ATTACHMENT 1

Toxic Substances Control Act Section 4

15 USC 2603

TITLE 15 - COMMERCE AND TRADE
CHAPTER 53 - TOXIC SUBSTANCES CONTROL
SUBCHAPTER I - CONTROL OF TOXIC SUBSTANCES

Sec. 2603. - Testing of chemical substances and mixtures

(a) Testing requirements

If the Administrator finds that -

(1)(A)(i)

the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii)

there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii)

testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i)

a chemical substance or mixture is or will be produced in substantial quantities, and

(I)

it enters or may reasonably be anticipated to enter the environment in substantial quantities or

(II)

there is or may be significant or substantial human exposure to such substance or mixture,

(ii)

there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii)

testing of such substance or mixture with respect to such effects is necessary to develop such data; and

(2)

in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule require that testing be conducted on such substance or mixture to

develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

(b) Testing requirement rule

(1)

A rule under subsection (a) of this section shall include -

(A)

identification of the chemical substance or mixture for which testing is required under the rule,

(B)

standards for the development of test data for such substance or mixture, and

(C)

with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), in a rule under subsection (a) of this section, the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule. Any such rule may require the submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).

(2)(A)

The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B)

From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) of this section and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3)(A)

A rule under subsection (a) of this section respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B)

The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule under subsection (a) of this section:

(i)

Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) of this section with respect to the manufacture of such substance or mixture.

(ii)

Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) of this section with respect to the processing of such substance or mixture.

(iii)

Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) of this section with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(4)

Any rule under subsection (a) of this section requiring the testing of and submission of data for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B) of this section) which is applicable to test data for such substance or mixture unless the Administrator repeals the rule before such date; and a rule under subsection (a) of this section requiring the testing of and submission of data for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to test data for such substance or mixture unless the Administrator before such date repeals the application of the rule to such substance or mixture or repeals the rule.

(5)

Rules issued under subsection (a) of this section (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5 except that

(A)

the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions;

(B)

a transcript shall be made of any oral presentation; and

(C)

the Administrator shall make and publish with the rule the findings described in paragraph (1)(A) or (1)(B) of subsection (a) of this section and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

(c) Exemption

(1)

Any person required by a rule under subsection (a) of this section to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2)

If, upon receipt of an application under paragraph (1), the Administrator determines that -

(A)

the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule under subsection (a) of this section or for which data is being developed pursuant to such a rule, and

(B)

submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with such rule or which is being developed pursuant to such rule, the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture under the rule with respect to which such application was submitted.

(3)(A)

If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i)

to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii)

to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission,

consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B)

For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period -

(i)

beginning on the date such data is submitted in accordance with a rule promulgated under subsection (a) of this section, and

(ii)

ending -

(I)

five years after the date referred to in clause (i), or

(II)

at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such data, whichever is later.

(4)(A)

If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule promulgated under subsection (a) of this section, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i)

to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rule, and

(ii)

to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B)

If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing test data pursuant to a rule promulgated under subsection (a) of this section and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall

(i)

after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and

(ii)

notify in writing such person of the requirements of the rule with respect to which such exemption was granted.

(d) Notice

Upon the receipt of any test data pursuant to a rule under subsection (a) of this section, the Administrator shall publish a notice of the receipt of such data in the Federal Register within 15 days of its receipt. Subject to section 2613 of this title, each such notice shall

(1)

identify the chemical substance or mixture for which data have been received;

(2)

list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and

(3)

describe the nature of the test data developed. Except as otherwise provided in section 2613 of this title, such data shall be made available by the Administrator for examination by any person.

(e) Priority list

(1)(A)

There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a) of this section. In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including -

(i)

the quantities in which the substance or mixture is or will be manufactured,

(ii)

the quantities in which the substance or mixture enters or will enter the environment,

(iii)

the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv)

the extent to which human beings are or will be exposed to the substance or mixture,

(v)

the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi)

the existence of data concerning the effects of the substance or mixture on health or the environment,

(vii)

the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii)

the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) of this section with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a) of this section. The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B)

As soon as practicable but not later than nine months after January 1, 1977, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceeding [1] sentence, the committee shall make such provisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) of this section or

if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

(2)(A)

The committee established by paragraph (1)(A) shall consist of eight members as follows:

(i)

One member appointed by the Administrator from the Environmental Protection Agency.

(ii)

One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.).

(iii)

One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv)

One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v)

One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi)

One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii)

One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii)

One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(B)(i)

An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii)

No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(iii)

Initial appointments to the committee shall be made not later than the 60th day after January 1, 1977. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C)(i)

No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this chapter or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii)

No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this chapter or of any rule promulgated or order issued thereunder.

(iii)

The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D)

The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(f) Required actions

Upon the receipt of -

(1)

any test data required to be submitted under this chapter, or

(2)

any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under section 2604, 2605, or 2606 of this title to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5. This subsection shall not take effect until two years after January 1, 1977.

(g) Petition for standards for the development of test data

A person intending to manufacture or process a chemical substance for which notice is required under section 2604(a) of this title and who is not required under a rule under subsection (a) of this section

to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 2613 of this title, in the Federal Register the reasons for such denial

[1] So in original. Probably should be "preceding".

ATTACHMENT 2

40 CFR 790

Procedures Governing Testing Consent Agreements and Test Rules

Title 40: Protection of Environment

PART 790—PROCEDURES GOVERNING TESTING CONSENT AGREEMENTS AND TEST RULES

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. If such a consensus does not exist and the Agency believes that it can make the findings specified in section 4(a), EPA will initiate proceedings to promulgate test rules which will be codified in part 799 of this chapter.

(d) Appendix A to this part presents timetables for various steps in the evaluation of chemicals under consideration for testing, the initiation and completion of negotiations to develop consent agreements, and the proposal and promulgation of test rules. All deadlines which are imposed by the Act are binding on EPA and will be observed by the Agency. The remaining deadlines represent target dates that EPA intends to meet.

[51 FR 23712, June 30, 1986]

§ 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.

Chemical means a chemical substance or mixture.

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 uninitentionally 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]

§ 790.5 Submission of information.

(a) All submissions to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule, or indicate the identity of the consent agreement. For all submissions under this part, six copies must be provided to EPA.

(b) Submissions containing both confidential business information or non-confidential business information must be addressed to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G–099, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: TSCA Section 4.

[50 FR 20656, May 17, 1985, as amended at 51 FR 23712, June 30, 1986; 58 FR 34205, June 23, 1993; 60 FR 31922, June 19, 1995; 60 FR 34466, July 3, 1995]

§ 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]

Subpart B—Procedures for Developing Consent Agreements and Test Rules

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

§ 790.20 Recommendation and designation of testing candidates by the ITC.

(a) Recommendations with intent to designate. The ITC has advised EPA that it will discharge its responsibilities under section 4(e) of the Act 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 the Act.

(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 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 the Act.

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

(b) EPA consideration of ITC recommendations. (1) Where a substance or mixture is designated for EPA action under section 4(e)(1)(B) of the Act, 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 the Act.

(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 the Act are unnecessary if it determines that the findings specified in section 4(a) of the Act cannot be made or if the Agency has entered into a consent agreement requiring testing in accordance with the provisions of this subpart.

(2) Where a substance or mixture has been recommended for testing by the ITC 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 responsiblities. EPA may respond to the ITC's recommendations either by:

(i) Initiating rulemaking proceedings under section 4(a) of the Act.

(ii) Publishing a Federal Register notice explaining the Agency's reasons for concluding that testing is unnecessary.

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

§ 790.22 Procedures for gathering information and negotiating consent agreements on chemicals which the ITC has recommended for testing with an intent to designate.

(a) Preliminary EPA evaluation. 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. Appendix A 1 to this part presents the schedule that EPA intends to follow for this purpose.

(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 notice adding all ITC-recommended chemicals to the

automatic reporting provisions of its rules under sections 8(a) and 8(d) of the Act (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 the 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.

(b) Negotiation procedures for consent agreements. Where EPA believes that testing is necessary, the Agency will explore whether a consent agreement can be negotiated that satisfies the testing needs identified by the Agency. EPA will use the following procedures for negotiating, formulating and accepting consent agreements. Appendix A 1 to this part presents the schedule that EPA intends to follow for this purpose.

(1) In the Federal Register notice described in paragraph (a)(1) of this section, EPA will explain its procedures and timetable for negotiating consent agreements and invite persons interested in participating in or monitoring negotiations to contact the Agency in writing.

(2) Persons who respond to EPA's notice by the announced date of the Agency's course-setting meeting will be deemed “interested parties” for purposes of any negotiations that EPA conducts.

(3) Following the course-setting meeting announcing EPA's preliminary testing determinations, the Agency will meet with manufacturers, processors and other interested parties for the purpose of attempting to negotiate a consent agreement. To facilitate attendance at these meetings, EPA will contact all interested parties who have expressed a desire to participate in or monitor negotiations under paragraph (b)(2) of this section and advise them of meeting dates.

(4) All negotiating meetings will be open to members of the public. The minutes of each meeting will be prepared by EPA. Meeting minutes, testing proposals, background documents and other materials exchanged at or prepared for negotiating meetings will be included in the public file established by EPA on each ITC-recommended chemical. Materials in this file will be made available for inspection in the OPPTS Reading Room during EPA working hours.

(5) While negotiations are underway, EPA will promptly circulate meeting minutes, testing proposals, correspondence and other relevant materials to interested parties who expressed a desire to participate in or monitor negotiations pursuant to paragraph (b)(2) of this section.

(6) As negotiations progress, EPA will make a tentative decision either to proceed with formulation of a consent agreement or to initiate rulemaking. EPA will terminate negotiations after 10 weeks and proceed with rulemaking unless negotiations are likely to result in a draft consent agreement within 4 additional weeks. By the end of this 4-week period, EPA either will have prepared a draft consent agreement reflecting the apparent consensus of the parties or will terminate negotiations and proceed with rulemaking. If EPA decides to proceed with rulemaking, no further opportunity for negotiations will be provided. EPA will promptly send written notice to all interested parties of the termination of negotiations.

(7) Where EPA prepares a draft consent agreement, it will be circulated for comment to all interested parties who expressed a desire to participate in or monitor negotiations under paragraph (b)(2) of this section. A period of 4 weeks will be provided for submitting comments or written objections under §790.24(a).

(8) If necessary, EPA will hold a public meeting to discuss comments on the draft consent agreement and to determine whether revisions in the agreement are appropriate.

(9) Where a consensus exists concerning the contents of a draft consent agreement, it will be circulated to EPA management and interested parties for final approval and signature.

(10) Upon final approval of a consent agreement, EPA will publish a Federal Register notice that summarizes the agreement, describes the ITC recommendations for the test substance, outlines the chemical's use and exposure characteristics, and explains the background, objectives and rationale of the testing to be conducted, and codifies in subpart C of part 799 the name of the substance(s) to be tested and the citation to the Federal Register notice of the agreement.

§ 790.24 Criteria for determining whether a consensus exists concerning the provisions of a draft consent agreement.

(a) 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 §790.22(b)(2). EPA will not enter into a consent agreement in either of the following circumstances:

(1) EPA and affected manufacturers and/or processors cannot reach a consensus on the testing requirements or other provisions to be included in the consent agreement.

(2) A draft consent agreement is considered inadequate by other interested parties who, pursuant to §790.22(b)(2), have asked to participate in or monitor negotiations; and these parties 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.

(b) EPA may reject objections described in paragraph (a)(2) of this section only where the Agency concludes the objections are either:

(1) Not made in good faith.

(2) Untimely.

(3) 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 the Act.

(4) Not accompanied by a specific explanation of the grounds on which the draft agreement is considered objectionable.

(c) The unwillingness of some manufacturers and/or processors of a prospective test chemical 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 the Act in all other respects.

§ 790.26 Initiation and completion of rulemaking proceedings on ITC-designated chemicals.

(a) Where EPA concludes that a consensus does not exist concerning the provisions of a draft consent agreement and that the findings specified by section 4(a) can be made, the Agency will proceed with rulemaking under section 4(a) of TSCA.

(b) When EPA decides to proceed with rulemaking under paragraph (a) of this section, the Agency intends to publish a rulemaking proposal and a final rule or a notice terminating the rulemaking proceeding in accordance with the schedule specified in Appendix A 1 to this part.

1Editorial Note: Appendix A appears at the end of subpart E.

(c) 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 publish an

Advance Notice of Proposed Rulemaking (ANPR). The schedule that EPA intends to follow for rulemaking proceedings initiated by publication of an ANPR is presented in appendix A 1 to this part.

§ 790.28 Procedures for developing consent agreements and/or test rules for chemicals that have not been designated or recommended with intent to designate by the ITC.

(a) Where EPA believes that testing is needed, it may also develop consent agreements and/or test rules on chemical substances or mixtures that either:

(1) Have been recommended but not "recommended with intent to designate" by the ITC.

(2) Have been selected for testing consideration by EPA on its own initiative.

(b) When EPA wishes to initiate negotiations concerning chemicals described in paragraph (a) of this section, it will publish a Federal Register notice describing its tentative evaluation of testing needs, announcing a date for a public course-setting meeting, and inviting persons interested in participating in or monitoring negotiations to contact the Agency in writing. Any negotiations that EPA conducts will conform to the procedures specified in §790.22(b) and, to the extent feasible, will follow the schedules presented in appendix A 1 to this part.

(c) EPA will enter into consent agreements on chemicals described in paragraph (a) of this section only if there is a consensus among EPA, affected manufacturers and/or processors, and any other persons who have asked to participate in or monitor negotiations. In determining whether such a consensus exists, EPA will employ the criteria specified in §790.24. In the absence of consensus, EPA will initiate rulemaking if it concludes that the findings specified in section 4(a) of the Act can be made. The schedule for initiating and completing such rulemaking proceedings will, to the extent feasible, follow the schedule specified in appendix A 1 to this part.

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 rule and required to comply with the requirements of that rule as provided in §790.42(a) must, for each test required, 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.

(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.

(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.

§ 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 (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 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 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).

(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]

§ 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 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.

(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 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 §790.24. 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 order 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. EPA will consider only those applications that request modifications to mandatory testing conditions or

requirements (“shall statements” in the consent order). Where a test sponsor requests EPA to provide guidance or to clarify a non-mandatory testing requirement (i.e., “should statements”), the test sponsor should submit these requests to EPA at the address in section 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]

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) The final Phase II test rule which adopts the study plans in two-phase rulemaking, a separate Federal Register notice in single-phase rulemaking, or a letter by certified mail will give exemption applicants final notice that they have received a conditional exemption. All conditional exemptions thus granted are contingent upon the test sponsors' successful completion of testing according to the specifications in the test rule.

§ 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 in writing and must be received by EPA within 30 days of receipt of the letter or publication of the Federal Register notice described in §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.

§ 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 of notification or publication of a notice in the Federal Register that EPA intends to terminate a conditional exemption, the exemption holder may submit information to rebut EPA's preliminary decision or notify EPA by letter of its intent to conduct the required test pursuant to the test standard established in the final 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 in writing 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.

§ 790.97 Hearing procedures.

(a) Hearing requests must be in writing to EPA and 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.

§ 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.

Appendix A to Subpart E of Part 790—Schedule for Developing Consent Agreements and Test Rules

EPA intends to follow the schedule set forth in this Appendix to evaluate testing candidates, conduct negotiations, develop consent agreements where appropriate, and propose and promulate test rules in those instances where testing can be required under section 4(a) of TSCA but agreement cannot be reached in timely manner on a consent agreement. Where deadlines are imposed by the statute, they are binding on EPA and will be observed by the Agency. The remaining dates represent targets that EPA intends to meet.

This schedule is based on what EPA currently believes are reasonable target dates. As EPA gains experience with the process and determines the feasibility of these schedules, it may adjust the schedule accordingly. EPA will solicit public comment before implementing any changes in the schedule.

Week \1\	Event
0	Receive ITC report, recommendation.
2	Publish ITC report, 8(a) and 8(d) notices, and invitation for public participation in negotiations.
3-6	Comment period on ITC report.
6	Public focus meeting.
7-14	8(a) and 8(d) reporting period.
22	Public meeting on course-setting decision and deadline for requests to participate in negotiations.
22-30	Negotiations.
32	EPA decision point: consent agreement or test rule.

\1\ The dates contained in the left-hand column are calculated from the date EPA receives the ITC report recommending a chemical for testing.

Week	Consent Agreement	Week	Test Rule
36-40	Comment period on consent agreement.	32-60	Rule preparation, agency review and sign-off.
42	Comment resolution meeting if necessary.	62	Publish proposed rule in Federal Register.\1\
48	Sign-off consent agreement and Federal Register notice.	70-106	Agency reviews comments; preparation of final rule or no-test decision, agency review and sign-off.\1\
50	Publish Federal Register notice.	108	Publish final rule or no-test decision in Federal Register.\1\

\1\ As stated in § 790.26, EPA may publish an Advance Notice of Proposed Rulemaking (ANPR) where the testing recommendations of the ITC raise unusually novel and complex issues that require additional Agency review and opportunity for public comment. EPA intends to publish such ANPRs by Week 62 following receipt of the initial ITC report; to publish a proposed rule or decision-not-to-test by Week 108; and to publish a final rule or notice terminating the rulemaking process by Week 154.

[51 FR 23717, June 30, 1986]

ATTACHMENT 3

OPPT TSCA Test Guidelines Cost Summary

Wage Rates Estimation

1. Overview

Wage rates including fringe benefits and overhead for government labor and three broad industry categories of labor (managerial, technical, and clerical) were used in this cost analysis. The labor categories and loaded wage rates were developed during previous studies. The methodology used in developing wage rates is summarized below.

LABOR CATEGORY	LOADED HOURLY RATE
Government	
GS-13, Step 1	$55.47
Industry	
Managerial	$53.82
Technical	$46.08
Clerical	$24.47

2. Government

The Federal government collection activity procedures described in this report are expected to be accomplished by a GS-13, Step 1, Federal full-time equivalent (FTE) employee. One FTE is equivalent to 2,080 hours per year. The 2004 cost of an FTE employee was based on the Office of Personnel Management's 2004 General Schedule Locality Rates of Pay for Washington-Baltimore, DC-MD-VA-WV (OPM 2004).

The annual costs per FTE are derived by multiplying the annual pay rate by 1.6, the benefits multiplication factor. The multiplication factor used is recommended in EPA's Office of Policy, Planning, and Evaluation's *Instructions for Preparing Information Collection Requests* (ICRs) (June 1, 1992). The benefits multiplication factor of 1.6 includes not only benefits but also overhead.[1] See Table A-1 for the full calculation.

[1] Internal EPA phone call between Carol Rawie (OPPT/EETD/RIB) and Carl Koch (OPPE/RMD/IMB), May 3, 1994.

3. Technical, Managerial, and Clerical Labor

The basic method used to derive loaded wage rates for technical, managerial, and clerical personnel is described more fully in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002).

December 2003 average wages for technical, managerial, and clerical labor were taken from the Employer Costs for Employee Compensation (ECEC) report from the Bureau of Labor Statistics (BLS) for all goods-producing, private industries.[2]

The additional cost of benefits, such as paid leave and insurance ("fringe benefits"), specific to each labor category, are also taken from the same BLS series. Fringe benefit as a percentage of wage is then calculated separately for each labor category. For example, the average wage rate in December 2003 for technical labor was $28.36; the average fringe benefit was $12.90. So fringe benefit as a percentage of wage rate for technical labor was 12.90/28.36, or approximately 45.5 percent.

An additional loading factor of 17 percent is applied to wages for overhead.[3] This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage. The fully loaded wage for technical labor, for example, is $28.36*(1+0.455 + 0.17) = $28.36*(1.625) = $46.08.

Fully loaded costs for managerial and clerical labor were calculated in a similar manner. See Table A-1 for the full calculations.

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[2] Employer Costs for Employee Compensation, Private industry workers, Goods-producing industries, white-collar occupations, as published by the U.S. Department of Labor, Bureau of Labor Statistics. The December 2003 values for these series are listed in Table 11 of the *Employer Costs for Employee Compensation Summary*, released February 2004.

[3] An overhead rate of 17 percent applied to wages is used for consistency with recent EPAB economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, June 10, 2002, and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*, August 2002. In reports for an earlier SNUR (EPAB 1999), the 17 percent was applied to wages-plus-fringe benefits. Applying it only to wages reduces calculated overhead.

4. References

BLS 2004. Bureau of Labor Statistics. *Employer Costs for Employee Compensation - December 2003: Private industry, goods-producing workers by occupational group (Table 11)*, February 24, 2004.

EPAB 1999. *Economic Analysis of Expedited Significant New Use Rules for 41 Chemical Substances and Background Support Document for Economic Analysis of Significant New Use Rules.* Washington, DC: U.S.EPA/OPPT/EETD/EPAB, July 20, 1999. EPA Docket OPPTS

OPM 2004. U.S. Office of Personnel Management. *Salary Table 2004-DCB (Washington-Baltimore).*

Rice 2002. Cody Rice. *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, Washington, DC: U.S. EPA, Office of Environmental Information, Environmental Analysis Division, June 10, 2002.

Table A-1 Derivation of Loaded Wage Rates

Labor Category	Data Sources	Uninflated wages and fringes / hour			Fringe benefits as % of wage	Over-head as % of wage*	Fringe + Overhead factor	Loaded Wage Rate before inflation	Inflation factor	Loaded Wage Rate (2003 dollars)
		Date	Wages $	Fringe benefits $						
Technical	*BLS Employer Costs for Employee Compensation*, Table 11. Private industry, goods-producing industries, professional, specialty and **technical**. Dec 03. [BLS 2004]	Dec 2003	$28.36	$12.90	45.5%	17%	1.625	$46.09	1	$46.09
Managerial	*BLS Employer Costs for Employee Compensation*, Table 11. Private industry, goods-producing industries, executive, administrative, and **managerial**. Dec 03. [BLS 2004]	Dec 2003	$32.90	$15.33	46.6%	17%	1.636	$53.82	1	$53.82
Clerical	*BLS Employer Costs for Employee Compensation*, Table 11. Private industry, goods-producing industries, administrative support, including **clerical.** Dec 03. [BLS 2004]	Dec 2003	$15.09	$6.81	45.1%	17%	1.621	$24.46	1	$24.46
EPA staff FTE	Office of Personnel Management (OPM) pay rates for GS-13 Step 1 for 2004. [OPM 2004]	2004	$72,108 per year	-	-	-	1.6	$115,373 per year	1	$115,373 per year $55.47 per hour**

*An overhead rate of 17 percent applied to wages is used for consistency with recent EPAB economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, June 10, 2002, and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*, August 2002.

** Hourly rate = Annual salary/2,080 hours

ATTACHMENT 4

Wage Rates Estimation

E. Overview

Wage rates including fringe benefits and overhead for government labor and three broad industry categories of labor (managerial, technical, and clerical) were used in this cost analysis. The labor categories and loaded wage rates were developed during previous studies. The methodology used in developing wage rates is summarized below.

LABOR CATEGORY	LOADED HOURLY RATE
Government	
GS-13, Step 1	$55.47
Industry	
Managerial	$53.82
Technical	$46.08
Clerical	$24.47

F. Government

The Federal government collection activity procedures described in this report are expected to be accomplished by a GS-13, Step 1, Federal full-time equivalent (FTE) employee. One FTE is equivalent to 2,080 hours per year. The 2004 cost of an FTE employee was based on the Office of Personnel Management's 2004 General Schedule Locality Rates of Pay for Washington-Baltimore, DC-MD-VA-WV (OPM 2004).

The annual costs per FTE are derived by multiplying the annual pay rate by 1.6, the benefits multiplication factor. The multiplication factor used is recommended in EPA's Office of Policy, Planning, and Evaluation's *Instructions for Preparing Information Collection Requests* (ICRs) (June 1, 1992). The benefits multiplication factor of 1.6 includes not only benefits but also overhead.[4] See Table A-1 for the full calculation.

[4] Internal EPA phone call between Carol Rawie (OPPT/EETD/RIB) and Carl Koch (OPPE/RMD/IMB), May 3, 1994.

G. Technical, Managerial, and Clerical Labor

The basic method used to derive loaded wage rates for technical, managerial, and clerical personnel is described more fully in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002).

December 2003 average wages for technical, managerial, and clerical labor were taken from the Employer Costs for Employee Compensation (ECEC) report from the Bureau of Labor Statistics (BLS) for all goods-producing, private industries.[5]

The additional cost of benefits, such as paid leave and insurance ("fringe benefits"), specific to each labor category, are also taken from the same BLS series. Fringe benefit as a percentage of wage is then calculated separately for each labor category. For example, the average wage rate in December 2003 for technical labor was $28.36; the average fringe benefit was $12.90. So fringe benefit as a percentage of wage rate for technical labor was 12.90/28.36, or approximately 45.5 percent.

An additional loading factor of 17 percent is applied to wages for overhead.[6] This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage. The fully loaded wage for technical labor, for example, is $28.36*(1+0.455 + 0.17) = $28.36*(1.625) = $46.08.

Fully loaded costs for managerial and clerical labor were calculated in a similar manner. See Table A-1 for the full calculations.

H. References

BLS 2004. Bureau of Labor Statistics. *Employer Costs for Employee Compensation - December 2003: Private industry, goods-producing workers by occupational group (Table 11)*, February 24, 2004.

[5] Employer Costs for Employee Compensation, Private industry workers, Goods-producing industries, white-collar occupations, as published by the U.S. Department of Labor, Bureau of Labor Statistics. The December 2003 values for these series are listed in Table 11 of the *Employer Costs for Employee Compensation Summary*, released February 2004.

[6] An overhead rate of 17 percent applied to wages is used for consistency with recent EPAB economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, June 10, 2002, and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*, August 2002. In reports for an earlier SNUR (EPAB 1999), the 17 percent was applied to wages-plus-fringe benefits. Applying it only to wages reduces calculated overhead.

EPAB 1999. *Economic Analysis of Expedited Significant New Use Rules for 41 Chemical Substances and Background Support Document for Economic Analysis of Significant New Use Rules.* Washington, DC: U.S.EPA/OPPT/EETD/EPAB, July 20, 1999. EPA Docket OPPTS

OPM 2004. U.S. Office of Personnel Management. *Salary Table 2004-DCB (Washington-Baltimore).*

Rice 2002. Cody Rice. *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, Washington, DC: U.S. EPA, Office of Environmental Information, Environmental Analysis Division, June 10, 2002.

Table A-1 Derivation of Loaded Wage Rates

Labor Category	Data Sources	Uninflated wages and fringes / hour			Fringe benefits as % of wage	Over-head as % of wage*	Fringe + Overhead factor	Loaded Wage Rate before inflation	Inflation factor	Loaded Wage Rate (2003 dollars)
		Date	Wages $	Fringe benefits $						
Technical	*BLS Employer Costs for Employee Compensation*, Table 11. Private industry, goods-producing industries, professional, specialty and **technical**. Dec 03. [BLS 2004]	Dec 2003	$28.36	$12.90	45.5%	17%	1.625	$46.09	1	$46.09
Managerial	*BLS Employer Costs for Employee Compensation*, Table 11. Private industry, goods-producing industries, executive, administrative, and **managerial**. Dec 03. [BLS 2004]	Dec 2003	$32.90	$15.33	46.6%	17%	1.636	$53.82	1	$53.82
Clerical	*BLS Employer Costs for Employee Compensation*, Table 11. Private industry, goods-producing industries, administrative support, including **clerical.** Dec 03. [BLS 2004]	Dec 2003	$15.09	$6.81	45.1%	17%	1.621	$24.46	1	$24.46
EPA staff FTE	Office of Personnel Management (OPM) pay rates for GS-13 Step 1 for 2004. [OPM 2004]	2004	$72,108 per year	-	-	-	1.6	$115,373 per year	1	$115,373 per year $55.47 per hour**

*An overhead rate of 17 percent applied to wages is used for consistency with recent EPAB economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, June 10, 2002, and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*, August 2002.

** Hourly rate = Annual salary/2,080 hours

ATTACHMENT 5

Supplemental Break-Outs for Table 4

Annual Respondent Burden Estimates for Reporting - By Program

COLLECTION ACTIVITY	Unit	Programs								GRAND TOTAL	
		Test Rule		Consent Order		Children's Health		HPV			
	Hrs	#	Hrs	#	Hrs	#	Hrs	#	Hrs	#	Hrs
INTERIM REPORTS											
Letter of Intent and Study Plans	40	3	120	8	320	2	80	100	4,000	113	4,520
Prepare Progress Report	8	300	2,400	800	6,400	660	5,280	0	0	1,760	14,080
INTERIM REPORTS Subtotal			2,520		6,720		5,360		4,000		18,600
FINAL REPORTS											
Short-term Studies											
Record and Prepare Test for Submission	40	105	4,200	280	11,200	220	8,800	9,061	362,440	9,666	386,640
Laboratory Review	6	105	630	280	1,680	220	1,320	9,061	54,366	9,666	57,996
Corporate Review	6	105	630	280	1,680	220	1,320	9,061	54,366	9,666	57,996
Type and Print Results	20	105	2,100	280	5,600	220	4,400	9,061	181,220	9,666	193,320
Record Keeping	1	105	105	280	280	220	220	9,061	9,061	9,666	9,666
Short-term Subtotal			7,665		20,440		16,060		661,453		705,618

COLLECTION ACTIVITY	Unit	Programs								GRAND TOTAL	
		Test Rule		Consent Order		Children's Health		HPV			
	Hrs	#	Hrs	#	Hrs	#	Hrs	#	Hrs	#	Hrs
Long-term Studies											
Record and Prepare Test for Submission	80	60	4,800	160	12,800	132	10,560	0	0	352	28,160
Laboratory Review	9	60	540	160	1,440	132	1,188	0	0	352	3,168
Corporate Review	9	60	540	160	1,440	132	1,188	0	0	352	3,168
Type and Print Results	40	60	2,400	160	6,400	132	5,280	0	0	352	14,080
Record Keeping	1	60	60	160	160	132	132	0	0	352	352
Long-term Subtotal			8,340		22,240		18,348		0		48,928
FINAL REPORTS SUBTOTAL			16,005		42,680		34,408		661,453		754,546
Total			18,525		49,400		39,768		665,453		773,146

Annual Respondent Cost Estimates for Reporting - By Program

COLLECTION ACTIVITY	UNIT		Test Rules		Consent Orders		Children's Health		HPV		GRAND TOTAL	
	Hrs$	Supply	#	$	#	$	#	$	#	$	#	COSTS
INTERIM REPORTS												
Letter of Intent and Study Plans	$2,572	$20	3	$7,776	8	$20,736	2	$5,184	100	$259,200	113	$292,896
Prepare Progress Report	$514	$5	300	$155,820	800	$415,520	660	$342,804	0	$0	1,760	$914,144
Interim Reports Subtotal				$163,596		$436,256		$347,988		$259,200		$1,207,040
FINAL REPORTS												
Short-term Studies												
Record and Prepare Test for Submission	$2,572	$0	105	$270,060	280	$720,160	220	$565,840	9,061	$23,304,892	9,666	$24,860,952
Laboratory Review	$386	$0	105	$40,509	280	$108,024	220	$84,876	9,061	$3,495,734	9,666	$3,729,143
Corporate Review	$521	$0	105	$54,722	280	$145,925	220	$114,655	9,061	$4,722,231	9,666	$5,037,533
Type and Print Results	$513	$0	105	$53,823	280	$143,528	220	$112,772	9,061	$4,644,669	9,666	$4,954,792
Record Keeping	$26	$5	105	$3,216	280	$8,576	220	$6,739	9,061	$277,538	9,666	$296,070
Short-term Subtotal				$422,330		$1,126,213		$884,882		$36,445,064		$38,878,489
Long-term Studies												
Record and Prepare Test for Submission	$5,144	$0	60	$308,640	160	$823,040	132	$679,008	0	$0	352	$1,810,688
Laboratory Review	$579	$0	60	$34,722	160	$95,592	132	$76,388	0	$0	352	$203,702
Corporate Review	$782	$0	60	$46,904	160	$125,078	132	$103,190	0	$0	352	$275,172
Type and Print Results	$1,025	$0	60	$61,512	160	$164,032	132	$135,326	0	$0	352	$360,870
Record Keeping	$26	$5	60	$1,838	160	$4,901	132	$4,043	0	$0	352	$10,782
Long-term Subtotal				$453,616		$1,209,643		$997,956		$0		$2,661,215
Final Reports Subtotal				$875,946		$2,338,856		$1,882,837		$36,445,064		$41,539,704
Total				$1,039,542		$2,775,112		$2,230,825		$36,704,264		$42,746,744