Food Quality Protection Act

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In 1996, the Food Quality Protection Act (FQPA) amended the two federal laws governing pesticides: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drugs, and Cosmetics Act (FFDCA). Congress's goal was to address disparities between the two laws governing pesticide regulation and to address concerns that federal pesticide regulations were overly stringent. At the time, the onerous pesticide standards were leading the U.S. Environmental Protection Agency (EPA) to cancel many vital pesticide uses.[1]

The hope was that the FQPA would ensure a more scientifically sound process that kept risks low while allowing continued use of many important products. However, the FQPA created new and unexpected problems and may, in fact, prove as onerous as the former law. Although many have claimed that the problems emanate from poor EPA implementation, problems have also resulted from new onerous standards written into the FQPA. Addressing these issues will likely require congressional action.

Statutory Scheme

Before entering commerce, pesticides must gain registration for each specific use (e.g., use as indoor bug spray or on a specific crop) under FIFRA. To gain registration, registrants must provide data that demonstrate that does not pose an unreasonable safety risk. Without such EPA approval, firms may not sell any pesticidal

1. For an overview of the history before this law, see the policy brief titled "Pesticide Regulation Overview."

product, although EPA can allow for emergency uses of certain products. In addition, the FFDCA requires that the EPA set "tolerance levels" for pesticides used on foods (as opposed to other uses, such as to control insects, rodents, or microbes). Tolerance levels specify how much pesticide exposure the EPA will allow as residue on foods. For example, the EPA sets a level that it believes, on average, will limit individuals' exposure to pesticide residues found on apples, assuming an individual eats a certain number of apples every day for 70 years.

The FQPA added some additional considerations. The law sets a general standard wherein the EPA must show "reasonable certainty" that a pesticide will "do no harm."[2] The requirement alone is quite stringent. The language and the legislative history indicate that this standard is equivalent to a risk not greater than one in a million.[3] But that is just the beginning. The standards must be even more stringent because under the FQPA, the EPA must now also consider the following:

- **Aggregate exposure.** The "aggregate exposure" standard requires the EPA to consider all exposure pathways of a single pesticide when setting tolerances. For example, the EPA must consider whether a person eating an apple that contains specific pesticide residue also is exposed to the same pesticide from consumer products, such as bug sprays or household disinfectants. Hence, the tolerance level for a pesticide would have to include all conceivable exposures—reducing the amount of allowable residue.
- **Cumulative exposure.** Under the "cumulative exposure" standard, the EPA must consider the impact of groups of various pesticides. There are two aspects in particular. First, it must group pesticides that supposedly cause cancer in a similar way—pesticides that have a so-called common mechanism for toxicity. Second, it must add all the exposures—inhalation, oral, dermal—of these pesticides and limit exposure to them as a group. This task is very difficult because the science is not always clear on the mechanisms for causing cancer for all of these substances, nor is it clear whether cumulative exposures actually increase risk. Claims about such cumulative exposure risks gained steam with a study conducted by researchers at Tulane University. It claimed that, when combined, endocrine disrupters were 1,000 times more potent. When other researchers could not replicate this result, the Tulane researchers retracted the study.[4] Despite the redaction, the idea that synergistic effects of chemicals multiply potency prevails among activists. And the concept has even made its way into law. After the Tulane study was published in *Science*, Congress passed provisions in the 1996 FQPA calling on the EPA to consider such cumulative exposures when issuing regulations. Subsequently, several studies reported no synergistic interactions with the chemicals.
- **Safety Factor for Children.** The new law requires the EPA to consider risks to children

2. 21 USC § 346a(b)(2)(A)(ii).

3. For an analysis, see Frank Cross, "The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act," *Washington University Law Quarterly* 75, no. 3 (1997): 1155–206.

4. The original study was Steven F. Arnold, Diane M. Klotz, Bridgette M. Collins, Peter M. Vonier, Louis J. Guillette Jr., and John A. McLachlan, "Synergistic Activation of Estrogen Receptor with Combinations of Environmental Chemicals, *Science* 272, no. 5267 (1996): 1489–92; the retraction is John A. McLachlan, "Synergistic Effect of Environmental Estrogens: Report Withdrawn," *Science* 277, no. 5325 (1997): 459–463.

and to apply a 10-fold safety factor unless the EPA determines that a lower safety factor is acceptable. The EPA notes that it will apply this 10-fold factor in addition to the 100-fold safety factor it currently applies when setting standards. Hence, when the EPA applies the 10-fold safety factor for children, it will actually apply a 1,000-fold safety factor.

Already Conservative Risk Estimates Become More Stringent

Even before Congress made the law more stringent with the FQPA, the EPA used very conservative risk estimates. Given EPA risk assessment methodologies, pesticide safety regulations already applied safety margins that ensured exposure levels were thousands of times lower than levels EPA deemed safe. For example:

- Bureaucrats set standards to ensure safe exposures even if a farmer applied the full legal limit of all pesticides licensed for use on a given crop. Yet farmers apply only a fraction of the legal limits and do not apply all pesticides licensed for a particular crop. For example, University of Texas Professor Frank Cross notes that one study shows that farmers in California use about 25 percent of their legal limit for tomatoes, and each farmer uses no more than 5 of 54 licensed pesticide products.[5]
- Frank Cross highlights a number of studies showing that the EPA's conservative risk estimates overstate pesticide exposure by as much as 99,000 to 463,000 times actual exposure levels.[6]
- When researchers recalculated risks by considering actual pesticide exposure levels measured by the U.S. Department of Agriculture (USDA), they found that risks were "from 4,600 to 100,000 times lower than EPA estimates."[7]

Applying the New Standards

The combination of "reasonable certainty" of "no harm," "aggregate risk," "cumulative effects," and additional safety factors for children poses a host of new challenges for the EPA when conducting risk assessments for setting tolerances.

To assess aggregate exposure, the agency must estimate how much exposure the public has to a pesticide from the various pathways—on and in foods, in the home, and in drinking water. Then the agency must limit enough of those exposures to ensure that total exposure does not exceed the level it deems safe. To facilitate understanding of this process, the agency developed a theoretical construct called the "risk cup." The cup represents the total amount of exposure to the public of a pesticide that the EPA will allow. The EPA then registers only the amount of pesticide uses that "fill" the cup. When filling the cup, the EPA considers all potential exposure pathways. For example, regulators will estimate that certain agricultural use will fill 50 percent of the cup, drinking water exposure will fill 1 percent, home consumer products will fill 29 percent, and "other" exposures (which they assume but do not specify) will fill the rest.

5. Cross, "The Consequences of Consensus," 1174.
6. Ibid., 1177.
7. Sandra O. Archibald and Carl S. Winter, "Pesticides in Our Food," in *Chemicals in the Human Food Chain*, ed. Carl K. Winter, James N. Seiber, and Carole Nuckton (New York: Van Nostrand Reinhold, 1990), 39.

Various groups have complained that the EPA has grossly exaggerated exposure levels. A key problem is that when the agency lacks data on actual exposures or when levels are below the agency's ability to detect them, regulators use default numbers that assume a certain amount of exposure. Hence, the cup fills, but it does not represent real risks to society. Once the cup is full, the EPA will not register any further uses of the pesticide.

When filling the cup, the EPA can consider the impacts of numerous pesticides—placing several in one cup. For example, the EPA has placed certain organophosphate products into one category and is working on a cumulative risk assessment for those products. Placing them all in one cup could demand dramatic reduction in registered uses. For example, home exterminators may not gain a registered use for many organophosphates, leaving them with fewer options for controlling pests such as cockroaches. Such changes can have serious public health impacts. In addition to carrying diseases, cockroaches are believed to contribute to asthma, a serious health ailment affecting many children.[8]

"Minor Uses"

Ironically, a major problem relates to what people call "minor uses" of pesticides. Minor uses include key public health uses to control pests, ranging from disease-carrying mosquitoes to rodents. In addition, they include uses on many fruits and vegetables. These uses are anything but minor, yet the law has made many of them an unprofitable enterprise for a couple of reasons. First is cost. The law requires that firms spend a considerable amount of resources—submitting data and paying very hefty registration fees—to obtain a registration. Such high costs basically make many markets unprofitable for companies, so they do not bother to register those uses. The total cost of pesticide registration is estimated to be more than $50 million, and the process can take from 9 to 10 years.[9] Second, the FQPA standards limit the number of uses that the EPA will register for various products.

These factors serve as disincentives for the development of new minor use pesticides as well as for the reregistration of old ones. In fact, to continue business in more profitable markets, firms are negotiating the elimination of minor uses when they reregister products. Syngenta, for example, came to an agreement with the EPA in June 2000 to eliminate many of the minor uses—particularly home-related pest control—for the pesticide diazinon. Syngenta explained that the product was safe when used properly. Agreeing to phase out certain uses was purely a "business decision," the company noted, because the product was no longer profitable for those uses.[10]

The FQPA's impact on minor uses promises to have serious public health outcomes because these products meet critical needs: to ensure affordable fruits and vegetables and to protect against disease-carrying pests. As one USDA official noted,

8. Floyd J. Malveauz and Sheryl A. Fletcher-Vincent, "Environmental Factors of Childhood Asthma in Urban Centers," *Environmental Health Perspectives* 103, Suppl. 6 (1995): 59. See also the policy brief titled "Pesticides and Public Health."

9. USDA, "EPA and Pesticide Registration Issues," Agricultural Research Service, Washington, DC, http://www.ars.usda.gov/is/np/mba/jan97/epa.htm.

10. Glenn Hess, "EPA Phases out Pesticide Diazinon: Syngenta Cites Declining Margins." *Chemical Market Reporter*, December 11, 2000.

> Even though the FQPA provisions were intended by Congress to ensure that existing public health pesticide uses are not lost without economically effective alternatives, the provisions may not be adequate. If the FQPA results in cancellation of major agricultural uses of a pesticide that is also used in public health, it may become no longer profitable for the manufacturer to produce small quantities for mosquito control, thus ending production of the pesticide. Since adulticides used for mosquito control were registered decades ago, the data supporting their registrations may be insufficient to meet current requirements.[11]

FQPA Impacts

The 1996 law has produced some serious impacts. For example, consider the effect of the law on products that use organophosphate pesticides. At the time the FQPA passed, there were 49 of these products on the market, representing about one-third of all pesticide sales.[12] The EPA picked this broad category of products in its first effort to implement the law's provisions on cumulative exposure. By the time the EPA released its draft cumulative risk assessment for these products in 2002, 14 products had already been canceled and 28 had to meet risk mitigation measures that include limitations on use, voluntary cancellations, cancellations of certain uses, and other restrictions.

Recently, EPA completed a 10-year study of 230 organophosphates and carbonates pesticides. It concluded that the Food Quality Protection Act demands that the agency ban 3,200 uses of pesticide products in these categories and places restrictions on 1,200 other uses. It deemed 5,237 uses as "safe" under the act.[13] Hence, the Food Quality Protection Act could increase regulations on 46 percent of the uses of the 230 chemicals—a substantial increase. Among recommended the restrictions are bans on a majority of uses of carbofuran, a product used for a variety of crops. EPA also announced its intention to ban major agricultural uses of the product lindane, a product targeted by environmental groups.

Researchers at the University of California note problems with the elimination of so many products:

> Economic theory suggests that these increased restrictions and cancellations from the eventual implementation of the FQPA will result in reduced supply of commodities currently relying on [organophosphate] pesticides for pest control. This will result in higher prices for consumers and lower quantity [of produce] sold … . If consumers respond to the increased prices by reducing consumption of the affected fruits and vegetables (and perhaps consuming less nutritious foods), they may suffer a loss of health benefits association with the change in consumption.[14]

Indeed, the researchers note that another study assessing the impacts of such laws reveals

11. Robert I. Rose, "Pesticides and Public Health: Integrated Methods of Mosquito Management," *Emerging Infectious Diseases* 7, no. 1 (January–February 2001): 17–23; http://www.cdc.gov/ncidod/eid/vol7no1/rose.htm.

12. Sean B. Cash and Aaron Swoboda, "Food Quality Protection Act and California Agriculture," *Agricultural and Research Economics Update* 6, no. 4 (2003): 9–11, http://www.agecon.ucdavis.edu/extension/update/articles/v6n4_3.pdf.

13. Kate Phillips, EPA Recommends Restrictions on Pesticide Usage, *Chemical Week* 168 no. 2 (August 9, 2006).

14. Ibid., 10.

a potential negative health effect resulting from the FPQA.

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Recommended Reading

Cross, Frank B. "The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act." *Washington University Law Quarterly* 75, no. 3 (1997): 1155–206.

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