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Pesticide Residue Regulation: Analysis of Food Quality Protection Act Implementation

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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 new safety standard by August 2006. The Act directs EPA to evaluate aggregate exposure risks of 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 reported that it reassessed one-third of tolerances before August 1999, but many tolerances for relatively high-risk pesticides have not been evaluated. A test case for FQPA implementation is evaluation of risks for organo-phosphate (OP) insecticides, used on many fruits, vegetables, and grains. EPA already has canceled registrations for some OP uses. Cumulative OP risks will be evaluated in 2001. 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, other stakeholders, and the Clinton and Bush Administrations have carefully observed and sometimes criticized EPA

implementation of the new safety standard. This report discusses the status of FQPA implementation and potential effects on regulation of pesticides used in food production and processing. For 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 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 was 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. Section 408(b)(2)(A)(ii) of the FFDCA, as amended, 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 existing tolerances for food-use pesticides against the new food 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:

- the susceptibility of children to exposure and/or to adverse 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, environmental, and consumer groups want prompt regulation of pesticides that in their view are not safe.

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 completed reevaluation of more than 3,000 tolerances before August 3, 1999, the earliest statutory deadline. Thus, the Agency asserts that it achieved its first milestone for food-use pesticide regulations. Through March 2001, EPA had completed reassessments for 3,622 tolerances. However, critics contend that EPA did not evaluate the riskiest pesticides by the 1999 deadline, 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 allege in a lawsuit filed August 3, 1999 in the U.S. Court of Appeals for the Ninth Circuit, that delays already have 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. U.S. Environmental Protection Agency*, No. C993701CAL). Governor Whitman signed an amended agreement to settle the lawsuit March 19, 2001. It provides milestones for the review of certain pesticides, greater opportunities for public involvement, and external peer review of critical decisions.

EPA has not yet been able to implement the FQPA directive to assess cumulative risks of pesticides with a common mechanism of toxicity. On June 30, 2000, the Agency released for comment a draft policy interpreting this FQPA requirement. The final policy has yet to be released. However, a nonprofit group, the Hampshire Research Institute, of Alexandria, Virginia, developed software with EPA support and made it available for public use late in 2000. The software allows pesticide regulators and others to assess risks posed by multiple pesticides from multiple exposure sources. EPA has stated that it is "not endorsing" the product.[4] The FIFRA Science Advisory Panel reviewed the Lifeline Model March 28, 2001.

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

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

[2] Amendments to FIFRA in 1972 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] "Computer Modeling Software Available for Aggregate, Cumulative Risk Assessment," *Daily Environment Report*, Dec. 27, 2000, n. 248, p. A-10.

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. EPA established the Food Safety Advisory Committee (FSAC), consisting of growers, pesticide companies, environmental groups, and state officials, immediately after FQPA passage, and it developed interim decision policies, which still are being employed. This committee finished its work in December 1996. A permanent, broadly representative advisory committee to EPA, the Pesticide Program Dialogue Committee, has had on-going discussions about FQPA implementation. EPA also has involved the Scientific Advisory Panel, a FIFRA-mandated advisory body of independent scientists selected by EPA. It helped EPA develop implementation approaches for several of the more technically challenging FQPA provisions. Another standing committee advising EPA is the State FIFRA Research and Evaluation Group. In addition, several task forces and working groups have worked on specific issues, such as minor uses.

Despite these consultative efforts, growers and chemical manufacturers expressed concerns about a perceived lack of opportunities to comment on evolving EPA strategies. In response, Vice President Gore sent a memorandum April 8, 1998, directing EPA to work more closely with the U.S. Department of Agriculture (USDA) and stakeholders in implementing the FQPA. In response, EPA established an advisory group and 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. EPA and 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, the purpose of CARAT "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] It is tackling some of the most difficult implementation decisions about which pesticides will be allowed on which crops.

Implementation Issues. TRAC identified nine "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 guidance documents on 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, 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)). The American Farm Bureau Federation et al. amended the suit a few weeks after NRDC filed its suit in August, echoing NRDC concerns about delays.

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; EPA failure to order a data call in was another issue raised by the lawsuit filed June 7, 1999 (see above). 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 published a call-in notice for 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, common OPs such as methyl parathion and malathion are used as broadly effective insecticides, for

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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 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.

example, to kill boll weevils, fruit flies, or aphids. Various OPs are used on fruit trees, vegetables, ornamental plants, cotton, corn, soybeans, rice, and wheat, as well as for mosquito control.

EPA has determined that OPs are among the 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 be considered as a group. The Agency began to evaluate their safety during the first 3-year period following enactment of FQPA. In 1996, there were 1,691 tolerances for OP residues on crops. By October 2, 2000, EPA had assessed 505 OP tolerances (about 30%).

Growers and pesticide makers are concerned about the FQPA impact on future availability of widely used pesticides. EPA already has determined that risks of methyl parathion are unacceptable, and canceled registrations for all fruit uses and many other food and non-food 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. Then in December 2000, EPA announced a plan to phase out all home uses of diazinon, another widely used OP pesticide. In a December 8, 2000, press release announcing the diazinon phase out, the EPA Administrator stated, "Today's action will significantly eliminate the vast majority of OP insecticide products in and around the home". In 2001, EPA will estimate the cumulative risk of all OPs and decide whether additional measures are needed to ensure safety.[8] As more data are collected, revised risk assessments might narrow the range of likely risks, showing 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 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.

Four and one-half years after enactment, EPA claims to be meeting statutory deadlines. However, lawsuits filed in mid-1999 question 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 allegedly going beyond what the Act requires.

Increased congressional oversight and support for legislative remedies may be expected as FQPA implementation proceeds. In 2001, EPA expects to assess the combined risk of exposure to hundreds of various OP pesticide residues on various crops, along with any air and water contamination and other sources of pesticide exposure. The

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[8] Werner, Karen L. "NAS Urges Research, Policy Focus to Boost Uses of Chemical Alternatives," *Daily Environment Report*, July 19, 2000. p. A-7.

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.