

(i) If a change that does not meet the criteria in paragraph (g)(4) of this section is made to a process unit subject to subparts H and I of this part, and the change causes equipment to become subject to the provisions of subpart H of this part, then the owner or operator shall comply with the requirements of subpart H of this part for the equipment as expeditiously as practicable, but in no event later than 3 years after the equipment becomes subject.

(1) The owner or operator shall submit to the Administrator for approval a compliance schedule, along with a justification for the schedule.

(2) The Administrator shall approve the compliance schedule or request changes within 120 calendar days of receipt of the compliance schedule and justification.

\* \* \* \* \*

15. Section 63.191 is amended by adding in alphabetical order definitions for "bench-scale batch process," "process unit," and "source" to paragraph (b) and revising the definition of "pharmaceutical production process" in paragraph (b) to read as follows:

**§ 63.191 Definitions.**

(b) \* \* \*

*Bench-scale batch process* means a batch process (other than a research and development facility) that is capable of being located on a laboratory bench top. This bench-scale equipment will typically include reagent feed vessels, a small reactor and associated product separator, recovery and holding equipment. These processes are only capable of producing small quantities of product.

\* \* \* \* \*

*Pharmaceutical production process* means a process that synthesizes pharmaceutical intermediate or final products using carbon tetrachloride or methylene chloride as a reactant or process solvent. Pharmaceutical production process does not mean process operations involving formulation activities, such as tablet coating or spray coating of drug particles, or solvent recovery.

\* \* \* \* \*

*Process unit* means the equipment assembled and connected by pipes or ducts to process raw materials and to manufacture a product. For the purposes of this subpart, process unit includes all unit operations and associated equipment (e.g., reactors and associated product separators and recovery devices), associated unit operations (e.g., extraction columns), any feed and product storage vessels,

and any transfer racks for distribution of final product.

\* \* \* \* \*

*Source* means the collection of equipment listed in § 63.190(d) to which this subpart applies as determined by the criteria in § 63.190. For purposes of subparts H and I of this part, the term *affected source* as used in subpart A of this part has the same meaning as the term source defined in this definition.

\* \* \* \* \*

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**40 CFR Part 63**

[AD-FRL-5182-5]

RIN 2060-AC19

**National Emission Standards for Hazardous Air Pollutants for Source Categories: Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

**SUMMARY:** This action proposes to correct errors and clarify regulatory text of the "National Emission Standards for Hazardous Air Pollutants for Source Categories: Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks," which was issued as a final rule on April 22, 1994 and June 6, 1994. This rule is commonly known as the Hazardous Organic NESHP or the HON. Because the revisions merely correct errors and clarify regulatory text the Agency does not anticipate receiving adverse comments. Consequently the revisions are also being issued as a direct final rule in the final rules section of this **Federal Register**. If no significant adverse comments are timely received, no further action will be taken with respect to this proposal and the direct final rule will become final on the date provided in that action.

**DATES:** *Comments.* Comments must be received on or before May 10, 1995, unless a hearing is requested by April 20, 1995. If a hearing is requested, written comments must be received by May 25, 1995.

*Public Hearing.* Anyone requesting a public hearing must contact the EPA no later than April 20, 1995. If a hearing is

held, it will take place on April 25, 1995, beginning at 10:00 a.m.

**ADDRESSES:** *Comments.* Comments should be submitted (in duplicate, if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A-90-20 (see docket section below), room M-1500, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460. The EPA requests that a separate copy also be sent to the contact person listed below.

*Public Hearing.* If a public hearing is held, it will be held at the EPA's Office of Administration Auditorium, Research Triangle Park, North Carolina. Persons interested in attending the hearing or wishing to present oral testimony should notify Mrs. Kim Teal, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone (919) 541-5580.

*Docket.* Dockets No. A-90-20 and A-89-10, containing the supporting information for the original NESHP and this action, are available for public inspection and copying between 8:00 a.m. and 5:30 p.m., Monday through Friday, at the EPA's Air and Radiation Docket and Information Center, Waterside Mall, room M-1500, first floor, 401 M Street SW, Washington, DC 20460, or by calling (202) 260-7548 or 260-7549. A reasonable fee may be charged for copying.

**FOR FURTHER INFORMATION CONTACT:** Dr. Janet S. Meyer, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5254.

**SUPPLEMENTARY INFORMATION:** If no significant, adverse comments are timely received, no further activity is contemplated in relation to this proposed rule and the direct final rule in the final rules section of this **Federal Register** will automatically go into effect on the date specified in that rule. If significant adverse comments are timely received on any provision, that provision of the direct final rule will be withdrawn and all public comment received on that provision will be addressed in a subsequent final rule based on the relevant portions of this proposed rule. Because the Agency will not institute a second comment period on this proposed rule, any parties interested in commenting should do so during this comment period.

For further supplemental information, the detailed rationale, and the rule provisions, see the information provided in the direct final rule in the

final rules section of this **Federal Register**.

#### **Executive Order 12866 Review**

The HON rule promulgated on April 22, 1994 was considered "significant" under Executive Order 12866 and a regulatory impact analysis (RIA) was prepared. Today's proposed revisions clarify the rule and do not add any additional control requirements. The EPA believes that these revisions would have a negligible impact on the results of the RIA and the change is considered to be within the uncertainty of the analysis.

#### **Regulatory Flexibility Act**

The Regulatory Flexibility Act of 1980 requires the identification of potentially adverse impacts of Federal regulations upon small business entities. The Act specifically requires the completion of a Regulatory Flexibility Analysis in those instances where small business impacts are possible. Because this rulemaking imposes no adverse economic impacts, a Regulatory Flexibility Analysis has not been prepared.

#### **List of Subjects in 40 CFR Part 63**

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: March 28, 1995.

**Carol M. Browner,**

*Administrator.*

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#### **40 CFR Part 799**

[OPPTS-42111E, FRL-4927-8]

RIN 2070-AB94

#### **Test Rule; Office of Water Chemicals Proposed Withdrawal of Certain Testing Requirements**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to withdraw certain testing requirements for two of the chemical substances listed in the Office of Water Chemicals test rule published in the **Federal Register** of November 10, 1993 (58 FR 59667). EPA required specified health effects testing for the two chemical substances because the substances are produced in substantial quantities and there may be substantial exposure to these substances, there are insufficient data to determine or predict the health effects from exposure to these substances in

drinking water, and the testing required is necessary to determine or predict these health effects. EPA believes that data recently made available to it are sufficient to determine or predict the health effects posed by short and long-term exposures to 1,1-dichloroethane in drinking water and are sufficient to determine or predict the health effects posed by long-term exposures to 1,1,2,2-tetrachloroethane in drinking water. Therefore, EPA is proposing the withdrawal of the 90-day subchronic testing requirement for 1,1,2,2-tetrachloroethane and the 90-day and 14-day testing requirements for 1,1-dichloroethane.

**DATES:** Written comments must be received by EPA on or before May 10, 1995.

**ADDRESSES:** Submit written comments, identified by the document control number (OPPTS-42111E) in triplicate to: TSCA Document Receipts Office (Mail stop 7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. ET G-99, 401 M St., SW., Washington, DC, 20460. A public version of the administrative record supporting this action, without confidential business information, is available for inspection at the above address from 12 p.m. to 4 p.m., Monday through Friday, except legal holidays.

**FOR FURTHER INFORMATION CONTACT:** James G. Willis, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

**SUPPLEMENTARY INFORMATION:** EPA is proposing to withdraw the 90-day subchronic testing requirement for 1,1,2,2-tetrachloroethane and the 90-day and 14-day testing requirements for 1,1-dichloroethane in the Office of Water Chemicals test rule referenced above.

#### **I. Proposed Modification**

Pursuant to section 4 of the Toxic Substances Control Act (TSCA), EPA proposed a test rule in the **Federal Register** of May 24, 1990 (55 FR 21393) and finalized the test rule in the **Federal Register** of November 10, 1993 (58 FR 59667), finding that four chemical substances; chloroethane (CAS No. 75-00-3); 1,1-dichloroethane (CAS No. 75-34-3); 1,1,2,2-tetrachloroethane (CAS No. 79-34-5); and 1,3,5-trimethylbenzene (CAS No. 108-67-8) are produced in substantial quantities and that there may be substantial exposure to these substances, that there are insufficient data to determine or predict the health effects from short and

long-term exposures to the substances in drinking water, and that testing is required to determine or predict the health effects from short and long-term exposures. Thus, EPA required subacute toxicity (oral 14-day repeated dose) and subchronic (oral 90-day) toxicity tests. The data from these studies would be used to develop Health Advisories (HA's) for the four unregulated drinking water contaminants that are monitored under section 1445 of the Safe Drinking Water Act (SDWA).

EPA has recently received requests to withdraw all or part of the testing required for two substances, 1,1-dichloroethane and 1,1,2,2-tetrachloroethane. On June 28, 1994, the Halogenated Solvents Industry Alliance (HSIA) requested that EPA revoke the subchronic (oral 90-day) toxicity test requirements for 1,1,2,2-tetrachloroethane (Ref. 1). This request was based on the availability of a 90-day subchronic toxicity drinking water study of 1,1,2,2-tetrachloroethane conducted in rats and mice by the National Toxicology Program (Ref. 2). EPA reviewed this study and believes that the study is sufficient to meet the 90-day subchronic toxicity test required under the test rule and to establish long-term Health Advisories for the Office of Water (OW) (Ref. 3). Therefore, EPA believes it is appropriate to withdraw the 90-day subchronic testing requirements for 1,1,2,2-tetrachloroethane.

HSIA also requested that EPA withdraw the 14- and 90-day subchronic toxicity testing required under the test rule for 1,1-dichloroethane. This request was based on a study conducted by Muralidhara et al. (Ref. 6) that characterizes the acute (24 hour), subacute (5 and 10 days), and the subchronic (90 days) toxicity potential of 1,1-dichloroethane. EPA reviewed the study and believes the study is sufficient to determine or predict both the short and long-term effects of exposure to 1,1-dichloroethane (Ref. 7). Therefore, EPA believes it is appropriate to withdraw both the 14- and 90-day subchronic toxicity tests required for 1,1-dichloroethane under the test rule for the OW substances.

EPA is providing 30 days from publication of this proposed modification for submission of written comments on the elimination of the subchronic toxicity (oral 90-day) test requirement for 1,1,2,2-tetrachloroethane and of both the subacute (oral 14-day repeated dose) and subchronic (oral 90-day) toxicity test requirements for 1,1,2,2-tetrachloroethane. If the 30 day deadline passes and no public comments have