US Environmental Protection Agency
Office of Pesticide Programs

Questions and Answers - Exclusive Use Data Protection for Minor Use Registrations

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Questions and Answers

Exclusive Use Data Protection for Minor Use Registrations

FIFRA authorizes a period of time after initial registration of a new active ingredient or a new use for an already registered product during which only the registrant who developed the data may use it to support additional registrations. This is similar to a patent, allowing exclusive use of the supporting data for a specific period of time. In some circumstances, registration of a minor use may either extend the exclusive use period or establish a new exclusive use period.

Minor uses of pesticides are those for which the total United States production for a crop is fewer than 300,000 acres. Minor use also applies to pesticide uses that do not provide sufficient economic incentive for a registrant to support initial or continuing registrations.

Minor uses include some fruits and vegetables, and control of disease vectors, such as mosquitoes, ticks, cockroaches, rodents and disease-causing organisms.

General:

1. What is the FIFRA exclusive use provision?

The exclusive use provision is in § 3(c) (1) (F) (i) of FIFRA. The text follows:

> With respect to pesticides containing active ingredients that are initially registered under this Act after the date of enactment of the Federal Pesticide Act of 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

This section of FIFRA allows registrants exclusive use of data developed in support of the registration of a new active ingredient or new use. During the period of exclusive use, no other registrant can use the same data in support of registration of another product unless they have the written permission of the original registrant.

2. What are exclusive use data?

"Exclusive use data" applies to studies submitted to the Agency in support of an application for registration of a new pesticide active ingredient or amendment adding new use(s) to this registration. The regulations implementing FIFRA § 3(c) (1) (F) (1) contain a definition of an exclusive use study. According to 40 C.F.R. § 152.83(c), an exclusive use study must meet each of the following requirements:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;
(2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such a new chemical or new combination (first registration), or an application to amend such registration to add a new use; and
(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); Provided that, a study is an exclusive use study only during the 10-year period following the date of the first registration.

3. What sections of FIFRA provide for petitioning the Agency for extension of the exclusive use period for registering minor uses OR establishing a new exclusive use period for data associated with new minor uses?

Depending on the circumstances of registration of the minor use, the exclusive use period may be extended or a new exclusive use period may be established.

The exclusive use period may be extended if new minor uses are registered within the first 7 years of the commencement of the exclusive use period. In addition, the new uses must meet at least one of the four criteria outlined in FIFRA section 3(c) (1) (F) (ii). For each 3 minor uses registered within this timeframe that meet the necessary standards, the exclusive use period may be extended for 1 year.

The maximum that the exclusive use period may be extended under this section of FIFRA is 3 years. For example, if a new active ingredient was registered on January 1, 2000, the exclusive use period would expire on January 1, 2010. If 3 new minor uses are registered before January 1, 2007 and meet the criteria outlined below, the exclusive use period could be extended to January 1, 2011. The maximum potential extension of this exclusive use period would be January 1, 2013.

Extending the Exclusive Use Period - FIFRA § 3(c) (1) (F) (ii)

FIFRA § 3(c) (1) (F) (ii) sets forth the criteria to be met for extending the exclusive use period. The threshold requirement is that the new minor use must be registered within the first 7 years of the commencement of the exclusive use period.

The following is the text of FIFRA § 3(c) (1) (F) (ii):

> The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that there are insufficient efficacious alternative registered pesticides available for the use;
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> (I) The alternatives to the minor use pesticide pose greater risks to the environment or human health;

(II) The minor use pesticide plays or will play a significant part in managing pest resistance; or

(III) The minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause one minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the products for such minor uses.

Establishing a New Exclusive Use Period - FIFRA § 3(c) (1) (F) (VI)

Once an exclusive use period has expired, a registrant may request a new exclusive use period for the data developed to add a minor use to an existing registration that does not have exclusive use protected data. The registrant must request this new exclusive use period at the time of application, unlike the extension request described above. See the information on FIFRA § 3(c)(1)(F)(vi) below for a detailed description of new exclusive use periods for adding minor uses to an existing registration after the initial data exclusivity period expires.

FIFRA § 3(c) (1) (F) (VI) applies to data submitted to add a minor use to an existing registration after the initial data exclusivity period expires. It provides for a new exclusive use period for data generated by an applicant or registrant to register a new minor use. It allows registrants to request at the time they submit their application for a new minor use (the use does not have exclusive use protected data) that the data be given exclusive use protection.

The following is the text of FIFRA § 3(c) (1) (F) (VI):

With respect to data submitted after the date of enactment of this clause by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant **at the time the new minor use is requested** shall notify the Administator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provision of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a non-minor use, the data shall no longer be subject to the exclusive use provision of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

4. What is a minor use?

The definition of a "minor use" as defined in FIFRA § 2(ll), as follows, pertains to the extension of exclusive use for minor use registrations provisions.

> 2(ll) MINOR USE.—The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—
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> (1) The total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
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> (2) The Administrator, in consultation with the Secretary of Agriculture determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and
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> (A) There are insufficient efficacious alternative registered pesticides available for the use;
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> (B) The alternatives to the pesticide use pose greater risks to the environment or human health;
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> (C) The minor use pesticide plays or will play a significant part in managing pest resistance; or
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> (D) The minor use pesticide plays or will play a significant part in an integrated pest management program.
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> The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

5. Is extension of the exclusive use period or establishment of a new exclusive use period for minor use registrations automatic?

No. Extension of the exclusive use period or establishment of a new exclusive use period for minor use registrations is not automatic. Registrants must submit a request to the Agency to be considered.

Exclusive use extension requests are now a covered registration activity under the Pesticide Registration Improvement Extension Act (PRIA 3) implemented on October 1, 2012. M007 is the PRIA 3 category for exclusive use extension requests under FIFRA section 3(c)(1)(F)(ii), and M008 is the PRIA 3 category for exclusive use extension requests under FIFRA section 3(c)(1)(F)(vi). See the Fee Determination Decision Tree [http://www2.epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers] or the PRIA 3 Fee Table [http://www.gpo.gov/fdsys/pkg/USCODE-2012-title7/html/USCODE-2012-title7-chap6-subchapII-sec136w-8.htm] for further information.

To qualify to be considered under § 3(c)(1)(F)(ii) of FIFRA for an extension of the exclusive use period, the **minor uses must be registered <u>within</u> the first 7 years from the start of the exclusive use period and meet <u>one</u> of the four criteria listed in FIFRA § 3(c)(1)(F)(ii).** A request can be made at any time prior to the expiration of the exclusive use period once the criteria outlined in

FIFRA § 3(c) (1) (F) (ii) have been met. EPA prefers that the requests come in as soon as the registrant determines that it meets the criteria and not later than six (6) months before the expiration of the exclusive use period.

To qualify to be considered under § 3(c) (1) (F) (VI) of FIFRA to establish a new exclusive use period, the request must be **made at the same time** that the application for adding the new minor use(s) is submitted. The request must indicate that to the best of the registrant or applicant's knowledge, the exclusive use period has expired and that data submitted to support the minor use(s) are eligible for exclusive use protection.

6. How is an application submitted for extension of exclusive use or establishment of a new exclusive use period?

Applicants must submit fee payments at the time of application, and EPA will reject any application that does not contain evidence that the fee has been paid. See information on Fee Payments [http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees] for further information. Payments may be made by check, bank draft, money order, or online with a credit card or wire transfer. The applicant should attach documentation that the fee has been paid with the application. The application should be sent to:

(1) By USPS Mail:
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

(2) By Courier
Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. EPA, Room S-4400
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202-4501

When preparing the request for a M007 (extension of exclusive use), address to the attention of the following person in the cover letter:

Conventional pesticide that was registered by the Registration Division (RD). The contact person in RD is:

Stephen Schaible
Registration Division
Telephone: 703-308-9362

Biopesticide that was registered in the Biopesticide and Pollution Prevention Division (BPPD). The contact person in BPPD is:

Nicole Berckes
Biopesticide and Pollution Prevention Division
Telephone: 703-308-0152

Antimicrobial that was registered in the Antimicrobial Division (AD). The contact person is:

Sharon Carlisle
Antimicrobial Division
Telephone: 703-308-6427

7. How does the Agency make public the results of petitions for exclusive use data protection for minor use registrations?

All petitions for extensions and new exclusive use periods and the determinations From the Agency regarding the petitions will be posted on the EPA Pesticide Web site at http://www2.epa.gov/pesticide-registration/minor-uses-and-grower-resources.

8. What documentation does the Agency provide to the registrant to reflect the Agency's decision regarding extension of the exclusive use data period?

Once the Agency makes a final determination, it sends a letter to the registrant either granting or denying the extension. The letter also includes the rationale for granting or denying the extension. A copy of the letter will be kept in the official Agency file for the active ingredient and all product files. In some cases the Agency may send an interim letter requesting additional information in order to make a final determination on the petition. Determinations from the Agency to registrants regarding the petitions will be posted on the EPA Pesticide Web site at http://www2.epa.gov/pesticide-registration/petitions-requesting-extend-exclusive-use-period-active-ingredient

9. Who at EPA determines whether the application satisfies the criteria for minor use treat ment?

The determination whether the application satisfies the criteria for minor use treatment is made by the applicable registering division [i.e., Registration Division (RD), Antimicrobial Division (AD) and Biopesticides and Pollution Prevention Division (BPPD)].

10. Has EPA established a form by which the applicant could be clearly advised of the type of data and information needed to qualify a use as a minor use?

No, a form has not been developed, but these Questions and Answers will be updated regularly and posted to the EPA Pesticide Web site at http://www2.epa.gov/pesticide-registration/minor-uses-and-grower-resources to provide general information. To submit questions, contact William

Chism, Specialty Crop Advisor, Biological and Economic Analysis Division (7503P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8189; fax number: (703) 308-8091; e-mail chism.bill@epa.gov

11. What guidance does EPA rely on in making minor use determinations under the statute?

To make the determination, EPA reviews all available data, including the data provided in the petition and other data available to the Agency. EPA also consults with the United States Department of Agriculture, as required by the statute.

The Agency believes the statute is clear on what is required to be submitted and how to make a determination on the request. However, to provide further clarity on issues that have arisen through the petitioning process, EPA will provide more information on its EPA Pesticide Web site as necessary. See question 11. Below under **Information for Section 3(c) (1) (F) (ii)** for additional guidance.

Extending the Exclusive Use Period -Information for Section 3(c) (1) (F) (ii) of FIFRA:

1. Can extensions of exclusive use data protection be made for minor uses registered after 7 years of the commencement of the exclusive use period?

No. There are no provisions for providing extensions for minor uses registered after 7 years of the commencement of the exclusive use period and before the expiration of the exclusive use period (i.e., the time between 7 years and 1 day through expiration of the exclusive use period, which can be from year 10 to year 13 after the commencement of the exclusive use period).

2. If I submit minor use registrations at the same time I apply for registration of a new active ingredient, can I request an extension at the same time?

No. The petition for extension of exclusive use rights should not be made until the criteria outlined in FIFRA § 3(c) (1) (F) (ii) have been met, which includes the **registration** of the minor uses. If however, the registration of the minor uses for an active ingredient occurs at the same time as the initial registration of the chemical, the petition for extension of exclusive use rights can be made once a registration containing the qualifying minor uses has been granted.

3. Are FIFRA 24(c) uses eligible to be counted as minor uses?

No. FIFRA § 3(c) (1) (F) (ii) contains the requirements that the minor uses be "registered by the Administrator." Since 24(c) registrations are granted by a state and are not registered by the Administrator they do not count towards the number of minor uses necessary to extend the period of data exclusivity.

4. Can the request for an extension of exclusive use protection be made at any time after the initial submission including after the 7-year window?

A request can be made at any time prior to the expiration of the exclusive use period once the criteria outlined in FIFRA § 3(c) (1) (F) (ii) have been met, but the minor use must have been registered within the first 7 years of the commencement of the exclusive use period. EPA will not accept requests after the exclusive use period has expired. EPA prefers that the requests come in as soon as the registrant determines that it meets the criteria and not later than 6 months before the expiration of the exclusive use period.

5. If the exclusive use period ends while the Agency is reviewing the petition and an identical or substantially similar product application is submitted, will the Agency make a determination on the exclusive use before granting the identical or substantially similar registration?

Yes. EPA prefers that the request come in as soon as the registrant determines that it meets the criteria and not later than 6 months before the expiration of the exclusive use period.

6. How many of the four criteria identified in § 3(c) (1) (F) (ii) must be met for a minor use registration to qualify for Agency consideration towards extension of the exclusive use period?

Only one of the four following criteria must be met to qualify a minor use registration toward extension of the exclusive use data period:

1. There are insufficient efficacious alternative registered pesticides available for the use;
2. The alternatives to the minor use pesticide pose greater risks to the environment or human health;
3. The minor use pesticide plays or will play a significant part in managing pest resistance; **OR**
4. The minor use pesticide plays or will play a significant part in an integrated pest management program.

7. If a minor use registration that is eligible for extension has been determined to be a reduced-risk use by the Agency, will it automatically qualify for extension under criterion (II) "*the alternatives to the minor use pesticide pose greater risks to the environment or human health*;" of FIFRA § 3(c)(1)(F)(ii)?

The Agency believes that the reduced risk determination for a minor use may support a request for extension of the exclusive use period under criterion II. However, the reduced risk determination may be less relevant to criterion II if it was made a significant time before the request for extension is made.

Therefore, EPA requests that the submission for extension of exclusive use period be made within 2 years of the reduced risk determination which includes the use(s). If the PRIA due date for the submission is negotiated such that the registration decision occurs more than two years from the reduced risk determination, the exclusive use extension request should be made within 2 months of the registration decision which includes the use(s). The Agency believes that this represents a reasonable amount of time within which to submit the exclusive use extension request and still have the alternatives analysis that supported the reduced risk determination be applicable, and suggests that the request be submitted in this time frame.

The registrant needs to provide sufficient information to the Agency to determine that the reduced risk use meets the criterion. This information should include:

- References to the reduced risk submission, including MRID numbers if available;
- The Agency's reduced risk approval letter; and
- Any new information necessary to satisfy criterion II.
    - The applicant needs to indicate in the petition if there have been changes in the human health and ecological toxicity end points since the reduced risk status determination was made.

Once the information is provided, the Agency will determine if the risk assessment for the individual chemical has changed.

Please note that EPA determines reduced risk classification by specific crop or site. Information about reduced risk pesticides and be found on the EPA web site at (http://www2.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program).

8. Does the Agency only count the representative crops of a crop group for which data were submitted when determining the number of eligible minor uses in an application?

No. If the data for the representative crops in a crop grouping have been submitted and support establishment of the crop grouping, the Agency will count the non-representative minor crops within a crop grouping provided that they were registered within 7 years of the commencement of the initial exclusive use period for the active ingredient and the registrant is marketing the product for the minor crops. However, the non-representative minor crops must meet one of the four criteria identified in § 3(c) (1) (F)(ii) in order to be eligible to be considered for extension of exclusive use data protection. A detailed explanation and listing of crop group is in the Code of Federal Regulations 40 Parts 180.40 and 180.41 (http://www2.epa.gov/laws-regulations)

9. If an active ingredient is registered on a crop group where all of the representative crops are major crops, will credit be given toward the additional years of exclusive use data?

Minor crops within a crop grouping that has only major representative crops can be counted if the data for the major representative crops have been provided and support the establishment of the crop grouping. The minor uses must have been registered within 7 years of the commencement of the initial exclusive use period for the active ingredient and the registrant must be marketing the product for the minor crops. The minor crops must also meet one of the four criteria identified in § 3(c) (1) (F)(ii) in order to be eligible to be considered for extension of exclusive use data protection.

10. Is there a process for prioritizing applications for extending the years of data exclusivity?

It has not been necessary to prioritize applications to date.

11. What level of detail is required in the petition to satisfy any of the criteria in FIFRA § 3(c)(1)(F)(ii) to extend the exclusive use period?

The level of detail required will vary, depending on the situation and criterion being met. EPA needs enough information to make a determination for each use. Some suggestions and examples follow but the actual information provided will depend on the site and situation. Documentation does not need to be extensive and can include references to a statement in a Crop Profile, Pest Management Strategic Plan or extension publication. Only one of the criteria in FIFRA § 3(c) (1) (F) (ii) need to be met to qualify for extension. If a criterion is not satisfied in a petition, it can be resubmitted with additional information to meet it or one or more of the remaining criteria.

The alternatives to the pesticide use pose greater risks to the environment or human health:
If the Agency has already determined that the use is reduced-risk, through the reduced risk process (http://www2.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program), it is possible that the use will meet criterion II. See Question 7 above for details on how the Agency will evaluate reduced-risk minor uses for extension of data exclusivity. If the use is not reduced-risk but you can document that the alternatives pose greater risks to the environment or human health, it is likely that the use will meet criterion II.

There are insufficient efficacious alternative registered pesticides available for the use: The registrant must provide documentation that the pesticide is effective and that other pesticides registered are either not effective or otherwise provide inadequate control of the pest. FIFRA Section 18 Emergency Exemptions may provide useful information regarding insufficient efficacious alternatives for certain minor uses. It is helpful to document that the pest in question is actually of concern for crop production. This information is generally available in state extension crop recommendations, Crop Profiles or Pest Management Strategic Plans.

The minor use pesticide plays or will play a significant part in managing pest resistance: The registrant must submit documentation that the pest has developed or tends to develop resistance to pesticides and that the minor use pesticide is effective and offers a new mode of action that can be rotated with other pesticides to manage pest resistance. Websites such as the International Survey of Herbicide Resistant Weeds (http://www.weedscience.org/summary/home.aspx) and the Arthropod Pesticide Resistance Database (http://www.pesticideresistance.org/) provide pest resistance information. Consideration for meeting this criterion will be given if the label for the minor use follows the guidance from Pesticide Registration (PR) Notice 2001-5 *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling*.

The minor use pesticide plays or will play a significant part in an integrated pest management program. The registrant must demonstrate that the pesticide is or will be important in integrated pest management (IPM). For example, documentation that an insecticide is relatively safe for beneficial insects may support a finding that it plays a significant role in integrated pest management (IPM) programs. The documentation could also include a reference to a publication, such as a recent Crop Profile, Pest Management Strategic Plan or Cooperative Extension Service recommendation that states the pesticide is a tool in the IPM programs.

12. Will the Agency consider the justifications made to extend the exclusive use period for any of the four criteria specified in FIFRA § 3(c)(1)(F)(ii) based on the situation during the time when the new use is developed or when the petition is submitted to EPA?

The Agency will base its decisions on the conditions existing at the time the petition for the extension of exclusive use is made. However, the criteria outlined in FIFRA § 3(c) (1) (F) (ii) must be met at the time the petition for extension is made, based on any of the four statutory criteria. For reduced-risk-status minor use registrations, see Question 7 above.

13. What timeframe for review and decision is the Agency targeting for applications to extend the period of data exclusivity under FIFRA § 3(c) (1) (F) (ii)?

There is no statutorily defined review time for decision. The Agency aims to have reviews and determinations done within 6 months.

14. Do minor use registrations supported by IR-4 count toward the number of minor uses necessary to extend the period of data exclusivity?

Yes, if they meet one of the four criteria. However, only the data that the registrant generated to support the registration of a new active ingredient may receive the extension of the exclusive use period. Data generated by IR-4 do not receive exclusive use protection because they have been generated with government funds and therefore considered to be government-generated.

15. Will the Agency evaluate combination products that contain more than one active ingredient?

Yes, in the situation where at least one of the active ingredients has exclusive use data associated with its original individual registration. The Agency will count a minor use which is registered on the combination product if: (1) the minor use was registered within 7 years of the commencement of the initial exclusive use period for the individual active ingredient, and (2) the individual active ingredient can meet, on its own, one of the four criterion under FIFRA section 3(c) (1) (F) (ii). It is possible that a minor use registered on a combination product containing two active ingredients could be eligible for extension of data protection for only one of the active ingredients in the product. When submitting a petition that uses as support a combination product, the registrant must provide sufficient information to show that the individual active ingredient(s) meets one of the four criterions. Information on the combination product only will not be sufficient to meet the statutory requirements.

Establishing a New Exclusive Use Period - Information for Section 3(c) (1) (F) (VI) of FIFRA:

1. Does FIFRA § 3(c) (1) (F) (VI) also extend the exclusive use period?

No. FIFRA § 3(c)(1)(F)(vi) does not extend exclusive use; it provides a new 10-year period of exclusive use protection for the minor use-specific data generated by an applicant or registrant to register a minor use after the initial exclusive use period expires.

2. When should a request to the Agency for new exclusive use protection be made?

The request must be **made at the same time** that the application for adding the new minor use(s) is submitted. The request must indicate that to the best of the registrant's or applicant's knowledge, the exclusive use period has expired and that data submitted to support the minor use(s) are eligible for exclusive use protection.

3. Is a registrant limited on the number of minor uses for which the data can be accorded exclusive use treatment?

No. The limits that apply to extension of the exclusive use period (i.e., a maximum of 3 additional years of exclusive use data protection) § 3(c) (1) (F) (ii) do not apply to this section of FIFRA.

4. Must one of the four criteria identified in § 3(c) (1) (F) (ii) to extend exclusive use be met for a minor use registration to qualify for Agency consideration toward establishing a new exclusive use period, per § 3(c) (1) (F) (VI)?

No, however, the use site must meet the definition of a "minor use" as defined in FIFRA § 2(ll) as follows:

> 2(ll) MINOR USE.—The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where:
>
> 1. The total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; **or**
> 2. The Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, 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.

5. Does the Agency anticipate that the data submitted to establish a new data exclusive use period would generally extend beyond residue or metabolism studies?

Although the Agency does not anticipate it, the data needed to make a determination for exclusive use protection could extend beyond residue or metabolism studies. For instance, if the minor use were an aquatic crop, there is a possibility that some new ecological data might be needed to register the use.

6. If data solely relating to multiple minor uses are submitted can all such data receive exclusive use protection?

Yes, if an applicant or registrant generated the data and meet the regulatory definition of exclusive

use as well as the requirements under FIFRA section 3(c)(1)(F)(vi). However, if such data are subsequently used to support a non-minor use or the minor use is voluntarily canceled, the data will no longer have exclusive use protection.

7. What timeframe for review and decision is the Agency targeting for applications to establish a new period of data exclusivity under FIFRA § 3(c) (1) (F) (VI)?

See the Fee Determination Decision Tree [www.epa.gov/pesticides/fees/tool/decisiontree/] for information on the decision review time for this category – M008. However, since the request for data exclusivity must be made at the same time that the application for adding the new minor use(s) is submitted and the granting of the data exclusivity will be based on the final determination regarding the registration of the new use, the decision timeframe will need to be linked to the review time for the additional minor use registration action. This timeframe can range from 10 to 15 months.

8. Will the Agency establish a new data exclusive use period for data generated by IR-4?

No. The Agency will only provide a new exclusive use period for minor use data that satisfy the regulatory definition of exclusive use data. IR-4 data are considered to be government-generated. The exclusive use status of a government-generated study is defined in 40 C.F.R. § 152.94 as follows:

(b) In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA section 3(c)(1)(F).
