

Federal Register

40 CFR Part 799**[OPTS-42059A; FRL-2877-7]****1,1,1-Trichloroethane; Proposed Test Standard****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: EPA has issued a final rule under section 4(a) of the Toxic Substances Control Act (TSCA) requiring that manufacturers and processors of 1,1,1-trichloroethane (TCEA, CAS No. 71-55-6) test this chemical for developmentally toxic effects. The Agency is now proposing that the protocols and schedule submitted by an industry consortium be adopted as the test standards for TCEA under this test rule.

DATE: Submitted written comments on or before September 23, 1985.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42059A), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E-108, 401 M Street SW., Washington, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-543, 401 M Street SW., Washington, D.C. 20460. Toll free: (800-424-9065). In Washington, D.C.: (544-1404). Outside the U.S.A.: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: In the Federal Register of October 10, 1984 (49 FR 39810), EPA issued a final rule under section 4(a) of TSCA to require testing of TCEA for developmentally toxic effects. The Agency is now proposing that the industry-submitted protocols

and schedule be adopted as the test standards and reporting deadlines for the required testing.

I. Background

1.1.1-Trichloroethane (TCEA, CAS No. 71-55-6) was designated by the Interagency Testing Committee (ITC) for priority testing consideration (46 FR 30300; June 5, 1981). EPA promulgated a final phase I rule requiring testing of TCEA on October 10, 1984 (49 FR 39810). For a detailed discussion of EPA's findings and testing requirements for TCEA refer to the final phase I rule. In accordance with the Test Rule Development and Exemption Procedures for two-phase rulemaking in 40 CFR Part 790, persons subject to this rule were required to submit letters of intent to perform the testing or exemption applications. Those submitting letters of intent were required to submit proposed study plans and schedules for the testing required in the final phase I rule.

On December 20, 1984 (Ref. 7), the U.S. manufacturers and an importer of TCEA notified EPA of their intent to sponsor the testing required in the Phase I test rule and submitted proposed study plans on February 21, 1985 (Refs. 1 through 5).

EPA is now proposing that the submitted protocols and schedules be adopted as the test standards and reporting deadlines for the required testing of TCEA.

II. Proposed Test Standards

A consortium of manufacturers of TCEA, known as the Halogenated Solvents Industry Alliance (HSIA), including Dow Chemical Co., ICI Americas, Inc., PPG Industries, Inc., and Vulcan Materials Co. has notified EPA of their agreement to sponsor the testing required in the final phase I rule for TCEA in 40 CFR 790.4400. HSIA has submitted a proposed study plan for the required testing (Refs. 1 through 5). HSIA proposes to conduct the following studies: Inhalation Developmental Toxicity Probe Study in rabbits; Inhalation Developmental Toxicity Study in rabbits; Inhalation Developmental Toxicity Probe Study in rats. HSIA also proposes that if the rat probe study demonstrates that previous rodent studies conducted by industry and NIOSH were conducted at maternally toxic doses, no further rodent testing will be required; if this is not verified, an Inhalation Developmental Toxicity Study will be conducted on rats. However, EPA continues to believe that both the probe and Inhalation Developmental Toxicity Study need to be conducted in rats in order to fully characterize the toxicity of TCEA.

Therefore, as previously stated in the final Phase I rule (49 FR 39810), EPA requires that the full Developmental Toxicity Study be conducted on both the rat and rabbit.

HSIA has stated that these studies will be conducted in accordance with EPA TSCA Good Laboratory Practice Standards as set forth in 40 CFR Part 792.

Exposure levels of 0, 1,000, 3,000, and 6,000 ppm for 6 hr/day have been proposed for both the rat (days 6 through 15 of gestation) and rabbit (days 6 through 18 of gestation) probe studies, with exposure levels for the full inhalation developmental toxicity study based on results of the probe studies. HSIA has further specified that TCEA from a commercial source stabilized with less than 0.1 percent butylene oxide will be used as the test material. Either Sprague Dawley or Fisher 344 rats and New Zealand white rabbits will be used in this testing. The full protocol is available in the public docket for this action. The protocol submitted by HSIA has been reviewed by the Agency and conforms to the OTS Health Effects Test Guidelines for Inhalation Toxicity Testing. The Agency is proposing that these protocols be adopted as test standards for performing the developmental toxicity testing of TCEA required under 40 CFR 799.4400.

III. Reporting Requirements

HSIA has proposed that if the protocol can be made final in 1985, the testing could begin the second quarter of 1986. This is consistent with the schedule submitted by the EPA to and adopted by the Court in its final order for *NRDC v. EPA* (Ref. 6).

HSIA has proposed that within 90 days after the effective date of the final Phase II rule establishing the test standards, the manufacturers will make a final selection of the testing facility. The testing would be initiated within 6 months after the effective date of the final Phase II rule. Final reports of the probe studies will be submitted by week 36 for rabbits and week 37 for rats. The final report for the complete study on rabbits will be submitted by week 61. The final report for the complete study in rats will be submitted by week 70 (Ref. 5). EPA is proposing that this schedule be adopted for the developmental toxicity testing of TCEA.

As required by TSCA section 4(d), the Agency plans to publish in the Federal Register a notice of the receipt of any test data submitted under this test rule within 15 days after receipt of the data. Except as otherwise provided in TSCA, section 14, such data will be made

available for examination by any person.

IV. Issues for Comment

The Agency invites comments on the proposed study plans submitted by HSIA; copies of these study plans are included in the public record for this action. EPA also invites public comment on the proposed schedule for the required testing.

V. Public Record

EPA has established a record for this rulemaking, [docket number (OPTS-42059A)]. This record includes basic information considered by the Agency in developing this proposal and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received.

This record includes the following information:

A. Supporting Documentation

- (1) Final Phase I rule on 1,1,1-trichloroethane.
- (2) Written public comments and letters.
- (3) Contact reports of telephone conversations.

B. References

- (1) HSIA. Protocol. 1.1.1-Trichloroethane (TCEA): Inhalation Developmental Toxicity Probe Study in Rats. Halogenated Solvents Industry Alliance. Washington, D.C. January 1985. Submitted to EPA February 21, 1985.
- (2) HSIA. Protocol. 1.1.1-Trichloroethane (TCEA): Inhalation Developmental Toxicity Study in Rats. Halogenated Solvents Industry Alliance. Washington, D.C. January 1985. Submitted to EPA February 21, 1985.
- (3) HSIA. Protocol. 1.1.1-Trichloroethane (TCEA): Inhalation Developmental Toxicity Study Probe Study in Rabbits. Halogenated Solvents Industry Alliance. Washington, D.C. January 1985. Submitted to EPA February 21, 1985.
- (4) HSIA. Protocol. 1.1.1-Trichloroethane (TCEA): Inhalation Developmental Toxicity Study in Rabbits. Halogenated Solvents Industry Alliance. Washington, D.C. January 1985. Submitted to EPA February 21, 1985.
- (5) HSIA. Letter from H. Farber to J. Moore. OPTS. USEPA. April 17, 1985.
- (6) Southern District of New York. Final judgement and Order in *NRDC v. EPA*, 595 F. Supp. 1253 (S.D.N.Y., Oct. 30, 1984).
- (7) HSIA. Letter to USEPA from Halogenated Solvents Industry Alliance. December 20, 1984.

The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday except legal holidays, in Rm. E-107, 401 M Street SW., Washington, DC 20460.

VI. Other Regulatory Requirements**A. Executive Order 12291**

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirements of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The economic analysis of the testing of TCEA is discussed in the Phase I test rule (49 FR 39810).

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments received from OMB are included in the public record for this rulemaking.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses for the following reasons:

1. There are not a significant number of small businesses manufacturing TCEA.
2. Small processors will not perform testing themselves, or participate in the organization of the testing efforts.
3. Small processors will experience only very minor costs, if any, in securing exemption from testing requirements.
4. Small processors are unlikely to be affected by reimbursement requirements, and any testing costs passed on to small processors through price increases will be small.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070-0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB, marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection. Hazardous material, Chemicals.

Dated: July 31, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

It is proposed that 40 CFR Part 799 be amended as follows:

PART 799—[AMENDED]

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By amending § 799.4400 by revising paragraph (d)(1)(ii) and adding new paragraph (d)(1)(iii) to read as follows:

§ 799.4400 1,1,1-Trichloroethane.

(d) . . .

(1) . . .

(ii) *Test Standards.* The testing shall be conducted in accordance with the following study plans developed by the Halogenated Solvents Industry Alliance (HSIA), 1812 K St., NW., Washington, D.C. 20006, and submitted to the Agency on February 21, 1985: Inhalation Developmental Toxicity Probe Study in Rats, Inhalation Developmental Toxicity Study Rats, Inhalation Developmental Toxicity Probe Study in Rabbits, and Inhalation Development Toxicity Study in Rabbits which are incorporated by reference. Copies of these study plans are located in the public record for this rule (docket no. OPTS-42059A) and are available for inspection in the OPTS Reading Rm., E-107, 401 M Street SW., Washington, D.C. 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. These study plans are hereby incorporated by reference.

These incorporations by reference were approved by the Director of the Federal Register on [date]. These materials are incorporated as they exist on the date of the approval, and a notice of any change in these materials will be published in the Federal Register.

(iii) *Reporting requirements.* (A) The developmental toxicity testing shall be initiated within 6 months of the effective date of the final Phase II rule.

(B) The developmental toxicity tests shall be completed and the final results submitted to the Agency within 18 months of the effective date of the final Phase II rule.

(C) Progress reports shall be submitted quarterly to the Agency.

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