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Pesticide Registration and Tolerance Fees: Overview

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Summary

The U.S. Environmental Protection Agency (EPA) is responsible for regulating the sale, use, and distribution of pesticides under the authority of two statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C.136-136y), a licensing statute requiring EPA to review and register the use of pesticide products within the United States; and the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 346a), requiring the establishment of maximum limits (tolerances) for pesticide residues on food in interstate commerce. Fees paid by pesticide manufacturers and other registrants supplement appropriations to EPA for the administration of specified requirements of these Acts. This report provides an overview of the authorities for the collection of federal pesticide fees, and legislation passed in the 108th Congress modifying existing fee authority. For a more complete overview of the federal pesticide laws, refer to CRS Report RL31921, *Pesticide Law: A Summary of Statutes*, and CRS Report RS20043, *Pesticide Residue Regulation: Analysis of Food Quality Protection Act Implementation*.

The Omnibus appropriations bill (H.R. 2673) passed in the House at the end of the first session of the 108th Congress on December 8, 2003, the Senate in the second session on January 22, 2004, and signed into law (P.L. 108-199) on January 23, 2004, includes provisions for fees to support the activities of the EPA's pesticide program. Based primarily on S. 1664 and H.R. 3188, introduced in September, 2003, the Omnibus bill's provisions reauthorize and increase current pesticide "maintenance fees" used primarily for reviewing "older" (pre-1984) pesticide registrations ("reregistration"), introduce new authority for collect fees for establishing tolerances over the next five years. In addition, EPA is required to develop a schedule to accelerate processing of pesticide registration applications and re-registration reviews.

Authority for collecting pesticide fees dates back as far as the 1954 amendments to FFDCA (P.L. 518, July 22, 1954), which, as passed, required the collection of fees "sufficient to provide adequate service" for establishing maximum residue levels (tolerances) for pesticides on food. Authority to collect fees was expanded with the 1988 FIFRA amendments (P.L. 100-532), primarily to support acceleration of the reregistration process (i.e., re-evaluation of pesticides registered prior to 1984). EPA was authorized to collect a one-time re-registration fee, and through FY1997, annual maintenance fees. The 1996 amendments to FIFRA and FFDCA, or the Food Quality Protection Act (FQPA; P.L. 104-170), extended EPA's authority to collect the annual maintenance fees through FY2001, including the use of these fees for purposes of re-evaluating "old" tolerances (tolerance reassessment).

Timely completion of the registration, re-registration, and tolerance assessment requirements, continues to be an issue. Recent EPA proposals to modify the fee structure to significantly increase revenues supporting these activities, and attempts to include increased fee revenues annually in EPA budget proposals from FY1998 through FY2004, have been prohibited by Congress. As an interim solution, authority for maintenance fees, that expired in FY2001, had been extended annually through appropriations legislation. This report will be updated as events warrant.

Contents

Introduction
Background1
Key Provisions of the Pesticide Fee Legislation
Reauthorization of Pesticide Registrant Maintenance Fees
Registration Services Fees
Pesticide Registration Fund
Prohibition of "Tolerance Fees"
Pesticide Registration Process Reforms
Overview of Pesticide Fee Authorities and Fee Revenues
FIFRA and FFDCA Pesticide Fee Collection Authority
Other Pesticide Fee Authority and Proposed Changes
Revenues from Pesticide Fees
Distribution of Pesticide Program Appropriated Funds and Fee Revenues
Conclusion

List of Figures

Figure 1. Pesticide Program Fees Collected by EPA, FY1983-FY2003	
	. 11
Figure 2. EPA FY2003 Pesticide Budget Allocations Budget	. 12

List of Tables

Table 1. Timeline of Pesticide Fee Authorities	7
Table 2. EPA Appropriations and Fee Revenues for Pesticide Program	n Activities,
FY2001-FY2004	14

Pesticide Registration and Tolerance Fees: Overview

Introduction

General U.S. revenues are used to cover most of the administrative costs of the U.S. Environmental Protection Agency (EPA) pesticide program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C.136-136y), and the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 346a), as amended, but fees also have been imposed on those manufacturing and distributing pesticides in commerce in the U. S. (i.e., registrants¹), to supplement EPA appropriations. The collection of fees to support EPA pesticide program activities has been a complex issue during the last 20 years. Recent proposals to modify and increase fees have been at odds with the views of a range of stakeholders, and controversial in Congress.

The 108th Congress passed legislation that would modify EPA authorities to collect fees to support specified activities of the EPA's pesticide programs implemented under the authority of FIFRA and FFDCA. In late November, 2003, Congressional conferees agreed to include pesticide fees provisions in the FY2004 appropriations for EPA (H. Report 108-401). The Omnibus appropriations bill (H.R. 2673) passed in the House at the end of the first session of the 108th Congress on December 8, 2003, the Senate on January 22, 2004, and signed into law on January 23, 2004 (P.L. 108-199), includes similar pesticide fees provisions. This report summarizes the key elements of this legislation, and provides a brief overview of federal pesticide fee authority, including the amount of fee revenues collected.

Background²

FIFRA is a licensing statute, requiring EPA to register pesticide products before they can be sold, used, and distributed within the United States. EPA evaluates proposed pesticide registrations under a set of science-based safety standards to ensure that they will not harm human health or the environment. Before a registration can be granted for a "food use" pesticide, FFDCA³ requires that a tolerance (the maximum amount of pesticide residue permitted in or on food and feed) or tolerance exemption be in place. EPA establishes tolerances through

¹ A registrant is defined as a person who has registered any pesticide pursuant to the provisions of FIFRA.

² For a more complete overview of the federal pesticide laws and their key provisions, refer to CRS Report RL31921, *Pesticide Law: A Summary of Statutes*, and CRS Report RS20043, *Pesticide Residue Regulation: Analysis of Food Quality Protection Act Implementation.*

³ FFDCA Sections 408 and 409.

rulemaking, based on risk assessments and human health criteria to ensure a "reasonable certainty of no harm." EPA is also required to re-evaluate older, registered pesticides (i.e., "re-registration"),⁴ and to reassess existing tolerances (i.e., "tolerance reassessment"),⁵ to ensure they meet current stricter safety standards, in particular, those standards introduced by the 1996 amendments (the Food Quality Protection Act or FQPA; P.L. 104-170) to FIFRA and FFDCA. Congress has amended FFDCA and FIFRA over time to authorize the collection of fees to supplement appropriated funds for these pesticide review activities. (A more detailed overview of pesticide fee authorities, and fee revenues collected, is presented later in this report).

The 1954 amendments to FFDCA⁶ authorized the collection of fees to provide adequate service for establishing maximum allowable residue levels (tolerances) for pesticides on food, and remain the basis for current "tolerance fee" authority. Congress amended FIFRA in 1988 (P.L. 100-532), authorizing the collection of a one-time "re-registration fee," and through FY1997, annual "maintenance fees," in an effort to accelerate re-registration (review of pesticides registered before 1984). In the 1996 amendments to FIFRA and FFDCA (FQPA; P.L. 104-170), concerned with the continued pace of re-registration, Congress extended EPA's authority to collect the annual maintenance fees through FY2001. In addition, in an attempt to provide resources to address increased responsibilities of implementing new safety standards introduced with the 1996 amendments, maintenance fee authority was expanded to allow a portion of the revenues collected to be used to support the reevaluation of "old" existing tolerances (tolerance reassessment). These pesticide maintenance fees, and tolerance fees based solely on petitions for establishing new tolerances, were the only pesticide fees collected by EPA for the past 8 years (FY1996-FY2003).

The current, and previous Administration, had recommended modifications to the fee structure to significantly increase revenues, primarily to obtain supplemental resources to support increased administrative costs associated with implementing the requirements of FQPA. Recent proposals focused on discontinuing the legislative prohibition on pesticide registration fee authority⁷ originally promulgated in 1988, and finalizing a 1999 EPA proposal⁸ to substantially revise tolerance fees. Questioning the appropriateness of the statutory authority cited, the final pesticide registration fee regulation was challenged in court by the Chemical Specialties

⁴ The 1988 amendments to FIFRA (P.L. 100-532) define "re-registration" as re-evaluation of pesticides registered prior to 1984.

⁵ Per the 1996 amendments to FIFRA and FFDCA (FQPA; P.L. 104-170), "tolerance reassessments" refers to those tolerances in existence as of August 1996.

⁶ Section 408(o) per the Pesticide Residue Amendment of 1954 (P.L. No. 518, 21 U.S.C. 346(a)). The current authority resides in FFDCA Section 408(m), per the 1996 amendments to FFDCA (FQPA)).

⁷ EPA promulgated a rule for collecting registration fees under the authority of the Independent Offices Appropriation Act (IOAA) of 1952 (31 U.S.C. 9701). See Subpart U of CFR part 152, at 53 *Federal Register* 19108, May 26, 1988.

⁸ U.S. EPA, 64 *Federal Register* 31039-31050, June 9, 1999.

Manufacturers' Association,⁹ and the collection of registration fees under this authority was temporarily suspended through FY1997 by the 1988 amendments to FIFRA (Section 4(i)(6)). Collecting registration fees under this authority continued to be prohibited by law, and in annual appropriations bills, including the FY2004 Continuing Resolution. EPA's 1999 proposal to restructure the collection of tolerance fees met with similar resistance. Industry groups questioned the authority to expand fee collection under FFDCA¹⁰ and the lack of a clearly defined schedule of specific Agency activities to be supported by fee revenues. These groups also generally opposed the EPA's justification for proposing a tenfold increase, payment of fees retroactively, and imposing fees for inert ingredients.¹¹ Congress prohibited promulgation of the tolerance fee rule in EPA's FY2000 appropriations (P.L. 106-377). Similar proposals to increase tolerance fees in EPA's annual budget requests through FY2004 have been prohibited each year through appropriations legislation.

The pesticide fees legislation passed in the 108th Congress (Section V of Division G, H.R. 2673), temporarily supersedes the 1988 registration fee authority,¹² and suspends tolerance fee authority under FFDCA through FY2008. The legislation, which appears to address many of the issues and concerns associated with other recently proposed modifications, has the support of a large cross section of stakeholders, including organizations representing manufacturers and formulators, agricultural producers, and environmental and public interests.¹³ The groups jointly favor the expected reforms and acceleration of EPA's decision process, the simplification of the fee authority, and the detailed schedule of activities determining the allocation of fees collected.

Key Provisions of the Pesticide Fee Legislation

The "Pesticide Registration Improvement Act of 2003," originally introduced as S. 1664 and H.R. 3188 on September 25, 2003, amends FIFRA and modifies the framework for collecting fees to enhance and accelerate the completion of pesticide registration applications and re-registration reviews. The pesticide fees provisions in Title V of Division G of the FY2004 Omnibus appropriations bill will:

⁹ Chemical Specialties Manufacturers Association (now the Consumer Specialty Products Association) v. EPA, No. 88-1525. D.D.C., July 25, 1988.

¹⁰ Several industry groups disagreed and were concerned with EPA's interpretation that the statute provided authority to collect 100% of the cost of tolerance reassessment using fees. (*EPA Docket # OPPT-301151 and OPPT-301151B*).

¹¹ Inert ingredients can be solvents or surfactants and often comprise the bulk of the pesticide product. Some inerts are known to be toxic, and some are known to be harmless, but EPA lists most in the category "inerts of unknown toxicity."(U.S. EPA website [http://www.epa.gov/pesticide/inert]).

¹² The legislation (H.R. 2673; P.L. 108-199) removes the prohibition on "other fees" by amending FIFRA Section 4(i)(6), replacing Sections 33 and 34 (7 U.S.C. 136x and 136y) through 2010. Thus the legislation temporarily replaces registration fee authority codified in 1988 (Subpart U of CFR part 152), through 2010.

¹³ September 12, 2003, letter addressed to President George W. Bush, from a coalition of 30 organizations representing industry and public interests.

- extend the existing authority to collect maintenance fees at increasing, then declining levels;
- provide new authority for EPA to collect "registration services fees,"which would be phased out at the end of FY2010;
- prohibit collection of any tolerance fees through FY2008; and
- require EPA to identify reforms to the pesticide registration process to substantially reduce the decision review period.

Reauthorization of Pesticide Registrant Maintenance Fees. Annual maximum maintenance fees per registrant, and in aggregate, will increase each year above the FY2003 levels for the first three years, and decline in the final two years.¹⁴ For example, the annual maximum fee for registrants with less than 50 pesticide registrations will increase from the current \$55,000 in FY2003 to \$84,000 for FY2004, and \$87,000 in FY2005 and FY2006. That fee will decline in FY2007 to \$68,000, before returning to the FY2003 level of \$55,000 in FY2008. Similar changes from FY2003 fee levels will occur for registrants with more than 50 registrations, and for small businesses (as redefined in the legislation). The ability to obtain waivers will continue for public health pesticides. The annual statutory aggregate limit increases from the current \$21.5 million in FY2003 to \$26 million in FY2007 and \$15 million for FY2008.¹⁵

Maintenance fees will continue to be assessed on existing pesticide registrations to fund re-registration, tolerance reassessment, and expedited processing of "similar" pesticides,¹⁶ and public health pesticides. Provisions in the bill also amend FIFRA (7 U.S.C. 136a-l(k)(3)) to explicitly designate the use of a portion of maintenance fees for the review of "inert" ingredients.¹⁷ The 1996 FQPA placed greater emphasis on inert ingredients and clarified that these chemicals are covered by the definition of a pesticide chemical under FFDCA (section 201(q)(1)). Therefore EPA must make a determination regarding the establishment of tolerances for inert ingredients.

Registration Services Fees. Registration services fees¹⁸ apply only to new pesticide applications (submitted on or after the effective date of the legislation), with provisional transitional allowances for pending applications. These fees are expected

¹⁴ See H.R. 2673 (enrolled), Division G, Title V, Section 501(c)(1)(D) and (E).

¹⁵ Per the provisions of the 1988 amendments to FIFRA (P.L. 100-532), EPA calculates and adjusts the amount of annual maintenance fees collected per registrant, based on the number of registrants and the number of pesticide registrations, which is determined by the Agency at the beginning of each fiscal year.

¹⁶ "Me-too" pesticides; see FIFRA section 4(k)(3)(i), "... the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide..."

¹⁷ Approximately \$3.3 million for FY2004 through FY2006, and between 1/8 and 1/7 of the annual aggregate maintenance fee amount authorized for FY2007 and FY2008, can be used for the review of inert ingredients (P.L.108-199, Division G, Title V, Section 501(e)).

¹⁸ H.R. 2673 (enrolled), Division G, Title V, Section 501(f)(2) amends FIFRA and inserts *"Sec. 33. Pesticide Registration Services Fees."*

to cover a portion of the cost for review and decision-making associated with a registration application, including associated tolerance determinations. As defined in the legislation, these costs include staff, contractors, and advisory committees engaged in relevant activities for pesticide applications, associated tolerances, and corresponding risk and benefits information and assessment.

The EPA Administrator is directed to publish a detailed schedule of covered pesticide applications, and corresponding registration service fees as reported in the September 17, 2003, Congressional Record (S11631 through S11633). The amount of the fees vary depending on the specific "service" required. Authority to collect service fees ends at the conclusion of FY2008, with phase-out authority at reduced levels for FY2009 and FY2010.

Pesticide Registration Fund. The legislation establishes a Pesticide Registration Fund ("the Fund") in the U.S. Treasury, to be made available to EPA for purposes defined in the legislation, without fiscal year limitation. The legislation includes a mandatory adjustment (5% increase) by FY2006, and provisions requiring the use of a portion of the amount in the Fund (not less than \$750,000 and not more than \$1 million) to enhance scientific and regulatory activities for worker protection for FY2004 through FY2008. An additional portion of the Fund (not to exceed \$500,000) is to be used for the evaluation of new inert ingredients.

Waivers or reductions of registration service fees for minor uses or small businesses are authorized, as are partial fee refunds, when applications are withdrawn or at the Administrator's discretion. To assure that the appropriated funds are not reduced in lieu of fee revenues for the first three fiscal years (FY2004-FY2006), the legislation prohibits authorizing registration services fees unless the amount of appropriations for specified functions conducted by the EPA Office of Pesticide Programs in those years are no less than the corresponding FY2002 appropriation.¹⁹

Prohibition of "Tolerance Fees". The legislation prohibits EPA from collecting "any" tolerance fees under the authority of section 408(m)(l) of FFDCA (21 U.S.C. 346a(m)(l)) through FY2008. Fee revenues to support tolerance review activities will be allocated from maintenance fees (for tolerance reassessments) and registration service fees (for new and amended tolerances) for the next 5 years.

Pesticide Registration Process Reforms. In conjunction with the increased fee revenues, a key provision of the legislation is the requirement for EPA to identify reforms²⁰ to the Agency's pesticide registration process with the intent of reducing the current decision review period. The EPA Administrator is directed to publish in the Federal Register a schedule of decision review periods for pesticide registration activities covered by this legislation. The schedule is to be the same as the applicable schedule appearing in the September 17, 2003, *Congressional Record* (S11631 through S11633).

¹⁹ *Ibid.*, see *Section 33(d) Assessment of Fees*, under this heading.

²⁰ Ibid., see Sections 33(e) Reforms to reduce Decision Time Periods, and (f)Decision Review Time Periods

Overview of Pesticide Fee Authorities and Fee Revenues

Various changes and proposed changes to pesticide fee authority led up to the current legislation. Fees collected by EPA over time to support the pesticide program have included tolerance fees, registration fees, re-registration fees, and maintenance fees (see Table 1: Timeline of Pesticide Fee Authorities). Since 1996, EPA has only collected tolerance fees, generally for the establishment of pesticide residue limits on food, and maintenance fees, primarily for re-registration reviews and reassessment of existing tolerances.

FIFRA and FFDCA Pesticide Fee Collection Authority. Authority for the collection of pesticide fees dates back as far as the 1954 amendments to FFDCA.²¹ At the time, Section $408(0)^{22}$ required the collection of fees to cover the costs of establishing maximum residue levels, "tolerances," for pesticides on food. Until 1988, these tolerance fees were the only pesticide fees collected by EPA.

The 1988 amendments to FIFRA (P.L. 100-532) extensively expanded pesticide fee authority. The amendments included a 9-year schedule to accelerate the process of re-registration. To help defray the costs of the accelerated process, EPA was authorized to collect a one-time re-registration fee from producers for their pesticide active ingredients registered prior to 1984, and annual maintenance fees from pesticide registrants through FY1997, for each registered pesticide product. The amount of fees per registrant were tiered, depending on the number of registrations per registrant, as determined by EPA each fiscal year.

Congress amended FIFRA in 1996 (FQPA; P.L. 104-70), extending EPA's authority to collect the annual maintenance fees through FY2001. FQPA also expanded the authority under FFDCA to include the use of fees for purposes of reevaluating "old" tolerances (tolerance reassessment). The new FQPA requirements, including "reasonable certainty" of "no harm," and analysis of aggregate risk assessment, cumulative effects of pesticides, and safety factors for children, introduced a host of new responsibilities for EPA, particularly when establishing new tolerances and the reassessment of old tolerances.²³ Since its expiration September 30, 2001, the statutory authority for maintenance fees has been extended in annual EPA appropriations bills.²⁴

²¹ Pesticide Residue Amendment of 1954, P.L. No. 518, 21 U.S.C. 346(a).

²² This authority currently resides in FFDCA Section 408(m) (1996 FQPA).

²³ See CRS Report RS20043, *Pesticide Residue Regulation: Analysis of Food Quality Protection Act Implementation.*

²⁴ The FY2001 statutory aggregate level of \$14 million established by the 1988 FIFRA amendments, was increased to \$17 million in FY2002 (P.L. 107-73) and \$21.5 million in FY2003 (P.L. 108-10). The final Continuing Resolution for FY2004 (P.L. 108-135) extended the maintenance fee as authorized in FY2003 (see H. Joint Res. 69 Section 118).

Table 1. Timeline of Pesticide Fee Authorities

Year	Action	Pesticide Fee Authority		
1952	Independent Appropriations Act of 1952 (IOAA)	Authorizes Federal regulatory Agencies to recover costs of services for identifiable recipients.		
1954	Federal Food Drug and Cosmetic Act, amended (FFDCA; P.L. No. 518, 21 U.S.C. 346 (a))	Fees to accompany initial or modified petitions for establishing tolerances under FFDCA section 408 (o).		
1986	EPA Registration Fee Regulation: Proposed (51 Federal Register 42974, Nov. 26, 1986)	Proposed schedule of fees to accompany pesticide registration and experimental use permit applications, citing the authority of IOAA.		
1988	EPA Registration Fee Regulation (40 CFR 152(u) and 40 CFR 172)	Fees to accompany pesticide registration and experimental use permit applications; authority suspended by the FIFRA amendments passed later that same year (1988).		
	Federal Insecticide, Fungicide and Rodenticide Act, amended (FIFRA; P.L. 100-532)	Re-registration and expedited processing fund: a one-time "re-registration" fee, and annual "maintenance" fees through FY1997. Prohibited collection of other fees (including "registration fees" as defined in 40 CFR 152(u) and 40 CFR 172).		
1996	Food Quality Protection Act (FQPA) (P.L. 104- 170): FIFRA and FFDCA, amended	Maintenance fees authorization extended through FY2001. FFDCA authority (Section 408(m)) amended to cover costs of all tolerance activities and EPA directed to deposit funds collected as maintenance fees to be used for reassessing existing tolerances as needed. Collection of registration fees prohibited through FY2001.		
1999	EPA Tolerance Fee Rule: Proposed (64 Federal Register 31039-31050, June 9, 1999)	Tenfold increase in tolerance fees; new "tolerance reassessment" fees, including fee for reviewing tolerances for inert ingredients. Fees, to be collected retroactively from 1996, would supplement authorized maintenance fees.		
	FY2000 EPA Appropriations (P.L. 106-377)	Prohibited promulgation of a final tolerance fee rule based on the 1999 proposal.		
2000	FY2001 EPA Appropriations (P.L. 106-774)	Continued prohibition on promulgation of a final tolerance fee rule as proposed in 1999.		
2001	FY2002 EPA Appropriations (P.L. 107-73)	Continued the prohibition on promulgation of a final tolerance fee rule based on the 1999 proposal, and collection of registration fees as codified in 1988 is prohibited. Maintenance fees reauthorized and aggregate limit increased.		

CRS-8	
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Year	Action	Pesticide Fee Authority		
2002	Farm Security Act	Proposed pesticide fee authorities in Conference; no provisions included in final bill.		
2002- 2003	 EPA Appropriations: FY2003 (P.L. 108-10), and FY2004 (P.L. 108-135, Continuing Resolution through Jan. 31, 2004) S. 1664, H.R. 3188, proposed; H.R. 2673 (Omnibus Appropriations Bill; Division G, Title V): Proposed and passed in the House 	 Prohibits promulgation of a final tolerance fee rule based on the 1999 proposal. Continued prohibition of the collection of registration fees as codified in 1988. Maintenance fees reauthorized; maximum aggregate levels increased. New registration service fee, maintenance fees reauthorize, pesticide regulation process reforms required, prohibits collection of tolerance fees. 		
2004	H.R. 2673 (Omnibus Appropriations Bill; Division G, Title V) Passed in the Senate and signed into law (P.L. 108-199)	New registration service fee, maintenance fees reauthorize, pesticide regulation process reforms required, prohibits the collection of tolerance fees.		

Other Pesticide Fee Authority and Proposed Changes. Prior to the 1988 amendments, EPA promulgated a final pesticide registration fee regulation²⁵ on May 26, 1988, citing the authority of the Independent Offices Appropriation Act (IOAA) of 1952 (31 U.S.C. 9701). Intended to defray increasing administration costs of pesticide registration reviews, the final rule includes a prescribed schedule of fees to be submitted with each application for registration, amended registration, or experimental use permit. Registration fees would be deposited in the U.S. Treasury, and not directly available to EPA. The regulation was challenged in court by the Chemical Specialties Manufacturers' Association,²⁶ and the collection of registration fees under this authority was temporarily suspended through FY1997 by the 1988 amendments to FIFRA (Section 4(i)(6)). Collecting registration fees under this authority in annual appropriations bills FY2002 through current FY2004 Continuing resolution.²⁷

In June 1999, EPA published a proposed rule restructuring tolerance fees²⁸ in an effort to cover the cost of establishing initial tolerances, and tolerance reassessments, including tolerance activities for "other" ingredients (namely, inert ingredients ²⁹). EPA proposed as much as a tenfold increase, and payment of fees retroactively for tolerance petitions submitted and reassessments initiated after FQPA was enacted in August 1996. Industry groups generally opposed the proposal. According to comments submitted to the EPA, several industry groups disagreed and were concerned with, among other issues, EPA's interpretation that the statute provided authority to collect 100% of the cost of tolerance reassessment using fees, These groups also generally opposed EPA's justification for the tenfold increase in fees, imposing fees retroactively, and the potential impacts resulting from imposing fees for inert ingredients.³⁰ Congress prohibited promulgation of the tolerance fee rule in EPA's FY2000 appropriations (P.L. 106-377). Similar proposals to increase tolerance fees, included in EPA's annual budget requests through FY2004,³¹ have been prohibited each year in appropriations legislation.³²

²⁸ 64 *Federal Register* 31039-31050, June 9, 1999.

²⁹ The 1996 FQPA clarified that "inert" ingredients are covered by the definition of a pesticide chemical under FFDCA (section 201(q)(1)).

³⁰ EPA Docket # OPPT-301151 and OPPT-301151B.

³¹ See EPA Budget Proposals and Congressional Justifications for FY2001-FY2004 on EPA's website [http://www.epa.gov.ocfo.budget].

²⁵ 40 CFR 152(u) and 40 CFR 172

²⁶ Chemical Specialties Manufacturers Association (now the Consumer Specialty Products Association) v. EPA, No. 88-1525. D.D.C., July 25, 1988. The lawsuit has been held in abeyance since the passage of the 1988 FIFRA amendments.

²⁷ Appropriations bills for VA-HUD and Independent Agencies passed by the 107th Congress (P.L. 107-73), and the 108th Congress (P.L. 108-10; P.L. 108-135, Continuing Resolution for FY2004, expired January 31, 2004) contained similar prohibitive language.

³² Appropriations bills for VA-HUD and Independent Agencies passed by the 106th Congress (P.L. 106-377 and P.L. 106-774), the 107th Congress (P.L. 107-73), and the 108th Congress (continued...)

The 107th Congress considered approaches to revise the overall fees structure for pesticide programs, including incorporating a manager's amendment to the Senate version of the 2002 farm bill (S. 1731). The Conference substitute deleted the fee provisions and it was not included in the final Farm Security and Rural Investment Act of 2002 (P.L. 107-171). In the Conference Report accompanying the final bill (H.R. 2646), the managers "strongly encouraged" the EPA to withdraw its proposed tolerance fee rule, and instead, work with the appropriate committees.³³

Revenues from Pesticide Fees. Figure 1 provides a graphic illustration of the amount of tolerance fees, re-registration fees, and maintenance fees collected during the period FY1983 through FY2003. The highest combined amount collected from the three fees for one year (estimated \$39.1 million) was in 1990, the peak year for collection of the one-time re-registration fees.

The annual tolerance fee amount collected is based on the specific action required, and varies depending on the number and type of petitions received by the Agency in a given year. The amount has been adjusted over time, based on an inflation calculation defined in statute.³⁴ For the past 20 years, annual tolerance fees collected by EPA have averaged about \$1.8 million.

Re-registration fees varied considerably and were based, among other things, on whether the pesticide is an active ingredient registered for a major food or feed use, or is registered only for non-food or non-feed uses. The one-time active ingredient fee for re-registration ranged from zero for a pesticide used exclusively for minor uses and for certain antimicrobial active ingredients, to \$150,000 for a major food or feed use active ingredient. By 1994, all authorized one-time re-registration fees had been collected, an estimated total of \$31.64 million (Figure 1).

The annual amount collected per registration for maintenance fees is set in statute, dependent on the number of registrations held by a registrant. The fee amount is subject to adjustment by EPA, based on the annual aggregate limit, also established by statute. The initial 1988 authorization for maintenance fees set the annual aggregate at \$14.0 million for the 9-year period, FY1989-FY1997. The 1996 FQPA authorized collection of an additional \$2 million (maximum aggregate of \$16 million) per year for FY1998, FY1999, and FY2000, and returned to the original aggregate limit of \$14 million in FY2001. The statutory authority for maintenance fees expired September 30, 2001, but has been reauthorized in the annual appropriations bills. The amount authorized was increased to \$17 million in FY2002 (P.L. 107-73), and \$21.5 million in FY2003 (P.L. 108-7) and FY2004 (Continuing

 $^{^{32}}$ (...continued)

⁽P.L. 108-10 and P.L. 108-135), contained similar prohibitive language.

³³ H.Rept. 107-424, May 1, 2002; p. 666.

³⁴ Tolerance fees can be adjusted annually based on annual percentage changes in federal salaries (40 CFR 180.33(o)). The most recent adjustment in May of 2003 was an increase of 4.27%, based on the 2003 pay raise for General Federal Schedule (GS) employees in the Washington DC/Baltimore MD metropolitan area (68 FR 24370, May 7, 2003).





Figure 1. Pesticide Program Fees Collected by EPA, FY1983-FY2003

- * Tolerance fees for FY1983-FY1988 are based on the average number of petitions per year, 8-12, and the average fee per petition, \$150,000.
- ** Note: Maintenance fees are capped by legislation for each fiscal year: \$14 million for FY1989-FY1997; \$16 million for FY1998-FY2000; \$14 million for FY2001; \$17 million for FY2002; and \$21.5 million for FY2003.

Source: U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, October 2003.

Resolution P.L. 108-135,³⁵ through January 31, 2004). Figure 1 shows that EPA generally collected the maximum aggregate limit as set by the statute in a given year.

Distribution of Pesticide Program Appropriated Funds and Fee Revenues

The registration, re-registration, and tolerance reassessment budgets for the past few years provide context for the discussion of fees imposed on pesticide registrants to supplement EPA appropriated revenues. EPA's FY2003 allocation of appropriated funds³⁶ totaled \$95.3 million, \$42.2 million for pesticide registration, \$38.8 million for re-registration activities, and approximately \$14.6 million for tolerance reassessment. FY2003 appropriations were supplemented by an estimated \$22.8 million in authorized fees, including \$21.5 million in maintenance fees, and \$1.3 million in tolerance fees primarily for establishing new tolerances. An estimated \$10.3 million of the maintenance fees were for processing tolerance reassessments. Figure 2 illustrates the distribution of FY2003 appropriated funds and fees for the three program activities.

Figure 2. EPA FY2003 Pesticide Budget Allocations Budget



³⁵ See also P.L. 108-84, September 30, 2003, and H.J.Res. 69 Section 118, 108th Congress 1st Session (2003).

³⁶ U.S. Environmental Protection Agency FY 2003 Enacted Operating Plan as of December 11, 2003 (EPA website [http://www.epa.gov/ocfo/.budget])

The combined revenues of \$118.4 million for FY2003 represent an increase of roughly \$4.1 million from the \$114.3 million for the three programs in FY2002. The FY2002 total included \$17 million in maintenance fees and \$2 million in tolerance fees. The total for FY2001 was \$108.2 million, including \$14 million in maintenance fees.

The President's proposed FY2004 budget for EPA³⁷ decreased appropriated funding for registration to \$36 million, increased appropriations for re-registration to \$51.5 million (assumes \$8.2 million offset based on reauthorization of maintenance fees), and reduced appropriations for tolerance reassessment to \$12.8 million. The total amount of appropriated funds budgeted for the three programs would have increased to \$100.3 million. The total proposed allocation for FY2004 includes \$28.3 million in fee revenues, and assumes that a revision of the "Tolerance Fee Rule" proposed by EPA in 1999, would be promulgated.

Revenues generated by the proposed increased tolerance fees would support establishing new tolerances as well as the reassessment of existing ("old") tolerances, but no portion of the authorized maintenance fees would be used to support tolerance reassessments, as in previous years. The proposed \$8.2 million in maintenance fees was expected to fund re-registration program activities at a level equivalent to expenditures for these activities in prior years. The proposed FY2004 budget also assumed the prohibition on the collection of registration fees would be rescinded, resulting in an estimated \$27 million in additional revenues. These funds would be deposited in the U.S. Treasury, and would not directly available to EPA. Therefore, this revenue would not be represented in EPA's overall budget total.

An allocation of funds for the three pesticide program activities is not available for the FY2004 Omnibus bill, but it is anticipated that the funding will be comparable to the President's FY2004 request of \$100.3 million. The fees provisions included in the Omnibus bill are anticipated to supplement FY2004 appropriated funds by \$26.0 million in reauthorized maintenance fees, and \$19.4 million in registration service fees.³⁸ No revenues would be collected in the form of tolerance fees, since the legislation prohibits collection of all tolerance fees, and the 1988 registration fee authority is replaced by the service fee provisions, through FY2008.

Table 2 presents a summary of the distribution of enacted, and estimated, appropriated funds and fee revenues supporting the EPA's pesticide registration, reregistration and tolerance programs for FY2001 through FY2004.

³⁷ U.S. EPA Office of the Chief Financial Officer, *FY 2004 Annual Performance Plan and Congressional Justification (EPA's Proposed Budget)*, November 19, 2003. (EPA website at *www.epa.gov/ocfoc/budget/2004/2004cj*).

³⁸ U.S. EPA Office of Prevention, Pesticides and Toxic Substances estimates (January 20, 2004).

Table 2. EPA Appropriations and Fee Revenues for PesticideProgram Activities, FY2001-FY2004

Funding Source	FY2001	FY2002	FY2003	FY2004 (proposed)	FY2004 Omnibus
Appropriations	\$92.7	\$95.3	\$95.6	\$100.3	Not Available
Maintenance Fees ^a	\$14.0	\$17.0	\$21.5	\$8.2	\$26.0
Tolerance Fees	\$1.5	\$2.0	\$1.3 (projected)	\$28.3	\$0
Registration Fees	\$0	\$0	\$0	(\$27.0) (U.S. Treasury) ^b	\$0
Registration Service Fees	\$0	\$0	\$0	\$0	\$19.4
Total	\$108.2	\$114.3	\$118.4	\$136.8	\$145.7°

(in millions of dollars)

Sources: Estimates are based on the EPA's Enacted Operating Plan (Dec. 2003), the President's Budget Proposal for FY2004, the FY2004 Omnibus appropriations bill (H.R. 2673; P.L. 108-199), and the EPA Office of Prevention, Pesticides, and Toxic Substances.

- a. Total for each year represents the aggregate authorized by statute.
- b. Not directly available to EPA therefore not included in the total budget.
- c. Allocation of appropriated funds is not available; for purposes of comparison, the total estimate for FY2004 Omnibus assumes an amount comparable to the President's FY2004 budget request of \$100.3 million.

Conclusion

Although EPA has been making progress,³⁹ timely completion of the registration, re-registration, and tolerance assessment requirements continues to be a concern for Congress, EPA, industry, and public interest groups. Recent attempts to defray increased costs of administering the pesticide program by modifying existing pesticide fee requirements through regulation and legislation have not been successful. The pesticide fee provisions passed in the 108th Congress (H.R. 2673; P.L. 108-199) and signed into law seems to address several of the key issues and concerns of previous approaches.

³⁹ At the end of FY2003, EPA had made re-registration decisions for 457 of the original 612 cases, including 226 Re-registration Eligibility Documents (REDs) completed and 231 cases that were cancelled voluntarily (68 *Federal Register* 44767). The Agency has reassessed a cumulative 68 percent (6,627) of the 9,721 tolerances required under the FQPA. In 2004, EPA plans to complete 35 Re-registration Eligibility Decisions (REDs), 400 product re-registrations, and 1050 tolerance reassessments. (U.S. EPA FY2004 Annual Budget Plan and Overview, U.S. EPA website *www.epa.gov/ocfo/budget*).

Most notably, the new provisions requiring specific decision process and schedule reforms, in conjunction with increasing fee revenues, is expected to lead to more timely completion of registration applications and re-registration reviews. Reforming the overall process implies accelerated implementation of stricter FQPA standards, and expected associated improvements in the safety of pesticides in the market. It also suggests the possibility of greater availability of desired products, potentially safer and more effective, that reach the market sooner. The prescriptive detailed schedule for the service fees is more commensurate with the specific EPA actions required than previous registration and tolerance fee provisions, which tended to be more generic, and is expected to further promote efficiency in the overall process. The pesticide fee provisions passed by the 108th Congress are expected to provide stability for purposes of resource planning, which has not been available in recent years with annual reauthorization of maintenance fees and Administration budget proposals to modify fee authority.

How efficient the EPA's decision making process becomes is dependent in large part on the Agency's ability to establish and effectively implement the reforms while maintaining the integrity of protection required by the statutes. To meet stricter statutory standards⁴⁰ and related "sound science" demands, EPA continues to develop and refine its scientific protocols and guidelines with input from stakeholders and the scientific community through various public forums.⁴¹ However, as past experience has shown, this is a complex and time consuming undertaking, affected by uncertainties and advances in technology that could enhance or inhibit acceleration of the pesticide review process. EPA will utilize existing advisory committees and workgroups, and has initiated establishing additional workgroups in anticipation of the provisions being introduced by the legislation passed by the 108th Congress, to develop strategies and recommendations to improve the registration and reregistration decision making process

⁴⁰ Stricter standards primarily refer to requirements introduced by FQPA in 1996 to perform more comprehensive risk assessment of pesticides, considering: aggregate exposure, cumulative effects from pesticides sharing a common mechanism of toxicity, possible increase susceptibility of vulnerable populations (particularly infants and children), and possible endocrine or estrogenic effects(see CRS Report RS20043, *Pesticide Residue Regulation: Analysis of Food Quality Protection Act Implementation*).

⁴¹ Examples of existing EPA advisory workgroups for pesticide science and procedural issues include, the Committee to Advise on Reassessment and Transition (CARAT), Pesticide Program Dialogue Committee (PPDC), FIFRA Science Advisory Panel, and Tolerance Reassessment Advisory Committee (TRAC). For information about these and other related workgroups see EPA website *www.epa.gov/pesticides/science/committees* Another relevant advisory workgroup is the Endocrine Disruptor Methods Validation Subcommittee (*www.epa.gov/scipoly/oscpendo/index*).