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Pesticide Residue Regulation: Analysis of Food Quality Protection Act Implementation

Linda-Jo Schierow
Specialist in Environmental Policy
Resources, Science, and Industry Division

Summary

The Food Quality Protection Act of 1996 (FQPA) amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), governing U.S. registration, sale, and use of pesticide products, and the Federal Food, Drug, and Cosmetic Act (FFDCA), under which the Environmental Protection Agency (EPA) sets allowable pesticide residue levels for food (tolerances). The FQPA mandates a "reasonable certainty of no harm" from pesticide exposure and requires reevaluation of tolerances against this standard by August 2006. The Act directs EPA to evaluate aggregate exposure risks of individual pesticides and cumulative risks of various pesticides with similar toxic effects. EPA must modify tolerances that are not safe and amend registrations (labels) for the associated pesticides. EPA has reported that it is meeting statutory deadlines, but this claim is disputed by environmental groups. A test case for FQPA implementation is evaluation of risks for organophosphate (OP) insecticides, used on many fruits, vegetables, and grains. EPA already has canceled registrations for some OP uses. EPA has issued a preliminary and a revised cumulative OP risk assessment, and plans to complete evaluation of OP risks in 2003. Agricultural and public health groups have challenged the FQPA implementation pace and process in court. This report will be updated as events warrant.

Introduction

The 104th Congress enacted significant changes to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), governing registration, sale, and use of pesticide products, and the Federal Food, Drug, and Cosmetic Act (FFDCA), under which the U.S. Environmental Protection Agency (EPA) sets allowable pesticide residue levels for food and animal feed (tolerances). The changes were wrought by the "Food Quality Protection Act of 1996" (FQPA; Public Law 104-170), which established a new standard of food safety: a "reasonable certainty of no harm" from any legally permissible pesticide residue on food, while recognizing the benefits of pesticide use on food crops.

Farmers, chemical manufacturers, environmentalists, and other stakeholders have carefully observed and sometimes criticized EPA implementation of the FQPA. This report discusses the status of FQPA implementation and potential effects on regulation of pesticides used in food production and processing. For background and a detailed summary of the FQPA, see CRS Report 96-759 ENR, *Pesticide Legislation: The Food Quality Protection Act of 1996 (Public Law 104-170)*. For descriptions of recent legislative proposals to amend the FQPA, see the pesticide section in CRS Issue Brief IB10067, *Environmental Protection Issues in the 107th Congress*.

Food Quality Protection Act Mandates

A key expressed purpose of the FQPA is to coordinate pesticide registration under FIFRA with FFDCA tolerances, to ensure that any pesticide approved for use on food would leave only a "safe" residue. The FFDCA, as amended by the FQPA, defines "**safe**" to mean that EPA has determined there is "a reasonable certainty that no harm will result from aggregate exposure ... , including all anticipated dietary exposures and all other exposures for which there is reliable information." The FQPA directs EPA to reevaluate all existing tolerances for food-use pesticides against this safety standard: 33% by August 3, 1999, 66% by August 3, 2002, and 100% by August 3, 2006. The FQPA requires EPA to consider tolerances for the riskiest pesticides first.

If EPA finds that residues of a pesticide used on food may pose a risk greater than FQPA allows, the Act requires a change in the FFDCA tolerance level, as well as in the FIFRA registration (that is, product label) to restrict the number or manner of approved pesticide uses, and so to reduce human exposure to a "safe" level. In assessing the risk of pesticide residues allowed by a tolerance, the FQPA requires EPA to consider:

- children's exposure to pesticides and susceptibility to health effects;
- potential disruptive effects on endocrine systems;
- potential effects of *in utero* exposure;
- aggregate risk from all sources and through all routes of exposure; and
- cumulative risks due to exposure to all pesticides with similar toxic effects (i.e., a "common mechanism of toxicity").

FQPA Implementation

EPA has worked with stakeholders to implement the new law. Pesticide producers and users want assurances that the risks of popular pesticides will be evaluated by EPA based on real data rather than worst-case assumptions. Public health and environmental groups want prompt action to reduce risks from pesticides.

Progress toward Milestones. On the date of FQPA enactment, there were 9,728 residue tolerance levels and exemptions in effect for active and inert pesticide ingredients. EPA divided these into groups, based largely on relative risk to public health, and published a schedule for reevaluation of tolerances in the *Federal Register* on August 4, 1997. The first group of pesticides subject to tolerance reassessment includes:

- Organophosphates, carbamates, and organochlorines;
- Probable and some possible human carcinogens;

- High-hazard inert ingredients;
- Pesticides that exceed their reference dose (RfD)[1];
- Pesticides that EPA will be considering for reregistration[2]; and
- Pesticides whose tolerances and exemptions are being revoked.

EPA reevaluated more than 3,000 tolerances before August 3, 1999, the earliest statutory deadline. Thus, the Agency asserted that it achieved its first milestone for food-use pesticide regulations. On August 3, 2002, EPA announced that it had completed reassessments for more than 6,400 tolerances, meeting the second statutory deadline, including nearly two-thirds of tolerances for foods commonly eaten by children. EPA has revoked more than 1,900 tolerances. However, critics contend that EPA has not evaluated the riskiest pesticides, since many of the reevaluated tolerances posed no significant risks to human health: many were for residues on crops that did not occur, because the crops were not treated with the pesticide, or the pesticide was no longer used.[3]

Environmental, consumer, and public health advocacy groups accuse EPA of "dragging its feet" in implementing FQPA. They believe that the new safety standard mandates reducing the use of many older pesticides. The Natural Resources Defense Council (NRDC) and six California-based public interest groups alleged in lawsuits filed August 3, 1999 in the U.S. District Court for the Northern District of California that delays caused EPA to miss the first FQPA deadline for reassessment of one-third of existing tolerances for higher-risk chemicals by August 3, 1999 (*Natural Resources Defense Council v. Whitman*, No. C993701CAL). The Court approved a consent decree to conclude litigation on September 25, 2001.[4] The consent decree provides milestones for the review of certain pesticides, greater opportunities for public involvement, and external peer review of critical decisions. The agreement also requires an annual EPA report on its progress in meeting the milestones.

EPA has made progress in implementing the FQPA directive to assess cumulative risks of pesticides with a common mechanism of toxicity. In January 2002, the Agency released a final policy interpreting this FQPA requirement. A preliminary cumulative risk assessment for the organophosphates (OPs) was issued in December 2001, and a revised assessment was published in June 2002. However, the OP risk assessment is not yet complete. EPA plans to release the final OP cumulative risk assessment during 2003.

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[1] A reference dose estimates the daily exposure level that is likely to be safe over a lifetime.

[2] Amendments to FIFRA in 1988 directed EPA based on current safety standards to "reregister" products first registered prior to 1984.

[3] On the other hand, the numbers released by EPA do not include any OP that has been reassessed and regulated – e.g., methyl parathion – unless its registration was cancelled. All of these will be counted as reassessed when the cumulative reassessment is done for all registered OPs.

[4] The consent decree originally was reached with the Clinton Administration and filed on Jan. 19, 2001. The Bush Administration reviewed the consent decree and ratified it in March 2001. Approval was delayed for several months due to a legal challenge by pesticide and chemical trade groups. A separate settlement agreement, filed on January 19, 2001, requires EPA to begin screening pesticides for endocrine disruption potential using validated non-animal tests when they are available, feasible, and scientifically appropriate. The settlement agreement is not legally enforceable, but NRDC may re-initiate its litigation if EPA fails to comply.

Stakeholder Involvement. According to EPA, pesticide regulations directly affect approximately 30 major pesticide producers, 100 smaller producers, 2,500 formulators, 29,000 distributors and retailers, 40,000 commercial pest control firms, 1 million farms, 3.5 million farm workers, several million industry and government users, and all households. Within each of these groups, distinct subgroups have diverse views of the federal role in pesticide regulation. A handful of contentious issues has potentially far-reaching impacts on the availability of pesticides for particular uses, the cost of food and other consumer products, and international competitiveness of U.S. agricultural products. These issues are summarized below. EPA is seeking to resolve them through cooperative discussions and negotiations involving the major stakeholders.

EPA has worked with several committees since passage of the law to ensure an open decision-making process, including the Food Safety Advisory Committee (FSAC), the Pesticide Program Dialogue Committee, the Scientific Advisory Panel (a FIFRA-mandated advisory body of independent scientists selected by EPA), and the State FIFRA Research and Evaluation Group. Despite these consultative efforts, growers and chemical manufacturers expressed concerns about a perceived lack of opportunities to comment on evolving EPA implementation strategies. In response, EPA committed itself to apply sound science, employ an open process of decision making, and ease any necessary transition to new rules so as not to jeopardize agriculture, and EPA and the U.S. Department of Agriculture (USDA) jointly established the Tolerance Reassessment Advisory Committee (TRAC) on April 30, 1998. During the first year of its existence, the 45 committee members represented environmental and public interest groups; pesticide industry and trade associations; users, growers, and commodity organizations; pediatric and public health organizations; federal agencies, tribal, state, and local governments; academia; and consumer groups. However, the Environmental Working Group, a consumer advocacy group, resigned from TRAC in October 1998, claiming that the Clinton Administration had failed to protect children from pesticide risks. The remaining environmental, consumer, and public health advocacy groups resigned in April 1999, citing EPA's slow pace of tolerance reassessment.

EPA formed a new advisory group, the Committee to Advise on Reassessment and Transition (CARAT), in June 2000. A subcommittee of EPA's National Advisory Council for Environmental Policy and Technology, its purpose "is to provide advice and counsel to the Administrator of EPA and the Secretary of Agriculture regarding strategic approaches for pest management planning and tolerance reassessment for pesticides as required by the ... FQPA".[5] CARAT is tackling some of the most difficult implementation decisions about which pesticides will remain available for use on which crops.

Issues. TRAC identified "science policy" issues affecting implementation of the FQPA with regard to tolerances; most of these revolve around how to estimate levels of aggregate pesticide exposure or cumulative risk, given exposure.[6] EPA developed policy

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[5] 65 *Federal Register* 35925, June 6, 2000.

[6] For the most part, arguments surrounding these issues are technical. The impact of decisions may be substantial. For example, EPA generates risk estimates that are intended to protect 99.9% of the exposed population from pesticide exposure with potentially adverse health effects. According to a summary of a March 1998 meeting of the FIFRA Scientific Advisory Panel, "The (continued...)

guidance documents for such issues. Pesticide industry and agricultural organizations would like EPA to use a notice-and-comment rulemaking process to establish FQPA implementation procedures, but EPA has resisted that approach, fearing loss of flexibility and delays. Consequently, 18 organizations filed a complaint June 7, 1999 with the U.S. District Court of the District of Columbia, challenging EPA's consultative process (*American Farm Bureau Federation v. U.S. Environmental Protection Agency*, No. 99-CV-1405 (D.D.C. filed June 7, 1999)). According to the American Farm Bureau Federation, a negotiated settlement with EPA is pending before the court.

A particularly contentious implementation issue revolves around the FQPA directives to use "available data" and "reliable data," as well as the FQPA mandate to order testing if EPA determines that data are "reasonably required to support the continuation of a tolerance or exemption that is in effect ... for a pesticide chemical residue on a food," (FFDCA, Section 408(f)(1)). Stakeholders disagree about what is an appropriate course of action for EPA when there is insufficient "reliable" data to estimate risk. Pesticide producers ideally would like EPA to delay estimating risk until reliable data can be collected; public health advocates would like EPA to estimate risk based on "available" data and to reduce the potential for human exposure to unacceptable risks.

Members of the pesticide industry also want EPA to "call in" data. Although pesticide producers conduct toxicity testing, and they need not wait for EPA to order data production, an EPA order provides certain legal and financial protections not otherwise available to those who perform toxicity studies. EPA failure to order a data call-in was another issue raised by the lawsuit filed June 7, 1999, but this claim was dismissed by the court. However, EPA published a call-in notice for specific data on developmental neurotoxicity and pesticide residues on August 6, 1999.[7]

Food Tolerances for Organophosphate Pesticide Residues

Organophosphates (OPs) are complex synthetic compounds. In agriculture, OPs such as methyl parathion and malathion are used as broadly effective insecticides, for example, to kill boll weevils or fruit flies. Various OPs are used on fruit trees, vegetables, ornamental plants, cotton, corn, soybeans, rice, and wheat, and for mosquito control.

EPA has determined that OPs are among pesticides posing the greatest risks to human health and the environment. OPs have a highly variable, toxic effect on the nervous systems of people and other animals. Some are acutely toxic, others much less so; but, because they exert the effect in the same way, they are the first pesticides that will

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[6] (...continued)
Panel differed on whether setting criteria at the 99.9th percentile is a conservative approach. However, if the 99.9th percentile is utilized, a percentage of the population (e.g., 23,000 children) would still be exposed to acute effects." Some experts argue that data are too sparse to calculate reliably the 99.9th percentile; they would prefer to use a more easily measurable 95th percentile, which might increase the abundance and quality of food in children's diets, but that would leave a larger group of children potentially exposed. In addition to reliability of estimates, and the benefits and risks of pesticide use, additional factors also may be relevant to the decision about which percentile to employ, such as the "conservativeness" of other EPA inputs to risk analyses.

[7] 64 *Federal Register* 42945-42947, Aug. 6, 1999.

be considered as a group. In 1996, when FQPA was enacted, there were 1,691 tolerances for OP residues on crops. By August 2, 2002, EPA had assessed 1,127 OP tolerances (about 67%), and revoked 703 OP tolerances.[8]

Growers and pesticide makers are concerned about the FQPA impact on future availability of widely used OP pesticides. EPA already has canceled methyl parathion registrations for all fruit uses. In June 2000, EPA and the manufacturer of the OP chlorpyrifos (Dursban) agreed to eliminate nearly all household uses, and to reduce residues on several foods eaten regularly by children. In December 2000, EPA announced a plan to phase out all home uses of diazinon, another widely used OP pesticide. In 2001, EPA decided to cancel, phase out, or continue under time-limited registrations the crop uses of azinphos-methyl and phosmet. In addition, EPA and the registrant have decided to voluntarily cancel certain uses of propargite.

The goal of these and other regulatory actions for individual OPs is to reduce cumulative OP risk to a safe level. As noted above, EPA released a preliminary cumulative risk assessment for the OPs in December 2001, and a revised cumulative OP risk assessment in June 2002. However, the final OP cumulative risk assessment is not yet complete. As EPA collects more data, the revised cumulative OP risk assessment might produce lower risk estimates, indicating that pesticide residue levels are reasonably certain to be safe, as farm groups and pesticide producers contend. On the other hand, data might support the view of public health advocacy groups, that despite regulatory actions, children are exposed to unsafe levels of OPs on pears, apples, grapes, and peaches, risking damage to developing brains and nervous systems.

Conclusion

When Congress passed the FQPA by unanimous votes in both Chambers, many hailed it as an example of a rational, scientific, and risk-based law that would be good for producers and consumers alike. It established a new standard for food safety that recognized the benefits of pesticide use on food crops but also guaranteed pesticide residues almost certainly would be harmless.

Six years after enactment, EPA claims to be meeting statutory deadlines, but various interest groups have challenged that claim, as well as the EPA implementation process. As food uses of some popular pesticides have been canceled, some policy makers have argued that FQPA needs to be amended, or that EPA needs to be restrained from going beyond what the Act requires. Increased congressional oversight and support for legislative remedies might be expected as FQPA implementation proceeds. In 2003, EPA expects to complete a cumulative risk assessment of OP pesticide exposure and to make final decisions about remaining OP pesticide registrations. The FQPA provides little guidance on how EPA should weigh one pesticide use against another; EPA arguably has considerable discretionary power to decide which OP uses to permit and which to eliminate. Some EPA decisions almost certainly will be challenged in court, quite possibly both by producers and by environmental or public health interests.

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[8] EPA Office of Pesticides. "OP Tolerance Reassessment Status." [http://www.epa.gov/pesticides/tolerance/pdf_files/OPXTab-8-02-2002.PDF, visited Nov. 13, 2002].