

# Chapter Three REGISTRATION

## Table of Contents

	<u>Page</u>
<b>PESTICIDE REGISTRATION</b> .....	<b>3-1</b>
Amendments of 1996 .....	3-1
Amendments of 1988 .....	3-1
Background on FIFRA .....	3-1
<b>REGISTRATION PROCEDURES</b> .....	<b>3-5</b>
New Registration (40 CFR 152.42) .....	3-6
Amended Registration (40 CFR 152.44) .....	3-6
Supplemental Distribution (40 CFR 152.132) .....	3-6
Section 24(c) Registrations (40 CFR 162.150 - 162.156) .....	3-7
 Exhibit 3-1: Application for Registration .....	 3-8
Exhibit 3-2: Application for Supplemental Registration of Distributor .....	3-9

**CHAPTER THREE**

# REGISTRATION

---

**PESTICIDE REGISTRATION**

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) States that no person in any State may distribute or sell to any person a pesticide that is not registered, unless exempted by section 3(b). The Code of Federal Regulations 40 Parts 152 to 167 (40 CFR 152-167) establishes the requirements for product registration.

**Amendments of 1996**

On August 3, 1996, the President signed into law the Food Quality Protection Act (FQPA) which amended FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). The FQPA directly affects pesticide registration and re-registrations.

**Amendments of 1988**

On October 25, 1988, the President signed into law the 1988 Amendments to FIFRA. Among other things, the amendments required a substantial acceleration of the re-registration process for previously registered pesticides and authorized the collection of fees to support re-registration activities. The law also changed EPA's responsibility and funding requirements for the storage and disposal of suspended and canceled pesticides and the indemnification of holders of remaining stocks of such canceled pesticides. The provisions of the new law went into effect on December 24, 1988.

**Background on FIFRA**

Under FIFRA [unless exempt under section 25(b)], pesticides must be registered by EPA before they can be sold or distributed in commerce to any person. FIFRA sets an overall risk-benefit standard for pesticide registration requiring that pesticides perform their intended function, when used according to labeling directions, without posing unreasonable risks of adverse effects on human health or the environment.

When making pesticide registration decisions, EPA is required by law to take into account the economic and environmental costs and benefits of pesticide uses.

FIFRA was first enacted in 1947. Thousands of pesticide products have been registered since then. The standards for pesticide registration have not remained the same since 1947, but have evolved with science and public policy. In particular, test data requirements for pesticides have increased in light of advances in such areas as toxicology and analytical chemistry. Under FIFRA, pesticide registrants (companies that hold pesticide registrations) must provide all test data necessary to satisfy EPA's registration requirements.

To ensure that previously registered pesticides measure up to current scientific and regulatory standards, FIFRA requires the review and “re-registration” of all existing pesticides. Of the approximately 600 pesticide active ingredients that require re-registration under FIFRA, EPA has issued Registration Eligibility Decisions (REDs) for many of the pesticide active ingredients. A RED includes a comprehensive review of all the available data on the chemical, a list of additional data needed for a complete re-evaluation and re-registration, and the Agency's current regulatory position on the pesticide.

FIFRA authorizes EPA to cancel the registration of an existing pesticide if data show that it causes unreasonable adverse effects on human health or the environment, and for failure to pay maintenance fees. In addition, EPA can take action to suspend the registration of a pesticide to prevent an imminent hazard or for failure to provide required data to support the re-registration.

Under FIFRA, EPA is required to notify all existing registrants if it determines that additional data are required to maintain an existing registration of a pesticide. Each registrant of such a pesticide must provide evidence within 90 days after receipt of notification that it is taking appropriate steps to secure the additional data.

Two or more registrants may agree to develop jointly, or to share in the cost of developing, the required data if they agree and advise the EPA of their intent within 90 days after notification. Any registrant who agrees to share in the cost of producing the data can examine and use the data in support of maintenance of the registration. If an agreement on the terms of the data development arrangement or procedure for reaching the agreement has not been reached in 60 days after advising EPA, the registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator.

All parties to the arbitration share equally in the payment of the fee and the expenses of the arbitrator.

If EPA determines that a registrant failed to take appropriate steps to secure the required data within the required time, participate in a procedure for reaching agreement concerning a joint data development arrangement or in an arbitration proceeding, or comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement, it may issue a notice of intent to suspend the registrant's registration of the pesticide for which additional data is required. The suspension

becomes final and effective 30 days after receipt of the notice of intent to suspend, unless during that time a request for hearing is made in a timely and adequate manner, or EPA is satisfied that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend.

EPA will publish in the Federal Register a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice provides for a period of 30 days in which any federal agency or any other interested person may comment.

The Registration Division, Office of Pesticide Programs, undertakes pesticide registration and review to determine whether registration is necessary. The Registration Division may also review suspected violative labels obtained during inspections as part of ECRs to determine whether they meet the labeling requirements.

A product is required to be registered if the following conditions exist:

- < A product meets the definition of a pesticide section 2(u) of FIFRA and 40 CFR 152.15.
- < The product's labeling and other material make pesticidal claims.
- < A product is represented in any manner that implies it is being used as a pesticide.
- < The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used or is intended to be used for a pesticidal purpose.

Certain products do not meet these criteria and are not considered to be pesticides (40 CFR 152.8 and 152.10). These products include:

- < Deodorizers, bleaches, and cleaning agents.
- < Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly.
- < Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints to trees.
- < Products intended for use only for the control of fungi, bacteria, viruses, or other microorganisms in or on living man or animals, and labeled accordingly.
- < Products intended for use only for control of internal invertebrate parasites or nematodes in living man or animals, and labeled accordingly.
- < Products intended only to aid the growth of desirable plants.

Other products are considered to be pesticide products but are exempt from registration [section 25(b) of FIFRA and 40 CFR Part 152, Subpart B].

An unregistered pesticide, or a pesticide whose registration has been cancelled or suspended may be distributed, sold, or transferred as follows (40 CFR 152.30):

- < An unregistered pesticide may be transferred between registered establishments operated by the same producer. The pesticide must be labeled in accordance with 40 CFR 156.
- < An unregistered pesticide may be transferred between registered establishments not operated by the same producer if:
  - (1) the transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered,
  - (2) each active ingredient in the pesticide at the time of transfer is present as a result of incorporation into the pesticide of either a registered product, or a pesticide that is produced by the registrant of the final product, and
  - (3) the product is labeled in accordance with 40 CFR 156.
- < An unregistered pesticide may be distributed or sold in accordance with the terms of an experimental use permit issued under FIFRA section 5 if the product is labeled in accordance with 40 CFR 172.6. In addition, an unregistered pesticide may be distributed or sold in accordance with the provisions of 40 CFR 172.3 (use of a pesticide for which an experimental use permit is not required) provided the product is labeled in accordance with 40 CFR 156.
- < An unregistered pesticide may be transferred within the United States solely for export if it meets the following conditions: (1) the product is prepared and packaged according to the specifications of the foreign purchaser; and (2) the product is labeled in accordance with 40 CFR 156.
- < An unregistered pesticide may be distributed or sold in accordance with the terms of an emergency exemption under FIFRA section 18 if the product is labeled in accordance with 40 CFR 156.
- < An unregistered, suspended or cancelled pesticide may be transferred solely for disposal in accordance with FIFRA section 19 or an applicable Administrator's order. The product must be labeled in accordance with 40 CFR 156.

- < Existing stocks of a formerly registered pesticide that has had its registration canceled or suspended may be distributed or sold to the extent and in the manner specified in an order concerning existing stocks issued by the EPA.

Other products exempt from registration include the following (40 CFR 152.25):

- < Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.
- < Pheromones and pheromone traps. Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps and pheromone traps in which those compounds are the sole active ingredient(s). [see 40 CFR 152.25 (b)].
- < Preservatives for biological specimens [see 40 CFR 152.25 (c)].
- < Vitamin hormone horticultural products consisting of mixtures of plant hormones, plant nutrients, inoculants, or soil amendments that meet all of the criteria in 40 CFR 152.25 (d).
- < Products consisting of foods and containing no active ingredients, which are used to attract pests.
- < Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all of the criteria in 40 CFR 152.25 (f).
- < Minimum risk pesticides - Exempted products. Products containing the active ingredients listed in 40 CFR 152.25 (g) are exempt from the requirements of FIFRA, alone or in combination with other substances listed, provided that all of the criteria of 40 CFR 152.25 are met.

Products exempt from registration are, however, subject to the misbranding provisions of the Act, which require adequate labeling and identification of products to ensure safe shipment and use.

---

## **REGISTRATION PROCEDURES**

All applications for product registration (devices need not be registered) are to be submitted to the Registration Division(s) (e.g., antimicrobial, insecticide, rodenticide, fungicide biotechnology), Office of Pesticide Programs.

Application procedures for registering a pesticide are codified in 40 CFR 152.40 through 152.175. FIFRA provides for several types of pesticide registrations: new, amended, supplemental, re-registration, renewal, and section 24(c) registrations.

### **New Registration (40 CFR 152.42)**

Any person seeking to obtain a registration for a new pesticide product must submit an application for registration, containing the information specified in 40 CFR 152.50. An application for new registration must be approved by the Agency before the product may legally be distributed or sold, except as provided by 40 CFR 152.30.

### **Amended Registration (40 CFR 152.44)**

An application for amended registration must be submitted when changes are proposed in the labeling or when changes are proposed in the formulation of the pesticide. 40 CFR 152.46 and PR Notice 98-10, however, allow registrants to make minor modifications to their registration (label) that have no potential to cause unreasonable adverse effects to the environment. Such changes are submitted via “Notification;” an Application for Registration form (EPA Form 8570-1) (Exhibit 3-1) marked “Notification” submitted to the Document Processing Desk. Notifications are processed separately. The following modifications can be made by Notification:

- < Adding alternate brand names.
- < Adding and deleting pests (except public health pests and termites).
- < Adding indoor, non food sites for anti microbial products.
- < Adding, revising or deleting advisory statements (except for Ground water Advisory Statements).
- < Changes in packaging and related labeling statements.
- < Use deletions related to Data Call-Ins.
- < Storage and disposal statements.
- < Adding bilingual labeling and use of symbols or graphics.
- < Changing language to delete redundant labeling statements.
- < Changes in Warranty Statements.
- < Other revisions (minor label changes).

### **Supplemental Distribution (40 CFR 152.132)**

A registered product can be supplementally registered and distributed (also known as private labels), which allows a distributor to market the product under his/her own brand name. The following conditions must be met:

- < The product must have the same composition as the primary registered pesticide, and is produced, labeled, and packaged in a registered establishment operated by the same producer (or under contract in accordance with 40 CFR 152.30).
- < The product labeling must bear the same claims as the primary product provided. Specific claims may be deleted if by so doing no other changes are required.
- < The distributed product is not repackaged (remains in the producer's unopened container). However, distributors can repackage and relabel provided they are registered pesticide producing establishments and they have a contract with the registrant for repackaging.
- < The label must bear the registration number of the primary registered product.
- < The distributor's company number must appear as a suffix to the registration number.
- < Distributor products may bear the name and address of the distributor.

The registrant must submit an Application for Supplemental Registration of Distributor (EPA Form 8570-5) (Exhibit 3-2).

### **Section 24(c) Registrations (40 CFR 162.150 - 162.156)**

Under section 24 (c), States may register a federally registered product for additional uses if a special local need exists. In addition, 40 CFR 152.152 allows State registration of new formulations under certain circumstances. States must notify EPA in writing within 10 working days from the date a State issues, amends or revokes a registration. Notification of State registrations or amendments to registrations include the effective date of the registration or amendment, a confidential statement of the formula of any new product and a copy of the draft labeling reviewed and approved by the State (provided that labeling previously approved by EPA as part of a federal registration does not need to be submitted). The notification of revocation of a registration by a State must indicate the effective date of revocation and State the reasons for revocation. Within 60 days after the effective date of the registration or amendment, States must submit a copy of the final printed labeling approved by the State.

EPA may request, when appropriate, that a State submit any data used to determine that unreasonable adverse effects will not be caused when it registers any use described in 40 CFR 162.135 (c)(1). States are required to submit two copies of the requested data within 15 working days of receipt of this request from EPA.

The State may not issue a 24(c) registration that requires a new food or feed tolerance.

### Exhibit 3-1: Application for Registration

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060, Approval expires 2-28-95

<b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number	
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification	
4. Company/Product (Name)	PM #	<input type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant <i>(Include ZIP Code)</i>  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____		
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.)			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No  <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No  If "Yes" Unit Packaging      No. per wgt.                      container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No  If "Yes" Package      No. per wgt.                      container	2. Type of Container  <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			
<b>Section - IV</b>			
1. Contact Point <i>(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</i>			
Name	Title	Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature	3. Title		
4. Typed Name	5. Date		

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

### Exhibit 3-2: Application for Supplemental Registration of Distributor

<b>EPA</b>	United States <b>Environmental Protection Agency</b> Office of Pesticide Programs (7505C) Washington, DC 20460
<b>Notice of Supplemental Distribution of a Registered Pesticide Product</b>	
<i>Instructions</i>	
<p>After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.</p> <p>If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.</p> <p>This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.</p>	
EPA Registration Number of Product	Distributor Company Number
<b>Note: Do not submit distributor product labels</b>	
Name of Registered Product ( <i>basic product name accepted by EPA</i> )	Distributor Product Name
Name and Address of Distributor ( <i>Type; include ZIP code</i> )	
<i>Read All Conditions Before Signing</i>	
<ol style="list-style-type: none"> <li>1. The distributor product must have the same composition as the basic product.</li> <li>2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.</li> <li>3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.</li> <li>4. The product must remain in the manufacturer's unbroken container.</li> <li>5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.</li> <li>6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.</li> <li>7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.</li> </ol>	
<b>Distributor</b>	
<i>We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified in this Notice.</i>	
Signature and Title of Distributor	Date
_____	_____
<b>Registrant</b>	
<i>I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified in this Notice.</i>	
Signature and Title of Registrant	Date
_____	_____

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.