

# **Pesticide Registration Improvement Renewal Act (PRIA 2): Overview of Fee Reduction and Refund Formula**

Under PRIA 2, refunds of a portion of the registration service fee are provided following the withdrawal of a PRIA covered application and as a credit for a portion of the Agency's work having been completed prior to March, 2004 or with another application. Although refund decisions are made on a case-by-case basis, the Agency intends to use the formulas below as a guide in calculating the amount of any refunds. The formulas were developed based upon the unique review processes within the Antimicrobials Division (**A** fee categories), the Biopesticides and Pollution Prevention Division (**B** fee categories), and the Registration Division (**R** fee categories). The formulas take into consideration that 25% of the total fee for each category is non-refundable. Since the Agency retains 25% of the fee, a refund will not be given if a 75% fee waiver or reduction has been granted. For 50% fee waivers and other fee reductions, the formulas will be applied to the remainder of the fee after the 25% of the fee has been subtracted.

## **Refunds Following a Withdrawal**

Pursuant to FIFRA Section 33(b)(8)(a), if an application is withdrawn during the first 60 days after the beginning of the PRIA decision review period, the Agency will refund all but 25% of the registration fee. Refunds for applications withdrawn after the first 60 days of the decision review period will be proportional to the work remaining at the time the action is withdrawn. The maximum that can be refunded is 75%. The Agency will determine the amount of the refund within 90 days after withdrawal and provide any refund as soon as practicable thereafter.

Once withdrawn, any future submission related to the application must be submitted as a new application. It requires either the appropriate full fee (or a portion of the fee (25% or 50%) with a request for a fee waiver for the remainder) or a request for an exemption.

## **Fee Reduction - Voluntary Payments**

Under Section 33(b)(8)(C) of FIFRA, the Agency has discretionary authority to issue refunds of registration service fees for portions of an application's review that were completed before March 23, 2004 (the effective date of the Pesticide Registration Improvement Act of 2003). The Agency has decided to utilize this discretionary authority for all applications for which a voluntary registration service fee is submitted under section 33(b)(4).

As a general matter, the amount due to the Agency will be calculated by subtracting any previously submitted tolerance fees from the appropriate PRIA fee for the action. The fees may be further reduced in proportion to the amount of work that was completed on the action prior to March 23, 2004. The maximum of all fee reductions can not exceed 75%. The Agency will use the formulas below as guidance to determine the amount of any discretionary refund. Applicants should consult the appropriate [registration ombudsman](#) to obtain an estimate of the fee or pay the full fee minus any tolerance fee paid. The Agency will then provide any refund, if appropriate, at a later date. Documentation that a tolerance fee was paid must accompany the application.

## **Fee Reduction – Discretionary Refund**

Under Section 33(b)(8)(C) of FIFRA, the Agency has discretionary authority to issue a partial refund (up to 75%) of the registration service fee on the basis that, in reviewing the application,

the Agency has considered data submitted in support of another pesticide registration application. 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.

Other reductions in the fee must be requested and should first be discussed with the appropriate [Registration Ombudsman](#). Although refund decisions are made on a case-by-case basis, the Agency intends to use the following formulas as a guide in calculating the amount of these discretionary refunds. Because the Agency must retain 25% of any registration service fee, discretionary refunds will not be considered if an application's fee has already been reduced by 75% as a result of a small business fee waiver.

### Guide to Reading the Tables

The Agency has developed division specific tables for each of the three registering divisions within the Office of Pesticide Programs: the Antimicrobials Division, the Biopesticides and Pollution Prevention Division, and the Registration Division. These formulas were developed in collaboration with the three registering divisions and differ only in ways that reflect the review processes within each division.

The tasks listed in the tables are the sequential steps in the Agency's review process. Column 1 reflects the task or activity involved in the review process. Column 2 reflects the percentage of work that particular task generally entails for the entire Agency review process. Column 3 reflects, as a general matter, the total percentage of work that the Agency has usually completed if all tasks through that stage in the process are complete. Column 4 is the reciprocal of Column 3 and generally reflects the percentage of work remaining once the Column 3 stage is completed.

For example, if an application to amend a registration to add a new use is withdrawn more than 60 days after the beginning of the PRIA decision review period, and the front end screen, data review, and risk assessment have been completed with only the regulatory decision remaining, as a general matter, the Agency would refund 15% of the application's fee. However, if a 75% fee waiver was granted with the application, the applicant would not receive a refund since 25% of the fee is non-refundable.

The amount of any fee and information on the type of application covered by the fee may be found on the [Fee Determination Decision Tree](#).

## Antimicrobials Division

### New Active Ingredients and New Uses

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage Remaining if Item is Completed
<b>Non-refundable portion of fee*</b>	25%	25%	75%
<b>Primary Review</b>	30%	55%	45%
<b>Secondary Review</b>	12%	67%	33%
<b>Risk Assessment – End point Selection</b>	18%	85%	15%
<b>FR Notice, Registration</b>	15%	100%	0

<b>Decision</b>			
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\* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

#### New Products and Amendments

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage Remaining if Item is Completed
<b>Non-refundable portion of fee*</b>	25%	25%	75%
<b>Science Reviews</b>	65%	90%	10%
<b>Registration Decision</b>	10%	100%	0

\* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

### Biopesticides and Pollution Prevention Division

#### New Active Ingredients and New Uses

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage Remaining if Item is Completed
<b>Non-refundable portion of fee*</b>	25%	25%	75%
<b>Primary Review</b>	30%	55%	45%
<b>Secondary Review</b>	15%	70%	30%
<b>Risk Assessment</b>	15%	85%	15%
<b>BRAD, FR Notice, Registration Decision</b>	15%	100%	0

\* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

#### New Products and Amendments

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage Remaining if Item is Completed
<b>Non-refundable portion of fee*</b>	25%	25%	75%
<b>Science Reviews</b>	65%	90%	10%
<b>Registration Decision</b>	10%	100%	0

\* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

NOTE: If a data gap or significant deficiency is identified during review of the data/studies which require resubmission of data that need to be reviewed before the risk assessment can be conducted, then it may be determined that only 50 percent of the work is completed. It is anticipated that in such cases negotiations of decision review periods are likely to be needed.

## Registration Division (conventional pesticides)

Whereas the Antimicrobials Division and the Biopesticides and Pollution Prevention Division are interdisciplinary divisions where both the regulatory review and science assessment occur within self-contained units, the Registration Division utilizes the services of the Environmental Fate and Effects Division (EFED) and the Health Effects Division (HED) to complete science reviews for the majority of registration actions. Therefore, the Registration Division has developed formula for two scenarios: A) where the Registration Division relies upon support from OPP's science divisions and B) where the Registration Division completes both science review and regulatory review within the Registration Division (e.g., New Product–Fast Track, and some Non-Fast-Track Actions).

### A) New Active Ingredients, New Uses, and Other Actions Required Review by EFED and HED

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage Remaining if Item is Completed
Non-refundable portion of fee*	25%	25%	75%
Primary Review	20%	45%	55%
Secondary Review	15%	60%	40%
Risk Assessment	25%	85%	15%
FR Notice, Registration Decision	15%	100%	0

\* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

NOTE: The science review generally reflects 60 percent of the Agency's review work for a particular registration action for a conventional chemical. The Agency has divided this 60 percentage in half – 30% for review by EFED (environmental/ecological risk assessments) and 30% for review by HED (human health risk assessments). In calculating the progress in completing the registration action, the Agency will generally multiply the percentage of work completed in each division using the table below by 30% in order to document the total percentage of work completed for a particular registration action.

### B) Science and Regulatory Reviews Completed for Conventional Applications

Tasks Completed	EFED	HED
Primary Review	50%	40%
Secondary Review	15%	20%
Drinking Water Assessment	15%	----

<b>Risk Assessment</b>	20%	40%
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**New Products and Amendments and Actions RD Completes within the Division**

<b>Tasks to Be Completed</b>	<b>Percent of Work by Task</b>	<b>Percent of Work Completed</b>	<b>Percentage Remaining if Item is Completed</b>
<b>Non-refundable portion of fee*</b>	25%	25%	75%
<b>Science Reviews</b>	65%	90%	10%
<b>Registration Decision</b>	10%	100%	0

\* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen