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.