

APPENDIX F
PESTICIDE LAW AND DEFINITIONS



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This appendix briefly outlines some of the Federal laws that regulate pesticides in the United States. It does not include every law that pertains to pesticides but touches on those most pertinent for surveillance of acute human illness and injury. The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticide products marketed in the United States. Each State will have its own set of statutes and administrative rules that address pesticides and reflect these Federal laws.

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F.1 FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

FIFRA was first passed in 1947. It was primarily a consumer protection law aimed at protecting pesticide users from products that did not contain active ingredients or sufficient active ingredients to be effective. FIFRA underwent extensive amendments by Congress in 1972 that required comprehensive testing of both old and new products. This required the review of 600 active ingredients and 50,000 registered pesticide products. These amendments shifted the emphasis of FIFRA to protecting human health and the environment from unreasonable adverse risks associated with the use of pesticides. This was intended by Congress to include protections for farmers, farmworkers, and others who were in contact with pesticides. The regulatory approach required an evaluation of risks and benefits from the use of pesticide products. The data requirements issued in 1975 were quite extensive. They required manufacturers to provide information about general chemistry, environmental fate, short- and long-term toxicity, ecological effects, and crop residues. In 1982, the EPA proposed additional changes to the data requirements, and in 1983, published technical guidelines for carrying out the required studies for registration. Registration review is based on an assessment of the potential effects of a product on human health and the environment when it is used according to the label. Because the labels are considered to have the force of law, use not in accordance with the label may result in civil or criminal penalties.

The 1988 amendments to FIFRA required that reregistration of products be completed more rapidly and imposed timelines for portions of the pesticide registration process. These amendments also made changes in EPA's funding, authorized fee collection for some new activities, and significantly altered

responsibilities relating to suspended and canceled pesticides. These changes removed the requirement that EPA accept and dispose of canceled and suspended pesticides at EPA expense and eliminated certain clauses requiring EPA to provide compensation for the storage and disposal of suspended or canceled pesticides.

Other more recent amendments to FIFRA are discussed under the specific sections of the statute and will reference the associated codified regulations. The pesticide regulations are found in the *Code of Federal Regulations, Title 40, Protection of the Environment, Chapter 1, Environmental Protection Agency, Parts 150 to 189 (40 CFR 150–189)*. In addition to the provisions already mentioned, FIFRA requires EPA and the States to establish programs to provide training to and certification of applicators, and to protect workers. It is important for surveillance program staff to have a basic understanding of FIFRA and the regulations that codify it. This will aid interagency cooperation since section numbers of FIFRA are often used in referring to types of enforcement inspections and pesticide product registrations. This section provides a brief summary of the sections of FIFRA pertinent to surveillance for pesticide-related illness.

SECTIONS 1 AND 2: DEFINITIONS

FIFRA Sections 1 and 2 are a table of contents and definitions. Selected definitions that are particularly important for surveillance are as follows:

“PEST—The term *pest* means (1) any insect, rodent, nematode, fungus, weed or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under Section 25(c)(1).”

Note that the definition of *pest* is based only on humans deciding that a particular organism is deleterious or undesirable. An organism may be a pest to an individual or locale and may be considered a desirable part of the ecosystem in another location. This is particularly true for plant species where what is considered a weed in one area may be grown as a crop in another area.

“Pesticide—The term *pesticide* means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, . . .”

Although the majority of the public tends to think of pesticides primarily as chemicals that kill pests, it is important to note that this definition in FIFRA also includes products that repel, prevent, and mitigate pests.

“To Use Any Registered Pesticide in a Manner Inconsistent with its Labeling—The term *to use any registered pesticide in a manner inconsistent with its labeling* means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the label

specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with Section 5, 18, or 24 of this Act, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in Section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.”

This definition is a critical one for determining whether pesticides are used correctly, and it is frequently used at the State level when regulatory actions are taken.

SECTIONS 3, 4, AND 24(C): PESTICIDE REGISTRATION AND REREGISTRATION

The registration of pesticide products is covered under Sections 3 and 4 of FIFRA. The specific requirements for product registration are covered in 40 CFR Parts 152 to 167. As already mentioned this includes the review and “reregistration” of all pesticides. This also includes the review of pesticide product labels to ensure that they meet product labeling requirements codified in Part 156. Products must be registered if they meet the definition of a pesticide under 40 CFR, Section 152.15; and the product label or other materials indicate claims of pesticidal activity; or the product is represented in a manner that results in its being used as a pesticide. Requirements relating to worker protection are codified in 40 CFR 170; these will be discussed separately.

Products that are not considered pesticides and are exempt from FIFRA include those designed to control fungi, bacteria, viruses, microorganisms, or internal parasites/nematodes in living man or animals and are labeled for that purpose (e.g., pharmaceuticals). Other nonpesticides are plant nutrients, soil amendments, fertilizers, and disinfectants (including deodorizers and bleaching or cleaning agents) that do not make pesticidal claims.

Some additional products meet the definition of pesticides but are exempt from registration. These include pesticides regulated by another Federal agency, such as certain biological control agents and certain human drugs. Other exempted products with specific criteria are described in CFR 40 Section 152.25 and include treated articles or substances such as fabrics or paints where a registered pesticide is used to preserve the product itself; pheromones and pheromone traps meeting particular labeling criteria; preservatives for biological specimens and foods; natural cedar (not including oils, extracts, or mixtures); and minimum risk pesticides. Certain conditions allow pesticides to be transferred, sold, or distributed without registration as specified in CFR 40 Section 152.30.

Six registration types are provided for in FIFRA: new, amended, supplemental, reregistration, renewal, and Section 24(c) registrations. The requirements for submitting an application for registration are covered in CFR 40 Sections 152.40 through 152.175. The new registration is strictly that (that is, registration for a new pesticide product). An amended registration must be submitted if there is a proposed change in a product's composition, label, or packaging.

Reregistration and *renewal* refer to the processes for updating and reviewing previously approved uses on the basis of new data and standards. Section 4 of FIFRA covers the complex process established for reregistration.

Supplemental registrations allow distributors to assign their own brand name to a product that is registered by the producer. The product must be the same composition and be produced, labeled, and packaged in a registered establishment of the same producer. The supplemental product label must make the same claims as the primary product (some claims may be deleted), the product must be in the producer's container, and the registration number must have the distributor's company number added as a suffix.

Section 24(c) registrations are also referred to as *special local needs registrations*. These are issued when a State assigns an additional use for a federally registered product based on a local need. The State gives the product a special local need registration number and informs the EPA of this action within 10 days. The EPA then publishes the registration change in the Federal Register.

SECTION 5: EXPERIMENTAL USE PERMITS (EUPs)

EUPs are issued by the EPA to allow applicants to develop data needed to submit an application under FIFRA Section 3. These permits have specific terms, conditions, and time limitations and may be revoked at any time. A State with an approved State plan may issue EUPs.

SECTION 6: ADMINISTRATIVE REVIEW; SUSPENSION

This section provides the EPA with the authority to cancel and/or suspend a pesticide registration. A registration must be canceled after 5 years if the registrant or an interested party does not request renewal of the registration before the end of the 5 years. The registrant is also required to submit additional information about adverse effects that is obtained after the registration (Section 6[a] [2]). The actual reporting requirements under this part of FIFRA were codified in 1997 by the addition of Part 159 to 40 CFR. The specific information that must be reported on toxic or adverse effect incident reports are addressed in Section 159.184. For more information about the 6(a)(2) regulations and reporting requirements, refer to <http://www.epa.gov/pesticides/fifra6a2.htm>.

The EPA may also issue a Notice of Intent to Cancel if there is information indicating that a pesticide, its label, or other required material does not comply with FIFRA. A hearing process and additional consultations are required as part of this process to cancel or reclassify a pesticide. Canceled pesticides

that are already in the channels of trade may be sold or used after cancellation unless this is specifically prohibited in the cancellation order.

A suspension order may be issued after notifying the registrant and if EPA determines that there is an “imminent hazard” to human health posed by the continued use of a pesticide during the time necessary for cancellation. (Note: There may also be hearings as part of a suspension order.) Typically, the distribution, sale, or use is prohibited when a pesticide is suspended, although there are some circumstances when the sale or use of existing stocks is allowed.

SECTION 7: REGISTRATION OF ESTABLISHMENTS

This section requires that producers register establishments engaged in producing pesticide products or active ingredients used in these products. EPA assigns an establishment number that is associated with the name and address of the establishment. The types of records that must be maintained by establishments are described here. Specific annual reporting requirements exist for establishments and descriptions of what portion of required information is considered confidential.

SECTION 11: USE OF RESTRICTED USE PESTICIDES; APPLICATORS

The certification of applicators by EPA or State designees is described in this section. It includes requirements for making instruction on integrated pest management techniques available upon request. It establishes that there should be separate standards for commercial and private applicators.

SECTION 12: UNLAWFUL ACTS

A wide range of unlawful acts involving the sale, shipment, adulteration, registration, use, and testing of pesticides are described in this section. The FIFRA amendments of 1972 added the following language that designates the label as a legal document: “to use any registered pesticide in a manner inconsistent with its labeling.”

SECTION 13: STOP SALE, USE, REMOVAL, AND SEIZURE

EPA or State designees are given the authority to issue stop sale, use, or removal orders if a pesticide or device is in violation of any portion of FIFRA. This includes pesticides that have been canceled by final order or suspended. The seizure of pesticides or devices through district court is prescribed for as described below:

- Pesticides that are adulterated or misbranded, not registered, improperly labeled, not colored, or discolored as required by FIFRA
- Product claims or directions for use are not those made in connection with its registration
- Misbranded devices
- A pesticide or device, when used in accordance with the requirements imposed by FIFRA and according to the label, still causes unreasonable adverse effects on the environment

Disposition of seized pesticides or devices, associated costs, and court costs are also covered in this section.

SECTION 18: EXEMPTION OF FEDERAL AND STATE AGENCIES

The EPA may exempt Federal or State agencies from any provision of FIFRA if it is determined that there are emergency conditions that require such an exemption. A Federal or State agency may request the determination from EPA that an emergency exists. EPA must consult with the U.S. Secretary of Agriculture and the governor of the concerned State when making the determination.

SECTIONS 22, 23, 26, AND 27: DELEGATION AND COOPERATION

Section 22 allows the Administrator to delegate authority to employees and directs the Administrator to cooperate with the U.S. Department of Agriculture (USDA) and appropriate State or political subdivisions to carry out the act and secure uniform regulations. Section 23 of FIFRA describes the authority for cooperative agreements between EPA and States. Under Sections 26 and 27, when information of an alleged violation of FIFRA or complaints are received by EPA, these will be referred to the State, and only “significant” complaints are tracked and followed by EPA. These sections authorize States to conduct inspections using Federal authority when such inspections are not authorized by State statutes. Funding of cooperative programs is shared by EPA and the State participants. The state may refer cases to EPA for Federal, civil, or criminal enforcement action.

WORKER PROTECTION STANDARD (WPS)

Under the 1972 revisions to FIFRA, changes required new wording on labels to increase worker safety, and in 1974, rules were promulgated that specifically addressed worker protection in 40 CFR 170. The 1974 changes were the addition of four basic requirements that pertained to hand laborers and included the following: workers should not be directly sprayed with pesticides; re-entry into treated areas was prohibited until dust was settled or spray dry with longer re-entry intervals for 12 specific pesticides; protective equipment was required for early re-entry; and “appropriate and timely warnings” regarding pesticide applications. The rules exempted many operations that use pesticides and did not include pesticide handlers. Reports of worker poisonings and concerns about the vagueness of the rules caused EPA to review these standards in 1983. An extensive process led to proposed revisions released in 1988. The final proposed rule was promulgated in 1992 and made changes to 40 CFR Part 170 and 40 CFR Part 156. These became fully effective in January of 1995.

Provisions of WPS include changes in labeling, an expanded scope of coverage to cover more workers and operations, prohibition of employer retaliation for attempting to comply with the standard, and requirements for

- warnings about pesticide applications
- use of personal protective equipment (PPE)
- restriction on re-entry into treated areas

- decontamination
- emergency assistance
- maintaining contact with handlers of highly toxic pesticides
- pesticide safety training

Following WPS enactment, EPA initiated a process to evaluate the impact of the standard. More information about WPS, compliance guides, training materials, and a *Field Inspection Pocket Guide* can be obtained from the EPA. (See Appendix G or go to <http://www.epa.gov/pesticides/safety/workers/amendmnt.htm>.) This Web site also contains information about EPA's ongoing assessment of WPS.

F.2 FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA)

This act requires the establishment of tolerances for the maximum amount of pesticide residues allowed in or on human food and animal feed products. It is jointly administered by EPA and the Food and Drug Administration (FDA).

F.3 FOOD QUALITY PROTECTION ACT (FQPA)

This law is a 1996 amendment to FIFRA and FFDCA, which changes the way standards are set for tolerances. It requires a health-based standard for assessing the risks of pesticide residues in food and feed. This standard differs significantly from past approaches in that it requires evaluating aggregated risk from dietary exposure as well as other nonoccupational sources of exposure such as drinking water and residential pesticide use. It also emphasizes the risks to infants and children. Additionally, EPA must consider cumulative exposure by evaluating the combined effects of different pesticides that may act in similar ways on the human body. The law also established a new standard for evaluating food-use pesticides: "reasonable certainty of no harm." This is in contrast to the previous standard of "no unreasonable adverse effects" that required a risk-benefit assessment. FQPA also requires reevaluation of all existing tolerances within 10 years. FQPA also

- includes authority to require testing for endocrine effects
- allows FDA to impose civil violations
- requires that a brochure on the health effects of pesticides be placed in grocery stores and allows States to require warnings or specific labeling of food that has been treated with pesticides
- prevents States from setting tolerances that are different from the Federal levels (*Note: There is a process for exceptions*)
- sets a 15-year cycle for pesticide reregistration renewal and provides additional funding for EPA processing of reregistration applications
- provides a faster registration process for new, safer pesticides
- establishes a minor use program to address EPA and USDA management of pesticides that have minor uses

- establishes new requirements for antimicrobial pesticides and clarifies jurisdiction
- establishes definitions and registration requirements for public health pesticides
- establishes definitions and regulation of two new categories of pesticide applicators: (1) maintenance applicators and (2) service technicians

Appendix G contains references for more information about FQPA.

F.4 SAFE DRINKING WATER ACT (SDWA)

SDWA was enacted to protect the quality of surface and below-ground sources of drinking water. It authorizes EPA to set standards for contaminants in drinking water including pesticides. As amended in 1996, it includes establishment for screening and testing programs for a variety of chemicals and pesticides, including endocrine effects of these chemicals.

F.5 OCCUPATIONAL SAFETY AND HEALTH ACT (OSH ACT)

The OSH Act was originally passed in 1970 and has undergone extensive amendments over the last 30 years. It provides for a safe and healthful working environment by giving authority to OSHA or its State partners to develop standards and enforce them. The act allows civil and criminal penalties to be issued for violations. There are 26 states with authorized State plans with standards that are at least as strict as Federal standards codified in 29 CFR Parts 1900–2400. State programs are based in a variety of State agencies depending upon the structure of State government; frequently the State OSH Act program is in the State bureau of labor or the State department of business and consumer affairs or equivalent. The State plans in Connecticut and New York cover only State and local government employees. Federal OSHA maintains offices in the non-State plan States to enforce provisions of the OSH Act.

At the Federal level, the interpretation of jurisdiction is that enforcement of issues associated with labeled pesticide products are within the purview of the EPA. State plans may have stricter interpretations and separate agreements with EPA or the State agency EPA designee responsible for enforcing FIFRA.

Responsibility for enforcing issues associated with the manufacture of pesticides prior to the placement of a FIFRA registered label on a container would fall under OSHA. The general industry-relevant portions of 29 CFR 1910 related to pesticide exposure are contained in

Subpart G—Occupational Health and Environmental Control (1910.94 to 1910.98)

Subpart H—Hazardous Materials (1910.101 to 1910.126)

Subpart I—Personal Protective Equipment (1910.132 to 1910.139)

Subpart J—General Environmental Controls (1910.141 to 1910.147 Appendix A)

Subpart K—Medical and First Aid (1910.151 to 1910.152)

Subpart Z—Toxic and Hazardous Substances (1910.1000 to 1910.1450 and Appendices), which includes air contaminants and hazard communication

A variety of other Federal regulations that involve pesticides are not highlighted in this manual since they may not be relevant to pesticide poisoning surveillance. These include, but are not limited to, the Resource Conservation and Recovery Act, the Clean Air Act, and the Endangered Species Act. Surveillance programs may need to become familiar with these acts or State laws related to them to address issues raised during particular case investigations. Other issues related to interagency coordination and overlapping jurisdictions are addressed in Chapters 5 and 6.