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Pesticide Legislation: Food Quality Protection Act of 1996 (P.L. 104-170)

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ABSTRACT

This report summarizes the Food Quality Protection Act of 1996 (FQPA), enacted by the 104th Congress as Public Law 104-170. It also analyzes issues in the regulation of pesticide sales and use and the potential impact of FQPA amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Appendix A briefly describes the authorities and provisions of the FIFRA and FFDCA, as amended by FQPA. Appendix B provides a section-by-section summary of Public Law 104-170. This report will not be updated.

Pesticide Legislation: Food Quality Protection Act of 1996 (P.L. 104-170)

Summary

The 104th Congress enacted significant changes to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), governing U.S. sale and use of pesticide products, and the Federal Food, Drug, and Cosmetic Act (FFDCA), which limits pesticide residues on food. The vehicle of these changes was H.R. 1627, the "Food Quality Protection Act of 1996" (FQPA), enacted August 3, 1996, as P.L. 104-170. Under FIFRA, the new law will facilitate registrations and reregistrations of pesticides for special (so-called "minor") uses and authorize collection of maintenance fees to support pesticide reregistration. Coordination of regulations implementing FIFRA and FFDCA will be required. Food safety provisions will establish a single standard of safety for pesticide residue on raw and processed foods; provide information through large food retail stores to consumers about the health risks of pesticide residues and how to avoid them; preempt state and local food safety laws if they are based on concentrations of pesticide residues below recently established federal residue limits (called "tolerances"); and ensure that tolerances protect the health of infants and children.

Contrary to widespread reports, the FQPA does not repeal the Delaney Clause or amend FFDCA Section 409: food additives that are not pesticide residues remain subject to the "zero-risk" Delaney standard. Rather, P.L. 104-170 eliminated the distinction between raw and processed food tolerances so that all pesticide residues will be regulated under an amended FFDCA Section 408. New Section 408 requires all tolerances to be "safe," ensuring a "reasonable certainty of no harm" from pesticides. It authorizes slightly higher residue concentrations on foods when pesticide use avoids greater health risks to consumers or significant disruptions to domestic production of an adequate, wholesome, and economical food supply.

The FQPA, as enacted, does not address two issues that were addressed by H.R. 1627, as introduced and reported in the House, but were deleted before the House and Senate debates. The FQPA does not include a proposal to federally preempt local pesticide use regulations which was opposed by several states with laws either authorizing or preempting local regulation. The FQPA also omits a provision opposed by Indian tribes and the Administration that would have prohibited tribal enforcement of pesticide use laws on land within tribal boundaries if less than half that land were owned by the tribe or tribal members.

The FQPA has widespread support in the community of growers, food processors, chemical suppliers, environmental and consumer advocacy groups, and state government agriculture officials. The Clinton Administration also generally supports its provisions.

For readers not familiar with the statutes, Appendix A describes key FIFRA and FFDCA authorities and provisions. Appendix B provides a brief section-by-section summary of P.L. 104-170.

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Introduction

The 104th Congress enacted significant changes to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), governing 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 H.R. 1627, the "Food Quality Protection Act of 1996" (FQPA), enacted August 3, 1996 as Public Law 104-170. This report summarizes and analyzes provisions of the new law. It also describes key provisions in the bill as reported in the House that were omitted prior to debate on the House floor and markup in the Senate.

In general, key FIFRA issues revolved around: the roles of state, local, and tribal governments in pesticide regulation and federal law enforcement; the cost of scientific tests required by the U.S. Environmental Protection Agency (EPA) to support pesticide registration and reregistration, and delays in processing applications for new or amended registrations, especially for minor uses; and long delays in reregistration of older pesticides and the need for fees to support the effort. A lesser issue involved state authority to require training of persons who regularly apply non-restricted pesticides in urban and suburban areas.

In this context, congressional concerns about FFDCA centered on the so-called "zero-risk" standard of Section 409 (the Delaney Clause) for concentrated residues in processed foods of pesticides that produce cancer in experimental animals. There also were generally recognized needs for better data on risks to infants and children from pesticide residues on food; coordination of tolerance revocations with pesticide food-use cancellation; and increased monitoring of food imports for pesticide residues. Other issues included a proposal for federal preemption of state and local authority to impose requirements on food with pesticide residues that are not unsafe based on federal law and EPA adoption of international residue standards.

All of these issues were addressed in H.R. 1627, as introduced; provisions related to pesticide use were approved, amended, in May 1995 by a subcommittee of the House Agriculture Committee. The full Committee further amended and reported the bill in July 11, 1996. Food safety provisions were referred to the House Commerce Committee, which reported July 23, 1996 (H.Rept. 104-669, Parts I and II). The bill was further amended after being reported in the House but prior to House debate and passage July 23, 1996. The Senate Committee on Agriculture, Nutrition, and Forestry incorporated House-passed language as a substitute for the

provisions of S. 1166, and the Senate passed H.R. 1627 the same night, July 24, 1996. The FQPA was amended after it was reported but before it was debated and passed in the House and referred to the Senate. This amended FQPA omitted provisions that were controversial in the House-reported bill that would have preempted local pesticide use ordinances and prohibited tribal enforcement of pesticide use laws within reservation boundaries.

Key Issues Addressed by the Food Quality Protection Act of 1996

In the following text, analysis of provisions related to pesticide uses, including amendments to FIFRA, precedes analysis of food safety provisions and FFDCA amendments. Within this framework, issues are considered roughly in the order they are treated in the FQPA.

Pesticide Use Provisions and Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Expediting Suspensions of Registration for Imminent Hazards. Cancelling a pesticide registration, when it is found to cause "unreasonable adverse effects," can be a prolonged process, lasting 4 to 8 years or more. To prevent an "imminent hazard" during this period, EPA can suspend registration — meaning that use of the pesticide is immediately prohibited — but not before EPA has published, or provided the registrant with, a notice of its intention to cancel the registration. Before the FQPA, FIFRA allowed EPA in an emergency to issue a suspension order at the same time it proposed to cancel or change a registration, and the suspension could become final after 30 days. However, the Clinton Administration wanted to allow suspensions in cases of "imminent hazard" *before* any cancellation action. Others, such as the National Association of State Departments of Agriculture (NASDA), which represents the 54 leading public officials for agricultural policy in each state and territory, found the existing authority adequate.

Public Law 104-170 allows EPA to issue a suspension order in an emergency, before issuing a notice that it intends to cancel a registration or to change a classification of the pesticide, but the suspension order will expire after 90 days if EPA does not provide notice by that time.

Training Pesticide Applicators in Urban and Suburban Areas. While not a particularly large proportion of total pesticide use by volume, household and business uses of pesticides in urban and suburban settings may lead to exposure of larger and more diverse populations than in agricultural applications. Concerns about such exposures include immediate toxic reactions in sensitive individuals, as well as less visible but longer-term health effects such as cancer. Pesticides that end up in rivers, lakes, and groundwater are considered a significant water pollution problem. This can result from excessive and improper application or improper disposal of pesticide containers, for example. While these concerns apply to agricultural applications as well, urban/suburban uses are sometimes at higher concentrations and may be applied by persons unfamiliar with risks or proper application practices.

Moreover, when pesticides are applied to lawns and gardens, golf courses, roadsides, public buildings, apartment buildings, and single-family homes, the people exposed may be very young or elderly and in robust or fragile health. People may be exposed to pesticides in such settings unknowingly or at least without prior warning, as for example, when entering a recently treated roadside area or public building.

Concerns about routine applications of pesticides in urban and suburban areas have led to calls for training of "maintenance applicators" of unrestricted pesticides, such as janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. (Applicators of restricted pesticides already must be trained.) The FQPA, Title I, Subtitle B adds a new section to FIFRA authorizing, but not requiring, states to establish minimum requirements for training of maintenance pesticide applicators and any individual who uses or supervises the use of pesticides not classified for restricted use for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. Any training provided must include instruction in the safe and effective handling and use of pesticides in accordance with EPA-approved labels and in integrated pest management techniques. Requirements do not apply to government employees, individuals who use antimicrobial pesticides, private (e.g., household) use of pesticides, or any use of ready-to-use consumer products. The bill authorizes EPA only to inform states about the provisions of this subtitle.

Facilitating Minor Use Registration and Reregistration. According to experts, about 1000 pesticide use registrations important to the agricultural community for low-acreage, specialty crops (so-called "minor" agricultural uses) may be canceled rather that reregistered.[1] Another 2,600 new minor-use registrations would be submitted through FY1997 to meet new pest control needs or to replace disappearing minor-use registrations.[2] Without such registrations, production of many fruit, nut, and vegetable crops might be more costly, result in lower quality, and diminish availability to consumers. Any loss in productivity could have a detrimental economic impact on agricultural interests, and possibly an adverse impact on consumer nutrition. About $35 billion in fruit, vegetable, and other specialty crops are produced annually in the United States (20% of total farm receipts, 42% of total crop receipts). Some farmers also believe the loss of minor-use pesticide products will put them at a competitive disadvantage with foreign producers who would continue to have access to the pesticides.

Although producers sometimes may cancel a registration because they fear complete safety testing will reveal an unreasonable risk from the pesticide use, the more common obstacle to maintaining the availability of pesticides for minor uses is economic: for some pesticides the markets are not large enough to economically justify the testing costs of maintaining minor-use registrations. These problems persist despite amendments to FIFRA in the 1990 farm bill (Public Law 101-624) which: eliminated a requirement for field residue data — the data most often lacking for minor food uses — for minor use pesticides in geographic areas where the

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[1]Pesticides: Minor Uses/Major Issues. Council for Agricultural Science and Technology. Ames, Iowa, 1992. P. 3, 5.

[2]Ibid.

pesticide would not be registered for use; authorized EPA to reduce or waive the fee for a minor use pesticide registration; required public notice of voluntary registration cancellations and established a grace period to transfer registrations for minor use pesticides to new registrants; and authorized research that emphasized minor or local pests.

EPA would like to expedite procedures for registering minor-use pesticides. The Agency claims that it is now doing as much as possible administratively under FIFRA to expedite the process of minor-use approval. Concerned growers have organized the Minor Crop Farmers Alliance to seek legislative remedies. One of their goals is to increase federal funding through such programs as the USDA interregional project (IR-4) for data collection in support of minor-use registration.

The FQPA, Title II, Subtitle A, addresses minor uses of pesticides. All interest groups as well as EPA backed these provisions. In support of minor-use registrations and reregistrations, the FQPA will:

- extend time periods allowed for submissions of pesticide residue chemistry data;
- authorize EPA to waive data requirements for minor-use pesticides;
- direct EPA to expedite processing of complete minor-use registration applications;
- temporarily extend registration for 180 days, rather than the current 90 days, to provide additional time for registrants who do not support continued registration of a minor use to arrange transfer of the registration to another producer;
- facilitate registration transfers;
- establish a program in EPA to coordinate its minor use pesticide activities;
- require USDA to coordinate its minor use pesticide activities; and
- establish and authorize funding for a minor use grant program to develop required data.

The FQPA also extends the period of exclusive use — that is, the years during which no one but the original registrant may use the safety data — for registrants of minor uses. This will provide more time for the registrant to recover costs and make a profit. The current 10-year period of exclusive use is expanded one additional year for each 3 minor uses registered within 7 years of the first use registration. No exclusive use period can be longer than 13 years. Data supporting a new minor use registered after the original exclusive use period has lapsed is protected for 10 years, as long as the data are not used to support a registration for a non-minor use and the minor use registration remains in effect.

The FQPA requires EPA to report within 3 years of enactment on its progress in registering minor uses.

A second category of minor-use pesticides are the "antimicrobial pesticides" used, for example, as preservatives in paint, antifoulants in industrial cooling water, disinfectants, and sanitizers. The FQPA, Title II, Subtitle B sets time limits for registration of such pesticides and directs EPA to identify and evaluate reforms to the registration process to reduce review periods to the maximum extent practicable. Maximum time periods for review are specified in Subtitle B for various activities. EPA believes that these provisions might divert scarce EPA resources from more important tasks.

Some pesticides used to protect public health from diseases carried by insects or other animals are considered minor-use pesticides. The FQPA, Title II, Subtitle C extends some of the provisions for agricultural minor uses to "public health pesticides," but also increases the involvement of the DHHS Secretary in decisions about pesticide registration.[3] It also directs EPA to identify pests of significant public health importance and to analyze and compare public health benefits of pesticide use against the risks. This subtitle authorizes appropriations up to $12 million for FY1997 and "such sums as may be necessary" thereafter to implement FIFRA Section 4.[4] EPA supported these provisions.

Title II, Subtitle D of the FQPA establishes an expedited review process for applications to register or amend registrations for pesticides that are expected to reduce overall pesticide risks. EPA also supported this subtitle.

Promoting Integrated Pest Management (IPM). Title III defines "integrated pest management" and directs USDA and EPA to cooperate in establishing a research, demonstration, and education program to support adoption of IPM techniques. In addition, federal agencies would be directed to use and promote IPM. This provision was not controversial.

Coordinating FIFRA and FFDCA Regulations for Food-Use Pesticides

EPA has a long-standing policy of coordinating implementation of all statutory provisions governing pesticides for food uses, which the agency recently reaffirmed (61 *Federal Register* 2378, Jan. 25, 1996). Based on this coordination policy, EPA revoked FFDCA Section 408 tolerances for raw agricultural commodities if it revoked the corresponding FFDCA Section 409 food additive tolerances for residues in processed foods. Public Law 104-170 eliminates the distinction between raw and processed food tolerances and the need to coordinate two sets of tolerances, because FFDCA now regulates all pesticide residues under an amended FFDCA Section 408.

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[3]The DHHS Secretary delegates duties under FFDCA to FDA.

[4]Based on the heading for subsection (m), "Authorization of Funds To Develop Public Health Data," this $12 million is intended to develop data to support registration of public health pesticides, but the sentence authorizing appropriations states that it is "to carry out the purposes of this section" [emphasis added].

To ensure that pesticide registrations are based on current scientific and legal standards, FIFRA requires EPA to reregister all pesticides registered for use prior to 1984. Prior to enactment of P.L. 104-170, FFDCA did not have a similar requirement for revisiting pesticide residue tolerances. EPA partly addressed concerns about tolerances for older pesticides through its coordination policy: EPA revoked FFDCA pesticide residue tolerances after it canceled the corresponding FIFRA pesticide registrations for food uses if (and vice versa). However, EPA took 6 years on average, far longer than necessary, according to a December 1994 GAO report, to revoke tolerances after food-use pesticide registrations were canceled.[5] Delays in completing the reregistration process were further cause for concern about the adequacy of older tolerances to protect human health.

Public Law 104-170 mandates FIFRA-FFDCA coordination as well as periodic review of tolerances for pesticide residues. All tolerances and exemptions in effect when P.L. 104-170 was enacted must be reviewed within 10 years. The law also requires EPA to reevaluate FFDCA tolerances and exemptions when reregistering older pesticides for uses on food and animal feed. It requires EPA to revoke or suspend tolerances for pesticides if the relevant food-use registration is canceled or suspended under FIFRA. Revocation of a tolerance will become effective within 180 days of the date on which the pesticide use becomes unlawful, unless residue of the pesticide will unavoidably persist. The reverse situation also is covered: by amending the FIFRA definition of "unreasonable adverse effects on the environment" to include human dietary risk from pesticide residue that violates a tolerance, it will prevent EPA from registering a pesticide (or will require cancellation of an existing registration) for a food use if a tolerance cannot be established (or is revoked) for *that* pesticide on *that* food. The FQPA also requires EPA to establish tolerances for residues that are expected to result from pesticide applications to foods allowed because EPA has granted an emergency exemption from FIFRA registration requirements under FIFRA Section 18.

Food Safety Provisions and Amendments to the Federal Food, Drug, and Cosmetic Act

Reducing Reregistration Delays. Since 1972, FIFRA has required EPA to reregister older pesticides based on data that meet current registration and scientific standards. Long concerned with EPA's progress in reregistration, Congress strengthened and accelerated FIFRA requirements in 1988 and directed the Agency to reregister by 1997 all pesticides originally registered before 1984, when less toxicity information was available. By September 30, 1995, EPA had completed reregistration actions for 170 or about 30% of the active pesticide ingredients for which manufacturers support reregistration. Early in 1996, EPA expected to complete reregistration by the end of FY2004, 7 years after the 1988-mandated deadline of FY1997.

During the debate over H.R. 1627, EPA argued that timely completion of reregistration required that Congress increase and extend EPA's funding authority;

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[5]U.S. GAO. Pesticides: Reducing Exposure to Residues of Canceled Pesticides, GAO/RCED-95-23. Gaithersburg, MD.

this authority would have expired September 30, 1997.[6] Reregistration is financed through a combination of appropriated funds and registration "maintenance" fees paid by pesticide manufacturers. Fee collections have been lower and costs higher than originally anticipated, according to EPA. EPA and pesticide registrants agreed upon a schedule of increased revenues that Congress authorized in a package of technical amendments to the 1990 farm bill (P.L. 102-237). It increased the annual registration maintenance fee cap while allowing continued agency discretion to adjust product fees to generate $14 million annually to carry out reregistration. In spite of this change, last year EPA estimated a budget deficit of $105 million to complete reregistration. In 1996, the Assistant Administrator for Prevention, Pesticides, and Toxic Substances predicted that FY1996 registration and reregistration would be at least 20% less than in FY1995 due to budget constraints and the government shutdown.

The FQPA, Title V, extends EPA authorization to collect $14 million annually in registration maintenance fees from pesticide registrants until the end of FY2001. It authorizes collection of up to $2 million in additional fees in FY1998, FY1999, and FY2000. EPA is required to complete processing of all pending applications for expedited review within 5 years of enactment.

Although pesticide manufacturers supported this extension of the maintenance fees, they argued that historical funding levels had been adequate, and they questioned whether EPA had managed funds efficiently. The industry wanted the Agency to develop a system of accountability for expenditures on reregistration. A recent General Accounting Office (GAO) report responding to a request by the House Committee on Agriculture appeared to support industry's position.[7] GAO recommended that Congress require a fiscal 1996 full scope audit of the FIFRA fund to consider "the reasonableness of the overhead allocation and the adequacy of disclosures of direct and indirect costs."[8] In addition, EPA should prepare a schedule for the reregistration process indicating how many reregistration decisions will be completed each year and specifying the chemical cases to which decisions will apply, according to the report. GAO indicated that such measures would allow Congress to oversee EPA efforts to ensure that the high-risk pesticides are addressed first. (FIFRA requires EPA to give priority in reregistration to certain pesticides, including pesticide active ingredients used on food that may result in post-harvest residues (7 USC 136a-1(c)(1)(A)). GAO suggested amending H.R. 1627 to incorporate these recommendations.

As GAO suggested, Congress enacted FQPA provisions directing EPA to establish and publish annually performance measures and goals, including goals for reregistration, and to ensure that expenditures from fees are used only to accomplish

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[6]The President's "Balanced Budget Act of 1995 for Economic Growth and Fairness" proposes extending until 1999 existing EPA authority to impose maintenance fees; this authority expires in FY1997. The President also would authorize collection of additional fees to support reregistration.

[7]U.S. GAO. FIFRA Reporting Requirements. GAO/AIMD/RCED-96-21R. Gaithersburg, MD.

[8]Ibid.

those goals. The FQPA also requires an annual audit of the fees collected and disbursed, and EPA attainment of performance goals.

One reason for higher than expected costs and reregistration delays has been late and deficient reregistration package submissions, according to EPA, and these problems are being addressed. EPA requires manufacturers applying to register or reregister a pesticide to submit reports of scientific studies on pesticide toxicity and behavior in the environment. The Agency requires that studies conducted by industry conform to EPA standards of scientific quality. Studies that do not meet EPA standards are rejected and must be repeated and then reevaluated. Rejected studies contribute to the high cost of registration. While pesticide registrants have argued that EPA's scientific standards for maintaining pesticide registrations are excessive, EPA has insisted that registration decisions should be based on the best available science. In the past, EPA rejected approximately 30% of studies submitted. A 1991 analysis of factors contributing to late and deficient study submissions prompted a joint EPA-industry project to improve performance. Due to workshops, additional EPA guidance, and independent efforts of individual companies, the study rejection rate today is half of what it was 3 years ago and many submissions are more timely, according to EPA.

Some argued that industries have little incentive to submit timely and adequate applications to maintain registrations of older pesticides; while a decision is pending about the safety of the older pesticides, manufacturers may continue to market them. The sooner the application is complete, the sooner EPA will be able to make a reregistration eligibility decision (RED), and there is no guarantee that EPA will declare the pesticide eligible to be reregistered for all uses, given current safety standards. Delayed REDs (and delayed potential registration cancellations), in turn, reduce demand for alternative pesticide products. This is true in part because new product alternatives, although they may be less hazardous and equivalently effective for similar uses, tend to be more expensive than older products that have not been subjected to the full battery of safety studies, giving them a competitive advantage over newer pesticides.

Provisions of the FQPA meant to reduce potential disincentives to registration and reregistration of certain minor-use pesticides were discussed above. In addition, the FQPA directs the Administrator to require the submission of data when necessary for registration review which the FQPA requires periodically, with a goal of every 15 years. To ensure data submission in a timely manner, the FQPA requires EPA to suspend a registration if the registrant fails to take appropriate steps to secure the data required within the time required by the Administrator.

Protecting Infants and Children from Pesticide Residues in the Diet. For several years, Congress has been concerned about pesticide residues in the diets of infants and children. A 1993 National Academy of Sciences (NAS), National Research Council (NRC) report concluded that there are both quantitative and sometimes qualitative differences between children and adults in toxicity of

pesticides and in exposure to pesticide residues in foods.[9] It recommended that "better data on dietary exposure to pesticide residues should be combined with improved information on the potentially harmful effects of pesticides on infants and children."[10] Information on the potentially harmful effects of pesticides would be improved, it stated, by toxicological testing of pesticides to determine perinatal and childhood toxicity and developing better methods to estimate exposure and the magnitude of potential adverse health effects. The committee also advised EPA to revise its process for setting pesticide residue tolerances under the FFDCA so as to safeguard the health of infants and children.

The FQPA, Title III requires that the USDA Secretary, in consultation with EPA and DHHS —

- develop and implement procedures to collect data on food consumption patterns of infants and children;
- improve residue data collection by providing guidelines for analysis and reporting and increasing sampling of foods most likely consumed by infants and children; and
- collect data of statewide or regional significance on pesticide use on major crops and crops of dietary significance.

In addition, EPA is required to ensure that pesticide tolerances adequately safeguard the health of infants and children (Section 405, amending FFDCA Section 408(b)(1)(E)).

Some scientists have argued that data gathering provisions alone are not adequate to protect the health of infants and children; their sensitivities and exposures must be taken into account in risk assessment and tolerance setting, these scientists say. The Administration asked Congress to require EPA to consider the diets and sensitivity of children in setting tolerances.[11] Congress added such provisions by amending tolerance setting procedures of the FFDCA Section 408. (See the discussion below.)

In addition, Title III requires EPA to report to Congress on progress in improving federal efforts to collect pesticide use information, including an analysis of the quality and reliability of information collected by USDA, EPA, and other federal agencies and of options to improve performance with respect to costs, burdens on pesticide users, and tracking of risk reduction.

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[9]Pesticides in the Diets of Infants and Children, Washington, DC, National Academy Press. (1993) 386 p.

[10]Ibid. P. 12.

[11]U.S. Congress. House. Committee on Agriculture. Subcommittee on Department Operations, Nutrition, and Foreign Agriculture. Food Quality Protection Act of 1995. Hearing, 104th Cong., 1st Sess., May 16, 1995. Washington, U.S. Govt. Print. Off., 1995. P. 15.

Revising Tolerance-Setting Criteria for Pesticide Residues in Food.

The Delaney Clause. A key issue in the 104th Congress was whether to revise the so-called "zero-risk" standard of the Delaney Clause (FFDCA, Section 409) which prohibits the addition of potentially cancer-causing substances to foods. The application of the Delaney Clause to pesticide residues has been criticized for being unscientific and creating a confusing and inconsistent set of standards for safety, depending on whether a pesticide was on a raw or processed food and whether it was a carcinogen or not.

Critics of pesticide regulation under the Delaney Clause maintained that it was unscientific, because very small pesticide residues pose no significant risk to health. Technology is now sophisticated enough to detect extremely small amounts of pesticides in food, in some cases levels of parts per trillion. Thus, food industry representatives claimed that rigid enforcement of the Delaney Clause (i.e., banning any measurable pesticide concentration) stifled research and development of new pesticides which might have been safer than products on the market. Critics noted that many foods contain natural carcinogens (which are not regulated under Delaney) that may be more concentrated and more potent than pesticide chemical residues; they said that residues might even have resulted from pesticide use to control fungi or bacteria that produce natural carcinogens. In addition, they claimed that in some cases, the distinction between raw and processed foods made no sense: the absolute 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 the residue in processed food, because the residue had concentrated relative to the total food weight (due to drying or other processing).

Delaney Clause supporters argued that the public does not want to be exposed to carcinogenic pesticides in their food, no matter how small the risk. With regard to naturally occurring carcinogens in food, they argued that federal agencies could not readily assess and reduce that risk, especially since natural anti-carcinogens often are found in the same food as the carcinogens. To reduce the overall cancer risk, therefore, they believe the federal government should minimize pesticide chemical residues in food.

The Delaney Clause also was problematic, according to some, because it required regulators to treat potentially carcinogenic pesticides more stringently than pesticides that may exert other health effects. This situation set up a paradox: by stringently regulating carcinogens, Section 409 may have reduced the safety of some foods. Section 409 allowed approval of pesticide residues that posed greater risks than residues of carcinogens which Section 409 did not permit, because many registered pesticide products have health effects other than cancer. For this reason, the National Research Council (NRC) of the National Academy of Sciences recommended in 1987 that all pesticide residues in food, whether raw or processed, should be regulated on the basis of a consistent "negligible risk" standard.[12]

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[12]National Research Council, National Academy of Sciences. Regulating Pesticides in Foods: The Delaney Paradox, Washington, National Academy Press, 1987. 272 p.

A New Standard of Food Safety. H.R. 1627, as introduced, proposed a single "negligible risk" standard for pesticide residue tolerances. This provision was strongly supported by food processors, growers, the agricultural chemical industry, and the National Association of State Departments of Agriculture (NASDA). Others preferred keeping the "zero-risk" standard and phasing out the use on food of pesticides classified as "probable human carcinogens."[13]

The Administration favored a single statutory standard for pesticide residues in raw and processed food. However, it argued that for pesticide residues with health effects other than cancer, such as birth defects or neurotoxicity, it was unclear how a negligible risk standard would apply.[14] EPA wanted to set tolerances based on the health-based standard for non-carcinogens in the FFDCA, Section 409 — "a reasonable certainty of no harm."[15] The Administration's view is reflected in the FQPA.

The FQPA, Title IV amended the FFDCA, but did not amend or repeal Section 409 which contains the Delaney Clause; Section 409 remains in effect for food additives that are not pesticide residues. Rather, the FQPA redefined terms such as "pesticide chemical" and "food additive" so that residues of pesticides in processed as well as raw foods will be regulated under an amended Section 408, rather than under Section 409. Section 408 tolerances also will apply to residues of breakdown products of pesticides — i.e., substances resulting from metabolism or degradation of pesticides — and to residues of inert ingredients and their breakdown products in raw and processed food.

As amended by the FQPA, Section 408 authorizes EPA to set a tolerance for a pesticide residue in or on food (whether raw or processed) only if the Administrator decides that the tolerance is "safe." A "safe" tolerance is defined as a level at which

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[13]Depending on the overall weight of scientific evidence for carcinogenicity, EPA has classified some chemicals, including pesticides, as:
Group A - Known human carcinogens
Group B - Probable human carcinogens
Group C - Possible human carcinogens
Group D - Inadequate evidence to classify, or
Group E - Not likely to be carcinogenic to humans

This classification scheme may soon change: EPA has proposed new guidelines for cancer risk assessment. The new scheme would describe the cancer-causing potential of a chemical in a narrative up to two pages long. Carcinogenic potential would be categorized as "likely," "known," "not likely," and "cannot be determined."

[14]U.S. Congress. House. Committee on Agriculture. Subcommittee on Department Operations, Nutrition, and Foreign Agriculture. Food Quality Protection Act of 1995. Hearing, 104th Cong., 1st Sess., May 16, 1995. Washington, U.S. Govt. Print. Off., 1995. P. 15.

[15]The phrase "a reasonable certainty of no harm" is taken from the legislative history of FFDCA, Section 409: "Safety requires proof of a reasonable certainty that no harm will result from a proposed use of an additive. It does not — and cannot — require proof beyond any possible doubt that no harm will result under any conceivable circumstance" (H. Rept. 2284, 85th Cong., 2d Sess. (1958)).

there is "a reasonable certainty of no harm" from the exposure. This is the same standard that formerly was applied to non-carcinogenic pesticide residues in processed foods under Section 409. However, the new law requires EPA to assess safety in terms of total exposure to the pesticide (that is, to the concentration of pesticide allowed by the tolerance together with all other dietary and non-food exposures for which there is reliable information) and to other pesticides that have the same toxic effects on people. No quantitative standard of safety is established by the new law, but the Committee on Commerce expects EPA to continue setting standards to ensure safety as it has in the past:

> ... the Committee expects that a tolerance will provide a 'reasonable certainty of no harm' if the Administrator determines that the aggregate exposure to the pesticide chemical residue will be lower by an ample margin of safety than the level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. The Committee further expects, based on discussions with the Environmental Protection Agency, that the Administrator will interpret an ample margin of safety to be a 100-fold safety factor applied to the scientifically determined 'no observable effect' level when data are extrapolated from animal studies.[16]

In determining a safe level, EPA is directed to take into account many factors, including available information on dietary exposure to pesticides among infants and children.

Costs and Benefits. Prior to P.L. 104-170, EPA set tolerances for pesticide residues in processed foods under Section 409 to ensure that they were safe, without considering benefits of pesticide use. In contrast, EPA balanced risks and benefits in setting tolerances under Section 408. H.R. 1627, as introduced, would have regulated pesticide residues under the old Section 408 standard. It also would have allowed EPA to set tolerances for residues posing more than a negligible risk if the risk were "not unreasonable" relative to the benefits of pesticide use. The Administration objected to this proposal. In its view, agencies should weigh only health risks and benefits that accrue to consumers, without consideration of the "broader benefits considerations, such as regional benefits, regional economic benefits, or economic benefits that are not direct benefits to consumers."[17] In contrast, NASDA wanted benefits to the agricultural economy weighed against the risks of pesticide use.

As enacted, FQPA strictly limits the nature and influence of benefits considered in tolerance setting under Section 408. It allows EPA to maintain or modify existing tolerances (but not to establish new tolerances) at higher than "safe" residue levels only if the pesticide use avoids other greater risks to consumers or is necessary to avoid significant disruption in domestic production of an adequate, wholesome, and economical food supply. Such higher tolerance levels may be set only for pesticides that are potential carcinogens (or have some other health effect) for which there is no known level of exposure at which no harm is anticipated (known as a non-threshold

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[16]U.S. House. Committee on Commerce. Food Quality Protection Act of 1996, H.Rept. 104-669, Part 2, 104th Congress, 2nd Sess. 1996. P. 6.

[17]Ibid.

effect). The higher tolerance level allowed for such pesticide residues must be "safe" for infants and children as well as with respect to health effects for which there is a known threshold (that is, a level below which exposure is known to be harmless). The higher cancer (or other non-threshold) risk posed by the tolerance may not be more than 10 times the risk at a "safe" level of exposure on an annual basis and not more than twice the risk of a "safe" level over a lifetime.

For nonthreshold effects, the House Commerce Committee provided additional guidance for establishing a level of residue that should be considered "safe."

> In the case of a nonthreshold effect which can be assessed through quantitative risk assessment, such as a cancer effect, the Committee expects, based on its understanding of current EPA practice, that a tolerance will be considered to provide a 'reasonable certainty of no harm' if any increase in lifetime risk, based on quantitative risk assessment using conservative assumptions, will be no greater than 'negligible.' It is the Committee's understanding that, under current EPA practice, ... EPA interprets a negligible risk to be a one-in-a-million lifetime risk. The Committee expects the Administrator to continue to follow this interpretation.[18]

The FQPA also requires EPA to distribute to major food stores nationwide easily understood information for public display about the risks and benefits of such pesticide residues on food and how consumers may avoid the risks without sacrificing nutrition.

The National Coalition Against the Misuse of Pesticides reportedly has criticized the new law for "legalizing levels of pesticides that cause cancer and other adverse effects."[19] However, very small risks from low concentrations of pesticide residues such as those permitted under the FQPA also were permitted prior to passage of the new law. In addition, low concentrations of potential carcinogens were legal on raw food before passage of the FQPA, as long as the risks were reasonable considering the benefits of the pesticide. The new Section 408 tightens the standard for pesticide residues in food. In the future, raw food tolerances, as well as tolerances for processed foods, must be "safe" and ensure with "a reasonable certainty" that no harm will result from exposure to that residue, other residues on other foods, other sources, and other pesticides that have the same toxic effects on people. Only pesticides with health effects that have no known threshold (e.g., some cancers) are excepted from the "safe" standard, only under specified conditions, and only if the increased risk is within strict limits. Moreover, the new law allows growers to avoid use of pesticides that pose relatively large risks of health effects other than cancer by allowing pesticide residues in processed foods that pose smaller cancer risks.

Other Provisions Affecting Tolerances. The FQPA directs EPA to develop a screening program to evaluate whether pesticides may have effects in humans that are similar to effects produced by naturally occurring estrogen or other endocrine

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[18]Ibid.

[19]Broderick, Brian, "House repeals Delaney Clause in compromise FIFRA, FFDCA bill, Daily Environmental News, July 24, 1996. Bureau of National Affairs, Washington, p. A-1.

effects. If EPA finds such effects, it is required to use its existing statutory authority to ensure the protection of public health.

Finally, the FQPA directs EPA to review within 10 years of enactment all pesticide residue tolerances and exemptions in effect before enactment. It authorizes anyone to petition EPA to establish, modify, or revoke a tolerance or an exemption, and provides 60 days for public comments on pending proposals. In addition, a person adversely affected by a final regulation has twice the time provided under previous law — 60 days rather than 30 — to file an objection.

Preempting State Pesticide Residue Tolerances. Although federal pesticide residue tolerances are typically accepted across the nation, the FFDCA, before it was amended by P.L. 104-170, authorized states to impose tighter restrictions. For example, California requires businesses to warn the public about pesticide residues on food that pose a "significant risk" (defined as more risky than one chance in 100,000) of causing cancer or birth defects. The agricultural sector, particularly the food industry, wanted federal standards to preempt state standards. The National Food Processors Association argued that differing state tolerances disrupt interstate commerce. In addition, it said farmers in states with tighter standards might be at a competitive disadvantage to those in states with weaker regulations or enforcement. Supporters of the balance of authority reflected by the FFDCA before amendment argued that unique regional demographic or food consumption characteristics made it prudent to allow states flexibility concerning food safety. Such flexibility is built into most environmental federal laws. EPA opposed preemption, while NASDA supported preemption of tolerance setting and warning requirements.

The FQPA establishes federal preemptive authority over tolerance setting and exemptions when federal standards ensure that residues are "safe", but allows for state action under compelling local conditions with EPA approval. State and local laws requiring a warning when a pesticide residue is present in food are permitted.[20]

Enforcement of Tolerances: Imports. The United States imports approximately 15% of total domestic consumption of agricultural products, according to EPA, and pesticides are used in producing and storing many of these imports. The FFDCA prohibits importation of food with a pesticide residue that exceeds its tolerance. According to GAO, in 1994 FDA tested about 1% of all imported shipments for pesticide residue levels.[21]

Critics such as NASDA, contended that this monitoring rate was too low, making it unlikely that illegal pesticide residues would be detected on imported foods. FDA argued in the past that the low sampling rate understated the effectiveness of its detection program, because the agency concentrated its efforts on the foods and countries likely to be the source of residues and also on shippers with

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[20]The introduced version of H.R. 1627 would have preempted such warnings, but this provision was dropped from the reported bill.

[21]U.S. GAO. Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food, GAO/RCED-94-192. Gaithersburg, MD. P. 50.

a history of violations. Such a strategy was intended to identify violations more successfully than a more frequent but random sampling. However, FDA officials said that inadequate resources were the primary reason that the agency had not tested a larger percentage of imported foods, according to GAO.[22]

Some questioned the cost and effectiveness of greatly increased FDA monitoring, arguing that it would be better to prevent problems from happening than to try to remedy them after the fact. They preferred developing bilateral agreements with trading partners to achieve equivalent, but not necessarily identical, inspection systems that could prevent contaminated products from arriving at U.S. ports of entry. The Clinton Administration favored increasing support for FDA monitoring of imported foods. The Administration also wanted enhanced authority to penalize those who introduced into interstate commerce foods with residues above FFDCA tolerances.

The FQPA authorizes an additional $12 million spread over FY1997, FY1998, and FY1999 for increased FDA monitoring of pesticide residues on imported and domestic foods. It also authorizes civil money penalties in lieu of penalties assessed under FFDCA criminal authorities, seizure authorities, or injunction authorities for persons who introduce adulterated food into interstate commerce, but not for growers. Such penalties may not exceed $50,000 for individuals and $250,000 for other persons, and may not exceed $500,000 for all such violations adjudicated in a single proceeding. See CRS Report 93-821 *The Safety of Imported Food* for more information about this issue.

Harmonizing U.S. Tolerances with International Standards. The United States and its trading partners are concerned about facilitating trade as well as ensuring the safety of food imports. Because diverse health and safety standards can be barriers to international trade, the 104th Congress considered whether to require EPA to "harmonize" tolerances with international pesticide residue limits. Because diverse standards may be justified based on regional or local health and safety concerns, the goal of harmonization is agreement on appropriate scientific and other non-economic bases for setting standards, not a single international set of standards. Proponents of harmonization argue that equivalent standards among countries would promote international economic development by facilitating trade. Critics on the other hand are fearful of weakening U.S. standards and compromising "sovereign rights." They favor harmonization only if countries with less stringent food safety standards are obliged to meet more stringent U.S. standards, a process referred to as "upward harmonization." It is not clear whether they also would favor U.S. adoption of more stringent standards established by other countries.

U.S. agencies have participated for years in the activities of an organization sponsored by the United Nations, the Codex Alimentarius (that is, "food code") Commission, which negotiates international criteria for chemical testing, certification, and laboratory accreditation. The FQPA amends FFDCA Section 408 to encourage EPA to set tolerances at the "Maximum Residue Levels" (MRLs) established by the Codex, if such standards exist. If EPA chooses not to adopt the

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[22]Ibid.

Codex MRL, the FQPA requires the agency to publish a notice in the *Federal Register* explaining why.

Issues Considered and Dropped Prior to Passage

Preempting State, Tribal, and Local Pesticide Use Laws

Those who register and distribute pesticides sometimes complain that given federal standards, local and state pesticide use restrictions are unnecessary and burdensome to commerce. FIFRA specifically authorizes state regulation of the sale and use of federally registered pesticides, as long as state regulations are at least as restrictive as federal standards. Under FIFRA, for example, states may prohibit the distribution and sale of a federally registered pesticide or restrict pesticide use locally to protect groundwater, wildlife, or human health. (The FQPA does not allow labeling or packaging requirements on pesticides in addition to, or different from, FIFRA requirements.) Where states have not enacted preemptive legislation, local jurisdictions also have the authority under FIFRA to regulate pesticide sales and use, according to the U.S. Supreme Court (*Wisconsin Public Intervenor v. Mortier*, 111 S.Ct.2321). Environmentalists and some states' rights advocates are determined to preserve this interpretation of FIFRA. The Coalition for Sensible Pesticide Policy, an umbrella group for many representing manufacturers and users of pesticides, proposed to amend FIFRA to establish federal preemption of state regulations and state preemption of local ordinances to facilitate national distribution of pesticide products.[23]

H.R. 1627, Section 106, as reported by the House Committee on Agriculture, would have prohibited local, but not state regulation of pesticide products. NASDA strongly supported preemption of local pesticide use restrictions, but many states did not. This preemption provision was dropped after the bill was reported in the House but before the bill was debated on the House floor. (FFDCA federal preemption authority is discussed below.)

Clarifying and Limiting Tribal Pesticide Enforcement

H.R. 1627, Title VI would have authorized Indian tribes to regulate the sale or use of any federally registered pesticide or device and to enforce against violations of pesticide use laws within the boundaries of a federal Indian reservation for such tribe, but would have prohibited these tribal activities if less than 50% of such lands were owned by members of the tribe or the tribe. The FQPA, as enacted, does not include this title.

In general, with regard to pesticide laws, EPA treats tribes in the same way it treats states. EPA has approximately 23 cooperative enforcement agreements with

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[23]According to its literature, the Coalition for Sensible Pesticide Policy consists of state, regional and national trade associations for users and manufacturers of pesticides. Members include associations for nursery, arbor, floral, lawn and garden, agricultural, and structural pest control companies, as well as the American Farm Bureau Federation, the National Association of State Departments of Agriculture, and the U.S. Chamber of Commerce.

tribes. These delegate to designated tribal officers certain authority to conduct activities related to enforcement, such as inspections of pesticide establishments, within reservation boundaries (including land owned by non-members). In addition, tribes may refer violations to EPA for enforcement under FIFRA. However, EPA does not delegate to tribes federal enforcement authority to invoke the penalty provisions in FIFRA. The Agency has encouraged tribes to adopt and implement pesticide laws and regulations that are similar to FIFRA. Where they have done so, tribes enforce tribal codes.

Some who supported Title VI argued during debate on the House floor that states rather than tribes should enforce pesticide laws within reservation boundaries on land owned by people who are not tribal members, if most land within reservation boundaries is owned by nonmembers of the tribe.[24] However, tribes opposed this provision, as did the Clinton Administration. The Administration expressed strong support for tribal authority to regulate pesticide use on all lands within tribal jurisdiction, arguing that the federal government lacks resources to implement pesticide programs at the local level, and that significant gaps in environmental protection on reservations might be created if tribal authority were limited. EPA claimed that the historical record of tribal regulation of pesticide use on reservation lands "is one of sensible environmental protection, respect, cooperation, and a few, well-justified enforcement actions" (Goldman, Lynn R., Letter to the Honorable Pat Roberts, Aug. 1, 1995). Four tribal enforcement actions are recorded by EPA Headquarters, three in South Dakota and one in Idaho.

Conclusion

The FQPA has widespread support in the community of growers, food processors, chemical suppliers, environmental and consumer advocacy groups, and state government agriculture officials. The Clinton Administration also generally supports its provisions. The FQPA aims to facilitate FIFRA registration and reregistration of pesticides for minor uses, including public health pesticides, antimicrobial pesticides, and reduced risk pesticides; to improve data collection relevant to pesticide residue risks to children; and to protect consumer health by requiring FFDCA tolerances for pesticide residues on food that are "safe" and provide "a reasonable certainty of no harm" from aggregate exposure. The new law tightly links EPA actions under FFDCA and FIFRA and requires both tolerances and registrations to be reviewed periodically.

The FQPA does not repeal the "zero-risk" Delaney Clause in FFDCA Section 409, but it does ensure that pesticide residues in processed foods are not governed by that provision. Instead, the FQPA subjects all pesticide residues in food to FFDCA Section 408 and tightens the safety standard. In the future, raw food tolerances, as well as tolerances for processed foods, must be "safe" and ensure with "a reasonable certainty" that no harm will result from exposure to that residue, other residues on other foods, other sources, and other pesticides that have the same toxic effects on people. Only pesticides with health effects that have no known threshold (e.g., some

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[24]The Honorable Doug Bereuter, Congressional Record, July 24, 1996, p. H8146.

cancers) are excepted from the "safe" standard, only under specified conditions, and only if the increased risk is within strict limits.

Congressional Hearings

U.S. Congress. House. Committee on Agriculture. Subcommittee on Department Operations, Nutrition, and Foreign Agriculture. Food Quality Protection Act of 1995. Hearing, 104th Congress, 1st session, May 16, 1995. Washington, DC, Govt. Print. Off., 1995. 248 p.

U.S. Congress. Senate. Committee on Agriculture, Nutrition, and Forestry, Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation. The Federal Insecticide, Fungicide, and Rodenticide Act (S. 958, S. 1478, and S. 2050). Hearing, 103rd Congress, 2nd session, July 28, 1994. Washington, DC, Govt. Print. Off., 1995. 145 p.

U.S. Congress. Senate. Committee on Agriculture, Nutrition, and Forestry. Testimony from Administration Witnesses on Pesticide Legislation (S. 985, S. 1478, and S. 2050). Hearing, 103rd Congress, 2nd session, June 29, 1994. Washington, DC, Govt. Print. Off., 1995, 79 p.

Appendix A. Authorities and General Provisions of Pesticide Laws, as Amended by the FQPA

FIFRA Authority and General Provisions

FIFRA, as amended (7 USC 136-136y),[25] requires the U.S. Environmental Protection Agency (EPA) to regulate the sale and use of pesticides in the United States through registration and labeling of the estimated 21,000 pesticide products currently in use.[26] The Act directs EPA to restrict the use of pesticides as necessary 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 this end, EPA registers each pesticide for each approved use, for example, to control boll weevils on cotton. FIFRA prohibits sale of any pesticide in the United States unless it is registered. In addition, FIFRA requires EPA to reregister older pesticides based on new data that meet current regulatory and scientific standards. Most pesticides currently registered in the United States are older pesticides and were not subject to the modern safety reviews.

When pesticide manufacturers apply to register or reregister a pesticide 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. EPA may require any combination of more than 100 different tests. To register a pesticide 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, assuming that the pesticide is applied according to the manufacturers' recommended rates and methods. Based on the data submitted, EPA determines whether and under what conditions the proposed pesticide use presents an unreasonable risk to human health or the environment, and if proposed for use on a food crop, whether a safe level of pesticide 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, which the registrant must explain 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 may classify and register a pesticide product for general or restricted use. Restricted-use products are considered more dangerous (to the applicator or the environment) and can be used only by trained pesticide applicators certified by states. Individual states and Indian tribes generally are responsible for training pesticide applicators for certification.

EPA also evaluates the safety of pesticides after they are registered (or reregistered). Registrants are required to report promptly any new evidence of adverse effects of pesticide exposure. If evidence indicates that a registered pesticide

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[25]FIFRA also is known as the Act of June 25, 1947.

[26]Exceptions are noted in 40 CFR 152.20, 152.25, and 152.30.

may pose an unreasonable risk, EPA may initiate a special review of available information and may reevaluate the risks and benefits of each registered use. Registrants also may be required to conduct new studies to fill gaps in scientific understanding to permit risk assessments. If a special review or reregistration evaluation finds that a registered use may cause "unreasonable adverse effects," the registration may be amended or canceled.[27] 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 for a specified period of time, U.S. farmers may use remaining stocks, and commerce may continue for commodities that were legally treated with the pesticide. An EPA decision to cancel a registration may be appealed by the registrant. An appeal initiates a lengthy decision review process during which the product may continue to be marketed. However, if there is threat of an "imminent hazard" during the time required to cancel registration, EPA is authorized to suspend registration. Suspension orders, which also may be appealed, stop sales and use of the pesticide.

Generally, FIFRA requirements are enforced by EPA. However, FIFRA Section 26 gives states primary authority, including inspection authority, for enforcing FIFRA provisions related to pesticide use.

Prior to enactment of P.L 104-170, the last significant changes to the general provisions of FIFRA were enacted in 1988 (P.L. 100-352). Authorization for appropriations expired on September 30, 1991, although appropriations have continued. The history and provisions of FIFRA are summarized in CRS Report 97-49 ENR, *Summaries of Environmental Laws Administered by the Environmental Protection Agency*, pages 95-101.

FFDCA Authority and General Provisions

FFDCA, as amended (21 USC 301-392), requires various federal agencies to regulate foods, drugs, and cosmetics to ensure that they are safe for use. For the approximately 300 pesticides registered for use in food production, the FFDCA directs EPA to establish allowable pesticide residue levels (called tolerances) in food and animal feed. Under FFDCA, foods with a residue of a pesticide for which there is no tolerance established, or with a residue level exceeding an established tolerance limit, are declared "unsafe" and "adulterated;" such foods cannot be sold in interstate commerce in the United States.

Any person who has registered a pesticide may petition EPA proposing establishment of a tolerance or an exemption for that pesticide to permit its use on

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[27]Registrations also may be canceled under other conditions, for example, if data are not submitted in response to EPA's request for additional information to maintain a registration or if a registrant fails to pay the maintenance fee.

food.[28] Tolerance petitions must include information about pesticide application rates, measured concentrations of pesticide residues on the food after the pesticide has been applied according to directions on its label, and safety of pesticide use on food. FFDCA requires EPA to respond to each petition by establishing a tolerance or exempting the pesticide from the requirement. If the pesticide will not leave residues above an established safe level, EPA will register the pesticide for use on that food and set the tolerance level by issuing a regulation. EPA tolerances for pesticide residues preempt state and local restrictions on food if they are based on lower residue levels. States may petition for an exception if the residue level threatens public health.

Prior to P.L. 104-170, the FFDCA directed EPA to establish tolerances for pesticide residues on food according to criteria which differed for raw and processed commodities. Residues in raw commodities were subject to Section 408 of FFDCA. This provision required that residue tolerances be set at levels necessary to protect public health considering: 1) "the necessity for the production of an adequate, wholesome, and economical food supply," and 2) the opinion of the Secretary of Agriculture as to the usefulness of the pesticide. EPA interpreted this directive to require a balancing of risks and benefits in the setting of tolerances. If a tolerance was not necessary to protect public health, EPA was required to grant the pesticide an exemption from the requirement for a tolerance. Section 408 made no reference to cancer-causing chemicals.

In contrast, the former FFDCA treated pesticide residues in processed food as food additives, which are governed by Section 409. This provision requires tolerances for food additives to be based on "a fair evaluation of the data" establishing that the proposed use of the additive is safe. Moreover, Section 409(c)(3)(A) prohibits a finding that a food additive is safe, if it has been found "to induce cancer in man or animal," Thus, it prohibits the addition of potentially carcinogenic substances to foods. This FFDCA clause is known as the Delaney Clause. Notwithstanding the provisions of Section 409, however, a pesticide residue in processed food was not unsafe if it: resulted from pesticide use on a raw food in accord with a prescribed tolerance (or exemption), was "removed to the extent possible in good manufacturing practice," and was in ready-to-eat food at a concentration not greater than the tolerance for the raw food product (FFDCA Section 402(a)(2)(C)).[29] A pesticide residue in processed food was "safe," therefore, if it had not concentrated during food processing. If it did concentrate, the food could be sold only if a food additive tolerance (i.e., a Section 409 tolerance) had been established (indicating that the pesticide residue was "safe" at or below that level), and the pesticide residue on the processed food was below that tolerance level, or an exemption had been granted for the pesticide in that food. However, if the pesticide was a potential carcinogen, no food additive tolerance could be established. Therefore, processed foods could contain no greater concentration of a potentially

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[28]That is, use on food crops, animal feed crops, or food products directly (e.g., grains, fruits, or vegetables after harvest).

[29]Section 402 has become known as the "flow-through" provision. This means that if the amount of the pesticide residue in the processed food is less than the tolerance for the raw food, then EPA does not need to establish a tolerance under Section 409.

carcinogenic pesticide residue than was permitted in the same food before processing, and no residue at all if the pesticide was not used on the raw food. A 1992 decision by the U.S. Court of Appeals for the Ninth Circuit explicitly barred balancing of risks and costs in setting a Section 409 tolerance for a carcinogenic pesticide, no matter how small the cancer risk (*Les v. EPA*, CA 9, No. 91-70234). This decision led EPA to propose revoking several food additive tolerances for potentially carcinogenic pesticide residues in processed foods.

Pesticide residues in processed food, even if they have concentrated during processing, are no longer subject to Section 409 or the Delaney Clause. All pesticide residues are regulated under the amended FFDCA Section 408. The standard for tolerance setting under this revised standard is that aggregate exposure to the pesticide must be "safe". See pages 11 to 12 in the main body of this report for more information about the revised food safety standard.

EPA has long coordinated pesticide registrations for food uses under FIFRA with tolerance setting under FFDCA. Public Law 104-170 codifies this policy. Thus, if EPA revokes a residue tolerance under FFDCA, it cancels the FIFRA pesticide registration for that food use. EPA explains, "Legally-used pesticides should not result in illegal food" (61 *Federal Register* 2379, Jan. 25, 1996). EPA traces the origin of its coordination policy to the legislative history of FFDCA Section 408 (S. Rept. 1635, 83rd Cong., 2nd Sess. 1954, p. 3). Similarly, if a pesticide registration for use on a food crop is canceled, EPA also cancels the residue tolerance for the food. However, just as FIFRA allows continued use of remaining pesticide stocks after a registration is canceled, FFDCA allows continued commerce in commodities legally treated with a pesticide. Thus, EPA does not immediately revoke the tolerance for the pesticide residue, when it cancels the corresponding registration. (Formerly, the Agency also coordinated pesticide residue tolerances for raw foods with food additive tolerances for the corresponding processed foods: when it revoked a Section 409 (food additive) tolerance for a processed food, it also revoked the corresponding tolerance for the raw agricultural commodity. This effort will no longer be required as both raw and processed foods are subject to the same Section 408 tolerance.)

FFDCA directs the Food and Drug Administration (FDA) in the Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA) to monitor pesticide residue levels in food in interstate commerce and to enforce tolerances through their food inspection programs. USDA is responsible for inspecting meat and poultry; FDA inspects all other foods. States also may monitor pesticide residues in food sold within their jurisdictions.

Prior to P.L. 104-170, FFDCA provisions related to pesticide residues on food were last significantly amended in 1958 by the Food Additives Amendments of 1958 (P.L. 85-929). There is no specific authorization for FFDCA appropriations.

Appendix B. Section-by-Section Summary of P.L. 104-170

Provision	P.L. 104-170
Short Title	§1 - The Act is the "Food Quality Protection Act of 1996"
Title I — Suspension - Applicators	
Reference	§101 - Title I amends FIFRA
Subtitle A - Suspension	
Suspension	§102 - Amends FIFRA §6(c); authorizes an emergency suspension order before EPA issues a notice of its intention to cancel the registration or to change the classification of the pesticide. Such emergency order expires after 90 days if EPA has not issued a notice under Section 6(b).
Reregistration of Food-Use Pesticides	§103 - Amends FIFRA §4(g)(2) to require reassessment of residue tolerances and exemptions issued under the FFDCA as soon as EPA has sufficient information about the dietary risk of an active ingredient and at the time EPA makes a reregistration decision
Science Review Board Established	§104 - Amends FIFRA §25(b) to establish a Science Review Board of 60 scientists to assist in Scientific Advisory Panel (SAP) reviews; SAP selects Board members
Nitrogen Stabilizers	§105 - Distinguishes "nitrogen stabilizers" from other pesticides
State and Local Authority	§106 - Amends FIFRA to eliminate Section 6 requirement to cancel registration after 5 years; adds new subsection (g) to Section 3 requiring periodic registration review, with a goal of every 15 years
Subtitle B - Training for Maintenance Applicators and Service Technicians	
Definitions	§120 - Defines "maintenance applicator" and "service technician"
Training of Maintenance Workers	§121 - Authorizes States to establish requirements for training maintenance applicators and service technicians in handling and use of pesticides; limits EPA authority

Provision	P.L. 104-170
Title II - Minor Use Crop Protection, Antimicrobial Pesticide Registration Reform, and Public Health Pesticides	
Reference	§201 - Title II amends FIFRA
Subtitle A - Minor Use Crop Protection	
Definitions	§210(a) - Defines “minor use”
Time to Submit Data Supporting Minor Use Registration	§210(b) - Extends exclusive data use period 1 year for each 3 minor uses registered; protects for 10 years data supporting a new minor use of a registered pesticide with no remaining period of data protection
Deadline for Residue Data	§210(c) - Extends deadline for residue chemistry data for a minor use registration until final submission date for other pesticide uses
Authority to Waive Data Requirements	§210(d) - Authorizes data waiver for minor use registration if risk still could be assessed and would be reasonable
Expedited Registration	§210(e) - Requires EPA to act expeditiously on a complete application for minor use registration
Unsupported Minor Use Registrations	§210(f) - Requires EPA to temporarily extend registration for a minor use that is not supported for reregistration until after the final data submission deadline for all supported uses
Cancellation of a Minor Use Registration	§210(g) - Lengthens from 90 days to 180 days the EPA waiting period prior to granting a request for voluntary cancellation of a pesticide registered for a minor use
Registration Transfers	§210(h) - Requires EPA to consider an application to register a minor use in light of a substantially similar pesticide use that was registered if such registration was voluntarily canceled while the new application was pending
EPA Minor Use Coordination	§210(i) - Establishes a minor use program in EPA; requires EPA report on progress in registering minor uses
USDA Minor Use Coordination and Grant Program	§210(j) - Requires USDA to coordinate its minor use activities; establishes a minor use matching grant program to develop data supporting minor use pesticide registrations and reregistrations; establishes a Minor Use Pesticide Data Revolving Fund; authorizes appropriations of $10 million annually

Provision	P.L. 104-170
Subtitle B - Antimicrobial Pesticide Registration Reform	
Definition	§221 - Defines “antimicrobial pesticide”
Coordination of Requirements and Deadlines	§222 - Amends FIFRA to require coordination of FIFRA data requirements for pesticide registration
Changes to Labels	§223 - Allows specified changes to labels for antimicrobial pesticides 60 days after the registrant notifies EPA, if EPA does not disapprove within 30 days of receiving notice
Antimicrobial Pesticide Registration Reform	§224 - Adds a new subsection (g) to FIFRA §3; directs EPA to reduce registration requirements for antimicrobial pesticides; establishes goals and limits for review and notification requirements; requires annual report on reform progress
Transportation, Storage, and Disposal of Disinfectants and Sanitizers	§225 - Removes EPA authority to specify requirements for pesticide registration and labeling with respect to storage, disposal, transportation, and recall of household, industrial, and institutional antimicrobial products that are not subject to the Solid Waste Disposal Act (42 USC 6901 et seq.), unless regulation is necessary to prevent an unreasonable adverse effect
Subtitle C - Public Health Pesticides	
Definition	§230 - Amends the definition of “unreasonable adverse effects on the environment;” requires EPA to weigh pesticide risks against health risks posed by the pesticide target, e.g., disease-carrier insects; defines “public health pesticide” and “vector”
Data Requirements	§231 - Requires EPA to consider the public health and agricultural need for a minor use pesticide and beneficial or adverse effects on the environment when establishing data requirements
Reregistration of Public Health Pesticides	§232 - Exempts public health pesticides from reregistration fees if economic return does not support registration; requires EPA to use existing expedited processing funds to assure expedited review of public health pesticide applications
Changes in Public Health Pesticide Registrations	§233 - Requires DHHS to provide benefits and use information and analysis when a public health use is affected by a proposed change in a pesticide registration
DHHS Comments	§234 - Requires EPA to solicit DHHS views prior to publishing a regulation for a public health pesticide
Consideration of Public Health Pesticides	§235 - Requires EPA to take into account the risk and relevant data for public health pesticides

Provision	P.L. 104-170
Control of Significant Public Health Pests	§236 - Requires EPA to identify pests of "significant public health importance" and to promote methods to control them
Authorization of Appropriations	§237 - Authorizes arrangements to conduct studies to develop data needed to register or reregister public health pesticides; authorizes appropriations for FIFRA Section 4 of up to $12 million for FY1997, and thereafter, such sums as may be necessary
Subtitle D - Expedited Registration of Reduced Risk Pesticides	
Reduced Risk Pesticides	§250 - Amends FIFRA §3(c); directs EPA to develop procedures to expedite reviews of pesticide uses that may: reduce pesticide risks to human health, reduce pesticide risks to nontarget organisms, reduce contamination of valued environmental resources, or broaden adoption of integrated pest management (IPM) strategies
Title III - Data Collection Activities to Assure the Health of Infants and Children and Other Measures	
Data Collection to Assure the Health of Infants and Children	§301 - Requires USDA, EPA, and DHHS to coordinate in developing and implementing survey procedures to ensure collection of adequate data on food consumption of infants and children (Also see §405 amendment to FFDCA §408(b)(2)(C))
Pesticide Use Data	§302 - Requires USDA to collect data of statewide or regional importance on pesticide use on major crops and crops of dietary significance
Integrated Pest Management	§303 - Requires USDA to cooperate with EPA to conduct research, demonstration, and education programs supporting IPM; directs federal agencies to use and promote IPM
FIFRA-FFDCA Coordination	§304 - Amends FIFRA definition of "unreasonable adverse effects on the environment" to include dietary risk from pesticide residues inconsistent with the EPA-established food tolerance under FFDCA §408
Pesticide Use Data Report	§305 - Requires USDA, in consultation with EPA, to report on pesticide use data collection by federal agencies
Title IV - Amendments to the Federal Food, Drug, and Cosmetic Act	
Short Title and Reference	§401 - Title IV may be cited as the Food Quality Protection Act of 1996; it amends FFDCA
Definitions	§402 - Amends and adds definitions for "pesticide chemical," "pesticide chemical residue," "food additive," "processed food," and "Administrator"
Confidential Data	§403 - Amends FFDCA §301(j) to prohibit disclosure of confidential data

Provision	P.L. 104-170
Adulterated Processed Food	§404 - Amends FFDCA §402(a)(2) so that pesticide residues on raw or processed food that are "unsafe" within the meaning of §408 cause a food to be deemed adulterated
Pesticide Residues in Food	§405 - Amends FFDCA §408 regulating pesticide residues in food
Safety of Pesticide Residues	New §408(a)(1) - Defines raw and processed food products as "food" and a pesticide residue on food as "unsafe," unless a tolerance is in effect and the residue level is below the tolerance, or an exemption from the requirement exists
Safety of Residues in Processed Food	New §408(a)(2) - Defines a pesticide chemical residue on processed food as not unsafe if the residue results from pesticide use that conforms to a tolerance for the raw commodity, the residue has been removed to the extent possible in "good manufacturing practice," and the concentration of processed food residue is not greater than the raw food tolerance, or an exemption is in effect for the raw food
Pesticide Degradation Products	New §408(a)(3) - Defines a food residue of a degradation product of a pesticide as safe if: (A) EPA has determined that the dietary health risk posed by the breakdown product is not likely to be different than that posed by the parent pesticide; (B)(i) a tolerance exists for the parent pesticide and the combined residue of the parent pesticide and breakdown product is less than the tolerance; or (ii) a tolerance exemption exists for the parent pesticide; and (C) the tolerance or exemption for the parent pesticide does not state that it applies only to the parent pesticide or that it does not apply to the breakdown product
Effect of a Tolerance or Exemption	New §408(a)(4) - Food with pesticide residue shall not be "adulterated" within the meaning of §402(a)(1) while a tolerance or exemption is in effect for that pesticide residue on that food
Authority for Tolerance Setting	New §408(b)(1) - Authorizes EPA to establish, modify, or revoke tolerances for pesticide residues on food in response to a citizen petition or on its own initiative
Standard for Tolerances	New §408(b)(2)(A) - (i) Prohibits setting or retaining a tolerance unless EPA determines that the level is "safe;" directs EPA to modify or revoke any tolerance that is not "safe;" (ii) defines "safe" to mean that there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," considering all sources of exposure for which there is reliable information; (iii) a pesticide chemical residue for which a "safe" tolerance exists is not an eligible pesticide chemical residue (see below)

Provision	P.L. 104-170
Eligible Pesticide Chemical Residues	New §408(b)(2)(B) - (i) Defines "eligible pesticide chemical residue" as a residue for which a harmless exposure level cannot be identified (that is, it exerts a nonthreshold health effect), the lifetime risk of such effect has been estimated using quantitative risk assessment, and aggregate exposure to the residue is safe with respect to other effects for which EPA is able to identify a harmless level (that is, threshold effects) (ii) - Allows EPA to maintain a tolerance for an eligible residue if (iii) the pesticide use protects consumers from greater health risks than are posed by the residue, or the pesticide use is needed to avoid a "significant disruption in domestic production of an adequate, wholesome, and economical food supply;" and (iv) aggregate exposure to the pesticide chemical (including dietary exposure at the tolerance level) poses a yearly risk not more than 10 times and a lifetime risk not more than twice that of aggregate pesticide exposure when the tolerance is at a "safe" level (v) - Requires review of tolerances for eligible residues at least every five years (vi) - Requires tolerances for eligible residues to protect the health of infants and children (see below)
Exposure of Infants and Children to Eligible Residues	New §408(b)(2)(C) - Directs EPA when evaluating an existing tolerance or exemption, (i) to assess the risk to infants and children considering consumption patterns, special susceptibility, and cumulative effects, and (ii) to ensure with a reasonable certainty that no harm will result to infants and children; EPA may apply a tenfold margin of safety for potential pre- and post-natal toxicity and inadequate exposure and toxicity data
Mandated Considerations in Tolerance Decisions	New §408(b)(2)(D) - Requires EPA to consider certain factors when it establishes or reconsiders a tolerance or exemption
Residue Data	New §408(b)(2)(E) - Authorizes EPA to consider data on anticipated residue levels and actual residue levels; 5 years after a tolerance is set, requires data submissions demonstrating residues are below those used to set tolerances; requires tolerance to be modified or revoked if data are not provided or fail to demonstrate that residues are below those used to set the tolerance
Percent of Food Treated with Pesticide	New §408(b)(2)(F) - Authorizes EPA when setting tolerances to consider data on the percent of food actually treated with the pesticide, but only if EPA finds that the data meet certain criteria and provides for periodic reevaluation of the estimate derived from the data
Tolerances Near the Level of Detection	New §408(b)(3) - (A) Prohibits tolerance setting unless a practical method is identified for detecting and measuring pesticide levels; (B) Prohibits setting a tolerance below the limit of detection of the specified method

Provision	P.L. 104-170
International Residue Levels	New §408(b)(4) - Directs EPA to explain its reasons if it proposes a tolerance inconsistent with the international Codex Maximum Residue Level
Authority for Issuing Exemptions	New §408(c) - Authorizes EPA to establish, modify, or revoke a tolerance exemption in response to a petition or on its own initiative; permits EPA to allow an exemption only if it is "safe," meaning that there is a "reasonable certainty that no harm will result from aggregate exposure" to the pesticide residue from all sources for which information is reliable; requires consideration of certain factors; prohibits exemptions if there is no practical method for detecting and measuring the levels of residue, unless there is no need for such a method and a reason is provided
Petitions	New §408(d) - Authorizes any person to file a petition for issuance, modification, or revocation of a tolerance or exemption; requires specified petition contents and authorizes EPA regulations requiring information and data to support a petition; directs EPA to publish a notice of each complete petition and to respond by issuing a regulation revising the tolerance or exemption or an order denying the petition; establishes priorities and an expedited procedure for reviews of petitions relating to residue tolerances that appear safer than existing residue tolerances for other pesticides with similar uses; requires EPA action within 180 days respecting a tolerance for an "eligible pesticide residue" if a tolerance or exemption is established for a safer pesticide residue for a similar use
Administrative Procedures	New §408(e) - Authorizes EPA to issue regulations to set, suspend, or revoke tolerance or an exemption or to establish general implementation procedures; requires 60-day comment period
Data to Support Existing Tolerances and Exemptions	New §408(f) - Requires EPA to collect additional data when they are reasonably required to support an existing tolerance or exemption; directs EPA to issue a notice under FIFRA §3(c)(2)(B), a rule under the Toxic Substances Control Act 4, or an order to request testing and data submissions; authorizes modification or revocation of a tolerance or exemption if data are not submitted on time
Objections and Hearings	New §408(g) - Provides any person 60 days to file an objection to a rule or order and to request a hearing; authorizes EPA to decide whether a hearing is necessary
Judicial Review	New §408(h) - Authorizes persons adversely affected to petition for judicial review of a regulation establishing general implementation procedures under new §408(e) or an order requesting data submissions under new §408(f) or stating EPA's response to objections filed under new §408(g); 60 days are provided for filing petitions after the regulation or order is published

Provision	P.L. 104-170
Confidential Business Information	New §408(i) - Requires confidential treatment of data supporting a tolerance
Technical Corrections	New §408(j) - Makes technical corrections to FFDCA
Substances Generally Recognized as Safe	New §408(k) - Requires EPA to publish a list of substances that are generally recognized as safe (GRAS) and that are exempt from tolerance regulations
FFDCA-FIFRA Coordination	New §408(l) - (1) Directs EPA when possible to coordinate suspension or revocation of a tolerance or exemption with related necessary action under FIFRA; (2) Requires revocation of tolerances and exemptions permitting a pesticide residue on a food within 180 days after EPA has canceled the registration of that pesticide for that food use due to dietary risks posed by residues; (3) Requires suspension of a tolerance or exemption within 60 days of the date a pesticide registration is suspended under FIFRA; (4) Authorizes EPA to set tolerances for unavoidable residues of canceled or suspended pesticides; (5) Declares food is not unsafe solely because it contains a residue for which the tolerance has been revoked, suspended, or modified, if the residue results from a legal application of pesticide and was within the tolerance set at that time and EPA has not determined that consumption would pose an unreasonable dietary risk; (6) Requires EPA to issue a tolerance or exemption, consistent with the safety standard of §408(b)(2) and (c)(2) and for a limited time, for pesticide residues resulting from pesticide use during an emergency exemption from registration requirements under FIFRA §18
Fees	New §408(m) - Retains current requirements for collecting fees to cover costs of the tolerance program; directs EPA to deposit fees in the FIFRA Reregistration and Expedited Processing Fund
State and Local Preemption	New §408(n) - Preempts state and local regulation of food with residues below the tolerance or which are exempt; allows state petitions for exceptions; allows state and local warning requirements for such foods
Consumer Right to Know	New §408(o) - Requires EPA to publish and distribute to large retail grocers for public display easily understood information about the risks and benefits of pesticide residues on food, including information identifying reasonable nutritional substitutes for foods with “eligible pesticide residues” for which special tolerances or exemptions have been established

Provision	P.L. 104-170
Endocrine Effects	New §408(p) - Directs EPA to develop a screening program to determine whether pesticides or other substances have effects in humans that are similar to effects produced by naturally occurring estrogens or other endocrine effects; requires EPA to order testing and submission of reports and to suspend registration for a registrant's failure to comply with testing requirements; authorizes penalties for others who fail to comply with test orders; requires EPA action when necessary using existing statutory authority if a substance is found to have an endocrine effect on humans
Review of Tolerances and Exemptions	New §408(q) - Requires EPA to review all tolerances and exemptions for pesticide residues within 10 years of enactment; tolerances and exemptions not meeting the standard of §408 as amended must be revised or revoked; directs EPA to prioritize reviews based on relative risk to public health
Temporary Tolerances or Exemptions	New §408(r) - Authorizes EPA to establish a temporary tolerance or exemption for a residue that results from pesticides uses covered by an experimental permit
Savings	New §408(s) - Notes that §408 does not amend or modify TSCA or FIFRA
Monitoring Pesticide Residues on Food	§406 - Authorizes additional appropriations for FY1997 through FY1999 of $12 million (total) for increased monitoring by FDA of pesticide residues in imported and domestic food
Alternative Enforcement	§407 - Authorizes civil money penalties in lieu of penalties assessed under FFDCA criminal authorities, seizure authorities, or injunction authorities for persons who introduce adulterated food into interstate commerce, but not for growers; penalties may not exceed $50,000 for individuals and $250,000 for other persons and may not exceed $500,000 for all such violations adjudicated in a single proceeding
Title V - Fees	
Fees	§501 - Extends EPA authorization to collect FIFRA registration maintenance fees of $14 million annually through FY2001; authorizes collection of an additional $2 million per year for FY1998, FY1999, and FY2000; requires annual full-scale audit of the reregistration fees collected and expended

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