Environmental Protection Agency

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

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

(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.

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 Notice 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.

§ 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