

## § 790.80

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

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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]

### 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

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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