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FQPA: Origins and Outcome

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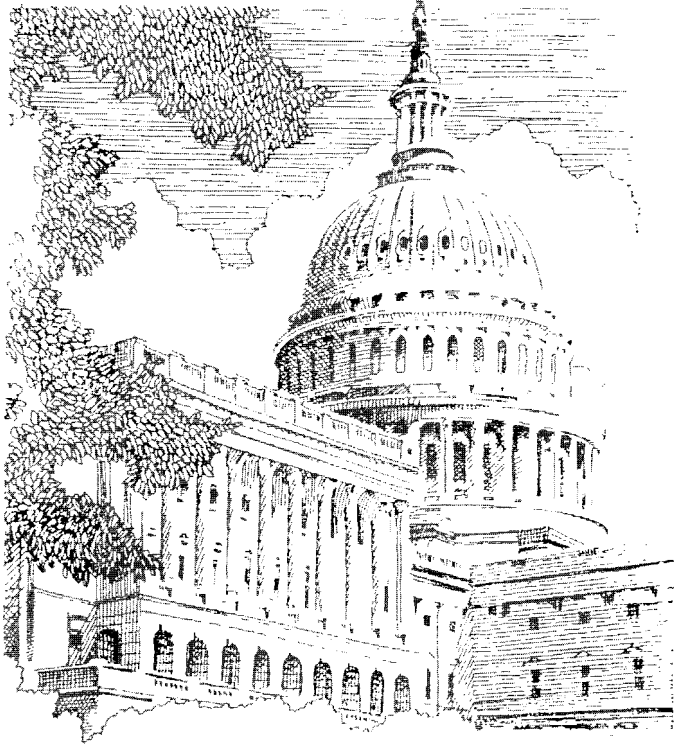

FQPA: Origin and Outcome

Four years after enactment, many are wondering whether FQPA needs to be amended, or if the EPA is going beyond what the Act allows.

By Linda-Jo Schierow

On August 3, 1996, the U.S. Congress unanimously voted for significant changes to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which governs the U.S. sale and use of pesticide products, and to the Federal Food, Drug, and Cosmetic Act (FFDCA), which limits pesticide residues on food in interstate commerce. The vehicle of these changes was the Food Quality Protection Act (FQPA). The FQPA:

- established "a reasonable certainty of no harm" as the new safety standard for pesticides used on food crops;
- established special protections for children; and
- coordinated FIFRA and FFDCA.

At the time of enactment, the FQPA was hailed as an example of a rational, scientific, and risk-based law that would be good for producers and consumers alike — a triumph over the simplistic and unscientific "zero-risk" standard of the Delaney Clause. Other FQPA provisions mandated activities that already were part of the pesticide regulation process at the U.S. Environmental Protection Agency (EPA), although some were more consistently and thoroughly practiced than others.

Regulating Pesticide Products

The U.S. Congress first authorized regulation of pesticide sale and use to protect human health in 1947, when the original version of FIFRA became law. The U.S. Department of Agriculture (USDA) administered the law until 1970, when responsibility was shifted to the newly created EPA. Congressional concerns about long- and short-term toxic effects of pesticide exposure to applicators, wildlife, non-target insects and birds, and food consumers led to a complete revision of FIFRA in 1972.

The 1972 law is the basis of current federal policy. FIFRA requires regulation of the sale and use of pesticides in the United States through registration and labeling of the estimated 21,000 pesticide products now in use. The Act directs EPA to restrict the use of pesticides to prevent unreasonable adverse effects on people and the environment, taking into account the economic, social, and environmental costs and benefits of various pesticide uses. To do this, EPA registers each pesticide for each approved use. FIFRA prohibits sale of any pesticide in the United States unless it is registered. In addition, FIFRA requires EPA to re-register older pesticides based on new data that meet current regulatory and scientific standards. Most pesticides currently registered in the United States are older pesticides that have not been subject to today's safety reviews.

When pesticide manufacturers apply to register or re-register a pesticide's active ingredient or a particular use of a registered pesticide, EPA requires them to submit scientific data on pesticide toxicity and behavior in the environment. To register a pesticide for use on food, EPA also requires applicants to identify analytical methods that can be used to test food for residues and to provide data on the amount of pesticide residue that could remain on crops as well as on (or in) food products, if the pesticide is applied according to the manufacturer's recommended rates and methods. EPA then determines under what conditions the proposed pesticide use presents an unreasonable risk to human health or the environment. If the pesticide is proposed for use on a food crop, EPA determines whether a safe level of residue can be established. Establishing a safe level of residue is necessary before granting a pesticide registration for a food use. If a registration is granted, the Agency specifies the approved uses and conditions of use. These must appear on the product label. FIFRA requires that federal regulations for pesticide labels preempt state,

local, and tribal regulations. Use of a pesticide product in a manner inconsistent with its label is prohibited.

EPA also evaluates the safety of pesticides after they are registered or re-registered. Registrants are required to report any new evidence of adverse effects of pesticide exposure. If the evidence indicates that a registered pesticide may pose an unreasonable risk, EPA initiates a special review of available information and reevaluates the risks and benefits of each use. Registrants also may be required to conduct new studies to fill gaps in scientific data required for risk assessments. If an EPA review finds that a registered use may cause "unreasonable adverse effects," the registration may be amended or canceled. Registrants also may voluntarily request cancellation or amendment of a registration to terminate selected pesticide uses. A request for voluntary cancellation sometimes reflects a registrant's conclusion that the cost of additional studies is not worth the expected benefit (that is, profit) from sales if the registration is maintained. If a registration is canceled for one or more uses of a pesticide, it may no longer be sold or distributed for those uses in the United States, although U.S. farmers may use remaining stocks for a specified period of time.

An EPA decision may be appealed. This initiates a lengthy review process during which the product may continue to be marketed. However, if there is threat of an "imminent hazard" during the time required for review, EPA is authorized to suspend registration. Suspension orders stop sales and use of the pesticide.

Generally, FIFRA requirements are enforced by EPA. However, the Act gives states primary authority, including inspection authority, for enforcing FIFRA provisions related to pesticide use.

Regulating Pesticide Residues on Food

FFDCA authorizes various federal agencies to regulate foods, drugs, and cosmetics in U.S. commerce. Pesticide residues on food commodities were first addressed in the 1938 FFDCA amendments. These authorized the Food and Drug Administration (FDA) to set maximum residue limits (tolerances) for food containing residues of "poisonous and deleterious" substances necessary for the production of food.

FFDCA amendments in 1954 gave FDA more regulatory power, directing FDA to set tolerances for pesticide residues on raw food crops and prohibiting the sale of crops with pesticide residues for which no tolerance had been established. The law allowed FDA to weigh the benefits of pesticides against the risks. Significantly, these FFDCA amendments shifted the burden of proving that a residue was safe from the federal government to the pesticide user.

FFDCA amendments in 1958 established federal requirements for food additives, which included any increased concentration of pesticide residues that occurred during food processing. In this case, Congress required FDA to set "safe" tolerances. Text accompanying the law explained that the intent was to ensure "a reasonable certainty of no harm" considering total risk from all pesticide exposures with similar toxic effects. The food additive amendments also contained the Delaney Clause, which prohibited adding to food any substance found to induce cancer in animals or humans. In 1970, Congress gave the responsibility for tolerance setting to EPA.

In 1996, the FQPA amended FFDCA to change the basis for setting tolerances. The FFDCA now directs EPA to establish allowable pesticide residue levels (tolerances) for roughly 300 pesticides registered for use in food and animal feed. Foods with a residue of a pesticide for which there is no established tolerance, or with a residue level exceeding an established tolerance limit, are "unsafe" and "adulterated." Such foods cannot be sold in interstate commerce.

In 1970, Congress gave the responsibility for tolerance setting to EPA.

How Regulation Changed after 1996

The FQPA amended FIFRA to reduce the regulatory burden for "minor-use" pesticides, reduced-risk pesticides, and other special groups of pesticides. The 1996 law also gave EPA authority to collect fees to fund re-registration procedures. FFDCA was amended to:

- collect information about the diets of infants and children;
- prohibit states from regulating pesticide residues in food;
- support adoption of integrated pest management through research and education; and
- inform consumers about the health risks of pesticide residues and how to avoid them.

Prior to 1996, the FFDCA directed EPA to establish tolerances for pesticide residues on food in different ways for raw and processed commodities. EPA considered the benefits of pesticide use as well as the risks when setting tolerances for raw food, but only the human health risks of pesticide residues were considered for processed foods. The Delaney Clause assured that no tolerance would be permitted if there was an indication of a cancer risk. Critics of the Delaney Clause said it was unscientific, because very small pesticide residues pose no significant risk to health, and technology is now sophisticated enough to detect extremely small amounts of pesticides in food. The Delaney Clause would force EPA to revoke tolerances for economically important pesticide uses. Critics also noted that many foods contain unregulated natural carcinogens, which may pose greater risks than pesticide residues. In addition, they claimed that in some cases the

Photos for this CHOICES Special Focus cover courtesy, Capitol Clear Window girls USDA Colorado potato beetle, Clemson University, fruit spraying, courtesy John Deere

actual amount of pesticide in a food before and after processing might be the same, yet a tolerance could be set for the residue in raw food and prohibited for processed food, because the residue had been concentrated relative to the total food weight due to drying or other processing. Delaney Clause supporters argued that people do not want cancer-causing pesticides in their food, no matter how small the risk.

Contrary to widespread reports, the FQPA did not repeal the Delaney Clause. Food additives that are not pesticide residues remain subject to it. However, pesticide residues are no longer subject to the clause. The distinction between raw and processed food tolerances was eliminated, and the safety standard for tolerances was tightened.

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FQPA strictly limits the extent to which benefits may be considered in tolerance setting. It allows EPA to maintain or modify existing tolerances at higher than "safe" residue levels only if the pesticide use prevents other greater risks to consumers or is necessary to avoid "significant disruption in domestic production of an adequate, wholesome, and economical food supply." Tolerances still must be "safe" for infants and children.

The FQPA directs EPA to reevaluate existing tolerances against the new safety standard: 33 percent of existing residue limits for food-use pesticides by August 1999, 66 percent by August 2002, and 100 percent by August 2006. The FQPA directed EPA to reevaluate tolerances for the riskiest pesticides first.

If EPA finds that residues of a pesticide pose a risk greater than allowed by FQPA, EPA must change the FFDCA tolerance level and the FIFRA registration (including the product label) to restrict pesticide use and reduce human exposure to a "safe" level. In assessing the risk of pesticide residues, the FQPA requires EPA to consider:

- the likelihood that children will be exposed and/or suffer health effects if exposed, and the adequacy of available information on children;
- potential health effects due to interference with hormones;
- potential effects of exposure on children in the womb;
- cumulative risk from all pesticides with similar toxic effects; and
- aggregate risk due to all routes of exposure.

The Devil Will Be in the Details

The FQPA had widespread support when enacted in 1996, but the enthusiasm has cooled among most stakeholder groups as EPA has struggled to translate FQPA goals and directives into bureaucratic procedures while meeting its legal obligations for registering and re-registering pesticide products. Putting FQPA mandates into practice has been much more difficult than many people expected, and the law allowed no time for EPA to change its procedures. Stakeholder participation in the implementation process has been useful, but also time-consuming, confrontational, and frequently limited to legal wrangling about what the law requires.

The difficult work is just beginning. Last year, when EPA effected the cancellation of all fruit uses of perhaps the most dangerous organophosphate, methyl parathion, the Agency was criticized, not only by users of the pesticide, but also by those who found the action "too little, and too late." Next year (2001), EPA will assess the combined risk of exposure to some 1,600 residues of various organophosphate pesticides on various crops. Almost certainly, EPA will find that the total risk of exposing children to organophosphates is greater than allowed under the FQPA, and the Agency will regulate to reduce the risk. How many tolerances will EPA revoke, and how will registrants and users respond? FQPA provides little or no guidance on how EPA should weigh one pesticide use against another. Instead, the Act arguably gives EPA enormous discretionary power to decide which pesticide uses are permitted and which eliminated, authority that almost certainly will be challenged in court, quite possibly both by producers and by environmental or public health interests. ■

■ For More Information

Food Quality Protection Act of 1996, Public Law 104-170.

Schierow, Linda-Jo. *Pesticide Legislation: The Food Quality Protection Act of 1996* (Public Law 104-170) Washington DC: Congressional Research Service, CRS Report 96-759 ENR, September 1996 (Available through U.S. Senators and Representatives.)

Environmental Protection Agency Web site available at <http://www.epa.gov/oppfead1/fqpa/fqpa-ltr.htm>.

The views expressed in this paper are the author's own and do not necessarily represent those of the Congressional Research Service.