

## SUBCHAPTER R—TOXIC SUBSTANCES CONTROL ACT (CONTINUED)

### PART 790—PROCEDURES GOVERNING TESTING CONSENT AGREEMENTS AND TEST RULES

AUTHORITY: 15 U.S.C. 2603.

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#### Subpart A—General Provisions

##### § 790.1 Scope, purpose, and authority.

(a) This part establishes procedures for gathering information, conducting negotiations, and developing and implementing test rules or consent agreements on chemical substances and mixtures under section 4 of TSCA.

(b) Section 4 of the Act authorizes EPA to require manufacturers and processors of chemical substances and mixtures to test these chemicals to determine whether they have adverse health or environmental effects. Section 4 (a) empowers the Agency to promulgate rules which require such testing. In addition, EPA has implied authority to enter into enforceable consent agreements requiring testing where they provide procedural safeguards equivalent to those that apply where testing is conducted by rule.

(c) EPA intends to use enforceable consent agreements to accomplish testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing.

[51 FR 23712, June 30, 1986, as amended at 75 FR 56475, Sept. 16, 2010]

##### § 790.2 Applicability.

This part is applicable to manufacturers and processors of chemical substances or mixtures who are subject to the testing requirements of a consent agreement or a rule under section 4(a) of the Act. The procedures for test rules are applicable to each test rule in part 799 or this chapter unless otherwise stated in specific test rules in part 799 of this chapter.

[51 FR 23712, June 30, 1986]

##### § 790.3 Definitions.

Terms defined in the Act and not explicitly defined herein are used with the meaning given in the Act. For the purpose of this part:

## § 790.5

*Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

*Additive* means a chemical substance that is intentionally added to another chemical substance to improve its stability or impart some other desirable quality.

*Chemical* means a chemical substance or mixture.

*Consortium* means an association of manufacturers and/or processors who have made an agreement to jointly sponsor testing.

*EPA* means the U.S. Environmental Protection Agency.

*Equivalence data* means chemical data or biological test data intended to show that two substances or mixtures are equivalent.

*Equivalent* means that a chemical substance or mixture is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance.

*Exemption* means an exemption from a testing requirement of a test rule promulgated under section 4 of the Act and part 799 of this chapter.

*Impurity* means a chemical substance which is unintentionally present with another chemical substance.

*Joint sponsor* means a person who sponsors testing pursuant to section 4(b)(3)(A) of the Act.

*Joint sponsorship* means the sponsorship of testing by two or more persons in accordance with section 4(b)(3)(A) of the Act.

*Person* means an individual, partnership, corporation, association, scientific or academic establishment, or organizational unit thereof, and any other legal entity.

*Principal sponsor* means an individual sponsor or the joint sponsor who assumes primary responsibility for the direction of a study and for oral and written communication with EPA.

*Protocol* means the plan and procedures which are to be followed in conducting a test.

*Reimbursement period* refers to a period that begins when the data from the last non-duplicative test to be completed under a test rule are submitted to EPA and ends after an amount of time equal to that which had been re-

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quired to develop data or after five years, whichever is later.

*Sponsor* means the person or persons who design, direct and finance the testing of a substance or mixture.

*Test substance* means the form of chemical substance or mixture that is specified for use in testing.

[49 FR 39782, Oct. 10, 1984, as amended at 51 FR 23712, June 30, 1986]

### § 790.5 Submission of information.

(a) All submissions to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule, or indicate the identity of the consent agreement. For all submissions under this part, six copies must be provided to EPA.

(b) Submissions containing both confidential business information or non-confidential business information must be addressed to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: TSCA Section 4.

[50 FR 20656, May 17, 1985, as amended at 51 FR 23712, June 30, 1986; 58 FR 34205, June 23, 1993; 60 FR 31922, June 19, 1995; 60 FR 34466, July 3, 1995; 71 FR 33642, June 12, 2006]

### § 790.7 Confidentiality.

(a) Any person subject to the requirements of a consent agreement or a test rule under section 4 of the Act may assert a claim of confidentiality for certain information submitted to EPA in response to the consent agreement or the test rule. Any information claimed as confidential will be treated in accordance with the procedures in part 2 of this title and section 14 of the Act. Failure to assert a claim of confidentiality at the time the information is submitted will result in the information being made available to the public without further notice to the submitter.

(b) A claim of confidentiality must be asserted by circling or otherwise marking the specific information claimed as confidential and designating it with the words "confidential business information," "trade secret," or another appropriate phrase indicating its confidential character.