that likewise wind up contaminated.[162] Fish and shellfish also easily pick up PFAS from their environment.[163]

As a result of the widespread presence, mobility, and persistence of PFAS in the environment and the many different food manufacturing practices that include PFAS as an active ingredient, PFAS have now been found in beef, chicken, dairy, eggs, produce,

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[154] *Perfluoroalkyl and polyfluoroalkyl substances (PFAS)*, NIH (2024), https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm.
[155] *See, e.g.,* Hebert P. Susmann et al., *Dietary Habits Related to Food Packaging and Population Exposure to PFASs*, 127 ENV'T HEALTH PERSP. 107003-1, 107003-1–10 (2019).
[156] SWRCB, *PFAS – Frequently Asked Questions,* at 4 (March 19, 2020), https://www.ehn.org/pfas-pasta-sauce-2657142422.html.
[157] K.L. Smalling et al., *Per- and polyfluoroalkyl substances (PFAS) in United States tap water: Comparison of underserved private-well and public-supply exposures and associated health implications*, ENV'T INT'L 178 (2023).
[158] *See generally* Cronin, *supra* n. 59.
[159] *See, e.g., Our Current Understanding of the Human Health and Environmental Risks of PFAS*, EPA (2024), https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas. *See also* M. Brusseau et al., *PFAS concentrations in soils: Background levels versus contaminated sites,* SCI TOTAL ENVIRON. (2020).
[160] *See, e.g.,* G. Jha et al., *Per- and Polyfluoroalkyl Substances (PFAS) in Integrated Crop-Livestock Systems: Environmental Exposure and Human Health Risks*, 18 INT'L J. ENVIRON. RES. & PUBLIC HEALTH 23 (2021).
[161] *Id.*
[162] *Id.*
[163] *Our Current Understanding of the Human Health and Environmental Risks of PFAS*, EPA (2024), https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas.

fish, shellfish, and packaged goods, such as orange juice, butter, microwave popcorn, and chocolate cake.[164] Certifications such as organic, free-range, grass-fed, or sustainable do nothing to ensure lack of PFAS contamination, as they only regulate an isolated aspect of farming or food production that does not touch upon PFAS use or historic environmental contamination.[165]

E. Current Regulation of PFAS

Although environmental contamination with PFAS dates to as early as the 1940s, scientific knowledge of the enormous ecological and health consequences of these chemicals began emerging only about a decade and a half ago.[166] As is always the case, where science lags, regulation lags even farther behind. Some of the oldest-in-use long-chain substances—PFOS and PFOA—have been widely recognized as extremely harmful and, through the efforts of both EPA and FDA, these chemicals were voluntarily phased out of production and use on the U.S. market by 2015.[167] To date, however, no binding regulation exists covering these or any other PFAS compounds.

The last two years have seen a strong push toward future regulation of PFAS driven by EPA's PFAS Strategic Roadmap. In 2023 alone, the EPA released a final rule under the Community Right-to-Know Act and the Pollution Prevention Act, removing the de minimis exemption for PFAS reporting,[168] and another final rule under the Toxic Substances Control Act, requiring reporting and record-keeping of PFAS use in a wide array of products.[169] It also gave advance notice of a proposed future rule to include PFAS

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[164] *See, e.g.,* Tom Neltner, *FDA finds surprisingly high levels of PFAS in certain foods – including chocolate cake* (June 3, 2019), https://blogs.edf.org/health/2019/06/03/fda-high-levels-pfas-chocolate-cake/. *See also New report finds most US kale samples contain 'disturbing' levels of 'forever chemicals'*, THE GUARDIAN (June 30, 2023), https://www.theguardian.com/environment/2023/jun/30/kale-pfas-forever-chemicals-contamination; Robin Lasters, et al., *Home-produced eggs: An important human exposure pathway of perfluoroalkylated substances (PFAS)*, 308 CHEMOSPHERE, Pt. 1 (2022).

[165] *See, e.g.,* THE GUARDIAN, *supra* note 163; DTU National Food Institute, *PFAS found in organic eggs in Denmark*, https://www.food.dtu.dk/english/news/pfas-found-in-organic-eggs-in-denmark?id=789f9ba1-bdfc-4a7d-908b-fc6cccff4742; Environmental Health News, *Evidence of PFAS in organic pasta sauces* (April 13, 2022), https://www.ehn.org/pfas-pasta-sauce-2657142422.html.

[166] *See* Mark P. Nevitt & Robert V. Percival, *Can Environmental Law Solve the "Forever Chemical" Problem?*, 57 WAKE FOREST L. REV. 239, 242 (2022).

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

[168] 40 C.F.R. Part 372. *See also Changes to TRI Reporting Requirements for Per-Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Concern*, EPA (Last Updated Oct. 31, 2023), https://www.epa.gov/toxics-release-inventory-tri-program/changes-tri-reporting-requirements-and-polyfluoroalkyl.

[169] *TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*, EPA (Last Updated Oct. 11, 2023), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping.

as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[170] And it proposed a National Primary Drinking Water Regulation pursuant to its Safe Drinking Water Act authority, which seeks to establish legally enforceable maximum contaminant levels for six PFAS present in drinking water.[171] In 2021, EPA also initiated rule making efforts to include four PFAS under the Resource Conservation and Recovery Act, which would allow for cradle-to-grave clean-up of PFAS contamination.[172] In January 2024, finalized a Significant New Use Rule under RCRA for 329 inactive PFAS and added two more PFAS to the Toxic Release Inventory.[173] And, in February 2024, EPA released wo proposed regulations under RCRA, adding nine more PFAS to the list of RCRA hazardous constituents.[174]

Although each of these encouraging steps would result in less PFAS being discharged into the environment, none specifically addresses the widespread uptake of PFAS into food. And direct regulation of PFAS in the food supply is markedly lacking. Currently, USDA's involvement with PFAS is limited to (1) its "Screening, Determination, and Confirmation of PFAS" initiative, which establishes testing methods and laboratory procedures for the detection of PFAS in food, (2) its Dairy Indemnity Payment Program, which seeks to support financially farmers whose livestock was contaminated with PFAS,[175] and (3) its Euthanization Program, administered by Animal Wildlife Services, which likewise handles livestock that (usually through accidental discovery or private testing and under applicable state levels) has been marked as contaminated and unfit for food consumption.[176] No quantitative regulatory levels for PFAS in meat, poultry, or eggs have been set, even though FSIS is statutorily obligated to ensure that products under its jurisdiction are "safe and fit for human food."[177]

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[170] *Advanced Notice of Proposed Rulemaking on Potential Future Designations of Per- and Polyfluoroalkyl Substances (PFAS) as CERCLA Hazardous Substances*, EPA (2024), https://www.epa.gov/superfund/advanced-notice-proposed-rulemaking-potential-future-designations-and-polyfluoroalkyl.

[171] *Proposed PFAS National Primary Drinking Water Regulation*, EPA https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.

[172] EPA Response to New Mexico Governor's PFAS Petition October 2021, https://www.epa.gov/system/files/documents/2021-10/oct_2021_response_to_nm_governor_pfas_petition_corrected.pdf.

[173] *Key EPA Actions to Address PFAS*, EPA https://www.epa.gov/pfas/key-epa-actions-address-pfas#:~:text=In%20January%202024%2C%20the%20EPA%20finalized%20a%20rule%20that%20prevents,EPA%20review%20and%20risk%20determination.

[174] *Id.*

[175] Maeve Sheehey, *Cow-Harming 'Forever Chemicals' Strain USDA's Relief Resources*, Bloomberg Law (Oct. 25, 2022), https://news.bloomberglaw.com/environment-and-energy/cow-harming-forever-chemicals-strain-usdas-relief-resources.

[176] CLG-PFAS2.04 Screening, Determination, and Confirmation of PFAS by UHPLC-MS-MS.

[177] CLG-PFAS 2.04, Screening, Determination, and Confirmation of PFAS by UHPLC-MS-MS / CLG-PFAS2.04 Screening, Determination, and Confirmation of PFAS by UHPLC-MS-MS

FDA's actions on PFAS are even more anemic. FDA's entire engagement with PFAS has come through its Total Diet Study, pursuant to which the agency has tested at random less than 800 samples of food collected over four years.[178] Based on the results of these tests, a number of which have come back positive,[179] the FDA's general stance is that PFAS have been detected in very few samples and at low levels and therefore do not merit any regulatory attention.[180] This conclusion starkly contrasts with private and state testing, which has determined that PFAS are present in produce, milk, and packaged foods.[181]

Worse yet, as the agency vested with the sole authority to regulate food additives—including chemicals applied on food contact materials—FDA actually *permits* the use of many PFAS on such materials.[182] It does so despite copious scientific data that these substances migrate onto food[183] and that, as EPA has found, there are no safe doses of exposure.[184] To date, the FDA has permitted the use of 83 different PFAS compounds in food contact materials, has asked industry to voluntarily recall three, and has formally banned or disallowed none.[185] And there are no indications that the FDA plans to take any further steps on the use of PFAS in food or food-adjacent products anytime soon.[186]

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[178] *Per- and Polyfluoroalkyl Substances (PFAS)*, FDA (May 31, 2023), https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas#:~:text=Tested%20nearly%20800%20samples%20of%20foods%20on%20the,raised%2C%20or%20processed%20in%20known%20areas%20of%20contamination.

[179] *FDA Tests Confirm Suspicions about PFAS Chemicals in Food*, ENVIRON. WORKING GROUP (June 3, 2019), https://www.ewg.org/news-insights/news/fda-tests-confirm-suspicions-about-pfas-chemicals-food ("The FDA detected PFOS in approximately half of the meat and seafood products; PFPeA in chocolate milk and high levels in chocolate cake with icing; PFBA in pineapple; and PFHxS in sweet potato.").

[180] *Update on FDA's Continuing Efforts to Understand and Reduce Exposure to PFAS from Foods*, FDA (Feb. 24, 2022), https://www.fda.gov/food/cfsan-constituent-updates/update-fdas-continuing-efforts-understand-and-reduce-exposure-pfas-foods ("While the FDA found detectable levels of PFAS in certain seafood samples in this TDS survey, as in previous ones, the sample sizes are limited, and the results cannot be used to draw definitive conclusions about the levels of PFAS in seafood in the general food supply.")

[181] THE GUARDIAN, *supra* note 163; *Maine Dairy Farm Coming Out of Toxic Nightmare From 'Forever Chemicals'*, NEWS CENTER MAINE (March 8, 2023), https://www.newscentermaine.com/article/tech/science/environment/pfas/dairy-farm-coming-out-of-a-toxic-nightmare-from-forever-chemicals-pfas-environment-maine-business-agriculture/97-96c362b4-f9fd-42e8-9591-eeb69726c4f4; *Evidence of PFAS in Organic Pasta Sauces,* ENH (April 13, 2022), https://www.ehn.org/pfas-pasta-sauce-2657142422.html.

[182] *See* Cronin, *supra* n. 59, at 123-127.

[183] *See id.*

[184] *See Proposed PFAS National Primary Drinking Water Regulation,* EPA (2024), https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.

[185] *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-usedto-make-plastic-food-packaging; 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).

[186] *See generally Per- and Polyfluoroalkyl Substances (PFAS)*, FDA (2024), https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-

The other players in the food safety space likewise have not taken any actions that directly affect PFAS contamination of food. The CDC's activities have been limited to researching the spread of PFAS in the human population;[187] the ARS is researching potential remediation approaches for agricultural environments;[188] the Consumer Product Safety Commission has merely issued public notice requesting information on PFAS's potential uses and routes of human exposure;[189] and the National Marine and Fisheries Service is conducting preliminary research on the spread of PFAS in fish and seafood.[190]

F. PFAS-Specific Regulatory Challenges

On top of the general inefficiencies of the current food safety regulatory scheme,[191] PFAS contamination of food also poses unique challenges. Perhaps the biggest challenge is PFAS's ecological and commercial ubiquity. Because these substances are present virtually everywhere in our environment,[192] ascertaining the likely route of food product contamination is challenging.[193] This, in turn, poses challenges in determining which agency's jurisdiction is implicated and what actions may be most appropriate to remedy the situation. PFAS's entrenched use in almost every industry—from national security operations to firefighting foam and toilet paper[194]—also threatens daunting

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pfas#:~:text=The%20FDA%20has%20authorized%20certain,%2C%20and%20water%2Dresistant%20properties (noting that "[t]he FDA has authorized certain PFAS for use in specific food contact applications" on the basis of "rigorous review of scientific data prior to their authorization for market entry" and "information [that] demonstrate[s] that there is a reasonable certainty of no harm under the intended conditions of use").

[187] *See Toxicological Profile for Perfluoroalkyls*, AGENCY FOR TOX. SUBS. AND DISEASE RES., https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf (last visited Jan. 3, 2024).

[188] Clinton Williams, USDA ARS, *PFAS Fate and Remediation in Agricultural Systems: Developing Conservation Assistance for Landowners, Project Number 2020-13000-005-017-I* (start date Aug. 1, 2023) https://www.ars.usda.gov/research/project/?accnNo=445481.

[189] Consumer Product Safety Commission, *Per- and Polyfluoroalkyl Substances (PFAS) in Consumer Products*, 88 FED. REG. 64890 (Sept. 20, 2023).

[190] *Ecotoxicity of Perfluorooctane Sulfonate and Fluorine-Free Fire Fighting Foams in Estuarine Organisms*, NCCOS (Aug. 2020), available at https://coastalscience.noaa.gov/project/ecotoxicity-of-perfluorooctane-sulfonate-and-fluorine-free-fire-fighting-foams-in-estuarine-organisms/.

[191] *See supra* Part II.B.

[192] *See* Juliane Glüge et al., *An Overview of the Uses of Per- and Polyfluoroalkyl Substances (PFAS)*, 12 ENV'T SCI.: PROCESSES AND IMPACTS (2020).

[193] *See PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024*, EPA (2024), https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024 (noting that "EPA cannot solve the problem of "forever chemicals" by tackling one route of exposure or one use at a time.").

[194] *See* Glüge et al., *supra* note 19; Katherine E. Boronow, Julia Green Brody, Laurel A. Schaider, Graham F. Peaslee, Laurie Havas & Barbara A. Cohn, *Serum concentrations of PFASs and exposure-related behaviors in African American and non-Hispanic white women*, 29 J. OF EXPOSURE SCI. & ENV'TL EPIDEM. 206 (2019); Jake T. Thompson, Boting Chen, John A. Bowden, & Timothy G. Townsend, *Per- and Polyfluoroalkyl Substances in Toilet Paper and the Impact on Wastewater Systems*, 10 ENVIRON. SCI. TECHNOL. LETT. 234 (2023); Kevin Loria, *Dangerous PFAS Chemicals Are in your Food Packaging*,

industry pushback against any effort to curtail these chemicals' use. As such, PFAS is a prime example of bystander apathy and the regulatory commons problem.[195] Because the problem is too vast and because no regulator has primary—or even stated—responsibility over PFAS in food, inaction, complacency, or bureaucratic paralysis are much likelier outcomes than risky, politically unrewarding, and resource-intensive action in a field of shared and diffused responsibility.[196]

Nor is it easy to scientifically capture the full scope of the problem. PFAS represent a vast—and growing—class of chemicals with definitions encompassing anywhere from 3000 to 15,000 possible chemical variations.[197] A single change in the molecular structure results in a new, and as of yet unknown, chemical that can easily avoid detection.[198] This is particularly true given that most labs are currently equipped to test for only two substances—PFOS and PFOA—and the most cutting-edge labs sponsored by USDA and FDA usually only test for 16 to 30 substances.[199] Add to that the fact that labs cannot test for concentrations lower than 4 parts per trillion[200] (even though the EPA has stated that concentrations lower than that can be harmful to human health), and a grim picture quickly emerges: labs routinely report "not detected" for samples that contain one or more PFAS in not insignificant quantities, either because they tested for only a few substances or the concentration of each individual substance fell slightly below the limit of detection (though the total concentration of PFAS may still be staggering).[201] Further complicating matters are the different limits that each agency has proposed in its advisory opinions. While the EPA has opined that there are no safe levels of PFAS and has proposed setting the maximum contaminant level goals for PFAS in drinking water at 4 ppt due to lab detection capabilities, the FDA's limit is currently at 50 ppt,[202] and the USDA's is at 500 ppt.[203] Therefore, even assuming that a lab is equipped to

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CONSUMER REPORTS (March 24, 2022), https://www.consumerreports.org/health/food-contaminants/dangerous-pfas-chemicals-are-in-your-food-packaging-a3786252074/

[195] *See* Part. I.C *supra.*

[196] *Id.*

[197] *See* CompTox Chemicals Dashboard, *Navigation Panel to PFAS Structure List*, EPA (2024), https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCT (listing 14,735 chemicals as satisfying the definition of PFAS).

[198] *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).

[199] *See* S. Genualdi, W. Young, E. Peprah, E. *et al.*, *Analyte and matrix method extension of per- and polyfluoroalkyl substances in food and feed*, ANAL. & BIOANAL. CHEM. (2023).

[200] Linda Cook and Kirk O'Reilly, *Regulating PFAS at the Edge of Detection*, ABA JOURNAL (June 21, 2023), https://www.americanbar.org/groups/environment_energy_resources/publications/wqw/regulating-pfas-at-edge-of-detection/.

[201] *See* Zhanyun Wang et al., *supra* note 197.

[202] *FDA Foods Program Compendium of Analytical Laboratory Methods: Chemical Analytical Methods*, at 15 FDA, https://www.fda.gov/media/131510/download (setting the lowest reference standard at 0.05 ng/g, which is equivalent to 50 ppt).

properly conduct a test for all PFAS that may be present in a product, the lab result may be interpreted as "not detected," "below method detection limit," or at a level of concern depending on the agency that ordered the test.

These scientific difficulties of capturing the extent of the PFAS threat also highlight the misguided approach of seeking to regulate individual PFAS substances rather than PFAS as a class. Regulators have long rejected this approach in the context of heavy metals, for example, where the FDA took into account "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."[204] Aside from cumulative exposure, regulating individual PFAS presupposes that each agency has to wait for definitive scientific studies on the negative health effects of *particular* individual substances. But, if a substance was only created in a lab yesterday, that means that it would be years before any scientific data can emerge on its individual operation.[205] Meanwhile, it would be put into the stream of commerce unimpeded, and consumers would continue to get sicker while they wait for regulatory certainty.[206] Such a substance-by-substance approach makes no sense in the face of strong scientific confidence that the entire class behaves similarly and poses equally devastating health risks. The only logical and effective regulatory tack is dealing with PFAS as a class,[207] but the enormity of that task leads right back to bureaucratic paralysis and the bystander effect.

The totality of these obstacles has so far prevented effective—or any—regulation of PFAS in food, leaving consumers exposed to dangerous chemicals with their every meal. Any proposed solution to this crisis must therefore take these difficulties into account and find a way to overcome them.

III. In Search of a Solution to the Crisis of PFAS in Food

> *"Progress, far from consisting in change, depends on retentiveness. […] Those who cannot remember the past are condemned to repeat it."* – George Santayana[208]

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[203] U. S. Dep't of Agr., *Screening, Determination and Confirmation of PFAS by UPLC-MS-M*S, OFFICE OF PUBLIC HEALTH SCIENCE, at 10, https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/CLG-PFAS2.03.pdf (setting the lowest reference standard at 0.5 ng/g, which is equivalent to 500 ppt).
[204] *See What FDA is Doing to Protect Consumers from Toxic Metals in Foods*, FDA (2018), https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxicmetals-foods.
[205] Nicholas "Hoo" Ray, *Emerging Trends in PFAS Litigation*, 52 TEX. ENVT'L. L.J. 73, 76 (2023).
[206] *Id.*
[207] *Id.* at 78.
[208] 1 GEORGE SANTAYANA, THE LIFE OF REASON: THE PHASES OF HUMAN PROGRESS, REASON IN COMMON SENSE (1905–1906).

The overall state of dysfunction of the food safety system has long been a subject of academic interest and many proposed fixes have been put forth over the years. The problem of PFAS in food, by contrast, is a recent, underpublicized, and underexamined issue, for which no currently viable solutions exist. In search of a feasible response to this public health crisis, this section first reviews (and rejects) the most commonly proposed fix to the broader regulatory fragmentation and dysfunction. It then looks to PFAS-specific long-term solutions, before zeroing in on a more practical, realistic, and readily applicable approach.

A. A Centralized Food Safety System

One of the most cited solutions to any food safety crisis—including those precipitated by foodborne illnesses and environmental contaminants—is complete reformation of the current regulatory system to a unified, single-agency paradigm. Such a centralized system, the premise states, would be better equipped to address all threats to food safety (including, by implication, PFAS) by avoiding duplicative, inconsistent, or under-regulation. As early as 1949, a commission chaired by former President Herbert Hoover showed significant concern over, among other things, the lack of proper regulation of chemicals and contaminants, and recommended consolidating all food safety regulation under a single agency (the USDA).[209] In 1977, the Senate Government Affairs Committee undertook a two-year investigation into the state of food and food safety regulation and likewise recommended consolidating all food safety functions into a single agency (the FDA).[210] In 1993, the Clinton Administration stated its support for folding in the functions of FSIS into the FDA.[211] And in 1998, a Committee to Ensure Safe Food from Production to Consumption conducted a thorough review of the shortcomings of a fragmented food safety system and concluded that "Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education."[212] This report did not opine on where exactly such authority should be located.[213] Many others in recent years have likewise noted that Congress should replace the existing food safety law with a "unified law covering the entire food supply," that encompasses the functions of FSIS, FDA, and EPA's pesticide program.[214] In

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[209] THE HOOVER COMMISSION REPORT, *supra* note 33, at 251.
[210] STAFF OF S. COMM. ON GOV'T AFF., 95TH CONG., FOOD REGUL.: A CASE STUDY OF USDA AND FDA 113, 138–143 (Comm. Print 1977)., FOOD REGUL.: A CASE STUDY OF USDA AND FDA, *supra* note 11, at 138–43.
[211] ALBERT GORE, FROM RED TAPE TO RESULTS: CREATING A GOVERNMENT THAT WORKS BETTER & COSTS LESS: REPORT OF THE NATIONAL PERFORMANCE REVIEW 101 (1993).
[212] INST. OF MED.AND NAT'L RSCH COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION, at 97 (1998) (e-book), http://www.nap.edu/catalog/6163.html.
[213] *See id.*

total, the Government Accountability Office has issued sixteen reports documenting the dysfunction of the current food safety system and calling for the creation of a single agency, its most recent report dating back to 2021.[215] And the last three presidents have all criticized the fragmented food safety system and have called for either coordination or consolidation of regulatory functions.[216]

Although a unified food safety system housed in a single agency has extremely high theoretical appeal, it universally lacks practical support. Even the most ardent proponents of a single-agency regulatory scheme admit the extreme difficulty involved in putting Humpty Dumpty back together again. Richard Merrill—one of the drafters of the 1998 Committee report that recommended a unified system—has explained in detail the insurmountable logistical hurdles inherent in such a proposal.[217] These include severing existing synergies and agency ties between food safety programs and other food regulation, attempting to mesh together personnel from different divisions and with different functions, allocating resources between the various programs, inevitably leaving programs behind or with no home, determining the agency leadership status and the bureaucratic location of the new agency (centralized like the FDA or heavily field-present like FSIS), and many others.[218] Beyond these open questions, there is the resounding lack of political will that has plagued Washington in recent years and that has left many a worthy bill to die. Congress has held more than twenty hearings on potential reforms to the food safety system and at least ten bills have been introduced to create a single agency.[219] None of these bills has seen the light of day past its first reading, however.[220] Even unimaginable tragedies involving children fatally poisoned by contaminated food have not been sufficient to move this issue forward and to garner sufficient legislative support.[221] Whatever the merits of a unified approach to food safety may be, the dire reality is that PFAS contamination of our food supply is both an entrenched and pressing

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[214] *See, e.g.,* Michael R. Taylor, *Reforming Food Safety: A Model for the Future*, RESOURCES FOR THE FUTURE (2002), https://media.rff.org/documents/RFF-IB-02-02.pdf (noting that if creating an entirely new agency is not an option, the food safety functions should be consolidated within HHS).

[215] Bernice Yeung, Micahel Grabell, & Mollie Simon, *The Low-And-Slow Approach to Food Safety Reform Keeps going up in Smoke*, PROPUBLICA (Dec. 23, 2021, 6:00 AM), https://www.propublica.org/article/the-low-and-slow-approach-to-food-safety-reform-keeps-going-up-in-smoke. *See also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-119SP, HIGH-RISK SERIES: DEDICATED LEADERSHIP NEEDED TO ADDRESS LIMITED PROGRESS IN MOST HIGH-RISK AREAS (2021).

[216] Yerung et al., *supra* note 214.

[217] Merrill & Francer, *supra* note 12, at 82.

[218] *Id. See also* ALEJANDRO CAMACHO & ROBERT GLICKSMAN, REORGANIZING GOVERNMENT, 58–64 (2019) (cataloguing the failure of scholars to account for function in assessing and proposing structural reform to the federal food system).

[219] *Id.*

[220] *See, e.g.,* Safe Food Act of 2019, S. 1995, 116th Cong. (2020) (introduced to Senate with no further action taken).

[221] *Id.*

need that must be addressed now, not in a hypothetical (and practically unattainable) future.

G. Banning PFAS in Food Products

A smaller scale—and thus presumably more feasible—solution is to replicate prior examples of environmental contaminant regulation. In the past, an Act of Congress directly banned the use of specific environmental contaminants and augmented EPA's authority to set limits and tolerances that were then delegated to USDA and FDA for monitoring and enforcement.[222] A similar scheme, where EPA would enforce a total ban on PFAS's use, while FDA and USDA would test for the presence of PFAS residue in food and recall adulterated products, would be an effective way to regulate PFAS in food.

Over the past few years, several proposed Acts to ban the use of PFAS have been introduced in Congress. In 2021, Rep. Debbie Dingell introduced a bill to designate PFOS and PFOA as "persistent, bioaccumulative, and toxic substances," and as hazardous under CERCLA and the CAA.[223] HR 117-2467, which passed in the House in 2021 but stalled in the Senate, also proposed further investigation into GenX contamination and empowering the EPA to designate all PFAS as hazardous under CERCLA and as toxic under the TSCA.[224] Three additional bills were introduced in 2021, mostly requiring EPA to demand additional reporting or provide information on PFAS.[225] In 2022, a bill sought to require the EPA to ask for analytical reference standards from PFAS manufacturers.[226] None of these bills advanced past a first reading on the floor.

Signaling the exponential increase in public awareness and concern over PFAS, legislators introduced more than 50 PFAS-related bills in 2023.[227] Only three made it out of Committee and only two of these have so far been enacted, and both favor industry, not consumers.[228] In addition to the general political gridlock in Congress, the proposed bills also faced significant industry opposition. Lobbying efforts by DuPont—one of the leading manufacturers of PFAS—totaled $2.5 million for the session that included the PFAS Action Bill, while the American Chemistry Council, which represents chemical companies, spent a total of $17 million to lobby Congress for that same period.[229] Beyond

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[222] *See* Part. I.D *supra.*
[223] *See* PFAS Action Act of 2021, H.R. 2467, 117th Cong. (2021).
[224] *Id.*
[225] *See* H.R.4224, 117th Cong. (2021); H.R.4381,117th Cong. (2021); H.R.4567, 117th Cong. (2021).
[226] PFAS Reference Standards Act, H.R.7897, 117th Cong.(2022).
[227] *See* Congress.Gov, Legislation Search, available at https://www.congress.gov/search?q=%7B%22source%22%3A%22legislation%22%2C%22search%22%3A%22PFAS%22%7D (last visited Jan. 2, 2024).
[228] *See* Tom Perkins, *Bills to Regulate Toxic 'Forever Chemicals' Died in Congress – with Republican Help*, THE GUARDIAN (Jan. 13, 2023, 5:00 AM), https://www.theguardian.com/environment/2023/jan/13/pfas-toxic-forever-chemicals-republican-house.
[229] *Id.*

these hurdles, with the exception of the No Toxins in Food Packaging Act of 2023, which sought to prohibit the use of PFAS in food packaging and failed in Congress, none of the proposed laws addressed food safety in any way.[230] Even if one of these proposals, or a hypothetical future bill, were to break away from the pack and make it through the morass of industry lobbying and the political impasse, substantial immediate regulation of PFAS in food is not likely to come through this route in the foreseeable future.

H. Relying on FDA and USDA Authority

Considering the near impossibility of passing new legislation to address PFAS in food, the only feasible solution must come from existing regulatory authority. Under the analytical framework of bystander apathy, the first step in forcing action on a pressing, complex, and diffuse issue, like the spread of PFAS in food, is to select an agency responsible for its implementation. Bystander no more, that agency is thus freed from bureaucratic paralysis and entrusted with using the full might of its regulatory power to resolve the issue that it now has a vested interested in.

Due to its primacy in the food space and its significant regulatory authority over food safety, at first blush, the FDA would be the obvious candidate to take the lead on this issue. Indeed, under its existing authority, the FDA could do a lot to address the spread of PFAS in the food supply. For one, the FDCA charges the FDA with regulating adulteration of crops because of "sewage, chemicals, heavy metals, pathogenic microorganisms, or other contaminants,"[231]—a lineup to which PFAS readily belongs. Thus, the FDA has the authority to remove from the market any domestic or imported products that it considers unfit for human consumption due to the presence of such contaminants.[232] The FDA also has exclusive authority over food additives in both food itself and in food contact materials.[233] It could therefore revoke any prior authorizations for the use of PFAS in paper, packaging, food processing equipment, or any other food-adjacent medium.[234] The FDA could also require labeling of food products with intentionally added PFAS or may set maximum allowable levels for PFAS, thus requiring manufacturer testing and self-reporting of products that contain PFAS as a byproduct of environmental contamination.[235] Lastly, the agency could systematically monitor the spread of PFAS in the food supply to better understand the types of commodities and environments most at risk for contamination, as it has done for heavy metals in the past.[236]

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[230] H.R. 6105, 118th Cong. (2023).
[231] 21 U.S.C. § 342(a)(4).
[232] *Id.* at § 334.
[233] *Id.* at § 348(h).
[234] *See* Cronin, *supra* note 59.
[235] 21 U.S.C. 343(a)(1). *Cf.* 21 C.F.R. Part 165.110 (setting labeling and testing requirements for contaminants in bottled water).

Despite this ample authority, the FDA has not chosen to act on PFAS to date in any meaningful way. This is primarily due to FDA's skepticism over the scope of the problem. Relying on its limited testing, the FDA currently finds "no indication that the PFAS at the levels found in the limited sampling of foods collected for the TDS present a human health concern."[237] With respect to food contact materials, the FDA likewise maintains that, for most products, there is only "a negligible amount of PFAS capable of migrating to food."[238] Therefore, despite petitions from consumer advocate groups to ban the use of PFAS in food contact materials, the FDA has refused to do so.[239]

The FDA makes room for the possibility that its "conclusions related to the potential human health concerns for certain levels of PFAS found in food may change."[240] It readily admits that its testing to date is "limited," and that it therefore cannot "draw definitive conclusions."[241] Indeed, in its 2024 budget, the FDA has asked for an additional $5 million to allow CFSAN to study PFAS further.[242] It has also asked for an additional $23 million for the "Healthy and Safe Food for All" initiative, which includes increased funding for field inspectors and for developing better testing methods for emerging contaminants, including PFAS.[243] FDA's recently issued draft guidance to industry on safe food also included PFAS as a potential contaminant.[244]

Beyond food, the FDA is also actively researching PFAS as part of its new obligations under the Modernization of Cosmetics Regulation Act.[245] Importantly, the agency also recently finalized its proposal for creating a Unified Human Food Program, which seeks to remedy many of the structural inefficiencies and organizational handicaps that have plagued FDA's food arm for years.[246] All of these factors may collide to produce

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[236] *See, e.g., Analytical Results for Arsenic in Food Intended for Babies and Young Children Sampled under the FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic Compliance Program (FY2009-FY2021*), FDA, https://www.fda.gov/media/164564/download?attachment.
[237] *Analytical Results of Testing Food for PFAS from Environmental Contamination*, FDA (Sept. 29, 2023), https://www.fda.gov/food/process-contaminants-food/analytical-results-testing-food-pfas-environmental-contamination.
[238] *Authorized Uses of PFAS in Food Contact Applications*, FDA (May 31, 2023), https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications.
[239] *See, e.g.,* 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-toFDA-FINAL-6-1-21.pdf.
[240] *Testing Food for PFAS and Assessing Dietary Exposure*, FDA (Aug. 28, 2023), https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure.
[241] *Id.*
[242] *Department of Health and Human Services, Fiscal Year 2024, Justification of Estimated for Appropriations Committees*, FDA, https://www.fda.gov/media/166182/download.
[243] *Id.*
[244] *Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry*, FDA (Jan. 2024), https://www.fda.gov/media/100002/download?attachment.
[245] H.R. 2617, 117 Cong. (2021).

a change in FDA's tack on PFAS and may eventually result in meaningful regulation of these toxins in food products by *the* food agency. However, much like a legislative ban on PFAS, FDA action on this issue is so far only hypothetical, currently counterfactual, and at best too distant.

The same can be said about USDA. FSIS has authority to inspect meat, poultry, and eggs for the presence of any contaminants under its National Residue Program and to order a recall of adulterated products.[247] Indeed, using this authority, the USDA has previously sampled animal products for the presence of PFAS, but its efforts have been extremely limited and unsystematic. Despite conducting daily inspections of all meat processing plants in the country for other hazards, FSIS has only sampled a total of 3156 cattle, poultry, and egg products in the span of two years (2021-2022).[248] FSIS also has authority to require product manufacturers to include toxic contaminants, such as PFAS, in their hazard analysis and risk assessment plans under HACCP,[249] but it has not shown any interest in doing so to date. USDA's ARS is currently conducting several research projects focused on learning more about PFAS in agriculture—including remediating agricultural systems,[250] improving farming practices to reduce PFAS,[251] and studying PFAS in soil, sediment, and water.[252] Much like the FDA, FSIS may therefore change its approach to PFAS in the products under its jurisdiction as more information becomes available from these planned research efforts. Hoping for such action, however, is too speculative to provide a reliable and current pathway for change.

I. Breaking Free from Bystander Apathy: Empowering the EPA to Act

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[246] *FDA's Proposal for a Unified Human Foods Program and New Model for the Office of Regulatory Affairs*, FDA (Dec. 13, 2023), https://www.fda.gov/about-fda/fda-organization/fdas-proposal-unified-human-foods-program-and-new-model-office-regulatory-affairs. *See also* Part I.B *supra.*

[247] FSIS Directive 8410.1, Rev. 6, Detention and Seizure (U.S.D.A. 2014).

[248] *See also CLG-PFAS2.04 Screening, Determination, and Confirmation of PFAS by UHPLC-MS-MS*, USDA, FSIS (Feb. 28, 2023), https://www.fsis.usda.gov/sites/default/files/media_file/documents/CLG-PFAS2.04.pdf.

[249] 9 C.F.R. § 417.2. *See also Guidebook for the Preparation of HACCP Plans*, USDA, FSIS (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Guidebook-for-the-Preparation-of-HACCP-Plans.pdf (noting that one goal of HACCP is to "prevent, or to reduce to an acceptable level, contamination with other biological, chemical, and physical hazards").

[250] Clinton Williams, USDA ARS, *PFAS Fate and Remediation in Agricultural Systems: Developing Conservation Assistance for Landowners*, Project Number: 2020-13000-005-017-I (2023-2027), https://www.ars.usda.gov/research/project/?accnNo=445481.

[251] Clinton Williams, USDA ARS*, Identifying Effective Farming Practices to Reduce Risks of Per- and Polyfluoroalkyl Substances (PFAS) in Food Crop Productions*, Project Number: 2020-13000-005-007-R (2021-2024), https://www.ars.usda.gov/research/project/?accnNo=438976.

[252] Clinton Williams, USDA ARS*, Multi-site Study of Soil, Sediments and Water for PFASs Analysis in North Carolina*, Project Number: 2020-13000-005-013-S (2023-2025), https://www.ars.usda.gov/research/project?accnNo=444359.

Although the USDA and the FDA have so far shown indifference to PFAS in food, the EPA has been highly active in the last few years in its attempts to address the broader PFAS crisis. Capitalizing on the Biden Administration's stated interest in combatting PFAS contamination,[253] the EPA issued its "PFAS Roadmap" in 2021 and has steadily been working towards remediating and reducing PFAS through multiple avenues under its existing regulatory authority.[254] Where other agencies are still in the early stages of researching these substances and refining their testing methods, EPA has amassed a significant knowledge bank on the spread, chemical profile, health effects, and environmental behavior of these chemicals.[255] This record of action makes it best suited to handle PFAS' scientific complexity and ubiquitous spread on an accelerated timeline.

EPA has also taken significant steps under its existing authority to regulate PFAS by using provisions of the TSCA, SDWA, CWA, RCRA, CERCLA, and the Emergency Planning and Community Right-to-Know Act.[256] While more could be done,[257] this willingness to act even in the face of fierce opposition by the chemical industry shows a pattern of behavior more consistent with a leadership paradigm than a bystander. It also makes the EPA best positioned to take on the issue of PFAS in food so long as it has an available jurisdictional hook to act.

And, as it turns out, it does. Through its authority to regulate pesticides under FIFRA, FDCA, and FQPA—a route that so far has remained unexplored in the scholarship—the EPA has at its disposal a regulatory mechanism that could allow it to directly reach food without the need for further Congressional action or a sweeping administrative reform.[258]

The parallels between pesticide use in the 1970s, when EPA was created, and use of PFAS today are astonishing. In 1964, Rachel Carson wrote in *Silent Spring* about the countless chemicals "sold under several thousand different brand names" which were

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[253] *See, e.g., Press Release, Fact Sheet: Biden- Harris Administration Launches Plan to Combat PFAS Pollution*, THE WHITE HOUSE, (Oct. 18, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/18/fact-sheet-biden-harris-administration-launches-plan-to-combat-pfas-pollution/; *Press Release, Fact Sheet: Biden- Harris Administration Combatting PFAS Pollution to Safeguard Clean Drinking Water for All Americans,* THE WHITE HOUSE (June 15, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/15/fact-sheet-biden-harris-administration-combatting-pfas-pollution-to-safeguard-clean-drinking-water-for-all-americans/.

[254] *See* Part II.C *supra.*

[255] *See Per- and Polyfluoroalkyl Substances (PFAS)*, EPA (last updated Feb. 8, 2024)https://www.epa.gov/pfas.

[256] *See* Part II.C *supra.*

[257] *See* Nevitt & Percival, *supra* n. 42. *See also* Robert L. Glicksman and Johanna Adashek*, Delegated Agency Authority to Address Chemicals of Emerging Concern: EPA's Strategic Use of Emergency Powers to Address PFAS Air Pollution*, 48 HARV. ENV'TL L. REV. (forthcoming 2024).

[258] *See* Merrill & Francer, *supra* n. 12 (noting that EPA's pesticide residue program "is the largest single federal unit responsible for evaluating the safety of chemicals added to food" but not analyzing its potential to expand to other toxic contaminants).

"applied almost universally to farms, gardens, forests, and homes" and have "the power to kill every insect, the 'good' and the 'bad,' to still the song of birds and the leaping of fish in the streams, to coat the leaves with a deadly film, and to linger on in soil."[259] Little needs to be changed in her words to accurately depict the state of PFAS use, contamination, and devastation today. Much like the FDA and USDA shared jurisdiction on pesticides and engaged in bystander apathy then, even in the face of dire safety and health warnings, they do so with regards to PFAS today.

Beyond poetic parallels, however, EPA's authority to regulate pesticides could be read to encompass PFAS because PFAS are not only *like* pesticides in many respects, they also are *in* pesticides. Pesticide products contain both active substances listed on the product label and inert ingredients added to the final product as "emulsifiers, solvents, carriers, aerosol propellants, fragrance and dyes."[260] According to latest research from the European Union, a significant percentage of all approved synthetic pesticides on the market in 2023 contain PFAS as either active or inactive ingredients.[261]

Under some definitions for PFAS, a number of active pesticide ingredients currently approved for use are PFAS themselves.[262] According to the Minnesota Department of Agriculture, for example, "[o]ver 90 active ingredients were identified as meeting the SF 1955 definition of PFAS."[263] Maine likewise found 55 PFAS compounds used as active ingredients in over 1,400 pesticide formulations.[264] That is far from a localized or one-off problem either. Scientists in Portugal found that nearly 70% of the pesticides used from 2015 to 2020 used fluorinated chemicals—many of which fit the definition of PFAS.[265] Similarly, research in the UK found that, of the fifty most widely used pesticide substances for arable crops, fourteen were fluorinated and fit the definition of PFAS.[266] Nine more fluorinated pesticides were used in the U.K. on vegetable crops

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[259] Carson, *supra* note 35.

[260] *Inert Ingredients Regulation*, EPA (last visited Jan. 1, 2024) https://www.epa.gov/pesticide-registration/inert-ingredients-regulation.

[261] *New EU Report Examines PFAS in Pesticides*, WASTE 360 (Nov. 15, 2023), https://www.waste360.com/pfas-pfoas/new-eu-report-examines-pfas-pesticides. *See also* Linda G.T. Gaines, *Historical and current usage of per and polyfluoroalkylsubstances (PFAS): A literature review*, 66 AMER. J. OF INDUSTR. MED. 349, 365–66 (discussing the many uses of PFAS, including in pesticide formulations as both active and inert ingredients).

[262] Lisa Held, *New Evidence Shows Pesticides Contain PFAS, and the Scale of Contamination is Unknown*, CIVIL EATS (Nov. 7, 2022), https://civileats.com/2022/11/07/pfas-forever-chemicals-pesticides-pollution-farmland-mosquito-control-epa-inert-ingredients/.

[263] Trisha Leaf, *Active and Inert PFAS*, MINNESOTA DEPT. OF AGRIC. (Last updated Jan. 2024), https://www.mda.state.mn.us/environment-sustainability/active-inert-pfas. (

[264] Monica Amarelo, *Maine data unveils troubling trend: 55 PFAS-related chemicals in over 1,400 pesticides*, ENVIRONMENTAL WORKING GROUP (June 6, 2023) https://www.ewg.org/news-insights/news-release/2023/06/maine-data-unveils-troubling-trend-55-pfas-related-chemicals.

[265] *Id.* (discussing Diogo A.M. Alexandrino, C. Marisa R. Almeida, Ana P. Mucha, Maria F. Carvalho, *Revisiting Pesticide Pollution: The Case of Fluorinated Pesticides*, 292 ENV. POLLUT. (2022)).

and nineteen on amenities (lawns, golf courses, highways, etc.) in 2021 alone.[267]

In addition, because of PFAS' water-, oil-, and degradation-resistant properties, these chemicals are often added to pesticide formulations as surfactants and penetrating agents. They are thus classified as inert ingredients that do not need to be explicitly listed on the product label. Some environmental toxicology studies have found various PFAS substances in pesticide formulations at levels of 4-19 million parts per trillion (which, even if diluted per label use, would still be hundreds of thousands of times higher than current EPA health advisories for PFAS in water).[268] States have likewise found PFAS in pesticides and insecticides they routinely apply to public land despite the lack of these substances on the ingredient labels. Massachusetts found high concentrations of several PFAS substances in the pesticide Anvil 10+10,[269] Maryland found 3,500 ppts of PFOA and 630 ppt of the newer generation Gen-X in the widely used mosquito insecticide Permanone 30-30,[270] and the Center for Biological Diversity found PFAS in high concentrations in three of seven agricultural pesticides it tested in California.[271]

The full extent of PFAS use and concentration in pesticides or the rate of transfer to humans from that specific source is unknown and nearly impossible to ascertain, given the lack of labeling for inert ingredients,[272] the fact that PFAS can also leach into pesticides from packaging,[273] and the many routes of human exposure to PFAS in daily life.[274] What is important for present purposes, however, is not quantifying the use of PFAS in *pesticides*, but more so providing a jurisdictional basis for EPA to regulate PFAS residues in *food products*.

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[266] *The Problem with PFAS in Pesticides*, PFAS FREE.UK (Mar. 22, 2023), https://www.pfasfree.org.uk/uncategorised/pfas_in_pesticides.
[267] *Id.*
[268] *Id.*
[269] *See Summary Table: PFAS Concentrations from MassDEP Anvil 10 + 10 Sampling Initiative*, MASS DEP'T OF ENV'T PROT. (Nov. 19, 2020), https://peer.org/wp-content/uploads/2020/11/Anvil-PFAS-sample-data-summary-table-11-20-20-final.pdf; *See also* Kyla Bennett, *Aerially Sprayed Pesticide Contains PFAS*, PUB. EMP. FOR ENV'T RESP. (Dec. 1, 2020) https://peer.org/aerially-sprayed-pesticide-contains-pfas/. (
[270] Ruth Berlin, *PFAS Found in Widely Used Insecticide* available at MARYLAND PESTICIDE EDUCATION NETWORK (Mar. 26, 2021), https://mdpestnet.org/pfas-found-in-widely-used-insecticide/.
[271] Nathan Donley & Tim Whitehouse, *Letter to the California Department of Pesticide Regulation and the California Department of Food and Agriculture Re: Agency Action needed to Address PFAS Contamination in Pesticides*, CENTER FOR BIOLOGICAL DIVERSITY (May 1, 2023), https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/PFAS-letter-to-CA.pdf (May 1, 2023).
[272] *Basic Information about Pesticide Ingredients, Evaluating Pesticide Ingredients*, EPA (Last updated July 6, 2023), https://www.epa.gov/ingredients-used-pesticide-products/basic-information-about-pesticide-ingredients.
[273] *See Updates on EPA Efforts to Address PFAS in Pesticide Packaging*, EPA (Sept. 29, 2021), https://www.epa.gov/pesticides/updates-epa-efforts-address-pfas-pesticide-packaging.
[274] *See Per- and Polyfluoroalkyl Substances (PFAS*), EPA (last update Feb. 8, 2023), https://www.epa.gov/pfas.

EPA Could Ban the Use of PFAS in Pesticides

Under FIFRA's licensing scheme for the sale and use of pesticides, "no person in any State may distribute or sell to any person any pesticide that is not registered" by the EPA.[275] EPA can in turn only register a pesticide if it determines that its ingredients do not pose "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. . ."[276] EPA regulations further define a "pesticide chemical" to include "all active and inert ingredients of such pesticide."[277] In other words, even though federal law does not require the disclosure of inert ingredient names or concentrations on product labels, EPA is required by statute to evaluate the safety of *all* pesticide ingredients—active and inert—before it may grant a registration for the product to be sold or used in the United States.[278] If the EPA has previously granted authorization for certain ingredients or products, it may subsequently revoke that authorization and remove certain ingredients from the list of approved substance if new data demonstrates lack of safety.[279]

When used as either active or inert ingredients in pesticides, PFAS squarely fall within the definition of pesticide chemical and are subject to EPA regulation for that use. Indeed, the EPA has already used its authority under FIFRA to remove PFAS substances from its list of inert ingredients previously approved for use in pesticide products.[280] After the discovery of PFAS in an insecticide formulation (which appear to have migrated into the liquid after a minute-long contact with the HDPE plastic fluorinated container[281]), and after a highly publicized September 2022 study, which found PFOS and other PFAS in 7 out of 10 insecticide formulations used on USDA crop research field,[282] the EPA removed 12 PFAS that were previously approved for use as inert ingredients in pesticides from the list of approved substances.[283] As part of that action, EPA also stated that it will

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[275] 7 U.S.C. § 136a(a).
[276] 7 U.S.C. § 136a(b).
[277] 40 C.F.R. 180.1(i); FDCA, § 201(q)(1)(A).
[278] *Evaluating Pesticide Ingredients*, EPA (Last updated July 6, 2023), https://www.epa.gov/ingredients-used-pesticide-products/basic-information-about-pesticide-ingredients.
[279] 7 U.S.C. § 136(d.) *See also, Inert Ingredients – Reassessment Decision Documents*, EPA (last updated May 30, 2023), https://www.epa.gov/ingredients-used-pesticide-products/inert-ingredients-reassessment-decision-documents.
[280] Pesticides; Removal of PFAS Chemicals From Approved Inert Ingredient List for Pesticide Products, 87 Fed. Reg. 76,488 (Dec. 14, 2022).
[281] *See Updates on EPA Efforts to Address PFAS in Pesticide Packaging*, EPA (Sept. 29, 2021), https://www.epa.gov/pesticides/updates-epa-efforts-address-pfas-pesticide-packaging.
[282] Steven Lasee, et al., *Targeted analysis and Total Oxidizable Precursor assay of several insecticides for PFAS*, J. OF HAZARDOUS MATERIALS LETTERS 3 (2022).
[283] *See EPA Stops Use of 12 PFAS in Pesticide* Products, EPA (Dec. 14, 2022), https://www.epa.gov/pesticides/epa-stops-use-12-pfas-pesticide-products. Alarmed by the findings of the Sept. 2022 study, the EPA attempted to repeat the testing and announced that its own lab found no detectable PFAS in the tested samples. *See* Memorandum from Yaorong Qian, EPA Senior Chemist, to

"continue[] to evaluate all pesticide active ingredients to determine if any meet the current structural definition of PFAS or are part of other related chemistries that have been identified by stakeholders as being of concern."[284] More than a year later, EPA is now armed with significantly more information on the detrimental environmental and health effects of all PFAS and is in a better position to take further action under this authority. Following its previous tack, EPA can therefore initiate proposed rulemaking to withdraw any preauthorization and disallow all known PFAS used in pesticides as either active or inert ingredients. It would do so by issuing public notice of the proposed rule, followed by a standard 60-day notice-and-comment period, and a final rule.[285] This action by itself does not guarantee that no PFAS would ever be permitted as a pesticide ingredient. Rather, it changes the approval process and documentation required—whereas preapproved ingredients can be readily used in product formulations without additional registration or approval, ingredients removed from the approved list require a new use application, which must include "studies to evaluate potential carcinogenicity, adverse reproductive effects, developmental toxicity, genotoxicity, as well as environmental effects associated with any chemical substance that is persistent or bioaccumulative," and must be reviewed on a case-by-case basis by EPA before they can be included in a product.[286]

EPA Could Set PFAS Tolerances for Food Products

More significantly, explicitly recognizing PFAS under the definition of "pesticide chemicals" would also permit the EPA to mandate testing for PFAS residue in food products. In addition to FIFRA's licensing scheme, the FDCA requires that the EPA set tolerance limits for any pesticide residue found on food products moving in interstate commerce.[287] This tolerance is the maximum permissible level of reside that the EPA has determined to be safe for ingestion.[288] A tolerance (or an exemption from tolerance) must be set for *all* active and inert ingredients in a pesticide formulation.[289] If a tolerance is not

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Anne Overstreet, Director of OPP, on Verification Analysis for PFAS in Pesticide Products (May 18, 2023), https://www.epa.gov/system/files/documents/2023-05/BEAD%20PFAS%20Study%20Results%202023.pdf

[284] *Id.*

[285] 7 U.S.C. 136 *et seq*. *See also* Removal of Certain Inert Ingredients From the Approved Chemical Substance List for Pesticide Products, 81 Fed. Reg. 90,356 (Dec. 14, 2016) (removing 72 chemicals from the list of pre-approved inert ingredients).

[286] Removal of Certain Inert Ingredients From the Approved Chemical Substance List for Pesticide Products, 81 Fed. Reg. 90,356 (Dec. 14, 2016) (removing 72 chemicals from the list of pre-approved inert ingredients).

[287] 21 U.S.C. § 346a(b)(1).

[288] 21 U.S.C. § 346a(b)(2)(A).

[289] *Pesticide Registration Manual: Chapter 11 - Tolerance Petitions*, EPA (last updated June 26, 2023, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions#main-content; *see also* 21 U.S.C. § 346a (regulating the "tolerances for poisonous or deleterious

set for a certain compound found in pesticides or if a previously-set tolerance is exceeded, the affected product is subject to enforcement actions, including seizure and removal from the market.[290] Tolerances can be set for both raw commodities and processed products separately, if the processing increases the pesticide concentration in the final product.[291] Otherwise, a tolerance set for a raw agricultural commodity automatically applies to any processed product that contains the raw commodity as an ingredient.[292]

While tolerances under the FDCA operate in tandem with pesticide product registration under FIFRA, there are three important caveats for present purposes. First, the tolerance level does not discriminate between residue present on the commodity due to direct pesticide use and residue from other environmental sources. Because many controlled pesticide chemicals (like DDT and glyphosates) are persistent in the environment, food products may get contaminated not only by direct pesticide application, but also by exposure to other contaminated media (like soil and water).[293] In setting the appropriate tolerance, the EPA considers the amount of the chemical likely to remain on food after pesticide application.[294] The EPA Administrator also "may"—but does not have to—exclude a substance from regulation if he determines that residue on food is primarily attributable to natural causes or other human activity *and*, after consultation with the HHS Secretary, determines that the substances should be regulated under a different provision.[295] But, once the EPA sets a tolerance limit after taking these factors into account, it is not EPA's burden under this provision to establish the actual route of contamination for each individual product.[296] In the case of PFAS, studies demonstrate that PFAS in pesticide formulations are increasingly more common in agriculture, can transfer onto food, and can also stay in the environment and cause long-term contamination.[297] Although PFAS in food may be present from many different routes

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substances in food"). Of note, 21 U.S.C. § 321(q)(1)(B) excludes from the definition of "pesticide chemical" for purposes of setting tolerances any substance that is applied to food packaging or certain other types of food contact materials for the express purpose of "prevent[ing], destroy[ing], repel[ing], or mitigat[ing] microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime)." Although 83 PFAS substances are authorized by the FDA for use in food contact materials, including food packaging, none of these are used for this express purpose. Therefore, this section does not provide reason to exclude any PFAS from the definition of pesticide chemical.

[290] 21 U.S.C. §§ 331(a), 342(a)(2)(B), 346a(a).

[291] 40 C.F.R. 180.7(10).

[292] 21 U.S.C. § 346a(a)(2).

[293] *See, e.g., Pesticide Residue Monitoring Program Fiscal Year 2021*, FDA (2021), https://www.fda.gov/media/173207/download?attachment (discussing DDT's persistence in the environment and resultant food contamination); Ramdas Kanissery et al., *Glyphosate: Its Environmental Persistence and Impact on Crop Health and Nutrition*, 8 PLANTS 499 (2019) (discussing the persistence of glyphosates).

[294] *Setting Tolerances for Pesticide Residues in Foods*, EPA (last updated May 11, 2024), https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#food-safety

[295] 21 U.S.C. § 321(q)(1)(B)(3).

[296] *Cf.* 21 U.S.C. § 346a(a).

unrelated to pesticide use, given the lack of PFAS regulation under any other provisions, the EPA Administrator should use his statutory discretion to include PFAS in the definition of a pesticide chemical residue. Once he does so, a tolerance will be in effect for PFAS residue from any source.

Second, prior registration of a pesticide chemical under FIFRA is not required for EPA to set a tolerance for the pesticide's ingredients.[298] Where a pesticide is registered abroad, for example, the EPA can still set a tolerance for that product's ingredients, at least for imported foods.[299] Therefore, even if the EPA has not formally registered a pesticide formulation containing PFAS, it may nonetheless act under this provision on the ground that pesticides used in the European Union and other foreign countries do contain PFAS, and therefore pesticide residue containing PFAS must be monitored for goods imported into the U.S. Lastly, active and inert ingredients found in pesticides are subject to tolerance limits and can be the basis for tolerance violations even after the EPA disallows the use of that ingredient in a pesticide formulation.[300] In other words, even if EPA declares all PFAS banned from use in pesticides under FIFRA, it still has authority under the FDCA to mandate testing for PFAS residue based on prior evidence of PFAS use in pesticides.[301]

EPA can set, modify, or revoke tolerances in response to public petitions or on its own initiative, by initiating a dietary risk assessment and issuing notice of proposed rulemaking followed by a 60-day period for public comments."[302] After a final rule, the

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[297] *See generally* Diogo A.M. Alexandrino, C. Marisa R. Almeida, Ana P. Mucha, Maria F. Carvalho, *Revisiting Pesticide Pollution: The Case of Fluorinated Pesticides*, 292 ENV. POLLUT. (2022) (discussing the increasing market share of fluorinated pesticides and their activity as both biocides and as environmental pollutants).

[298] Kate Z. Graham, *Federal Regulation of Pesticide Residues: A Brief History and Analysis*, 15 J. FOOD L. & POL'Y 98, 110 (2019).

[299] *Id.*

[300] *See, e.g.,* Carbofuran; Final Tolerance Revocation, 74 Fed. Reg. 23,046 (May 15, 2009); Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59,608 (Nov. 18, 2009). In these actions, the EPA both revoked a prior tolerance for carbofuran residue on food and also revoked a prior FIFRA registration of carbofuran usage in pesticide applications. Despite the FIFRA registration withdrawal, carbofuran remained a regulated substance for purposes of FDCA and tolerance enforcement and any residue of the substance found on domestic products constituted a tolerance violation subject to enforcement. *See also Pesticide Residue Monitoring Program Fiscal Year 2021*, FDA (2021) (https://www.fda.gov/media/173207/download?attachment ("This activity is carried out pursuant to the enforcement of tolerances established by EPA and includes the monitoring of food for residues of cancelled pesticides used in the past that persist in the environment, which may be addressed by the FDA action levels.")

[301] For banned chemicals that persist in the environment, such as DDT, the FDA may also set advisory, non-enforceable "action levels" to monitor for the long-term occurrence of these substances in the food supply. *See*, *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed*, FDA (Aug. 2000), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed

agency would accept potential objections and may grant a public evidentiary hearing if the requestor has shown "a genuine and substantial issue of fact" in determining whether "there is a reasonable certainty that no harm would result from aggregate exposure to the pesticide chemical residue."[303] In determining tolerance levels, the EPA takes into account toxicity levels, amount of chemical remaining on the crop assuming application of the pesticide at the maximum proposed usage rate, data from animal feeding studies to determine the amount of a pesticide chemical that could be present in muscle, milk, eggs, etc., and the amount of the chemical present in drinking water.[304] The 1996 FQPA amended the FDCA to add that the EPA must also consider the "aggregate exposure to the pesticide chemical residue" from "all anticipated dietary exposures and all other exposures for which there is reliable information," and the cumulative effects of substances that have a "common mechanism of toxicity."[305] Therefore, although EPA has to set a separate tolerance for each pesticide ingredient's use on each food commodity, it should consider ingredients with common mechanism of toxicity as a class when determining safety and tolerance limits. It also must consider a tenfold margin of safety for products consumed by infants and children.[306]

The EPA has already determined through "substantial examination" that certain PFAS are not safe for consumption at any level.[307] Considering the "aggregate exposure" to PFAS from all identifiable sources—including food, drinking water, indoor and outdoor air pollution, and other product usage (such as cosmetics, clothing, etc.)—and the cumulative effects of all known PFAS with a "common mechanism of toxicity," the EPA could reasonably determine that no safe tolerance exists for PFAS residue on food products.[308] Because PFAS in food may be an unavoidable byproduct of our current contaminated environment,[309] however, EPA may choose to set a low residue tolerance at the current level of laboratory detection capabilities (4 ppt).[310] Importantly, the regulations permit EPA to regulate a class of chemicals by mandating that "the tolerance for the total of such residues shall be the same as that for the chemical having the lowest numerical tolerance in the class."[311] Under this provision, EPA can thus set a tolerance

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[302] 21 U.S.C. §§ 346a(d)(2), 346a(f)(1).
[303] 21 U.S.C. §§ 346a(e)(1)(A), 346a (g)(2); 40 C.F.R. 178.32(b).
[304] William R Reeves et al., *Assessing the Safety of Pesticides in Food: How Current Regulations Protect Human Health*, 10(1) ADV. NUTR. 80, 84 (2019).
[305] 21 U.S.C. § 346a(b)(2)(A)(ii).
[306] 21 U.S.C. § 346a(b)(2)(C).
[307] *See Proposed PFAS National Primary Drinking Water Regulation,* EPA (Last updated Feb. 12, 2024), https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.
[308] *See About Pesticide Tolerances*, EPA (Last updated Sept. 25, 2023), https://www.epa.gov/pesticide-tolerances/about-pesticide-tolerances#:~:text=EPA%20establishes%20tolerances%20for%20each,in%20and%20around%20the%20home (noting that EPA considers the aggregate, non-occupational exposure from the pesticide chemical "through diet and drinking water and pesticides used in and around the home").
[309] 21 U.S.C. § 346a(l)(4).
[310] 21 U.S.C. § 346a(b)(3)(B).

limit for all PFAS, rather than merely for the individual substances that it has studied. Indeed, to address the issue of under-detection of PFAS that is so prevalent in most commercial labs, scientists have pioneered novel testing methods looking at total extracted organic fluorine (which prevents interference from inorganic fluoride through extraction methods) as a reliable indication of known and unknown PFAS compounds in the tested medium.[312] Using this method, a level of 4 ppt of total organic fluorine would be sufficient to trigger enforcement action for an adulterated food product without the need to identify specific PFAS compounds and their respective concentrations.[313] If methods of detection improve in the future, making it reliably feasible to detect quantities lower than 4 ppt, EPA always has the option to modify or altogether revoke these tolerances, thus mandating a zero level of PFAS residue in food.[314]

Following the establishment of such limits, the USDA and FDA would be charged with inspection, testing, and seizure where products are found to exceed EPA's threshold.[315] EPA would need to work with U.S. Customs to systematically enforce these tolerances for imported foods as well.[316]

IV. Advantages and Challenges

> *"There are risks and costs to a program of action. But they are far less than the long-range risks and costs of comfortable inaction."* – John. F. Kennedy[317]

Any action that has the potential to effectively curb the occurrence of PFAS in food is also likely to face stringent opposition by the chemical, agricultural, and food industries. This section catalogues the advantages of the proposed solution and responds to some anticipated criticism. It concludes that, even though the proposed approach is not without challenges, none of the arguments likely to be levied against it have sufficient merit to prevent its implementation and the potential difficulties pale by comparison to the grave cost of inaction.

A. Anticipated Benefits

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[311] 40 C.F.R. 180.3.
[312] *See, e.g.,* L. Schultes, et al., *Total Fluorine Measurements in Food Packaging: How Do Current Methods Perform?*, 6 ENVIRON. SCI. TECHNOL. LETT. 73–78 (2019).
[313] 21 U.S.C. § 342. Notably, inert ingredients in food packaging treated with a pesticide are specifically exempted from the definition of "pesticide chemical residue" and are instead expressly regulated only as food additives by the FDA. *See* 40 C.F.R. 180.4. Aside from PFAS in food contact materials, however, setting a tolerance limit for any PFAS otherwise present in or on food products as residue would cover most of the possible contamination of food.
[314] 21 U.S.C. § 346a.
[315] 21 U.S.C. § 342.
[316] 19 C.F.R. 12.110–12.117.
[317] *Times Call for Liberal Action, Says Kennedy*, NEWS SENTINEL (May 13, 1961).

The proposed regulatory mechanism has several key advantages over previously discussed approaches. First, it is readily implementable with a simple 60-day notice-and-comment period, followed by adjudication on any filed objections.[318] To be sure, EPA cannot make arbitrary or unsupported decisions.[319] So, the realistic period of implementation would certainly be longer to account for the necessary scientific studies, assessments, and deliberation. However, considering the many PFAS-related actions EPA has taken over the last two years in other areas,[320] the agency already has a tremendous amount of data and analysis compiled that can support its determinations here.

Second, the proposed action effectively circumvents or addresses the PFAS-specific regulatory challenges identified earlier in this article. Because this approach looks at the result—the presence of chemical residue on food—it does not require the EPA or other regulators to trace the actual routes of individual product contamination or to tailor rules designed to address each potentially contaminated medium.[321] This method also allows EPA to regulate all PFAS in food as a class, thus avoiding the issue of new and emerging substances blindsiding enforcement.[322] Because the action is limited to PFAS use in pesticide formulations, it is less likely to encounter the type of stringent industry opposition faced by total ban proposals. Lastly, although the proposal relies on EPA's primacy in promulgating pesticide regulation, it in no way precludes FDA, USDA, or any other actor in the field from taking additional PFAS-related actions.

Third, the proposal would accomplish two distinct and important goals. In the more immediate term, it would protect consumers from food contaminated with PFAS by allowing for widespread monitoring and removal of adulterated food from the market. In the long term, it would also serve as an information forcing mechanism which is sorely needed to fill the gap in data about the actual spread of PFAS in our food supply, including the types of food products and processing environments most susceptible to contamination. This data in turn can inform potential remediation strategies, scientific research efforts, and public policy designed to support farmers and food producers. And it can help push forward future actions by other regulators or even legislative reform, thus ensuring a more permanent, long-term solution to this public health crisis.

J. Major Questions Doctrine

[318] 21 U.S.C. §§ 346a(d)(2), 346a(f)(1), 346a(g)(2).
[319] *See, e.g.,* Red River Valley Sugarbeet Growers Ass'n v. Regan, 85 F.4th 881, 888 (8th Cir. 2023) (overturning EPA's total ban on chlorpyrifos in pesticide formulations because it held that EPA "reflexively rejected an approach it had the power to adopt.")
[320] *See supra* Part III.
[321] *See* 21 U.S.C. § 346a(b)(2)(A)(ii) (directing the EPA to look at cumulative exposure from all sources).
[322] *Id.* (permitting EPA to set one common tolerance limit for substances with common mechanism of toxicity).

Considering the significant expansion of the major questions doctrine in recent years,[323] the most immediate criticism of any attempt to assert agency jurisdiction is likely to be a major questions doctrine challenge. Although a thorough discussion of the doctrine's contours and implications is beyond the scope of this article, there are three significant reasons why a major questions challenge is not likely to succeed here, even in the current Supreme Court climate.[324]

First, an EPA decision to regulate PFAS as pesticide residue in food is not an expansion of EPA's current authority and thus should not invoke the major questions doctrine. Unlike FDA's attempt to regulate tobacco under its authority over "drugs" and "devices,"[325] or the CDC's proposed reach to institute a nationwide eviction moratorium under its authority to prevent the spread of diseases,[326] here, the EPA would not be seeking to regulate a new class of products or to reach outside its purview. Rather, it would simply be using its existing authority over pesticide residue in food to monitor and regulate one additional class of pesticide chemicals. EPA has previously used its authority both under FIFRA to ban the use of various other active or inert ingredients in pesticides and under the FDCA/FQPA to subsequently set or revoke tolerances for the occurrence of those same chemicals in food products.[327] As early as 1972, only two years after its creation, the EPA used its authority under FIFRA to ban almost all agricultural uses of DDT.[328] It has since banned a number of active pesticide compounds, such as ethylene dibromide.[329] It has also revoked prior authorizations under FIFRA for inert ingredients. Notably, in 2016, it removed seventy-two chemicals from the list of approved inert pesticide ingredients.[330] And, as explained earlier, in 2022, it even revoked its prior authorization on the use of 12 *PFAS* substances from the inert ingredient list.[331] (This

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[323] Daniel Deacon & Leah Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009 (2003) (noting that the major questions doctrine is "perhaps the most important [] constraint on agency power, particularly when it comes to some of the most pressing problems of our time").

[324] *See generally id.* (describing the Court's rapid expansion and politization of the doctrine to limit agency action).

[325] *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

[326] Alabama Assn. of Realtors v. Department of Health and Human Servs., 141 S.Ct. 2485, 2487 (2021).

[327] *Cf.* Alabama Ass'n of Realtors v. Dep't of Health and Human Servs., 141 S. Ct. 2485, 2608–10 (2023) (striking down an agency action that was "unprecedented," and where EPA asserted "newfound" authority that "had rarely been used in the preceding decades"); Biden v. Nebraska, 143 S. Ct. 2355, 2372 (2023) (holding that the major questions doctrine was properly invoked where the authority in question "has been used only once before to waive or modify a provision related to debt cancellation.").

[328] 37 Fed. Reg. 13,369 (July 7, 1972). The EPA did not immediately set tolerance for DDT in food, however, because DDT was so widely used and present in the environment, that banning all food that contained it "would seriously affect the total food supply." United States v. Goodman, 486 F.2d 847, 855 (7th Cir. 1973).

[329] *See* Nat'l Coal. Against The Misuse of Pesticides v. Thomas, 809 F.2d 875, 876 (D.C. Cir. 1987).

[330] *EPA Prohibits 72 Inert Ingredients from Use in Pesticides*, EPA (Dec.2022), https://19january2017snapshot.epa.gov/newsreleases/epa-prohibits-72-inert-ingredients-use-pesticides_.html#:~:text=WASHINGTON%2D%2DThe%20U.S.%20Environmental,information%20to%20demonstrate%20their%20safety.

action has gone unchallenged to date.) EPA has also used its authority under FDCA and FQPA to revoke related residue tolerances in food. In 1985, for example, it issued a zero tolerance for ethylene dibromide in imported fruit.[332] In 2009, the EPA issued a final rule revoking all tolerances for carbofuran,[333] and, more recently, in 2022, it did the same for chlorpyrifos.[334] Importantly, the EPA has also used its authority to set tolerances for ingredients that are used in applications other than pesticides, such as for arsenic.[335] Given the routine exercise of the asserted regulatory power in the past, there is no reason to consider EPA's regulation of additional substances of that same class under this authority as somehow expanding upon EPA's existing powers or as presenting the type of "extraordinary case" that would invoke the doctrine.[336]

Second, even if the major questions doctrine is invoked, the proposed action is not likely to satisfy the definition of "major"-ness. According to the most expansive definition of the doctrine, as outlined in *West Virginia v. EPA* and *Biden v. Nebraska*, a question would be considered "major" when the use of the claimed regulatory power (1) has "economic and political significance,"[337] (2) has been considered and rejected by Congress,[338] (3) "effec[ts] a 'fundamental revision of the statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind[339]—in other words, when the agency "acted outside its wheelhouse,"[340] or (4) has future implications for the

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[331] *See EPA Stops Use of 12 PFAS in Pesticide* Products, EPA (Dec. 2022), https://www.epa.gov/pesticides/epa-stops-use-12-pfas-pesticide-products. Alarmed by the findings of the Sept. 2022 study, the EPA attempted to repeat the testing and announced that its own lab found no detectable PFAS in the tested samples. *See* Memorandum from Yaorong Qian, *supra* note 282.

[332] *See Nat'l Coal. Against The Misuse of Pesticides*, 809 F.2d at 876.

[333] *See, e.g.,* Carbofuran; Final Tolerance Revocation, 74 Fed. Reg. 23,046 (May 15, 2009); Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59,608 (Nov. 18, 2009).

[334] EPA Press Office*EPA Takes Next Step to Keep Chlorpyrifos Out of Food, Protecting Farmworkers and Children's Health*, EPA (Feb. 25, 2022), https://www.epa.gov/newsreleases/epa-takes-next-step-keep-chlorpyrifos-out-food-protecting-farmworkers-and-childrens#:~:text=In%20August%202021%2C%20EPA%20issued,cauliflower%2C%20and%20other%20row%20crops. The Eighth Circuit recently overturned EPA's blanket revocation of tolerances on the grounds that EPA had not sufficiently considered eleven potential beneficial uses of the pesticide chemical. The court noted, however, that, on remand, "the agency remains free to exercise its discretion as long as it considers all "important aspect[s] of the problem" and gives a reasoned explanation for whichever option it chooses. Red River Valley Sugarbeet Growers Ass'n v. Regan, 85 F.4th 881 (8th Cir. 2023) The EPA is in the process of renewing its ban on all but those eleven uses and reissuing its tolerance revocations.

[335] CF Jelinek, CF & PE Corneliussen, *Levels of Arsenic in the United States Food Supply*, 19 ENV. HEALTH PERSPECTIVES 83 (1977).

[336] West Virginia v. EPA, 142 S.Ct. 2587, 2607–08 (2022).

[337] *See id.* at 2610.

[338] *See* Biden v. Nebraska, 143 S. Ct. 2355, 2373 (2023) (stating that "Congress is not unaware of the challenges facing student borrowers" and has in the past considered more than eighty student loan forgiveness bills).

[339] *Id.* at 2373.

[340] *Biden v. Nebraska*, 143 S. Ct. at 2382 (Barrett, J., concurring).

agency's authority, including its ability to "intrud[e] into an area that is the particular domain of state law."[341]

None of these factors cut against the proposed EPA actions here. For one, the solution does not seek to regulate the manufacture, commerce, or discharge of PFAS *at all*. As such, it has no direct economic impact on the chemical industry. The economic impact on the pesticide industry depends on the extent to which PFAS are currently used as active and inert ingredients—and part of the problem is that, due to lack of testing and regulation, that figure is currently unknown and impossible to ascertain. As a point of comparison, the EPA conducted a thorough economic review of the DDT ban in 1972, taking into account not only the impact on DDT manufacturers but also on crops heavily dependent on the pesticide at the time, such as cotton.[342] The EPA concluded that the costs are "of insufficient magnitude to cause sizeable shifts in economic parameters at the regional or national level."[343] Because PFAS are neither vital nor irreplaceable as pesticide ingredients, a ban on their use would likely have an even more negligible economic impact on the pesticide industry or the cost of food manufacturing.

The biggest economic impact that the solution would have would be on food producers affected by mandatory recalls. Here too, the extent of the impact is impossible to predict due to the scarcity of current data. A useful gauge is the experience of Maine, which has now instituted systematic testing for the presence of PFAS on farms. In 2023, after discovering a staggering number of PFAS-contaminated farms in the state, Maine created a PFAS fund designed to provide direct support to farmers affected by the issue. The fund totals $70 million for fiscal years 2024-2028, of which $30.3 million are for direct income replacement payments to farmers, $21.5 million are for compensation for contaminated land, $7.3 million are to cover medical expenses, and $11.2 million are earmarked for scientific research.[344] Even multiplied by 50 states (assuming equal levels of contamination across the nation), the total annual economic impact would be a mere $700 million—a far cry from the $430 billion of student loans affected by the Biden administration's proposed loan forgiveness program that the Court struck under the doctrine.[345] This figure also pales by comparison to the costs that the EPA, municipalities, and other stakeholders are incurring and anticipating in relation to EPA's (as of yet unchallenged in court) actions to address PFAS contamination of water.[346] Moreover, any

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[341] *West Virginia*, 142 S. Ct. at 2621 (Gorsuch. J., concurring).
[342] *DDT: A Review of Scientific and Economic Aspects of the Decision to Ban Its Use as a Pesticide*, EPA (Jul7 1975), https://www.epa.gov/archive/epa/sites/production/files/documents/DDT.pdf.
[343] *Id.* at 194.
[344] *Plan for the Administration of the Fund to Address PFAS Contamination*, ME. DEP'T OF AGRIC. CONSERVATION & Forestry (July 10, 2023), https://www.maine.gov/dacf/about/commissioners/pfasfund/docs/draft-all-plan-admin-of-pfasfund-final.pdf.
[345] *See Biden v. Nebraska*, 143 S. Ct. at 2355.

economic impact to food producers—which occurs even today, absent EPA action—can be mitigated at the federal level. The USDA already administers a Dairy Indemnity Payment Program that covers direct payments to farmers due to PFAS contamination of their dairy and the currently proposed Relief for Farmers Hit with PFAS Act likewise seeks to minimize the economic impact of PFAS food contamination on food producers.[347] Finally, the Maine blueprint demonstrates that systematic testing and data-gathering efforts actually *decrease* costs to all stakeholders in the long run, as they reveal likely paths of contamination and make quick and effective remediation possible.[348] The economic impact of the proposed measure, therefore, is not likely to be significant.[349]

Nor is the question of regulating PFAS as pesticide residue in food one of significant political importance. The proliferation of PFAS in general is certainly a relevant and pressing issue—though it is also one that garners somewhat bipartisan support.[350] However, as this article makes clear, the issue of PFAS in *food* unfortunately goes largely unnoticed and unaddressed to date. What attention is directed at this issue is in the form of concern for consumer safety, rather than the type of stringent opposition or "robust debate" envisioned by the majority and concurrence in *West Virginia v. EPA*.[351] Indeed, not one of the 53 PFAS-related bills proposed in Congress last term sought to regulate the occurrence of PFAS in food products, let alone the use of PFAS as pesticide ingredients or their occurrence on food products as pesticide residue.[352] There is a good reason for that: not only is this issue not on the legislators' radar as a major political concern, but the EPA already has been granted authority (way back in 1972 and repeatedly thereafter) to regulate all pesticide chemicals and their residues on food. In the words of Justice Barrett, the proposed solution in this article is very much *in* EPA's "wheelhouse."[353] Finally, an EPA rule under its FIFRA, FDCA, and FPQA authority does not threaten a future impermissible expansion of that power. That authority is statutorily

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[346] *See, e.g.,* Alissa Cordner, et al., *The True Cost of PFAS and the Benefits of Acting Now*, 55 ENVIRON. SCI. TECHNOL. 9630 (2021) (noting that the cost of cleaning up PFAS from drinking water in California alone would cost around $1 billion).

[347] S.747, 118th Cong. (2023).

[348] *See, e.g., Maine Dairy Farm Coming Out of Toxic Nightmare from 'Forever Chemicals*, NEWS CENTER MAINE (Mar. 8, 2023, 3:42 PM), https://www.newscentermaine.com/article/tech/science/environment/pfas/dairy-farm-coming-out-of-a-toxic-nightmare-from-forever-chemicals-pfas-environment-maine-business-agriculture/97-96c362b4-f9fd-42e8-9591-eeb69726c4f4.

[349] In any event, the FDCA allows the EPA administrator to exempt certain substances from regulation under the residue tolerance provisions if "[u]se of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B)(iii).

[350] *See, e.g., Press Release: Reps. Lawler and Kileed Introduce Legislation to Provide access to Health Care for Veteran exposed to* PFAS, CONGRESSMAN MIKE LAWLER (June 21, 2023), https://lawler.house.gov/news/documentsingle.aspx?DocumentID=449.

[351] West Virginia v. EPA, 142 S.Ct. 2587, 2620–21 (2022) (Gorsuch, J., concurring).

[352] *See* supra Part III.B & note 220.

[353] Biden v. Nebraska, 143 S. Ct. 2355, 2382 (Barrett, J., concurring).

confined to regulating chemicals that are actually used in pesticide formulations—an inherently limited class. Nor is the issue threading on states' rights; rather, it implicates a fundamentally federal power and the few states that have turned their attention to the problem of PFAS in food are in fact actively soliciting federal action.[354]

Third, even if somehow the proposal rises to the level of a major question, Congress has provided clear authority to the EPA to act under the applicable federal statutes.[355] While the Supreme Court has not yet qualified what level of clarity is required for an agency to pass this test, EPA's grant of authority to regulate pesticide residues in food can meet any level of stringency. The EPA itself was created on the premise that it should serve as "the nucleus" for "dealing with air and water pollution, *pesticides registration and regulation*, solid waste management, and radiation standard-setting, including their closely related monitoring and research facilities."[356] Shortly after its creation,[357] the EPA was explicitly endowed with authority not only over pesticide registration and regulation, but also, over pesticide residues in *food*—authority that was explicitly transferred from the FDA and the USDA to EPA.[358]

Subsequent amendments of the pesticide regulatory scheme continued to grant EPA augmented power over this area. The legislative history of the FQPA, for example, demonstrates that, at that time, Congress debated what could be considered a major political issue. Representative John Dingell described the enactment of the act as "a historic moment, for today we consider in the House a piece of legislation that literally has been pending before Congress for over a decade" and "an amazing compromise that has been reached, which has brought together some of the most staunch and bitter rivals in this debate."[359] Congress' clear delegation of authority to the EPA on this issue was *the resolution* of this bitter political debate and "the product of that successful negotiation."[360] By explicitly endowing the EPA with sole authority over "establishing safety tolerances that apply to all Americans,"[361] the FQPA "overhaul[ed] the way the Government regulates pesticides, and at long last deals with the thorny issue of differing standards for different kinds of food products."[362] Moreover, not only did Congress grant the EPA express authority to regulate pesticide residue—of any pesticide chemical, inert or

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[354] Letter from Gov. Mills to U.S. Senators, Re: Request for federal funding to address contamination from per- and poly-fluoroalkyl substances (PFAS) (March 25, 2021).
[355] *See West Virginia*, 142 S. Ct. at 2616 (Gorsuch, J., concurring) (describing the Court's articulation of the major questions doctrine as a clear statement rule).
[356] Ash Council Memo, Memorandum from the President's Advisory Council on Executive Organization to President Nixon (Apr. 29, 1970), https://www.epa.gov/archive/epa/aboutepa/ash-council-memo.html.
[357] Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15, 623 (1970), reprinted in 42 U.S.C. §4321.
[358] Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (1972).
[359] 142 CONG. REC. H8143 (daily ed. July 23, 1996) (statement of Rep. John Dingell).
[360] *Id.*
[361] 142 CONG. REC. H8143 (daily ed. July 23, 1996) (statement of Rep. Henry Waxman).
[362] 142 CONG. REC. H8143 (daily ed. July 23, 1996) (statement of Rep. John Dingell).

active[363]—but it also "provide[d] wide latitude for the Environmental Protection Agency to adapt its regulatory system to meet the constantly improving scientific information that is available.[364]

Whatever the expansive reach of the major questions doctrine may be nowadays, a challenge under this theory is unlikely to succeed against the actions outlined in this article.

K. Temporary Nature of the Solution

The proposed solution may also be viewed skeptically for its inherently temporary nature, being vulnerable to the political whims of whichever administration happens to be in power. As an initial matter, this criticism can be levied against any agency action grounded in regulatory authority and cannot, by itself, be a sufficient reason not to engage in what is otherwise a viable step to resolving a pressing problem. Beyond that, the phenomenon of regulatory inertia—ordinarily studied for its deleterious effects on progress in rule-making—tells us that, once an agency enacts a rule, it is much more likely to adhere to it even in the face of changing circumstances that may warrant a reversal of the agency's previous decision.[365] A change in administration, therefore, is unlikely to undo all that has been set in motion, or at least not immediately. Indeed, during the Trump Administration, despite an overall decline in enforcement actions,[366] the EPA continued to aggressively implement measures to curb the spread of PFAS in the environment.[367]

Most importantly, the proposed solution here does not aim to be permanent. Rather, it seeks to serve as an information forcing mechanism to engender future, more permanent Congressional action, all-the-while bridging the gap between now and that hypothetical future by immediately addressing the final-stage issue of PFAS-contaminated food through a monitoring and enforcement mechanism.

L. Limited Testing Capabilities

Lastly, although EPA would be the actor banning the use of PFAS in pesticides and establishing tolerances in food, the ultimate implementation of the proposal—testing

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[363] FDCA, 21 U.S.C.§ 201(q)(1)(A).
[364] 142 CONG. REC. H8141 (daily ed. July 23, 1996) (statement of Rep. Pat Roberts).
[365] Asaf Eckstein, *Regulatory Inertia and Interest Groups: How the Structure of the Rulemaking Process Affects the Substance of Regulations*, MICH. BUS. & ENTREPRENEURIAL L. REV. (2015); William Samuelson & Richard Zeck, *Status Quo Bias in Decision Making*, 1 J. RISK & UNCERTAINTY 7 (1988).
[366] *New EPA Enforcement Data Show Continued Downward Trend During Trump Administration*, Environmental Integrity Project (January 14, 2021), https://environmentalintegrity.org/news/epa-enforcement-data-downward-trend-during-trump-administration/
[367] EPA Press Office, *Trump EPA Continues to Aggressively Address PFAS on the Federal, State, and Local Level*, EPA (July 28, 2020), https://www.epa.gov/newsreleases/trump-epa-continues-aggressively-address-pfas-federal-state-and-local-level

and enforcement—would still fall in the hands of the USDA and FDA. Given these agencies' demonstrated unwillingness to engage with the issue of PFAS and general difficulties in enforcing food safety standards, it is reasonable to express doubt at their ability to effectively partner with EPA to make this a workable solution. There are, however, key differences between relying on the USDA and FDA to set policy and promulgate rules, on the one hand, and to enforce EPA-mandated standards, on the other. While the agencies suffer from significant encumbrances and dysfunction in promulgating safety rules, they are equipped to administer EPA's tolerances in a wide array of commodities. These differences prompted the original division of responsibilities in the 1970s: the FDA and USDA's failure to address the issue of pesticide spread in the food supply prompted President Nixon and, later, Congress, to delegate to EPA sole registration and tolerance-setting authority, but the food agencies' larger field presence and research capabilities advocated in favor of "redelegating to FDA the actual enforcement of pesticide residue standards," and to the USDA the continued "research on the economic effectiveness of pesticides."[368]

Pursuant to this division of responsibilities, in 1991, USDA's Agricultural Marketing Service designed the Pesticide Data Program, which partners with states to annually test commodities for a wide variety of pesticides. The annual sampling selection is dictated by the EPA, based on its data needs for the types and amounts of food most consumed by children.[369] PDP does not serve an enforcement function, but it provides information to EPA, FSIS, and FDA of violations.[370]

The FDA and FSIS, in turn, conduct their own pesticide monitoring both through routine sampling of the products in their jurisdiction and through targeted samples in areas of concern.[371] Under its National Residue Program, FSIS samples about 95% of domestic meat and poultry consumption.[372] Unlike the statistical approach taken by the FSIS, the FDA conducts sampling for target commodities under its Pesticide Residue Monitoring Program and also partners with state agencies through MOUs, which allows it to receive additional field data.[373] The FDA is in charge of enforcing EPA's tolerance

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[368] *See* Ash Council Memo, Memorandum from the President's Advisory Council on Executive Organization to President Nixon (Apr. 29, 1970), https://www.epa.gov/archive/epa/aboutepa/ash-council-memo.html.

[369] Agric. Mkt. Serv., *Pesticide Data Program 2020 Annual Summary*, USDA (Jan. 2022), https://www.ams.usda.gov/sites/default/files/media/2020PDPAnnualSummary.pdf.

[370] *Id.*

[371] *Pesticide Residue Monitoring Program Fiscal Year 2021*, FDA, https://www.fda.gov/media/173207/download?attachment; Dep't of Agric. FOOD SAFETY & INSPECTION SERV., U.S. NAT'L RESIDUE PROGRAM FOR MEAT POULTRY, AND EGG PRODUCT: 2019 RESIDUE SAMPLING PLANS, 2 (2018).

[372] Dept't of Agric., FOOD SAFETY & INSPECTION SERV., U.S. NAT'L RESIDUE PROGRAM FOR MEAT POULTRY, AND EGG PRODUCT: 2019 RESIDUE SAMPLING PLANS2 (2018), https://www.fsis.usda.gov/wps/wcm/connect/394f0bd4-2c5d-47bc-ba4f-f65992972e43/2019-blue-book.pdf?MOD=AJPERES.

levels in most domestic and imported food, including by recalling or seizing adulterated products.[374]

This type of functional allocation of jurisdiction and responsibilities in the food safety system has the advantage of higher effectiveness, efficiency, and accountability.[375] While this system could of course stand to be improved and issues of understaffing and insufficient budgets are inevitably part of the discussion,[376] the overall pesticide monitoring and enforcement scheme works much better than anything currently done regarding the presence of PFAS in food. Therefore, challenges of scale notwithstanding, by invoking USDA's and FDA's statutorily mandated obligation to monitor food for pesticide residues and to enforce EPA's tolerances for PFAS in food, the proposed solution could make a tremendous difference in consumers' daily intake of PFAS.

CONCLUSION

> *"One thing is all things. To resolve one matter, one must resolve all matters. Changing one thing changes all things."* – Masanobu Fukuoka[377]

The U.S. food regulatory regime is fractured and badly in need of reform. Over a century of division, bureaucratic infighting, and antiquated food safety laws have produced a hopelessly paralyzed, impotent, and broken system. The pressure of ever-increasing consumer demand and complex environmental, agricultural, and industrial factors further exacerbate the issue, creating numerous intractable threats to food safety.

But not all hope is lost. Fortunately, it is not necessary to engage in herculean structural reform to effectively address food safety issues at the federal level. This article offers proof that even within the confines of this imperfect system, regulatory agencies can make considerable progress in resolving the most pressing food safety issues of our day. The article's proposed solution has the potential to (1) provide regulators and legislators with ground truth about the spread of PFAS in our food supply, (2) immediately and meaningfully protect consumers from the daily threat of PFAS in their meals, (3) push forward long-term legislation banning the use of PFAS writ-large, and (4) provide concrete pathways for helping farmers and other food producers in their remediation efforts.

More broadly, by taking on the spread of PFAS in food as a case study, this article also offers an analytical blueprint for avoiding bystander apathy on any other seemingly insurmountable food safety problems. Psychologists posit that general cries for help are

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[373] *Id.*
[374] *Id.*
[375] *See* Camacho & Glicksman, *supra* note 217, at 68–69.
[376] *See generally* Graham, *supra* note 297, at, 120–29.
[377] MASANOBU FUKUOKA, THE NATURAL WAY OF FARMING: THE THEORY AND PRACTICE OF GREEN PHILOSOPHY (1987).

ineffective in an emergency; what is needed is a direct appeal to a single actor. By laying the responsibility for acting at the feet of one concrete individual, they argue, the person in distress can break through the bystander effect and can mobilize meaningful engagement. Likewise, by analyzing a problem through the lens of which agency is best positioned to spearhead actions on it, scholars, policymakers, and consumer safety advocates could navigate the morass of the food regulatory system more effectively and could find creative and workable ways to combat bystander apathy to other food safety threats.

As the last few years of pandemic living have taught us, public health and safety must be of paramount importance to legislators and regulators alike. The fact that both our political and administrative systems are struggling cannot be a sufficient excuse for letting consumers unwittingly continue to ingest poisons with their every meal. Any amount of positive change and forward momentum is better than idly standing by, paralyzed by fear or apathy, as toxic chemicals infect our environment, our food, and—ultimately—all of us.

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