



Revised November 2016

Questions and Answers

Extension of Exclusive Data and Minor Use Designation, Suggestions to Applicants for Agronomic Information

This document contains questions and answers that the Office of Pesticide Programs aimed at assisting applicants/registrants of conventional pesticides when they prepare to request an extension of exclusive use of data or a request for a minor use designation for sites other than crops grown on less than 300,000 acres. This document is intended to provide guidance to pesticide applicants/registrants and EPA personnel and is not binding on either EPA or any outside parties. It is intended to clarify the information that may be needed to evaluate the requests under the statutory criteria. This guidance document only provides clarification on the criteria evaluated for each minor use. [For further information regarding exclusive use data protection and minor use registrations, refer to “Questions and Answers – Exclusive Use Data Protection and Minor Use Registrations.”](#)

What criteria in FIFRA Section 3(c)(1)(F)(ii) are used to evaluate extensions of exclusive use data?

In addition to the other statutory requirements, an extension of data requires that the registrant provide information that the pesticide meets one of four criteria for each minor use crop as described in Section 3(c)(1)(F)(ii). This guidance is provided to assist the requestor in meeting the following criteria:

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

The Environmental Protection Agency, Office of Pesticide Programs, Biological and Economic Analysis Division (BEAD) reviews the applications to determine if they meet criteria [I](#), [III](#), or [IV](#). Information supporting extension of data based on Criteria [II](#) is reviewed by the Human Effects Division (HED) or Environmental Fate and Effects Division (EFED).

What level of detail could be provided to OPP to assist in determining whether the request satisfies any of the criteria in FIFRA 3(c)(1)(F)(ii)?

There is no set format that must be followed to provide this information. However, the request package may be written on a crop-by-crop basis to make it easier for the reviewer to assess your request. BEAD finds information presented in a bulleted list easier to follow rather than a narrative. For each crop/site OPP recommends that the applicant/registrant describe the following:

- The date of first registration and date when the minor uses were registered.
- How the pesticide is being marketed for these minor uses.
- The acres grown (with reference to the source of these data), minor crop status can be determined based on total acreage or economics (see sections below).
- The target pest (i.e. a pest that can lead to economic impacts if not controlled) or beneficial insect (i.e. the pesticide is less toxic to beneficial insects).
- The criterion that is being met (BEAD only reviews criteria I, III, and IV) and a detailed description of why the pesticide meets the criteria, and all supporting evidence (publications, websites, reports, etc.).

The pesticide only needs to meet one of the criteria for each specified crop. Because an applicant needs nine crops to get the maximum number of three years of additional data protection, it may be beneficial if the applicant includes information on more than nine crops to help ensure a sufficient number of crops that meet the criteria. Table 1 lists examples of information to help describe how a pesticide can fulfill a specific criterion.

What is the appropriate source that applicants can use to verify minor use status based on crop acreage?

To be eligible for extension of exclusive use of data, the criteria above must apply to minor uses. Minor uses under FIFRA 2(11)(1) include crops for which the total U.S. area grown is less than 300,000 acres, such as some fruits and vegetables. Based on discussions with the United States Department of Agriculture (USDA) National Agricultural Statistics Service (NASS) and Farm Service Agency (FSA), EPA will first rely on the most current Census of Agriculture to determine crop acres for minor crops. This publication is a census and not a survey of crops. It provides the most accurate information on crop production and is much broader in scope than a yearly survey. It is produced every 5 years and it includes all agricultural operations that produce more than \$1,000 of a product.

The Census of Agriculture is publically available on the USDA website and we recommend that the applicant consult the most current Census of Agriculture when developing the application (available online at <http://www.agcensus.usda.gov/>).

How does one show that there is not sufficient economic incentive?

The Agency proposed a method for addressing the economic incentive in 2016. Please refer to docket number [EPA-HQ-OPP-2015-0814](#) for more information. The Agency is currently reviewing comments prior to finalizing guidance.

What quality of data verify criteria?

In order to meet a specific criterion, the site and pest combination needs to have sufficient supporting evidence so that the case can be clearly described. The information must be readily available to those who need to use it in developing pest management programs (e.g., crop consultants, growers, university researchers). High quality data can be found from:

- university extension publications;
- primary research data;
- company literature, resistance databases; or
- other authoritative sources.

Other data that may not be as valuable, but could still be helpful may come from other sources – this may require additional knowledge or extrapolation by the applicant before it can fulfill the criterion.

How is information used to review the request for extension of exclusive use protection?

The pesticide only needs to meet one of the four criteria for a specific crop. The following table is set forth to assist the requestors in providing information to meet the statutory criteria. If addressing criterion II, explain whether you are addressing environmental or human health issues.

Table 1. List of Criteria and Example Recommended Information for Extension of Exclusive Use *

Criteria	Example Recommended Information
Criterion I (<i>there are insufficient efficacious alternatives</i>)	<ul style="list-style-type: none"> a. The chemical fills a void in the current program (e.g., unique timing window). For example, a Section 18 approved because of insufficient alternatives. b. Information that the pesticide controls a broader range of pests than currently registered alternatives. c. Information that the pesticide controls a different life stage for the pest. This example could also be suitable for Criteria IV below. d. Information that the pesticide provides a crucial timing advantage (i.e., has a shorter Pre-harvest interval or Re-entry interval). This example could also be suitable for Criteria IV below depending on the situation.
Criterion II (<i>alternatives pose greater risks to environment or human health</i>)	<p>Before submitting information to support this claim (e.g., crop, pest, appropriate alternative, etc.), OPP suggests that the requestor discuss their situation with BEAD and EFED or HED. If a pesticide was registered in the last 2-3 years under reduced risk status it might be appropriate to consider this criterion. The reduced risk information could be helpful in meeting this criterion.</p>
Criterion III (<i>play a significant part in managing pest resistance</i>)	<ul style="list-style-type: none"> a. The pesticide is listed or recommended as part of a published resistance management plan for the proposed crop and pest. b. The target pest(s) have known and documented resistance issues to other registered pesticides, but not to the requested pesticide. c. Is the pesticide of a different chemical class than other registered pesticides such that resistance development may be delayed and pest management improved? Do resistance concerns dictate rotation of different chemistries?
Criterion IV (<i>play a significant part in an integrated pest management program</i>)	<ul style="list-style-type: none"> a. The pesticide is currently recommended (e.g., by state/university extension services) for use in an IPM program. b. The pesticide works more effectively with beneficial insects, natural enemies, biocontrol agents and/or cultural practices. The insecticide controls only a target insect(s) without harming the beneficial insects (e.g., bees). c. The pesticide allows a different or unique application timing (e.g., seed treatment, soil application, and foliar application) or a longer period of residual control than other registered pesticides for the crop. d. The pesticide controls a different life stage for the pest. This example could also be suitable for Criteria I above depending on the situation. e. The pesticide provides a crucial timing advantage (i.e., have a shorter Pre-harvest interval or Re-entry interval). This example could also be suitable for Criteria I above depending on the situation. f. The pesticide avoids negative interactions with other types of pesticides (i.e., fungicide or insecticide).

Footnote: * For these criteria FIFRA Section 2(l)(1) uses the letters A through D instead of I through IV.

REFERENCES

FIFRA. 2008. FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT [As Amended Through P.L. 110–246, Effective May 22, 2008]

<http://www.epa.gov/opprd001/registrationmanual/FIFRA.pdf>

FRAC. 2013. Fungicide Resistance Action Committee. FRAC Code List 2013: Fungicides sorted by mode of action (including FRAC Code numbering).

<http://www.frac.info/publication/anhang/FRAC%20Code%20List%202013-update%20April-2013.pdf>

U.S.D.A. 2012. Census of Agriculture. 2012. Updated May 2, 2014. Available online at:

<http://www.agcensus.usda.gov/>