

# Pesticide Registration Improvement Extension Act of 2018 (PRIA 4): Overview of Fee Reduction and Refund Formula

Under FIFRA section 33(b), refunds for a portion of the registration service fee are provided following the withdrawal of a PRIA covered application and at the request of an applicant. Refunds may be provided as a credit for a portion of the Agency's work conducted in support of 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 refund. 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), the Registration Division (**R** fee categories) and the review process for pesticide inert ingredients (**I** fee categories). The formulas take into consideration that 25% of the Registration Service fee for each category is non-refundable (Section 33(b)(2)(G)). Since the Agency must retain 25% of the fee, a refund will not be given if a 75% fee waiver or reduction has been granted.

## 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Pursuant to FIFRA Section 33(b)(8)(a), if an application is withdrawn during the first 60 days after the beginning of the PRIA decision review period, the Agency will refund all but 25% of the registration fee. Refunds for applications withdrawn after the first 60 days of the decision review period will be proportional to the work remaining at the time the action is withdrawn.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Once withdrawn, any future submission related to the application must be submitted as a new application

## 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 in certain situations. The Agency may refund a portion of a covered registration service fee for one of the following bases: 1) in reviewing the application, the Agency has considered data submitted in support of another pesticide registration application; 2) the Agency has completed portions of the review of the application before the effective date of section 33 of FIFRA; or 3) the Agency has rejected the application under the initial content or preliminary technical screen. Some discretionary refunds are routine and, if requested, are applied at the time of submission. The second basis listed above may apply for certain applications that previously were not subject to pesticide registration service fee but became subject to fees under FIFRA section 33. Additional guidance on refunds may be obtained on the [primary/secondary Web page](#) or by contacting the appropriate Registration Ombudsman.

Requests for other reductions in the fee should 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 specific tables for each of the three registering divisions within the Office of Pesticide Programs (Antimicrobials Division, Biopesticides and Pollution Prevention Division, and Registration Division) as well as a table for inert ingredient approvals. These formulas were developed in collaboration with the three registering divisions and the inert ingredient review program and differ only in ways that reflect the review processes unique to each.

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 cumulative percentage of work that the Agency has typically 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 which could be refunded once the Column 3 stage is completed.

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

#### A) New Active Ingredients and New Uses

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Preliminary technical screen	5%	30%	70%
Data - Primary Review	20%	50%	50%
Data - Secondary Review	10%	60%	40%
Risk Assessment	25%	85%	15%
FR Notice Registration Decision	15%	100%	0%

#### B) New Products and Amendments where registrant is relying on substantially similar claims

##### B.1 where application passes 45/90 screen & similarity assessment on first pass

Tasks to be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 screen & similarity assessment	30%	55%	45%
Data (science) review	35%	90%	10%
Registration Decision	10%	100%	0%

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<sup>1</sup> Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

**B.2 where application fails the similarity assessment after 2 passes**

<b>Tasks to Be Completed</b>	<b>Percent of Work by Task</b>	<b>Percent of Work Completed</b>	<b>Percentage to be Refunded</b>
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Preliminary Technical screen & decision by similarity clinic	75%	100%	0%

**C) All Other PRIA Actions**

<b>Tasks to Be Completed</b>	<b>Percent of Work by Task</b>	<b>Percent of Work Completed</b>	<b>Percentage to be Refunded</b>
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Day Preliminary Technical Screen	15%	40%	60%
Data (Science)Review	50%	90%	10%
Registration Decision	10%	100%	0%

<sup>1</sup> 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**

**A) New Active Ingredients and New Uses**

<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>
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Preliminary Technical Screen	15%	40%	60%
Data – Primary Review	20%	60%	40%
Data - Secondary Review	10%	70%	30%
Risk Assessment	15%	85%	15%
FR Notice/ BRAD/ Registration Decision	15%	100%	0%

<sup>1</sup> Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

**B) New Products and Amendments where registrant is relying on substantially similar claims**

**B.1 where application passes 45/90 screen & similarity assessment on first pass**

Tasks to be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 screen & similarity assessment	30%	55%	45%
Data (science) review	35%	90%	10%
Registration Decision	10%	100%	0%

**B.2 where application fails the similarity assessment after 2 passes**

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Preliminary Technical screen & decision by similarity clinic	75%	100%	0%

**C) All Other PRIA Actions**

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage Remaining if Item is Completed
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Preliminary Technical Screen	15%	40%	60%
Data (Science)Review	50%	90%	10%
Registration Decision	10%	100%	0%

<sup>1</sup> 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 renegotiations of decision review periods are likely 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 formulas 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 Manufacturing or End Use Products).

**A) New Active Ingredients, New Uses, or Other Actions that Require Review by EFED or HED**

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Preliminary Technical Screen	5%	30%	70%
Data - Primary Review	15%	45%	55%
Data - Secondary Review	15%	60%	40%
Risk Assessment	25%	85%	15%
FR Notice Registration Decision	15%	100%	0%

<sup>1</sup> 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.

**Science and Regulatory Reviews Completed for Conventional Applications**

Tasks Completed	EFED	HED
45/90 Preliminary Technical Screen	5%	5%
Data - Primary Review	45%	35%
Data - Secondary Review	15%	20%
Drinking Water Assessment	15%	---
Risk Assessment	20%	40%

**B) New Products or Amendments where Registrant is Relying on Substantially Similar Claims - Reviewed within the Registration Division**

**B.1 where application passes 45/90 screen & similarity assessment on first pass**

Tasks to be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 screen & similarity assessment	30%	55%	45%
Data (science) review	35%	90%	10%
Registration Decision	10%	100%	0%

## B.2 where application fails the similarity assessment after 2 passes

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 day Preliminary Technical Screen and Decision by Similarity Clinic Team <sup>2,3</sup>	75%	100%	0%

- 1 Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen
- 2 Citing data on registered product to support or amend a proposed product
- 3 The second pass seeking to claim substantially similarity to a second registered end use product exceeds the cost of the category

## C) All other PRIA Actions – reviewed within RD

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Day Preliminary Technical Screen	15%	40%	60%
Data (Science)Review	50%	90%	10%
Registration Decision	10%	100%	0%

<sup>1</sup> Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

## Inert Ingredients

### All Inert Ingredient Approvals and Amendments

Tasks to Be Completed	Percent of Work by Task	Percent of Work Completed	Percentage to be Refunded
Non-refundable <sup>1</sup>	25%	25%	75%
45/90 Preliminary Technical Screen	5%	30%	70%
Data - Primary Review	15%	45%	55%
Data - Secondary Review	15%	60%	40%
Risk Assessment	25%	85%	15%
FR Notice Registration Decision	15%	100%	0%

<sup>1</sup> Includes Front End or In-processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

## How Refunds are Calculated

Refunds are calculated from the category registration service fee. If an action is withdrawn after 60 days, and the % of work completed (as determined in the tables above) is 45%, then the percent to be refunded would be 55% of the original registration service fee unless a portion of the original fee was waived. The formula for calculating a refund is:

(1) Amount of refund = amount of fee paid – \$ value of work completed

Where

(2) \$ value of work completed = full registration service fee category cost x percent of work completed

(3) No refund is provided if the value of equation (1) is  $\leq 0$ .

See the example below:

### EXAMPLE

Type of applicant	Registration service fee	% of work completed	\$ value of work completed	Fee amount paid	Amount to be refunded
standard	\$1,000	45%	\$450	\$1,000	\$550
Small business (75% fee waiver)	\$1,000	45%	\$450	\$250	\$0
Small business (50% fee waiver)	\$1,000	45%	\$450	\$500	\$50