

§ 159.195

methods specified on the label if either of the following conditions is met:

(1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions.

(2) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

§ 159.195 Reporting of other information.

(a) The registrant shall submit to the Administrator information other than that described in §§159.165 through 159.188 if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product. Examples of the types of information which must be provided if not already reportable under some other provision of this Part include but are not limited to information showing:

(1) Previously unknown or unexpected bioaccumulation of a pesticide by various life forms.

(2) Greater than anticipated drift of pesticides to non-target areas.

(3) Use of a pesticide may pose any greater risk than previously believed or reported to the Agency.

(4) Use of a pesticide promotes or creates secondary pest infestations.

(5) Any information which might tend to invalidate a study submitted to the Agency to support a pesticide registration.

(b) A registrant is not obligated under paragraph (a) of this section to provide information to the Administrator if the registrant is aware of facts which establish that otherwise reportable information is not correct.

(c) The registrant shall submit to the Administrator information other than that described in §§159.165 through 159.188 if the registrant has been informed by EPA that such additional information has the potential to raise

40 CFR Ch. I (7-1-06 Edition)

questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

[62 FR 49388, Sept. 19, 1997; 63 FR 33583, June 19, 1998]

PART 160—GOOD LABORATORY PRACTICE STANDARDS

Subpart A—General Provisions

Sec.

160.1 Scope.

160.3 Definitions.

160.10 Applicability to studies performed under grants and contracts.

160.12 Statement of compliance or non-compliance.

160.15 Inspection of a testing facility.

160.17 Effects of non-compliance.

Subpart B—Organization and Personnel

160.29 Personnel.

160.31 Testing facility management.

160.33 Study director.

160.35 Quality assurance unit.

Subpart C—Facilities

160.41 General.

160.43 Test system care facilities.

160.45 Test system supply facilities.

160.47 Facilities for handling test, control, and reference substances.

160.49 Laboratory operation areas.

160.51 Specimen and data storage facilities.

Subpart D—Equipment

160.61 Equipment design.

160.63 Maintenance and calibration of equipment.

Subpart E—Testing Facilities Operation

160.81 Standard operating procedures.

160.83 Reagents and solutions.

160.90 Animal and other test system care.

Subpart F—Test, Control, and Reference Substances

160.105 Test, control, and reference substance characterization.

160.107 Test, control, and reference substance handling.

160.113 Mixtures of substances with carriers.

Subpart G—Protocol for and Conduct of a Study

160.120 Protocol.

160.130 Conduct of a study.

Environmental Protection Agency

§ 160.3

160.135 Physical and chemical characterization studies.

Subparts H-I [Reserved]

Subpart J—Records and Reports

160.185 Reporting of study results.

160.190 Storage and retrieval of records and data.

160.195 Retention of records.

AUTHORITY: 7 U.S.C. 136a, 136c, 136d, 136f, 136j, 136t, 136v, 136w; 21 U.S.C. 346a, 348, 371, Reorganization Plan No. 3 of 1970.

SOURCE: 54 FR 34067, Aug. 17, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 160.1 Scope.

(a) This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3, 4, 5, 8, 18 and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136a, 136c, 136f, 136q and 136v(c)) and sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a, 348).

(b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after October 16, 1989.

§ 160.3 Definitions.

As used in this part the following terms shall have the meanings specified:

Application for research or marketing permit includes:

(1) An application for registration, amended registration, or reregistration of a pesticide product under FIFRA sections 3, 4 or 24(c).

(2) An application for an experimental use permit under FIFRA section 5.

(3) An application for an exemption under FIFRA section 18.

(4) A petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408.

(5) A petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409.

(6) A submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B).

(7) Any other application, petition, or submission sent to EPA intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.

Batch means a specific quantity or lot of a test, control, or reference substance that has been characterized according to § 160.105(a).

Carrier means any material, including but not limited to feed, water, soil, nutrient media, with which the test substance is combined for administration to a test system.

Control substance means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance for known chemical or biological measurements.

EPA means the U.S. Environmental Protection Agency.

Experimental start date means the first date the test substance is applied to the test system.

Experimental termination date means the last date on which data are collected directly from the study.

FDA means the U.S. Food and Drug Administration.

FFDCA means the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 321 *et seq.*).

FIFRA means the Federal Insecticide, Fungicide and Rodenticide Act as amended (7 U.S.C. 136 *et seq.*).

Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

Quality assurance unit means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.