

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

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

#### **Subpart A—General Provisions**

Sec.

- 790.1 Scope, purpose, and authority.
- 790.2 Applicability.
- 790.3 Definitions.
- 790.5 Submission of information.
- 790.7 Confidentiality.

#### **Subpart B—Procedures for Developing Consent Agreements and Test Rules**

- 790.20 Recommendation and designation of testing candidates by the ITC.
- 790.22 Procedures for gathering information and negotiating consent agreements on chemicals which the ITC has recommended for testing with an intent to designate.
- 790.24 Criteria for determining whether a consensus exists concerning the provisions of a draft consent agreement.
- 790.26 Initiation and completion of rule-making proceedings on ITC-designated chemicals.
- 790.28 Procedures for developing consent agreements and/or test rules for chemicals that have not been designated or recommended with intent to designate by the ITC.

#### **Subpart C—Implementation, Enforcement, and Modification of Test Rules**

- 790.40 Promulgation of test rules.
- 790.42 Persons subject to a test rule.
- 790.45 Submission of letter of intent to conduct testing or exemption application.
- 790.48 Procedure if no one submits a letter of intent to conduct testing.
- 790.50 Submission of study plans.
- 790.52 Phase II test rule.
- 790.55 Modification of test standards or schedules during conduct of test.
- 790.59 Failure to comply with a test rule.

#### **Subpart D—Implementation, Enforcement and Modification of Consent Agreements**

- 790.60 Contents of consent agreements.
- 790.62 Submission of study plans and conduct of testing.
- 790.65 Failure to comply with a consent agreement.
- 790.68 Modification of consent agreements.

#### **Subpart E—Exemptions From Test Rules**

- 790.80 Submission of exemption applications.
- 790.82 Content of exemption application.
- 790.85 Submission of equivalence data.
- 790.87 Approval of exemption applications.
- 790.88 Denial of exemption application.
- 790.90 Appeal of denial of exemption application.
- 790.93 Termination of conditional exemption.
- 790.97 Hearing procedures.
- 790.99 Statement of financial responsibility.

#### **APPENDIX A TO SUBPART E—SCHEDULE FOR DEVELOPING CONSENT AGREEMENTS AND TEST RULES**

AUTHORITY: 15 U.S.C. 2603.

#### **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. If such a consensus does not exist and the Agency believes that it can make the findings specified in section 4(a), EPA will initiate proceedings to promulgate test rules which will be codified in part 799 of this chapter.

## § 790.2

## 40 CFR Ch. I (7–1–03 Edition)

(d) Appendix A to this part presents timetables for various steps in the evaluation of chemicals under consideration for testing, the initiation and completion of negotiations to develop consent agreements, and the proposal and promulgation of test rules. All deadlines which are imposed by the Act are binding on EPA and will be observed by the Agency. The remaining deadlines represent target dates that EPA intends to meet.

[51 FR 23712, June 30, 1986]

### § 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:

*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 required 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