**Pesticide Registration Manual:**

# Chapter 10 - Data Compensation Requirements

# Introduction

This chapter describes the information that an applicant must submit with the application for registration, amended registration, reregistration or registration review to comply with the provisions of FIFRA section 3(c)(1)(F). This chapter also describes the procedures by which data submitters may challenge registration actions that allegedly failed to comply with these procedures. Addressing data compensation obligations is a critical part of the registration and reregistration processes. If the Agency determines that an applicant has failed to comply with the requirements in FIFRA and its implementing regulations, the application may be denied or a registration previously issued may be canceled.

# FIFRA Provisions Relating to Data Compensation Obligations

A substantial amount of scientific data and information are required to support the registration of a pesticide. These data and information can be very costly to the data submitter. To protect the interests of data submitters, Congress included provisions in FIFRA that provide data submitters certain rights to the data they submit to EPA. In particular, FIFRA section 3(c)(1)(F) provides for both "exclusive-use" and compensation rights in data submitted to EPA to support registration actions.

"Exclusive-use" treatment for data means that the data may not be relied upon by other applicants or registrants to support FIFRA registration and reregistration actions without the permission of the data submitter. As a general matter, exclusive-use protections apply to those data that are submitted to support the initial registration of a product containing a new active ingredient. A 10-year period of protection for such data begins from the date of the original registration of the pesticide. This 10-year period of protection also extends to data submitted solely to support the addition of any new use to that registration during the 10-year period (note that such new use data are entitled to exclusive-use treatment only for the balance of the 10-year period remaining following addition of the new use to the registration).

While exclusive-use rights apply to data submitted to EPA in support of the first registration of a pesticide, "compensation" rights extend to all data necessary to support or maintain a registration or that are necessary to support of an experimental use permit. Applicants and registrants may not rely on data that retain compensation rights to support registration or reregistration unless they have first offered the data submitter compensation for the use of such data. Section 3(c)(1)(F) provides for a 15-year period of protection for such data

following the date of submission of that data to the Agency. There is a more detailed discussion below describing how the Agency protects data rights.

# Expansion of Exclusive-Use Rights by FQPA

The Food Quality Protection Act (FQPA) of 1996 amended the data protection rights section of FIFRA by expanding exclusive-use rights. Under FIFRA section 3(c)(1)(F)(ii), the Agency may extend the 10-year period of exclusivity for a period of up to three years by the addition of new minor uses to the original registration (three minor uses required for each additional year of exclusive-use protection). The new minor uses must have been **registered** within seven years of the date the original registration was granted to qualify and they must also meet at least one of the statutory criteria (e.g., there are insufficient efficacious alternatives registered).

It is the registrants' responsibility to request the extension. Registrants must also provide information to the Agency explaining how they meet the applicable statutory criteria in order for EPA to determine whether the registration is entitled to the extension of exclusive-use protection rights. Read more about expanding exclusive-use rights.

FQPA also amended the FIFRA data protection provisions by adding section 3(c)(1)(F)(vi) that provides the Agency with the authority to afford exclusive-use protection to data submitted by an applicant, or by a registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use. The data associated with the new minor use are entitled to 10 years of exclusive-use protection from the date the data are submitted if the data relate solely to a new minor use. In order to obtain the exclusive-use protection, the applicant or registrant **must at the time the new use is requested** notify the Agency that to the best of its knowledge the exclusive-use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide are eligible for the protection under this section of FIFRA.

**Important Notes**: The registrant or applicant must request the exclusive-use protection of section 3(c)(1)(F)(vi) at the time they request the amendment for the new minor use.

Under 3(c)(1)(F)(ii), as appropriate, EPA shall modify or terminate the exclusive-use period if the registrant voluntarily cancels the product or deletes from the registration the minor uses that formed the basis for the extension of exclusive use, or if EPA determines that the registrant is not actually marketing the product for such minor uses.

# Complying with Data Compensation Procedures

As stated in 40 CFR 152.81(a), data compensation procedures apply to each application for:

- registration of a new product;
- amendment to add a new use to an existing product registration; and
- reregistration and registration review of an existing product.

However, (a) is limited by 40 CFR 152.81(b) in that data compensation procedures ***do not*** apply to the following types of applications:

- applications for registration submitted by states under FIFRA section 24(c);
- applications for experimental use permits under FIFRA section 5;
- applications for emergency exemptions under FIFRA section 18; and
- applications to make only one or more of the following types of amendments to existing registrations, unless the consideration of scientific data would be necessary in order to approve the amendment under FIFRA section 3(c)(5) per 40 CFR 152.81(b)(4)
    - an increase or decrease in the percentage in the product of one or more of its active ingredients or deliberately added inert ingredients;
    - a revision of the identity or amount of impurities present in the product;
    - the addition or deletion of one or more deliberately added inert ingredients;
    - the deletion of one or more active ingredients;
    - a change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under FIFRA section 3;
    - deletion of approved uses of claims;
    - redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;
    - change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the changes;
    - clarification of directions for use;
    - correction of typographical errors;
    - changes in the registrant's name or address;
    - adding or deleting supplemental registrants;

- changes in the package or container size;
- changes in warranty, warranty disclaimer, or liability limitation statements, or addition to or deletion of such statements;
- "splitting" a label for the sole purpose of facilitating the marketing of a product in different geographic regions with appropriate labels, where each amended label will contain previously approved use instructions (and related label statements) appropriate to a particular geographic region;
- any other type of amendment, if the Administrator or his designee determines, by written finding, that the Agency consideration of scientific data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5); and
- compliance with Agency Regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or cancelled, or that a hearing will be held under FIFRA section 6. (However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.)

## Methods for Complying with the Data Compensation Requirements of FIFRA Section 3(c)(1)(F)

In order for the Agency to evaluate an application for registration or to amend a registered product, the applicant generally must either submit its own data or cite to data previously submitted by it or others that cover the required data to support the application or amendment. 40 CFR 152.80-99 and 152.116-119 provide detailed information on how to comply with the data compensation provisions of FIFRA section 3(c)(1)(F).

The methods for complying with data requirements may be addressed in one of two ways and are discussed in detail in this chapter:

- **Cite-All:** The applicant cites to all the data in the Agency files that are pertinent to EPA's consideration of the requested registration action. See 40 CFR 152.86.
- **Selective Method**: The applicant lists the specific data requirements that apply to its product, its active ingredients, and use patterns and then selectively cites to individual studies, including the applicant's own data. The selective method also allows an applicant to "cite all" data in the Agency's files to satisfy specific data requirements (commonly referred to as "selective cite-all"). See 40 CFR 152.90(b)(5).

## Categories of Data

FIFRA section 3(c)(1)(F) establishes three categories of data and the regulations and legislative history provide further information on each:

- **Exclusive-Use Data**. Under FIFRA section 3(c)(1)(F)(i), data submitted to the Agency in support of the initial registration of a new active ingredient, a new combination of active ingredients, or in support of an application to amend the original registration to add a new use have "exclusive-use" protection for a period of 10 years after the date of the initial registration. The Agency cannot consider these data in support of an application for registration or amendment to a registration unless written authorization from the original data submitter is obtained authorizing the Agency to use these data to support the application. After the "exclusive" use period has expired, the owner of the data may still be entitled to compensation as described below. See 40 CFR 152.83(c) and 40 CFR 152.116.

As described above, FIFRA sections 3(c)(1)(F)(ii) and (vi) provide for extensions of the 10-year period and establish exclusive-use protection for certain minor use data where the data no longer retain exclusive-use protection, respectively.

- **Compensable Data**. The Agency may, without the permission of the original data submitter, consider data that: (1) no longer retains exclusive-use protection, (2) were submitted to support an application, and (3) are within the 15-year compensatory period (period begins on the date the data were originally submitted to EPA), as long as the applicant/registrant relying on these data has certified to the Agency that it has offered to pay compensation to the original data submitter(s). In addition, the applicant must provide a notification to the registrants who own the data being relied upon of its intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients.
- **All Other Data**. Data not falling into the first two categories (e.g., public literature articles, government-generated studies, and data for which all periods of exclusive use and compensation have expired) may be cited by an applicant without permission or an offer of compensation. However, the applicant or registrant is still required to submit a data compensation certification form. See 40 CFR 152.94.

* Note that when a study is developed jointly with government and private resources, the private component may be compensable under certain circumstances. For further information, see Question and Answer 13 below.

## When Materials Must Be Submitted to the Agency

Information and materials required to demonstrate compliance with data compensation procedures must be submitted at the time of application (40 CFR 152.84), unless it is determined that data compensation procedures do not apply to the application 40 CFR 152.81(b).

## The Cite-All Method of Support

Applicants may comply with the data compensation requirements under the cite-all method (40 CFR 152.86 and 40 CFR 152.95) for an application to register a new product or to amend or reregister a product by:

- citing all pertinent data in the Agency's files and making appropriate offers to pay compensation. If exclusive-use data are being used, written permission from the original data submitter is required.

**Information to be submitted if an applicant chooses the cite-all method of support***:*

- Certification with Respect to Citation of Data (EPA Form 8570-34)

  Except for applications for amendments that require no supporting data, applicants must complete this form to indicate how they will meet their data submission/data citation obligations under FIFRA. When a registrant relies on another company's data, it generally must certify that an offer of compensation has been made to the original data submitter or that it has the original data submitter's permission to cite the data. For further information on how to comply with data compensation requirements see FIFRA section 3(c)(1)(F), 40 CFR 152, Subpart E and the PRIA Web page.

  - Check the first box in section I, indicating the cite-all method of support; and
  - Check the box in section II indicating a general offer to pay compensation to other data submitters to the extent required by FIFRA section 3(c)(1)(F).

- Data Matrix (EPA Form 8570-35)

  Applicants/registrants must include with the data certification form a completed list of companies sent offers of compensation. Data Matrix (EPA Form 8570-35) should be used for this purpose.

  When submitting a Certification with Respect to Citation of Data (EPA Form 8570-34) under the cite-all method, the data matrix should indicate the companies to whom offers of compensation were made.

  There are two different copies of Form 8570-35: the "Public File Copy" and the "Agency Internal Use Copy." The Agency Internal Use Copy is normally retained for Agency use but is available by request under the Freedom of Information Act (FOIA). The Public File Copy will not contain the guideline reference number, the guideline study name, and the MRID number but will indicate the submitter and status of the data. (MRID numbers are not confidential.) This version of the data matrix will be available for public inspection along with Form 8570-34 once a product is registered.

  **Important Note:** The data tables and bibliography in an applicable Registration Standard and/or Reregistration Eligibility Document can be very helpful in developing a data matrix.

## The Selective Method of Support

Applicants may comply with the data compensation requirements under the selective method by listing the specific data requirements that apply to their product (its active ingredients and/or use patterns) and by demonstrating compliance with the data requirements by either submitting the actual studies, citing individual studies, or by demonstrating that no study has been previously submitted to the Agency (a data gap). The selective method also allows an applicant to "cite all" data in the Agency's files to satisfy specific data requirements. This is known as the "cite-all" option under the selective method. Please refer to 40 CFR 152.90 for a detailed discussion of the selective method.

**Important Note**:The Data Gap option is not available to certain applicants, i.e., those seeking the registration of a product containing a new active ingredient or those seeking to add a new use pattern to a registered product. Please refer to 40 CFR 152.96 for additional information on documentation of a data gap.

- Certification with Respect to Citation of Data (EPA Form 8570-34)

  Except for applications for amendments that require no supporting data, applicants must complete this form to indicate how they will meet their data submission/data citation obligations under FIFRA. When a registrant relies on another company's

data, it generally must certify that an offer of compensation has been made to the original data submitter or that it has the original data submitter's permission to cite the data. For further information on how to comply with data compensation requirements see FIFRA section 3(c)(1)(F) and 40 CFR 152, Subpart E and the PRIA Web page.

    - Check the second box in section I, indicating the selective method of support.
    - Check the box in section II indicating a general offer to pay compensation to other data submitters to the extent required by FIFRA section 3(c)(1)(F) if using the cite-all option under the selective method of support.
- Data Matrix (EPA Form 8570-35)

  Include with this form a completed list of data requirements. Data Matrix (EPA Form 8570-35) must be used for this purpose. See PR Notice 98-5.

## Access to Data Matrices in the Pesticide Product and Label System

Effective April 2021, EPA has modified the Pesticide Product and Label System (PPLS) to display Certification with Respect to Citation of Data (EPA Form 8570-34) and Data Matrix (EPA Form 8570-35) forms.

Forms submitted on or after April 19, 2021 will be available in PPLS.

EPA will ensure the most up-to-date data matrix is available in PPLS by always uploading the final data matrix affiliated with the pesticide product being registered along with the product label. EPA will not post any non-final or draft versions of data matrices in PPLS. Earlier data matrices are available as part of the registration file.

Data matrices updated for reasons other than product changes, such as use changes, require a new label and a new data matrix. EPA will post the final data matrix in PPLS when the new label is posted.

No data matrices are sent in with a response to a Generic Data Call In (GDCI).

Data matrices submitted to EPA prior to April 2021 are not currently available in PPLS and can be obtained by submitting a Freedom of Information Act request.

# Data Compensation Charges/Payment Disputes

FIFRA sections 3(c)(1)(F)(iii) and 3(c)(2)(B)(iii) state that the terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant or, failing such agreement, by binding arbitration under the procedure and rules of the Mediation and Conciliation Service. EPA is not involved with such disputes or the procedures for arbitration. The arbitrator is to be appointed from the roster of arbitrators maintained by such Service.

The findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. Please refer to 29 CFR Part 1440 for details on the arbitration procedures.

## Petitions to Cancel Registration

40 CFR 152.99 describes the procedures by which data submitters may challenge registration actions that allegedly failed to comply with FIFRA section 3(c)(1)(F).

**Grounds for petition.**

If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration for any of the following reasons 40 CFR 152.99(a)(1):

1. the applicant failed to reach an agreement on the amount and terms of compensation;
2. the applicant failed to comply with the terms of an agreement on compensation;
3. the applicant failed to participate in an arbitration proceeding; or
4. the applicant failed to comply with the terms of an arbitration decision.

When no offer to pay has been made, grounds for challenge include but are not limited to the following 40 CFR 152.99(a)(2):

1. the applicant has failed to list a data requirement applicable to its product, or has failed to demonstrate compliance with all applicable data requirements;
2. the applicant has submitted or cited a study that is not valid;
3. the applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited;
4. the applicant has failed to comply with the procedure for showing that a data gap exists;
5. the applicant has improperly certified that a data gap exists (An original data submitter who has failed without good cause to respond to an applicant's request for confirmation of a data gap may not petition the Agency for review on this basis.); or
6. the applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

**Timing of Petition** 40 CFR 152.99(b)

A petition under paragraph (a)(1) above may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) above must be filed within one year after the Agency makes public the issuance of the registration.

# Questions and Answers

The following questions reflect those most frequently asked inquiries regarding data compensation procedures:

**1. What data compensation information does the Agency require for a product or an amendment under the Cite-All Method of Support?**

The Agency requires a completed and signed Certification With Respect to Citation of Data (EPA Form 8570-34) including a completed list of companies sent offers of compensation. Data Matrix (EPA Form 8570-35) should be used for this purpose. The PRIA Web page provides information on the contents of an application. Information on exclusive use and data rights extensions can be found on the minor use Web page.

**2. What are the data compensation requirements when submitting an application for an amendment to the registration of a product, when the Selective Method of Support is selected?**

If an applicant wishes to use the Selective Method of Support, the Agency requires a completed and signed Certification With Respect to Citation of Data (EPA Form 8570-34 (PDF)) and a Data Matrix (EPA Form 8570-35 (PDF)) with appropriate information showing how each data requirement is to be satisfied for the amendment, taking into consideration the most up-to-date information, i.e., the data tables and bibliography in the most recent Registration Standard or Reregistration Eligibility Document (if any) and the data requirements in 40 CFR Part 158 and for antimicrobials, 40 CFR 161. The PRIA Web page provides information on the contents of an application.

If a data matrix previously submitted in support of the product's initial registration or amendment is still valid, and no additional data are required, an applicant may reference that data matrix in support of its current applications for amended registration. If additional data are required to support their current amendment requests, then an updated data matrix must be submitted.

**3. Does an applicant requesting a registration for 100% repackaging of a registered technical grade, manufacturing-use or end-use product qualify for a formulators' exemption?**

Yes, within the limits prescribed in 3(c)(2)(D) and 40 CFR 152.85. Other than the formulators' exemption form, no other data compensation form needs to be submitted to EPA. Under 40 CFR 152.116, if the registered product to be repackaged has exclusive-use data associated with it, OPP will send a Notice of Intent to register the product to the original data submitter(s).

**4. When submitting an application for an amendment to the registration of a product, and data are required to support the proposed amendment, does an applicant have to once again offer to pay compensation for all of the data necessary to support the amendment?**

Yes. The entire product is subject to the data compensation provisions, including any amendment. There are several reasons for this requirement:

- either generic data or product-specific data may have been submitted to the Agency to fill data gaps since the first offer to pay compensation was made with the initial application for registration or amendment; and
- some of the data initially used to support the registration may have been determined to be unacceptable and may have been replaced. As a result, if additional data are required to support the proposed amendment to the registration,

the entire product including the proposed amendment is subject to the data compensation requirements of section 3(c)(1)(F) of FIFRA.

**5. If an applicant obtains a letter from a company on the Data Submitters List indicating that the company does not want any compensation for its data, may the applicant use this letter to demonstrate that the company has granted permission to use its data? What is necessary to comply with the permission required for the use of exclusive-use data?**

The contents of a letter of authorization are described in 40 CFR 152.93(b)(1). Only in the case of exclusive use is explicit permission required. Otherwise, if the applicant goes through the proper data compensation procedures, permission from the data submitter is not required.

**6. If an applicant has a letter from a data submitter in its files granting the applicant permission to use the data submitter's data, can the applicant use the letter to support its application without getting new authorization to use the same data?**

EPA will allow an applicant to use such a letter to certify that it has received written permission from the data submitter to cite its data, provided the letter of authorization is sufficiently clear that it extends to the use of the data to support the action in question.

The Agency will honor the terms and conditions of an original letter of authorization to cite data and will not accept a letter withdrawing that authorization unless both the original data submitter and the applicant relying on the data submitter's data agree that such authorization has been withdrawn.

**7. If an applicant has a product that contains multiple active ingredients, some of which are purchased from registered sources and others that are not, can they claim a formulators' exemption for those active ingredients that are purchased from a registered source?**

Yes, within the limits prescribed in 3(c)(2)(D) and 40 CFR 152.85, EPA will allow the formulators' exemption for the registered active ingredients if the use patterns on the applicant's label are supported by the applicant's registered source. Applicants should submit a properly completed Formulator's Exemption Statement (EPA Form 8570-27).

**8. If the Cite-All Method of Support is used, does t he applicant also have to submit a list of data requirements and references?**

The cite-all method does not require an accompanying list of data requirements such as that required for the selective method; however, the Data Matrix (EPA Form 8570-35) must be submitted under the cite-all method to indicate the companies to whom offers of compensation were made.

**9. What is the specific timeframe by which a data submitter must respond to an applicant's offer to pay for data compensation, and if a data submitter does not respond, is the applicant still liable to pay for data compensation?**

FIFRA and the regulations in 40 CFR Part 152, Subpart D do not require a data submitter to respond to offers within a specific timeframe to preserve data compensation rights. A data submitter may seek compensation at any time. Generally, the offer is made and negotiation commences shortly thereafter concerning the amount of compensation and the timing of payment.

**10. If an applicant writes to a company on the Data Submitters' List via certified mail and the letter is returned with an indication that the data submitter's company cannot be located, what else is required to find the company?**

If the applicant has obtained a certified or registered mail statement that there is no known address for the data submitter's company, then the applicant has made a reasonable effort to notify that company. Of course, the applicant may pursue the matter further if so desired. Under these circumstances, the applicant should indicate in the application the actions undertaken to locate the data submitter. This documentation would be especially useful should a data submitter wish to challenge a registration in the future based on the applicant's failure to make an offer of compensation.

**11. If eligible for the formulators' exemption, does an applicant have to submit anything else in addition to the Formulator's Exemption Statement (EPA Form 8570- 27) and the Confidential Statement of Formula (EPA Form 8570-4)?**

Unless the product is a 100% repack, i.e., the registered product purchased from another producer has only been repackaged or placed in a different container with no changes to the formulation, an applicant must submit information required for either the Selective or the Cite All Method of Support in addition to submitting the Formulator's Exemption Statement and Confidential Statement of Formula.

**12. Do applicants have to get permission from, or make an offer to pay, the person whose study appears in the public literature in order to cite that literature?**

No, there is no such requirement. Under 40 CFR 152.94(b), submission of a public literature study or government-generated study does not confer any rights on the data submitter to exclusive use of data or compensation.

**13. If a study is jointly developed with government and private funds, are there circumstances when the private component may be subject to data compensation?**

Yes. Provided the data are submitted by an applicant or registrant to support or maintain the registration of a pesticide, the private portion of the data development effort is subject to compensation, even when there may have been some measure of government involvement in the generation or funding of the data. EPA expects that the data submitter and the follow-on applicant will, through negotiation (or arbitration, should negotiations fail), determine the portion of the data development activity that was supported by private funds and therefore subject to compensation. It is important to note, however, that when EPA receives data directly from a government agency rather than from an applicant or registrant, it will presume these data to be entirely government-generated data under 40 CFR 152.94(b), and therefore "public literature" within the meaning of FIFRA section 3(c)(1)(F) that may be freely cited. Thus if applicants wish to receive compensation for data that may have been jointly developed with a government agency, the data must be submitted to EPA by the applicant or registrant.

While compensation rights may apply to government-generated studies, exclusive use rights do not extend to these studies. EPA believes it would be inconsistent with the intent of Congress in enacting FIFRA to provide exclusive use treatment for data that have been generated or funded to some extent by the government. Since exclusive use rights, unlike compensation rights, are not segregable, rewarding such data with exclusive use treatment would be contrary to the direction in FIFRA that allows public literature to be cited freely.

# Contacts for Additional Information

For assistance concerning the data compensation procedures, please contact the appropriate Branch for your pesticide product. Refer to Chapter 21.

# References Cited in Chapter 10

Refer to Chapter 19 for information on the sources of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide registration and classification procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 158 - Data Requirements for Registration
- Part 161 - Data Requirements for Registration of Antimicrobial Pesticides

Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act of August 3, 1996

- Section 3(c)(1)(F)
- Section 3(c)(2)(B)
- Section 3(c)(5)
- Section 3(c)(7)

PR Notices

- PR Notice 94-1 Withdrawal of PR Notice 91-8
- PR Notice 98-5 New forms for the Certification with Respect to Citation of Data

Data Submitters List