(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.

(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.

[51 FR 23715, June 30, 1986, as amended at 54 FR 36314, Sept. 1, 1989]

§ 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 at the address 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]

§ 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 to be a ''prohibited act'' under section 15 of TSCA, subject to all of 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.

§ 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