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FEDERAL REGULATION OF PESTICIDE RESIDUES:
A BRIEF HISTORY AND ANALYSIS
Kate Z. Graham

Federal Regulation of Pesticide Residues: A Brief History and Analysis

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I. Introduction

In the United States today, there are over 900 pesticides in use¹ and over 400 are approved for use in food production,² whether used as part of the growing process or in post-harvest handling. Although the history of pesticide use in food crops goes back centuries, the post-war period has seen an enormous growth in the varieties and amounts of pesticides used in our food system. As our reliance on pesticides has grown, pesticides have become a divisive issue. Pesticide advocates view them as essential to a secure and reliable food supply needed to feed a growing world population. Detractors, however, point out the public health risks—both known and not yet fully understood—that widespread pesticide use may entail. Meanwhile, consumer demand for products grown without the use of pesticides is increasing, while at the very same moment farmers are applying more and different pesticides to combat pesticide-resistant “superweeds.” These tensions are playing out both globally and locally in a variety of arenas, from debates over pesticide bans within international organizations and national governments, to the litigation of personal injury claims in American courts.

As policy-makers and the public rethink the current regulatory framework, it is helpful to have a basic understanding of what that framework is. This paper seeks to explain the process by which the U.S. government approves the use of pesticides for food production, manages potential public health risks associated with pesticides in our diets, and enforces these policies throughout the food system. First, I will begin with a discussion of what pesticides are and the relationship of pesticides to the history of agriculture in the U.S., tying together both this history with the history of our laws addressing pesticide use in food. Second, I will describe the features

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¹John E. Casida, *The Greening of Pesticide-Environment Interactions: Some Personal Observations*, 120 ENVTL. HEALTH PERSPECTIVES 487, 487 (2012).

² U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-38, FOOD SAFETY: FDA AND USDA SHOULD STRENGTHEN PESTICIDE RESIDUE MONITORING PROGRAMS AND FURTHER DISCLOSE MONITORING LIMITATIONS 25 (2014), <https://www.gao.gov/assets/670/666408.pdf> [hereinafter GAO FOOD SAFETY REPORT].

and complexities of our current pesticide-residue regulatory system. Finally, I will discuss criticisms of our current regulatory system and opportunities for improvement.

But first, what are pesticides? Simply put, pesticides are any substance used to kill or mitigate the harmful effects of organisms viewed as “pests.” “Pests,” broadly defined, are any organisms that are unwelcome from a human perspective.³ In the context of food and agriculture, pests of concern include weeds and insects that compete with crops or predate upon them, as well as fungi and rodents that attack food plants in the field and after harvest.

The U.S. government has defined “pesticides” as “(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, [and] (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.”⁴ “Pests” are defined in the law as “(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of [Title 7].”⁵ Basically, any chemical applied to a food crop or to the medium in which a food crop is grown is most likely regulated in the U.S. as a pesticide.

II. A Brief History of Pesticide Use and Regulations

Pesticides are nearly as old as agriculture itself. Pre-Roman civilizations used sulfur as a fumigant and insect repellent, a practice recorded by Homer in the *Odyssey* in 1000 BC.⁶ Until the 19th century, however, most pesticides were derived from botanical preparations, sulfur, oil soaps, kerosene emulsions, lime, and sodium chloride (i.e. salt).⁷ In 1867, a grape-grower in Europe discovered that the paint known as Paris Green, a substance that contained

³ NATIONAL ACADEMY OF SCIENCES, THE FUTURE ROLE OF PESTICIDES IN US AGRICULTURE 18 (2000).

⁴ 7 U.S.C. § 136(u) (2012) (including “nitrogen stabilizers,” defined under subsection (hh). The definition expressly excludes substances that are considered “new animal drugs” under 21 U.S.C. § 321(w) and liquid chemical sterilants for use on devices defined in 21 U.S.C. § 321).

⁵ *Id.* at § 136(t).

⁶ FREDERICK M. FISHEL, U. FLA./INST. FOOD & AG. SCI. EXTENSION, PEST MANAGEMENT AND PESTICIDES: A HISTORICAL PERSPECTIVE 2 (2016), <https://edis.ifas.ufl.edu/pdf/PI/PI21900.pdf>.

⁷ NATIONAL ACADEMY OF SCIENCES, *supra* note 3, at 23.

arsenic and copper, not only deterred would-be grape thieves, but also kept insects away.⁸ This led to the widespread use of arsenicals as both insecticides and herbicides.⁹ Not only were arsenicals highly effective on a broad array of insects, they were cheap, allowing farmers to boost yields and profits.¹⁰ Other heavy-metals were also employed as pesticides, such as the mixture of hydrated lime and copper sulfate known as Bordeaux mixture, a fungicide still in use today to control downy mildew,¹¹ and lead arsenate, used to halt the spread of the gypsy moth.¹²

During the first three decades of the 20th century, use of arsenicals as insecticides increased significantly.¹³ Aside from the fact that these chemicals were inexpensive and effective against pests, other changes in agriculture drove farmers to embrace pesticides in a way they had not previously. Advances in agricultural technology, including the adoption of mechanized plows, cultivators, and harvesters and the application of crop rotation and fertilizers allowed farmers to grow more crops in large monocultures with a much smaller labor force.¹⁴ But these monoculture fields presented a veritable buffet for would-be pests, a problem compounded by the loss of natural habitat for pest predators and alternative sources of pest foods.¹⁵ Thus, between 1919 and 1929, total insecticide use quadrupled from 14.5 million pounds to 58 million pounds.¹⁶

As the number of pesticide chemicals on the market increased, so too did the number of fraudulent products. Farmers had no way of knowing that the products they purchased actually worked. Thus, the first law regulating pesticides was intended to ensure their efficacy rather than their safety. Passed in California, the Insecticide Law of 1901 standardized arsenic content in arsenical pesticides.¹⁷ Shortly thereafter, the U.S. Congress passed the first federal law

⁸ *Id.*; see also ERIC L. TAYLOR, ET AL., SOUTHERN REGIONAL EXTENSION FORESTRY, PESTICIDE DEVELOPMENT: A BRIEF LOOK AT THE HISTORY 3 (2007), https://sref.info/resources/publications/pesticide-development--a-brief-look-at-the-history/at_download/file (noting that “Paris green . . . was used extensively to control the potato beetle and protect grapes from insect damage.”)

⁹ NATIONAL ACADEMY OF SCIENCES, *supra* note 3, at 23.

¹⁰ FREDERICK ROWE DAVIS, BANNED: A HISTORY OF PESTICIDES AND THE SCIENCE OF TOXICOLOGY 4 (2014).

¹¹ NATIONAL ACADEMY OF SCIENCES, *supra* note 3, at 23; see also Eric L. Taylor, et al., *supra* note 8, at 3.

¹² DAVIS, *supra* note 10, at 4.

¹³ *Id.* at 10.

¹⁴ *Id.* at 3.

¹⁵ *Id.*

¹⁶ *Id.* at 11.

¹⁷ NATIONAL ACADEMY OF SCIENCES, *supra* note 3, at 24.

aimed at regulating pesticides. The Insecticide Act of 1910 prohibited the manufacture, sale, and transportation of adulterated or misbranded pesticides.¹⁸ The law also standardized the content of the two most popular pesticides of the time: Paris green and lead arsenate.¹⁹ The U.S. Department of Agriculture (USDA), whose mission was to support and promote U.S. agriculture, was tasked with enforcement of the new pesticide law.²⁰

Arsenical pesticides were the mainstay of pest control until the introduction of synthetic organic compounds following World War II. Dichlorodiphenyl trichloroethane (DDT) was first synthesized in 1874 but was not used as an insecticide until 1939 when a researcher discovered it was extremely toxic to a wide variety of insects.²¹ During the war, DDT was used effectively to reduce casualties of malaria and other insect-borne diseases for troops in the Pacific theater, and likely saved the lives of many troops.²² DDT was the first in a long line of these second-generation pesticides developed during WWII, including organophosphates like parathion (originally developed by the Germans as a nerve gas) and the herbicide 2,4-D, still widely used today.²³ Insecticide use in this period increased significantly as farmers were advised to apply chemicals at rates intended to totally eradicate pests and “sterilize” farm fields.²⁴ This sterilization approach eliminated crop pests but also eliminated beneficial insects, and as was later discovered, it had a disastrous effect on bird populations.²⁵

Meanwhile, a revolution in food safety was taking place. A grassroots movement known as the Pure Food movement led to the creation of the first federal law governing food safety in 1906.²⁶ Passage of the law was finally made possible following public outcry over the publication of Upton Sinclair’s novel, *The Jungle*, a book intended to spotlight dangerous labor practices in the meatpacking industry but caused a greater stir over its revelations about what was

¹⁸ JORGE FERNANDEZ-CORNEJO, ET AL., U.S. DEP’T AGRIC. ERS, PESTICIDE USE IN U.S. AGRICULTURE: 21 SELECTED CROPS, 1960-2008 3 (2014), https://www.ers.usda.gov/webdocs/publications/43854/46734_eib124.pdf.

¹⁹ DAVIS, *supra* note 10, at 5.

²⁰ *Id.*

²¹ *Id.* at 24.

²² *Id.*

²³ TAYLOR, ET AL., *supra* note 8, at 4.

²⁴ *Id.* at 5.

²⁵ *Id.*

²⁶ Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER MAG. 1, 2 (1981), <https://www.fda.gov/downloads/aboutfda/history/forgshistory/e-volvingpowers/ucm593437.pdf>.

in the meat that people were consuming.²⁷ The 1906 Food and Drugs Act prohibited the interstate transport of unlawful food and drugs.²⁸ The law focused on the accuracy of food and drug labeling and prohibited certain food adulterants, including ingredients intended to substitute for the food, conceal, damage, harm human health, or constitute a filthy or decomposed substance.²⁹

Despite the benefits of the 1906 law, by the 1930s it became clear that the law was insufficient to protect consumers. For example, the law had no judicial enforcement mechanism to halt the sale of adulterated food products.³⁰ Because the law did not punish noncompliance, adulterated products continued to proliferate in the marketplace. Further, the economic climate of the 1930s exacerbated the impacts of the law's shortcomings and spurred renewed interest among the public in better food safety regulation.³¹ These concerns led to the passage of the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA), which ushered in our modern regulatory framework for food labeling. Among other things, the new law beefed up enforcement by authorizing courts to issue injunctions to halt the sale of adulterated products and allowed the federal government to establish food standards to promote honesty and fair dealing.³²

But it was not until the 1950s that the two most important sections of the FFDCA relating to pesticide use were passed. In 1952, a committee of the U.S. House of Representatives released a report that investigated the "nature, extent and effect of the use of chemicals" in food and food production.³³ The committee, led by Congressman John Delaney, concluded that many chemicals used in food production may be linked to cancer and that additional regulation of chemical residues in food was necessary.³⁴ As a result, Congress passed the Miller Amendment in 1954, which added Section 408 to the FFDCA.³⁵ Section 408 directed the federal government to establish limits, known as "tolerances," on the amount

²⁷ DAVIS, *supra* note 10, at 1.

²⁸ *History of FDA's Internal Organization – Part I: The 1906 Food and Drugs Act and Its Enforcement*, FDA (Feb. 1, 2018), <https://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm054819.htm>.

²⁹ *Id.*

³⁰ Janssen, *supra* note 26, at 8.

³¹ *Id.* at 9.

³² *Id.* at 7.

³³ Bruce S. Wilson, *A Legislative History of the Pesticide Residues Amendment of 1954 and the Delaney Clause of the Food Additives Amendment of 1958*, in *REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX*, 161, 163 (1987).

³⁴ *Id.*

³⁵ *Id.* at 165.

of chemical residues permitted in food.³⁶ In order to establish appropriate tolerances, the government was directed to balance the interest of food safety against the interest in providing an adequate food supply. This risk-benefit balancing standard appealed broadly to industry groups because it meant the government could only curtail pesticide use to the extent that it did not interfere with agricultural production.³⁷ Prior to the establishment of the Environmental Protection Agency (EPA) in 1970, pesticide residue tolerances were set by the Food and Drug Administration (FDA).³⁸

Four years later, Congress passed Section 409 of the FFDCFA, which required that all food additives be found “safe” before being allowed on the market.³⁹ Pesticide residues were included in the definition of food additives and regulated under Section 409 if they became concentrated in the food product through processing such that it exceeded the tolerance in the raw product, or where the residue had not been sufficiently reduced through good manufacturing practices.⁴⁰ In addition, the law included what became known as the Delaney Clause (named for Congressman Delaney), which prohibited any food additive known to induce cancer in humans or animals.⁴¹ Although technically the Delaney Clause only applied to processed foods, because pesticides are generally applied to the raw product prior to processing it was impossible to omit such residues without also banning them from use on the raw product. Thus, the Delaney Clause had the practical effect of banning virtually all pesticides linked to cancer from use in the food system.

By the 1950s, over 300 million pounds of pesticides were being manufactured each year, a huge increase from the 100 million pounds produced in 1945.⁴² This growth in production mirrored a steady increase in the number of different products available on the market. It soon became clear that the 1910 Insecticide Act was stretched to the limits. In 1947, Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in an attempt

³⁶ *Id.* at 25.

³⁷ *Id.* at 165.

³⁸ David M. Bearden et al, *Environmental Laws: Summaries of Major Statutes Administered by the Environmental Protection Agency*, CONG. RES. SERV. 1, 114 (Dec. 20, 2013), <https://fas.org/sgp/crs/misc/RL30798.pdf>.

³⁹ James Smart, *All the Stars in the Heavens Were In the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENVTL. L. J. 273, 279 (1998).

⁴⁰ *Id.* at 280.

⁴¹ *Id.* at 279.

⁴² Pamela A. Finegan, *FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?*, 6 PACE ENVTL. L. REV. 615, 619 (1989).

to update the law, and in doing so established the basic framework for pesticide regulation that is still in effect today.⁴³ Although it enhanced enforcement mechanisms, the law remained essentially a labeling law that prohibited the manufacture and sale of any pesticide that was adulterated or mislabeled. Once again, the emphasis was on protecting pesticide purchasers from fraud rather than protecting applicators and the public at large from pesticide exposures.⁴⁴ In 1959, FIFRA was amended to require the registration of all new pesticides prior to sale to the public.⁴⁵ The USDA continued to be the agency responsible for enforcement of pesticide regulations under FIFRA.

By the 1960s, public outcry over the widespread use of pesticides was again piqued by the publication in 1962 of *Silent Spring* by Rachel Carson, a scientist and former employee of the federal Bureau of Fisheries (a predecessor to the US Fish and Wildlife Service).⁴⁶ In her book, which sold 162,000 copies in hardback and several million in paperback, Carson described serious harms to the environment and human health from pesticide exposures.⁴⁷ Such harms included massive die-offs of fish and birds, cow's milk containing pesticide residues, and pesticide-induced diseases in humans.⁴⁸ Carson's work galvanized the emerging environmental movement, led to an all-out ban on DDT, and

⁴³ Federal Insecticide, Fungicide and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (1947).

⁴⁴ See Finegan, *supra* note 42, at 623 (noting that the “[Federal Insecticide Act] prevented the manufacture, sale, or shipment of certain adulterated insecticides in order ‘to protect farmers and consumers against fraudulent products.’”).

⁴⁵ Barbara Kennedy Kahn, *New Developments in Pesticide Regulation*, 13 TEMP. ENVTL. L. & TECH. J. 309, 310-11 (1994).

⁴⁶ See JoAnne L. Dunec, *On a Farther Shore: The Life and Legacy of Rachel Carson*, 27-SPG NAT. RESOURCES & ENV'T 62, 62 (2013) (noting how Rachel Carson (a scientist and former employee of the federal Bureau of Fisheries, a predecessor to the US Fish and Wildlife Service) published her book *Silent Spring* in 1962, creating a “national debate” over the “growing concern among scientists as to the possibility of dangerous long-range side effects from the widespread use of DDT and other pesticides”).

⁴⁷ Edwin McDowell, *Silent Spring, 20 Years a Milestone*, N.Y. TIMES, Sept. 27, 1982, at C16, <https://timesmachine.nytimes.com/timesmachine/1982/09/27/178690.html?action=click&contentCollection=Archives&module=LedeAsset®ion=ArchiveBody&pgtype=article>.

⁴⁸ See Finegan, *supra* note 42, at 619–20 (“In the 1960s, public enthusiasm for pesticide use dwindled following publication of Rachel Carson's *Silent Spring* which focused public awareness on the environmental and public health problems posed by pesticides. Carson presented a frightening picture of massive fish kills, residue-saturated milk from cows grazing on treated pastures, a poisoned wildlife population, and a human population plagued by a host of new pesticide-induced diseases.”).

contributed in no small part to the creation of the Environmental Protection Agency (EPA) in 1970.⁴⁹

Shortly thereafter, Congress passed the Federal Environmental Pesticide Control Act (FEPCA), which contained a number of amendments to FIFRA.⁵⁰ First, the law shifted regulatory enforcement from USDA to the new EPA.⁵¹ Second, the law amended the criteria for pesticide registration to include consideration of a pesticide's adverse impacts on the environment and human health.⁵² Third, the law required the EPA to reregister all previously registered pesticides in light of this new standard.⁵³ The law kept in place the risk-benefit balancing test, however. Following these changes, FIFRA emerged not only as a consumer protection law but as an environmental protection law as well.

Despite these changes, however, the law had little effect on the amount of pesticides making their way into the environment. In fact, pesticide use in the US hit a peak in 1979.⁵⁴ For the next twenty years, there were no major changes in the pesticide regulatory system, but the use and variety of pesticides continued to grow and change. By 1981, farmers in the U.S. were applying 632 million pounds of pesticides annually.⁵⁵ The increased use of pesticides resulted from the increase in the total number of acres planted as well as a decline in herbicide costs.⁵⁶ Additionally, whereas most pesticides applied in the 1950s and 1960s were insecticides, by the 1980s and 1990s the vast majority of pesticides applied to crops were herbicides.⁵⁷ With the rising popularity of organophosphates, like atrazine and 2,4-D, farmers shifted their dependence from the more acutely toxic and persistent heavy metals to compounds that were

⁴⁹ See McDowell, *supra* note 47 (“[*Silent Spring*] led to a spate of state and local laws regulating the use of pesticides, it helped to make ecology one of the great popular causes of the 1960’s, and eventually it helped lead to the creation of the Environmental Protection Agency.”).

⁵⁰ Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (1972).

⁵¹ Finegan, *supra* note 42, at 624.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ GAO FOOD SAFETY REPORT, *supra* note 2, at 5–6.

⁵⁵ FERNANDEZ-CORNEJO, ET AL., *supra* note 18, at 11.

⁵⁶ See *id.* at 13–15 (describing how increasing herbicide use due to relatively falling prices combined with increasing crop acreage contributed to increased pesticide use from the early 1960s to early 1980s).

⁵⁷ See *id.* at 11 (“Pesticide use more than tripled between 1960 and 1981. Herbicide use increased more than tenfold (from 35 to 478 million pounds) as more U.S. farmers began to treat their fields with these chemicals. By contrast, insecticide use declined from 114 million pounds in 1960 to 97 million pounds in 1981.”).

less persistent in the environment but entailed different health and environmental risks.⁵⁸ Further, the overall increase in the use of pesticides led to an increase in the potential human exposures to these chemicals.

In 1993, the National Research Council issued a groundbreaking study examining pesticide exposures in infants and children.⁵⁹ *Pesticides in the Diets of Infants and Children* revealed that the EPA was failing to adequately consider the different physiologies of young children when calculating pesticide residue tolerances.⁶⁰ Compared to adults, children consume more food per pound of body weight, which means that they also consume more pesticides relative to their body weight when pesticide residues are present in their food.⁶¹ In addition, infants and children tend to consume a lesser variety of foods compared to adults, which can lead to a greater concentration of certain pesticides in their diets.⁶² The report raised concerns about the heavy reliance on organophosphates in particular, which have been shown to cause neurological problems and developmental delays in children.⁶³ The report urged the EPA to take infants and children into account when determining tolerance levels, to move away from the risk-benefit balancing test, and to consider exposures from a variety of dietary and nondietary exposures.⁶⁴

In reaction to the study and public outcry, Congress passed the 1996 Food Quality Protection Act (FQPA), which revised Section 408 of the FFDCA. The new law replaced the risk-benefit balancing test for establishing tolerances with a new test focused entirely on safety. In establishing tolerances, the EPA was required to determine “to a reasonable certainty” that “no harm would result” from “aggregate exposures” to pesticide residues.⁶⁵ In addition, the

⁵⁸ *See id.* at 16 (“In 1968, atrazine and 2,4-D were among the top five pesticides used, but the other three were insecticides: toxaphene, DDT, and methyl parathion (fig. 9). In 2008, each of the top five herbicides (glyphosate, atrazine, acetochlor, metolachlor, and 2,4-D) were more heavily used than the top insecticide.”).

⁵⁹ COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL RESEARCH COUNCIL, *PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN* i (1993).

⁶⁰ *See id.* at 344–45 (discussing how traditional toxicity tests do not make allowances for the unique feature of infants and children).

⁶¹ *See id.* at 4 (noting how children are at more risk to pesticide exposure because they eat more food per unit of body weight than adults do).

⁶² *See id.* (discussing how children are at more risk to pesticide exposure because they consume fewer types of foods than adults do).

⁶³ *Id.* at 63.

⁶⁴ *Id.* at 8–9.

⁶⁵ Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 408(b)(A)(ii), 110 Stat. 1489, 1516.

EPA had to take into account the particular susceptibilities of infants and children, including incorporating an additional tenfold safety factor when setting tolerances.⁶⁶ This new standard required not only that the EPA solely consider health risks when setting tolerances in most cases, but also that the EPA had to obtain and incorporate data on American diets to determine what an average person's aggregate exposure to pesticides might be.⁶⁷ In addition, the new law removed the Delaney Clause which had barred pesticides linked to cancer; now, all pesticides would be subjected to the same scrutiny, whether they were linked to cancer or to other health problems.⁶⁸ Finally, the law required the EPA to re-evaluate all existing tolerances using the new "no harm" standard within the following ten years.⁶⁹

In the years that followed, the EPA canceled some registrations for certain highly toxic organophosphates for use on some crops and farmers began to shift away from a reliance on more acutely toxic organophosphates to new products believed to be safer and less persistent in the environment.⁷⁰ The introduction in the 1990s of herbicide-resistant seed varieties developed with the use of genetic engineering and generated a significant increase in the use of the herbicide glyphosate. Glyphosate, originally released under the tradename RoundUp by Monsanto (now Bayer), was believed to be both safe for humans and wildlife and able to break down quickly in the environment. Even though glyphosate is a type of organophosphate, which is known to cause neurological and development issues, initial studies indicated there were few health risks. Combined with glyphosate-resistant crop varieties, farmers could apply significant amounts of glyphosate to control weeds throughout the growing season without damaging their crop. By the 2000s, glyphosate was the number one most applied pesticide in the U.S., amounting to 38% of all pesticides used in 2008, trailed by atrazine at only 13%.⁷¹ By 2008, farmers were applying approximately 516 million pounds of pesticides.⁷² About 80% of

⁶⁶ Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 408(b)(C)(ii)(II), 110 Stat. 1489, 1517.

⁶⁷ See *id.* (discussing what the EPA is required to determine by law).

⁶⁸ See Andrew J. Miller, *The Food Quality Protection Act of 1996: Science and Law at a Crossroads*, 7 DUKE ENVTL. L. & POL'Y F. 393, 396 (1997) (discussing how the new law steps away from the Delaney act).

⁶⁹ Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 408(b)(C)(ii)(II), 110 Stat. 1489, 1517.

⁷⁰ FERNANDEZ-CORNEJO, ET AL., *supra* note 18, at 40.

⁷¹ *Id.* at 20.

⁷² *Id.* at 5.

pesticides are applied to five major crops: corn, soybeans, potatoes, cotton, and wheat.⁷³

III. Pesticide Regulation Today: A Patchwork of Agencies and Laws

Our current system of pesticide regulation reflects the complex history and evolution of our laws governing the various disciplines that touch on pesticide use, including agricultural law, environmental law, and human health law. The laws that make up this regulatory framework include FIFRA, enforced by the EPA, and the FFDCA, enforced by the FDA and the USDA. In brief, the following agencies have the following responsibilities in regulating pesticide residues in food:

- EPA registers pesticides and establishes tolerances;
- FDA enforces pesticide residue limits on most foods;
- USDA Food Safety and Inspection Service (FSIS) enforces pesticide residue limits in meat and poultry; and
- USDA Agricultural Marketing Service (AMS) researches and issues reports on the levels of pesticide residues found in foods.

A. Pesticide Registration: FIFRA

All pesticides must be registered with the EPA in accordance with FIFRA.⁷⁴ Recall that FIFRA is essentially a labeling law, which means that the applicant must provide the EPA with information about the product along with a proposed label to qualify for registration.⁷⁵ FIFRA allows the EPA to approve a pesticide for sale on the market so long as the manufacturer's claims about the product are warranted, the product is properly labeled, and when used "with widespread and commonly recognized practice" it will not "cause unreasonable adverse effects on the environment."⁷⁶ In certain circumstances, the EPA may classify a pesticide as "restricted-use," meaning that the pesticide may only be applied by or under the supervision of a trained and certified applicator.⁷⁷ The EPA may also issue "conditional use" registrations, which means that a pesticide

⁷³ *Id.* at 27.

⁷⁴ *About Pesticide Registration*, EPA, <https://www.epa.gov/pesticide-registration/about-pesticide-registration> (last visited Apr. 22, 2019).

⁷⁵ 40 C.F.R. § 152.50(d) (2018).

⁷⁶ 7 U.S.C. § 136a (2012).

⁷⁷ 40 C.F.R. § 152.170(a) (2018).

may be available for purchase and use even before the agency has received all data regarding the safety and efficacy of the product.⁷⁸ A pesticide may be conditionally registered in situations where a similar product is already on the market or where the manufacturer can show that no harm will come about as a result of the conditional use registration.⁷⁹ If a product receives a conditional use registration, however, the manufacturer is still required to provide the necessary information at some future date.⁸⁰ The applicant must also specify the intended use for the product. If a new use is proposed for a product that is already registered, the applicant must still go through the registration application process, although it may qualify for conditional registration.⁸¹

After a pesticide registration application is received, whether for a new active ingredient or a new use, the EPA issues a notice of receipt in the Federal Register describing the new active ingredient or proposed new use and soliciting public comment.⁸² Once the EPA reviews the application and issues a decision to conditionally or unconditionally register the product for the proposed use, it publishes a notice of issuance in the Federal Register. The notice of issuance describes the new chemical or new use, summarizes the EPA's conclusions, lists any missing data and the conditions for their submission, and responds to comments received from the initial notice of application.⁸³

B. Tolerance Setting: FFDCA

In addition to the registration requirement under FIFRA, a pesticide intended for use on food must also receive a tolerance pursuant to the FFDCA. A tolerance is the maximum residue level of a pesticide that may legally be present in food, measured in parts per million (ppm).⁸⁴ According to the FFDCA, a food is considered adulterated if it contains a pesticide residue for which no tolerance is established (and no exemption from the tolerance requirement was

⁷⁸ 7 U.S.C. § 136a(c)(7) (2012).

⁷⁹ 40 C.F.R. § 152.113–14 (2018).

⁸⁰ *Id.* at § 152.115.

⁸¹ *See id.* at § 152.102.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Pesticide Registration Manual: Chapter 11 - Tolerance Petitions*, EPA, <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions#main-content> (last visited Apr. 22, 2018); *see also* 21 U.S.C. § 346 (2012) (regulating the “tolerances for poisonous or deleterious substances in food”).

established) or where the amount of the residue is in excess of the established tolerance.⁸⁵ A tolerance may be established for pesticide residues in a raw agricultural commodity or in a processed commodity under the same procedures.⁸⁶ But where pesticide residues are not in greater concentration after processing, the tolerance in effect for the raw agricultural product is applicable and a separate processed tolerance is not necessary.⁸⁷

Prior registration of the pesticide is not necessary to obtain a tolerance from EPA. In fact, there are certain situations in which obtaining a registration for a product for which a tolerance is required is not possible, such as where the product is approved for use in a foreign country but is not in use in the U.S.⁸⁸ To register a product under FIFRA, the applicant must either state that a tolerance or exemption from tolerance was previously obtained or that the applicant is requesting that a tolerance be obtained pursuant to EPA regulations.⁸⁹ A tolerance or an exemption from tolerance must be established for all active and inert ingredients in a pesticide.⁹⁰

In order to obtain a tolerance determination from the EPA, the applicant must provide, among other things, a description of the chemical, data regarding how the chemical is used and how much of its residue remains on food, a summary of studies regarding the safety of the chemical, proposed tolerances, methods for removing residues in excess of the proposed tolerance, whether processing increases the concentration of residues, practical methods for detecting and measuring the chemical's residues in foods, and a description of any effects on infants and children or to the human reproductive or endocrine systems.⁹¹ The applicant must also provide a summary of the application, which the EPA will publish in the Federal Register along with a notice of filing of a petition for tolerance.⁹² After the application is submitted and published, the EPA must decide whether to issue an order establishing, modifying, or revoking a tolerance regulation, or whether to publish a proposed regulation and request public comment, or whether to deny the petition.⁹³

⁸⁵ 21 U.S.C. § 346a(a) (2012); 21 U.S.C. § 342(a)(2)(B) (2012).

⁸⁶ 40 C.F.R. § 180.7(10) (2018).

⁸⁷ 21 U.S.C. § 346a(a)(2) (2012).

⁸⁸ *Pesticide Registration Manual*, *supra* note 84.

⁸⁹ 40 C.F.R. § 152.50(i) (2018).

⁹⁰ *Pesticide Registration Manual*, *supra* note 84.

⁹¹ 40 C.F.R. § 180.7 (2018).

⁹² *Id.* at § 180.7(d), (f).

⁹³ *Id.* at § 180.7(h).

The standard by which EPA must establish a tolerance is whether the tolerance is “safe.”⁹⁴ “Safe” means the EPA has determined “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”⁹⁵ EPA applies this standard differently depending on whether a chemical is deemed to have a no observed adverse effect level (NOAEL), which is also known as a threshold effect, or, whether no threshold can be identified.⁹⁶ Residues below a NOAEL are considered to have no known or anticipated adverse effects, whereas residues for nonthreshold chemicals have no dose below which there is any certainty that no harm will occur.⁹⁷ For threshold chemicals, EPA applies a 100-fold safety factor to account for potential differences between human and animal physiologies since safety studies are generally conducted on animals and not humans.⁹⁸ In addition, EPA is directed to apply an additional 10-fold safety factor to account for the unique susceptibilities of infants and children.⁹⁹ But EPA is permitted to use a different (i.e. lower) safety factor if “on the basis of reliable data, such margin will be safe for infants and children.”¹⁰⁰

For nonthreshold chemicals, the “safe” test is satisfied if the increased lifetime adverse risk is “negligible,” which is defined as no greater than a one-in-a-million lifetime risk.¹⁰¹ Cancer risks generally fall into the nonthreshold category.¹⁰² Recall that, prior to passage of the FQPA, the Delaney Clause effectively established a zero-tolerance policy for chemicals associated with cancer risks; post-FQPA, cancer-causing chemicals may receive a tolerance so long as the established tolerance does not exceed this “negligible” risk limit.¹⁰³ In addition, for certain nonthreshold chemicals that entail up to a ten-in-a-million annual risk or a two-in-a-million lifetime risk of adverse health effects, the EPA is permitted to

⁹⁴ 21 U.S.C. § 346a(b)(2)(A)(i) (2012).

⁹⁵ *Id.* at § 346a(b)(2)(A)(ii).

⁹⁶ *See id.* at § 346a(b)(2)(B) (stating that a pesticide chemical residue that has a nonthreshold effect is assessed by quantitative risk analysis while a pesticide chemical residue that has a threshold effect is assessed by determining the level of aggregate exposure that is safe); *see also* LYNN L. BERGESON, FIFRA: FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT 31 (2000).

⁹⁷ BERGESON, *supra* note 96, at 31.

⁹⁸ *Id.*

⁹⁹ 21 U.S.C. § 346a(b)(2)(C)(ii) (2012).

¹⁰⁰ *Id.*

¹⁰¹ BERGESON, *supra* note 96, at 31.

¹⁰² *Id.*

¹⁰³ Wilson, *supra* note 33, at 161; CONG. RES. SERV., 96-759 ENR, PESTICIDE LEGISLATION: FOOD QUALITY PROTECTION ACT OF 1996 (P.L. 104-170) 11 (1998).

consider the pesticide's offsetting benefits when establishing a tolerance.¹⁰⁴ EPA may consider benefits to human health and to avoid a "significant disruption in domestic production of an adequate, wholesome, and economical food supply."¹⁰⁵

In general, if a pesticide residue is found on a food for which there is no tolerance or exemption from tolerance, the food is considered adulterated. However, if the residue is unavoidable through good agricultural and manufacturing practices, the food may still be marketable. For instance, many pesticides that are no longer authorized for use on food are persistent and remain in the soil, finding their way into the food supply even though they are no longer registered and approved for use.¹⁰⁶ In this case, the FDA may issue an "action level."¹⁰⁷ An "action level" is a recommended level above which an environmental contaminant in food should not exceed.¹⁰⁸ The action level is not legally binding, and FDA may take enforcement action, or not, at its sole discretion.¹⁰⁹ In addition, while the EPA sets tolerances for most pesticides used on crops, the FDA establishes tolerances for animal drug residues found in food-producing animals.¹¹⁰

C. Diet Surveys: FDA & USDA

As previously discussed, FFDCFA requires the federal government to establish tolerances by taking into account all dietary exposures to pesticide residues. As a practical matter, this requirement also mandates that the government monitor American diets for the presence of pesticide residues in the foods most commonly consumed. USDA and FDA each have a program that monitors the amount of pesticide residues consumed in the average American diet.¹¹¹ While these programs sometimes find tolerance

¹⁰⁴ 21 U.S.C. § 346a (Westlaw through P.L. 116-5).

¹⁰⁵ 21 U.S.C. § 346a (Westlaw through P.L. 116-5).

¹⁰⁶ *Pesticide residues in food*, WORLD HEALTH ORG. (Feb. 19, 2018), <https://www.who.int/news-room/fact-sheets/detail/pesticide-residues-in-food>.

¹⁰⁷ *Pesticide Residue Monitoring Program Question and Answers*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/foodborneillnesscontaminants/pesticides/ucm583711.htm> (last visited Apr. 14, 2019).

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ U.S. DEPT. HEALTH & HUM. SERV., GENERAL PRINCIPLES FOR EVALUATING THE HUMAN FOOD SAFETY OF NEW ANIMAL DRUGS USED IN FOOD-PRODUCING ANIMALS: GUIDANCE FOR INDUSTRY 4 (2018), <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052180.pdf>.

¹¹¹ *Pesticide Data Program*, U.S. DEPT. AGRIC. <https://www.ams.usda.gov/datasets>

violations, they are not designed for enforcement purposes; rather, they are intended to simply gather data to inform EPA's tolerance-setting process and other government food safety and nutrition programs and policies.¹¹²

i. FDA Total Diet Study

The FDA's Total Diet Study (TDS) is an annual report of the levels of various contaminants and nutrients in commonly consumed foods in the U.S.¹¹³ The TDS has been conducted continuously by FDA since the early 1960s.¹¹⁴ To conduct the study, the FDA buys, prepares, and tests about 280 different foods and beverages for the presence of about 800 different contaminants and nutrients.¹¹⁵ The study adopts a "market basket" methodology: Researchers purchase the same foods from retailers around the country four times a year and at least once in each of four regions per year (West, North Central, South, and North East).¹¹⁶ The list of foods purchased is based upon food consumption surveys performed by USDA.¹¹⁷ To select which foods will be added to the list of products to be tested, FDA groups similar foods together, choosing the one specific food that is most commonly consumed in that group to represent an entire group of foods.¹¹⁸ About every ten years, FDA revises its list of tested foods to account for changes in eating patterns.¹¹⁹ In performing the tests, the researchers attempt to closely mimic how the average consumer would likely consume the food by purchasing it from a retail outlet and preparing it as it would normally be prepared (i.e., peeling, cooking, etc.).¹²⁰ The testing methods used

/pdp (last visited Apr. 14, 2019); *Pesticide Residue Monitoring Program Reports and Data*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/foodborneillnesscontaminants/pesticides/ucm2006797.htm> (last visited Apr. 14, 2019).

¹¹² U.S. DEP'T AGRIC. AGRIC. MKTG. SERV., PESTICIDE DATA PROGRAM ANNUAL SUMMARY, CALENDAR YEAR 2016 ii (2018), <https://www.ams.usda.gov/sites/default/files/media/2016PDPAnnualSummary.pdf.pdf>.

¹¹³ *Total Diet Study*, U.S. FOOD & DRUG ADMIN. (Feb. 23, 2018), <https://www.fda.gov/food/foodscienceresearch/totaldietstudy/default.htm>.

¹¹⁴ Katie Egan, *FDA's Total Diet Study: Monitoring U.S. Food Supply Safety*, FOOD SAFETY MAG. (June/July 2002), <https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2002/fdas-total-diet-study-monitoring-us-food-supply-safety/>.

¹¹⁵ *Total Diet Study*, *supra* note 113.

¹¹⁶ *Total Diet Study Design*, U.S. FOOD & DRUG ADMIN. (Mar. 21, 2018), <https://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184232.htm>.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*; see Lauran Neergaard, *Monitoring the Chemicals We Eat*, MONT. STANDARD (Aug. 7, 2003), https://mtstandard.com/special-section/news/monitoring-the-chemicals-we-eat/article_2ad357d5-4e7f-5f23-afda-de5c09ab12d5.html.

to detect contaminants are extremely sensitive, able to detect chemicals in concentrations as low as 100 parts-per-billion (ppb), which is significantly more sensitive than the tests used for regulatory enforcement.¹²¹

While the TDS results are not generally used for enforcement, they have in some cases led to further investigation and regulatory action. For example, test results from the 1970s revealed unusually high levels of iodine in dairy products that was traced back to the use of iodine-based cleaners in the dairy industry, the use of which was subsequently reduced.¹²² And in 1971, higher concentrations of polychlorinated biphenyls (PCBs) were identified in boxed cereals; it was subsequently discovered that cereal boxes made with PCB-contaminated recycled paper were leaching PCBs into the breakfast cereals. The federal government issued regulations limiting PCB content of packaging and industry began bagging foods inside paper boxes to prevent chemical contamination.¹²³

ii. AMS Pesticide Data Program

The Pesticide Data Program (PDP) is a national pesticide residue monitoring program conducted by the Monitoring Programs Division of the USDA's Agricultural Marketing Service (AMS) since 1991.¹²⁴ PDP data are primarily used by EPA to assess dietary exposure to pesticide residues to assist with the establishment of tolerance levels.¹²⁵ PDP data are also used by FDA in planning its enforcement and regulatory programs, such as the TDS (discussed above).¹²⁶ The PDP is similar to the TDS in that it samples foods determined to be representative of the foods most commonly eaten in the U.S., with a special emphasis on the diets of infants and children.¹²⁷ In addition, the samples are collected from a variety of sampling sites in ten states representing each of the four census regions of the U.S.¹²⁸ However, rather than purchase samples from retail outlets, PDP researchers acquire samples from "terminal

¹²¹ Egan, *supra* note 114.

¹²² *Id.*

¹²³ *See id.*

¹²⁴ U.S. DEP'T AGRIC. AGRIC. MKTG. SERV., THE PESTICIDE DATA PROGRAM HELPING MONITOR THE SAFETY OF AMERICA'S FOOD SUPPLY 2 (2015), <https://www.ams.usda.gov/sites/default/files/media/PDP%20factsheet.pdf>.

¹²⁵ U.S. DEP'T AGRIC., AGRIC. MKTG. SERV., *supra* note 112, at 1.

¹²⁶ *See id.*

¹²⁷ *Id.* at ii.

¹²⁸ *Id.* at 3 (currently, the ten states involved in the PDP are Washington, California, Colorado, Texas, Michigan, Ohio, New York, Maryland, North Carolina, and Florida).

markets,” which are generally wholesale distributors that voluntarily participate in the program.¹²⁹ AMS coordinates with state governments to select the samples and ship them to the appropriate laboratories for testing.¹³⁰ In addition, instead of a “market basket” approach to testing, the PDP does not test the same foods each year. Rather, it cycles commodities through the testing program about once every five years for “high-consumption items,” and less frequently for other items.¹³¹ In any given year, the majority of products tested are fruits and vegetables, whereas grains and dairy are only rarely tested.¹³² In 2012, AMS decided to stop testing beef, pork, and poultry products with the expectation that USDA FSIS would provide this data to the EPA.¹³³ PDP tests are performed after the food is prepared in a manner that emulates consumer practices.¹³⁴

Like the TDS, the PDP tests for a variety of pesticides at the lowest detectable levels. In 2016, about 77% of samples tested positive for the presence of pesticide residues, but over 99% of samples had residues below the tolerance established by the EPA.¹³⁵ 15.7% of samples tested positive for 1 pesticide and 61.6% tested positive for more than one pesticide.¹³⁶ In addition to testing for pesticide residues, the PDP tests for environmental contaminants, which include pesticides that are no longer authorized for use in the U.S. but persist in the environment, and pesticides found on imported goods;¹³⁷ for example, a metabolite of DDT was found in 39.2% of spinach samples.¹³⁸ About 2.6% of samples tested in 2016 contained residues with no established tolerance and .46% contained pesticide residues in excess of tolerance.¹³⁹ These tolerance violations were reported to the FDA for enforcement, but by the time the PDP study results are available it is often too late for the FDA to issue any enforcement action.¹⁴⁰

¹²⁹ *Id.* at 3.

¹³⁰ *Id.* at 5.

¹³¹ *Id.* at 4.

¹³² See *id.* at ix (90.3% of samples collected and analyzed in 2016 were fruits and vegetables).

¹³³ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 54, at 14.

¹³⁴ U.S. DEP'T AGRIC. AGRIC. MKTG. SERV., *supra* note 112, at 1.

¹³⁵ *Id.* at ix–x.

¹³⁶ *Id.* at 20.

¹³⁷ *Id.* at 18.

¹³⁸ *Id.* at 20.

¹³⁹ *Id.* at 22.

¹⁴⁰ See *id.* at 21.

D. Enforcement Programs: FDA & USDA

The USDA and the FDA are charged with enforcing EPA tolerances in the foods that each agency is required to regulate. Due to the unique histories of these two organizations, USDA is charged with regulating meat, poultry, egg products (not shell eggs), and catfish, whereas FDA is charged with regulating nearly everything else, including fruits, vegetables, dairy, seafood, and spices.¹⁴¹ Both agencies also regulate imports as well as domestically produced goods in the categories of food for which each agency has jurisdiction. Each agency also takes a different approach to its regulatory enforcement procedures. Because USDA regulates a comparatively much smaller segment of the food system, it has greater enforcement resources available to it relative to the number of products it oversees, which enables it to take a more rigorous approach to testing and enforcement.¹⁴² The FDA, by contrast, is saddled with regulating around 75% of the food system, requiring it to divert limited resources to known problem areas.

i. FSIS National Residue Program

The National Residue Program (NRP) is designed to identify and control chemical and pesticide residues, including veterinary drug residues, found in the products that the USDA regulates.¹⁴³ The Food Safety and Inspection Service, a division of USDA, administers the program under the Federal Meat Inspection Act (FMIA),¹⁴⁴ the Poultry Products Inspection Act (PPIA),¹⁴⁵ and the Egg Products Inspection Act (EPIA).¹⁴⁶ In carrying out the program, FSIS conducts random sampling of carcasses at the slaughter establishments it regulates,¹⁴⁷ testing for over 80 veterinary drugs and over 100 pesticides as well as certain metals.¹⁴⁸ Meat carcasses

¹⁴¹ Daniela Galarza, *USDA vs. FDA: What's the Difference?*, EATER (Mar. 24, 2017), <https://www.eater.com/2017/3/24/15041686/fda-usda-difference-regulation>.

¹⁴² See *USDA and FDA One Step Closer to Securing More Government Funding for FY 2019*, FOOD SAFETY MAG. (May 24, 2018), <https://www.foodsafetymagazine.com/news/usda-and-fda-one-step-closer-to-securing-more-government-funding-for-fy-2019/>.

¹⁴³ U.S. DEPT. AGRIC., FOOD SAFETY & INSPECTION SERV., UNITED STATES NATIONAL RESIDUE PROGRAM FOR MEAT, POULTRY, AND EGG PRODUCTS: 2019 RESIDUE SAMPLING PLANS 2 (2018), <https://www.fsis.usda.gov/wps/wcm/connect/394f0bd4-2c5d-47bc-ba4f-f65992972e43/2019-blue-book.pdf?MOD=AJPERES>.

¹⁴⁴ 21 U.S.C. §§ 601–695 (Westlaw through Pub. L. No. 116-5).

¹⁴⁵ 21 U.S.C. §§ 451–472 (Westlaw through Pub. L. No. 116-5).

¹⁴⁶ 21 U.S.C. §§ 1031–1056 (Westlaw through Pub. L. No. 116-5); U.S. DEPT. AGRIC., FOOD SAFETY & INSPECTION SERV., *supra* note 143, at 1.

¹⁴⁷ U.S. DEPT. AGRIC., FOOD SAFETY & INSPECTION SERV., *supra* note 143, at 4.

¹⁴⁸ *Id.* at 3.

are required to be held pending the testing results, whereas poultry and catfish are not required to be held but FSIS regulations recommend that establishments hold these items pending the testing results.¹⁴⁹ Not all livestock are included in the sampling program, however; each year FSIS generates a sampling plan to identify which classes of livestock will be tested.¹⁵⁰ A Surveillance Advisory Team (SAT), consisting of representatives from FSIS, FDA, EPA, USDA's Agricultural Research Service (ARS), USDA's AMS, and HHS's Centers for Disease Control and Prevention, assist FSIS in identifying its sampling targets each year.¹⁵¹ For 2019, FSIS's sampling plan will sample production classes covering about 95% of domestic meat and poultry consumption.¹⁵² In addition, FSIS conducts random sampling of imported meat and poultry.¹⁵³

In addition to gathering data on the presence of residues in the food system, the NRP plays an important role in enforcement. A violation occurs when an FSIS laboratory detects a chemical compound in excess of an established tolerance or FDA action level or if the detected chemical has no established tolerance.¹⁵⁴ FSIS enters violation data into the Residue Violator Tracking (RVT) system, which is an FDA/FSIS interagency database.¹⁵⁵ FSIS notifies the slaughter establishment and the producer of the violation, and recommends that the establishment also notify the producer of the violation.¹⁵⁶ FSIS also shares the violation data with the EPA and the FDA, giving the FDA the opportunity to further investigate the producer in cooperation with state agencies, and to take further enforcement action if necessary.¹⁵⁷ Information about repeat violators is posted publicly on FSIS's website each week on the Residue Repeat Violators List to warn processors and deter violations.¹⁵⁸ In addition, FSIS requires all slaughter establishments to implement Hazard Analysis and Critical Control Point (HACCP) inspection systems that identify and mitigate all food safety hazards posed by chemical residues.¹⁵⁹ In general, data from the NRP show that tolerance violations in FSIS-regulated products are extremely rare. For example, FSIS found a total of 30 pesticide residue

¹⁴⁹ *Id.* at 4.

¹⁵⁰ *Id.*

¹⁵¹ *Id.* at 1.

¹⁵² *Id.* at 4.

¹⁵³ *Id.* at 6–7.

¹⁵⁴ *Id.* at 2.

¹⁵⁵ *Id.*

¹⁵⁶ *See id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

violations out of nearly 55,000 random samples of domestic and imported products between 2000 and 2011.¹⁶⁰ The most frequently found violations were for products that are now banned but have persisted in the environment, such as hexachlorobenzene, DDT, and chlordane.¹⁶¹

ii. FDA Pesticide Residue Monitoring Program

Whereas the USDA regulates meat, poultry, egg products (except shell eggs), and catfish, the FDA regulates all other food products, amounting to 75% of the U.S. food supply.¹⁶² The amount and variety of food products that fall within the FDA's jurisdiction is staggering, amounting to \$417 billion worth of domestic food and \$49 billion worth of imported food.¹⁶³ In addition, the number of imports within the FDA's jurisdiction has increased dramatically, doubling in the ten years between 1999 and 2009 and reaching 9.7 million individual "entry lines" in 2012.¹⁶⁴ The FDA also tests and regulates animal food products, focusing on feed for animals intended for human consumption.¹⁶⁵ The sheer magnitude of products that fall within the FDA's jurisdiction underscores the important role the FDA plays in ensuring the safety of the U.S. food supply, but also evidences the growing strain on the FDA's limited enforcement resources.

In contrast to the USDA, the FDA does not take a statistical approach to its sampling program to test for pesticide residue violations. The agency acknowledges that such an approach would be impossible given the limited resources allocated to it for enforcement and the magnitude of its regulatory jurisdiction.¹⁶⁶ Instead, the FDA focuses its limited resources on sampling targeted commodities based on a number of different factors, including the frequency of consumption, the history of prior violations, findings from other studies (including the TDS and PDP), and toxicity of

¹⁶⁰ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 54, at 38.

¹⁶¹ *Id.* at 39.

¹⁶² U.S. FOOD & DRUG ADMIN., FDA AT A GLANCE 1 (2017), <https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM553532.pdf>.

¹⁶³ CFSAN – *What We Do*, U.S. FOOD & DRUG ADMIN. (Feb. 19, 2018), <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm>.

¹⁶⁴ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 54, at 38.

¹⁶⁵ U.S. FOOD & DRUG ADMIN., PESTICIDE RESIDUE MONITORING PROGRAM FISCAL YEAR 2016 PESTICIDE REPORT 12 (2016), <https://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Pesticides/UCM618373.pdf>.

¹⁶⁶ *See id.* at 10–11.

particular pesticide residues.¹⁶⁷ The FDA also partners with state and local regulators to coordinate sampling and testing of targeted commodities.¹⁶⁸ When a tolerance violation is identified in a product, the FDA may issue a Warning Letter to the producer, or it may seize the product or issue an injunction to correct the cause of the violation.¹⁶⁹ The FDA may also request that a company recall its products, or in very serious cases the FDA has the authority to require a recall if the FDA believes the product would cause serious health consequences or death in humans.¹⁷⁰ For imported products, the shipment may be refused entry into U.S. commerce, or the FDA may place an import alert for all future shipments of the product, allowing future shipments to be detained without physical examination.¹⁷¹ The import alert also shifts the burden to the producer or shipper to prove their products are not in violation of tolerance levels before the product will be permitted to enter U.S. commerce.¹⁷²

As part of its sampling program, the FDA uses a multi-residue method (MRM) capable of detecting a majority (but not all) of the approximately 400 pesticides with EPA tolerances, plus several others that lack tolerances.¹⁷³ Occasionally, the FDA also uses selective residue methods to test for the presence of specific residues that are not picked up by the MRM.¹⁷⁴ No one test is capable of detecting all pesticide residues.¹⁷⁵ Results of the FDA's enforcement sampling generally show very low levels of tolerance violations; however, the FDA's sample size is small relative to the total number of products available for human or animal consumption. For 2016, FDA tested just 7,413 samples, of which 6,946 were human foods and 467 were animal foods (mostly foods for livestock).¹⁷⁶ Of all the samples, 2,670 were from domestically-produced foods and 4,276 (60% of samples) were imported, reflecting FDA's targeted enforcement of imports based on historical data indicating more frequent violations in imported goods.¹⁷⁷ Violative residues were detected in 0.9% of domestic samples and 9.8% of import samples.¹⁷⁸ Of domestic samples, 46.2% contained

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 13.

¹⁶⁹ *Id.* at 9.

¹⁷⁰ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 54, at 12.

¹⁷¹ U.S. FOOD & DRUG ADMIN., *supra* note 165, at 9–10.

¹⁷² *Id.* at 10.

¹⁷³ *Id.* at 12.

¹⁷⁴ *Id.*

¹⁷⁵ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 54, at 11.

¹⁷⁶ U.S. FOOD & DRUG ADMIN., *supra* note 165, at 15.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 18.

some pesticide residues below tolerance (non-violative), whereas 39.5% of imports contained some pesticide residues below tolerance.¹⁷⁹

IV. Criticism of Pesticide Residue Regulatory Framework

Since the passage of the FQPA in 1996, many of the most toxic pesticides have been taken off the market or their usage has been significantly decreased.¹⁸⁰ By one measure, overall dietary risk from pesticide residues declined 81% between 1996 and 2013.¹⁸¹ Even so, USDA residue data indicate that residues from highly toxic pesticides are still a significant risk factor, particularly for certain organophosphate pesticides still in use and for fungicides applied post-harvest.¹⁸² In addition, the use of lower-toxicity pesticides, such as glyphosate and neonicotinoids, raises questions about their safety relative to their dosage as such chemicals are being applied in larger and larger quantities on more and more crops.¹⁸³ The reliance on genetically engineered (GE) herbicide resistant crops has led to overapplications of herbicides and the development of herbicide-resistant weeds, leading to even greater increases in the use of herbicides to eliminate these “superweeds.”¹⁸⁴ During the first 15 years of commercial use, genetically engineered crops caused an increase of 527 million pounds of herbicides used.¹⁸⁵ Recently, with the introduction of GE crops resistant to 2,4-D, the USDA estimates that the use of 2,4-D will increase from 77.8 million pounds per year to 176 million pounds per year.¹⁸⁶

In the following sections, I discuss some of the criticisms leveled at the current pesticide regulatory system. These criticisms primarily described the following shortcomings: inadequate protection of children and infants, insufficient protection from nonthreshold effects, and tolerance setting that fails to consider sufficient nonbiased data.

¹⁷⁹ *Id.*

¹⁸⁰ See CONSUMER REP., PESTICIDE REPORT: FROM CROP TO TABLE 15 (2015), https://advocacy.consumerreports.org/wp-content/uploads/2015/08/CR_FSASC_FromCropToTablePesticides_Mar2015-4.pdf.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 26.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

A. Protection of Children

The protection of infants, children, and pregnant women were the focus of the reforms brought about by the FQPA, and with good reason—immature humans suffer a greater detrimental impact from exposure to pesticide residues than adults. Children consume more food relative to their body weight and are less able to detoxify their bodies due to differences in their metabolism and the immaturity of their immune systems and neurological development.¹⁸⁷ Empirical studies have shown that children exposed to pesticide residues disproportionately suffer from neurological disorders. For example, several studies of children living on or near farms have shown that such children suffer from increased rates of neurological problems, including autism and developmental delays.¹⁸⁸

In particular, a class of pesticides known as organophosphates are especially neurotoxic to humans, with serious implications for infants and children.¹⁸⁹ The National Institutes of Health has concluded that exposure to organophosphate pesticides at even very low, infrequent doses can permanently affect developing brains, leading to changes in brain chemistry and behavior, including hyperactivity.¹⁹⁰ A Harvard School of Public Health study showed that children with higher detectable levels of organophosphate pesticide metabolites in their urine were more likely to be diagnosed with attention deficit hyperactivity disorder (ADHD).¹⁹¹ While the use of organophosphate pesticides declined 70% between 2000 and 2012, their use still represented 33% of all insecticides applied in 2012.¹⁹² For example, residues of malathion, a highly toxic organophosphate, were detected in 6.2% of samples of strawberries tested by the USDA in 2016.¹⁹³

The FQPA requires the EPA to impose an additional ten-fold safety factor to account for the particular susceptibilities of children, unless the EPA finds that “on the basis of reliable data, such [other]

¹⁸⁷ *Id.* at 12.

¹⁸⁸ *Id.* at 17–18.

¹⁸⁹ *Id.* at 12–13.

¹⁹⁰ *Id.*

¹⁹¹ *Id.* at 13.

¹⁹² DONALD ATWOOD & CLAIRE PAISLEY-JONES, U.S. ENVTL. PROTECTION AGENCY, PESTICIDE INDUSTRY SALES AND USAGE: 2008-2012 MARKET ESTIMATES 16 (2017), https://www.epa.gov/sites/production/files/2017-01/documents/pesticides-industry-sales-usage-2016_0.pdf.

¹⁹³ See U.S. DEP’T AGRIC., AGRIC. MKTG. SERV., *supra* note 112, at 60.

margin [of safety] will be safe for infants and children.”¹⁹⁴ Despite this requirement, a 2001 report showed that in more than two-thirds of cases, the EPA was not applying the ten-fold safety factor in organophosphate pesticides.¹⁹⁵ Overall, the EPA has applied the ten-fold safety factor in only 16% of tolerances.¹⁹⁶ The EPA’s evident reluctance to apply the mandated additional safety factor to pesticide tolerances along with its sanction of organophosphate pesticides for use on fruits that are commonly consumed by children raises questions about whether the EPA is sufficiently protecting the health of U.S. children.

B. Protection from Nonthreshold Effects

In establishing tolerances for pesticide residues in food, the EPA categorizes chemical compounds into two classes based upon empirical data: (1) those chemicals with no discernable harms below a certain dosage, and (2) those chemicals without an identifiable “threshold” dosage below which no adverse effects are detected. The latter category is referred to as “nonthreshold” chemicals. This distinction is significant because the EPA is permitted to use a different regulatory approach for nonthreshold chemicals. Even though there is no known dosage of a nonthreshold chemical that entails no health risk from exposure, the EPA is permitted to consider the chemical’s offsetting benefits to society when determining the appropriate tolerance.¹⁹⁷ Thus, even though exposure to a pesticide may entail an increased risk of cancer, such risk may be balanced against the benefit that use of the pesticide would provide in increased access to a low-cost and stable food supply.

Many critics have expressed concern that the EPA’s approach to regulating nonthreshold chemicals does not go far enough to protect human health from risks of cancer and other health problems. Many chemicals in common use in agriculture have been linked to the development of various cancers. For example, the commonly-used herbicide 2,4-D and related chlorophenoxy herbicides are listed by the International Agency for Research on Cancer (IARC), a division of the World Health Organization of the United Nations, as “possibly carcinogenic to humans.” At least one study has found a correlation between cancer mortality and proximity to farm fields treated with 2,4-D.¹⁹⁸ Glyphosate, the leading

¹⁹⁴ 21 U.S.C. § 346a(b)(2)(C) (Current through P.L. 116-5).

¹⁹⁵ CONSUMER REP., *supra* note 180, at 14.

¹⁹⁶ *Id.*

¹⁹⁷ See 21 U.S.C. § 346a(b)(2)(B) (Current through P.L. 116-5).

¹⁹⁸ CONSUMER REP., *supra* note 180, at 24.

pesticide in agriculture today, was identified as a “probable” carcinogen by the IARC in 2015.¹⁹⁹ In all, around 40 different EPA-registered pesticides are classified as carcinogens, probable carcinogens, or possible carcinogens by the IARC.²⁰⁰

In addition, emerging research has shown that even low-dose exposure to pesticide residues can cause adverse health effects, and may be linked to neurological disorders, obesity, heart disease, and diabetes.²⁰¹ The concern stems in large part from the fact that many pesticides are “endocrine disrupting chemicals” (EDCs), meaning they interfere with the body’s natural hormone-driven processes, including metabolism, reproduction, and the development of some cancers.²⁰² While much of the concern is focused on the organophosphate pesticides, some of which (like DDT) are no longer in use, even newer generation pesticides may pose serious risks, although the research is less settled. For example, neonicotinoid pesticides have generally been considered a safer alternative to organophosphate pesticides.²⁰³ But at least one study has shown that these chemicals’ effects mimic the effects of nicotine in developing mammal brains, indicating they may disrupt brain development.²⁰⁴ Although food is not the only pesticide-exposure pathway, it is one of the most significant ones.²⁰⁵

¹⁹⁹ Reuters, *W.H.O. Report Links Ingredient in Roundup to Cancer*, N.Y. TIMES (Mar. 20, 2015), <https://www.nytimes.com/2015/03/21/business/who-report-links-ingredient-in-roundup-to-cancer.html>.

²⁰⁰ SUZANNE H. REUBEN, PRESIDENT’S CANCER PANEL, *REDUCING ENVIRONMENTAL CANCER RISK: WHAT WE CAN DO NOW 2008-2009 ANNUAL REPORT* 45 (2010), https://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.

²⁰¹ See Duk-Hee Lee, et al., *Low Dose Organochlorine Pesticides and Polychlorinated Biphenyls Predict Obesity, Dyslipidemia, and Insulin Resistance Among People Free of Diabetes*, 6 PLOS ONE e15977, e15977 (Jan. 2011).

²⁰² See JULIE GUTHMAN, *WEIGHING IN: OBESITY, FOOD JUSTICE, AND THE LIMITS OF CAPITALISM*, 99-104 (2011); Wissem Mnif, et al., *Effect of Endocrine Disruptor Pesticides: A Review*, 8 INT. J. ENV. RES. & PUB. HEALTH 2265, 2290–2291 (June 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3138025/>.

²⁰³ Elizabeth Grossman, *Are Bee-Killing Pesticides Impacting Our Health?*, CIVIL EATS (Feb. 3, 2016), <https://civileats.com/2016/02/03/are-bee-killing-pesticides-impacting-our-health-neonicotinoids/>.

²⁰⁴ Daniel Cressey, *Controversial Pesticides Linked to Human Neurotoxicity*, NATURE.COM NEWS BLOG (Dec. 17, 2013), <http://blogs.nature.com/news/2013/12/c-ontroversial-pesticides-linked-to-human-neurotoxicity.html>; Junko Kimura-Koda, et al., *Nicotine-Like Effects of the Neonicotinoid Insecticides Acetamiprid and Imidacloprid on Cerebellar Neurons in Neonatal Rats*, 7 PLOS ONE e32432, e32432 (Feb. 29, 2012), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0032432>.

²⁰⁵ Eveline Dirinck, et al., *Obesity and Persistent Organic Pollutants: Possible Obesogenic Effect of Organochlorine Pesticides and Polychlorinated Biphenyls*, 19 OBESITY 709, 710 (Apr. 2011).

The possibility that even low-dose exposure to pesticide residues entails serious health risks is particularly concerning given the extent to which most people are now exposed to pesticides through their diets. According to data from the 2016 PDP, a mere 22.7% of the fruits, vegetables, and milk sampled that year contained no pesticide residues; 15.7% contained residues of 1 pesticide, and the majority of samples (61.6%) contained residues from at least two or more pesticides.²⁰⁶ And, the U.S. Centers for Disease Control and Prevention (CDC) has found that the bodies of most Americans contain the metabolites of 29 different pesticides.²⁰⁷

C. *Insufficient Data*

The FFDCRA requires the government to establish residue tolerances at safe levels, considering aggregate exposures from all possible exposure sources.²⁰⁸ However, the government no longer has a program that tracks the aggregate amount of pesticides applied each year.²⁰⁹ The last year for which we have such data is 2007, and in that year an estimated 684 million pounds of pesticides were applied, which was an increase from the prior year, but less than the peak of 843 million pounds in 1979.²¹⁰ In addition, there is no reliable data on the breakdown of which types of active ingredients are in use, which is significant because one type of pesticide may be significantly more toxic to human health than another, meaning that a total increase or decrease in the use of all pesticides does not mean the risk to human health has proportionately changed.²¹¹ In short, we simply do not know the quantity and types of pesticide chemicals in use, making it difficult to predict the quantity and types of residues that will end up in American diets.

²⁰⁶ See U.S. DEP'T AGRIC. AGRIC. MKTG. SERV., *supra* note 112, at 20. However, results vary greatly year to year since the PDP tests a different mix of commodities each year. Compare U.S. DEP'T AGRIC. AGRIC. MKTG. SERV., PESTICIDE DATA PROGRAM ANNUAL SUMMARY, CALENDAR YEAR 2017 20 (2017), <https://www.ams.usda.gov/sites/default/files/media/2017PDPAnnualSummary.pdf> (For 2017, 53% of samples had no pesticide residues, 19.5% of samples contained residues of one pesticide, and 27.5% contained residues of two or more pesticides); with U.S. DEP'T AGRIC. AGRIC. MKTG. SERV., PESTICIDE DATA PROGRAM ANNUAL SUMMARY, CALENDAR YEAR 2015 20 (2015), <https://www.ams.usda.gov/sites/default/files/media/2015PDPSummary.pdf> (For 2015, 15.5% of samples contained no pesticide residues, 11.5% contained residues of just one pesticide, and 73.0% of samples contained residues of two or more pesticides.).

²⁰⁷ CONSUMER REP., *supra* note 180, at 8.

²⁰⁸ 21 U.S.C. § 346a(b)(2)(A)(ii) (Current through P.L. 116-5).

²⁰⁹ See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 5.

²¹⁰ *Id.* at 6.

²¹¹ *Id.* at 7.

In addition, the EPA generally relies on animal studies when establishing tolerances. But whether and to what extent the animal subjects of studies respond in the same way human subjects would is a question that is not well understood. In fact, animal studies may not accurately represent the reproductive and endocrine-disrupting harms caused by pesticide exposure in humans.²¹² The EPA attempts to compensate for this information gap by applying a 100-fold safety factor, and in some cases, the EPA applies an additional 10-fold safety factor to account for the susceptibilities of children and infants. But it is not known whether a 100-fold or 1,000-fold safety factor accurately accounts for the differences between humans and the animals subjected to study. Further, these safety factors can only be applied where the chemical demonstrates a threshold effect; for non-threshold effects where there is no level below which there is no risk of harm, the safety factor is inapplicable.

Finally, the tolerance-setting system depends upon data supplied by the chemical makers, which creates a conflict of interest that invites bias into the system. Industry-sponsored studies have been shown to be more likely to provide results favorable to the pesticide manufacturer.²¹³ And in most cases, the EPA makes its findings based primarily on data supplied by industry rather than independent researchers, in part due to the way the study criteria are determined. The EPA develops the research methodologies and study design with industry representatives, a process that results in stringent and prohibitively expensive study criteria that effectively excludes independent researchers from the process.²¹⁴ While some of these additional criteria are necessary to exclude inherently flawed studies, some industry-proposed criteria eliminate from consideration so-called “qualitative studies” that may provide useful data on cause and effect relationships.²¹⁵ In some cases, the EPA applies rigid study criteria retroactively to existing independent laboratory studies; unsurprisingly, few or no independent studies meet the qualifications for consideration by the EPA.²¹⁶ In addition, the EPA may disregard studies that do not show a uniform response at the species or population level or that were done *in situ* instead of in the laboratory. Studies have shown, however, that, there is

²¹² See, CONSUMER REP., *supra* note 180, at 10.

²¹³ *Pesticide Residue Monitoring Program Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Oct. 1, 2018), <https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm583711.htm>.

²¹⁴ Michelle D. Boone, et al., *Pesticide Regulation Amid the Influence of Industry*, 64 *BioScience* 917, 918 (Oct. 2014), <https://academic.oup.com/bioscience/article/64/10/917/1782021>.

²¹⁵ *Id.*

²¹⁶ *Id.*

significant natural variation among organism response at individual, population, and species levels, and further that laboratory research is not inherently better than experiments conducted in the field.²¹⁷ By excluding data from independent researchers and relying primarily on industry-supplied data, the EPA may not be seeing the whole picture when it engages in tolerance setting.

D. Lack of Enforcement

i. FDA

The FDA is tasked with enforcing pesticide residue tolerances for the vast majority of foods produced in and imported to the United States. The FDA enforces tolerances by taking samples of domestic and imported foods and testing those samples for the presence of chemical residues.²¹⁸ But the FDA's sampling procedure does not use statistical methods; instead the FDA aims its limited resources at targeting products that the FDA believes are more likely to be out of tolerance. This means that its sampling results and the number of tolerance violations is not representative of the entire portion of the food system that falls within the FDA's jurisdiction.²¹⁹ Further, when the FDA does sample a commodity, it takes very few samples, which further dilutes the representational quality of its testing.²²⁰ Thus, the fact that the FDA's targeted enforcement program shows very low rates of tolerance violations is not generalizable to the food system as a whole. For example, compare the results of the FDA's sampling of lettuce with AMS's sampling of lettuce in the same year. In 2005, the FDA took 26 samples of head lettuce and 44 samples of leaf lettuce. Of those samples, none of the head lettuce was violative, and 2.3% of the leaf lettuce was violative, with one sample presenting with a residue that was out of tolerance.²²¹ By contrast, data from AMS in 2005 found presumptive residue violations in 17.77% of lettuce samples.²²² As previously discussed, AMS uses a statistically valid sampling method and tests a greater number of samples of the small number of products it tests.

²¹⁷ *Id.* at 919.

²¹⁸ U.S. FOOD & DRUG ADMIN., *supra* note 213.

²¹⁹ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 19.

²²⁰ *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 19–20.

²²¹ FDA, *Pesticide Residue Monitoring Program Results and Discussion FY 2005*, U.S. FOOD & DRUG ADMIN. (June 20, 2017), <https://wayback.archive-it.org/7993/20170723105235/https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm125186.htm#appa-05>.

²²² *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 21.

In addition, the FDA has decreased the amount of samples it takes from a high of over 12,000 domestic and imported food samples in 1993 to a low of about 5,000 total samples in 2008.²²³ In 2016, FDA tested just 7,413 samples.²²⁴ In addition, roughly 60% of these samples were from imports, even though the majority of the U.S. food supply is domestic in origin.²²⁵ Even looking solely at imports, however, FDA tests less than 1/10th of 1% of imports.²²⁶ The FDA's methodology for targeting certain samples of the food supply often misses the mark. For example, its PREDICT system designed to recommend which imported foods to test based on prior history and other data has failed to accurately estimate which foods will have the highest violation rates.²²⁷ The FDA relies on data from its Total Diet Study and AMS's Pesticide Data Program to supplement its enforcement data. But while these programs use statistical sampling methods, the sample sizes used in these studies are too small to be representative. For example, the PDP tests only about 20 to 30 foods each year.²²⁸

When the FDA tests a food sample, it does not test for all known pesticide residues because doing so would be prohibitively expensive. Instead, the FDA uses a multi-residue method test (MRM) that detects many different pesticides, but not all. The FDA's MRM cannot detect six of the most commonly used pesticides.²²⁹ And the FDA only rarely uses selective residue methods (SRMs) due to their cost.²³⁰ The following pesticides are listed in the top 25 most used pesticides, but the FDA rarely if ever tests for their presence in the food supply: glyphosate, 2,4-D, MCPA, mancozeb, paraquat, and methyl bromide.²³¹ Further, the FDA does not disclose in its reports that its testing methods cannot detect these pesticides.²³²

In a 2014 report, the U.S. Government Accountability Office made the following observation:

If, for example, the agency wanted to know incidence and level of pesticide residues across all

²²³ See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 23.

²²⁴ U.S. FOOD & DRUG ADMIN., *supra* note 165, at 15.

²²⁵ *Id.* at 11; See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 25.

²²⁶ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 24.

²²⁷ *Id.* at 33.

²²⁸ *Id.* at 37.

²²⁹ *Id.* at 25.

²³⁰ *Id.*

²³¹ *Id.* at 26.

²³² *Id.*

domestic and imported foods, it would need to design statistically valid random samples of those two broad categories of foods. If, on the other hand, FDA wanted to know about residue levels within particular commodities, it would need to design a survey of random samples of those commodities that meets statistical standards. FDA is not currently taking either of these approaches in its regulatory monitoring program. Finally, FDA's ability to evaluate the effectiveness of its targeted monitoring program (i.e., enforce pesticide residue tolerances in foods established by EPA) is limited because it has not determined the incidence and level of pesticide residues in the foods it regulates against which it can compare the results of its targeted compliance and enforcement monitoring.²³³

ii. USDA

Compared to the FDA, the USDA is tasked with regulating a much smaller proportion of the U.S. food system. Its jurisdiction is limited to meat, poultry, some (but not all) egg products, and catfish.²³⁴ Like the FDA, the USDA uses a multi-residue method to test for veterinary drugs and pesticide residues as part of its enforcement program. Its methods test for over 80 veterinary drug analytes and over 100 pesticide analytes.²³⁵ However, as of 2014, there were 191 pesticides with established tolerances for direct or indirect use in animals.²³⁶ In addition, of the pesticides for which the USDA tests, it does not perform all tests on all categories of animal products.²³⁷ For instance, the USDA only recently began using the multi-residue pesticide method on egg products.²³⁸ The USDA does not disclose in its reports which pesticides its tests do not detect or the potential bias caused by its selection of production classes for testing.²³⁹ Although the USDA tests samples from the production classes that represent that vast majority of the animal products

²³³ *Id.* at 34–35.

²³⁴ *Principal Food Safety Regulatory Organizations: FDA vs. USDA-FSIS*, N.C. ST., <https://ncfsma.ces.ncsu.edu/wp-content/uploads/2018/01/FDA-versus-USDA.pdf?fw=no> (last visited Apr. 24, 2019).

²³⁵ U.S. DEPT. AGRIC. FOOD SAFETY & INSPECTION SERV., *supra* note 143, at 3.

²³⁶ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 41.

²³⁷ *See* U.S. DEPT. AGRIC. FOOD SAFETY & INSPECTION SERV., *supra* note 143, at 11.

²³⁸ U.S. DEPT. AGRIC. FOOD SAFETY & INSPECTION SERV., *supra* note 143, at 7.

²³⁹ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 42.

consumed in the U.S., it routinely does not test whole production classes that are less frequently consumed, like ducks and rabbits.²⁴⁰

Although the USDA reduced the number of scheduled samples it took from over 8,000 per year in 2000 to less than 1,900 per year in 2009, it has since increased the number of scheduled samples.²⁴¹ In Fiscal Year 2017, the USDA took over 7,000 scheduled domestic samples and over 2,700 import samples.²⁴² In addition, for that same year, FSIS took over 177,000 inspector-generated (i.e. non-random) samples.²⁴³

The USDA is also responsible for the Pesticide Data Program (PDP), conducted by AMS. Although the PDP uses statistically valid sampling methods, the number of food types sampled each year is very small. The AMS reports do not demonstrate to what extent the foods chosen for testing differ from or are similar to other foods in the overall food system or to what extent the distribution centers chosen for study differ from or are representative of all distribution centers in the food system.²⁴⁴ The PDP is limited by not having a complete record of all food distribution centers and data regarding how food obtained from non-participating centers may differ from the food obtained from those that voluntarily participate.²⁴⁵

V. Conclusion

On August 10, 2018, a California jury ordered Monsanto (now a division of Bayer) to pay \$289 million to Dewayne Johnson, a former pest control manager for a public-school system who contracted non-Hodgkin's lymphoma.²⁴⁶ Johnson's doctors stated that his cancer is aggressive, and it is unlikely that Johnson will live past 2020.²⁴⁷ Johnson's lawyers persuaded the jury that Monsanto,

²⁴⁰ *Id.* at 43; *see also*, U.S. DEPT. AGRIC. FOOD SAFETY & INSPECTION SERV., *supra* note 143, at 19.

²⁴¹ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 43.

²⁴² U.S. DEPT. AGRIC. FOOD SAFETY & INSPECTION SERV., NATIONAL RESIDUE PROGRAM FOR MEAT, POULTRY, AND EGG PRODUCTS: FY 2017 RESIDUE SAMPLE RESULTS 5 (2017), <https://www.fsis.usda.gov/wps/wcm/connect/93ae550c-6fac-42cf-8c11-006748a4d817/2017-Red-Book.pdf?MOD=AJPERES>.

²⁴³ *Id.* at 6.

²⁴⁴ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 54–55.

²⁴⁵ *Id.* at 54.

²⁴⁶ Tina Bellon, *Monsanto Ordered to Pay \$289 Million in World's First Roundup Cancer Trial*, REUTERS (Aug. 10, 2018), <https://www.reuters.com/article/us-monsanto-cancer-lawsuit/monsanto-ordered-to-pay-289-million-in-worlds-first-roundup-cancer-trial-idUSKBN1KV2HB>.

²⁴⁷ *Id.*

the maker of the glyphosate-based herbicide RoundUp, was responsible for Johnson's cancer. The verdict was the first of its kind, but possibly not the last—Monsanto faces more than 5,000 similar lawsuits across the U.S.²⁴⁸

Glyphosate is one of many pesticides previously assumed to be safe, but new research is casting doubt on this assumption and raising questions about the efficacy of our current regulatory system. This system, originally devised to guarantee the effectiveness of pesticides, has since been tasked with guaranteeing their safety and limiting the public's exposure to them. But limited resources and industry influence may be hampering the ability of federal regulators to carry out this task. And due to the unique history of the regulatory system, enforcement authority is fragmented among several different federal agencies. These shortcomings are now giving rise to a wave of litigation over pesticide safety and an increase in the demand for products made without pesticides such as foods that are certified organic. Maintaining and restoring public confidence in the safety of the U.S. food system may depend on the ability of policy makers to reform our current regulatory system to better guarantee the public's protection from the adverse health effects of pesticide residues.

²⁴⁸ *Id.*