

http://www.epa.gov/pesticides/factsheets/registration.htm#whatis
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Pesticides: Topical & Chemical Fact Sheets

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Pesticide Registration Program

Pesticide Registration Program

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The term pesticide includes many kinds of ingredients in products, such as insect repellants, weed killers, disinfectants, and swimming pool chemicals which are designed to prevent, destroy, repel or reduce pests of any sort. Pesticides are found in nearly every home, business, farm, school, hospital and park in the United States. EPA must evaluate pesticides thoroughly before they can be marketed and used in the United States to ensure that they will meet federal safety standards to protect human health and the environment. Pesticides that meet the requirements are granted a license or "registration" which permits their distribution, sale, and use according to specific use directions and requirements identified on the label. This Fact Sheet outlines some of the fundamental aspects of EPA's registration program.

Resources

- Questions On Pesticides? National Pesticide Information Center (NPIC) 1-800-858-7378
 EXIT Disclaimer
- Registering Pesticides
- Letter from Universities regarding the strobilurin, pyraclostrobin (Headline), supplemental label (5 pp, 117 K PDF)

Note: The Agency is looking into the concerns expressed by the authors of this letter and will make its response publicly available.

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1. What is Pesticide Registration?

The process of registering a pesticide is a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. The producer of the pesticide must provide data from tests done according to EPA guidelines.

These tests evaluate whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish, and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or ground water from leaching, runoff, and spray drift. Potential human risks range from short-term toxicity to long-term effects such as cancer and reproductive system disorders. EPA also must approve the language that appears on each pesticide label. A pesticide product can only be used legally

according to the directions on the labeling accompanying it at the time of sale. Following label instructions carefully and precisely is necessary to ensure safe use.

Types of Pesticides

There are many classes of pesticides, each designed to destroy or repel certain species.

Туре	Targets
Insecticides	flying and crawling insects
Herbicides	undesirable plants/weeds
Rodenticides	mice, rats and other rodents
Fungicides	fungi that cause plant disease/ wood rot, etc.
Nematicides	invertebrates (worms)
Fumigants	insects/fungi
Antimicrobials	microorganisms such as bacteria, molds, fungi
Biopesticides	natural materials such as animals, plants, bacteria, and certain minerals that target a variety of pests
Plant or insect growth regulators	plant (accelerate or retard, the rate of growth of a plant), insect (affect the growth of insects)

2. Federal Pesticide Laws

EPA regulates pesticides under broad authority granted in two major statutes, which were amended by the Food Quality Protection Act of 1996.

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires all pesticides sold or distributed in the United States (including imported pesticides) to be registered by EPA. EPA can authorize limited use of unregistered pesticides or pesticides registered for other uses to address emergencies and special local needs.
- Federal Food, Drug and Cosmetic Act (FFDCA) Requires EPA to set pesticide tolerances for all pesticides used in or on food. A tolerance is the maximum permissible level for pesticide residues allowed in or on commodities for human food and animal feed.

Under the **Food Quality Protection Act, of 1996**, which amended to both FIFRA and FFDCA, EPA must find that a pesticides poses a "reasonable certainty of no harm" before that pesticide can be registered for use on food or feed. Several factors must be addressed before a tolerance can be established, including:

- the aggregate, non-occupational exposure from the pesticide (exposure through diet, from using pesticides in and around the home, and from drinking water);
- the cumulative effects from exposure to different pesticides that produce similar effects in the human body;
- whether there is increased susceptibility to infants and children, or other sensitive subpopulations, from exposure to the pesticide; and

• whether the pesticide produces an effect in humans similar to an effect produced by a naturally-occurring estrogen or produces other endocrine-disruption effects.

3. Types of Registrations Under FIFRA

- **Federal Registration Actions:** Under Section 3 of FIFRA, EPA can register pesticides for use throughout the United States. Some pesticides are registered by EPA for more limited use in certain states. In addition, States, Tribes and Territories can place further restrictions on pesticides, EPA-registered products used or sold within their own jurisdictions.
- Experimental Use Permits (EUPs): Under Section 5 of FIFRA, EPA can allow manufacturers to field test pesticides under development. Manufacturers of conventional pesticides are required to obtain experimental use permits before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water. Biopesticides also require EUPs when used in experimental settings.
- Emergency Exemptions: Under Section 18 of FIFRA, EPA can allow State and Federal agencies to permit the unregistered use of a pesticide in a specific geographic area for a limited time if emergency pest conditions exist. Usually, this arises when growers and others encounter a pest problem on a site for which there is either no registered pesticide available, or for which there is a registered pesticide that would be effective but is not yet approved for use on that particular site. Also, exemptions can be approved for public health and quarantine reasons.
- **State-Specific Registrations**, Under Section 24(c) of FIFRA, States can register a new pesticide product for any use, or a federally-registered product for an additional use, as long as there is both a demonstrated "special local need," and a tolerance, exemption from a tolerance, or other clearance under FFDCA. EPA can disapprove a State's special local need registration.

4. Registration Priorities

EPA's registration program places high priority on registering pesticides that are safer than pesticides currently on the market, those pesticides with public health benefits, and pesticides that are of particular economic importance to producers. For more information on this priority system, please refer to Pesticide Registration Notices 97-2 and 98-7, available online at http://www.epa.gov/PR Notices/.

5. The Pesticide Label

All label language must be approved by EPA before a pesticide can be sold or distributed in the United States. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. It is a violation of federal law to use a pesticide in a manner inconsistent with its labeling. The courts consider a label to be a legal document. In addition, following <u>labeling instructions</u> carefully and precisely is necessary to ensure safe and efficacious use.

6. For More Information

• **Registration for conventional chemicals**, call Sherada Hobgood, Registration Division Ombudsman, at 703-308-8893.

- Antimicrobial pesticides, call ShaRon Carlisle at 703-308-6427.
- **Biopesticides**, call Nicole Berckes at 703-308-0152.
- General information about the Office of Pesticide Programs (OPP), call the Communication Services Branch at 703-305-5017. Also, visit the OPP Website (<u>www.epa.gov/pesticides/</u>), or call the National Pesticide Information Center at 800-858-7378.

7. Pesticide Registration Process

I. EPA Processes Applications and Conducts Evaluation

The Application Includes:

Required Test Data:

- Product Chemistry
- Human and environmental assessment for food safety
- Tolerance information, consisting of information about pesticide residues on food
- Proof that the manufacturing process is reliable

Labeling Information:

- Occupational data
- Directions for use
- Appropriate warnings

Evidence of Meeting All Legal and Financial Obligations

II. EPA Processes Applications and Conducts Evaluation

Upon arrival:

- 1. EPA assigns applications to the appropriate pesticide division, where it is processed and tracked. A project manager is then assigned to:
 - Complete a detailed review of the application
 - Assign and coordinate the appropriate scientific review
 - Set priorities and a timetable
 - Coordinate administrative action
 - Communicate with applicant, otherwise known as the registrant, about the review
 - A. EPA evaluates human health risks (emphasizing sensitive groups such as children and immune-suppressed individuals), by reviewing data on:
 - Aggregate risks-through food, water, and residential uses
 - Cumulative risks-from different pesticides with the same effects
 - B. EPA evaluates occupational risks
 - C. EPA evaluates environmental risks by reviewing data on:
 - Potential for ground water contamination
 - Risks to endangered species
 - Potential for endocrine-disruption effects

2. Risk Assessment and Peer Review:

- EPA compiles all the scientific data on the pesticide product into a comprehensive health and environmental risk assessment to determine the impact that the product or ingredient will have on the human population and surrounding environment
- The health and environmental risk assessment undergoes a process of peer review by scientific experts.

3. Risk Management and Regulatory Decisions, where EPA:

- Considers its risk assessments and the peer review
- Reviews risk mitigation measures
- Researches alternative pesticides already registered
- Coordinates risk management with applicants