New Standards For Food Pesticide Levels

The Food Quality Protection Act of 1996 (FQPA) creates a new, uniform, health-based standard for allowable pesticide-related risks in food. In passing the act unanimously, Congress aimed at reducing dietary risks from pesticide residues and providing special protection to infants and children.

The act amends the two major laws regulating pesticides in the U.S.—the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). The law also establishes a new risk assessment process and requires the U.S. Environmental Protection Agency (EPA) to review all residue tolerances against the new safety standard within 10 years.

Additional provisions define and streamline the registration of minor-use pesticides; address uniformity among state, Federal, and international residue standards; require improved data collection to support implementation of the law; and establish a program of Federal communication to consumers about the risks and benefits of pesticide use.

For a pesticide to be registered for food or feed use, a residue tolerance—the maximum allowable level for a pesticide on a specific food or feed—must be established or a tolerance exemption granted. Before FQPA, pesticide residue tolerances in raw and processed foods were set according to different rules.

Pesticide residues in processed foods came under the jurisdiction of the Delaney Clause of FFDCA, which prohibited any food additives, including residues of any pesticides, "found to induce cancer when ingested by man or animal"—essentially a zero-risk cancer standard. Pesticide residues on raw foods, on the other hand, were regulated under a different section of FFDCA, and the Delaney Clause did not apply. Residue tolerances for raw commodities were set at levels to protect public health. Benefits of pesticide use could be considered in setting residue tolerance levels for raw commodities, but not for processed commodities.

If residues of a pesticide used on a raw commodity appeared in a processed food product, the Delaney Clause applied only if the residue concentration in the processed food exceeded the raw commodity tolerance. In the latter case, EPA would deny (or revoke) the tolerance for the processed food, and would not register the pesticide for use (or would cancel the existing registered use) on the raw commodity.

A 1992 Federal court decision requiring EPA to strictly enforce these provisions of the Delaney Clause precipitated a tolerance review by EPA. As a result, new rules revoked some pesticide residue tolerances on some food and feed products, leading to cancellation of those registered uses under FIFRA. But EPA withdrew all actions revoking tolerances under the Delaney Clause that were not final the day FQPA was signed into law, allowing those tolerances to be assessed under the new review process.

New Safety Standards for Residue Assessments

Parties to the debate that preceded FQPA over appropriate tolerance standards for pesticide residue in foods generally agreed that a uniform standard should apply to both raw commodities and processed products. But disagreement continued over whether the standard should be zero risk or negligible risk for cancer. Some scientists questioned the human cancer risk of residues found at very low levels—parts per billion or trillion.

A 1987 National Academy of Sciences (NAS) report contended that a uniform negligible risk standard would eliminate most existing dietary carcinogenic risk, while allowing low-risk chemicals to be used. The NAS report argued that strict enforcement of the Delaney Clause zero-risk standard would leave several major fruit and vegetable crops without adequate pest control options. Moreover, strict enforcement would also constrain EPA's ability to reduce dietary risks, prohibiting tolerances for pesticides with a slight cancer risk that could be used in place of more hazardous, but not carcinogenic, materials. Required enforcement of the Delaney Clause standards, the NAS report argued, also diverted EPA resources that might address more significant public-health and environmental risks.

The FQPA defined a new safety standard for residue tolerances that would apply to both raw and processed foods. The standard is based on "a 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."

In setting tolerances, EPA must consider dietary exposures to a pesticide from all food uses and from drinking water, as well as from nonoccupational exposure, such as homeowner use of the pesticide for lawn care. If total risk from all currently registered uses of a pesticide exceeds the safety standard, one or more uses will have to be canceled or residue tolerances reduced, and no new uses of the pesticide registered, unless new information shows the risks to be within the standard.

Cumulative effects from other substances with a "common mechanism of toxicity"—substances which create toxic effects through similar chemical processes—are to be considered when evaluating total risk. The effects of these other substances, whether or not they are pesticides themselves, can reduce the allowable risk for a pesticide under review and result in more uses being canceled or residue tolerances reduced. EPA is in the process of defining criteria to group such substances for use in risk evaluations.

The new standard is applied differently for threshold and nonthreshold effects of pesticide residues. For threshold effects—those with an identified level of no known or anticipated harm to human health (no-effect level)—tolerances are set so that aggregate exposure to the residue will be 100 times lower than at the no-effect level. For nonthreshold effects, for which no-effect levels cannot be identified, including many carcinogenic effects, FQPA allows negligible increases in lifetime risk—currently interpreted as an

increased cancer risk of less than 1 in a million over a 70-year lifetime.

As a result of a 1993 NAS study of the risks of pesticide exposure in the diets of infants and children, FQPA also requires EPA to ensure, with reasonable certainty, that no harm will result to infants and children from aggregate exposure. EPA must consider food consumption patterns of infants and children; any special susceptibility to pesticide exposure, including the effects of *in utero* exposure; and the cumulative effects on infants and children of pesticide residues and substances with a common mechanism of toxicity. For threshold effects, an additional tenfold margin of safety will be applied to protect infants and children, which EPA may alter only if reliable data indicate a lower margin of safety will fully protect infants and children.

EPA must review all residue tolerances—more than 9,000—against these new criteria within 10 years of FQPA enactment, giving priority to those that may pose the greatest risk. The timetable specifies 33 percent within 3 years, 66 percent within 6 years, and the remainder within 10 years.

EPA had been reviewing pesticide residue tolerances through its established reregistration process, but FQPA changed the EPA pesticide reregistration process from a one-time review to an ongoing program of periodic reviews of registered uses. EPA will coordinate the new tolerance reviews with registration reviews to the extent possible. Factors to be considered in tolerance reviews include reliability and completeness of data, the nature of any toxic effect, dietary consumption patterns of consumers and major identifiable subgroups, cumulative effects and aggregate exposure levels of consumers, and variable sensitivities of subgroups.

Prior to FQPA, the benefits of a pesticide's use (including such factors as potential changes in production, costs, and consumer prices) could be considered in residue tolerance decisions on raw commodities. Benefits of use can no longer be considered in setting *new* tolerances, but can be considered when evaluating *existing* tolerances on raw commodities or processed foods for pesticides classified as carcinogens. Carcinogenic risks from existing tolerances may be slightly higher than negligible, if use of the pesticide protects consumers from greater health risks or prevents a significant disruption in domestic food production. If necessary, these tolerances may have time limits to meet risk standards defined in FQPA.

The effects of the new limits on benefit considerations in setting tolerance levels for raw commodities should be minimal, since EPA rarely considered benefits in setting tolerances before FQPA. Many observers anticipate that few, if any, existing tolerances will be justified or modified due to benefits, because the tolerances would be identified in FQPA-mandated annual EPA consumer pesticide information pamphlets, and grower and food industry groups would be concerned about public reaction. However, benefits may serve a role in evaluating how to meet a safety standard in a cost-effective manner.

Other Provisions Address Array of Issues

Because the costs of meeting EPA's pesticide registration data requirements have caused voluntary cancellations of some existing minor-use registrations and discouraged new ones, FQPA contains provisions to streamline regulatory procedures for minor uses of pesticides. FQPA defined a minor use as the use of a pesticide on a crop of less than 300,000 acres in total, use on an animal or crop to protect public health from diseases carried by insects or animals, or a use that provides insufficient financial incentive for registration.

In the case of insufficient financial incentive, the pesticide must play a significant role in managing pest resistance or in an integrated pest management (IPM) program, or have insufficient effective alternatives, in order for the new procedures to apply. EPA has extended the deadline for data submissions to support a minor-use registration and can waive data requirements, if the waiver does not prevent a risk determination or allow potential adverse effects on the environment. To further assist in registration of pesticides for minor uses, USDA is required to establish a matching-grant program to develop data needed for registration and reregistration of minor-use pesticides.

FQPA also included provisions affecting uniformity of safety standards within the U.S. and internationally. FQPA generally prohibits states from setting tolerances that differ from EPA tolerances, unless they are justified by compelling local conditions and would cause no food residue levels to be in violation of Federal law. States still may require that foods containing a pesticide residue carry a warning. Supporters of such flexibility, including some environmental groups, argued it is justified by the unique demographic or consumption characteristics of some states. However, many industry representatives voiced concerns about states setting regulatory standards stricter than Federal ones, maintaining such standards could burden interstate commerce; add compliance, testing, and product reformulation costs; expose firms to expensive litigation; and create international trade barriers.

To avoid constraints on international food trade, FQPA requires EPA to consider international *Codex Alimentarius* standards when determining U.S. tolerances. The international *Codex Alimentarius* Commission, sponsored by the United Nations Food and Agriculture Organization and the World Health Organization, establishes maximum residue levels for many chemicals on foods. EPA must publish a notice for public comment when departing from a *Codex* standard.

A number of FQPA provisions require interagency cooperation on IPM adoption and collection of data related to pesticide use and risk estimation. FQPA directs all Federal agencies to promote IPM, and in particular, directs USDA to work with EPA on research, demonstration, and education programs to support IPM adoption. In consultation with EPA and the Department of Health and Human Services (HHS), USDA must conduct surveys to document food consumption by infants and children and to improve collection of pesticide residue data. USDA must also collect state or regional pesticide use data for all major crops and for crops of dietary significance.

By August 1998, EPA, in consultation with USDA and HHS, must develop and annually distribute a pamphlet discussing, in nontechnical terms, the risks and benefits of pesticide residues in food. The pamphlet must cover recommendations for reducing exposure to pesticide residues while maintaining a healthy diet, EPA actions that may result in higher residue risks from certain foods, and a list of reasonable substitutes for these foods. EPA will distribute the pamphlets to large retail grocers, who may determine how to display them.

Also by August 1998, EPA, in consultation with HHS, must develop a screening program to determine if pesticides or other environmental contaminants produce estrogenic or other endocrine effects in humans. If a substance is found to have such an effect, EPA must take action to protect the public. The program must be implemented by August 1999 and reported to Congress by August 2000.

Effect on Availability Of Pesticides

With passage of the FQPA, Congress clearly expressed its concern for reducing health risks associated with pesticides. However, the implications of FQPA for the availability of agricultural pesticides, especially for minor uses, are potentially profound.

The pesticide industry and grower groups are concerned that many registered uses of pesticides will be canceled and that new uses will not be registered. In particular, they fear registrants may cancel uses for small-market crops, such as fruits, nuts, or vegetables, in order to minimize impacts on returns to the registrant.

Reductions in pest control options could ultimately lower yields or increase production costs per acre, unless new options are found. Substantial yield reductions or cost increases would result in reduced U.S. acreage and production,of affected crops, and thus higher prices, as well as regional production shifts and increased imports of those crops, and increased production of crops less affected by the FQPA. The consumer information provisions could shift demand away from "high-risk" foods, lowering their prices and raising prices of substitutes.

The overall balance between negative and positive effects of implementing FQPA is unclear, since some provisions work to increase the number of pesticide registrations, while others reduce them. Certainly, pesticide tolerances and registrations that were subject to the Delaney Clause but meet safety standards under FQPA will be retained, so that producers will not be forced to find alternatives. On the other hand, the consideration of aggregate exposure, substances with a common mechanism of toxicity, risks to infants and children, estrogenic effects, and other risk assessment provisions could result in tolerance revocations and registration cancellations.

New risk provisions for infants and children, in particular, could focus regulatory concerns on fruits and vegetables that are common in children's diets, such as apples, grapes, and corn, disproportionately reducing the number of registered materials for such crops. Moreover, the new, limited role for considering pesticide benefits in the setting of residue tolerances could increase tolerance revocations for raw commodities, although the effects should be minimal, since EPA rarely used its previous broader authority to consider benefits when setting tolerances.

The minor-use provisions of FQPA lower the costs of registering minor-use pesticides and lessen the possibility that important uses will not be registered. But this might not offset the loss of uses due to the new safety standard's aggregate exposure and other risk assessment provisions.

Currently, organophosphate insecticides, carbamate insecticides, and probable and possible carcinogens are high priorities for tolerance review. EPA and USDA will be assembling information for computing exposure, such as dietary consumption of foods, pesticide residues on food, and pesticide use information (e.g., extent of use, application rates, and timing and method of application). Such information may allow reduction of risk estimates from the worst-case level and reduce the number of registered uses lost. But development of cost-effective pest control options, including registration of new pesticides to replace those lost, will ultimately be necessary to minimize the economic impact.

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Upcoming Reports—USDA's Economic Research Service

The following reports will be issued electronically on dates and at times (ET) indicated.

October

1	*Floriculture & Environmental Horticulture**
2	*Fruit & Tree Nuts Yearbook**
3	*Aquaculture (3 pm)*
14	*Cotton & Wool Outlook (4 pm)***
	*Feed Outlook (4 pm)***
	*Oil Crops Outlook (4 pm)***
	*Rice Outlook (4 pm)***
	*Wheat Outlook (4 pm)***
17	*Livestock, Dairy & Poultry (12 noon)*
20	*Newly Independent States Update (previously Former USSR Update)**
21	*Agricultural Outlook**
	*U.S. Agricultural Trade Update**
24	*Oil Crops Yearbook**

*Release of summary, 3 pm.
**Available electronically only.