# **Environmental Protection Agency**

159.188 if the registrant has been informed by EPA that such additional information has the potential to raise 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 and applicability.

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.

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, 371, Reorganization Plan No. 3 of 1970.

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

# Subpart A—General Provisions

## § 160.1 Scope and applicability.

(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, as amended, and section 408 or 409 of the Federal Food, Drug and Cosmetic Act.

(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.

[73 FR 75597, Dec. 12, 2008]

## § 160.3 Definitions.

As used in this part the following terms shall have the meanings speci-

Application for research or marketing permit means any of the following:

- (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.