

Environmental Protection Agency

§ 790.20

(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 con-

fidentiality 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, recommendation with an intent to designate, and designation of testing candidates by the ITC.

(a) *ITC recommendations and recommendations with intent to designate.* The ITC has advised EPA that it will discharge its responsibilities under section 4(e) of TSCA 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 TSCA.

(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 chemical 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 TSCA.

(4) The ITC reserves its right to designate any chemical substance or mixture that it determines the Agency should, within 12 months of the date

first designated, initiate a proceeding under section 4(a) of TSCA.

(b) *Preliminary EPA evaluation of ITC recommendations with intent to designate.* 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 on those chemical substances that the ITC has recommended with intent to designate:

(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 document adding all ITC-recommended chemicals to the automatic reporting provisions of its rules under sections 8(a) and 8(d) of TSCA (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 TSCA 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.

(c) *EPA response to ITC designations and recommendations*—(1) Where a chemical substance or mixture is designated for EPA action under section 4(e)(1)(B) of TSCA, 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 TSCA. 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 initiate rulemaking by publishing an Advance No-

tice of Proposed Rulemaking (ANPRM).

(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 TSCA are unnecessary if it determines that the findings specified in section 4(a) of TSCA cannot be made or if the Agency entered into a consent agreement requiring the testing identified by the ITC.

(2) Where a chemical substance or mixture has been recommended for testing by the ITC, whether with or 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 responsibilities. EPA may respond to the ITC's recommendations with action such as:

(i) Initiating rulemaking proceedings under section 4(a) of TSCA,

(ii) Publishing a FEDERAL REGISTER notice explaining the Agency's reasons for concluding that testing is unnecessary, or

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

[75 FR 56475, Sept. 16, 2010]

§ 790.22 Procedures for developing consent agreements.

(a) *Preliminary EPA evaluation of proposed consent agreement.* Where EPA believes that testing of a chemical substance or mixture may be needed, and wishes to explore whether a consent agreement may satisfy the identified testing needs, EPA will invite manufacturers and/or processors of the affected chemical substance or mixture to submit a proposed consent agreement to EPA. EPA will evaluate the proposal(s) and may request additional clarifications of or revisions to the proposal(s).

(b) *Negotiation procedures for consent agreements.* If, after evaluating the proposed consent agreement(s), EPA believes it is likely that proceeding with negotiation of a consent agreement would be an efficient means of developing the data, EPA will use the following procedures to conduct such negotiations: