

US EPA ARCHIVE DOCUMENT

Guidance on Economic Minor Use Status – Session VI

1. What is a Minor Use? Under what circumstances is a registration of a pesticide for a certain use considered an “economic minor use”?

FIFRA Section 2(II)(2) defines a minor use of a pesticide as one where “the total United States acreage for the crop is less than 300,000 acres” or “the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and:

- (A) there are insufficient efficacious alternative registered pesticides available for the use;
- (B) the alternatives to the pesticide use pose greater risks to the environment or human health;
- (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or
- (D) the minor use pesticide plays or will play a significant part in an integrated pest management program.”

A use registered for a crop that has more than 300,000 acres can still be a minor use if it meets the criteria for “economic minor use.” That is, a “minor use” can exist for a major crop or for a non-agricultural use if it meets two criteria: (1) insufficient economic incentive and (2) one of the four criteria listed in A through D.

2. What information should I include in a request for an “economic minor use”?

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

1. **Applicant 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 request.
2. **Certification Statement:** A certification signed by a responsible officer that the documentation submitted to support the request is true, complete, and correct.
3. **Economic information:** Historical or projected costs and revenues from the sale of the pesticide for the intended use. Historical records or projections of costs and revenues should be provided for a period of at least three years.
4. **Biological information:** Data to indicate how the use meets one or more of the four criteria.

3. What should the certification statement say?

The following is an example of a certification statement.

Sample 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 fee waiver request is true, complete, and correct in all material respects.”

Applicant's Name
 Applicant Signature
 Title
 Date

4. What data should I submit to show revenues from the sale of the pesticide for the particular use?

Gross revenue is the total sales of the pesticide for the minor use, e.g., sales of [chemical X] for use on [site Y]. If the registrant has been selling the pesticide for the use for which it is requesting economic minor use status, it should furnish records of sales of the pesticide for that use for at least three years, if available. If the pesticide has not yet been registered for the use for which economic minor use status is being requested, the registrant should submit revenue projections (i.e., predictions of annual revenues) for at least three years. If the registrant submits projections, it should also provide a written rationale for its projections and conditions that are expected to alter their accuracy. For example, the registrant could submit data on expected acres to be treated, given the extent of target pests, the application rate, and the price per unit.

Net revenue is gross revenues minus costs. The costs of production of a pesticide for a particular use include, but are not necessarily limited to, the following categories:

- Cost of raw materials
- Wages of production and sales workers for hours when assigned to production, sale, or distribution of the pesticide for this use
- Machinery & equipment depreciation for time producing the pesticide for this use
- Energy costs and waste disposal costs specific to production of the chemical for this use

[NOTE: EPA is uncertain as to the value of data on costs of production, distribution, advertising, etc., compared to the difficulty in gathering and reviewing the data. A simpler alternative may be to provide information about the size of production for the minor use relative to production for all uses that could be used qualitatively in the Agency's determination.]

5. What data should I submit to show the costs of production of the pesticide for the particular use?

The costs of registration of a pesticide for a particular use include, but are not necessarily limited to, the following categories:

- FIFRA data requirements – e.g., residue trials, toxicity data, etc. (A list of data requirements is sufficient; EPA has data on testing costs)
- Registration application (PRIA) fees
- Others, if/as applicable

[NOTE: EPA is uncertain as to the value of data on other registration costs compared to the difficulty in gathering and reviewing the data. A simpler alternative may be to use information about the context of the application (e.g., one of many actions versus a single action) that could be used qualitatively in the Agency's determination.]

6. What data/information should I submit to show that this use meets one of the four criteria FIFRA Sec. 2(II)(2)?

In addition to the having insufficient incentive, the use must meet at least one of the four criteria (A) through (D) listed in Question #1. For information on how to satisfy any of the four criteria, see "Questions and Answers – Exclusive Use Data Protection for Minor Use Registrations" at <http://www.epa.gov/pesticides/minoruse/exclusive-use-questions.pdf>. See the answer to Question #11 on pages 10-11.

7. How will my request for economic minor use status be evaluated?

Evaluation of the registrant's request for economic minor use status will consist of two phases: (1) determination of sufficient economic incentive and (2) determination of whether the use meets one of the four criteria.

8. What additional data can I submit to assist EPA in the evaluation of whether the registration of the pesticide for the particular use qualifies as an economic minor use?

The registrant is always welcome to submit additional data and information that it believes to demonstrate its lack of economic incentive for producing a pesticide for a particular use.

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