

§ 790.2

40 CFR Ch. I (7-1-06 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 Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT),

Environmental Protection Agency

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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.

(c) If a person asserts a claim of confidentiality for study plan information described in §§ 790.50(c)(1)(iii)(D), (iv), (v), and (vi) and 790.62(b)(6), (7), (8), (9), and (10), the person must provide a detailed written substantiation of the claim by answering the questions in this paragraph. Failure to provide written substantiation at the time the study plan information is submitted will be considered a waiver of the claim of confidentiality, and the study plan information will be disclosed to the public without further notice.

(1) Would disclosure of the study plan information disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur.

(2) Would disclosure of the study plan information disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur.

(3) What harmful effects to your competitive position, if any, do you think

would result from disclosure of this information? How would a competitor use such information? How substantial would the harmful effects be? What is the causal relationship between disclosure and the harmful effects?

(4) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(5) What measures have you taken to guard against disclosure of this information to others?

(6) To what extent has this information been disclosed to others? What precautions have been taken in connection with such disclosures?

(7) Has this information been disclosed to the public in any forms? Describe the circumstances.

(8) Has the information been disclosed in a patent?

(9) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determination regarding this information? If so, copies of such determinations must be included in the substantiation.

(d) If the substantiation provided under paragraph (c) of this section contains information which the submitter considers confidential, the submitter must assert a separate claim of confidentiality for that information at the time of submission in accordance with paragraph (b) of this section.

[49 FR 39782, Oct. 10, 1984, as amended at 51 FR 23713, June 30, 1986]

Subpart B—Procedures for Developing Consent Agreements and Test Rules

SOURCE: 51 FR 23713, June 30, 1986, unless otherwise noted.

§ 790.20 Recommendation and designation of testing candidates by the ITC.

(a) *Recommendations with intent to designate.* The ITC has advised EPA that it will discharge its responsibilities under section 4(e) of the Act in the following manner:

(1) When the ITC identifies a chemical substance or mixture that it believes should receive expedited consideration by EPA for testing, the ITC