Pesticide Registration Manual:

Chapter 2 - Registering a Pesticide Product

Registering a Pesticide Product

This chapter discusses what information must be submitted to the Agency when applying for a pesticide product registration. The chapter also outlines how the process for reviewing pesticide applications can vary based on what type of pesticide is being registered and that chemical's or product's previous registration history. This chapter also discusses the importance of correctly formatting data submissions to avoid delays or rejection of application packages.

Registrant Summary of Pesticide Petitions for EPA's Notice of Filing provide a company with the ability to electronically prepare a pesticide tolerance petition for submission to EPA.

Pre-Registration Meeting

The Agency welcomes requests for a pre-registration meeting. This type of meeting can provide useful guidance to the applicant regarding information needed for registration. Applicants are encouraged to contact the appropriate branch (see Chapter 21) assigned to the active ingredient in their product before submitting an application for registration. Contact the ombudsman for the division if the appropriate branch is unknown.

General Pesticide Categories

EPA separates pesticides into three general categories. Based on which type of pesticide is being reviewed for a pesticide registration decision, different divisions of EPA's Office of Pesticide Programs will evaluate the action, and the data requirements for registration will vary.

The three general categories of pesticides are:

- Conventional chemical pesticides.
- Biopesticides.
- Antimicrobial pesticides.

Conventional pesticides are generally synthetic chemicals used predominantly to kill insects, weeds, and fungi.

Biopesticides include naturally occurring substances that control pests (biochemical pesticides), microorganisms that control pests (microbial pesticides), and pesticidal substances produced by plants containing added genetic material (plant-incorporated protectants or PIPs).

Antimicrobial pesticides are substances or mixtures of substances intended to destroy or suppress the growth of harmful microbiological organisms, and pesticides that protect inanimate objects and surfaces from organisms such as bacteria, viruses, or fungi. See FIFRA section 2(mm).

The three divisions of EPA's Office of Pesticide Programs that review applications to register a pesticide or product and the types of product review they oversee are:

- Registration Division (RD) for conventional chemicals.
- Biopesticides & Pollution Prevention Division (BPPD) for biopesticides and plant-incorporated protectants.
- Antimicrobials Division (AD) for antimicrobial pesticides.

This chapter provides the basic information on registering any type of pesticide. However, additional information on the unique nature of biopesticides and antimicrobials is available in other chapters:

- Chapter 3 provides additional detailed information on registration requirements for biopesticides.
- Chapter 4 provides additional detailed information on registration requirements for antimicrobial pesticides.

Reduced Risk Pesticides

FIFRA section 3(c)(10)(B) provides for expediting the review of certain types of applications for registration. This program is referred to as the Conventional Reduced Risk Pesticide Program. The Reduced Risk program expedites the review and regulatory decision-making process of conventional pesticides that meet one or more of the following criteria:

- Reduce the risks of pesticides to human health.
- Reduce the risks of pesticides to non-target organisms.
- Reduce the
- potential for contamination of groundwater, surface water, or other valued environmental resources.
- Broaden the adoption of integrated pest management strategies, or make such strategies more effective.

Expediting registrations for pesticides considered to be reduced risk ensures that these reduced risk pesticide uses get into the marketplace and are available to growers and users as soon as possible. For more information, see the Conventional Reduced Risk Pesticide Program Web page.

This program does not apply to biological or antimicrobial pesticides, which are handled through separate expediting processes.

Examples of Pesticide Registration Applications

In addition to the three broad categories of pesticide type described above that influence the registration process, EPA also takes into consideration the previous regulatory history of a pesticide registration application. New pesticide products and uses are further delineated in the following manner:

New Chemical or New Active Ingredient

"New Chemical" or "New Active Ingredient" is an Agency term that refers to a pesticide registration application for a product that contains a pesticide active ingredient that is not contained in any other pesticide product currently registered with the Agency.

New Use

A "New Use" pesticide registration application amendment refers to adding a use for previously registered active ingredient(s), where the requested use is not currently included in the labeled directions for use of any product that contains the active ingredient(s). New uses are defined in 40 CFR 152.3 as follows:

1. Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance or food additive regulation (please refer to Chapter 11 for a discussion of tolerances).
2. Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern.
3. Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

Identical/Substantially Similar (Formerly "Me-Too") Product

An "Identical/Substantially Similar" pesticide registration application refers to a request to register a new pesticide product that is:

- identical in its uses and formulation; or
- substantially similar in its uses and formulation to one or more products that are currently registered and marketed in the United States; or
- differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

This section discusses only new “identical/substantially similar” product registrations. See:

- Chapter 6 of this document for a discussion of “identical/substantially similar”
- Chapter 10 for discussion of data compensation issues for both.

Common terms used for some “identical/substantially similar” products are:

- Identical Repack Registrations – A complete (100%) repackaging of an identical, already-registered product, where an identical label is used for the product other than name, address, name of product, and registration number.
- Old Chemical New Product Registrations – A previously registered active ingredient that is being reformulated to make a new product with the same use pattern as the registered active ingredient. (Note: the applicant will be required to explain how the labeling has been derived and justify certain aspects of the labeling. This is fully explained in Chapter 10.)

Important Note: The following examples illustrate when an application is not considered to be an “identical/substantially similar” product. These are differences between the currently registered product and the application for registration:

- the maximum use rate of the product is increased beyond that which is currently registered;
- a pre-harvest interval (PHI) is changed; or
- any other changes are made that might affect the pesticide residues in food or feed commodities or exposure to non-target organisms.

Other examples are provided in the section titled “Review of Applications for Identical/Substantially Similar (Formerly “Me-Too”) Products." Also note that for “identical/substantially similar” product applications, the source (producer or manufacturer) of the active ingredient must be registered. A product with an unregistered source will not be considered an “identical/substantially similar” product.

Required Contents of the Application Package

A pesticide registration application for a new product must include certain types of information regarding the applicant as well as the pesticide product and comply with fee requirements. Application requirements described here are derived from regulatory requirements codified in 40 CFR 152.50 (Contents of Application) and section 33 of FIFRA

as amended by the Pesticide Registration Improvement Extension Act (PRIA 3), which established registration service fees.

When EPA receives the application and the applicable fee required by PRIA 3, the Agency will screen the application during a 21-day period to determine if it contains all required forms, labeling, and data formatted as described in the Agency's guidance (PR Notice 11-3), and documentation of fee payment. The fee payment documentation may include a request for a fee reduction or waiver or an exemption. Any deficiencies identified during the 21-day Content Screen and uncorrected by the applicant may lead to the Agency's rejection of the application and retention of 25% of the fee.

After the 21-day Content Screen, PRIA 3 requires that a Preliminary Technical Screen be conducted within 45 days after the PRIA start date for submissions with PRIA decision review timeframes ≤6 months and within 90 days for submissions with PRIA decision review timeframes > 6 months. The purpose of the preliminary technical screen is to determine if the pesticide registration application and accompanying information and data are:

- accurate and complete;
- consistent with proposed labeling and any tolerance or tolerance exemption, and
- such that subject to full review could result in the granting of the application.

If the application fails the technical screen, and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of deficiencies, the Agency will reject the application and provide the appropriate refund, if warranted.

If applicants have any questions or concerns about the completeness of their application, the Agency strongly encourages applicants to contact the appropriate registration Ombudsman before submitting the application.

Aside from the applicable fee (and fee waiver or exemption request, if any), an application consists of required elements that should be organized into two parts:

- administrative information; and
- data.

Administrative Portion of the Application Package

The administrative portion of an application consists of the following documentation:

Fee Payment

For PRIA 3-covered applications, documentation or certification of fee payment should be the first page of or on the front of an application. The cover letter, application form, etc.,

should be underneath it to enable the Agency to match a payment with an application. Certification of payment may be:

- a copy of the check or pay.gov acknowledgement; or
- a request for an exemption from registration service fees.

Small business and minor use fee reductions or waiver requests should accompany the certification of payment as a document that can be separated from the rest of the application. Only applications received with a certification of payment will enter the review process.

Note: Applicants are required to pay the Agency 25% of the applicable fee even if an application is withdrawn or rejected for failure to pay a fee.

Cover Letter
A cover letter is not required but is highly recommended. The cover letter should state the general purpose of the submission and identify each item in the application package. It should also contain the email address of the applicant in order to receive the Agency's PRIA registration milestone tracking emails.

Application Form
Complete and submit an original Application for Pesticide Registration/Amendment form (EPA Form 8570-1 (PDF) with each application for registration. 40 CFR 152.50(a).

Detailed instructions on completing the application form are provided on the back of the form and summarized in this chapter. These instructions also specify the number of copies of each item in an application package that needs to be submitted. It is important to read and follow these instructions and provide complete and accurate information.

Tip: Remember to sign and date the application form.

Identity of the Applicant
Name of the Applicant: Applicants must identify themselves. An applicant not residing in the United States must also designate a U.S. agent (see below) to act on its behalf on all registration matters. 40 CFR 152.50(b)(1).

Address of Record: Applicants must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send notices imposing legal requirements and correspondence concerning the application and any subsequent registration information to that address. 40 CFR 152.50(b)(2).

- It is the responsibility of the applicant or registrant to ensure that EPA has a current and accurate address. Refer to Chapter 21 for how to notify the Agency of a change in address.

Important Note: If the Agency's good faith attempts to contact the applicant are not successful, the Agency will issue in the ***Federal Register*** a notice of intent to cancel all of the applicant's registered products under FIFRA section 6(b) (refer to 40 CFR 152.122).

Authorized Agent: Any applicant may designate a person residing in the United States to act as its agent. 40 CFR 152.50(b)(3). Applicants not residing in the United States must designate a U.S. agent to act on their behalf on all registration matters. 40 CFR 152.50(b)(1).

For list of agents see: List of Pesticide Regulatory Consultants.

An applicant who designates an agent must send a letter to the Agency stating the name and U.S. address of the agent. Applicants must also notify the Agency if they change their designated agent. An applicant may terminate a designated agent at any time by notifying the Agency in writing.

The Agency treats authorized agent notifications in the same way as company name and address changes. (See Chapter 21).

Company Number: If an applicant has been assigned a company number by the Agency, the application must reference that number.

Summary of the Application: Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by 40 CFR 158.32. The summary must state that it is releasable to the public after registration in accordance with 40 CFR 152.119.

Identity of the Product: The product for which the application is being submitted must be identified as follows:

- the product name;
- the trade name(s) (if different); and
- the EPA Registration Number, if currently registered.

Draft Labeling: Section 2(p)(1) of FIFRA defines the written, printed or graphic material on, or attached to, the pesticide or device or any of its containers or wrappers." The term "labeling" is defined as "all labels and all other written, printed, or graphic matter –

A. accompanying the pesticide or device at any time; or
B. to which reference is made on the label or in literature accompanying the pesticide or device." (See FIFRA section 2(p)(2)).

It is unlawful to sell or distribute a pesticide if any claims made for it differ from claims made on labeling required for registration. (See FIFRA section 12(a)(1)(B)) Therefore, advertising claims for a pesticide product must not contradict claims made in the product's labeling. Labeling requirements are codified in 40 CFR Part 156.

Labeling includes detailed information including the ingredients statement, warnings and precautionary statements, and directions for use. EPA has also developed a Label Review Manual as guidance to its staff on reviewing labels. This manual includes detailed information on content and format of labels and labeling.

Five copies of the proposed draft labeling must be submitted with an application. (See 40 CFR 152.50(e). The draft labeling may be typed or otherwise printed but must be legible, reproducible, and on 8-1/2 x 11-inch paper. EPA encourages electronic submission of the label. Applicants should refer to EPA's Web site for the Agency's guidance on submitting an electronic label.

Important Note: Only one complete set of the documents in the administrative portion of an application (as described in the instructions on the application form) is required (40 CFR 152.50(a)). The formal requirements included in PR Notice 11-3 apply to the data portion of an application package only, not to the previously described administrative portion.

Data Portion of an Application Package

Applicants are responsible for citing or generating all data to meet data requirements. The purpose of these data requirements is to demonstrate that the product will not cause unreasonable adverse effects and for pesticides that will need a tolerance or tolerance exemption to demonstrate a reasonable certainty of no harm. These requirements include, as applicable, data on:

- residue chemistry,
- environmental fate,
- toxicology,
- reentry protection,
- spray drift,
- wildlife and aquatic organisms,
- plant protection,
- non-target insects,
- product performance, and
- product chemistry.

Data requirements in support of applications for registration of a pesticide product are specified in 40 CFR Part 158 and for antimicrobial active ingredients and products in 40 CFR Part 161.

The data submitted in support of a registration must be formatted according to the requirements detailed in 40 CFR 158.32-34. See FIFRA section 33((f)(4)(B)(iii)(II). Please refer to the section "Pesticide Registration Notice 11-3" later in this chapter and also Chapter 15 of this manual for additional guidance on how to format a data submission.

Tip: Currently, three identical copies of all applicable data required to support the registration of a product must be submitted with an application. Alternatively, data may be submitted electronically as described in the electronic submission guidance.

Confidential Statement of Formula

Two copies of a Confidential Statement of Formula (EPA Form 8570-4 (PDF)) must be completed and submitted with each application for registration. See FIFRA section 3(c)(1)(D), 40 CFR 152.50(f) and 40 CFR 158.320. Detailed instructions for completing the form and providing acceptable information are provided on the back of the form. Additional information can be found in 40 CFR 158.300-355.

Important Note: The Confidential Statement of Formula (CSF) is Confidential Business Information (CBI) and should not be transmitted over FAX machines or through electronic submission such as email unless senders want to waive their CBI rights. If you wish to waive these rights, this should be clearly stated on the CSF.

A Confidential Statement of Formula must include

- all active ingredients;
- all inert ingredients;
- all impurities of toxicological significance associated with the active ingredient; and
- all impurities found to be present at a level equal to or greater than 0.1 percent by weight of the technical grade active ingredient. See 40 CFR 158.320.

In addition, all inert ingredients that are used in a product with food uses must have a tolerance or exemption from a tolerance. (Please refer to Inert Ingredients in Chapter 8.) See Appendix A for additional guidance on CSF issues.

Product Chemistry and Acute Toxicology Data

If a product is **not** substantially similar to another registered product, the applicant is required to submit, at a minimum, product chemistry and acute toxicity data for the product.

Type of Pesticide	Product Chemistry	Acute Toxicology
Conventional	40 CFR Part 158 Subpart D	40 CFR 158.500
Biopesticide	40 CFR Part 158, Subpart U and V	40 CFR Part 158, Subparts U and V
Antimicrobial	40 CFR Part 158, Subpart W	40 CFR Part 158, Subpart W

Additional information can be found in the OPPTS Harmonized Test Guidelines, Series 830 (Product Chemistry) and 870 (Toxicology). Additional guidance concerning product chemistry and CSF issues can be found in Appendix A.

If the source of the active ingredient used to formulate the final product is not an EPA-registered source, the applicant must provide, at a minimum, product chemistry data and acute toxicity data on the technical grade of the active ingredient in addition to the data for the formulated product.

Products Substantially Similar or Identical to Registered Products

At the very minimum, applications for products that claim to be substantially similar to other registered products must submit or reference the product-specific chemistry data, which are discussed in detail in 40 CFR 158.300-355, 40 CFR 158.2030, 40 CFR 158.2120 to determine if products are substantially similar. No product chemistry data are required to be submitted for identical products, i.e., 100% repackage of a currently registered product. View 40 CFR Part 158.

- Under a self-certification program begun in 1998, product chemistry information may be submitted in summary form for qualifying products. Refer to PR Notice 98-1 for details.

Efficacy Data (Product Performance Data)

Efficacy data are routinely required to be submitted to support products that control pests of public health significance, including but not limited to products to control:

- Pathogenic bacteria.
- Viruses.
- Mosquitoes.
- Ticks.
- Roaches.

- Fleas.
- Rats.
- Mice.

Efficacy data requirements related to these types of pest control products are detailed at 40 CFR 158.400, 40 CFR 158.2070, 40 CFR 158.2160 and 40 CFR 158.2220. View 40 CFR Part 158.

Also, refer to the OPPTS Harmonized Test Guidelines, Series 810 and Antimicrobial Science Policies.

Although efficacy data (product performance data) are not routinely required to be submitted for most insecticide, fungicide, or herbicide products, the applicant or registrant must conduct efficacy tests on each of its products in order to ascertain through testing that the product performs in accordance with its labeling and use directions claims.

- Efficacy data may be required to be submitted on a case-by-case basis and must be kept in the applicant's or registrant's files.

Generic Data

Generic data pertain to the active ingredient and not to the formulated end use pesticide product. These data must be submitted or cited for applicable new uses, products not formulated with a registered product, and new chemicals. These requirements include data on:

- residue chemistry;
- environmental fate;
- toxicology;
- wildlife and aquatic organisms;
- plant protection; and
- non-target insects.

Specific data requirements in support of applications for registration of a pesticide product are specified in 40 CFR Part 158.

If the Selective Method (40 CFR 152.90) of data support is used, the Data Matrix Form is used to show the data and corresponding EPA Master Record Identifier (MRID) numbers. When using the Cite-all Method (40 CFR 152.86) of data support, applicants must use the Data Matrix to list companies to whom they have made

offers to pay. Definitions of the different types of data support are also found in Chapter 10.

Data Compensation Requirements

FIFRA section 3(c)(1)(F) and its implementing regulations require that applicants applying for registration of a pesticide comply with data compensation procedures. This means that if an applicant decides to use data previously generated by another registrant in support of its own product registration, the applicant generally is required to offer payment to that original data submitter and in some cases must obtain permission to cite such data. See FIFRA section 3(c)(1)(F) and 40 CFR Part 152, Subpart E.

Normally, one or more of the following three data compensation forms are required to be submitted with an application for registration:

- A properly completed Certification with Respect to Citation of Data (EPA Form 8570-34) must accompany any application for which data are being submitted or cited.
- A properly completed *Data Matrix* must accompany any applications (EPA Form 8570-35) for which data are being submitted or cited under the selective method. Applicants should also use a Data Matrix when using the cite-all method for purposes of listing the persons to whom offers of compensation have been made.
- A properly completed *Formulator's Exemption Statement* (EPA Form 8570-27) must accompany any application (required only when utilizing the formulator's exemption)

These requirements and applicable forms are fully discussed in Chapter 10 of this manual. For further reference, see FIFRA section 3(c)(1)(F) and 40 CFR 152.80 - 152.99.

Data Waivers

A waiver of data requirements may be warranted when the Agency determines that certain data that would otherwise be required are not needed.

EPA will consider waiver requests for specific data requirements. Applicants must demonstrate in writing that a specific data requirement is unnecessary for their product. The waiver request should be accompanied by all of the pertinent information including copies of the references cited by the applicant.

There is often confusion as to what constitutes a data waiver. For example, regulations can state that certain data requirements are not applicable to a category of products (such as some footnoted items in the Data Requirement Tables in 40 CFR Part 158. These circumstances are not considered data waivers.

In some cases data requirements may be fulfilled because other data can be substituted to fulfill the data requirement. For example, an applicant could submit studies done by the paint industry, or threshold levels determined by NIOSH/OSHA, to fulfill the requirement for inhalation toxicity data for the product. In this situation, data are required, but are already available from an existing source. Using data from such a source is not a waiver of data requirements.

Thus, the term waiver is limited to those cases where data would ordinarily be required, but are not required in the given case because of an Agency determination that the data are not needed. Additionally, if the applicant or registrant believes a data requirement is not appropriate for its product, it should consider submitting a request for a data waiver.

Rationale for a Data Waiver

A waiver from a particular data requirement specified in 40 CFR Part 158 as applicable to a category of products, may be requested for an individual product in that category if that product has special features that make the development of such data inappropriate.

For example, some products may have unusual physical, chemical, or biological properties or atypical use patterns that would make a particular data requirement inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks of the product. In these cases the Agency may waive data requirements that it finds are inappropriate but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards. It is the applicant’s responsibility to provide compelling, substantiated information in the request for a data waiver.

The applicant may, under 40 CFR 152.91, demonstrate compliance for a data requirement by:

- claiming that a waiver previously granted by the Agency also applies to a data requirement for its product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Reregistration Eligibility Decision (RED) document and must explain why that waiver should apply to its product; or
- requesting and being granted a new waiver to satisfy the data requirement.

Procedures for Submitting Data Waiver Requests

To request a data waiver, the applicant must submit a written request which should accompany their PRIA registration application. Certain data waiver requests require a registration service fee. See Chapter 5.

- Tip: Applicants who plan to request a data waiver should discuss their plans with the EPA staff person responsible for their product before developing and submitting extensive support information for the request.

The waiver request must specifically identify the data requirement for which a waiver is requested and must provide specific information relative to each requirement for the compound in question, explaining why the applicant thinks the data requirement(s) should be waived.

The specific waiver must allow the Agency to determine if the kind and levels of exposure resulting from the proposed use may allow waiver of the ordinarily required data. In all cases, the Agency needs scientifically sound information to make a decision on specific data waiver requests. Simply stating that a product is ubiquitous in nature or is Generally Recognized as Safe (GRAS) is insufficient.

A Waiver Request May Include:

- description of unsuccessful attempts to generate the required data;
- other information the applicant believes would support the request; and
- suggestions of alternative means of obtaining data to address the concern that underlies the data requirement.

For example, to support a waiver for inhalation toxicity data, an applicant might submit information showing that the product is of a nature that precludes the potential for inhalation exposure.

Notice of Agency Decisions on Data Waiver Requests

EPA will review each data waiver request and inform the applicant in writing of its decision. For decisions that could apply beyond a specific product, the Agency may choose to send a notice to all registrants or to publish a notice in the Federal Register announcing its decision.

Agency decisions on data waiver requests will be available to the public at the Office of Pesticide Programs' Docket Reading Room, 2777 Crystal Drive, S-4400, Arlington, VA 22202. The telephone number is 703-305-5805. Hours are from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

- An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

Child-Resistant Packaging (CRP) Certification

The criteria for which products require child-resistant packaging are available at 40 CFR 157.20 – 157.36.

If a product meets the criteria requiring child-resistant packaging, the applicant must submit a certification (see 40 CFR 157.34) that the packaging to be used for the product meets the child-resistant packaging standards described in 40 CFR 157.32.

The certification must contain the following information:

4. The name and EPA registration number of the product to which the certification applies, the registrant's name and address, the date, and the name, title and signature of the company official making the certification.
5. A statement that the packaging that is being used for the product will meet the standards of 40 CFR 157.32. The statement, "I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32," will suffice for this purpose.

Also see PR Notice 97-9 and PR Notice 96-2 and Child-Resistant Packaging Web page.

Restricted Use Pesticide (RUP) Classification

EPA has classified some or all of the uses of certain pesticides as "Restricted Use." The "Restricted Use" classification restricts a product, or its uses, to use by a certified pesticide applicator or under the direct supervision of a certified applicator. (For detailed information on the "Restricted Use" Classification, 12.5). See 40 CFR Part 171 for more information on certification of pesticide applicators.

- Tip: Criteria used for determining whether a product requires the restricted use classification can be found in 40 CFR 152.170.
- More information on restricted use pesticides.

Statement Concerning Tolerances

If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed, the applicant must submit a statement indicating whether such residues are authorized by a tolerance, exemption from the requirement of a

tolerance, or food additive regulation issued under section 408 or 409 of FFDCA. If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations, in accordance with 40 CFR Part 180.

Registration Procedures

Procedures for submitting a complete application for registration of a pesticide product are detailed in regulations at 40 CFR 152.40-152.55 (entitled Registration Procedures).

A separate application for registration must be made for each pesticide product that will be distributed or sold. A pesticide product registration is required for each manufacturing use product or end use formulation.

A manufacturing use product is a product intended and labeled for formulation and repackaging into other pesticide products. A manufacturing use product label does not bear directions for use, but states that the product is for use only in formulating other products. An end-use formulation is a product that bears directions for use on the label.

Alternate Formulations

Any change in formulation must contain the same certified limits for each active ingredient as the basic formulation. Any variation in certified limits of active ingredients in a product requires a separate registration.

The percentages and identities of inert ingredients are allowed to vary as “alternate formulations” as long as these formulations are deemed to be substantially similar to the basic formulation (further information: 40 CFR 152.43 - Alternate Formulation).

- Applicants are responsible for the accuracy and completeness of all information submitted in connection with their applications.

Pesticide Registration Notice 11-3

In a Pesticide Registration Notice issued on July 29, 1986, EPA outlined how data should be submitted for review by the Agency. PR Notice 11-3 contains specific instructions on organizing and formatting submittals of supporting data. It does not address the substance of the test reports.

Common Errors

In an analysis conducted by the Office of Pesticide Programs in 2006, EPA identified common formatting errors of submitted data. These common errors included:

- Incorrectly formatted Confidential Business Information Statement.
- Missing or incomplete Good Laboratory Practice (GLP) Standards Compliance Statement.
- Incorrect pagination.
- Legibility problems.
- Unsigned documents.

Certain forms have been identified that are often missing from the data submission, including the:

- Certification of Data Compensation statement.
- Formulator's Exemption statement.
- Data Matrix Form.

Specific problems with Data Matrix requirements include failure to include all required generic and product-specific data and citing incorrect MRID Numbers.

Important Notes: Following the instructions in PR Notice 11-3 is essential. Taking time to ensure that data submissions follow these formatting guidelines will avoid rejection of the application or submission during PRIA 3's 21-day initial content review.

An application will be rejected if the required three copies of the data are not properly bound and formatted or the electronic submission does not follow Agency guidance. Read more about electronic submission of pesticide applications.

Completeness Reviews

When EPA receives applications for pesticide registration, there are three steps in processing an application to determine whether the application is complete and contains sufficient information for the Agency to make a regulatory decision. These steps are:

- Initial 21-day Content Screen.
- Preliminary Technical Screen.
- In depth review of data -- data deficiencies or need for additional information identified.

These reviews are described in the next three sections.

Initial 21-day Content Screen

Upon receipt, an application will be assigned a file symbol. A file symbol is a temporary identification number that is a combination of the applicant's company number and a letter, which is the precursor to the product number (ex. 12345-xxx). The Agency then conducts a 21-day initial content screen to determine whether the appropriate fee has been paid and that the application contains the necessary forms, draft labeling, and data formatted in accordance with Agency guidance (e.g., PR Notice 11-3). Applicants must correct applications within the 21-day initial content review period to successfully complete the screen.

Preliminary Technical Screen

After the 21-day Content Screen, PRIA 3 requires that a Preliminary Technical Screen be conducted within 45 days after the PRIA start date for submissions with PRIA decision review timeframes ≤6 months and within 90 days for submissions with PRIA decision review timeframes > 6 months. The purpose of the preliminary technical screen is to determine if the pesticide registration application and accompanying information and data are:

6. accurate and complete;
7. consistent with proposed labeling and any tolerance or tolerance exemption; and
8. such that subject to full review could result in the granting of the application.

If the application fails the technical screen and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of deficiencies, the Agency will reject the application.

In-Depth Review of Data -- Data Deficiencies or Need for Additional Information Identified

Once the application is placed into the Agency's review process, it is reviewed in depth. If during this in-depth review, the Agency determines that there are data deficiencies or that further information is needed in order to complete the Agency's review, the Agency will notify the applicant of the deficiencies per 40 CFR 152.105 and allow the applicant 75 days to make corrections or additions to complete the application. If the applicant believes that the deficiencies cannot be corrected within 75 days, he must notify the Agency within those 75 days of the date on which he expects to complete the application. If, after 75 days, the applicant has not responded, or if the applicant subsequently fails to complete the application within the time scheduled for completion, the Agency will terminate any action on such application, and will treat the application as if it had been withdrawn by the applicant. Any subsequent submission relating to the same product must be submitted as a new application.

If submitting in response to a deficiency letter from EPA, the applicant's submission (on EPA Form 8570-1) should be marked "Resubmission" at the top of the application form and should include a copy of EPA's deficiency letter.

Read more about application submission and screening.

Applications for Registration That May Qualify as Identical/Substantially Similar (Formerly "Me-Too") Products

Section 3(c)(3)(B)(ii) of FIFRA requires EPA to review, as expeditiously as possible, applications for registration of products that are "substantially similar" or "identical" in composition and labeling to other EPA-registered pesticide products or would differ in ways that would not significantly increase the risk of unreasonable adverse effects on the environment. In addition, the Agency is required to:

- Conduct an initial contents screen within 21 days of receiving the application and the applicable fee.
- Under PRIA 3 as part of the Preliminary Technical Screen, any similarity claim is evaluated by the EPA. The applicant is allowed 2 attempts to identify an already registered product that is substantially similar to the proposed product. If after the second attempt the applicant fails to identify a substantially similar product, the application is rejected, and no refund of the PRIA fee is granted.

Applications for Registration That May Qualify as Identical/Substantially Similar (Formerly "Me-Too") Products

For "Identical/substantially similar" applications, the applicant must provide the EPA registration number of the currently registered product that is believed to be "substantially similar" or "identical" to the proposed product.

Examples of end-use "identical/substantially similar" new product applications that may qualify as an identical/substantially similar product include:

- Applicant references substantially similar, registered pesticide product with no data review or only review of Product Chemistry data with cite-all data citation, or selective citation where the applicant owns all the required data (or the applicant submits a specific authorization letter from the data owner).
- Applicant references substantially similar, registered pesticide product with no data review or only review of Product Chemistry or selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where the

applicant does not own all required data and does not have a specific authorization letter from data owner.
- Applicant is repackaging a registered product that does not require the submission of data nor the submission of a data matrix.

Applications That Do Not Qualify as Identical/Substantially Similar New Products

Examples of end-use "identical/substantially similar" new product applications that may not qualify as an identical/substantially similar product include:

- inert ingredients that do not currently exist in any other pesticide formulation;
- a reference to a canceled product;
- significant changes in the percentage of active ingredient;
- new formulation types;
- directions for controlling new, nonpublic health pests;
- directions for new dosage rates;
- directions for different frequency and timing of applications;
- directions for use in geographical locations other than those previously registered; and
- directions for use on new sites and for new methods of application for the active ingredient or ingredients.

Applications that require review of acute toxicity and efficacy data do not qualify as identical/substantially similar new product applications since submission of such data would indicate that the product is not identical or substantially similar in composition and labeling to the currently registered pesticide identified in the application.

Examples of end-use product applications that do not qualify as an identical/substantially similar include:

- Applicant references similar, registered pesticide product and submits product chemistry and required efficacy for specific formulation purposes.
- Applicant asserts similarity but does not reference a registered pesticide product. Submits product chemistry.
- Applicant references a similar pesticide product and submits product chemistry and required nitrosamine data for a specific formulation.
- Applicant does not reference a pesticide product. Submits product chemistry and required nitrosamine data for a specific formulation.
- Applicant does not reference a pesticide product. Submits product chemistry and the full battery of acute data.

- Applicant references a similar registered pesticide product. Submits product chemistry, the full battery of acute data and required efficacy data.
- Applicant references a pending registration.

Important Note: Applications for new Manufacturing Use Products, including Technical Grade Products, are covered by a number of registration service fee (PRIA) fee categories.

How to Submit an Identical/Substantially Similar Product Application

If it is believed that product application qualifies as an identical/substantially similar new product application, the applicant should submit "Application for Pesticide Registration/Amendment" (EPA Form 8570-1) and identify – in Section II of the application form – the EPA Registration Number and name of the product to which it believes the product is substantially similar or identical.

Where to Submit an Application for Registration

Please refer to Chapter 21 for the address to be used in submitting all applications to the Agency.

Electronic Submissions

EPA's Office of Pesticide Programs (OPP) is pursuing use of electronic data submission and review tools to improve the efficiency and effectiveness of its regulatory processes. These improvements would apply to information delivery, review, exchange and archiving functions. The approach is being implemented using current technology, considers the needs of data submitters and reviewers, and addresses legal requirements regarding both the pesticide program and information technology choices. More information can be found in the Agency's electronic submission guidance.

Contacts for Additional Information

For additional information concerning a specific application for registration, contact the Branch Chief or Product Manager assigned to the active ingredient contained in your product. See Chapter 21 for contact information.

For questions concerning the status of a new product application for registration, please contact the Office of Pesticide Programs, Information Technology and Resources Management Division (ITRMD) Front End Processing Staff.

For questions of a general nature that do not pertain to any specific pesticide or pertain to a new pesticide active ingredient for which an application has not been submitted, contact the appropriate Ombudsmen (listed in Chapter 21).

References Cited in Chapter 2

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

To find current Code of Federal Regulations citations, use the e-CFR.

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 161 - Data Requirements for Registration
- Part 162 - State Registration of Pesticide Products

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

- Section 3 - Registration of pesticides
- Section 4 - Reregistration of pesticides

Pesticide Registration Notices (PR Notices)

- PR Notice 11-3 - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 96-2 - Changes to Child-Resistant Packaging (CRP) Testing Requirements

- PR Notice 97-9 - Electronic Submission of Child-Resistant Packaging Test Data for all Pesticides and Child-Resistant Testing of Prefilled, Nonrefillable Insecticide Bait Stations not Designed or Intended to be Opened or Activated in a Manner that Exposes the Contents to Human Contact
- PR Notice 98-1 - Self-Certification of Product Chemistry Data w/ Attachments

Label Review Manual

Test Guidelines for Pesticides and Toxic Substances