



Pesticide Registration Improvement Act Factsheet

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Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) provides that all pesticides sold or distributed in the United States must be registered with the Environmental Protection Agency (“EPA”).¹ Registration can be a long, complicated process which requires the registrant to supply a wide variety of information about the pesticide. Further, the registrant will need to consider whether it wants to pursue an unconditional registration, or a conditional registration.

An unconditional registration requires the registrant to supply all required information, and for EPA to determine that the pesticide “will not generally cause unreasonable adverse effects on the environment.”² For a conditional registration, EPA must determine that a registration decision can be made, but further data, studies or action by the registrant are required.³ FIFRA provides specific situations when EPA may grant a conditional registration.⁴ These situations include a new use registration, a new active ingredient registration, or an identical/substantially similar product registration.⁵

Regardless of what type of registration is ultimately pursued, a crucial aspect of registration is determining what type of label is appropriate for the registrant’s pesticide. During the registration process, EPA will review each product’s label to ensure that it provides adequate

¹ 7 U.S.C. § 136a(a) (2022).

² 7 U.S.C. § 136a(c)(5)(D) (2022).

³ 7 U.S.C. § 136a(c)(7)(A) (2022).

⁴ *Id.*

⁵ 7 U.S.C. § 136a(c)(7) (2022).

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instructions about how to safely use the pesticide product so as to avoid harm to human health and the environment.⁶ Additionally, FIFRA provides that a product’s labeling information shall not be false or misleading, shall not conflict with or detract from any statement required by the law or the EPA, and shall be substantiated at the request of the EPA.⁷ While FIFRA outlines some of the consequences of pursuing the wrong label, current events have raised another important labeling consideration.

In February 2024, a federal court in Arizona issued a ruling directing EPA to vacate the 2020 registrations allowing the use of three dicamba-based pesticide products formulated to be applied directly to crops grown from dicamba-resistant corn and soybean seeds.⁸ While the plaintiffs in the case made several arguments that the 2020 registrations violated substantive aspects of FIFRA and the Endangered Species Act, the court ultimately based its decisions on claims that EPA had violated FIFRA procedure by approving the 2020 registrations under the wrong type of pesticide label.⁹ Specifically, the court ruled that the pesticide registrants had submitted the dicamba registrations as so-called “me-too” registrations when, according to the court, a “new use” registration would have been more appropriate.¹⁰ Both types of registrations are outlined under amendments made to FIFRA in 2004 along with various other types of pesticide label that are each intended to be used for registering different types of pesticides under various different circumstances.¹¹

The decision from the federal court in Arizona marks one of the first times a court has vacated a pesticide label specifically because EPA approved the wrong type of label registration. Going forward, in order to develop pesticide labels that stand up to legal challenges, pesticide manufacturers and EPA will need to ensure that pesticides are registered with the appropriate type of label for the product and its intended uses. Read more about this case here: [LINK](#).

[Pesticide Registration Improvement Act](#)

While FIFRA provides much of the controlling law, it is not the only major piece of legislation that establishes the pesticide registration process. The Pesticide Registration Improvement Act (“PRIA”) was enacted in 2004 and established a new system for registering pesticides.¹² This new system included registration service fees, specified decision review times, and funding for farmworker protection activities.¹³ PRIA was reauthorized in 2007, 2012, 2019,

⁶ 7 U.S.C. § 136a(d)(1)(A) (2022).

⁷ 7 U.S.C. § 136a(c)(9)(B) (2022).

⁸ *Ctr. for Biological Diversity v. U.S. En’t Prot. Agency*, Case No. CV-20-00555-TUC-DCB, 2024 WL 455047, at *26 (D. Ariz. 2024).

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Pria 5 Implementation*, EPA (Aug. 2024), <https://www.epa.gov/pria-fees/pria-5-implementation>.

¹³ *Id.*



and most recently on December 29, 2022.¹⁴ PRIA has provided pesticide registrants with additional guidance on pesticide labeling by including processes such as applications for clean labels and label issue resolution periods.¹⁵ PRIA is found in Title 7 of the United States Code, and the different types of label categories a registrant may pursue are found in 7 U.S.C. § 136w-8.¹⁶

Before getting into the different labeling categories, it is important to note that certain labeling requirements apply to all pesticide labels. The Federal Register contains rules that mandate general labeling requirements, and says that every pesticide product must bear a label showing “clearly and prominently,” the name, brand or trademark the product is sold under, the name and address of the producer, the net contents of the product, the product’s registration number, the producing establishment number, an ingredient statement, hazard and precautionary statements, directions for use and use classifications.¹⁷ However, when it comes to deciding the contents of the label, the registrant is not the only individual who decides what is included. For example, when a registrant applies for pesticide registration it must provide EPA with a proposed label for the pesticide.¹⁸ Then, EPA will determine necessary precautions for the product’s label that the registrant must conform to.¹⁹

After conforming its label to the general labeling requirements, a pesticide registrant will need to determine which PRIA table includes the correct individual label for the pesticide product. . In order to do so, the registrant will need to determine whether the pesticide they are registering meets the definition of a conventional pesticide, antimicrobial pesticide, biopesticide, or an inert ingredient. Then, the registrant will need to determine what type of action is most appropriate for the type of registration it is pursuing. This is because PRIA provides 19 different tables of pesticide label categories that are first divided by type of chemical, and then by type of action.²⁰ The chemical divisions are categorized as: (1) conventional; (2) antimicrobial; (3) biopesticide; and (4) inert ingredients.²¹ Then, the type of action divisions are categorized as: (1) new active ingredient; (2) new use; (3) import and other tolerances; (4) new products; (5) amendments; and (6) miscellaneous.²² Under this system, each individual category corresponds to a certain registration service fee and decision review period.²³ Below is a discussion about the different types of chemical divisions, and some of the labeling concerns that affect each division.

¹⁴ *Id.*

¹⁵ *Pria Overview and History*, EPA (June 2024), <https://www.epa.gov/pria-fees/pria-overview-and-history>.

¹⁶ 7 U.S.C. § 136w-8 (2022).

¹⁷ 40 CFR § 156.10 (2024).

¹⁸ 7 U.S.C. § 136a(c)(1)(C) (2022).

¹⁹ 40 CFR § 152.112 (2024).

²⁰ *About Pesticide Registration Fees Under Pria*, EPA (Feb. 2024), <https://www.epa.gov/pria-fees/about-pesticide-registration-fees-under-pria>.

²¹ *Id.*

²² *Id.*

²³ *Id.*



The Chemical Divisions

The Conventional Division

The conventional division includes tables 1-6.²⁴ These tables include: (1) new active ingredients; (2) new uses; (3) import and other tolerances; (4) new products; (5) amendments; and (6) other actions.²⁵ The purpose of this division is to provide for pesticide labels for conventional pesticides. Conventional pesticides include all active ingredients other than biological pesticides and antimicrobial pesticides.²⁶ Conventional active ingredients are generally synthetic chemicals that prevent, destroy, or repel any pest; or that act as a plant growth regulator, desiccant, defoliant or nitrogen stabilizer.²⁷

The Antimicrobial Division

The antimicrobial division includes tables 7-10.²⁸ These tables include: (7) new active ingredients; (8) new uses; (9) new products and amendments; and (10) experimental use permits and other actions.²⁹ The purpose of this division is to provide for pesticide labels for antimicrobial pesticides. An antimicrobial pesticide is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or protect inanimate objects, industrial processes or systems, surfaces, water or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.³⁰ Wood preservatives and anti-foulants are classified as antimicrobial pesticides if the products have antimicrobial claims.³¹

For antimicrobial pesticides, there are additional labeling requirements that do not apply to the other divisions. For example, for antimicrobial pesticides that may be diluted for use, the label must provide different statements of caution or protective measures for the diluted solution compared to the concentrate, provided that adequate data supports these statements and the label offers adequate protection for exposure to the diluted solution.³²

The Biopesticides and Pollution Division

²⁴ 7 U.S.C. § 136w-8 (2022).

²⁵ *Id.*

²⁶ *Conventional Pesticide Registration*, EPA (Mar. 2024), <https://www.epa.gov/pesticide-registration/conventional-pesticide-registration#what>.

²⁷ *Id.*

²⁸ 7 U.S.C. § 136w-8 (2022).

²⁹ *Id.*

³⁰ *Antimicrobial Pesticide Registration*, EPA (Mar. 2024), <https://www.epa.gov/pesticide-registration/antimicrobial-pesticide-registration#what>.

³¹ *Id.*

³² 7 U.S.C. § 136a(c)(9)(D) (2022).



The biopesticides and pollution division includes tables 11-17.³³ These tables include: (11) new active ingredients; (12) new uses; (13) new products; (14) amendments, (15) straight chain lepidopteran pheromones; (16) other actions; and (17) plant incorporated protectants.³⁴ The general purpose of this division is to provide for pesticide labels for biopesticides. 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.³⁵

Inert Ingredients

The inert ingredients category includes table 18.³⁶ The purpose of this section is to provide pesticide labels for inert ingredients. Most pesticide products contain substances in addition to the active ingredient(s) that are referred to as inert or “other” ingredients.³⁷ An inert ingredient generally is any substance (or group of similar substances) other than an active ingredient that is intentionally included in a pesticide product.³⁸ Inert ingredients in pesticides require registration, and registrants must provide EPA with detailed information about each inert ingredient in a pesticide product.³⁹ If an ingredient is designated as an inert ingredient, it must be included as part of the total inert ingredients in the label ingredients statement.⁴⁰ Additionally, the total percentage by weight of inert ingredients must be included in the ingredient statement on the pesticide label.⁴¹

Miscellaneous

Finally, outside of the previous divisions, is table 19. Table 19 is miscellaneous and provides for any other type of pesticide in need of registration.⁴² This table includes pesticide labels needed for certain pesticide studies, conditional rulings and applicant-initiated cancer reassessments.⁴³

Type of Action Divisions

³³ 7 U.S.C. § 136w-8 (2022).

³⁴ *Id.*

³⁵ *Biopesticides*, EPA (Dec. 2023), <https://www.epa.gov/pesticides/biopesticides#what>.

³⁶ 7 U.S.C. § 136w-8 (2022).

³⁷ *Inert Ingredients Regulation*, EPA (Mar. 2024), <https://www.epa.gov/pesticide-registration/inert-ingredients-regulation#what>.

³⁸ *Id.*

³⁹ 40 C.F.R. § 158.320(b) (2024).

⁴⁰ 40 CFR § 153.125 (2024).

⁴¹ 40 CFR § 153.10(g) (2024).

⁴² 7 U.S.C. § 136w-8 (2022).

⁴³ *Id.*



After deciding which chemical division fits the pesticide product best, to find the correct PRIA table a pesticide registrant will need to determine which Action applies to its registration. Within each chemical division of tables included in PRIA, are individual tables for each type of action. These actions are: (1) new active ingredient; (2) new use; (3) import and other tolerances; (4) new products; (5) amendments; and (6) miscellaneous.⁴⁴ Below is a discussion about the different types of actions, and some of their specific labeling requirements.

New Active Ingredient

The new active ingredient action applies to registrants who want to register a pesticide product with a new active ingredient. An active ingredient prevents, destroys, repels, or mitigates a pest, or is a plant regulator, defoliant, desiccant, or nitrogen stabilizer.⁴⁵ If an ingredient is designated as an active ingredient, it must be identified in the label ingredients statement.⁴⁶ Further, EPA requires that the label of each pesticide product bear a statement which contains the name and percentage by weight of each active ingredient.⁴⁷ Finally, a pesticide product may require special labeling depending on what the active ingredient is.⁴⁸ For example, there are special labeling requirements for pesticides with active ingredients such as pyrethrins and pyrethroids.⁴⁹

New Uses

The new use action applies to registrants who have previously registered a pesticide product, but now want to register that product for a new use. A “new use” includes any additional use pattern that would result in a significant increase in the level or route of exposure to the active ingredient, to the active ingredient of man or other organisms.⁵⁰ When a pesticide registrant seeks a new use registration for a previously registered pesticide product, it must provide EPA with a copy of proposed supplemental labeling and a copy of the labeling from the federally registered product.⁵¹

⁴⁴ EPA, *supra* note 18.

⁴⁵ *Basic Information about Pesticide Ingredients*, EPA (June 2024), <https://www.epa.gov/ingredients-used-pesticide-products/basic-information-about-pesticide-ingredients>.

⁴⁶ 40 CFR § 153.125 (2024).

⁴⁷ 40 CFR § 153.10(g) (2024).

⁴⁸ *Label Guidance for Specific Types of Pesticides*, EPA (Aug. 2024), <https://www.epa.gov/pesticide-labels/label-guidance-specific-types-pesticides>.

⁴⁹ *Id.*

⁵⁰ 40 C.F.R. § 152.3 (2024).

⁵¹ 40 CFR § 162.153 (2024).



Import and Other Tolerances

Import and other tolerances refer to various actions related to establishing and amending tolerances for pesticide residues in imported commodities.⁵² However, this action can also include labels required to establish tolerances for inadvertent residues in one crop, and to establish tolerances for residues in rotational crops.⁵³ When a pesticide product is imported into the country, the EPA administrator has the authority to request samples of the imported pesticides or devices, together with all accompanying labels, circulars and advertising matter pertaining to the pesticide or device.⁵⁴ For tolerances, the registrant will mainly be concerned with submitting data surrounding the pesticide residues that may be left over after the product has been used on food crops. This is because the EPA administrator may cancel (or demand modification of) the registration for each pesticide that contains a particular chemical and is labeled for use on a particular food if the administrator determines that there are dietary risks to humans posed by residues of the pesticide chemical on that food.⁵⁵

New Products

The “new products” action applies to registrants who want to register a new pesticide product. A pesticide product is defined as a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold.⁵⁶ This term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold.⁵⁷ This action also includes labels for ‘substantially similar’ registrations or ‘me-too’ registrations, like in the aforementioned court case.⁵⁸

Amendments

The amendments action applies to registrants who want to amend a previously registered pesticide product. An amendment is any modification in the composition, labeling, or packaging of a registered product.⁵⁹ The application for the amendment must be approved by EPA before the modified product can be legally distributed or sold.⁶⁰ However, not every change to a label is considered an amendment in need of EPA approval. EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the

⁵² 7 U.S.C. § 136w-8 (2022).

⁵³ *Id.*

⁵⁴ 19 CFR § 12 (2024).

⁵⁵ 21 U.S.C. § 346a(1)(3)(A) (2022).

⁵⁶ 40 CFR § 152 (2024).

⁵⁷ *Id.*

⁵⁸ 7 U.S.C. § 136w-8 (2022).

⁵⁹ 40 CFR § 152 (2024).

⁶⁰ *Id.*



environment may be accomplished by notification to EPA, without requiring that the registrant obtain EPA approval.⁶¹

Other Actions

This last category of actions applies to any other action where EPA has provided a label. This can include actions such as experimental use permits (table 10) and straight chain lepidopteran pheromones (table 15).⁶² These actions exist in the antimicrobial division, the biopesticides and pollution division, inert ingredients, and in table 19, miscellaneous.⁶³

The Process

Ultimately, a pesticide registrant has two main questions to answer in order to identify the correct label to pursue during pesticide registration. First, the registrant will need to determine whether the pesticide they are registering meets the definition of a conventional pesticide, antimicrobial pesticide, biopesticide, or an inert ingredient. Then, the registrant will need to determine what type of action is most appropriate for the type of registration it is pursuing. For example, if a registrant is pursuing the registration of a naturally occurring substance that is used to control pests and it meets the definition of a new product, the registrant will want to look to table 13 (biopesticides division, new products) to find the correct pesticide label.⁶⁴ However, if a registrant is seeking registration for a pesticide that is intended to protect inanimate objects from contamination and it contains a new active ingredient, the registrant will want to look to table 7 (antimicrobial division, new active ingredients.)⁶⁵

Once the registrant determines what table it is looking at, it will need to determine which specific label included in the table it wants to choose. The decision of which label to choose can be critical because each label carries with it both decision review times (listed in months) and registration service fees.⁶⁶ These mandatory review times and registration service fees can vary greatly even between labels included in the same table.⁶⁷ Take for example, table 17. Table 17 is found within the biopesticides and pollution division and provides labels for plant-incorporated protectants (or PIPs).⁶⁸ Table 17 includes 36 different kinds of labels each with

⁶¹ 40 CFR § 152.46 (2024).

⁶² 7 U.S.C. § 136w-8 (2022).

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ 7 U.S.C. § 136w-8 (2022).

⁶⁷ *Id.*

⁶⁸ *Id.*



their own associated fees and review times.⁶⁹ Under this table, depending on the label a registrant ultimately chooses, the registrant will have a mandatory review time of anywhere between 3 and 22 months.⁷⁰ Further, the applicable service fees in this table range all the way from \$7,322.00 and \$292,682.00 depending on the chosen label.⁷¹

Between the disparities of the mandatory review times and the registration service fees, and the potentially dire consequences of pursuing the wrong label, a pesticide registrant is at a critical moment in the registration process when it chooses a label. While it may be tempting to select a label with a shorter mandatory review period or a lower registration service fee, it is ultimately in the registrant's best interest to select the pesticide label that best fits its product.

Typing it Back to Registration

As discussed, pesticide registration can be a long, arduous process but is required by FIFRA if the pesticide is to be sold in the United States. The first main question a registrant will consider is whether it wants to pursue a conditional registration or an unconditional registration. Regardless of which registration the registrant chooses for its product, it must decide what label it wants to pursue. Failing to pursue the correct pesticide label during the registration process can have significant consequences, including the possibility of having the registration vacated by a court years later. When considering which label to pursue, a registrant will first need to find the applicable table provided in PRIA. To find the

⁶⁹ *Id.*

⁷⁰ 7 U.S.C. § 136w-8 (2022).

⁷¹ *Id.*



STEPS TO PESTICIDE REGISTRATION

Step #1

Select Conditional vs. Unconditional

Affects the amount of data needed for registration and length of time the label will be registered for.

Step #2

Determine Pesticide Type

This determines the proper PRIA table to select the final label type from - Conventional, Antimicrobial, Biopesticide, or Inert Ingredient

Step #3

Identify Correct PRIA Table

PRIA table is based on the step above. Label types depend on the reason why the pesticide is being registered. For example, a pesticide being registered for a new use would require a New Use label.

Step #4

Choose Label Type from PRIA table

Each table outlines different label types with different data review requirements and registration fees.

correct table, the registrant will first need to determine which definition applies to their pesticide (conventional, antimicrobial, biopesticide or inert ingredient) and then the registrant will need to decide which action applies (new active ingredient, new use, import and other tolerances, new products, amendments, miscellaneous). The next steps to follow, including costs and timeline will differ depending on the table.

