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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 (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 by letter of his or her intent to conduct testing or submit to EPA an application for an exemption from testing requirements for the test.

(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 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 (b)(4) of this section, all manufacturers and processors 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 paragraph (b)(4) of this section.

(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 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 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 give the processors an opportunity to take corrective action.

(3) If no processor 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 (c)(2) of this section, all processors 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.

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

### § 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

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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 made in writing to EPA at the address in § 790.5(b). Each 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

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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 shall submit all amendments to study plans to the Director, Office of Compliance Monitoring at the address in § 790.5(d).

[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]

### § 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 in writing to EPA at the address in § 790.5(b), or by phone with written confirmation to follow within 10 working days. 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 should submit these requests to EPA at the address in § 790.5(b).