Pesticide Registration Manual:

Chapter 5 - Registration Fees

Registration Fees

Background

An amendment to FIFRA in 2004 created a registration service fee system for applications for specific pesticide registration, amended registration, and associated tolerance actions. This amendment, contained in the Consolidated Appropriations Act of 2004 (Pub. L. 108-199 (HR 2673)), established a new section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The goal is to create a more predictable evaluation process for affected pesticide decisions and couple the collection of individual fees with specific decision review periods. The provision specific to FIFRA is also known as the Pesticide Registration Improvement Act of 2003 (PRIA).

The registration service fee system was reauthorized by the Pesticide Registration Improvement Extension Act (PRIA 3) until September 30, 2019 although the decision times or the timeframe or amount of time that the Agency has to make a decision under the system do not apply to applications received after September 30, 2017.

Regulatory actions are categorized first by type of chemical (i.e., conventional, antimicrobial, or biopesticide chemical product), and next by the type of action (e.g., new active ingredient (nonfood use), new food use, new registration of an old product, etc.). Under this system, each individual category corresponds to a certain registration service fee and decision review period.

The fees and decision review periods may change between fiscal years and fees are periodically increased as prescribed by statute. Applicants should refer to the most recent fee schedule available on the PRIA 3 Web page prior to paying a fee.

The Pesticide Registration Improvement Extension Act can be reauthorized and revised by Congress at any time. Congress may amend provisions such as the fee categories, fees, and procedures at that time. Changes in policy and process may also occur. Applicants should refer to the Agency registration service fee and PRIA 3 Web page for the most recent regulations, policy and guidance and to determine whether their application requires a fee and the applicable decision review period. Some of the key links are provided below:

- Fee tables
- Fee category decision tree
- Small business waivers
- IR-4 exemptions
- Fee reduction and refund formula
- Paying fees

Actions that Require a Fee

A fee or a waiver from paying the fee is required for the following types of actions (refer to Chapter 2 for additional information):

- new active ingredients,
- new uses,
- new products,
- certain amendments,
- certain tolerances,
- certain inert ingredients,
- certain combination products,
- cancer reassessments and certain ecological/endangered species assessments,
- manufacturing use products (MUPs),
- experimental use permits (EUPs),
- human study protocols and completed studies that require review by the Human Studies Review Board,
- certain covered actions that require external review by the FIFRA Science Advisory Panel,
- Gold Seal letters,
- Exclusive use of data extension requests.

Actions **not** covered by fees include but are not limited to:

- the re-establishment of a time-limited tolerance;
- review of confirmatory data submitted in support of an already-issued registration (excluding efficacy data);
- Agency-initiated amendments (e.g., label amendments to comply with a reregistration eligibility decision);
- label amendments involving an advisory statement as described in Pesticide Registration Notice 95-2;SEARCH EPA ARCHIVE
- label amendments that involve only changes specified in Pesticide Registration Notice 2005-1
- submission of a sub-registrant/supplemental distributor label;
- Special Local Needs registrations submitted under FIFRA section 24(c);
- Emergency Exemption requests submitted under FIFRA section 18;
- notifications as described in Pesticide Registration Notice 98-10;

- Fast-track amendments;
- Minor formulation amendments as described in Pesticide Registration Notice 98-10
- registrant responses to State Label Information Tracking System (SLITS) inquiries; and
- 6(a)(2) submissions.

If, upon initial review by the Agency of an application submitted as a non-PRIA 3 action, the Agency determines that the application is covered by PRIA 3, the Agency will inform the applicant and invoice or bill the applicant for the registration service fee. The fee is due upon submission of the PRIA 3 application. If the applicant submits a pesticide registration application without a fee and withdraws the application before paying the fee, the applicant will nonetheless owe 25% of the fee.

Under PRIA 3, there are 189 fee categories that have been grouped to reflect the three major types of pesticidal products - antimicrobial (A categories), biopesticide (B categories), and conventional active ingredients (R categories) - and the type of action as well as inert ingredients and miscellaneous actions. EPA has issued and will update as needed its interpretation of the fee categories in fee interpretation guidance. Questions concerning whether a fee is required or the interpretation of a fee category should be referred to the Registering Division.

General definitions for the difference types of actions covered by PRIA 3 include:

New Active Ingredient

- An active ingredient that is not currently contained as an active ingredient in any registered pesticide product.

New Use (As Defined in 40 CFR 152.3)

- New use, when used with respect to a product containing a particular active ingredient, means:
    - any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance regulation under section 408 of the Federal Food, Drug, and Cosmetic Act;
    - any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or
    - any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, of the active ingredient to man or other organisms.

Experimental Use Permit (As Defined in 40 CFR 172.2)

A permit authorized under FIFRA section 5 that allows applicants to develop data to support an anticipated registration application and may involve a pesticide not registered with the Agency, or a registered pesticide for a use not previously approved in the registration of the pesticide.

Pesticides under experimental use permits may not be sold or distributed other than through participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit. Read more about EUPs in Chapter 12.

Fee Determinations and Payments

Under section 33(b)(2)(D), the fee is due upon submission of the application and is either

- the fee prescribed by the fee category;
- a request for an exemption from registration service fees; or
- a portion of the fee with the remainder covered by a request for a fee waiver or reduction.

A reduction of 50% or 75% in the fee can be granted for a qualified small business. Applications from federal and state agencies and those solely associated with a tolerance petition submitted by IR-4 can be exempted from registration service fees. Fees may be reduced or exempted for minor uses. Applications with exemptions and waivers are discussed in subsequent sections of this chapter.

Section 33(b)(2)(F) directs the Agency to reject any application submitted without the required registration service fee. A portion of the fee, 25%, is non-refundable once an application is submitted per section 33(b)(2)(G), even if it is rejected. If any fee is unpaid 30 days after the fee is due, it shall be treated as a claim of the U.S. government subject to subchapter II of chapter 37 of title 31, United States Code.

To help applicants identify the appropriate fee and pay it in advance of submitting an application (pre-payment) or upon submission to EPA, the Fee Determination Decision Tree is available. Through a series of questions and answers, pesticide registration applicants are led to the appropriate fee category and fee.

A certification of payment should be the first page of the submission or application and precede a cover letter or fee waiver or reduction request to enable the Agency to match a

payment with an application. Credit or debit card, PayPal, Dwolla or wire transfer payments (ACH) can be made using the Department of Treasury's pay.gov system, which provides an acknowledgement of payment. Credit card payments will only be accepted on amounts not greater than $24,999. PayPal or Dwolla payments will only be accepted on amounts not greater than $10,000. Wire transfer payments (ACH) will be accepted in any amount. Please note that checks will not be accepted after October 1, 2015.

Once the Agency receives an application covered by PRIA 3, the Agency assigns it a fee category and fee. If the Agency has not received the appropriate payment, the Agency invoices the applicant for the unpaid portion, typically within 48-72 hours of receipt of an application. During an in-depth review of the application, the Agency may determine that the application belongs to a different fee category and if fees are due, will invoice the applicant for any difference owed. The invoice will contain payment instructions. In the case of an overpayment, the Agency will provide a refund for the overpaid amount. If upon receiving an invoice, an applicant disagrees with the PRIA 3 fee category or amount, it should not pay the fee and contact the appropriate Registration Ombudsman to discuss the situation. The phone number of the Registration Ombudsman will be included in the invoice.

Unless the applicant is requesting a fee waiver or exemption, the decision review period (i.e., the PRIA 3 timeframe) begins 21 days after receipt of the application and the fee. When a fee category is changed, the PRIA 3 timeframe will be recalculated.

Small Business Fee Waivers

Each request must be submitted with supporting documentation and a certification. If more than one registration application is submitted at the same time, the supporting documentation should be submitted with each registration request.

The Agency will review the documentation provided by the applicant as well as other available information to determine if the applicant meets the applicable criteria for a fee waiver. The Agency will respond in writing to the applicant with the decision regarding the waiver. If the waiver is denied, the letter or invoice will include the amount to be paid and instructions for submitting payment. Should an applicant disagree with the Agency's decision on a fee waiver or reduction, the applicant should respond to the invoice with a written appeal including a rationale explaining why the original request should be granted or the Agency's decision should be reversed, following the instructions on the small business fee waiver Web pages. Once received by the Office of Pesticide Programs, the Agency will review the appeal and then call the applicant to explain the Agency's decision, followed by a confirmatory letter.

Waiver Decisions and Decision Review Times

- If no additional fees are required, the decision review period begins the earlier of
  - the date the Agency grants the small business fee waiver or
  - 60 days after submission of the application.
- If the Agency grants the small business request but additional fees are still due, the decision review period begin when the Agency receives certification of payment of the outstanding portion of the registration service fee.
- If the Agency denies the request for a small business fee waiver, the decision time review period begins when the Agency receives certification of payment of the registration service fee.
- If the fee is paid in full before the Agency completes its review of the fee waiver request, the fee waiver request will not be considered further.

CBI Claims

A business confidentiality claim covering part or all of the information in the application may be claimed at the time it is submitted to the Agency. Information on such claims may be found in Chapter 10 and Chapter 15 describes how to submit Confidential Business Information (CBI).

Fee Exemptions

Under FIFRA section 33(b)(7)(E), the Agency shall exempt an application from the registration service fee if it determines that the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Research Project Number 4 (IR-4) and that the exemption is in the public interest. Submission of the application and the request for the exemption are coordinated by IR-4. Guidance on IR-4 exemptions is available and should be closely followed. Applications from agencies of the federal government or a state government are also exempt from registration service fees.

The Agency will review the exemption request and confirm that the request meets the criteria in section 33 – specifically, whether the application is solely associated with an IR-4 tolerance petition and the exemption is in the public interest or, in the case of a federal or state government exemption, whether the applicant qualifies as a federal or state agency. It is the applicant's responsibility to establish that it is in fact a state agency under applicable state law. EPA will generally defer to the opinion of a state attorney general on matters of state law and whether an applicant is a "state agency." The decision time review period begins when the Agency grants the exemption from a registration service fee.

Minor Use Fee Waivers/Exemptions

Either a fee waiver or exemption may be requested with an application for a new minor use under FIFRA section 33(b)(7)(D). In general, the Agency may exempt the fee or waive a portion of the registration service fee for an application for minor uses of a pesticide. Applicants requesting such a waiver or exemption shall provide supporting documentation that demonstrates to the satisfaction of the Agency that anticipated revenues from the uses that are the subject of the application would be insufficient to justify imposition of the full application fee. Applicants may also contract a Registration Ombudsman.

The Agency will review a minor use exemption or partial fee waiver request to determine whether the use is a minor use and that anticipated revenues will be insufficient to justify imposition of the entire fee. In the case of a request for a minor use exemption, the decision review period begins when the Agency grants the exemption from a registration service fee. In the case of a request to waive a portion of the fee, the start of the decision review period will be calculated in the same manner as a small business waiver request.

Other Fee Reductions

Under section 33(b)(8)(C) of FIFRA, the Agency has discretionary authority to issue a partial refund (up to 75%) of registration service fee on the basis that, in reviewing the application, the Administrator has considered data submitted in support of another pesticide registration application or submitted in support of an application pending with the Agency on March 24, 2004. Some discretionary refunds are routine and are applied at the time of submission. Guidance on these refunds may be obtained on the primary/secondary Web page and by contacting a Registration Ombudsman.

All discretionary refund requests **must be requested** up front and be included in the application. Before submitting an application, it is recommended that discretionary refunds first be discussed with the appropriate Registration Ombudsman. In most instances, the applicant will pay the appropriate fee and the Agency will then provide the discretionary refund after the data have been reviewed and the Agency knows the amount of work involved. The request must be submitted either in the cover letter for the application or on the application form. The Agency suggests that the applicant as part of the request submit a rationale for the request. The rationale should reference the previous applications and could contain a comparison of the data submitted previously and with the application against the data requirements. To calculate the amount of any discretionary refund, the Agency will compare the data and information reviewed in past applications with that submitted in the new application. (For more information on refunds see **Fee reduction and refund formula**). The maximum amount of any fee reduction is 75%. If a fee is reduced by 75% as a result of a discretionary refund, the fee cannot be further reduced by a small business fee waiver. A portion of the fee, 25%, is always nonrefundable. Also, if an application is rejected, a refund may be appropriate.

Initial Contents Screen

FIFRA section 33(f)(4)(B), "Initial Content and Preliminary Technical Screenings," first directs the Agency, no later than 21 days after receiving an application and the required registration service fee, to conduct an initial screening of the contents of the application. In conducting this screen, the Agency must determine:

1. whether the applicable registration service fee has been paid; or
2. at least 25% of the applicable registration service fee has been paid and the application contains a waiver or refund request for the outstanding amount and documentation establishing the basis for the waiver request; and
3. that the application contains all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Agency.

A screening worksheet was developed and tested for the Agency's internal use and is available to help applicants assemble their submission. In conducting the screen, the Agency will verify that the payment requirements have been met. If they have not, the applicant must resolve any fee issue by the end of the 21-day period. The Agency will reject applications with an unpaid fee and invoice the applicant for 25% of the fee. If there are other missing contents, an Agency representative will contact the applicant with instructions on how to submit the missing form, label, data, or other information.

If the application fails the screen and cannot be corrected by the applicant within the 21-day period, the Agency will reject the application not later than 10 days after making the determination and will retain 25% of the fee.

Certain forms that are often missing from the data submission include the Offer to Pay statement, Formulator's Exemption statement, and the Data Matrix Form.

Specific problems with Data Matrix requirements include failure to include all required generic and product-specific data, and for data previously submitted to EPA, citing incorrect EPA Master Record Identifier (MRID) Numbers or the unique cataloging numbers assigned to individual pesticide studies at the time of their submission to EPA. The Certification with Respect to Citation of Data form (EPA Form 8570-34) must always accompany a Data Matrix form.

An application will be rejected if the required three copies of the data are not properly bound and formatted.

Do not forget to provide a Data Matrix Form showing the data and for data previously submitted to EPA, corresponding MRID numbers if the Selective Method of data support is

used. Applicants must use the Data Matrix to list companies to whom they have made offers to pay when using the Cite-all Method of data support.

After the 21-day initial content screen is completed, PRIA 3 directs the Agency to conduct a Preliminary Technical Screen of the application.

Preliminary Technical Screen

FIFRA section 33(f)(4)(B), "Initial Content and Preliminary Technical Screenings" directs the Agency to conduct a preliminary technical screen of the application. This screening is conducted no later than 45 days after the start of the decision review period for actions with decision review time periods equal to or less than 6 months and no later than 90 days after the start of the decision review period for actions with decision review time periods greater than 6 months. In conducting this technical screen, the Agency determines whether:

1. the application and the data and information submitted with the application are accurate and complete, and
2. the application, data and information are consistent with the proposed labeling and any proposed tolerance or tolerance exemption, and
3. the application, data and information are such that subject to full review could result in the granting of the application.

If the application fails the technical screen, and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of the failure, the Agency will reject the application.

Withdrawn Applications

If the applicant withdraws a pesticide registration application before paying the fee, the applicant still owes the nonrefundable portion, 25%, of the fee. An invoice will be sent to the applicant for the amount due. Fees that are not been paid within 30 days of submission of the application are subject to collections.

If the applicant withdraws a pesticide registration application after paying a fee and during the first 60 days after the beginning of the applicable decision time review period, EPA must refund all but 25% of the total registration service fees. The Agency will confirm that the application has been withdrawn, and the refund will be sent to the applicant as soon as

practical. However, if the applicant was granted a small business fee waiver of 75%, no refund will be provided since 25% of the fee is nonrefundable.

If a pesticide registration application is withdrawn after paying a fee and after the first 60 days after the beginning of the applicable decision time review period, EPA must determine what portion, if any, of the total registration service fee for the application may be refunded based on the proportion of the work completed at the time of withdrawal. The maximum that can be refunded is 75% of the total fee. The Agency uses a fee-reduction formula, updated for PRIA 3, and has 90 days to make this determination. The Agency will confirm that the application has been withdrawn and in this confirmation letter notify the applicant of the percentage of the fee that will be refunded. Any refund will be sent to the applicant as soon as practical. If the applicant was granted a small business fee waiver of 75%, no refund will be provided since 25% of the fee is nonrefundable.

Once an application has been withdrawn, any future submission related to the withdrawn application must be submitted as a new application that requires either the appropriate fee, a percentage of the fee with a fee waiver request for the remainder, or a request for an exemption of the registration service fee.

Decision Review Periods (PRIA 3 Timeframes)

Each PRIA 3 fee category has an associated period of time in which the Agency must make a determination, which has been called a decision review period or PRIA 3 timeframe. The Agency is committed to meeting the "PRIA 3 due dates." For applications that do not include a request for a waiver or exemption, the PRIA 3 timeframe begins 21 days after receipt of the application and fee. As previously described, for applications with a waiver or exemption request, the PRIA 3 timeframe begins when the request is granted, or in the case of a waiver request, if no additional fee is required, the earlier of (i) the date the Agency grants the waiver or (ii) the date that is 60 days after receipt of the application. If the Agency denies the request for a waiver or if it grants the waiver and additional fees are required, the decision review period begins when the Agency receives payment of the outstanding portion of the registration service fee.

At any time after the 21-day initial content screen and the 45-day or 90-day preliminary technical screen, during the Agency's in-depth review of an application, the Agency may determine that an application is incomplete or that further information is needed in order to complete the Agency's review. A 75-day deficiency letter may be issued pursuant to 40 CFR 152.105 notifying the applicant that the applicant has 75 days in which to address the deficiencies or provide a schedule for addressing the deficiencies. If, after 75 days, the applicant has not responded, or fails to address the deficiencies within the time scheduled, the Agency will treat the application as if it has been withdrawn by the applicant. Once the

Agency withdraws the application, a determination will be made on a refund as described in the section “Withdrawn Applications.”

The Agency may also determine that there will be insufficient time for an applicant to submit the needed data/information and/or the Agency to review the data/information within the PRIA 3 timeframe. The Agency will then contact the applicant and discuss the situation. Some possible outcomes include:

- withdrawal of the application (and a determination with respect to any refund);
- negotiation of a new due date with the Agency;
- a determination by the Agency on whether the application, in the absence of the data, can be granted; or
- a denial of the application based on data (or lack thereof) before the Agency.

Negotiated Due Dates or Due Date Extensions

The PRIA 3 due date may be extended by a mutual agreement between the applicant and the Agency. The new due date is called a negotiated due date. Negotiated due dates occur predominately as a result of missing information or data or data deficiencies identified during an in-depth review of the application. The due date then is extended to allow the applicant the time to submit the data or information and for the Agency to review the data and make a determination.

In estimating the amount of time that may be required to address the issues and then make a determination on the application, the Agency analyzes which steps in its process need to be completed and the amount of time required for each. Steps in processing an application may include in-processing or intake of a submission, screening to determine its contents, data review, secondary or management review of documents, risk assessment, and regulatory decision-making. The amount of time that the applicant may take to submit the data or information is estimated and then the registering division estimates the amount of time it will take to reach a determination on the application.

Delays in submitting information may result in the applicant requesting additional extensions in the due date; however, additional delays in submitting the data or information may result in a determination that the Agency cannot grant the application or denial of the application. If substantial delays are expected in submitting the data or information or a new due date cannot be estimated by the applicant, the applicant is advised to withdraw the application and submit a new application with the data or information at a later date. The withdrawal procedures in the section “Withdrawn Applications” would apply.

The process for reaching a negotiated due date generally involves the applicant submitting its request for or consent to an extension in writing (e-mail is sufficient) to the Agency representative, generally a Product Manager or Regulatory Action Leader. The registering

division then finalizes the agreement by obtaining the approval of the Office Director or Deputy Office Director.

PRIA 3 "Cannot Grant" Determination

A determination by the Agency that it cannot grant the application completes the Agency's review of the application under PRIA 3. Usually, it is a determination that on account of missing or deficient data, the Agency has determined that the application does not meet the standard for registration and, therefore, the application cannot be granted. It is not, however, a denial of the application pursuant to FIFRA section 3(c)(6). Once the Agency makes a determination that it cannot grant the application, the applicant may withdraw the application, continue to address any deficiencies without a PRIA 3 timeframe, or request a denial. If the applicant does not request the Agency to initiate denial proceedings or withdraw the application, the Agency may continue to diligently work with the applicant without a PRIA 3 timeframe or due date.

Denials

The denial process is described in section 3(c)(6) of FIFRA and 40 CFR Part 152. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

Annual Pesticide Registration Maintenance Fees

All section 3 and section 24(c) registrations are subject to an annual maintenance fee described in FIFRA Section 4(i)(5). PRIA 3 requires that $27.8 million in maintenance fees be collected for each of the five years of PRIA 3 (FY'13 – FY'17). Affected applicants will be contacted by mail in November with instructions for submitting the fee, which is due by January 15. No extensions of this due date are possible. The amount of the 2013 maintenance fee was $3,250 per product up to pre-set limits determined by legislation. The amount of the per product fee will vary from year to year as the fee is dependent upon the projected number of products for which registrants will pay this fee.

Although there are procedures for requesting a fee waiver for individual products, maintenance fees will be reduced by 25% for the first registration only, if the applicant can show that:

1. the applicant has 500 or fewer employees globally,
2. during the 3-year period prior to the most recent maintenance fee billing cycle the applicant has **average annual gross revenue** from all sources that do not exceed $10,000,000, and
3. the applicant holds a total of 5 or fewer registrations subject to the maintenance fee.

There also are maintenance fee waivers for products that meet certain narrow criteria in two categories: minor agricultural use products and public health pesticides. The procedure for requesting a fee waiver for individual products is described in the instructions.

Contacts for Additional Information

If an applicant has a question regarding the category in which a potential submission may fall, the applicant may contact one of the Registration Fee Ombudsmen (See Chapter 21).

References Cited in Chapter 5

Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act of August 3, 1996

- Section 3 - Registration of Pesticides
- Section 18 - Exemption of Federal and State Agencies
- Section 24(c) - Authority of States
- Section 33 - Pesticide Registration Service Fees

Code of Federal Regulation, Title 21

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 157 - Packaging Requirements for Pesticide and Devices

- Part 158 - Data Requirements for Registration
- Part 161 - Data Requirements for Registration of Antimicrobial Pesticides
- Part 162 - State Registration of Pesticide Products
- Part 172 - Experimental Use Permits
- Part 174 - Procedures and Requirements for Plant-Incorporated Protectants

Federal Register Notices

- Federal Register Notice:March 17, 2004 (Volume 69, Number 52) Pesticides; Fees and Decision Times for Registration Applications (PDF)(10 pp, 223 K, About PDF)
- Federal Register Notice: June 2, 2005 (Volume 70, Number 105), [Page 32327-32335] Pesticides; Revised Fee Schedule for Registration Applications (PDF)(9 pp, 178 K, About PDF)
- Federal Register Notice:October 30, 2007 (Volume 72, Number 209), [Page 61465-61477] Pesticides; Revised Fee Schedule for Registration Applications (PDF)(13 pp, 237 K, About PDF)
- Federal Register Notice: August 5, 2008 (Volume 73, Number 151)Page 45438-45450] Pesticides; Revised Fee Schedule for Registration Applications (PDF)(13 pp, 195 K, About PDF)
- Federal Register Notice: August 11, 2010 (Volume 75, Number 154) Page 48672-48683) Pesticides; Revised Fee Schedule for Registration Applications
- Federal Register Notice: September 26, 2013 (Volume 78, Number 187) [Page 59347 – 59359] Pesticides: Revised Fee Schedule for Registration Applications

PR Notices

- PR Notice 86-5 - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 95-2 - Notifications, Non-Notifications and Minor Formulation Amendments
- PR Notice 98-10 - Notifications, Non-Notifications and Minor Formulation Amendments