

**§ 790.24 Criteria for determining whether a consensus exists concerning the provisions of a draft consent agreement.**

(a) EPA will enter into consent agreements only where there is a consensus among the Agency, one or more manufacturers and/or processors who agree to conduct or sponsor the testing, and all other interested parties who identify themselves in accordance with § 790.22(b)(2). EPA will not enter into a consent agreement in either of the following circumstances:

(1) EPA and affected manufacturers and/or processors cannot reach a consensus on the testing requirements or other provisions to be included in the consent agreement.

(2) A draft consent agreement is considered inadequate by other interested parties who, pursuant to § 790.22(b)(2), have asked to participate in or monitor negotiations; and these parties have submitted timely written objections to the draft consent agreement which provide a specific explanation of the grounds on which the draft agreement is objectionable.

(b) EPA may reject objections described in paragraph (a)(2) of this section only where the Agency concludes the objections are either:

(1) Not made in good faith.

(2) Untimely.

(3) Do not involve the adequacy of the proposed testing program or other features of the agreement that may affect EPA's ability to fulfill the goals and purposes of the Act.

(4) Not accompanied by a specific explanation of the grounds on which the draft agreement is considered objectionable.

(c) The unwillingness of some manufacturers and/or processors of a prospective test chemical to sign the draft consent agreement does not, in itself, establish a lack of consensus if EPA concludes that those manufacturers and/or processors who are prepared to sign the agreement are capable of accomplishing the testing to be required and that the draft agreement will achieve the purposes of the Act in all other respects.

**§ 790.26 Initiation and completion of rulemaking proceedings on ITC-designated chemicals.**

(a) Where EPA concludes that a consensus does not exist concerning the provisions of a draft consent agreement and that the findings specified by section 4(a) can be made, the Agency will proceed with rulemaking under section 4(a) of TSCA.

(b) When EPA decides to proceed with rulemaking under paragraph (a) of this section, the Agency intends to publish a rulemaking proposal and a final rule or a notice terminating the rulemaking proceeding in accordance with the schedule specified in Appendix A<sup>1</sup> to this part.

(c) Where the testing recommendations of the ITC raise unusually complex and novel issues that require additional Agency review and opportunity for public comment, the Agency may publish an Advance Notice of Proposed Rulemaking (ANPR). The schedule that EPA intends to follow for rulemaking proceedings initiated by publication of an ANPR is presented in appendix A<sup>1</sup> to this part.

**§ 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.**

(a) Where EPA believes that testing is needed, it may also develop consent agreements and/or test rules on chemical substances or mixtures that either:

(1) Have been recommended but not "recommended with intent to designate" by the ITC.

(2) Have been selected for testing consideration by EPA on its own initiative.

(b) When EPA wishes to initiate negotiations concerning chemicals described in paragraph (a) of this section, it will publish a FEDERAL REGISTER notice describing its tentative evaluation of testing needs, announcing a date for a public course-setting meeting, and inviting persons interested in participating in or monitoring negotiations to

<sup>1</sup>Editorial Note: Appendix A appears at the end of subpart E.

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contact the Agency in writing. Any negotiations that EPA conducts will conform to the procedures specified in § 790.22(b) and, to the extent feasible, will follow the schedules presented in appendix A<sup>1</sup> to this part.

(c) EPA will enter into consent agreements on chemicals described in paragraph (a) of this section only if there is a consensus among EPA, affected manufacturers and/or processors, and any other persons who have asked to participate in or monitor negotiations. In determining whether such a consensus exists, EPA will employ the criteria specified in § 790.24. In the absence of consensus, EPA will initiate rulemaking if it concludes that the findings specified in section 4(a) of the Act can be made. The schedule for initiating and completing such rulemaking proceedings will, to the extent feasible, follow the schedule specified in appendix A<sup>1</sup> to this part.

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

SOURCE: 50 FR 20657, May 17, 1985, unless otherwise noted. Redesignated at 51 FR 23713, June 30, 1986.

#### § 790.40 Promulgation of test rules.

(a) If EPA determines that it is necessary to test a chemical substance or mixture by rule under section 4 of the Act, it will promulgate a test rule in part 799 of this chapter.

(b) EPA will promulgate specific test rules in part 799 of this chapter either by a single-phase rulemaking procedure or by a two-phase rulemaking procedure.

(1) Under single-phase test rule development, EPA will promulgate a test rule in part 799 of this chapter through a notice and comment rulemaking which specifies the following:

(i) Identification of the chemical for which testing is required under the rule.

(ii) The health or environmental effect or effects or other characteristics for which testing is being required.

(iii) Which test substance(s) must be tested.

(iv) Standards for the development of test data.

(v) The EPA Good Laboratory Practice requirements for the required testing.

(vi) Schedule for submission of interim reports and/or final reports to EPA.

(vii) Who must submit either letters of intent to conduct testing or exemption applications.

(viii) What types of data EPA will examine in determining equivalence if more than one test substance is to be tested.

(2) Under two-phase test rule development, EPA will promulgate a Phase I test rule in part 799 of this chapter through a notice and comment rulemaking which specifies the following:

(i) Identification of the chemical for which testing is required under the rule.

(ii) The health or environmental effect or effects or other characteristics for which testing is being required.

(iii) Which test substance(s) must be tested.

(iv) A reference to appropriate guidelines for the development of test data.

(v) The EPA Good Laboratory Practice requirements for the required testing.

(vi) Who must submit either letters of intent to conduct testing and study plans, or exemption applications.

(vii) What types of data EPA will examine in determining equivalence if more than one test substance is to be tested.

(3) Under two-phase test rule development, test standards and schedules will be developed in a second phase of rulemaking as described in §§ 790.50 and 790.52.

[50 FR 20657, May 17, 1985. Redesignated and amended at 51 FR 23713, June 30, 1986; 54 FR 36313, Sept. 1, 1989]

#### § 790.42 Persons subject to a test rule.

(a) Each test rule described in § 790.40 will specify whether manufacturers, processors, or both are subject to the requirement for testing of the subject chemical under section 4(b)(3)(B) of the

<sup>1</sup>Editorial Note: Appendix A appears at the end of subpart E.