

ENVIRONMENTAL PROTECTION
AGENCY

40 CFR PART 799

[OPTS-42059B; FRL-2940-5]

**1,1,1-Trichloroethane: Final Test
Standards and Reporting
Requirements**AGENCY: Environmental Protection
Agency (EPA).

ACTION: Final rule.

SUMMARY: On October 10, 1984 EPA 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 developmental toxicity. In August 1985, the Agency proposed that the protocols and schedule submitted by an industry consortium be adopted as the test standings and reporting requirements for TCEA under this test rule. EPA has reviewed public comments on the proposal and has decided to promulgate a final rule that specifies these protocols and schedule as the test standards and reporting requirements for TCEA.

DATES: In accordance with 40 CFR 23.5 (50 FR 7271; February 21, 1985), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ["daylight" or "standard" as appropriate] time on January 2, 1986. This rule shall become effective on February 3, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW, Washington, DC 20460. Toll free: (800-424-9065), in Washington, DC: (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 Phase I rule under section 4(a) of TSCA to require testing of TCEA for developmental toxicity. The Agency is now promulgating a final Phase II rule specifying that the industry-submitted protocols and schedule be the test standards and reporting requirements for this testing. This test rule for 1,1,1-trichloroethane is being promulgated under 40 CFR 799.4400.

I. Background

This document is part of the implementation of section 4 of the Toxic Substances Control Act (TSCA, Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C.

2801 *et seq.*), which contains authority for EPA to require development of data relevant to assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

1,1,1-Trichloroethane (TCEA, CAS No. 71-55-6) was designated by the Interagency Testing Committee (ITC) for priority testing consideration (43 FR 16684; April 19, 1978). EPA promulgated in the Federal Register of October 10, 1984 (49 FR 39810), a final Phase I rule requiring testing of TCEA. EPA based the final testing requirements for TCEA on the authority of section 4(a)(1)(B) of TSCA. The Agency found that TCEA is produced in substantial quantities and that there is substantial occupational and consumer exposure to TCEA resulting from its manufacture, processing, and use. 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, a consortium of U.S. manufacturers and an importer of TCEA, known as the Halogenated Solvents Industry Alliance (HSIA), notified EPA of their intent to sponsor the testing required in the Phase I test rule (Ref. 7). HSIA submitted proposed study plans on February 21, 1985 and April 17, 1985. In the Federal Register of August 7, 1985 (50 FR 31895), EPA proposed that the submitted protocols and schedules be adopted as the test standards and reporting requirements for the testing of TCEA. EPA is now promulgating a final Phase II rule requiring the HSIA to conduct this testing in accordance with the proposed test standards and reporting requirements.

II. Proposed Test Standards

The HSIA, comprised of Dow Chemical Co., ICI Americas, Inc., PPG Industries, Inc., and Vulcan Materials Co., 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 proposed study plans (Refs. 1 through 5) to conduct the following tests: Inhalation Developmental Toxicity Probe Study in rabbits; Inhalation Developmental Toxicity Study in rabbits; Inhalation Developmental Toxicity Probe Study in

rats; and Inhalation Developmental Toxicity Study in rats. HSIA stated that these tests 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 parts per million (ppm) for 6 hr/day were proposed for both the rat (days 6 through 15 or gestation) and rabbit (days 6 through 18 of gestation) probe studies, with exposure levels for the full inhalation developmental toxicity studies based on results of the probe studies. TCEA from a commercial source stabilized with less than 0.1 percent butylene oxide will be used as the test material. It was proposed that either Sprague Dawley or Fisher 344 rats and New Zealand white rabbits would be used for this testing. The full protocols are available in the public docket for this action. The protocols submitted by HSIA have been reviewed by the Agency and found to conform to the TSCA Health Effects Test Guidelines for Inhalation Toxicity Testing. The Agency proposed that these protocols be adopted as test standards for performing the developmental toxicity testing of TCEA required under 40 CFR 799.4400.

III. Proposed Reporting Requirements

HSIA proposed that if the protocol were made final in 1985, the testing could begin in the second quarter of 1986. The U.S. District Court in its final order for NRDC v. EPA required issuance of a final Phase II rule for TCEA by March 1986 (Ref. 6).

HSIA also proposed that within 90 days after the effective date of the final Phase II rule establishing the test standards, the manufacturers would make a final selection of the testing facility. The testing would be initiated within 8 months after the effective date of the final Phase II rule. Final reports of the probe studies would be submitted by week 36 for rabbits and week 37 for rats. The final report for the complete study on rabbits would be submitted by week 61. The final report for the complete study in rats would be submitted by week 70 (Ref. 5). EPA proposed that testing be initiated within 6 months and results reported to the Agency within 18 months of the effective date of the final Phase II rule for TCEA. In addition, it was proposed that quarterly progress reports be submitted to the Agency.

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. Response to Public Comments

The Agency received comments from Vulcan Chemicals and the HSIA. Both Vulcan Chemicals and the HSIA reiterated the HSIA's position that the rat probe study should be sufficient to characterize the developmental toxicity of TCEA in rats if the maternal toxic dose is greater than 3,000 ppm (Refs. 8 and 9). As stated in the final Phase I rule and the proposed test standard rule, the Agency believes that both the probe and full inhalation developmental toxicity studies in rats must be conducted to fully characterize the developmental toxicity of TCEA. The Agency's decision is partially based upon developmental toxicity test results submitted by industry that demonstrate that probe study results alone are inadequate for risk assessment, and at best can be used to set concentrations for definitive testing (Ref. 10). ~~Therefore, the Agency has rejected HSIA's proposed modification to the test rule.~~

V. Final Phase II Test Rule

A. Test Standards

The protocols submitted by HSIA (Refs. 1 through 5) that specify test methods and conditions for conducting both probe and definitive inhalation developmental toxicity studies in rats and rabbits shall be the test standards for the testing of TCEA required under 40 CFR 799.4400. The Agency believes that the conduct of the required studies in accordance with the HSIA-submitted protocols will assist in assuring that the resulting data are reliable and adequate.

B. Reporting Requirements

The Agency is requiring that all data developed under this rule be reported in accordance with the TSCA Good Laboratory Practice (GLP) Standards (40 CFR Part 792).

The Agency is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. On the basis of its experience with developmental toxicity testing, EPA is adopting HSIA's proposed schedule for the final Phase II rule. Accordingly, testing must be initiated within 6 months, and all results must be reported within 18 months of the effective date of the final Phase II rule. In additional quarterly progress reports must be submitted to the Agency.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon

receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

C. Judicial Review

The promulgation date for the TCEA Phase I final rule was established as 1 p.m. eastern standard time on October 24, 1984 (49 FR 39810, October 10, 1984). EPA received no petitions for review of that Phase I final rule. Accordingly, any petition for judicial review on this Phase II final rule will be limited to a review of the test standards and reporting requirements for TCEA established in this notice.

D. Other Provisions

Section 4 findings, required testing, test substance specifications, persons required to test, enforcement provisions, and the economic analysis are presented in the final Phase I rule for TCEA (49 FR 39810).

VI. Public Record

EPA has established a record for this rulemaking. [docket number OPTS-42059B]. This record includes basic information considered by the Agency in developing this rule and appropriate Federal Register Notices.

This record includes the following information:

A. Supporting Documentation

- (1) ITC designation of 1,1,1-trichloroethane to the Priority List (43 FR 16684; April 19, 1978).
- (2) Proposed Phase I rule on 1,1,1-trichloroethane (46 FR 30300; June 5, 1981).
- (3) Final Phase I rule on 1,1,1-trichloroethane (49 FR 39810; October 10, 1984).
- (4) Proposed Test Standards for 1,1,1-trichloroethane (50 FR 31895; August 7, 1985).
- (5) TSCA Good Laboratory Practice Standards (46 FR 33922; November 29, 1983).
- (6) Judicial Review Under EPA-Administered Statutes (50 FR 7270; February 21, 1985).
- (7) Final rule on two phase test rule development and exemption procedures (49 FR 39774; October 10, 1984).
- (8) Written public comments and letters.

B. References

- (1) HSIA. Protocol. 1.1.1-Trichloroethane (TCEA): Inhalation Developmental Toxicity Probe Study in Rats. Halogenated Solvents Industry Alliance. Washington, DC 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, DC January 1985. Submitted to EPA February 21, 1985.
- (3) HSIA. Protocol. 1.1.1-Trichloroethane (TCEA): Inhalation Developmental Toxicity Probe Study in Rabbits. Halogenated Solvents Industry Alliance. Washington, DC

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, DC January 1985. Submitted to EPA February 21, 1985.

(5) HSIA. Letter from H. Farber to J. Moore. U.S. Environmental Protection Agency, Washington, DC 20460. April 17, 1985.

(6) Southern District of New York. Final Judgement and Order in *NRDC v. EPA*. 595 F. Supp. 1255 (S.D.N.Y., Oct. 30, 1984).

(7) HSIA. Letter to USEPA from Halogenated Solvents Industry Alliance. December 20, 1984.

(8) Vulcan Chemicals, Birmingham, AL 35253. Letter from Thomas A. Robinson to TSCA Public Information Office. U.S. Environmental Protection Agency, Washington, DC 20460. September 6, 1985.

(9) HSIA. Letter from H. Farber to TSCA Public Information Office. U.S. Environmental Protection Agency, Washington, DC 20460. September 20, 1985.

(10) Dow Chemical Co., Midland, MI 48640. Letter and final report on the 2-phenoxyethanol dermal teratogenicity probe study from R.L. Hagerman to Ms. Letitia Tahan. U.S. Environmental Protection Agency, Washington, DC 20460. December 24, 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 St., SW., Washington, DC 20460.

VII. 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 final Phase II test rule 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 this final Phase II 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. No public comments on these requirements were submitted to the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 40 CFR Part 799

Testing; Incorporation by reference. Environmental Protection Agency, Environmental protection, Hazardous substances, Chemicals.

Dated: December 11, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

Therefore, Chapter I of 40 CFR Part 799 is amended as follows:

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

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

2. In § 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) *Testing standards.* The testing shall be conducted in accordance with the following study plans developed by the Halogenated Solvents Industry Alliance (HSIA), 1612 K St., NW., Washington, DC 20006, and submitted to the Agency on February 21, 1985 and April 17, 1985: Inhalation Developmental Toxicity Probe Study in Rats, Inhalation Developmental Toxicity in Rats, Inhalation Developmental Probe Study in Rabbits, and Inhalation Developmental 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-42059B) and are available for inspection at the Office of the Federal Register, Rm. 8401, 1100 L St., NW..

Washington, DC. These incorporations by reference were approved by the Director of the Federal Register in January 1985. 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. Copies of the incorporated material may be obtained from the Document Control Officer (TS-793), Office of Toxic Substances, EPA, Rm. 107, 401 M St., SW., Washington, DC 20460.

(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 beginning 90 days from the effective date of the final Phase II rule.

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