

New Pesticide Fees Legislation Takes Effect: EPA Publishes New Fees and Timeframes for Registration-related Actions

On January 23, President Bush signed the Pesticide Registration Improvement Act ("PRIA"), part of the Consolidated Appropriations Act of 2004. The Act established a new section 33 of FIFRA, which creates a registration service fee system for applications for 90 specified pesticide registration, amended registration, and tolerance actions. The new act became effective March 23, 2004. For covered applications, EPA must make a determination on the application with decision time frames specified. On March 17, 2004, EPA published its list of "enhanced registration service fees" and decision completion timeframes under the PRIA. This Bulletin summarizes EPA's new fee system.

► Introduction

New section 33 of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") establishes a new registration service fee system for 90 different types of registration, amended registration, and associated tolerance applications. The PRIA also authorizes EPA to collect \$116 million in new maintenance fees over the next five years. The maintenance fees are increased and front-loaded, to give EPA more money sooner. New section 33(b)(3) of FIFRA requires EPA to publish a schedule of the service fees and decision review times for the 90 types of registration-related applications covered by the PRIA. In the March 17, 2004 *Federal Register* (69 Fed. Reg. 12,772), EPA published its list of new service fees and decision times, which are effective on March 23, 2004.

► Duration of the New Fees

The new fee system is authorized through September 30, 2010. On October 1, 2005, fees will go up by 5%. If the legislation is not reauthorized, fees will decrease by 40% in fiscal year ("FY") 2009 and by 70% in FY 2010. For applications received after September 30, 2008, the reduced fees will apply, but the decision timeframes will no longer apply. In addition, the PRIA stops collection of tolerance fees and treasury registration fees until October 1, 2008 and October 1, 2010, respectively. EPA will use its new registration services fees to cover a variety of costs, including new EPA management and staff, contractors, advisory and peer review committees, information management costs, and fee collection, tracking, reporting, and auditing.

► Overview of the New Fees Program

EPA's enhanced registration service fees apply only to 90 specified registration-related applications or related actions set forth in ten tables in EPA's March 17, 2004

■ Contact Info

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Federal Register notice. The new fees do not apply to special local needs registrations under FIFRA § 24(c), emergency exemptions under FIFRA § 18, any registration amendments initiated by EPA, or notifications. Service fees are tied to specific decision completion timeframes, which are gradually reduced over time, between FY 2004 and FY 2008. The longer initial timeframes allow EPA to set up the registration services program and to address backlogs. EPA and applicants can mutually agree to extend decision timeframes for specific actions.

▶ **Actions Affected by Fees**

For new fee purposes, EPA classifies actions into two categories, “new applications” and “pending applications.” A “new application” is any one of the 90 listed types of pesticide regulatory actions that is received by EPA on or after March 23, 2004. A new application is subject to the corresponding published fee. If EPA disagrees with an applicant’s designation of the applicable fee category, the Agency will advise the applicant accordingly, in writing. A “pending application” is any one of the 90 listed actions that is received by EPA prior to March 23, 2004. In general, these actions are not subject to the new fees. There are two exceptions. One exception is for new active ingredient applications that are not on EPA’s FY 2003 Registration Division (“RD”) Work Plan. These pending applications are subject to prorated fees, according to how much work EPA has done on the case as of March 23, 2004, and also receive credit for any previously paid tolerance fees. The other exception is where an applicant elects to pay a service fee for a pending application, which it may do, provided that the pending application falls into one of the 90 listed fee categories and is, therefore, eligible for processing under a PRIA decision timeframe.

▶ **Timing Issues**

For most new applications, the prescribed review period will begin 21 days after receipt, although EPA indicates that it will initially “exercise flexibility” with start dates. For pending applications, the review period begins when EPA receives documentation certifying that the applicant has paid the applicable fee. One exception to this rule is pending new active ingredient applications already on RD’s FY 2003 Work Plan, for which the applicant can elect to pay a fee but is not required to do so. In such cases, the review period begins 30 days after the effective date. If EPA exceeds a decision timeframe by two years, an applicant for a new active ingredient or new use can seek judicial review, provided that the applicant first requests a meeting with the Agency at least 120 days before filing an action, to avoid needless litigation.

▶ **Special Provisions**

There are special provisions for certain products and uses under the PRIA. For example, there are shorter overall decision review periods for reduced-risk pesticides. Minor use actions are eligible for fee waivers, where anticipated revenues do not justify the cost of fees, and will still benefit from decision timeframes under the PRIA. EPA has earmarked \$500,000 of registration service fees for new inert ingredient reviews in FY 2004 and FY 2005, and PRIA authorizes EPA to use another \$3 million of maintenance fees each FY year for a combination of new inert ingredient reviews and expedited reviews of “fast-track” registration actions. In most cases, the decision timeframes for antimicrobials are unchanged from the deadlines currently existing in FIFRA § 3(h). In a few cases, the PRIA establishes decision timeframes for application types not addressed in FIFRA § 3(h). In one case, namely, an amendment to an antimicrobial registration requiring scientific review, the PRIA shortens the section 5(h) deadline from 240 to 120 days and also

eliminates the option for judicial review. Reregistration Eligibility Decisions (“REDs”) with food tolerances must be completed by August 3, 2006, all other REDs must be completed by October 3, 2008, and registrants will receive two extra years to submit data required in a RED before EPA make a reregistration decision.

▶ **Small Businesses**

If a company qualifies as a “small business,” it is eligible for a 50% fee waiver. If the company also can show average annual global revenues below \$10 million, it is eligible for a 100% fee waiver. The PRIA increases the employee limit for a small business from 150 to 500 employees. The PRIA also increases the revenue limit for a small business from \$40 million in annual gross global revenues from chemicals to \$60 million in annual global gross revenues from pesticides, including any such revenue from “affiliates,” the definition of which has been tightened to close loopholes. State and Federal agencies are exempt from fees. IR-4 is eligible for waivers for tolerance applications, if EPA determines that the waiver is in the public interest.

▶ **Refunds**

The PRIA permits refunds of fees in certain cases. If an application is withdrawn within 60 days of receipt by EPA, 90% of the fee is refunded. After 60 days from receipt, the refund is based on the percentage of work completed by EPA. EPA will determine refunds within 90 days after the application is withdrawn. EPA also has discretion to grants refunds in certain cases.

▶ **Expenditures from Fund**

EPA may make expenditures from the Fund only to cover costs associated with the review of covered applications, worker protection (not more than \$1 million and not less than \$75,000), and the review and evaluation of new inert ingredients (not more than \$500,000 per year). “New inert ingredients” is interpreted to mean petitions submitted for the establishment of a tolerance or exemption from tolerance for an inert ingredient. There are no registration service fees associated with inert ingredient submissions, nor are there specified decision time review periods for new inert ingredient actions. There are approximately 50 inert ingredient tolerance/exemption petitions pending before EPA. The Agency plans on increasing staff and contractor support for the review of these petitions, using resources from the Fund.

▶ **Additional Information**

Additional information on the PRIA, including the Q & A’s, the Agency’s March 17 *Federal Register* notice, and the presentations given at EPA’s March 11 public workshop are available on the Internet at <http://www.epa.gov/pesticides/fees>.

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