Pesticide Registration Manual:

Chapter 6 - Amending a Registered Pesticide Product

Amending a Registered Pesticide Product

Almost all modifications to the composition, labeling, or packaging of a registered product must be submitted to EPA with an application for amended registration (EPA Form 8570-1, Application for Pesticide Registration/Amendment).

Applications for amended registration must contain the information required by 40 CFR 152.50, as applicable to the change requested. While not all changes to current registrations require an application for amendment, if an application for amended registration is required, the application must be approved by the Agency before the modified product may be legally distributed or sold.

Amendments for certain minor changes may qualify as a "notification," which does not require approval before sale or distribution. These amendments are discussed in Chapter 7. General guidance for notifications is PR Notice 98-10.

Amendment Toolkit

Documents Necessary for Amendments Requiring an Application

Generally, one or more of the following items may be required when submitting an amendment to a product registration for EPA approval:

- EPA Form 8570-1, **Application For Pesticide/Amendment** (with the box checked [X] for Amendment);
- EPA Form 8570-34, **Certification with Respect to Citation of Data** (if applicable);
- EPA Form 8570-35, **Data Matrix** (if data are required);
- EPA Form 8570-4, **Confidential Statement of Formula** (if applicable);
- EPA Form 8570-27, **Formulator's Exemption Statement** (if applicable);
- Child-resistant packaging certification (if applicable);
- Submission of supporting data (if applicable); and
- Five copies of draft labeling (if applicable). Submitting labels electronically is highly encouraged. Submit a text PDF copy on a CD and a Certification with Respect to Label Integrity certifying that the text PDF copy is the same as the paper copy.

Amendments Requiring No Scientific Review of Data (Fast Track)

Fast track amendments include labeling changes or basic or alternate product formulation changes that do not require supporting data. Fast track amendments are also not subject to PRIA fees (for further information on PRIA fees, see Chapter 5).

If an amendment requests a change to a product that is "substantially similar" or "identical" to another product or "differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment" from another product, the similar or identical product and its applicable data may be cited instead of submitting required product-specific data. This amendment, now described as an "identical/substantially similar amendment," was formerly called a "**me-too" amendment**. Each applicant applying for an "identical/substantially similar" amendment must comply with the data compensation procedures as discussed in FIFRA section 3(c)(1)(F). A discussion of these requirements and the applicable forms are in Chapter 10 of this manual.

Fast track amendments require the following documentation:

Labeling Change

These amendments require an **Application for Pesticide Registration/Amendment** (EPA Form 8570-1), and five copies of the proposed labeling. Labeling changes must comply with current regulations, policies, and format. Please refer to the Label Review Manual for details regarding labeling changes. In addition, to facilitate processing, registrants are highly encouraged to submit their proposed label on a CD as a text PDF file with a Certification with Respect to Label Integrity.

Formula Change

Basic and alternate formula changes may be accomplished by amending a current registration only when the new formulation remains substantially similar to the original formula. See 40 CFR 152.43. **An Application for Pesticide Registration/Amendment** (EPA Form 8570-1, with the box checked [X] for Amendment); the **Confidential Statement of Formula** (EPA Form 8570-4); and **Formulator's Exemption Statement** (if applicable) (EPA Form 8570-27) are required when a revision to the basic formulation or an alternate formula is requested. Five copies of draft labeling are required if the revision to the formula results in a change in the ingredient statement on the label and in addition, registrants are highly encouraged

to submit their proposed label on a CD as a text PDF file with a Certification with Respect to Label Integrity.

Important Note: Some revisions to the formulation of pesticide products that control pests of public health significance may not be made through a fast track amendment. Such products (e.g., products to control pathogenic bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats, and mice), may require the submission of efficacy data to support the revised formulation.

Amendments Requiring Product-Specific Data

When a product is initially submitted for registration, data specific to the product are required to be submitted or cited (Chapter 2).

If an amendment proposes to change a product's claims, precautions, or use directions such that the product or its labeling is substantially changed, then additional product-specific data may be required (e.g., acute toxicity, product chemistry, or efficacy) in some cases. Such amendments with product-specific data will require submission of an administrative package and a data package. Data previously submitted with another application may be cited instead. Any amendments that require data review are subject to PRIA fees (Chapter 5).

Important Note: The discussion provided below concerning the information to be submitted with a data-supported amendment is general in nature and does not cover all possible types of amendments. Questions about the type of information to be submitted with the application should be addressed to the appropriate Product Branch or Divisional Ombudsman.

Administrative Portion of the Registration Amendment Package

The administrative portion of a registration amendment package includes the following:

- EPA Form 8570-1, **Application for Pesticide Registration/Amendment** (with box checked [X] for Amendment);
- For an "identical/substantially similar" amendment, a statement identifying the currently registered product that is "substantially similar" or "identical" or "differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment" by its EPA Registration Number and product name, and a description of the labeled change being proposed for the product;

- EPA Form 8570-4, **Confidential Statement of Formula**, if proposing a change in the formulation;
- EPA Form 8570-27, **Formulator's Exemption Statement**, if applicable;
- Five copies of the proposed draft labeling (Agency review is faster if the changes in the proposed labeling are:

    1. highlighted in a way that can be photocopied; or
    2. computer edited, with italics, shading, and strike-out; or
    3. hand marked on one copy; if a text PDF copy is submitted with a Certification with Respect to Label Integrity, the electronic label should not be marked up. The Agency will electronically compare the submitted label with the existing label to identify the proposed changes.

- EPA Form 8570-34, **Certification with Respect to Citation of Data**; and
- EPA form 8570-35, **Data Matrix**. The data required to support the application may be addressed by either submitting the actual data or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix.

Data Portion of Registration Amendment Requiring Product-Specific Data

The data portion of a registration amendment that requires product-specific data may include the following items, as applicable (refer to 40 CFR 158 for data requirements and test guidelines for pesticides and toxic substances for testing protocols):

- Acute toxicity data (40 CFR 161.340, 40 CFR 158.500, 40 CFR 158.2050, and 40 CFR 158.2140); especially if a change is proposed in the precautionary labeling or the signal word for the product, and if no previously submitted data can be cited or referenced;
- Product chemistry data 40 CFR 161.150-190, 40 CFR 158.300-355, 40 CFR 158.2030, and 40 CFR 158.2120 if the basic or alternate formulas are being changed substantially; and
- Efficacy (product performance) data 40 CFR 161.640, 40 CFR 158.400, 40 CFR 158.2070, and 40 CFR 158.2160 if proposing to add a new pest of public health significance, e.g., products to control pathogenic bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats, and mice. Changes to the basic product formulation may also require additional efficacy data.

Please note that efficacy data for nonpublic-health uses must be conducted and maintained on file by the registrant, although they are not generally required to be submitted for review.

Important Note: When submitting data, three copies are required, properly bound and formatted in accordance with PR Notice 86-5. The Agency will at some point revise PR Notice 86-5 to reflect changes in process as a result of electronic submission. Applicants are advised to periodically consult the Agency's pesticides website or the Agency's registration ombudsman for the latest guidance. Refer to Chapter 15 for additional information on submitting data.

Amendments Requiring Generic Data ("New Uses")

An amendment that proposes to add a "new use" (i.e., a crop or site that is not currently registered for any product containing a particular active ingredient) must be supported by new data. Examples would be a new crop or animal feed use, or a change in use pattern from indoor to outdoor use. New uses are defined in 40 CFR 152.3. Supporting data for a new active ingredient and a new use are called generic data because they support the registration of the active ingredient rather than a specific product. Applications to amend a registration to add a new use contain an administrative portion and a data portion.

Important Note: The discussion provided below concerning the information to be submitted with a new use amendment is general in nature and does not cover all possible types of new use amendments. Any questions concerning what information should be submitted with an application should be directed to the appropriate Product Branch for the product in the Antimicrobials Division, Biopesticides and Pollution Prevention Division or Registration Division (chemical pesticides).

Administrative Portion of the New Uses Amendment Package

The administrative portion of amendment applications includes the following:

- EPA Form 8570-1, **Application for Pesticide Registration/Amendment** (with the box checked [X] for Amendment);

- Five copies of the proposed draft labeling. (In addition, applicants should submit one label clearly marked to show the addition(s), deletion(s), or change(s) proposed for the amended labeling. This marked up label can be done on a copy of the proposed label or on the label that was previously registered.
- EPA's review is faster if the changes in the proposed labeling are:

    1. highlighted in a way that can be photocopied;
    2. computer edited with italics, shading, and strike-out; or

3. hand marked; if a text PDF copy is submitted with a Certification with Respect to Label Integrity, the electronic label should not be marked up.

- EPA Form 8570-34, **Certification with Respect to Citation of Data**;
- EPA Form 8570-27, **Formulator's Exemption Statement** (if applicable); and
- EPA Form 8570-35, **Data Matrix**. The data required to support the application may be addressed by either submitting the actual data or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

Data Portion of the Amendment Package

Applicants should refer to 40 CFR Part 158, and Test Guidelines for Pesticides and Toxic Substances to determine what data are required to support a new use. Applicants may be required to submit data on both the technical grade of the active ingredient and on the formulated product.

- In addition, new food or feed uses will require a petition for a tolerance or an exemption from the requirement of a tolerance. Please refer to Chapter 11 for a discussion on Tolerance Petitions.

Review of Identical/Substantially Similar and Fast Track Amendments

Section 3(c)(3)(B)(ii) of FIFRA requires EPA to expedite (fast track) the review of certain applications including amendments of a registered product for which scientific review of the data is not required. This section deals with fast track amendments that require no scientific data review by the Agency.

For these amendments, EPA is required to:

- determine within 21 days of receipt whether or not the application contains all of the necessary forms and labeling formatted in accordance with guidance published by the Agency and, if determined that contents are missing, to reject the application;
- notify the applicant within 90 days after receiving a complete application whether the application has been granted or denied; and
- notify the applicant in writing of the specific reasons if the application is denied.

Applications That Qualify for Expedited Review

Applications for amended registration that do not need scientific review qualify for expedited registration under FIFRA section 3(c)(3)(B)(ii). This includes any labeling or formulation change that is not significant (i.e., does not significantly increase risk) and for which either no data or minimal (i.e., confirmatory product chemistry, acute toxicity, or efficacy) data are submitted (for example, one or two acute toxicity bridging studies).

Applications That Do Not Qualify for Expedited Review

EPA will not expedite applications to amend the registration of products for which the proposed formulation or labeling varies significantly from that of currently registered products. Applications will not be expedited if the proposed amendments:

- change the product so that it is not "substantially similar" or "identical" to another EPA registered product, or
- substantially change the same product, or
- require review of scientific data.

Active Ingredients from Unregistered Sources

EPA will not expedite applications to amend the registration of products proposing unregistered source(s) of the active ingredient because extensive product chemistry and often toxicology data are required for these types of amendments. These data are more complex and require more time to review than the data associated with the administrative applications for an amended registration described above. These applications are subject to PRIA and have an associated fee.

Deletion of Use Patterns or Use Sites

EPA will not expedite applications to amend the labeling of a registered product to delete use patterns and sites of use. Amendments for use deletions must be accompanied by a request for voluntary cancellation as described in section 6(f) of FIFRA. FIFRA requires the Agency to publish 6(f) requests in the *Federal Register* and provide an opportunity for public comment on the requested use deletion before EPA may act upon such a request. Read about the voluntary cancellation process.

How to Submit an Amendment Application for Expedited Review

When submitting an application for amended registration to qualify for expedited "fast track" review, the word "**EXPEDITE**" (typed or printed) should appear at the top of the Application for **Pesticide Registration/Amendment** ((EPA Form 8570-1) with the box checked [X] for Amendment) to facilitate identifying the application for expedited review.

If the application is a submission of additional information in response to an objection letter from EPA, the word "**EXPEDITE-RESUBMISSION**" (typed or printed) should appear at the top of the **Application for Pesticide Registration/Amendment** (EPA Form 8570-1) with the box checked [X] for Amendment) and must include a copy of EPA's objection letter to allow the Agency to efficiently process the application.

Important Note: For an explanation of the review process and procedures for processing applications, refer to Chapter 2.

Final Printed Labeling

After acceptance of a new product registration, labeling amendment, or labeling notification, final printed labeling must be submitted before the product is sold or distributed. See 40 CFR 156.10(a)(6). Two copies of the final printed labeling that incorporate any labeling changes required by the acceptance letter and/or notification must be submitted.

Contacts for Additional Information

Any questions or need for additional information regarding label amendments should be directed to the appropriate Product Manager/Team Leader assigned the product in question. Refer to Chapter 21 for a listing of Product Branches. Please contact the Product Manager if there are questions concerning the status of identical/substantially similar or "me too" product applications.

References Cited in Chapter 6

Refer to Chapter 19 for information on the source 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 157 - Packaging Requirements for Pesticide and Devices
- Part 158 - Data Requirements for Registration
- Part 158W - Data Requirements for Antimicrobial Pesticides
- Part 180W – Tolerances and Exemptions from Tolerances for Pesticdie Chemicals in Foods

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

- Section 2 - Definitions
- Section 3 - Registration of pesticides
- Section 6 - Administrative review; suspensions
- Section 12 - Unlawful Acts

Pesticide Registration Notices Web Site

Label Review Manual