SUBCHAPTER R—TOXIC SUBSTANCES CONTROL ACT (CONTINUED)

PART 790—PROCEDURES GOVERNING TESTING CONSENT AGREEMENTS AND TEST RULES

Subpart A—General Provisions

Subpart B—Procedures for Developing Consent Agreements and Test Rules

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

Subpart D—Implementation, Enforcement and Modification of Consent Agreements

Subpart E—Exemptions From 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.

[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:

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.

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

Chemical means a chemical substance or mixture.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based tool for the completion and submission of data, reports, and other information, or its successors.

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; 78 FR 72829, Dec. 4, 2013]

§ 790.5 Submission of information.

(a) All submissions and correspondence to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule consent agreements.

(b) You must use the CISS tool to complete and submit via CDX all data, reports, other information, and correspondence required by rules promulgated under TSCA section 4, and for correspondence pertaining to consent agreements as required under this part. The submissions must be made only as set forth in this section.

(c) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html.*

[78 FR 72829, Dec. 4, 2013]

§ 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]

EFFECTIVE DATE NOTE: At 88 FR 37174, June 7, 2023, § 790.7 was revised, effective Aug. 7, 2023. For the convenience of the user, the revised text is set forth as follows:

§ 790.7 Confidentiality.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

Subpart B—Procedures for Developing Consent Agreements and Test Rules

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

§ 790.20 Recommendation, recommendation with an intent to designate, and designation of testing candidates by the ITC.

(a) *ITC recommendations and recommendations with intent to designate.* The ITC has advised EPA that it will discharge its responsibilities under section 4(e) of TSCA 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 may add the substance or mixture to its list of chemicals recommended for testing and include a statement that the ITC intends to designate the substance or mixture for action by EPA in accordance with section 4(e)(1)(B) of TSCA.

(2) Chemical substances or mixtures selected for expedited review under paragraph (a)(1) of this section may, at

a later time, be designated for EPA action within 12 months of such designation. The ITC's subsequent decision would be based on the ITC's review of TSCA sections 8(a) and 8(d) data and other relevant information.

(3) Where the ITC concludes that a chemical substance or mixture warrants testing consideration but that expedited EPA review of testing needs is not justified, the ITC will add the substance or mixture to its list of testing recommendations without expressing an intent to designate the substance or mixture for EPA action in accordance with section 4(e)(1)(B) of TSCA.

(4) The ITC reserves its right to designate any chemical substance or mixture that it determines the Agency should, within 12 months of the date first designated, initiate a proceeding under section 4(a) of TSCA.

(b) *Preliminary EPA evaluation of ITC recommendations with intent to designate.* Following receipt of an ITC report containing a recommendation with an intent to designate, EPA will use the following procedure for completing a preliminary evaluation of testing needs on those chemical substances that the ITC has recommended with intent to designate:

(1) EPA will publish the ITC report in the FEDERAL REGISTER and announce that interested persons have 30 days to submit comments on the ITC's testing recommendations.

(2) EPA will publish a FEDERAL REGISTER document adding all ITC-recommended chemicals to the automatic reporting provisions of its rules under sections 8(a) and 8(d) of TSCA (40 CFR parts 712 and 716).

(3) EPA will hold a public ''focus meeting'' to discuss the ITC's testing recommendations and obtain comments and information from interested parties.

(4) EPA will evaluate submissions received under TSCA sections 8(a) and 8(d) reporting requirements, comments filed on the ITC's recommendations, and other information and data compiled by the Agency.

(5) EPA will make a preliminary staff determination of the need for testing and, where testing appears warranted, will tentatively select the studies to be performed.

(6) EPA will hold a public meeting to announce its preliminary testing determinations.

(c) *EPA response to ITC designations and recommendations*—(1) Where a chemical substance or mixture is designated for EPA action under section 4(e)(1)(B) of TSCA, the Agency will take either one of the following actions within 12 months after receiving the ITC designation:

(i) Initiate rulemaking proceedings under section 4(a) of TSCA. 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 initiate rulemaking by publishing an Advance Notice of Proposed Rulemaking (ANPRM).

(ii) Publish a FEDERAL REGISTER notice explaining the Agency's reasons for not initiating such rulemaking proceedings. EPA may conclude that rulemaking proceedings under section 4(a) of TSCA are unnecessary if it determines that the findings specified in section 4(a) of TSCA cannot be made or if the Agency entered into a consent agreement requiring the testing identified by the ITC.

(2) Where a chemical substance or mixture has been recommended for testing by the ITC, whether with or without an intent to designate, EPA will use its best efforts to act on the ITC's recommendations as rapidly as possible consistent with its other priorities and responsibilities. EPA may respond to the ITC's recommendations with action such as:

(i) Initiating rulemaking proceedings under section 4(a) of TSCA,

(ii) Publishing a FEDERAL REGISTER notice explaining the Agency's reasons for concluding that testing is unnecessary, or

(iii) Entering into a consent agreement in accordance with this subpart.

[75 FR 56475, Sept. 16, 2010]

§ 790.22 Procedures for developing consent agreements.

(a) *Preliminary EPA evaluation of proposed consent agreement.* Where EPA believes that testing of a chemical substance or mixture may be needed, and wishes to explore whether a consent agreement may satisfy the identified testing needs, EPA will invite manufacturers and/or processors of the affected chemical substance or mixture to submit a proposed consent agreement to EPA. EPA will evaluate the proposal(s) and may request additional clarifications of or revisions to the proposal(s).

(b) *Negotiation procedures for consent agreements.* If, after evaluating the proposed consent agreement(s), EPA believes it is likely that proceeding with negotiation of a consent agreement would be an efficient means of developing the data, EPA will use the following procedures to conduct such negotiations:

(1) In the FEDERAL REGISTER, EPA will give notice of the availability of the proposal(s) that is the basis for negotiation, invite persons interested in participating in or monitoring negotiations to contact the Agency in writing, set a deadline for interested parties to contact the Agency in writing, and set a date for the negotiation meeting(s).

(2) The Agency will meet with interested parties at the negotiation meeting(s) for the purpose of attempting to negotiate a consent agreement. Only the submitter(s) of the proposal(s) that is the basis for negotiation and those persons who submit written requests to participate in or monitor negotiations by the deadline established under paragraph (b)(1) of this section will be deemed ''interested parties'' for purposes of this section.

(3) All negotiation meetings will be open to members of the public, but only interested parties will be permitted to participate in negotiations. The minutes of each meeting will be prepared by EPA. Meeting minutes, the proposed consent agreement(s), background documents, and other materials distributed at negotiation meetings will be placed in an Internet-accessible public docket established by EPA.

(4) If EPA concludes at any time that negotiations are unlikely to produce a final agreement, EPA will terminate negotiations and may proceed with rulemaking. If EPA terminates negotiations, no further opportunity for negotiations will be provided. EPA will notify all interested parties of the termination.

(5) The period between the first negotiation meeting and final agreement, if any (''the negotiation period''), will be no longer than 6 months, unless extended prior to its expiration in accordance with paragraph (b)(7) of this section. This period will include all negotiation meetings, and the processes discussed in paragraphs (b)(6) and (b)(9) of this section. If the negotiation period passes without the production of a final agreement, negotiations and development of the subject ECA will terminate automatically.

(6) EPA will circulate a draft of the consent agreement to all interested parties if EPA concludes that such draft is likely to achieve final agreement. A period of 30 days will be provided for submitting comments or written objections under paragraph (b)(8)(i)(B) of this section.

(7) If, prior to the expiration of the negotiation period, final agreement has not been reached, EPA may at its discretion provide one or more extensions, each of which may be up to 60 days, if it seems likely to EPA that a final agreement will be reached during that time. EPA will notify all interested parties of any extension(s).

(8) (i) 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 paragraph (b)(2) of this section. EPA will not enter into a consent agreement in either of the following circumstances:

(A) EPA and affected manufacturers and/or processors cannot reach a consensus in the timeframe described in paragraph (b)(5) of this section.

(B) A draft consent agreement is considered inadequate by other interested parties who 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.

(ii) EPA may reject objections described in paragraph (b)(8)(i)(B) of this section only where the Agency concludes the objections:

(A) Are not made in good faith;

(B) Are untimely;

(C) 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 TSCA; or

(D) Are not accompanied by a specific explanation of the grounds on which the draft agreement is considered objectionable.

(iii) The unwillingness of some manufacturers and/or processors 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 TSCA in all other respects.

(9) Where a consensus exists, as described in paragraph (b)(8) of this section, concerning the contents of a draft consent agreement, the draft consent agreement will be circulated to EPA management and the parties that are to conduct or sponsor testing under the agreement, for final approval and signature.

(10) Upon final approval and signature of a consent agreement, EPA will publish a FEDERAL REGISTER document announcing the availability of the consent agreement and codifying (in subpart C of 40 CFR part 799) the name of the chemical substance(s) and/or mixture(s) to be tested and the citation to the FEDERAL REGISTER document.

[75 FR 56475, Sept. 16, 2010]

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 Act and will indicate who will be required to submit letters of intent to conduct testing.

(1) If testing is being required to allow evaluation of risks:

(i) Primarily associated with manufacture of the chemical, or

(ii) Associated with both manufacturer and processing of the chemical, or

(iii) Associated with distribution in commerce, use, and/or disposal activities concerning the chemical, each manufacturer of the chemical will be subject and must comply with the requirements of the test rule.

(2) While legally subject to the test rule in circumstances described in paragraphs (a)(1) (ii) and (iii) of this section, processors of the chemical must comply with the requirements of the test rule only if processors are directed to do so in a subsequent notice as set forth in §790.48(b).

(3) If testing is being required to allow evaluation of risks associated solely with processing of the chemical, processors will be subject and must comply with the requirements of the test rule.

(4) While legally subject to the test rule in circumstances described in paragraph (a)(1) of this section, persons who manufacture less than 500 kg (1,100 lb) of the chemical annually during the period from the effective date of the test rule to the end of the reimbursement period, must comply with the requirements of the test rule only if such manufacturers are directed to do so in a subsequent notice as set forth in §790.48, or if directed to do so in a particular test rule.

(5) While legally subject to the test rule in circumstances described in paragraph (a)(1) of this section, persons who manufacture small quantities of the chemical solely for research and development (meaning quantities that are not greater than those necessary for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such chemical or another chemical, including such research or analysis for development of a product) from the effective date of the test rule to the end of the reimbursement period, must comply with the requirements of the test rule only if such manufacturers are directed to do so in subsequent notice set forth in §790.48, or if directed to do so in a particular test rule.

(6) If testing is being required to allow evaluation of risks associated primarily with manufacture of a chemical for research and development (R & D) purposes, manufacturers of the chemical for R & D will be subject and must comply with the requirements of the test rule.

(b) [Reserved]

[50 FR 20657, May 17, 1985. Redesignated at 51 FR 23713, June 30, 1986, and amended at 55 FR 18884, May 7, 1990]

§ 790.45 Submission of letter of intent to conduct testing or exemption application.

(a) No later than 30 days after the effective date of a test rule described in §790.40, each person subject to that test rule and required to comply with the requirements of that test rule as provided in §790.42(a) must, for each test required, send his or her notice of intent to conduct testing, or submit to EPA an application for exemption from testing by the method specified in §790.5(b).

(b) EPA will consider letters of intent to test as commitments to sponsor the tests for which they are submitted unless EPA agrees to the substitution

of an exemption application in instances where more than one person indicates an intent to sponsor equivalent tests.

(c) Each letter of intent to conduct testing must include:

(1) Identification of test rule.

(2) Name, address, and telephone number of the firm(s) which will be sponsoring the tests.

(3) Name, address, and telephone number of the appropriate individual to contact for further information.

(4) For sponsors participating in a testing consortium—a list of all members of the consortium, the signature of an authorized representative of each member, and a designation of who is to serve as principal sponsor.

(5) A list of the testing requirements for which the sponsor(s) intends to conduct tests.

(6) If EPA is requiring testing of more than one representative substance—which test substance the sponsor(s) intends to use in each of the tests.

(7) A payment identity number on the front page of the letter, as required in §700.45(g)(4) of this chapter.

(d)(1) Any person not manufacturing or processing the subject chemical as of the effective date of the test rule describing in §790.40 or by 30 days after the effective date of the rule who, before the end of the reimbursement period, manufacturers or processes the test chemical and who is subject to and required to comply with the requirements of the test rule must submit the letter of intent to test or an exemption application required by paragraph (a) of this section by the date manufacture or processing begins, or

(2) When both manufacturers and processors are subject to the rule, any person not processing the subject chemical as of the effective date of the test rule described in §790.40 or by 30 days after publication of the FEDERAL REGISTER notice described in §790.48(b)(2) who, before the end of the reimbursement period, processes the test chemical and who is required to comply with the requirements of the rule must submit the letter of intent to test or an exemption application required by §790.48(b)(3) of the date processing begins.

(e) Manufacturers subject to a test rule described in §790.40 who do not submit to EPA either a letter of their intent to conduct tests or a request for an exemption from testing for each test for which testing is required in the test rule will be considered in violation of that rule beginning on the 31st day after the effective date of the test rule described in §790.40 or on the date manufacture begins as described in paragraph (d) of this section.

(f) Processors subject to a test rule described in §790.40 and required to comply with the requirements of test rule pursuant to §790.42(a)(2) or a FEDERAL REGISTER notice as described in §790.48(b)(2) who do not submit to EPA either a letter of their intent to conduct tests or a request for an exemption for each test for which testing is required in the test rule will be considered in violation of that rule beginning on the 31st day after the effective date of the test rule described in §790.40 or 31 days after publication of the FEDERAL REGISTER notice described in §790.48(b)(2) or on the date processing begins as described in paragraph (d) of this section, as appropriate.

(g) Manufacturers and processors subject to a test rule described in §790.40 and required to comply with the requirements of that test rule as provided in §790.42(a) must remit the applicable fee specified in §700.45(c) of this chapter.

[50 FR 20657, May 17, 1985, as amended at 78 FR 72829, Dec. 4, 2013; 83 FR 52723, Oct. 17, 2018]

§790.48 Procedure if no one submits a letter of intent to conduct testing.

(a) *If only manufacturers are subject to the rule.* (1) This paragraph applies if testing is being required solely to allow evaluation of risks associated with manufacturing and the test rule described in §790.40 states that manufacturers only are responsible for testing.

(2) If no manufacturer subject to the test rule has notified EPA of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule described in §790.40, EPA will notify all manufacturers, including those described in §790.42(a)(4) and (a)(5), by certified mail or by publishing a notice of this fact in

the FEDERAL REGISTER specifying the tests for which no letter of intent has been submitted and will give such manufacturers an opportunity to take corrective action.

(3) If no manufacturer submits a letter of intent to conduct one or more of the required tests within 30 days after receipt of the certified letter or publication of the FEDERAL REGISTER notice described in paragraph (a)(2) of this section, all manufacturers subject to the rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication of the FEDERAL REGISTER notice described in this paragraph.

(b) *If manufacturers and processors are subject to the rule.* (1) This paragraph applies if testing is being required to allow evaluation of risks associated with manufacturing and processing or with distribution in commerce, use, or disposal of the chemical and the test rule described in §790.40 states that manufacturers and processors are responsible for testing.

(2) If no manufacturer subject to the rule has notified EPA of its intent to conduct testing for one or more of the required tests within 30 days after the effective date of the test rule described in §790.40, EPA will publish a notice in the FEDERAL REGISTER of this fact specifying the tests for which no letter of intent has been submitted.

(3) No later than 30 days after the date of publication of the FEDERAL REGISTER notice described in paragraph (b)(2) of this section, each person described in §790.40(a)(4) and (a)(5) and each person processing the subject chemical as of the effective date of the test rule described in §790.40 or by 30 days after the date of publication of the FEDERAL REGISTER notice described in paragraph (b)(2) of this section must, for each test specified in the FEDERAL REGISTER notice, either notify EPA of his or her intent to conduct testing, or submit to EPA an application for an exemption from testing requirements for the test. Each such notification to conduct testing or application for exemption from testing must be submitted to EPA by the method specified in §790.5(b).

(4) If no manufacturer or processor of the test chemical has submitted a letter of intent to conduct one or more of the required tests within 30 days after the date of publication of the FEDERAL REGISTER notice described in paragraph (b)(2) of this section, EPA will notify all manufacturers and processors by certified letter or publish a FEDERAL REGISTER notice of this fact specifying the tests for which no letter of intent has been submitted. This letter or FEDERAL REGISTER notice will give the manufacturers and processors an opportunity to take corrective action.

(5) If no manufacturer or processor submits a letter of intent to EPA through CDX within 30 days after either receipt of the certified letter or publication in the FEDERAL REGISTER notice described in (b)(4) of this section, all manufacturers and processors subject to the test rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication in the FEDERAL REGISTER.

(c) *Only processors are subject to the rule.* (1) This paragraph applies if testing is being required solely to allow evaluation of risks associated with processing and the test rule described in §790.40 states that only processors are responsible for testing.

(2) If no processor subject to the test rule has notified EPA through CDX of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule described in §790.40, EPA will notify all the processors by certified mail or publish a notice in the FEDERAL REGISTER of this fact, specifying the tests for which no letter of intent has been submitted and to give the processors an opportunity to take corrective action.

(3) If no processor submits a letter of intent through CDX to conduct one or more of the required tests within 30 days after receipt of the certified letter or publication of the FEDERAL REGISTER notice described in paragraph (c)(2) of this section, all processors subject to the test rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication of the FEDERAL REGISTER notice described in paragraph (c)(2) of this section.

[50 FR 20657, May 17, 1985. Redesignated at 51 FR 23713, June 30, 1986, and amended at 55 FR 18884, May 7, 1990; 78 FR 72829, Dec. 4, 2013]

§ 790.50 Submission of study plans.

(a) *Who must submit study plans.* (1) Persons who notify EPA of their intent to conduct tests in compliance with the requirements of a single phase test rule as described in § 790.40(b)(1) must submit study plans for those tests prior to the initiation of each of these tests, unless directed by a particular test rule or consent agreement to submit study plans at a specific time.

(2) Persons who notify EPA of their intent to conduct tests in compliance with the requirements of a Phase I test rule as described in § 790.40(b)(2) must submit the proposed study plans for those tests on or before 90 days after the effective date of the Phase I rule; or, for processors complying with the notice described in § 790.48(b)(2), 90 days after the publication date of that notice; or 60 days after the date manufacture or processing begins as described in § 790.45(d), as appropriate, to the address in § 790.5(b).

(3) Study plans must be prepared according to the requirements of this subpart B and part 792 of this chapter. Only one set of study plans should be prepared and submitted by persons who are jointly sponsoring testing.

(4) Any person subject to a test rule may submit a study plan for any test required by the rule at any time, regardless of whether the person previously submitted an application for exemption from testing for that test.

(5) Unless EPA has granted an extension of time for submission of proposed study plans, manufacturers who notify EPA that they intend to conduct testing in compliance with the requirements of a Phase I test rule as described in § 790.40(b)(2) and who do not submit proposed study plans for those tests on or before 90 days after the effective date of the Phase I test rule or 60 days after the date manufacture begins as described in § 790.45(d) will be considered in violation of the test rule as if no letter of intent to test had been submitted.

(6) Unless EPA has granted an extension of time for submission of proposed study plans, processors who notify EPA that they intend to conduct testing in compliance with the requirements of a Phase I test rule as described in § 790.40(b)(2) and who do not submit proposed study plans for those tests on or before 90 days after the effective date of the Phase I test rule or 90 days after the publication date of the notice described in § 790.48(b)(2), or 60 days after the date processing begins as described in § 790.45(d), as appropriate, will be considered in violation of the test rule as if no letter of intent to test had been submitted.

(b) *Extensions of time for submission of study plans.* (1) EPA may grant requests for additional time for the development of study plans on a case-by-case basis. Requests for additional time for study plan development must be submitted to EPA by the method specified in § 790.5(b). Any extension request must state why EPA should grant the extension.

(2) Under two-phase rulemaking, extension requests must be submitted to EPA within 60 days after the effective date of the Phase I test rule as described in § 790.40(b)(2); or for processors complying with the notice described in § 790.48(b)(2), 60 days after the publication date of that notice; or 30 days after the date manufacture or processing begins as described in § 790.45(d), as appropriate.

(3) EPA will notify the submitter by certified mail of EPA's decision to grant or deny an extension request.

(4) Persons who have been granted an extension of time for submission of study plans as described in paragraph (b)(1) of this section and who do not submit proposed study plans in compliance with the requirements of a Phase I test rule in accordance with the new deadline granted by EPA will be considered in violation of the test rule as if no letter of intent to test had been submitted as described in § 790.45(e) and (f).

(c) *Content of study plans.* (1) All study plans are required to contain the following information:

(i) Identity of the test rule.

(ii) The specific test requirements of that rule to be covered by the study plan.

(iii)(A) The names and addresses of the test sponsors.

(B) The names, addresses, and telephone numbers of the responsible administrative officials and project manager(s) in the principal sponsor's organization.

(C) The name, address, and telephone number of the appropriate individual to contact for oral and written communications with EPA.

(D)(*1*) The names and addresses of the testing facilities and the names, addresses, and telephone numbers of the testing facilities' administrative officials and project manager(s) responsible for the testing.

(*2*) Brief summaries of the training and experience of each professional involved in the study, including study director, veterinarian(s), toxicologist(s), pathologist(s), chemist(s), microbiologist(s), and laboratory assistants.

(iv) Identity and data on the chemical substance(s) being tested, including physical constants, spectral data, chemical analysis, and stability under test and storage conditions, as appropriate.

(v) Study protocol, including the rationale for any combination of test protocols; the rationale for species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; description of diet to be used and its source; including nutrients and contaminants and their concentrations; for *in vitro* test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

(vi) Schedule for initiation and completion of each short-term test and of each major phase of long-term tests; dates for submission of interim progress and final reports to EPA that are within the reporting deadlines specified by EPA In the final test rule.

(2) Information required in paragraph (c)(1)(iii)(D) of this section is not required in proposed study plans submitted in compliance with the requirements of a Phase I test rule if the information is not available at the time of study plan submission; however, the information must be submitted before the initiation of testing.

(d) *Incomplete study plans.* (1) Upon receipt of a study plan, EPA will review the study plan to determine whether it complies with paragraph (c) of this section. If EPA determines that the study plan does not comply with paragraph (c) of this section, EPA will notify the submitter that the submission is incomplete and will identify the deficiencies and the steps necessary to complete the submission.

(2) The submitter will have 15 days after the day it receives this notice to submit appropriate information to make the study plan complete.

(3) If the submitter fails to provide appropriate information to complete a proposed study plan submitted in compliance with the requirements of a Phase I test rule on or before 15 days after receipt of the notice, the submitter will be considered in violation of the test rule as if no letter of intent to conduct the test had been submitted as described in § 790.45(e) and (f).

(e) *Amendments to study plans.* Test sponsors must submit all amendments by the method specified in § 790.5(b).

[50 FR 20657, May 17, 1985. Redesignated and amended at 51 FR 23713, June 30, 1986; 52 FR 36569, Sept. 30, 1987; 54 FR 36313, Sept. 1, 1989; 55 FR 18884, May 7, 1990; 58 FR 34205, June 23, 1993; 60 FR 34466, July 3, 1995; 78 FR 72829, Dec. 4, 2013]

§ 790.52 Phase II test rule.

(a) If EPA determines that the proposed study plan described in § 790.50(a)(2) complies with § 790.50(c), EPA will publish a proposed Phase II test rule in the FEDERAL REGISTER requesting comments on the ability of the proposed study plan to ensure that data from the test will be reliable and adequate.

(b) EPA will provide a 45-day comment period and will provide an opportunity for an oral presentation upon the request of any person. EPA may extend the comment period if it appears from the nature of the issues raised by EPA's review or from public comments that further comment is warranted.

(c) After receiving and considering public comments on the study plan, EPA will adopt, as proposed or as modified in response to EPA review and public comments, the study protocol section of the study plan, as defined by § 790.50(c)(1)(v) of this chapter, as the test standard for the required testing, and the schedule section of the

study plan, as defined by §790.50(c)(1)(vi) of this chapter, as the schedule for the required testing in a final Phase II test rule.

[50 FR 20657, May 17, 1985. Redesignated at 51 FR 23713, June 30, 1986, and amended at 52 FR 36569, Sept. 30, 1987]

§ 790.55 Modification of test standards or schedules during conduct of test.

(a) *Application.* Any test sponsor who wishes to modify the test schedule for the mandatory testing conditions or requirements (i.e., ''shall statements'') in the test standard for any test required by a test rule must submit an application in accordance with this paragraph. Application for modification must be made by the method specified in §790.5(b). Applications must include an appropriate explanation and rationale for the modification. Where a test sponsor requests EPA to provide guidance or to clarify a non-mandatory testing requirement (i.e., ''should statements'') in a test standard, the test sponsor must submit these requests to EPA by the method format specified in §790.5(b).

(b) *Adoption.* (1) Where EPA concludes that the requested modification of a test standard or schedule for a test required under a test rule is appropriate, EPA will proceed in accordance with this paragraph (b).

(2) Where, in EPA's judgment, the requested modification of the test standard or schedule would not alter the scope of the test or significantly change the schedule for completing the test, EPA will not ask for public comment before approving the modification. EPA will notify the test sponsor by letter of EPA's approval. EPA will place copies of each application and EPA approval letter in the rulemaking record for the test rule in question. EPA will publish a notice annually in the FEDERAL REGISTER indicating the test standards or schedules for tests required in test rules which have been modified under this paragraph (b)(2) and describing the nature of the modifications. Until the FEDERAL REGISTER notice is published, any modification approved by EPA under this paragraph (b)(2) shall apply only to the test sponsor who applied for the modification under this paragraph (a) of this section.

(3) Where, in EPA's judgment, the requested modification of a test standard or schedule would significantly alter the scope of the test or significantly change the schedule for completing the test, EPA will publish a notice in the FEDERAL REGISTER requesting comment on the proposed modification. However, EPA will approve a requested modification of a test standard under paragraph (b)(3) of this section without first seeking public comment if EPA believes that an immediate modification to the test standard is necessary to preserve the accuracy or validity of an ongoing test. EPA may also modify a testing requirement or test condition in a test standard if EPA determines that the completion or achievement of this requirement or condition is not technically feasible. EPA may approve a test schedule extension under paragraph (b)(3) of this section without first seeking public comment if EPA determines, on a case-by-case basis, that a delay of over 12 months is not the fault of the test sponsor and is the result of unforeseen circumstances such as a lack of laboratory availability, lack of availability of suitable test substance (e.g., 14–C labelled test substance), lack of availability of healthy test organisms, or the unexpected failure of a long-term test. EPA will publish an annual notice in the FEDERAL REGISTER announcing the approval of any test standard modifications and test schedule extensions under paragraph (b)(3) of this section and provide a brief rationale of why the modification was granted.

(4) For purposes of this paragraph (b), a requested modification of a test standard or schedule for a test required under a test rule would alter the scope of the test or significantly change the schedule for completing the test if the modification would:

(i) Change the test species.

(ii) Change the route of administration of the test chemical.

(iii) Change the period of time during which the test species is exposed to the test chemical.

(iv) Except as provided in paragraph (b)(3) of this section, extend the final reporting deadline more than 12

months from the date specified in the final rule.

(c) *Disapproval.* Where EPA concludes that the requested modification of a test standard or schedule for a test required under a test rule is not appropriate, EPA will so notify the test sponsor in writing.

(d) *Timing.* (1) Test sponsors should submit all applications for test schedule modifications at least 60 days before the reporting deadline for the test in question.

(2) EPA will not normally approve any test schedule extensions submitted less than 30 days before the reporting deadline for the test in question.

(3) Except as provided in paragraph (b)(3) of this section, EPA may grant extensions for up to 1 year but will normally limit extensions to a period of time equal to the in-life portion of the test plus 60 days.

(4) EPA will normally approve only one deadline extension for each test.

(5) Test sponsors should submit requests for test standard modifications as soon as they determine that the test cannot be successfully completed according to the test standard specified in the rule.

[50 FR 20657, May 17, 1985. Redesignated at 51 FR 23713, June 30, 1986, and amended at 52 FR 36571, Sept. 30, 1987; 54 FR 36314, Sept. 1, 1989; 60 FR 34466, July 3, 1995; 78 FR 72830, Dec. 4, 2013]

§ 790.59 Failure to comply with a test rule.

(a) Persons who notified EPA of their intent to conduct a test required in a test rule in part 799 of this chapter and who fail to conduct the test in accordance with the test standards and schedules adopted in the test rule, or as modified in accordance with § 790.55, will be in violation of the rule.

(b) Any person who fails or refuses to comply with any aspect of this part or a test rule under part 799 of this chapter is in violation of section 15 of the Act. EPA will treat violations of the Good Laboratory Practice standards as indicated in § 792.17 of this chapter.

(c) Persons who fail to pay the requisite fee as specified in § 700.45(c) of this chapter will be in violation of the rule.

[50 FR 20657, May 17, 1985, as amended at 83 FR 52723, Oct. 17, 2018]

Subpart D—Implementation, Enforcement and Modification of Consent Agreements

SOURCE: 51 FR 23715, June 30, 1986, unless otherwise noted.

§ 790.60 Contents of consent agreements.

(a) *Standard provisions.* All consent agreements will contain the following provisions:

(1) Identification of the chemical(s) to be tested.

(2) The health effects, environmental effects and/or other characteristics for which testing will be required.

(3) The names and addresses of each manufacturer and/or processor who will sign the agreement.

(4) The name and address of the manufacturer, processor or other entity who has agreed to act as the principal test sponsor.

(5) The technical or commercial grade, level of purity or other characteristics of the test substances(s) or mixture(s).

(6) Standards for the development of test data.

(7) A requirement that testing will be conducted in accordance with the EPA Good Laboratory Practice (GLP) regulations (40 CFR part 792).

(8) Schedules with reasonable deadlines for submitting interim progress and/or final reports to EPA.

(9) A requirement that the principal sponsor will submit a study plan to EPA in accordance with § 790.62.

(10) A statement that the results of testing conducted pursuant to the consent agreement will be announced to the public in accordance with the procedures specified in section 4(d) of the Act and that the disclosure of data generated by such testing will be governed by section 14(b) of the Act.

(11) A requirement that the manufacturers and/or processors signing the consent agreement will comply with the notification requirements of section 12(b)(1) of the Act and part 707 of

this chapter if they export or intend to export the substance or mixture for which the submission of data is required under the agreement and a statement that any other person who exports or intends to export such substance or mixture is subject to the above cited export notification requirements.

(12) A requirement that, in the event EPA promulgates a significant new use rule applicable to the test chemical under section 5(a)(2), the consent agreement will have the status of a test rule for purposes of section 5(b)(1)(A) and manufacturers and/or processors signing the agreement will comply with the data submission requirements imposed by that provision.

(13) A statement that each manufacturer and/or processor signing the agreement agrees that violation of its requirements will constitute a ''prohibited act'' under section 15(1) of the Act and will trigger all provisions of TSCA applicable to a violation of section 15.

(14) A statement that, in the event one or more provisions of the agreement are determined to be unenforceable by a court, the remainder of the agreement would not be presumed to be valid and EPA will then either initiate a rulemaking proceeding or publish in the FEDERAL REGISTER the Administrator's reason for not initiating such a proceeding.

(15) A statement that the Agency may conduct laboratory inspections and/or study audits of the testing being conducted pursuant to the consent agreement in accordance with the authority and procedures contained in section 11 of the Act.

(16) A statement that EPA acceptance of a consent agreement constitutes ''final agency action'' for purposes of 5 U.S.C. 704.

(17) Any other requirements that the parties agree are necessary to achieve the purposes of the Act.

(18) Payment identity number, as required in § 700.45(g)(4) of this chapter.

(b) *Contents of standards for the development of data.* The standards for the development of the data included in consent agreements will be based on the TSCA test guidelines in 40 CFR parts 796, 797, and 798, the Organization for Economic Cooperation and Development (OECD) test guidelines, the EPA pesticide assessment guidelines published by The National Technical Information Service (NTIS), or other suitable test methodologies. During the negotiation of consent agreements, EPA will initially propose suitable test guidelines as the required test standards; manufacturers and processors or other interested parties may then suggest alternative methodologies or modifications to the Agency's proposed guidelines. These alternative methodologies or modifications will be adopted only where, in the judgment of EPA, they will develop at least equally reliable and adequate data on the chemical substance or mixture subject to the agreement.

(c) *Statement of rationale for consent agreement.* EPA will prepare a written explanation of the basis for each consent agreement. This document will summarize the agreement, describe any ITC testing recommendations for the chemical involved, outline the chemical's use and exposure characteristics, and explain the objectives of the testing to be conducted and the rationale for the specific studies selected. This document will be published in the FEDERAL REGISTER and, for ITC-designated chemicals, will constitute the statement of EPA's reasons for not initiating rulemaking required by section 4(e)(1)(B) of the Act.

(d) *Fees.* Manufacturers and/or processors signing the consent agreement are subject to the applicable fee specified in § 700.45(c) of this chapter.

[51 FR 23715, June 30, 1986, as amended at 54 FR 36314, Sept. 1, 1989; 83 FR 52724, Oct. 17, 2018]

§ 790.62 Submission of study plans and conduct of testing.

(a) *Timing of submission.* The principal sponsor of testing conducted pursuant to a consent agreement shall submit a study plan no later than 45 days prior to the initiation of testing.

(b) *Content of study plans.* All study plans are required to contain the following information:

(1) Identity of the consent agreement under which testing will be performed.

(2) The specific test requirements to be covered by the study plan.

(3) The name and address of the principal test sponsor.

(4) The names, addresses, and telephone numbers of the responsible administrative official[s] and project manager[s] in the principal sponsor's organization.

(5) The names, addresses, and telephone numbers of the technical contacts at each manufacturer and/or processor subject to the agreement.

(6) The names and addresses of the testing facilities responsible for the testing and the names, addresses, and telephone numbers of the administrative officials[s] and project manager[s] assigned to oversee the testing program at these facilities.

(7) Brief summaries of the training and experience of each professional involved in the study, including study director, veterinarian[s], toxicologist[s], pathologist[s], chemist[s], microbiologist[s], and laboratory assistants.

(8) Identity and supporting data on the chemical substance[s] being tested, including physical constants, spectral data, chemical analysis, and stability under test and storage conditions, as appropriate.

(9) Study protocol, including the rationale for any combination of test protocols; the rationale for species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; description of diet to be used and its source, including nutrients and contaminants and their concentrations; for *in vitro* test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

(10) A schedule, with reasonable timeables and deadlines, for initiation and completion of each short-term test and of each major phases of long-term tests, and submission of interim progress and/or final reports to EPA.

(c) *Review and modification.* (1) Upon receipt of a study plan, EPA will review it to determine whether it complies with paragraph (b) of this section. If EPA determines that the study plan does not comply with paragraph (b) of this section, EPA will notify the submitter that the plan is incomplete and will identify the deficiencies and the steps necessary to complete the plan. It is the responsibility of the test sponsor to review the study protocols to determine if they comply with all the mandatory testing conditions and requirements in the test standards (i.e., ''shall statements'').

(2) The submitter will have 15 days after the day it receives a notice under paragraph (c)(1) of this section to submit appropriate information to make the study plan complete.

(3) If the submitter fails to provide appropriate information to complete a study plan within 15 days after having received a notice under paragraph (c)(1) of this section, the submitter will be considered to be in violation of the consent agreement and subject to enforcement proceedings pursuant to § 790.65 (c) and (d).

(4) The test sponsor shall submit any amendments to study plans to EPA using the method specified in § 790.5(b).

(d) *Functions of the principal test sponsor.* When testing is being conducted pursuant to a consent agreement, the principal test sponsor will be responsible for submitting interim progress and final reports to EPA, informing the Agency of any proposed changes in standards for the development of data, study plans or testing schedules, and communicating with the Agency about laboratory inspections and other matters affecting the progress of testing.

[51 FR 23715, June 30, 1986, as amended at 54 FR 36314, Sept. 1, 1989; 60 FR 34466, July 3, 1995; 78 FR 72830, Dec. 4, 2013]

§ 790.65 Failure to comply with a consent agreement.

(a) Manufacturers and/or processors who have signed a consent agreement and who fail to comply with the test requirements, test standards, GLP regulations, schedules, or other provisions contained in the consent agreement, or in modifications to the agreement adopted pursuant to § 790.68, will be in violation of the consent agreement.

(b) The Agency considers failure to comply with any aspect of a consent agreement, including the failure to pay requisite fees as specified in § 700.45 of this chapter, to be a ''prohibited act'' under section 15 of TSCA, subject to all the provisions of the Act applicable to violations of section 15. Section 15(1) of

TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Consent agreements adopted pursuant to this part are ''orders issued under section 4'' for purposes of section 15(1) of TSCA.

(c) Manufacturers and/or processors who violate consent agreements are subject to criminal and/or civil liability. Under the penalty provisions of section 16 of TSCA, such firms could be subject to a civil penalty of up to $25,000 per violation with each day in violation constituting a separate violation of section 15. Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to one year. In addition, EPA could invoke the remedies available under section 17 of TSCA, including seeking an injunction to compel adherence to the requirements of the consent agreement.

(d) Noncompliance with a consent agreement will constitute conduct ''in violation of this Act'' under section 20(a)(1) of TSCA. Thus, failure to comply with the requirements of a consent agreement could result in a citizens' civil action under section 20(a)(1) of TSCA.

[51 FR 23715, June 30, 1986, as amended at 83 FR 52724, Oct. 17, 2018]

§ 790.68 Modification of consent agreements.

(a) *Changes in the scope of testing.* (1) Manufacturers or processors subject to a consent agreement, other persons or EPA may seek modifications in the scope of testing performed under the consent agreement. If, upon receiving a request for modification, EPA determines that new issues have been raised that warrant reconsideration of the scope of testing, or if EPA determines on its own that such reconsideration is appropriate, EPA will publish a FEDERAL REGISTER notice describing the proposed modification and soliciting public comment. If, based on the comments received, EPA concludes that differences of opinion may exist about the proposed modification, EPA will establish a schedule for conducting negotiations and invite parties who wish to participate in or monitor these negotiations to contact the Agency in writing. Any negotiations that EPA conducts will conform to the procedures specified in § 790.22(b).

(2) The scope of testing required by a consent agreement will be modified only where there is a consensus concerning the modified testing requirements among EPA, affected manufacturers and/or processors, and other persons who have asked to participate in or monitor negotiations under paragraph (a)(1) of this section. In determining whether a consensus exists, EPA will employ the criteria specified in § 790.22(b)(8). In the absence of consensus, EPA may initiate rulemaking under section 4(a) of the Act if it concludes that any testing beyond that required by the consent agreement is necessary and that the other statutory findings required by section 4(a) can be made. While such rulemaking proceedings are underway, the consent agreement will remain in effect unless EPA finds that the testing required by the agreement is or may be unnecessary in view of the testing requirements included in EPA's proposed rule.

(b) *Changes in test standards or schedules.* (1) Any test sponsor who wishes to modify the test schedule for any test required under a consent agreement must submit an application in accordance with this paragraph. Application for modification must be made using the method specified in § 790.5(b). Applications must include an appropriate explanation and rationale for the modification. EPA will consider only those applications that request modifications to mandatory testing conditions or requirements (''shall statements'' in the consent agreement). Where a test sponsor requests EPA to provide guidance or to clarify a non-mandatory testing requirement (i.e., ''should statements''), the test sponsor shall submit these requests to EPA using the method specified in § 790.5(b).

(2)(i) Where EPA concludes that the requested modification of a test standard or schedule for a test required under a consent agreement is appropriate, EPA will proceed in accordance with this paragraph (b)(2).

(ii) Where, in EPA's judgment, the requested modification of a test standard or schedule would not alter the

scope of the test or significantly change the schedule for completing the test, EPA will not ask for public comment before approving the modification. EPA will notify the test sponsor, and any other persons who have signed the consent agreement, by letter of EPA's approval. EPA will place copies of each application and EPA approval letter in the administrative record maintained for the consent agreement in question. EPA will publish a notice annually in the FEDERAL REGISTER indicating the test standards or schedules for test required in consent agreements which have been modified under this paragraph (b)(2)(ii) and describing the nature of the modifications.

(iii) Where, in EPA's judgment, the requested modification of a test standard or schedule would significantly alter the scope of the test or significantly change the schedule for completing the test, EPA will publish a notice in the FEDERAL REGISTER requesting comment on the proposed modification. However, EPA will approve a requested modification of a test standard under paragraph (b)(2)(iii) of this section without first seeking public comment if EPA believes that an immediate modification to the test standard is necessary to preserve the accuracy or validity of an ongoing test. EPA also may modify a testing requirement or test condition in a test standard if EPA determines that the completion or achievement of this requirement or condition is not technically feasible. EPA may approve a requested modification of a test schedule under paragraph (b)(2)(iii) of this section without first seeking public comment if EPA determines, on a case-by-case basis, that a delay of over 12 months is not the fault of the test sponsor and is due to unforeseen circumstances such as a lack of laboratory availability, lack of availability of suitable test substance (e.g., 14–C labelled test substance), lack of availability of healthy test organisms, or the unexpected failure of a long-term test. EPA will publish an annual notice in the FEDERAL REGISTER announcing the approval of any test standard modifications and test scheduled extensions under paragraph (b)(2)(iii) of this section, and provide a brief rationale of why the modification was granted.

(iv) For purposes of this paragraph (b)(2), a requested modification of a test standard of schedule for a test required under a consent agreement would alter the scope of the test or significantly change the schedule for completing the test if the modification would:

(A) Change the test species.

(B) Change the route of administration of the test chemical.

(C) Change the period of time during which the test species is exposed to the test chemical.

(D) Except as provided in paragraph (b)(2)(iii) of this section, extend the final reporting deadline more than 12 months from the date specified in the consent order.

(3) Where EPA concludes that the requested modification of a test standard or schedule for a test requirement under a consent agreement is not appropriate, EPA will so notify the test sponsor in writing.

(c) *Timing.* (1) Test sponsors should submit all applications for test schedule modifications at least 60 days before the reporting deadline for the test in question.

(2) EPA will not normally approve any test schedule extensions submitted less than 30 days before the reporting deadline for the test in question.

(3) Except as provided in paragraph (b)(2)(iii) of this section, EPA may grant extensions as shown necessary for up to 1 year but will normally limit extensions to a period of time equal to the in-life portion of the test plus 60 days.

(4) EPA will normally approve only one deadline extension for each test.

(5) Test sponsors should submit requests for test standard modifications as soon as they determine that the test cannot be successfully completed according to the test standard specified in the consent order.

[51 FR 23715, June 30, 1986, as amended at 52 FR 36571, Sept. 30, 1987; 54 FR 36314, Sept. 1, 1989; 60 FR 34466, July 3, 1995; 75 FR 56476, Sept. 16, 2010; 78 FR 72830, Dec. 4, 2013]

Subpart E—Exemptions From Test Rules

SOURCE: 50 FR 20660, May 17, 1985, unless otherwise noted.

§ 790.80 Submission of exemption applications.

(a) *Who should file applications.* (1) Any manufacturer or processor subject to a test rule in part 799 of this chapter may submit an application to EPA for an exemption from performing any or all of the tests required under the test rule.

(2) Processors will not be required to apply for an exemption or conduct testing unless EPA so specifies in a test rule or in a special FEDERAL REGISTER notice as described in §790.48(b)(2) under the following circumstances:

(i) If testing is being required to allow evaluation of risks associated with manufacturing and processing or with distribution in commerce, use, or disposal of the chemical and manufacturers do not submit notice(s) of intent to conduct the required testing; or

(ii) If testing is being required solely to allow evaluation of risks associated with processing of the chemical.

(b) *When applications must be filed.* (1) Exemption applications must be filed within 30 days after the effective date of the test rule described in §790.40 or, if being submitted in compliance with the FEDERAL REGISTER notice described in §790.48(b)(2), within 30 days after the publication of that notice.

(2) Exemption applications must be filed by the date manufacture or processing begins by any person not manufacturing or processing the subject chemical as of the effective date of the test rule described in §790.40 or by 30 days after the effective date of the test rule described in §790.40, who, before the end of the reimbursement period, manufactures or processes the test substance and who is subject to the requirement to submit either a letter of intent to test or an exemption application.

(3) When both manufacturers and processors are subject to the rule, exemption applications must be filed by the date processing begins by any person not processing as of the effective date of the test rule described in §790.40 or by 30 days after publication of the FEDERAL REGISTER notice described in §790.48(b)(2) who, before the end of the reimbursement period, processes the test substance and who is subject to the requirement to submit either a letter of intent to test or an exemption application.

(c) *Scope of application.* A person may apply for an exemption from all, or one or more, specific testing requirements in a test rule in part 799 of this chapter.

[50 FR 20660, May 17, 1985, as amended at 58 FR 34205, June 23, 1993]

§ 790.82 Content of exemption application.

The exemption application must contain:

(a) The identity of the test rule, the chemical identity, and the CAS No. of the test substance on which the application is based.

(b) The specific testing requirement(s) from which an exemption is sought and the basis for the exemption request.

(c) Name, address, and telephone number of applicant.

(d) Name, address, and telephone number of appropriate individual to contact for further information.

(e)(1) If required in the test rule to establish equivalence:

(i) The chemical identity of the test substance on which the application is based.

(ii) Equivalence data specified in §790.85.

(2) If a test rule requires testing of a single representative substance, EPA will consider all forms of the chemical subject to that rule to be equivalent and will not require the submission of equivalence data as described in §790.85.

[50 FR 20660, May 17, 1985, as amended at 54 FR 36315, Sept. 1, 1989]

§ 790.85 Submission of equivalence data.

If EPA requires in a test rule promulgated under section 4 of the Act the testing of two or more test substances which are forms of the same chemical, each exemption applicant must submit the following data:

(a) The chemical identity of each technical-grade chemical substance or mixture manufactured and/or processed by the applicant for which the exemption is sought. The exact type of identifying data required will be specified in the test rule, but may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining whether the applicant's substance or mixture is equivalent to the specific test substance.

(b) The basis for the applicant's belief that the substance or mixture is equivalent to the test substance or mixture.

(c) Any other data which exemption applicants are directed to submit in the test rule which may bear on a determination of equivalence. This may include a description of the process by which each technical-grade chemical substance or mixture for which an exemption is sought is manufactured or processed prior to use or distribution in commerce by the applicant.

§ 790.87 Approval of exemption applications.

(a) EPA will conditionally approve exemption applications if:

(1)(i) For single-phase test rules, EPA has received a letter of intent to conduct the testing from which exemption is sought;

(ii) For two-phase test rules, EPA has received a complete proposed study plan for the testing from which exemption is sought and has adopted the study plan, as proposed or modified, as test standards and schedules in a final Phase II test rule; and

(2) The chemical substance or mixture with respect to which the application was submitted is equivalent to a test substance or mixture for which the required data have been or are being submitted in accordance with a test rule; and

(3) Submission of the required test data concerning that chemical substance or mixture would be duplicative of data which have been or are being submitted to EPA in accordance with a test rule.

(b)(1) If a single representative substance is to be tested under a test rule, EPA will consider all forms of the chemical subject to that rule to be equivalent and will contact the exemption applicant only if information is missing or unclear.

(2) If two or more representative substances are to be tested under a test rule, EPA will evaluate equivalence claims made in each exemption application according to the criteria discussed in the test rule.

(i) If EPA finds an equivalence claim to be in error or inadequately supported, the applicant will be notified by certified mail. The applicant will be given 15 days to provide clarifying information.

(ii) Exemption applicants will be notified that equivalence has been accepted or rejected.

(c)(1) EPA will give exemption applicants final notice that they have received a conditional exemption through one of the following ways:

(i) A final Phase II test rule that adopts the study plans in a two-phase rulemaking.

(ii) A separate FEDERAL REGISTER notice in a single-phase rulemaking.

(iii) A letter by certified mail will give exemption applicants final notice that they have received a conditional exemption.

(2) All conditional exemptions thus granted are contingent upon the test sponsors' successful completion of testing according to the specifications of the test rule.

[50 FR 20660, May 17, 1985, as amended at 78 FR 72830, Dec. 4, 2013]

§ 790.88 Denial of exemption application.

(a) EPA may deny any exemption application if:

(1) EPA determines that the applicant has failed to demonstrate that the applicant's chemical is equivalent to the test substance; or

(2) The exemption applicant fails to submit any of the information specified in § 790.82; or

(3) The exemption applicant fails to submit any of the information specified in §790.85 if required in the test rule; or

(4)(i) For single-phase test rules, EPA has not received a letter of intent to conduct the test for which exemption is sought; or

(ii) For two-phase test rules, EPA has not received an adequate study plan for the test for which exemption is sought; or

(5) The study sponsor(s) fails to initiate the required testing by the deadlines adopted in the test rule; or

(6) The study sponsor(s) fails to submit data as required in the test standard and deadlines for submission of test data as adopted in the test rule or as modified in accordance with §790.55.

(b) EPA will notify the exemption applicant by certified mail or FEDERAL REGISTER notice of EPA's determination that the exemption application is denied.

§ 790.90 Appeal of denial of exemption application.

(a) Within 30 days after receipt of notification that EPA has denied an application for exemption, the applicant may file an appeal with EPA.

(b) The appeal shall indicate the basis for the applicant's request for reconsideration.

(c)(1) The applicant may also include a request for a hearing. Hearings will be held according to the procedures described in §790.97.

(2) Hearing requests must be submitted using the method specified in §790.5(b) and be received by EPA within 30 days of receipt of the Agency's notification under §790.88(b). Hearing requests must provide reasons why a hearing is necessary.

(d) If EPA determines that there are material issues of fact, then the request for a hearing will be granted. If EPA denies a hearing request, EPA will base its decision on the written submission.

(e) EPA will notify the applicant of its decision within 60 days after EPA receives the appeal described in paragraph (a) of this section or within 60 days after completion of a hearing described in paragraph (c) of this section.

(f) The filing of an appeal from the denial of an exemption shall not act to stay the applicant's legal obligations under a test rule promulgated under section 4 of the Act.

[50 FR 20660, May 17, 1985, as amended at 78 FR 72830, Dec. 4, 2013]

§ 790.93 Termination of conditional exemption.

(a) EPA shall terminate a conditional exemption if it determines that:

(1) The test which provided the basis for approval of the exemption application has not been started by the deadlines for initiation of testing adopted in the test rule or modified in accordance with §790.55; or

(2) Data required by the test rule have not been generated in accordance with the test standards or submitted in accordance with the deadlines for submission of test data that were adopted in the test rule or modified in accordance with §790.55; or

(3) The testing has not been conducted or the data have not been generated in accordance with the Good Laboratory Practice requirements in part 792 of this chapter.

(b) If EPA determines that one or more of the criteria listed in paragraph (a) of this section has been met, EPA will notify each holder of an affected conditional exemption by certified mail or FEDERAL REGISTER notice of EPA's intent to terminate that conditional exemption.

(c) Within 30 days after receipt of a letter notification or publication of a notice in the FEDERAL REGISTER that EPA intends to terminate a conditional exemption, the exemption holder may submit information using the method specified in §790.5(b) either to rebut EPA's preliminary decision or notify EPA of its intent to conduct the required test pursuant to the test standard established in the test rule. Such a letter of intent shall contain all of the information required by §790.45(c).

(d)(1) The exemption holder may also include a request for a hearing. Hearings will be held in accordance with the procedures set forth in §790.97.

(2) Hearing requests must be submitted using the method specified in §790.5(b) and must be received by EPA

within 30 days after receipt of the letter or publication in the FEDERAL REGISTER notice described in paragraph (b) of this section.

(e) EPA will notify the exemption holder by certified letter or by FEDERAL REGISTER notice of EPA's final decision concerning termination of conditional exemptions and will give instructions as to what actions the former exemption holder must take to avoid being found in violation of the test rule.

[50 FR 20660, May 17, 1985, as amended at 78 FR 72830, Dec. 4, 2013]

§ 790.97 Hearing procedures.

(a) Hearing requests must be submitted using the method specified in § 790.5(b). Such requests must include the applicant's basis for appealing EPA's decision.

(b) If more than one applicant has requested a hearing on similar grounds, all of those appeals will be considered at the same hearing unless confidentiality claims preclude a joint hearing.

(c) EPA will notify each applicant of EPA's decision within 60 days after the hearing.

[50 FR 20660, May 17, 1985, as amended at 78 FR 72830, Dec. 4, 2013]

§ 790.99 Statement of financial responsibility.

Each applicant for an exemption shall submit the following sworn statement with his or her application:

I understand that if this application is granted before the reimbursement period described in section 4(c)(3)(B) of TSCA expires, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit data and upon whose data the granting of my application was based.

PART 791—DATA REIMBURSEMENT

Subpart A—General Provisions

Sec.

Subpart B—Hearing Procedures

Subpart C—Basis for Proposed Order

Subpart D—Review

Subpart E—Final Order

Subpart F—Prohibited Acts

AUTHORITY: 15 U.S.C. 2603 and 2607.

SOURCE: 48 FR 31791, July 11, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 791.1 Scope and authority.

(a) This part establishes procedures and criteria to be used in determining fair amounts of reimbursement for testing costs incurred under section 4(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2603(a)).

(b) Section 4(c) of TSCA requires EPA to develop rules for the determination of fair and equitable reimbursement (15 U.S.C. 2603 (c)).

§ 791.2 Applicability.

(a) This rule is potentially applicable to all manufacturers, importers and processors who may be required by a specific test rule promulgated under section 4(a) of TSCA to conduct tests and submit data, and who seek the assistance of the Administrator in determining the amount or method of reimbursement. Persons subject to a test rule have an obligation from the date the test rule becomes effective until the end of the reimbursement period,