



Registration Service Fees: Regulating Pesticides

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On March 6, 2008, the President signed a technical correction to PRIA 2 to exempt fees for certain registration applications associated with IR-4 tolerance petitions which became effective retroactively to October 1, 2007.

1. **Under what circumstances am I eligible for an Inter-Regional Project Number 4 (IR-4) registration service fee exemption?**

If the Agency determines that an application is solely associated with a tolerance petition submitted in connection with [IR-4](#) [EXIT Disclaimer](#) and an exemption from registration service fees is in the public interest, such an application would be exempt from registration service fees. The public interest finding is being discussed within the Agency.

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2. **How must I submit the registration request to qualify for the service fee exemption?**

The registration request must be submitted simultaneously with the IR-4 tolerance petition or within 14 days of the petition. If the registration request or petition is delayed, EPA will determine that the registration request is not solely associated with an IR-4 tolerance petition and a registration service fee will be due. The registration application must be accompanied by the *notice of filing* for the tolerance petition. If you choose to submit the Section 3 registration application separately from the IR-4 petition but within the 14 days, reference the commodities and the date of the IR-4 tolerance submission so the Agency can link the submissions.

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3. **What do I do if I want to amend the application?**

Once the 14 days have elapsed, any changes to the application will require a new application that will be subject to a PRIA fee unless the original application and petition are withdrawn and then submitted simultaneously again with a request for an IR-4 exemption.

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4. How do I request an IR-4 exemption on EPA Form 8570-1, Application for Pesticide Registration?

To request an IR-4 exemption, include the following statement in the "Explanation" box of Section II:

"This application is being submitted with a tolerance petition submitted in connection with IR-4. I request that EPA exempt the registration service fee for this application under the IR-4 exemption provisions at FIFRA Section 33(b)(7)(E)."

Also in this section, reference the commodities that are the subject of the IR-4 petition.

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5. Who is the IR-4 contact coordinating submissions?

The IR-4 Program has agreed to coordinate the submission of requests for IR-4 exemptions. If you have any questions, contact:


Dr. Daniel L. Kunkel

IR-4 Project Headquarters

Phone: 732-932-9575 ext. 4616


Fax: 609-514-2612

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6. Are applications solely associated with IR-4 tolerance petitions and in the public interest subject to the 21-day initial content screen?

Yes. An application must contain all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Agency. If it does not, corrections to the application must be made by the end of the 21 days, beginning the day the exemption is granted. If EPA rejects an application and you wish the Agency to consider your application again, you must submit a new application. To qualify for the IR-4 exemption, the IR-4 tolerance petition must be withdrawn and then submitted simultaneously with the new application.

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7. What are some common issues that should be considered when developing these submissions?

A Section 3 label amendment must reflect the application rates and the formulations used in the IR-4 field residue trials.

Requests to change the use directions or the formulation submitted after 14 days of the submission of the IR-4 petition do not qualify for a PRIA exemption since the requests will not be solely associated with submission of the IR-4 petition.

Any requests to change/add formulations, REI, PPE, PHI, use rate, number of applications, or add aerial application after 14 days have elapsed will constitute a new request and will be subject to PRIA fees.

The Notice of Filing (NOF) provided by the registrant and submitted by IR-4 must list the same commodities and proposed tolerance levels listed in section "F" of the IR-4 petition request. EPA will only

be able to establish tolerances for commodities that were proposed in the *Federal Register* and discussed in the NOF.

The Agency encourages registrants to work with IR-4 to ensure that applications are complete when the Agency receives them.

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8. Are applications associated with non-food use data submitted by the IR-4 program eligible for the IR-4 exemption?

No. Under PRIA, this exemption only applies to applications solely associated with tolerance petitions submitted by the IR-4 program. Under the Federal Food, Drug, and Cosmetic Act, a non-food use application does not require a tolerance; therefore the application is not eligible for an IR-4 exemption. However, an application may be considered under the "minor use" provisions of FIFRA [Section 33(b)(7)(D)], or under the "small business waiver" provisions of FIFRA [Section 33(b)(7)(F)].

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

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

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http://www.epa.gov/pesticides/fees/questions/guidance_ir-4.htm
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