

Pesticide Law: A Summary of the Statutes

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Summary

This report summarizes the major statutory authorities governing pesticide regulation: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, as well as the major regulatory programs for pesticides. Text relevant to FIFRA is excerpted, with minor modifications, from the corresponding chapter of CRS Report RL30798, *Environmental Laws: Summaries of Major Statutes Administered by the Environmental Protection Agency*, coordinated by (name redacted), which summarizes more than a dozen environmental statutes.

Congress enacted the original version of FIFRA in 1947, but a revision in 1972 is the basis of current pesticide policy. Substantial changes were made in 1988, with a focus on the reregistration of older pesticides, and again in the 1996 Food Quality Protection Act (FQPA), which also amended the FFDCA. The Pesticide Registration Improvement Act of 2003 (PRIA 1), the Pesticide Registration Improvement Renewal Act of 2007 (PRIA 2), and the Pesticide Registration Improvement Extension Act of 2012 (PRIA 3; P.L. 112-177), enacted September 28, 2012, amended FIFRA to revise EPA authorities for collecting and expending fees imposed on pesticide manufacturers and formulators. These fees are used to supplement annual appropriations so as to expedite EPA processing of applications for pesticide registration and reregistration.

Congress first required limits on pesticide residues on raw food in 1954 amendments to the FFDCA. Limits were required for food additives (including pesticide residues in processed foods) in the 1958 FFDCA amendments. In the 1996 FFDCA amendments, Congress established a new standard of safety for pesticide residues in food (both raw and processed): maximum residue levels set by EPA must ensure with “a reasonable certainty” that “no harm” will result from pesticide exposure. The FQPA directed EPA to coordinate tolerance setting with pesticide registration under FIFRA for food-use registrations of pesticides.

FIFRA 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 pesticide products. The sale of any pesticide is prohibited in the United States unless it is registered and labeled. EPA is directed to restrict the use of pesticides as necessary to prevent unreasonable adverse effects on people and the environment, taking into account the costs and benefits of various pesticide uses. Pesticides manufactured solely for export do not require registration. FIFRA also requires EPA to review registrations for pesticides periodically and to reregister older pesticides based on new data that meet current regulatory and scientific standards. For pesticides to be registered for use in food production, FFDCA Section 408 authorizes EPA to establish allowable residue levels, called “tolerances,” that ensure that human exposure to pesticide residues in food will be “safe.” Foods with pesticide residues above the tolerance, or for which there is no tolerance established, may not be imported or sold in interstate commerce. A pesticide may not be registered under FIFRA for a food use unless a tolerance for that pesticide and food has been established under FFDCA.

FIFRA directs EPA to make public any data submitted to support a registration application, if EPA registers the pesticide, but certain data are protected as trade secrets, and other registrants may not use the same data to support registration applications for similar pesticides for a period of 10 years. EPA continues to evaluate the safety of pesticides after they are registered, as new information becomes available. A pesticide registration may be canceled or amended if EPA determines that current use may cause unreasonable adverse effects.

Contents

Introduction.....	1
Overview.....	1
History of Federal Pesticide Law.....	2
FIFRA.....	2
FFDCA.....	5
Registration of Pesticide Products.....	6
Tolerance Setting.....	7
Public Disclosure, Exclusive Use, and Trade Secrets.....	9
Reregistration.....	9
Registration Review.....	10
Special Review.....	11
Canceling or Suspending a Registration.....	11
Use of Unregistered Pesticides.....	12
Enforcement.....	12
Export of Unregistered Pesticides.....	12
Selected References.....	15

Tables

Table 1. Federal Insecticide, Fungicide, and Rodenticide Act and Amendments.....	4
Table 2. Federal Food, Drug, and Cosmetic Act, Section 408, and Amendments.....	5
Table 3. Major <i>U.S. Code</i> Sections of the Federal Insecticide, Fungicide, and Rodenticide Act.....	13
Table 4. Major <i>U.S. Code</i> Sections of the Federal Food, Drug, and Cosmetic Act Related to Pesticides.....	14

Contacts

Author Contact Information.....	15
Acknowledgments.....	15

Introduction

The Environmental Protection Agency (EPA) is responsible for implementing federal pesticide policies under two statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),¹ governing the sale and use of pesticide products within the United States, and the Federal Food, Drug, and Cosmetic Act (FFDCA), which limits pesticide residues on food in interstate commerce (including imports). This report defines key terms, provides a brief history of the federal pesticide laws, and describes key provisions of the laws, including the pesticide registration process and how it interfaces with food safety requirements. In addition, this report lists several references for more detailed information about the acts, and two tables cross reference sections of the *U.S. Code* with corresponding sections of the acts. The report is descriptive rather than analytic, highlights key provisions rather than providing a comprehensive inventory of s' numerous sections, and addresses authorities and limitations imposed by statute, rather than the status of EPA implementation or other policy issues. Other CRS products address current pesticide issues, including CRS Report RL32218, *Pesticide Registration and Tolerance Fees: An Overview*, by (name redacted), and CRS Report RL32884, *Pesticide Use and Water Quality: Are the Laws Complementary or in Conflict?*, by (name redacted).

Overview

There are an estimated 18,000 pesticide products currently in use.² These generally are regulated under FIFRA, but approximately 5,800 pesticide products used in food production also are regulated under the FFDCA, as discussed below. FIFRA requires EPA to regulate the sale and use of pesticides in the United States through registration and labeling.³ Pesticides are broadly defined in FIFRA Section 2(u) as chemicals and other products used to kill, repel, or control pests. Familiar examples include pesticides used to kill insects and weeds that can reduce the yield, and sometimes harm the quality, of agricultural crops, ornamental plants, forests, wooden structures (e.g., through termite damage), and pastures. But the broad definition of “pesticide” in FIFRA Section 2 also applies to products with less familiar “pesticidal uses.” For example, substances are pesticides when used to control mold, mildew, algae, and other nuisance growths on equipment, in surface water, or on stored grains. The term also applies to disinfectants and sterilizing agents, animal repellents, rat poison, and many other substances.

FIFRA directs EPA to restrict the use of pesticides as necessary to prevent unreasonable adverse effects on people and the environment, taking into account the costs and benefits of various pesticide uses. The act prohibits sale of any pesticide in the United States unless it is registered (licensed) and labeled to indicate approved uses and restrictions. It is a violation of the law to use a pesticide in a manner that is inconsistent with the label instructions. EPA registers each pesticide product for each approved use. For example, a product may be registered for use on green beans to control mites, as a seed treatment for cotton, and as a treatment for structural cracks. In addition, FIFRA requires EPA to reregister each older pesticide product that was first registered prior to 1984 and to review all registered pesticides (including those that have

¹ FIFRA also is known as the Act of June 25, 1947.

² Sven-Erik Kaiser, U.S. EPA, Office of Congressional and Intergovernmental Relations, personal communication, December 16, 2011.

³ Exceptions are noted in 40 CFR 152.20, 152.25, and 152.30.

completed the one-time reregistration requirement) periodically on a 15-year cycle based on new data that meet current regulatory and scientific standards. Establishments that manufacture or sell pesticide products must register with EPA. Facility managers are required to keep certain records and to allow inspections by federal or state regulatory officials.

For the 600 or more pesticides (i.e., active ingredients) registered for use in food production, the FFDCA Section 408 authorizes EPA to establish maximum allowable residue levels (also known as “tolerances”) to ensure that human exposure to the pesticide ingredients in food and animal feed will be “safe.”⁴ A “safe” tolerance is defined in the law as a level at which there is “a reasonable certainty of no harm” from the exposure, even when considering total cumulative and aggregate pesticide exposure of children. Under FFDCA, foods with a residue of a pesticide ingredient 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 or imported to the United States. Pesticides may not be registered under FIFRA for use on food unless tolerances (or exemptions) have been established under the FFDCA.

FIFRA authorizes EPA to fund registration-related activities (including registration reviews and tolerance assessments) by collecting fees from pesticide registrants (i.e., manufacturers and formulators) to supplement appropriations.

History of Federal Pesticide Law

Table 1 and **Table 2** summarize the history of FIFRA and FFDCA, respectively.

FIFRA

Federal pesticide legislation was first enacted in 1910; it authorized the U.S. Department of Agriculture (USDA) to set standards for the manufacture of insecticides and fungicides and to require them to be labeled. USDA then could inspect and remove from the market products that were “adulterated”⁵ or ineffective. The original 1947 version of FIFRA broadened the scope of pesticide law to include more types of pesticides, required product registration by USDA prior to interstate or international shipment, and required that labels carry adequate warnings and precautionary instructions for use.

The 1970s brought major changes to the federal role in regulating pesticide production and use. Responsibility for administering FIFRA was shifted to EPA when that agency was created in 1970. A complete revision of FIFRA in 1972 was precipitated by congressional concerns about long- and short-term toxic effects of pesticide exposure on people who applied pesticides (applicators), wildlife, insects and birds not targeted by the pesticide product, and on food

⁴ Ingredients in pesticide products are categorized as active or inert. Active ingredients are those that are intended to control the pest, while inert ingredients, now generally known as “other ingredients,” are used to deliver the active ingredients effectively to the pest. Other ingredients often are solvents or surfactants and often comprise the bulk of the pesticide product. Some inerts are known to be toxic, some are known to be harmless, and others have unknown toxicity.

⁵ FIFRA 2(c) defines “adulterated” in terms of quality, that is, the purity and strength of the product relative to the standards established for that product.

consumers. The 1972 law replaced the original 1947 law, and is the basis of current federal policy, which is summarized in this report. FIFRA, as amended in 1972,⁶ directed EPA to register pesticide products and to “reregister” older products in order to assess their safety in light of more demanding and current scientific standards.

Substantial changes to FIFRA also were made in 1978 (P.L. 95-396), 1988 (P.L. 100-532), 1996 (P.L. 104-170), 2004 (P.L. 108-199), and 2007 (P.L. 110-94). Concerns about the pace of pesticide reregistration were addressed in 1978 when Congress streamlined the process.⁷ The 1978 FIFRA amendments required EPA to review groupings of products having the same active ingredients, on a generic instead of individual product basis, and made provisions for registrants to share the cost of data generation. In addition, Congress authorized EPA to suspend registrations of products if registrants did not provide required test data in a timely fashion. The 1988 amendments focused on further accelerating reregistration (including tolerance assessment) by focusing on older pesticides (registered before 1984), authorizing additional registration fees, and establishing the Reregistration and Expedited Processing Fund in the U.S. Treasury to receive the fee payments (FIFRA Section 4(k)). Congress amended FIFRA Section 4 to require agricultural chemical producers to pay a one-time reregistration fee for each active ingredient and product registrants (manufacturers and formulators) to pay an annual registration maintenance fee for each product registration. The Reregistration and Expedited Processing Fund was intended to supplement appropriations to offset the cost of reregistration and tolerance reassessment.

The Food Quality Protection Act of 1996 (FQPA) established a new, more stringent safety standard for pesticide residues on food, required special protection for children, directed EPA to reassess pesticides posing the greatest risks first, facilitated registration of pesticides for special (so-called “minor”) uses, mandated a periodic review of all registered pesticides at least once every 15 years, and required coordination of regulations implementing FIFRA and FFDCA. The FQPA also authorized and reauthorized collection of new and existing fees to support reregistration and tolerance reassessments through FY2001. Exemptions from, or reductions in, fees were allowed for minor-use pesticides, public health pesticides, and small business registrants.

Current Fees Related to Pesticide Registration

Registration service fees: FIFRA Section 33 [7 U.S.C. 136w-8]

Annual maintenance fees: FIFRA Section 4(i)(5) [7 U.S.C. 136a-1(i)(5)]

Congress extended authority for fees annually through appropriations legislation after FY2001, until the omnibus appropriations legislation signed January 23, 2004 (P.L. 108-199), modified the types and amounts of fees that EPA could collect through FY2008. That legislation included the Pesticide Registration Improvement Act (PRIA 1), which amended FIFRA Section 4 to reauthorize collection of annual “maintenance” fees to support reregistration and tolerance reassessment activities and designated a portion of those fees for the review of inert ingredients. Maintenance fees are deposited in the “Reregistration and Expedited Processing Fund” in the

⁶ Federal Environmental Pesticide Control Act of 1972, P.L. 92-516, Section 4(c)(2).

⁷ Federal Pesticide Act of 1978, P.L. 95-396.

U.S. Treasury (initially established in 1988⁸). PRIA 1 extended the deadline for completion of reregistration. In addition, PRIA 1 added a new Section 33 to FIFRA to establish a system of “Registration Service Fees” (also known as “Enhanced Registration Service” fees) to expedite specific pesticide registration applications submitted to EPA, and established a new fund in the U.S. Treasury to receive those fees, the Pesticide Registration Fund (FIFRA Section 33(c)). PRIA 1 prohibited collection of fees other than maintenance and the new registration fees. The Pesticide Registration Improvement Renewal Act of 2007, or PRIA 2, reauthorized and revised these fee provisions through the end of FY2012, and the Pesticide Registration Improvement Extension Act of 2012, or PRIA 3 (P.L. 112-177), enacted September 28, 2012, further revised the fee collection provisions and extended reauthorization through the end of FY2017. Certain fee collections and apportionment are authorized under PRIA 3 on a reduced basis through FY2019.⁹

See **Table 3** for a listing of current provisions in FIFRA.

Table 1. Federal Insecticide, Fungicide, and Rodenticide Act and Amendments
(codified generally as 7 U.S.C. 136-136y)

Year	Act	Public Law Number
1947	Federal Insecticide, Fungicide, and Rodenticide Act	P.L. 80-104
1964	Federal Insecticide, Fungicide, and Rodenticide Act Amendments	P.L. 88-305
1972	Federal Environmental Pesticide Control Act	P.L. 92-516
1975	Federal Insecticide, Fungicide, and Rodenticide Act Extension	P.L. 94-140
1978	Federal Pesticide Act of 1978	P.L. 95-396
1980	Federal Insecticide, Fungicide and Rodenticide Act Amendments	P.L. 96-539
1988	Federal Insecticide, Fungicide, and Rodenticide Amendments of 1988	P.L. 100-532
1990	Food, Agriculture, Conservation, and Trade Act of 1990	P.L. 101-624
1991	Food, Agriculture, Conservation and Trade Amendments of 1991	P.L. 102-237
1996	Food Quality Protection Act (FQPA) of 1996	P.L. 104-170
2004	Pesticide Registration Improvement Act of 2003	P.L. 108-199
2007	Pesticide Registration Improvement Renewal Act of 2007	P.L. 110-94
2012	Pesticide Registration Improvement Extension Act of 2012	P.L. 112-177

Source: Congressional Research Service.

Note: The current FIFRA statute was established by P.L. 92-516, which completely replaced (by amendment) the original 1947 legislation.

⁸ Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988 (P.L. 100-532), enacted October 25, 1988, and retained in Section 501(b) P.L. 104-170, the Food Quality Protection Act of 1996, enacted August 3, 1996; 7 U.S.C. §136a-1(k)(1).

⁹ CRS Report RL32218, *Pesticide Registration and Tolerance Fees: An Overview*, provides a historical overview of federal authority regarding pesticide fees, including the amount of fee revenues collected over time, and summarizes the key elements of PRIA 1, the revisions reflected in PRIA 2 and in PRIA 3, and highlights of EPA’s registration and reregistration activities since the enactment of PRIA 1.

Authorization for appropriations for FIFRA expired on September 31, 1991, although appropriations bills have continued to provide funding to implement the law. Authority provided by FIFRA to EPA to issue and enforce regulations is, for the most part, permanent, and is not affected by the lack of authorization.

FFDCA

The original FFDCA of 1938 established the structure of the current law. With respect to food safety and possible contaminants, it required the Food and Drug Administration (FDA, then a part of USDA) to set tolerances for unavoidable poisonous substances in food. Congress acted to protect consumers from pesticide residues on food in 1954 by adding a new Section 408 to the FFDCA. It directed FDA to set residue tolerances for all pesticides in *raw* agricultural commodities. Congress expanded the requirement for tolerances in the Food Additives Amendment of 1958, which added Section 409, directing FDA to set tolerances for food additives, including pesticide residues in *processed* foods. Section 409 also forbade the addition to food of any additive (including pesticide residue), if it was found to be a potential cancer-causing agent. This provision is referred to as the Delaney Clause.

In 1970, authority to establish tolerances for pesticide residues was transferred to the newly formed EPA. FDA, in the Department of Health and Human Services (HHS), retained responsibility for enforcement of tolerances in food that is imported or sold across state boundaries.

In 1996, Congress substantially revised requirements for pesticide residue tolerance setting in the Food Quality Protection Act (FQPA). The FQPA redefined terms so that pesticide residues in processed foods were no longer regulated as food additives, and therefore no longer were subject to the Delaney Clause. The FQPA also established a new safety standard of a “reasonable certainty of no harm” from exposure to pesticides. (For details on the safety standard, see “Tolerance Setting” below.) See **Table 4** for a listing of current pesticide-related provisions in the FFDCA.

The Act of July 22, 1954, authorized such sums as may be necessary to carry out this FFDCA section (21 U.S.C. 346b). Fees for tolerance assessments are authorized by FFDCA Section 408(m), but PRIA 1 prohibited collection of tolerance fees in 2004. General appropriations supplemented by the Reregistration and Expedited Processing Fund and the Pesticide Registration Fund support EPA activities with respect to tolerance setting for food-use pesticides.

Table 2. Federal Food, Drug, and Cosmetic Act, Section 408, and Amendments
(codified generally as 21 USC 346a)

Year	Act	Public Law Number
1938	Federal Food, Drug, and Cosmetic Act	Act of June 25, 1938
1954	Federal Food, Drug, and Cosmetic Act Amendments	Act of July 22, 1954
1958	Food Additive Amendments of 1958 (including the Delaney Clause)	P.L. 85-929
1996	Food Quality Protection Act of 1996	P.L. 104-170

Source: Congressional Research Service.

Registration of Pesticide Products

When pesticide manufacturers apply to register a pesticide active ingredient¹⁰, pesticide product, or a new use of a registered pesticide under FIFRA Section 3, EPA requires them to submit scientific data on toxicity and behavior in the environment. EPA may require data from any combination of more than 100 different tests, depending on the potential toxicity of active and inert ingredients and degree of exposure. To register a pesticide use on food, EPA also requires applicants to identify analytical methods that can be used to test food for residues of active ingredients, certain inert ingredients, and their breakdown products and to determine the amount of residue that could remain on crops, as well as on (or in) food products, assuming that the pesticide product 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 would present an unreasonable risk to human health or the environment. If the pesticide is proposed for use on a food crop, EPA also determines whether a "safe" level of pesticide residue, or tolerance, can be established under the FFDCA. A tolerance must be established before a pesticide registration may be granted for use on food crops. If registration is granted, the agency specifies the approved uses and conditions of use, including safe methods of pesticide storage and disposal, which the registrant must explain on the product label. FIFRA requires that federal regulations for pesticide labels pre-empt 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 for restricted use. Products known as "restricted-use pesticides" are those judged to be more dangerous to the applicator or to the environment. Such pesticides can be applied only by people who have been trained and certified. Individual states and Indian tribes generally are responsible for training and certifying pesticide applicators.

FIFRA Section 3 also allows "conditional," temporary registrations if (1) the proposed pesticide ingredients and uses are substantially similar to currently registered products and will not create additional significant environmental risks; (2) an amendment is proposed for additional uses of a registered pesticide, and sufficient data are submitted indicating that there is no significant additional risk; or (3) data requirements for a new active ingredient require more time to generate than normally allowed, and use of the pesticide during the period will not cause any unreasonable adverse effect on the environment and will be in the public interest.

EPA has authority to collect fee revenues as a means of accelerating the pace of the agency's activities to meet its statutory obligations required under FIFRA and FFDCA. All Section 3 registrations are subject to a maintenance fee, collected annually from pesticide registrants (pesticide manufacturers and formulators) to continue existing registrations of their pesticides the year in which the fee is paid. In addition, Section 33 of FIFRA, "Pesticide Registration Services Fees," describes a fee system for new and certain pending applications for pesticide registrations, amended registrations, and associated tolerance actions. Fees are charged based on a statutorily prescribed schedule,¹¹ and fees received by EPA are deposited in the Pesticide Registration Fund

¹⁰ See footnote 4 for definitions of "active" and "inert" pesticide ingredients.

¹¹ The category or type of application, the amount of the pesticide registration service fee, and the corresponding decision review time frame in which the agency is to make a decision under PRIA 3 (P.L. 112-177) are prescribed in the act. Section 2(b)(1)(A) of P.L. 112-177 amends FIFRA by striking existing paragraph (3) under 7 U.S.C. §136w- (continued...)

in the Treasury of the United States, which was established by Congress under PRIA 1 (FIFRA Section 33(c)). PRIA 1 prohibited collection of additional tolerance fees authorized under FFDCA Section 408(m). Revenues from the Pesticide Registration Fund can be used for costs associated with review and decision making for applications for which registration service fees have been paid, but fees collected cover only a portion of EPA's registration activities. The remaining costs are expected to be paid from annual appropriations. To ensure that the appropriated funds are not reduced in lieu of fee revenues, PRIA 3 enacted September 28, 2012, revised and extended the prohibition on authorizing registration service fees unless the amount of congressional appropriations for specified functions conducted by the EPA Office of Pesticide Programs (OPP) (excluding any fees appropriated) remains no less than the corresponding FY2012 appropriation.¹² PRIA 1 and PRIA 2 had stipulated that appropriated funds for specific EPA OPP functions be maintained at no less than 3% below their FY2002 levels. PRIA 3 also continued to stipulate that the authorization to collect and obligate fees must be provided in advance in appropriations acts.¹³ These requirements have been met in EPA annual appropriations for FY2004 through FY2012,¹⁴ and until March 27, 2013, in the FY2013 continuing appropriations resolution (P.L. 112-175).

FIFRA-FFDCA Coordination

EPA has long coordinated pesticide registrations for food uses under FIFRA with tolerance setting under the FFDCA. The Food Quality Protection Act of 1996 (FQPA; P.L. 104-170) codified this policy. Thus, if EPA revokes a residue tolerance under FFDCA, it cancels the FIFRA pesticide registration for that food use. 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.

Tolerance Setting

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 food-related crops.¹⁵ 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 crops. The 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

(...continued)

8(b) and inserting new paragraph (3), "Schedule of Covered Applications and Registration Service Fees." Under PRIA 1 and PRIA 2, the EPA Administrator was directed to publish a detailed schedule of covered pesticide applications and corresponding registration service fees, as reported in the *Congressional Record*.

¹² P.L. 112-177 Section 2(b)(3)(A) through (C) amends 7 U.S.C. §136w-8(d)(2) and strikes paragraph (4).

¹³ FIFRA §33(c)(4) Collections and Appropriations (7 U.S.C. §136w-8(c)(4)(A)).

¹⁴ FY2004 (P.L. 108-199); FY2005 (P.L. 108-447); FY2006 (P.L. 109-54); FY2007 (P.L. 110-5); FY2008 (P.L. 110-161); FY2009 (P.L. 111-8); FY2010 (P.L. 111-88); FY2011 (P.L. 112-10, for EPA, §1101(a)(4) and §1104 in Title I of Division B in P.L. 112-10 provided continued authorization for the collection of pesticide fees during FY2011 pursuant to FY2010 P.L. 111-88, Division A); and FY2012 (P.L. 112-74).

¹⁵ That is, use on food crops, animal feed crops, or food products directly (e.g., grains, fruits, or vegetables after harvest).

for use on that food product and set the tolerance level by issuing a regulation. EPA tolerances for pesticide residues preempt state and local restrictions on food, if the state and local restrictions are based on lower residue levels. States may petition for an exception if the EPA-set residue level threatens public health.

The FFDCA, Section 408, as amended by the FQPA, 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) as well as to other pesticides that have the same toxic effects on people. No quantitative standard of safety is established by law, but the Committee on Commerce noted in its report on the bill that became the FQPA that EPA should continue setting standards to ensure safety as it had 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, the FFDCA directs EPA to take into account many factors, including available information on dietary exposure to pesticides among infants and children. The FQPA strictly limited the nature and influence of benefits considered in tolerance setting under Section 408 of the FFDCA. As amended, Section 408 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 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 on an annual basis may not be more than 10 times the risk at a “safe” level of exposure 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

¹⁶ U.S. House of Representatives, Committee on Commerce, *Food Quality Protection Act of 1996*, H.Rept. 104-669, part 2, 104th Cong., 2nd Session, 1996, p. 6.

one-in-a-million lifetime risk. The Committee expects the Administrator to continue to follow this interpretation.¹⁷

The “safe” standard applies to both raw and processed foods, and requires EPA to consider cumulative and aggregate exposure to pesticides in food, drinking water, air, and consumer products. Congress directed EPA to reevaluate all existing tolerances against this standard before August 2006.

FFDCA directs the FDA and 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.

Public Disclosure, Exclusive Use, and Trade Secrets

FIFRA Section 3 directs EPA to make the data submitted by the applicant for pesticide registration publicly available within 30 days after a registration is granted. However, applicants may claim certain data are protected as trade secrets under FIFRA, Section 10. If EPA agrees that the data are protected, the agency must withhold those data from the public, unless the data pertain to the health effects or environmental fate or effects of the pesticide ingredients. Information may be protected if it qualifies as a trade secret and reveals: (1) manufacturing processes; (2) details of methods for testing, detecting, or measuring amounts of inert ingredients; or (3) the identity or percentage quantity of inert ingredients.

Companies sometimes seek to register a product based upon the registration of similar products, relying upon the data provided by the original registrant that are publicly released. This is allowed. However, Section 3 of FIFRA provides for a 10-year period of “exclusive use” by the registrant of data submitted in support of an original registration or a new use. In addition, an applicant who submits any new data in support of a registration is entitled to compensation for the cost of data development by any subsequent applicant who supports an application with that data within 15 years of its submission. If compensation is not jointly agreed upon by the registrant and applicant, binding arbitration can be invoked.

Reregistration

For many years, Congress has been concerned about the tens of thousands of registered pesticide products that had not been subjected to modern safety reviews. FIFRA Section 4 directs EPA to reregister such products (if they were first registered prior to 1984), in order to assess their safety in light of current scientific standards. Many of those older pesticide products have had their registrations canceled, often because registrants did not request reregistration. At least 14,000 products are no longer in use. Nevertheless, the task for registrants and EPA of reregistering the remaining older pesticide products is immense and costly, and is ongoing.¹⁸

¹⁷ Ibid.

¹⁸ See EPA, “Product Reregistration,” as of November 2012, at <http://www.epa.gov/pesticides/reregistration/product-reregistration.htm>, and “Pesticide Reregistration Facts,” as of November 18, 2011, http://www.epa.gov/oppsrd1/reregistration/reregistration_facts.htm, visited November 2012.

For the purpose of reregistration, EPA considers groupings of products having the same active ingredients (known as “cases”), on a generic instead of individual product basis. For each active case, the agency evaluates existing scientific data to determine whether they are sufficient to inform EPA’s decision about the ingredient’s eligibility for reregistration, given the safety standards specified by FIFRA and FFDCA. For food-use pesticides, EPA evaluates a pesticide’s eligibility for reregistration at the same time the agency reassesses the tolerance for that pesticide under the FFDCA. If data are not sufficient, the agency issues a “data call-in” to registrants, who are responsible for generating the necessary new data following EPA protocols.¹⁹ Registrants may share the cost of testing and analysis. EPA is responsible for reviewing data and determining whether it adequately demonstrates the safety of the product. When all necessary data have been received and reviewed, EPA prepares and issues a Reregistration Eligibility Decision document, known as a “RED.” If registrants do not provide required test data in a timely fashion, EPA is authorized to suspend registrations of products.

FIFRA Section 4(i) directs EPA to collect one-time reregistration fees and to deposit them into the Reregistration and Expedited Processing Fund, established under FIFRA Section 4(k). Annual maintenance fees for registered products also are deposited into this fund. These funds supplement EPA appropriations and are meant to expedite EPA processing of applications for pesticide reregistration (including tolerance reassessment) and to offset costs associated with pesticide registration review (see below). PRIA 1 directed EPA to complete REDs for pesticides (i.e., active ingredients) with food uses/tolerances by August 3, 2006, and to complete REDs for all remaining non-food use pesticides by October 3, 2008. However, the reregistration process continues after that date, as explained on the EPA reregistration website:

After EPA has issued a RED and declared a pesticide eligible for reregistration, individual end-use products that contain the pesticide active ingredient still must be reregistered. Through this concluding part of the process, known as “product reregistration,” the Agency makes sure that the risk reduction measures called for in REDs are reflected on individual pesticide product labels. In some cases, the Agency uses Memoranda of Agreement or other measures to include risk reduction measures on pesticide labels sooner, before product reregistration is completed. EPA plans to complete the last product reregistration decisions several years after the last REDs are signed.²⁰

Registration Review

In anticipation of EPA’s completion of reregistration, Congress amended FIFRA Section 3(g), mandating periodic review of all pesticide registrations on a 15-year cycle. PRIA 2 authorized use of the moneys in the Reregistration and Expedited Processing Fund (FIFRA Section 4(k)) to offset costs of these reviews. PRIA 2 established a deadline of October 1, 2022, for EPA to complete registration review decisions for all pesticide products registered as of October 1, 2007. PRIA 3 (P.L. 112-177), enacted September 28, 2012, continued the authorization of the moneys in this Fund and retained the October 1, 2022, deadline. The registration reviews are intended to determine whether pesticides continue to meet the statutory standard of no unreasonable adverse effects (and a reasonable certainty of no harm, for food-use pesticides), taking into account

¹⁹ Test protocols and laboratory practices are issued as regulations and may be found in Title 40 of the *Code of Federal Regulations*, Sections 158 and 160.

²⁰ EPA, Pesticide Reregistration Facts, November 18, 2011, http://www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm.

changes in scientific capabilities for assessing risk, as well as changes in policies and pesticide use practices over time. Registration review is replacing EPA's reregistration and tolerance reassessment programs.²¹

Special Review

EPA continues to evaluate the safety of pesticides after they are registered as new information becomes available. FIFRA requires registrants to report promptly any new evidence of adverse effects from pesticide exposure. If evidence indicates that a registered pesticide may pose an unreasonable risk, EPA may initiate a special review of available information to reevaluate the risks and benefits of each registered use. FIFRA also authorizes EPA to require registrants to conduct new studies to fill gaps in scientific understanding to assist risk assessments. As a result of a special review EPA may conclude that registration is adequate, needs amendment, or should be canceled.

Cancelling or Suspending a Registration

If a special review or reregistration evaluation finds that a registered use may cause "unreasonable adverse effects," EPA may amend or cancel the registration.²² FIFRA also allows registrants to request cancellation or amendment of a registration to terminate selected pesticide uses. Requesting 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 would be maintained.

If a registration is canceled for one or more uses of a pesticide, FIFRA does not permit it to 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. FIFRA allows registrants to appeal an EPA decision to cancel a registration. An appeal initiates a lengthy 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 a registration, FIFRA authorizes EPA to suspend registration. Suspension orders, which also may be appealed, stop sales and use of the pesticide.

In the event of suspension and cancellation, FIFRA Section 15 directs EPA to request an appropriation from Congress to compensate anyone who owned any of the pesticide and suffered any loss due to the suspension or cancellation. The registrant of the suspended and canceled product is responsible, however, for all of the transportation and disposal costs, and most storage costs.

²¹ For a more detailed overview of EPA's registration review process, and updated information on EPA's schedule for opening dockets to begin pesticide registration reviews, see http://www.epa.gov/oppsrrd1/registration_review/reg_review_process.htm, updated May 9, 2012.

²² 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.

Use of Unregistered Pesticides

FIFRA also allows for unregistered use of pesticide products in special circumstances. Section 5 allows experimental use permits for purposes of research and to collect data needed to register a pesticide. Section 18 allows “emergency exemptions” from the provisions of FIFRA to be granted to federal or state agencies, for example, if there is a virulent outbreak of a disease that cannot be controlled by registered products. In addition, Section 24(c) permits states to allow additional uses of a federally registered product to meet “special local needs.”

Enforcement

Generally, EPA has the authority to enforce FIFRA requirements. However, FIFRA Section 26 gives states with adequate enforcement procedures, laws, and regulations primary authority, including inspection authority, for enforcing FIFRA provisions related to pesticide use. EPA is authorized by Section 27 to rescind a state’s primary enforcement responsibility if it is not being carried out.

FIFRA Section 11 authorizes EPA to form cooperative agreements with states, giving them the responsibility for training and certifying applicators of restricted use pesticides. States also may initially review and give preliminary approval to applications for emergency exemptions and special local needs registrations (although under some conditions FIFRA allows EPA later to deny state-approved applications).

Section 9 authorizes inspections by EPA and authorized state officials of pesticide products where they are stored for distribution or sale. Section 13 authorizes EPA to issue orders to stop sales and to seize supplies of pesticide products. Civil and criminal penalties for violations of FIFRA are established in Section 14, while Section 15 provides indemnity payments for end users, distributors, and dealers of pesticides when registrations are suspended and canceled.

Federal district courts are authorized in Section 16 to review EPA final actions and omissions when action is not discretionary. People adversely affected by an EPA order may file for judicial review of the order following a hearing. But FIFRA does not authorize citizen suits against violators.

Export of Unregistered Pesticides

FIFRA does not give EPA the authority to regulate domestic production for export of unregistered pesticides, even if U.S. registration has been canceled for health or environmental reasons. However, FIFRA does require exporters to prepare or pack pesticides as specified by the purchaser and in accord with some of the FIFRA labeling provisions. For example, exporters must translate warning information into the language of the destination. FIFRA also requires exporters of unregistered pesticides to obtain the purchaser’s signature on a statement acknowledging that the pesticide is unregistered and cannot be sold in the United States. EPA is required to notify governments of other countries and international agencies whenever a registration, cancellation, or suspension of any pesticide becomes or ceases to be effective in the United States.

Table 3. Major U.S. Code Sections of the Federal Insecticide, Fungicide, and Rodenticide Act
(codified generally as 7 U.S.C. 136-136y)

7 U.S.C.	Section Title	FIFRA
	Short title and table of contents	§1
136	Definitions	§2
136a	Registration of pesticides	§3
136a-1	Reregistration of registered pesticides	§4
136c	Experimental use permits	§5
136d	Administration review; suspension	§6
136e	Registration of establishments	§7
136f	Books and records	§8
136g	Inspection of establishments	§9
136h	Protection of trade secrets and other information	§10
136i	Restricted use pesticides; applicators	§11
136j	Unlawful acts	§12
136k	Stop sale, use, removal, and seizure	§13
136l	Penalties	§14
136m	Indemnities	§15
136n	Administrative procedure; judicial review	§16
136o	Imports and exports	§17
136p	Exemption of federal and state agencies	§18
136q	Storage, disposal, transportation, and recall	§19
136r	Research and monitoring	§20
136s	Solicitation of comments; notice of public hearings	§21
136t	Delegation and cooperation	§22
136u	State cooperation, aid, training	§23
136v	Authority of states	§24
136w	Authority of Administrator	§25
136w-1	State primary enforcement responsibility	§26
136w-2	Failure by the state to assure enforcement of state pesticide use regulations	§27
136w-3	Identification of pests; cooperation with Department of Agriculture's program	§28
136w-4	Annual report	§29
136w-5	Minimum requirements for training of maintenance applicators and service technicians	§30
136w-6	Environmental Protection Agency minor use program	§31
136w-7	Department of Agriculture minor use program	§32
136w-8	Pesticide Registration Service Fees	§33

7 U.S.C.	Section Title	FIFRA
136x	Severability	§34
136y	Authorization of Appropriations	§35

Note: This table shows only the major code sections. For more detail and to determine when a section was added, the reader should consult the official printed version of the *U.S. Code*.

Table 4. Major U.S. Code Sections of the Federal Food, Drug, and Cosmetic Act Related to Pesticides

(codified generally as 21 U.S.C. 321-346a)

21 U.S.C.	Section Title	FFDCA
Chapter II—Definitions		
321	Definitions	§201
Chapter III—Prohibited Acts and Penalties		
331	Prohibited acts	§301
332	Injunction proceedings	§302
333	Penalties	§303
334	Seizure	§304
Chapter IV—Food		
342	Adulterated food	§402
343	Misbranded food	§403
346	Tolerances for poisonous ingredients in food	§406
346a	Tolerances and exemptions for pesticide chemical residues	§408
346a(a)	Requirement for tolerance or exemption	§408(a)
346a(b)	Authority and standard for tolerance	§408(b)
346a(c)	Authority and standard for exemptions	§408(c)
346a(d)	Petition for tolerance or exemption	§408(d)
346a(e)	Action on Administrator's own initiative	§408(e)
346a(f)	Special data requirements	§408(f)
346a(g)	Effective data, objections, hearings, and administrative review	§408(g)
346a(h)	Judicial review	§408(h)
346a(i)	Confidentiality and use of data	§408(i)
346a(j)	Status of previously issued regulations	§408(j)
346a(k)	Transitional provision	§408(k)
346a(l)	Harmonization with action under other laws	§408(l)
346a(m)	Fees	§408(m)
346a(n)	National uniformity of tolerances	§408(n)
346a(o)	Consumer right to know	§408(o)
346a(p)	Estrogenic substances screening program	§408(p)
346a(q)	Schedule for review	§408(q)

21 U.S.C.	Section Title	FFDCA
346a(r)	Temporary tolerance or exemption	§408(r)
346a(s)	Savings clause	§408(s)

Note: This table shows only the major code sections. For more detail and to determine when a section was added, the reader should consult the official printed version of the U.S. Code.

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