

FOOD QUALITY PROTECTION ACT OF 1996

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Abstract

The Food Quality Protection Act of 1996 (P.L. 104-170), signed August 3, 1996, amends both the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act to provide a comprehensive and protective regulatory scheme for pesticides.

Food Quality Protection Act of 1996

Following are highlights of FQPA:

Federal Food, Drug, and Cosmetic Act (FFDCA) Provisions

Health-Based Safety Standard for Pesticide Residues in Food: FQPA establishes a strong, health-based safety standard for pesticide residues in all foods. It uses "a reasonable certainty of no harm" as the general safety standard.

- o A single, health-based standard eliminates long standing problems posed by different standards for pesticides in raw and processed foods.
- o Requires EPA to consider all non-occupational sources of exposure, including drinking water, and exposure to other pesticides with a common mechanism of toxicity when setting tolerances.

Special Provisions for Infants and Children: FQPA implements key recommendations of the National Academy of Sciences report, "Pesticides in the Diets of Infants and Children."

- o Requires consideration of children's special sensitivity to pesticides.
- o Requires an explicit determination that tolerances are safe for children.
- o Includes an additional safety factor, when necessary, to account for uncertainty in data relative to children.

Limitations on "Benefits" Considerations: FQPA places specific limits on benefits considerations.

- o Apply only in certain situations, such as most cases where the risk is for development of cancer.
- o Further limited by three "backstops" on the level of risk that could be offset by benefits considerations: (1) a

limit on the acceptable risk in any one year, (2) a limit on the lifetime risk, which would allow EPA to remove tolerances after specific phase-out periods, (3) benefits could not be used to override the health-based standard for children.

Tolerance Reevaluation: Requires review of all existing tolerances within 10 years to make sure they meet the new health-based safety standard.

Endocrine Disruptors (Environmental Hormones): Incorporates provisions for testing of pesticides and other chemicals for possible environmental hormone effects. Provides a schedule for testing and evaluation by EPA.

Right to Know: Requires distribution of a brochure on pesticide health effects, how to avoid risks, and which foods have tolerances based on benefits considerations. Specifically recognizes a state's right to require warnings or labeling of food treated with pesticides, such as California's Proposition 65.

Uniformity of Tolerances: States may not set tolerance levels that differ from national levels unless the state petitions EPA for an exception, based on state-specific situations. National uniformity, however, would not apply to tolerances that included benefits considerations.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Provisions

Pesticide Reregistration Program: Reauthorizes and increases pesticide registrant fees to allow completion of the review of older pesticides to ensure they meet current standards. Tolerances must be reassessed as part of the reregistration program.

Pesticide Registration Renewal: Requires EPA to periodically review pesticide registrations, with a goal of establishing a 15-year cycle, to ensure that all pesticides meet updated safety standards.

Registration of Safer Pesticides: Expedites review of safer pesticides to help them reach market sooner and replace older, potentially more risky chemicals.

Minor Use Pesticides: Establishes minor use programs within EPA and USDA. Encourages "minor use" registrations through extensions for submitting data, extensions for exclusive use of data, possible waivers of some data requirements, and expedited review of minor use applications.

Anti-microbial Pesticides: Establishes new requirements to expedite the review and registration of anti-microbial pesticides.

FQPA Implementation Activities

Shortly after passage of FQPA, EPA established a Food Safety Advisory Committee (FSAC) to help with strategic direction and to provide advice on implementation issues for the pesticide program. This group held four public meetings between September and December 1996. EPA has begun a number of implementation activities, taking into account the Committee's recommendations. A summary report of FSAC meetings will be available by late January.

Informing the Regulated Community and the Public.

EPA has scheduled a number of additional public meetings where implementation of FQPA may be discussed, such as our Pesticide Program Dialogue Committee. EPA is also drafting a Pesticide Registration (PR) Notice which will discuss what information the Agency feels is necessary to make registration decisions under FQPA, at what stage in the process EPA would like the relevant data submitted, and suggests a format to use in submitting data. This PR Notice, to be mailed by mid-February, will assist in "opening the gates" for pesticide registrations. Finally, also by mid-February, EPA will publish an implementation plan for FQPA which will provide details on what specific activities EPA is undertaking to comply with FQPA requirements (e.g. rules and regulations) and the timeframe for completion of each activity.

Registration Activities. Everyone agrees that additional resources are needed to implement FQPA. For example, the number of tolerances to be assessed quadruples annually. EPA did receive supplemental funding for 1997. The Agency is continuing to make registration decisions within the framework of FQPA.

Cotton Specific Registration Activities. There are currently two pending registration actions which have cotton uses.

Spinosad - a reduced risk product for which a final decision on registration should be made by late January.

Pirate - not reduced risk but has had an emergency exemption for the past two years. A registration decision is expected by mid-February for Pirate.

Emergency Exemptions under FIFRA Section 18. Last year, EPA worked with grower groups and interested states to develop a pre-emptive approach to Section 18s. Under this approach, approval for use of some pesticides was granted on the condition that use was delayed until certain infestation thresholds were met. This provided growers with information on what would be available if an emergency occurred. Based on input from growers and states, this approach proved very successful and EPA will begin discussions this week to develop threshold levels for this growing season.

Bt Cotton. In addition to new registrations and emergency exemptions, EPA is interested in your experience with Bt Cotton. We are concerned about potential development of resistance and will continue working with industry, growers, crop consultants, and public interest groups to refine and improve resistance management plans.

Pesticide Environmental Stewardship Program

Through the use of tools such as Bt Cotton, and applications for products such as Spinosad, cotton growers have become better environmental stewards. EPA has a program, the Pesticide Environmental Stewardship Program (PESP), to assist in this effort. PESP is a voluntary public/private partnership to reduce pesticide risk and use. As we move through FQPA implementation, the work being done through the PESP program will help find innovative ways to meet the law's requirements without sacrificing productivity.

Who Are Members of PESP? Partners are organizations representing pesticide users, for example the National Potato Council, the American Corn Growers Association, and the California Tomato Board. Supporters are organizations that are involved with pesticide users but are not pesticide users themselves, for example General Mills, Inc., Gerber Products Company, and the U.S. Golf Association.

What Are Members' Commitments? Partners agree to the principles of pesticide risk and use regulation, complete a strategy detailing how their organization will pursue pesticide risk and use reduction, and keep EPA updated on their progress. Supporters agree to the principles of pesticide risk and use reduction, develop a project to advance the goals of pesticide risk and use reduction, and update EPA on their progress.

What Are EPA's Commitments? In return for joining PESP as a partner or supporter, EPA provides a liaison who acts as a single point of contact for the Agency. In addition, EPA offers assistance with the development of PESP strategies and projects. Finally, EPA offers grants for risk and use reduction implementation and considers the needs of members when making regulatory decisions.

In Summary

FQPA contains many new obligations for the Environmental Protection Agency.

FQPA also presents many new opportunities for greater protection of human health and the environment.

The new law makes it imperative that pesticide users assume a greater role.

We welcome your input during the implementation process.

1997 will be a transitional year; we ask for your patience and support and we work together to bring about the worthy goals of the FQPA.