

## Section 3 Registration

Section 3 of FIFRA outlines the authority given to EPA for pesticide registration and outlines the process through which EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. EPA evaluates the pesticide to ensure that it will not have unreasonable adverse effects on humans, the environment and non-target species. Pesticides must be registered or exempted by EPA's Office of Pesticide Programs before they may be sold or distributed in the United States. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling (see FIFRA Section 2(ee) for exceptions).

After a pesticide is registered by EPA, states can register pesticides under specific state pesticide registration laws. A state may have more stringent requirements for registering pesticides for use in that state.

In order for a pesticide product to be registered under Section 3 of FIFRA, registrants must submit:

An application for pesticide registration, including the applicable fees, a copy of the product label, including all claims that will be made for the product, and a confidential statement of formula, which must include all of the ingredients in the pesticide product.

In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. Potential registrants must generate scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide. Over 100 studies are submitted for a typical registration.

There are separate data requirements for three categories of pesticides: antimicrobials, biopesticides, and conventional pesticides. Additional information on these requirements can be found in 40 CFR 158.

FIFRA is a risk-benefit statute that authorizes EPA to register a pesticide product if it will not cause unreasonable adverse effects on human health or the environment when used according to the label.

Before allowing the use of a pesticide on food crops, EPA sets a tolerance, or maximum residue limit, which is the amount of pesticide residue allowed to remain in or on each treated food commodity. The tolerance is the residue level that triggers enforcement

actions. That is, if residues are found above that level, the commodity may be considered adulterated and can be subject to seizure by the government.

In setting the tolerance, EPA must make a safety finding under the Food Quality Protection Act that the pesticide can be used with a "reasonable certainty of no harm." To make this finding, EPA considers the toxicity of the pesticide and its break-down products, how much of the pesticide is applied and how often, how much of the pesticide (i.e., the residue) remains in or on food by the time it is marketed and prepared.

The tolerance applies to food imported into this country, as well as to food grown here in the U.S. Tolerance levels and exemptions can be found at 40 CFR 180.