Pesticide Registration Manual:

Chapter 18 - Other Federal or State Agency Requirements

Introduction

Sometimes even after obtaining a federal registration, a pesticide registrant may need to meet other federal, state, or local requirements. The following listing is only intended to provide general information on some of these requirements and/or to provide a point of contact. It should be noted that the listing is not all inclusive. It remains the applicant's and the registrant's responsibility to comply with all federal, state, or local regulations.

State Regulation of Federally Registered Pesticides

FIFRA section 24(a) provides that "A state may regulate the sale or use of any federally registered pesticide or device in the state, but only if and to the extent that the regulation does not permit any sale or use prohibited by this Act."

Even though a federal registration may have been obtained for a given pesticide product allowing the distribution and sale of the product within the United States, a state may have additional requirements that must be met before the pesticide product can be distributed or sold within that state. The requirements vary from state to state, and may include:

- additional data requirements,
- additional restrictions on pesticide use within its jurisdiction, and
- licensing requirements.

The applicant should contact each state in which the product is to be marketed to determine what additional requirements may affect the sale, distribution, or use of that product.

Guidance on FIFRA Section 24(c) registrations.

Toxic Substances Control Act (TSCA)

The Environmental Protection Agency's (EPA's) New Chemicals Program, located in the Office of Pollution Prevention and Toxics, was established to help manage the potential risk from chemicals new to the marketplace. It is mandated by section 5 of the Toxic Substances

Control Act (TSCA). TSCA, enacted by Congress in 1976, gives EPA broad authority to identify and control substances that may pose a threat to human health or the environment.

Premanufacturing Notices for New Chemicals

The New Chemicals Program functions as a "gatekeeper" that can identify conditions up to and including a ban on production to be placed on the use of a new chemical before it is entered into commerce. Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity. This premanufacturing notice, or PMN, must be submitted at least 90 days before the manufacture or import of the chemical.

Inert Ingredients Must Be on TSCA Inventory

All applicants for new inert ingredients need to confirm that their chemical is on the TSCA inventory (either “grandfathered in” or reviewed in the PMN program). If it is not, they need to go through the PMN process to get the inert on the inventory as an initial step toward its approval as an inert ingredient. Refer to the TSCA New Chemicals Program for further information.

Nonindigenous and Genetically Engineered Microbial Products Including Killed Microbials

Products of recombinant DNA technology are also regulated by EPA under TSCA by the Office of Pollution Prevention and Toxics (OPPT) during stages of production before the products become pesticides (such as during fermentation). A Premanufacturing Notice (PMN) may be required for these products. PMNs are not required while the product is under research and development (such as under an EUP), and are also not required for nonindigenous or trans conjugant organisms. For information on TSCA requirements related to microbial pesticide production contact:

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Chemical Control Division (7405)
New Chemicals Notice Management Branch
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Telephone: Toxics Assistance Information System (202) 554-1404
OPPT New Chemicals Web site

Uses of Pesticides Regulated by the Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) and EPA have several areas of mutual regulatory responsibility, which may require review by one or both agencies. The following is a brief summary of these areas and the Antimicrobial Web pages should be consulted periodically for any recent agreements between FDA and EPA on emerging technologies and issues.

Antimicrobial Pesticides Regulated by FDA and EPA

Antimicrobial agents are subject to regulation by FDA and EPA, either singly or jointly, depending upon the use. The most complex area involves the use of antimicrobials in or on food. The descriptions provided below address both food and nonfood uses regulated by FDA; antimicrobial food uses subject to dual jurisdiction, regulated by both FDA and EPA; and antimicrobial food uses regulated by EPA.

Antimicrobial Uses Regulated Solely by the FDA

The following are uses of antimicrobials that are regulated exclusively by FDA. No section 3 registration under FIFRA is required.

- Use of an antimicrobial in/on processed food.
- Application of an antimicrobial to process water in a food processing facility where the water is only a vehicle for transporting the antimicrobial chemical to the processed food.
- Use of an antimicrobial in/on living man or animal.
- Use of an antimicrobial in/on cosmetics.
- Use of an antimicrobial in/on beverages.
- Use of an antimicrobial in/on drugs.
- Use of an antimicrobial in/on animal feed.

Antimicrobial Uses Subject to Dual Jurisdiction

The following are antimicrobial food uses that are subject to dual jurisdiction. FDA regulates residues that may occur on processed food through the indirect food additives process, which

is described in 21 CFR Parts 175 - 178. These uses are also considered pesticide uses subject to registration under FIFRA. However, a food additive clearance must be obtained from FDA before EPA will approve the application. Inquiries to FDA should be directed to the address listed at the end of this section.

- Treatment of raw agricultural commodities in a food processing facility.
- Application of an antimicrobial to process water in a food processing facility to control a pest in the water (e.g., pulp and paperboard use, use in cane-sugar and beet-sugar mills).
- Production of food packaging.
- Production of food contact articles other than food packaging; no intended effect on the surface of the article.

Antimicrobial Food Uses Regulated Solely by EPA

The following are antimicrobial food uses regulated exclusively by EPA:

- Use of an antimicrobial for pre- and/or post-harvest field use on crops.
- Use of antimicrobials by consumers on raw agricultural commodities (e.g., home gardens, home produce washes).
- Application of an antimicrobial to process water for post-harvest use (field washing) of raw agricultural commodities.
- Application of an antimicrobial to animal drinking water.
- Treatment of permanent or semi-permanent food contact surfaces (sanitizers).
- Use of an antimicrobial in the production of food contact articles, other than food packaging, where the antimicrobial is intended to have an ongoing effect on the article's food contact surface or in food that may contact the article.

Contact Information for FDA

Inquiries and questions concerning establishment of indirect food additive regulations and FDA jurisdiction should be sent to the following address:

Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
FDA Web site

Antimicrobial Pesticides Used on Medical Devices

An antimicrobial agent used on medical devices is considered by FDA to be an accessory to a medical device. Accordingly, FDA requires pre-market notification under section 510(k) of the FFDCA for marketing of such agents. FDA reviews the safety and efficacy of these antimicrobial products. Approval by both FDA and EPA must be obtained before these products may be sold or distributed. Section 510(k) petitions may be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Division of Gastroenterology-Urology and General Use Devices
Office of Device Evaluation
(HFZ-332) 8757 Georgia Avenue
Silver Spring, MD 20910
CDRH Web site

Human Drugs

FDA and EPA have areas of mutual responsibility with respect to applications for drugs under FFDCA and for registration of pesticides under FIFRA. In 1971, FDA and EPA issued a "Memorandum of Agreement" stating which agency has primary or secondary responsibility on specific matters (Federal Register Notice, 36 FR 24234). This agreement was updated in 1973 (38 FR 24233), in 1979 (44 FR 63749), in 1993 referring to pediculicides (58 FR 65452), and in 1994 (PR Notice 94-6). Briefly, EPA has primary jurisdiction for disinfectants and sanitizers.

FDA has primary jurisdiction for new human drugs, and products that are intended to:

- control parasites on humans,
- relieve the effect of insect bites,
- prevent diaper rash through treatment of diapers,
- treat athletes foot, and
- treat drinking water to control animal parasites or diseases.

Questions on these areas of jurisdiction may be referred to EPA's Antimicrobials Division for disinfectant and sanitizer treatments, and Registration Division, Insecticide Branch, for human or animal drug/pesticide treatments. Please refer to Chapter 21 of this manual.

Animal Drugs

The EPA and FDA are currently in discussion to determine what categories of products are regulated as pesticides and what categories of products are regulated as animal drugs. Applicants should contact either FDA or EPA for additional information.

Use of Pesticides Regulated by the Federal Aviation Administration (FAA)

Antimicrobial Fuel Additives

Any pesticide product intended for use in aviation fuel must have the approval of the Federal Aviation Administration (FAA) for use in aircraft engines. Persons who wish to obtain FAA approval must submit their request to:

U.S. Department of Transportation
Federal Aviation Administration
FAA Flight Standards Service
Engineering and Manufacturing Division
Washington, DC 20591
Telephone number: (202) 366-4000
FAA Flight Standards Service Web site

Use of Pesticides Regulated by the Department of Transportation (DOT)

Shipping (Transportation) of Pesticides

The U.S. Department of Transportation (DOT) and EPA have several areas of mutual regulatory responsibility, which may require review by one or both agencies.

The Hazardous Material Transportation Uniform Safety Act, as amended in 1990, requires that pesticides being shipped are properly packaged, marked, and labeled. If the pesticide to be shipped is considered a hazardous material, it will need to bear the proper DOT Hazard Warning Labels prominently on the product labeling. Also, depending upon the size of the shipment, trucks may need to be placarded.

If you wish to transport pesticides that may present physical or chemical hazards, you must obtain shipping papers from DOT before such shipment.

For additional information on the transportation of pesticides, and how to obtain shipping papers, contact:

Department of Transportation
Office of Hazardous Material Standards (Rm. 8100)
400 7th St., S.W.
Washington, DC 20590-0001
Phone: (202) 366-4488
HAZMAT Web site

U.S. Department of Agriculture (USDA)

Any organism (including plants) may be considered a potential plant pest. Such organisms may be regulated under either the Plant Pest Act and/or the Plant Quarantine Act. Such organisms may require a permit for import and/or introduction testing, and use. For information on USDA permit requirements contact:

U.S. Department of Agriculture
Plant Protection and Quarantine Service
Unit 133
4700 River Road
Riverdale, MD 20737
Telephone: (301) 734-8896
USDA Plant Web site

National Organics Program

The National Organic Program (NOP) develops, implements, and administers national production, handling, and labeling standards for organic agricultural products. The NOP also accredits the certifying agents (foreign and domestic) who inspect organic production and handling operations to certify that they meet USDA standards. Pesticide Registration Notice 2003-1 describes how registrants can obtain EPA approval of label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that pesticide meet the criteria defined in the USDA NOP Rule.

Occupational Safety and Health Administration (OSHA) Requirements

As employers, pesticide manufacturers and registrants may be subject to requirements designed to promote worker safety and health under the laws administered by OSHA.

OSHA under 29 CFR 1910 has established health standards (such as permissible exposure limits for certain hazardous chemicals) and safety standards (such as providing personal protective equipment). These standards may be applicable to workplaces where pesticides are manufactured, handled or stored, if these hazards are present. In addition, generally the Hazard Communication Standard (HCS) (29 CFR 1910.1200 requires labeling, material safety data sheets, and training for workers who may be exposed to hazardous chemicals. One exception is that pesticides bearing an EPA-approved FIFRA label are not subject to the OSHA label requirements, though the HCS data sheet and training requirements may still apply.

More information on OSHA requirements is available on OSHA's web site.

References Cited in Chapter 18

Refer to Chapter 19 for information on the source of these documents.

Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act of August 3, 1996

- Section 3 - Registration of pesticides
- Section 24 - Authority of States

Toxic Substances Control Act

- Section 5 - New Chemicals Program

Federal Food, Drug and Cosmetic Act

- Section 510(k)

Federal Register Notices

- 36 FR 24234
- 38 FR 24233
- 44 FR 63749
- 58 FR 65452

PR Notice 94-6 - Pesticide Products Registered for Use on Humans to Control Lice (Pediculicides)