

in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

#### V. Regulatory Assessment Requirements

EPA is proposing to revoke the requirements of the rule. Any costs or burdens associated with the rule will also be eliminated when the rule is revoked. Therefore, EPA finds that no costs or burdens must be assessed under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 605(b)), or the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Reporting and recordkeeping requirements, Significant new uses.

Dated: September 1, 1995.

**Charles M. Auer,**

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

#### PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

#### § 721.2225 [Removed]

2. By removing § 721.2225.

[FR Doc. 95-22730 Filed 9-12-95; 8:45 am]

BILLING CODE 6560-50-F

#### 40 CFR Part 721

[OPPTS-50608C; FRL-4911-5]

#### Ethane, 1,1,1-Trifluoro-; Revocation of a Significant New Use Rule

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to revoke a significant new use rule (SNUR) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for ethane, 1,1,1-trifluoro-, based on receipt of new data. The data indicate that for purposes of TSCA section 5, the substance will not present an unreasonable risk to human health.

**DATES:** Written comments must be received by October 13, 1995.

**ADDRESSES:** All comments must be sent in triplicate to: TSCA Document Receipt Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-G99, 401 M St., SW., Washington, DC 20460.

Comments that are confidential must be clearly marked confidential business information (CBI). If CBI is claimed, three additional sanitized copies must also be submitted. Nonconfidential versions of comments on this proposed rule will be placed in the rulemaking record and will be available for public inspection. Comments should include the docket control number. The docket control number for the chemical substance in this SNUR is OPPTS-50608C. Unit III. of this preamble contains additional information on submitting comments containing CBI.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: [ncic@epamail.epa.gov](mailto:ncic@epamail.epa.gov). Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPPTS-50608C. No CBI should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit IV. of this document.

#### FOR FURTHER INFORMATION CONTACT:

Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543A, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551, e-mail: [TSCA-Hotline@epamail.epa.gov](mailto:TSCA-Hotline@epamail.epa.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 8, 1993 (58 FR 32238), EPA issued a SNUR establishing significant new uses for ethane, 1,1,1-trifluoro-. Because of additional data EPA has received for this substance, EPA is proposing to revoke this SNUR.

#### I. Proposed Revocation

EPA is proposing to revoke the significant new use and recordkeeping requirements for ethane, 1,1,1-trifluoro- under 40 CFR part 721, subpart E. In this unit, EPA provides a brief description for the substance, including its PMN number, chemical name (generic name if the specific name is

claimed as CBI), CAS number (if assigned), basis for the revocation of the section 5(e) consent order for the substance, and the CFR citation removed in the regulatory text section of this proposed rule. Further background information for the substance is contained in the rulemaking record referenced in Unit IV. of this preamble.

#### PMN Number P-92-341

*Chemical name:* Ethane, 1,1,1-trifluoro-

*CAS number:* 420-46-2.

*Effective date of revocation of section 5(e) consent order:* August 29, 1994.

*Basis for revocation of section 5(e) consent order:* The order was revoked based on test data submitted by the PMN submitter under the terms of the consent order. Based on the Agency's analysis of the submitted data, EPA has sufficient information to determine, for purposes of TSCA section 5, that the manufacture, processing, distribution in commerce, use, or disposal of the PMN substance will not present an unreasonable risk to human health. Accordingly, EPA has determined that further regulation under section 5(e) of TSCA is not warranted at this time. *Toxicity testing results:* Cardiac sensitization (dogs): The PMN substance was found to be a cardiac sensitizer when exposures occurred at a 30 percent concentration in air (300,000 ppm (parts per million)) for 10 minutes. Lower exposures did not elicit a sensitization response. The substance is not mutagenic in the micronucleus assay. There were no observed adverse effects at concentrations up to 40,000 ppm in the developmental or 90-day subchronic study.

*CFR citation:* 40 CFR 721.3254.

#### II. Background and Rationale for Proposed Revocation of the Rule

During review of the PMN submitted for the chemical substance that is the subject of this proposed revocation, EPA concluded that regulation was warranted under section 5(e) of TSCA pending the development of information sufficient to make a reasoned evaluation of the health effects of the substance, and that the substance is expected to be produced in substantial quantities and there may be significant or substantial human exposure. EPA identified the tests necessary to make a reasoned evaluation of the risks posed by the substance to human health. Based on these findings, a section 5(e) consent order was negotiated with the PMN submitter and a SNUR was promulgated.

EPA reviewed testing conducted by the PMN submitter pursuant to the

consent order for the substance and determined that the information available was sufficient to make a reasoned evaluation of the health effects of the substance. EPA concluded that, for the purposes of TSCA section 5, the substance will not present an unreasonable risk and consequently revoked the section 5(e) consent order. The proposed revocation of SNUR provisions for the substance designated herein is consistent with the revocation of the section 5(e) order.

In light of the above, EPA is proposing a revocation of SNUR provisions for this chemical substance. When this revocation becomes final, EPA will no longer require notice of any person's intent to manufacture, import, or process this substance. In addition, export notification under section 12(b) of TSCA will no longer be required.

### III. Comments Containing Confidential Business Information

Any person who submits comments claimed as CBI must mark the comments as "confidential," "trade secret," or other appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR part 2. Any party submitting comments claimed to be confidential must prepare and submit a public version of the comments that EPA can place in the public file.

### IV. Rulemaking Record

The record for the rule which EPA is proposing to revoke was established at OPPTS-50608 (P-92-341). This record includes information considered by the Agency in developing the rule and includes the test data that formed the basis for this proposal.

A record has been established for this rulemaking under docket number OPPTS-50608C (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at:  
ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the

use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

### V. Regulatory Assessment Requirements

EPA is proposing to revoke the requirements of the rule. Any costs or burdens associated with the rule will also be eliminated when the rule is revoked. Therefore, EPA finds that no costs or burdens must be assessed under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 605(b)), or the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Reporting and recordkeeping requirements, Significant new uses.

Dated: September 1, 1995.

**Charles M. Auer,**

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

#### PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

#### § 721.3254 [Removed]

2. By removing § 721.3254.

[FR Doc. 95-22731 Filed 9-12-95; 8:45 am]

BILLING CODE 6560-50-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Part 493

[HSQ-225-P]

RIN 0938-AG99

#### Public Health Service; CLIA Program; Categorization of Waived Tests

**AGENCY:** Health Care Financing Administration (HCFA) and Public Health Service (PHS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** In this rule we are proposing criteria we would use to determine whether to categorize specific laboratory tests as waived from certain requirements of the Clinical Laboratories Improvement Amendments of 1988. We also propose revisions to requirements that laboratories performing waived tests must meet.

**DATES:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 13, 1995.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address:

Centers for Disease Control and Prevention, Public Health Service, Department of Health and Human Services, Attention: HSQ-225-P, 4770 Buford Hwy., NE., MS F11, Atlanta, Georgia 30341-3724.

If you prefer, you may deliver your written comments (1 original and 3 copies) to the following address:

CDC/Washington, Room 714-B, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ-225-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC