

## § 792.1

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AUTHORITY: 15 U.S.C. 2603.

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### Subpart A—General Provisions

#### § 792.1 Scope.

(a) This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing. This part is intended to ensure the quality and integrity of data submitted pursuant to testing consent agree-

ments and test rules issued under section 4 of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2006, 15 U.S.C. 2603 *et seq.*).

(b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after September 18, 1989.

(c) It is EPA's policy that all data developed under section 5 of TSCA be in accordance with provisions of this part. If data are not developed in accordance with the provisions of this part, EPA will consider such data insufficient to evaluate the health and environmental effects of the chemical substances unless the submitter provides additional information demonstrating that the data are reliable and adequate.

#### § 792.3 Definitions.

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

*Batch* means a specific quantity or lot of a test, control, or reference substance that has been characterized according to § 792.105(a).

*Carrier* means any material, including but not limited to, feed, water, soil, and 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 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

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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 response to a TSCA section 4(a) test rule and/or a person who submits a study under a TSCA section 4 testing consent agreement or a TSCA section 5 rule or order to the extent the agreement, rule or order references this part; or

(3) A testing facility, if it both initiates and actually conducts the study.

*Study* means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, environmental and chemical fate, persistence, or other characteristics in humans, other living organisms, or media. The term "study"

does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.

*Study completion date* means the date the final report is signed by the study director.

*Study director* means the individual responsible for the overall conduct of a study.

*Study initiation date* means the date the protocol is signed by the study director.

*Test substance* means a substance or mixture administered or added to a test system in a study, which substance or mixture is used to develop data to meet the requirements of a TSCA section 4(a) test rule and/or is developed under a TSCA section 4 testing consent agreement or section 5 rule or order to the extent the agreement, rule or order references this part.

*Test system* means any animal, plant, microorganism, chemical or physical matrix, including but not limited to, soil or water, or components thereof, to which the test, control, or reference substance is administered or added for study. "Test system" also includes appropriate groups or components of the system not treated with the test, control, or reference substance.

*Testing facility* means a person who actually conducts a study, i.e., actually uses the test substance in a test system. "Testing facility" encompasses only those operational units that are being or have been used to conduct studies.

*TSCA* means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*)

*Vehicle* means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

### § 792.10 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.