

EPA Regulatory Process for Microbial Pesticides

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The first microbial pesticide was registered in 1948. As we subsequently evaluated more microbial pesticides we realized we needed different kinds of tests than the standard toxicity and environmental fate tests required for conventional chemical pesticides. We began development of unique data requirements and tests in the 1970s. We consulted scientific experts and published regulations for how to register microbial pesticides and guidelines on how to perform the testing.

The data requirements that are currently in effect were published in 1984. We are just now finishing a revision to these data requirements that better reflects the regulatory process that we have evolved over the years since then.

The revised definition for a microbial pesticide now reads:

A Microbial pesticide is a microorganism intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

- (1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae, and fungi;
- (2) Is a procaryotic microorganism, including, but not limited to, bacteria, and archaea;

or

- (3) Is an parasitic replicating microscopic element, including but not limited to, viruses.

There are now over 78 registered microbial pesticides. The BioPesticides and Pollution Prevention Division was established in 1995 to handle the increasing numbers of these specialized pesticides.

Pesticide regulation is handled under several laws, the Federal Insecticide, Fungicide, & Rodenticide Act (FIFRA), and the Federal Food, Drug, & Cosmetic Act (FFDCA), which were both modified by the Food Quality Protection Act, and the Pesticide Regulatory Improvement Act, which sets fees for regulatory actions. The laws authorize publication of rules on how the laws will be administered. These rules are published as regulations, which are first announced in the Federal Register and later published in the Code of Federal Regulations, "Title 40" Pesticides. Regulations of particular relevance to the regulated community are the following:

- 40 CFR 152.3 Definitions
- 40 CFR 152.15 Defines pesticides that need registering
- 40 CFR 152.20 Exemptions for biocontrol organisms
- 40 CFR 152.158 Data requirements
- 40 CFR 152.172 Experimental Use Permits
- 40 CFR 152.180 Tolerances (residues on foods)

In addition to regulations, we have published Guidelines, which are recommendations on how to perform the studies listed in the data requirement regulations and can be found on our website at www.epa.gov/opptsfrs/home/guidelin.htm .

We use the standard pesticide risk assessment paradigm for microbial pesticides, in that we use hazard information and exposure information to assess risk. The hazard information for microbials includes both toxicity and pathogenicity. We need to assess risk for non-target organisms, humans, domestic animals, and have to consider potential effects on endangered species.

The microbial pesticide data requirements are published in 40 CFR 158, which is currently being updated. The proposed revised data requirements were published in the March 8, 2006 Federal Register. Additional regulatory assistance information can be found at our website, www.epa.gov/pesticides/biopesticides .