### **New Pesticide Fees Legislation** - Guidance on How to Request **Fee Waivers and Fee** Reductions

This is the Agency's current guidance on how to request fee waivers and fee reductions under the Pesticide Registration Improvement Act (PRIA). This guidance reflects the Agency's current thinking at this time. As the Agency gains experience with the review of fee waiver and fee reduction requests under 
•Reregistration PRIA, this guidance may change.

#### Questions and Answers on:

General Questions

 Actions Not Covered by Registration Service Fees

Biopesticides

Fee Payments

Fee Waivers

Fund Management

In-Processing of Applications

Inert Ingredients

•IR-4 Submissions

Registration Workplan for

**Conventional Chemicals** 

**General** • Small Business **Certification Example for Small Business** Minor Use • IR-4

#### **General Guidance**

#### 1. Can registration service fees be waived?

Yes. Under the new section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) a waiver or reduction in the registration service fee is allowed or required in certain situations.

- For applications limited to minor uses, EPA may grant a waiver or reduce the registration service fee if the application is accompanied by a request for a waiver or fee reduction and provides supporting documentation that demonstrates to the Agency's satisfaction that anticipated revenues from the uses that are the subject of the application will not be sufficient to justify the imposition of the full fee.
- EPA must grant a waiver for applications that are solely related to a tolerance petition submitted in conjunction with the Inter-Regional Research Project Number 4 (IR-4 program) and the Administrator has deemed such a waiver to be in the public interest.
- An applicant that qualifies as a small business is eligible for a partial or complete waiver of the registration service fee.
- An agency of the Federal Government or a state government is exempt from the registration service fee.

#### 2. When and where should I submit my request for a waiver or reduction of a registration service fee?

A request for a waiver or reduction must be submitted in writing together with the application and should be sent to:

By USPS Mail By Courier

**Document Processing Desk** Document Processing Desk (REGFEE)

(REGFEE) Office of Pesticide Programs

Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency U.S. Environmental Protection Agency One Potomac Yard Room S-4900

Ariel Rios Building 1200 Pennsylvania Avenue, NW Washington, DC 20460-0001 2777 S. Crystal Drive (Address prior to 5/01/06: 1801 South Bell Street) Arlington, VA 22202

#### 3. What is the time frame for the Agency's determination to grant or deny requests for waivers or reduction of registration service fees?

The Administrator must determine whether to grant or deny the request as soon as practicable, but not later than 60 days after the date on which the Administrator receives a request for a waiver or reduction of a registration service fee.

#### 4. How does EPA process waiver requests?

The Agency will review the documentation provided by the applicant and other information in the Agency databases as well as other publicly available information to determine if the applicant meets the applicable criteria for a waiver. The Agency will respond in writing to the applicant with the decision regarding the waiver. If a partial waiver is granted, the letter will include the amount to be paid and instructions for submitting payment.

### 5. When does the decision time review period begin when a waiver or fee reduction has been granted or denied?

If a full waiver is granted, the decision time review period begins on the date the full waiver is granted. If a partial waiver or fee reduction request is granted, the decision time review period begins when the correct payment amount is received. If a waiver or fee reduction request is denied, the decision time review period begins when the full payment is received or the partial waiver is granted, whichever is later.

#### 6. Will the registration service fees be refunded if the application is withdrawn?

If the applicant withdraws a covered pesticide registration application during the first 60 days after the beginning of the applicable decision time review period, the Administrator must refund all but 10 percent of the total registration service fees. If a covered pesticide registration application is withdrawn after the first 60 days of the applicable decision time review period, the Administrator 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.

#### 7. What should I do if my application contains confidential information?

You may assert a business confidentiality claim covering part or all of the information in the application at the time it is submitted to the Agency. If you wish to assert a claim of confidentiality, you must mark the document "CONFIDENTIAL BUSINESS INFORMATION" or with a similar designation, and must bracket all text so claimed. Information covered by a claim of confidentiality will be disclosed by EPA only to the extent, and by means of the procedures set forth under 40 CFR Part 2. If no claim of confidentiality accompanies the information when it is received by EPA, it may be made available to the public by EPA without further notice to the applicant.

# 8. I received an invoice from the Agency in response to my application. I had submitted a waiver request with my application and I disagree with the Agency's decision on the waiver request. How can I appeal this decision?

First, **do not pay the fee**. Instead, please submit a written response, including a rationale explaining your rationale for a different waiver determination. The written response should be submitted to:

By USPS Mail By Courier

Document Processing Desk (WAIVER Document Processing Desk (WAIVER APPEAL)

APPEAL) Office of Pesticide Programs

Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency U.S. Environmental Protection Agency One Potomac Yard Room S-4900

Ariel Rios Building 2777 S. Crystal Drive

1200 Pennsylvania Avenue, NW (Address prior to 5/01/06: 1801 South Bell Street)

Washington, DC 20460-0001 Arlington, VA 22202

Once received by the Office of Pesticide Programs, your response will be reconsidered by the PRIA Waiver Workgroup. After the Agency has completed its review of the rebuttal, you will receive a telephone call from the Agency explaining the Agency's decision. If the Agency changes the waiver determination and fees are still due, you will receive a new invoice from the Agency requesting payment. If the Agency determines that a full waiver can be granted, you will receive a letter granting your full waiver request. If the Agency decides to maintain its original decision on the waiver request, you will be instructed to remit payment in response to the initial invoice.

#### **Guidance on Small Business Waivers**

#### 1. Under what circumstances is a small business eligible for a fee waiver or reduction?

An applicant that meets the definition of a small business is eligible for a fifty percent (50%) waiver of the pesticide registration service fee. A small business means a corporation, partnership, or un-incorporated business that has 500 or fewer employees and during the 3-year period prior to the most recent maintenance fee billing cycle, has an average annual global gross revenue from pesticides that did not exceed \$60 million (including any such revenue from all of its affiliates). In addition, a small business that has average annual global gross revenues from pesticides of less than \$10 million (including any such revenue from all of its affiliates) over the past 3-year maintenance fee billing cycle at the time of the application is eligible for a full waiver (100%) of the pesticide registration service fee.

#### 2. What is the previous "maintenance fee billing cycle" referred to in the statute?

The "maintenance fee billing cycle" is a yearly cycle commencing on January 15th. Therefore, the relevant time periods for measuring whether an applicant meets the definition of a small business are the applicant's three fiscal years preceding the January 15th of the year in which the application is received.

### 3. What are affiliates of an applicant for purposes of requesting a small business fee waiver?

Affiliates include direct and indirect subsidiary and parent entities of the applicant as well as entities that are controlled directly or indirectly by the owner(s) or any parent entity of the applicant. In addition, two unrelated entities are affiliates if they are both owned or controlled by the same entity or person. Specifically, business entities are affiliates of each other if, directly or indirectly, either entity controls or has the power to control the other entity, or a third entity

controls or has the power to control both entities. Indicia of control include interlocking management or ownership, identify of interests among family members, shared facilities and equipment, and common use of employees. Accordingly, control is not limited to voting control over another entity.

NOTE: The Agency is considering appropriate criteria for determining affiliation. Initially, however, the Agency is considering using criteria similar to the criteria that the Small Business Administration uses for determining affiliation. Therefore, until the Agency has had an opportunity to fully consider the matter, for purposes of determining affiliation, the Agency will consider indicia of control such as ownership, management, identify of interests among family members, shared facilities and equipment, common use of employees, and previous relationship with or ties to another business concern (which may include an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust, or cooperative) in determining whether entities are affiliates.

#### 4. What information should I include in my request for a fee waiver as a small business?

The request should be in writing and include the following information:

- The company name and company number assigned by OPP to the applicant, the official
  mailing address under FIFRA, the telephone number and e-mail or fax number of the
  contact person regarding the fee waiver or reduction request.
- A certification signed by a responsible officer that the documentation submitted to support the waiver or reduction request is true, complete, and correct.
- An ownership structure chart depicting the relationship of the applicant to subsidiaries
  and parent entities that are directly or indirectly controlled by the owner(s) or any parent
  entity of the applicant, if appropriate. If the applicant does not have a parent entity, the
  percentage ownership interest of the direct and indirect owner(s) or shareholders of the
  applicant should be disclosed.
- A narrative or explanatory information, if appropriate, addressing whether related entities are affiliates.
- A narrative or explanatory information, if appropriate, explaining how the applicant differentiated its global gross receipts from pesticides from other revenue and how such revenue was calculated, both for the applicant and for any affiliates. The rationale should explain what types of revenues have been excluded.
- Appropriate supporting documentation demonstrating that the criteria for the waiver or reduction from the registration service fee are met.

#### 5. What information is required for certification for a fee waiver or reduction?

A certification should include:

- 1. information on business identification;
- 2. information regarding the number of employees of the applicant;
- 3. information regarding the ownership of the applicant and affiliated entities;
- 4. information regarding the global gross revenue from pesticides (of the applicant as well as any affiliates); and
- 5. a certification statement signed by a responsible officer that the information provided is true, complete, and correct. The following is a sample certification:

<u>Voluntary Small Business Waiver Form</u> <u>EXIT Disclaimer</u> (PDF, 1 p, 193 kb, <u>About PDF</u>) -- A workgroup comprising representatives of registrant companies and trade associations designed a form for assisting pesticide registrants when they submit small business waiver requests under the Pesticide Registration Improvement Act. EPA staff provided input to the

process. Use of the form is voluntary and information submitted using the forms will be accepted by the Agency. Other formats that meet the requirements of the statute will be acceptable to the Agency as well.

#### An Example of a Certification for Small Business

#### **Section 1: Business Identification**

- Name of the applicant
- Company number assigned by OPP to the applicant
- Official mailing address under FIFRA
- Name of the contact person for the waiver or fee reduction request
- Phone number, fax number, and e-mail for the contact person

#### Section 2: Small Business Criteria

A) Global Gross Revenue from Pesticides

- 1. Do you have any subsidiaries? Please include any indirect subsidiaries (subsidiaries of subsidiaries or other subsidiaries of a parent entity) as well.
- 2. Do you have any parent entities? Please provide information regarding the ownership of your ultimate parent (including the percentage ownership/membership interest of each stakeholder).
  - a. If you do not have a parent entity, please provide information on the ownership of the applicant and the percentage ownership/membership interest of each stakeholder.
- 3. Do any stakeholders with a controlling interest in the applicant or any parent entity also directly or indirectly control or have the ability to directly or indirectly control any other entity?
- 4. Which affiliates, if any, have global gross revenue from pesticides?
- 5. Including affiliates, what is your global gross revenue from pesticides, averaged over the applicable three year period?
- 6. If you are distinguishing global gross revenue from pesticides from other gross revenue, please explain how you differentiated and calculated global gross revenue from pesticides alone.

#### B) Employee Threshold

1. Do you employ 500 or fewer employees? What is the number of employees?

#### **Section 3: Certification Statement**

"I, [insert name of undersigned], the [insert title] of [insert name of applicant], am authorized and have personal knowledge sufficient to make this certification on behalf of [insert name of applicant]. I hereby certify under penalty of perjury that the documentation submitted in connection with [insert name of applicant]'s [insert whether this is a fee waiver or a fee reduction] request is true, complete, and correct in all material respects."

Applicant's Name Applicant Signature

#### 6. What should the certification statement say?

The new law requires the accuracy of the documentation supporting a small business waiver request is certified by a responsible officer. A responsible officer is someone who is authorized and has sufficient personal knowledge to make the certification. An agent for the applicant is not a responsible officer. In addition, the Agency considers the information to be accurate if it is true, complete, and correct in all material respects. Thus, the sample certification is an acceptable model that complies with the statutory requirements.

If a certification statement is qualified in a manner such that the Agency is unable to determine that it was made by someone who is authorized to do so and has sufficient personal knowledge, e.g., the certification is qualified with a blanket "to the best of my knowledge" statement, the waiver request will be denied.

### 7. What information should be included in an ownership structure chart submitted in connection with a small business fee waiver?

An ownership structure chart is a diagram that shows the relationship between the applicant and other entities, including parent and subsidiary entities. The ownership structure chart should show all the entities related to the applicant, either directly or through a parent or subsidiary entity, or by virtue of common ownership. If the applicant does not have a parent entity, the direct and indirect owner(s) or shareholders of the applicant should be disclosed. The ownership structure chart and accompanying narrative should include:

- all related entities and owners or shareholders (the company names and company numbers assigned by OPP to entities, if applicable; the official mailing address under FIFRA, if applicable; telephone number; fax number; and e-mail for each entity), and
- the relationship between the entities (i.e., identifying who the owners or interested parties are, identifying entities with any gross revenues from pesticides, and a factual disclosure with respect to the statutory "indicia of control").

### 8. What documentation must I provide if my total gross revenue exceeds the threshold for a waiver but my global gross revenue from pesticides is less than the threshold?

If the applicant is differentiating between gross revenue from pesticides from other gross revenue, the applicant should provide an explanation of how the applicant differentiated and calculated global gross revenue from pesticides from other gross revenue for itself and for its affiliates. If the applicant's total global gross revenues from all sales are well below the \$10 million threshold, the applicant does not need to differentiate between total global gross revenues and global gross revenues from pesticides alone.

#### 9. How should I calculate the number of employees?

To be eligible for a small business waiver, the applicant must have 500 or fewer employees at the time of submitting the application. Unlike the calculation for global gross receipts from pesticides, the calculation of the number of employees is limited to the employees of the applicant and does not include the employees of affiliates. The Agency currently believes that the number of employees should be calculated in a manner similar to how the Small Business Administration calculates the number of employees for purposes of its regulations. Therefore, the number of employees should be determined upon consideration of the totality of the circumstances, including factors relevant for tax purposes. Accordingly, the number of employees should include

all individuals employed on a full-time, part-time, and temporary basis (including shared employees). Supporting documentation may, in part, include payroll information and a recent IRS Form 941, together with a statement certifying the total number of individuals employed by the applicant.

#### 10. How should I calculate global gross revenues from pesticides?

Global gross revenue from pesticides (as defined in FIFRA and the implementing regulations) is not limited to revenue from pesticides for which the applicant is the registrant but includes all revenue from the distribution or sale by the applicant or any of its affiliates of a substance (or mixture of substances) that is intended for a pesticidal purpose or is advertised as having pesticidal purpose, either in the United States or abroad, even if (i) the applicant is not the registrant and (ii) the substance or device is not registered in the United States. Global gross revenue from pesticides also includes all revenue from the sale or distribution of so-called "Section 25(b)" exempt pesticides. Global gross revenue from pesticides does not, however, include revenue from devices that are sold separately from a pesticide.

## 11. What type of documentation should be included to support a small business waiver or fee reduction request?

The documentation to support the waiver or fee reduction request should be reliable, pertinent, and comprehensive. The Agency is still considering how best to meet this goal. The type of documentation that the Agency currently believes will aid it in making a decision regarding a small business waiver or fee reduction request includes, but is not limited to, such documents as: income tax returns filed with the Internal Revenue Service (such as IRS Forms 1065, 1120, or 1120S, as applicable), the applicant's most recent IRS 941, and audited financial statements.

# 12. What information should I include in my request for a small business waiver or fee reduction if my business is located in countries other than the United States?

Foreign entities must provide the same information provided by domestic entities. However, if the information is not in English, the applicant's request may be denied because the Agency is unable to determine that the applicant meets the statutorily defined criteria for a small business. Therefore, documentation not in English should be accompanied by a translation with a certification that the translation is accurate. The Agency will consider the appropriate documentation supporting the request on a case-by-case basis

# 13. My gross revenue includes global pesticide sales paid by foreign currencies. What exchange rates should I use to convert my global pesticide sales into U.S. dollars?

Global gross revenue from pesticides is calculated as an average during the 3-year period prior to the most recent maintenance fee billing cycle. The exchange rates to convert the global gross revenue into US dollars should also be the average during the same period. The applicant should include an explanation of the method used for averaging such revenues over the applicable period(s) as well as an explanation of how the exchange rate used was determined.

# 14. I'd like to request a fee waiver or reduction for small business, but I am a newly formed start-up company. What supporting documentation should I submit?

The Agency is considering what documentation is appropriate in this circumstance. To the extent possible, the applicant should provide the same information as other applicants regarding the number of employees and affiliates. The applicant should disclose whether the ownership or management of the new entity had control over other entities with gross global revenue from pesticides in the prior applicable three-year period. The Agency will not grant a waiver if it

determines that the entity submitting the application has been formed or manipulated primarily for the purpose of qualifying for the waiver

15. After the Agency has granted my request for a small business fee waiver or reduction on one registration application, how do I request the waiver or reduction for subsequent registration applications?

EPA must determine that the applicant meets the statutory criteria for a small business fee waiver or reduction at the time of the request for each registration application. Therefore, you must provide a certification with each registration application. To the extent that previously submitted documentation is still valid and represents your company's current small business status, you can rely on these materials by reference.

If the previous request occurred during a prior maintenance fee billing cycle (i.e., prior to January 15)

• The applicant must submit all of the necessary documentation supporting the fee waiver/reduction request as if the request were being made for the first time.

If the previous request occurred during the current maintenance fee billing cycle and the information provided in connection with the prior request has not changed

 The applicant may reaffirm the information and the underlying documentation previously submitted by submitting a new certification statement that could read as follows:

"I, [INSERT NAME OF UNDERSIGNED], the [INSERT TITLE] of [INSERT NAME OF APPLICANT], am authorized and have personal knowledge sufficient to make this certification on behalf of [INSERT NAME OF APPLICANT]. I hereby certify under penalty of perjury that, since [INSERT WHETHER THIS IS A WAIVER REQUEST OR A FEE REDUCTION REQUEST] request of [INSERT DATE], there has been no change in the number of [INSERT NAME OF APPLICANT]'s employees, entities affiliated with [INSERT NAME OF APPLICANT] or average gross global revenue from pesticides, including any such revenue from affiliates and that the documentation submitted in connection with the request of [INSERT DATE] remains true, complete, and correct and remains valid.

Applicant's Name Applicant's Signature Title Date

 While not required, the Agency asks that the applicant also provide a copy of the Agency letter granting the fee/waiver reduction as information in this letter helps the Agency expedite the waiver decision-making process.

If the previous request occurred during the current maintenance fee billing cycle and some of the information provided in connection with the prior request has changed

The applicant can reaffirm the information and underlying documentation
previously submitted to the extent that there have been no changes and provide
updated documentation with respect to those pieces of information that have
changed. In these instances, the applicant would provide the following:

- A letter indicating what information in the last certification continues to remain "true, complete, and correct".
- Materials documentation the information that has changed since the last certification.
- A new certification that could read as follows:

"I, [INSERT NAME OF UNDERSIGNED], the [INSERT TITLE] of [INSERT NAME OF APPLICANT], am authorized and have personal knowledge sufficient to make this certification on behalf of [APPLICANT]. I hereby certify under penalty of perjury that the documentation submitted in connection with [INSERT NAME OF APPLICANT]'s [INSERT WHETHER THIS IS A WAIVER REQUEST OR A FEE REDUCTION REQUEST] request is true, accurate, and complete in all material respects. I further certify under penalty of perjury that, since [INSERT NAME OF APPLICANT]'s [INSERT WHETHER THIS IS A WAIVER REQUEST OR A FEE REDUCTION REQUEST] request of [INSERT DATE] there has been no change in the [INCLUDE APPLICABLE ELEMENTS: number of employees/entity affiliations/average gross global revenue from pesticides, including any such revenue from affiliates] and the documentation submitted in connection with the request of [INSERT DATE] remains true, complete, and correct and remains valid."

Applicant's Name Applicant's Signature Title Date

> While not required, the Agency asks that the applicant also provide a copy of the Agency letter granting the fee/waiver reduction as information in this letter helps the Agency expedite the waiver decision-making process.

#### **Guidance on Minor Use Waivers**

### 1. Under what circumstances am I eligible for a fee waiver or reduction for an application related to a minor use?

FIFRA section 2(II) defines the term 'minor use' to mean "the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health" under certain conditions. These conditions includes where the total US acreage for the crop is less than 300,000 acres; or the use does not provide sufficient economic incentive to support the initial or continuing registration of the pesticide for the use, provided additional criteria are met, such as that the pesticide plays a significant part in managing pest resistance or in an integrated pest management program. The Administrator may waive or reduce a registration service fee if the application meets the statutory definition of a minor use and the anticipated revenues from the uses that are the subject of the application must be insufficient to justify the imposition of the full application fee.

### 2. What information should I include in my request for a fee waiver or reduction for minor uses?

The request should be in writing and including the following information:

- The company name and company number assigned by OPP to the applicant; the
  official mailing address under FIFRA; the telephone number and e-mail or fax
  number of the contact person regarding the fee waiver or reduction request.
- A certification signed by a responsible officer that the documentation submitted to support the waiver or reduction request is true, complete, and correct.
- A market analysis that demonstrates the anticipated revenues from the uses that are the subject of the application should be insufficient to justify the imposing of the full application fee.
- 3. What information should be included in a market analysis for a minor use waiver or reduction request?

The Agency is considering what information is appropriate for making a determination on a request for a minor use waiver or reduction. The Agency currently believes that the applicant should provide a detailed market analysis that demonstrates the anticipated revenue is expected to be insufficient to justify imposition of the full registration fee. In the market analysis, the applicant should to provide information on the anticipated revenue for the next three years based on projected market price and sales volume assumed for the calculation. The applicant should also provide information of the crops and use sites; primary target pests; application rates; and other supporting market information related to product advantage or disadvantages to competing alternatives.

#### **Guidance on IR-4 Waivers**

#### 1. Under what circumstances am I eligible for an IR-4 waiver?

Under PRIA, the Agency will waive the registration service fee for an application that is solely associated with a tolerance petition submitted by the IR-4 program and if the waiver is in the public interest. For an application to be considered to be solely associated with a tolerance petition submitted by IR-4, the section 3 registration request must be submitted at the same time as the tolerance petition. The registration application must be accompanied by the notice of filing for the tolerance petition.

#### 2. How do I request an IR-4 waiver?

To request an IR-4 waiver, you may include the following statement in Section II -- Explanation of EPA Form 8570-1 (Application for Pesticide Registration): "This application is being submitted with a tolerance petition submitted in connection with IR-4. I request EPA to waive the registration service fee for this application under the IR-4 waiver provisions at FIFRA Section 33(b)(7)(E)." The IR-4 Program has agreed to coordinate the submission of requests for IR-4 waivers. If you have any questions, you may contact Dan Kunkel at IR-4 Headquarters at 732-932-9575, extension 616.

## 3. Are applications associated with non-food use data submitted by the IR-4 program eligible for the IR-4 waiver?

No. Under PRIA, Congress explicitly stated that the IR-4 waiver only applies to applications solely associated with tolerance petitions submitted by the IR-4 program. Because non-food use applications do not require the submission of tolerance petitions under the Federal Food, Drug, and Cosmetic Act, non-food use applications are not eligible for consideration under the IR-4 waiver provisions. If appropriate, however, applicants may be eligible for consideration under the

minor use waiver provisions of FIFRA Section 33(b)(7)(D) or the small business waiver provisions of FIFRA Section 33(b)(7)(F).

# 4. If I request an IR-4 waiver, when will the decision review period for my application begin?

The decision review period will begin on the date the waiver is granted. Applicants will be notified by mail when the waiver has been granted.