

Pesticide Regulation Overview

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Pesticide residues found on domestic and imported produce pose little, if any, risk to public health, particularly compared with the enormous public health benefits of pesticide use.¹ However, for more than a decade, federal pesticide policies have placed in jeopardy the ability to address the greater risks associated with insects and other pests. Applying federal law, the U.S. Environmental Protection Agency (EPA) has banned numerous pesticides that are both safe and useful for farming, home pest control, and other public health purposes.

Statutory Scheme

The EPA regulates pesticides under three laws:

• Federal Food Drugs and Cosmetics Act (FFDCA). The FFDCA is the law under which the EPA sets tolerances for pesticides. The EPA can essentially ban a pesticide by not setting a tolerance—the amount of pesticide residue that is allowed to legally remain on food. The Agricultural Marketing Service, an agency of the U.S. Department

^{1.} According to one National Research Council report, "The great majority of individual naturally occurring and synthetic chemicals in the diet appear to be present at levels below which any significant adverse biological effect is likely, and so low that they are unlikely to pose any appreciable cancer risk." See Committee on Comparative Toxicity of Naturally Occurring Carcinogens, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, *Carcinogens and Anticarcinogens in the Human Diet* (Washington, DC: National Academies Press, 1996), 336–37.

of Agriculture (USDA), is responsible for monitoring residue levels in or on food. The U.S. Department of Health and Human Service's Food and Drug Administration uses this information to enforce tolerances on imported and domestically produced food in interstate commerce. The USDA's Food Safety Inspection Service enforces tolerances for meat, poultry, and some egg products.

- Federal Insecticide, Fungicide, and Roden-• ticide Act (FIFRA). To sell a pesticide, a company must also register it with the EPA under FIFRA. For pesticides used on food, the EPA can register uses only for pesticides that have a tolerance. Pesticide registrants must register and gain EPA approval of their products as well as for each specific use (i.e., use indoors as a bug spray requires one registration and use outdoors for a specific crop requires another). The EPA must review registered pesticides on a 15-year cycle. To gain registration, applicants must submit scientific data and research demonstrating that the products pose minimal risk. The EPA can limit uses by denying registration for such uses.
- Food Quality Protection Act (FQPA). The FQPA amended the first two laws. Details on these changes follow.

Brief History of Pesticide Regulation and Legislation

Before 1996, the FFDCA used two standards for setting tolerances. One standard allowed the EPA to regulate pesticide residues on raw produce using a cost-benefit approach. The agency could weigh the risks of using the pesticides versus the risks of not having them to help maintain the food supply. Under that legislative authority, the EPA applied what it called a "negligible risk" standard, allowing produce to contain pesticide residues that did not exceed a one-in-a-million cancer risk.

However, the FFDCA set a separate standard for pesticide residues found in processed food. It applied the "Delaney Clause," which prohibited the addition to food of any substance that caused cancer in laboratory animals. The Delaney Clause essentially set a zero-risk standard. It applied to pesticides used directly or indirectly in processed food. It also applied to pesticide residues found on raw agricultural products that were used in processed food, if the pesticide became more concentrated during processing.

As science became able to detect increasingly lower levels of residues, the Delaney Clause essentially demanded that the EPA ban many pesticides. In addition, having separate standards for raw produce and processed food created perverse effects, which the National Research Council (NRC)² noted could actually reduce safety. In a 1987 report, Regulating Pesticides in Food: The Delaney Paradox, the NRC highlighted problems with the existing policy.³ The NRC raised concerns about alternative pest control practices that could pose greater risks or could prove inadequate to maintain food supplies and control disease-carrying pests. The NRC called on Congress to address this issue, suggesting that it set a single standard for raw and processed foods.

In 1988, the EPA began applying the negligible risk standard to processed foods without legislative authorization. But in 1992, environmental groups succeeded in suing the

^{2.} The NRC is an affiliate of the National Academy of Sciences.

^{3.} Board on Agriculture, National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (Washington, DC: National Academies Press, 1987).

agency for not applying the Delaney Clause. A federal court held that the agency was obligated to apply the Delaney Clause to processed food.⁴

Hence, for those who used and produced pesticide products, reforming the law became an urgent matter. With numerous bans likely, many crops—and ultimately our food supply would be placed in jeopardy. In addition, concerns mounted about the increasing difficulty associated with controlling rising infectious diseases, carried by insects and other pests.⁵

Meanwhile, environmental groups worked to make the law more stringent. Their efforts were bolstered by a 1993 NRC report and the media hype that followed. The report, Pesticides in the Diets of Infants and Children, noted that children might be more susceptible to pesticides and hence they faced greater risks.⁶ Despite media hype suggesting the contrary, the study did not conclude that existing exposures were unsafe for children. Specifically, the study noted that "exposures occurring earlier in life can lead to greater or lower risk of chronic toxic effects such as cancer than exposures occurring later in life."7 Just to be safe, the report recommended that EPA use a 10-fold safety factor when setting pesticide regulations.

Food Quality Protection Act Reforms

The FQPA attempts to address the conflicting standards within the first two pesticide laws. The FQPA changed the standard for setting tolerances. It applies a single standard for all pesticide uses and requires the EPA to show "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."⁸ The FQPA mandated that the EPA apply this standard to all pesticide registrations, new and old. Accordingly, the EPA is working to reregister the thousands of pesticides registered before the passage of the FQPA.

The bill was supported unanimously by both houses of Congress and lauded by members of agricultural states and farm interests. Many believed that it would dramatically improve pesticide approvals. But rather than solving these problems, the FQPA gave vital ground to those pushing for more stringent regulation. Not surprisingly, environmental groups supported the FQPA because they believed that it would prove even more stringent and would lead to many pesticide bans in the future.⁹

Following the advice of *Pesticides in the Di*ets of *Infants and Children*, the reform included

^{4.} Les v. Reilly, 968 F.2nd 985 (9th Cir. 1992), cert. denied, 113 U.S. 1361 (1993).

^{5.} See Joshua Lederberg, Robert E. Shope, and Stanley C. Oaks Jr., eds., *Emerging Infections: Microbial Threats to Health in the United States* (Washington, DC: National Academies Press, 1992), especially 163–67, http://www.nap.edu/books/0309047412/html/index.html.

^{6.} Committee on Pesticides in the Diets of Infants and Children, National Research Council, *Pesticides in the Diets of Infants and Children* (Washington, DC: National Academies Press, 1993).

^{7.} Ibid., 359.

^{8. 21} USC § 346a(b)(2)(A)(ii).

^{9.} After passage of the FQPA, Competitive Enterprise Institute's Jonathan Tolman noted in the *Wall Street Journal* that the 1996 law was more stringent than the old law and would lead to bans. A response by the Natural Resources Defense Council's Albert Meyerhoff concurred that the law was more stringent and would enable environmental groups to pursue bans. See Jonathan Tolman, "The Real Pests Aren't in the Food," *Wall Street Journal*, September 18, 1996, A18, and Albert H. Meyerhoff, "Law Makes Food Safer for Children," Letters to the Editor, *Wall Street Journal*, October 7, 1996, A23.

several new criteria that now apply very strong standards to both processed and raw foods. When setting standards under the new law, the EPA must consider (a) the impacts of the pesticide on infants and children, applying a 10-fold safety factor unless information is available to demonstrate safety; (b) the aggregate exposure (the total exposure of individuals to various sources of the pesticide); and (c) whether the cumulative effects of a combination of pesticides could increase health risks.¹⁰

In addition, the law created the Endocrine Disrupter Screening Program, under which the EPA must study pesticides that are potential endocrine disrupters.¹¹ The program is designed to simply add to the body of research on endocrine disrupters, but the agency has indicated that the program will serve as a guide for regulatory decisions.¹²

The following briefs provide additional information on the FQPA and its implications. The first discusses some of the science and implementation issues in general. Two others address the impact that federal pesticide policy can have on public health and well-being related to agricultural productivity and control of disease-carrying pests. The final brief discusses the issue of pesticides in schools.

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^{11.} For more information on endocrine disrupters, see the policy brief titled "Endocrine Disrupters."

^{12.} See Draft User's Guide for the Endocrine Disrupter Priority Setting Database (Washington, DC: EPA and Eastern Research Group, 2000). A contractor produced this publication for the EPA. Page 1-1 states that the program will eventually help EPA "determine how best to regulate" chemicals.

^{10. 21} USC § 346a.