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.

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