§ 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.


*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.

*Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. “Raw data” may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

*Reference substance* means any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements.

*Specimen* means any material derived from a test system for examination or analysis.

*Sponsor* means:

1. A person who initiates and supports, by provision of financial or other resources, a study;
2. A person who submits a study to the EPA in support of an application for a research or marketing permit; or
§ 160.10 Applicability to studies performed under grants and contracts.

When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part.

§ 160.12 Statement of compliance or non-compliance.

Any person who submits to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types:

(a) A statement that the study was conducted in accordance with this part; or

(b) A statement describing in detail all differences between the practices used in the study and those required by this part; or

(c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.

§ 160.15 Inspection of a testing facility.

(a) A testing facility shall permit an authorized employee or duly designated representative of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies. The