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



## Subpart B—Organization and Personnel



## Subpart C—Facilities



## Subpart D—Equipment



## Subpart E—Testing Facilities Operation



## Subpart F—Test, Control, and Reference Substances



## Subpart G—Protocol for and Conduct of a Study



## Subparts H–I [Reserved]

## Subpart J—Records and Reports



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 specified:

*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.