ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42059; FRL-2626-7]

# Identification of Specific Chemical Substance and Mixture Testing Requirements; 1,1,1-Trichloroethane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In June 1981, the EPA proposed the testing of 1,1,1-trichloroethane (TCEA) under section 4(a) of the Toxic Substances Control Act (TSCA) for teratogenicity and for a number of environmental effects (46 FR 30300). Public comments on the proposal have been received and reviewed. The EPA has decided to promulgate a final test rule requiring that manufacturers and processors of 1,1,1-trichloroethane test this chemical for teratogenic effects or, more appropriately, developmentally toxic effects. EPA has decided not to require any environmental effects testing at this time due to its reevaluation of the available data. This rule requires that testing of this chemical be performed according to protocols submitted to and approved by the Agency.

DATES: These regulations shall be promulgated for purposes of judicial review at 1:00 p.m. eastern standard time on October 24, 1984. These regulations shall become effective on November 23, 1984.

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SUPPLEMENTARY INFORMATION: In the Federal Register of June 5, 1981 (46 FR 30300), EPA issued a proposed rule under section 4(a) of TSCA to require testing of TCEA for teratogenic effects and a number of environmental effects. The Agency is now promulgating a final rule requiring testing of TCEA for teratogenic effects or, more appropriately, develop mentally toxic effects, but not for environmental effects due to reevaluation of available data.

The rule was originally proposed under 40 CFR Part 773—Identification of Chemical Substances and Mixtures to be Tested. Part 773 has since been recodified to Part 799—Identification of Specific Chemical Substance Testing Requirements. This test rule for 1,1,1-trichloroethane is now being promulgated under 40 CFR 799.4400.

## I. Introduction

This notice is part of the overall implementation of section 4 of the Toxic Substances Control Act (TSCA, Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *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.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop health or environmental data if the Administrator finds that:

(A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

For a more complete understanding of the statutory section 4 findings, the reader is directed to the Agency's first proposed test rule package (chloromethane and chlorinated benzenes, published July 18, 1980; 45 FR 48510) and to the second package (dichloromethane, nitrobenzene, and 1,1,1-trichloroethane, published June 5, 1981; 46 FR 30300) for in-depth discussions of the general issues applicable to this action.

## II. Background

### A. Profile

1,1,1-Trichloroethane ($Cl_3C_2H_3$, methyl chloroform, TCEA, CAS No. 71-55-6) is a colorless, non-flammable, volatile liquid at standard temperature and pressure. Approximately 586 million pounds of TCEA were produced in the United States in 1983, of which about 57 million pounds were exported. Imports of the chemical were essentially negligible (Ref. 8).

The major use of TCEA is in the metal cleaning industry, primarily in cold cleaning and vapor degreasing processes. It is also used as a solvent in commercial and consumer products such as aerosols, adhesives, textiles, paints, inks, drain cleaners, film cleaners, spot removers, pharmaceuticals, and leather tanners (Ref. 6).

In the National Occupational Hazard Survey, approximately 2.6 million workers were estimated to be exposed to TCEA (Ref. 3), largely through inhalation during industrial uses of the chemical. Consumers are exposed to unknown levels of TCEA through use of the many consumer products containing it.

TCEA is released to the environment from evaporative losses during manufacture, processing, use and disposal. It has been found at levels of 1-10 ppb in air, soil, fresh and marine water, groundwater and rainwater (Ref. 6).

### B. ITC Recommendations

The Interagency Testing Committee (ITC) designated 1,1,1-trichloroethane for priority testing consideration in its Second Report, published in the Federal Register on April 19, 1978 (43 FR 16684). The ITC recommended that the Agency consider requiring industry to test TCEA for the following health effects: carcinogenicity, mutagenicity, teratogenicity, other chronic effects (with specific attention to the neurological, cardiovascular and renal systems) and that an epidemiologic study be performed. The ITC did not recommend that environmental effects testing for TCEA be considered.

The ITC's recommendations were based on U.S. production in 1976 of approximately 630 million pounds, an estimated 300 million pounds which could be released to the atmosphere, an estimation on the part of the ITC of 3 million persons exposed to TCEA in the workplace, and its view that there was a lack of data from which to reasonably determine or predict the various effects for which it recommended testing.

### C. Proposed Rule

EPA issued a proposed rule published in the Federal Register of June 5, 1981 (46 FR 30300) which would require that testing of TCEA be performed for teratogenicity and for the effects listed below:

1. Aquatic vertebrates-acute toxicity and chronic toxicity.

2. Aquatic invertebrates-chronic toxicity.

3. Terrestrial plants-root elongation/seed germination and early seedling growth.

4. Bioconcentration-plant uptake/translocation.

In the proposal, the EPA based its testing requirements on the authority of section 4(a)(1)(B) of TSCA. It found that: 1,1,1-trichloroethane was produced in substantial quantities; substantial numbers of persons were exposed to 1,1,1-trichloroethane both in occupational settings involving the manufacture, processing and use of the chemical, and as consumers of products containing the chemical; there was substantial release to the environment; and, with respect to the above listed areas, there were insufficient data and experience to reasonably determine or predict the effects on health and the environment of the manufacture, processing, distribution in commerce, use or disposal of 1,1,1-trichloroethane and that testing was necessary to develop such data.

EPA also presented its reasons for not proposing testing for several other effects of concern. Testing was not proposed for acute health effects, reproductive effects, chemical fate or for certain environmental effects (acute toxicity to aquatic invertebrates, toxicity to mammals, acute bird toxicity, toxicity to algae, and aquatic vertebrate and invertebrate bioconcentration) because EPA had concluded that existing information was sufficient to reasonably predict or determine these effects. EPA planned to perform testing for some environmental effects for which no test standards were available at the time.

Oncogenicity testing of 1,1,1-trichloroethane was being performed by the National Toxicology Program (NTP), and EPA believed that the NTP studies would be sufficient to reasonably predict or determine the oncogenicity of TCEA; therefore, no oncogenicity testing was proposed. Similarly, no chronic effects testing was proposed because EPA was awaiting the results of the NTP study which it expected to provide sufficient data on chronic effects.

EPA believed that mutagencity testing according to a testing sequence would be appropriate, and planned to perform the initial testing itself because no criteria specifying the progression from initial tests to higher level tests were available at the time the proposed rule was issued. EPA planned to propose a test rule requiring manufacturers and processors of TCEA to perform higher tier tests if needed, based on analysis of lower tier results.

The EPA also decided not to propose an epidemiologic study at the time because a suitable study population had not been identified. The scientific support used by EPA at that time for the proposed section 4 findings and the proposed rule was set forth in the 1,1,1-Trichloroethane Support Document (Ref. 6), which is available from the Office of Toxic Substances' TSCA Assistance Office and in the public record for this rulemaking.

## III. Public Comment

The comments received by the Agency in response to the proposed rule for TCEA were from the affected industry and several trade associations. The Agency did not receive any comments which in the Agency's judgment rebutted the substantial production and substantial human exposure findings for TCEA. Major issues identified during the comment period are discussed below.

### *A. Health Effects Testing*

#### 1. Developmental Toxicity

a. *Terminology.* Comments on EPA's proposed test rule for the testing of TCEA for teratogenicity in June 1981, have shown that use of the term "teratogenicity" may be interpreted differently by different scientists and in its strictest definition could be limited to just the production of structural malformations. Recognizing that abnormal development may be manifested not only as the production of structural malformations, but also as *in utero* death, growth retardation, or functional deficits (Ref. 14), the Agency believes that the term "developmental toxicity" is more appropriate in summarizing its concern for agents that adversely affect development. Although the terminology in this final rule may be different from that in the proposed rule, the Agency in its proposed rule clearly expressed the concern that TCEA should be evaluated not only for structural malformations, but also for fetal resorptions, decreased fetal body weight, and other adverse developmental effects which are encompassed by the term "developmental toxicity." *See* 46 FR 30300, 30303 and 30311 (June 5, 1981) and 44 FR 44054, 44088 (July 29, 1979).

b. *Review of existing teratology studies.* The Agency has identified three studies that address the potential of 1,1,1-trichloroethane to cause adverse developmental effects: Schwetz et al. (Ref. 5), York et al. (Ref. 7), and Lane et al. (Ref. 1). The Schwetz and York studies were evaluated by the Agency in preparing the proposed rule (46 FR 30300; June 5, 1981) and were discussed in its accompanying support document (Ref. 6).

In the Schwetz et al. study pregnant female rats and mice were exposed by the inhalation route of exposure to 875 ppm of TCEA for 7 hours daily at days 6–15 of gestation. Schwetz et al. concluded that TCEA did not cause significant maternal, embryonal or fetal toxicity and was not teratogenic in either mice or rats at 875 ppm.

In the York et al. study, female rats were exposed by inhalation to TCEA at a concentration of 2,100 ppm. Study animals were divided into the following three groups depending upon the timing of exposure to TCEA: (A) those exposed for two weeks prior to mating and during pregnancy, (B) those exposed prior to mating only, and (C) those rats exposed during pregnancy only. The control group was exposed to filtered air before mating and during pregnancy. The York study reported decreased fetal weights and some developmental anomalies (predominantly skeletal and kidney development) in offspring of exposed dams. However, the developmental anomalies occurred only in the offspring of those rats exposed to 2,100 ppm two weeks prior to mating and then during gestation. Although there were statistically significant decreases in fetal bodyweight in exposure groups A and C, soft-tissue and skeletal anomalies were not significant in the offspring of rats exposed to 2,100 ppm TCEA during gestation only, possibly due to the shorter dosing period. York et al. questioned the biological significance of the skeletal anomalies and fetal weight reductions, noting that the skeletal malformations were relatively rare structural changes not obviously detrimental to the offspring and that the depression in body weights was not present postnatally. The York et al. study reported no evidence of maternal toxicity in any of three exposure groups.

In its proposed test rule for TCEA (46 FR 30300, June 5, 1981), EPA concluded that the Schwetz et al. and York et al. studies were insufficient to reasonably determine whether exposure to TCEA would pose a risk of developmental effects in humans. The Agency reached this conclusion in large part because although developmental effects had not been observed in the Schwetz et al. study or in the offspring of animals in the York et al. study exposed only during gestation, the failure of both studies to employ a maternally toxic dose level fails to provide adequate

assurance that developmentally toxic effects will not occur at exposure levels designed to protect adult humans from adverse health effects.

In a study obtained after publication of the proposal, Lane et al. (Ref. 1) examined the effects of TCEA in drinking water on reproduction and development in mice. Concentration levels of 0, 0.58, 1.75, and 5.83 mg/ml were administered; these concentrations were designed by the investigators to yield doses of 0, 100, 300 or 1,000 mg/kg/day. Nine to fifteen litters were examined per dose group. The authors reported no evidence of reproductive or teratologic effects in this study and no evidence of maternal toxicity.

c. *EPA response to industry comments.* Industry commentors (Dow and Vulcan) took the position that the three studies taken together clearly demonstrate that TCEA does not represent a teratogenic risk to humans. With regard to the lack of maternal toxicity, they pointed out that TCEA is of very low toxicity in adult animals and that the primary adverse effect of TCEA is central nervous system (CNS) depression. In their view, conventional measurements of maternal toxicity, such as weight loss, would not be observed at test concentrations below those which produce CNS depression. The commentors further stated that the studies have been conducted at sufficiently high levels and that, in the light of the available data, EPA cannot justify a finding of insufficient data to determine or reasonably predict the teratogenic effects of TCEA.

EPA had seriously considered these points. The results of these studies (Refs. 1, 5 and 7) do not preclude the possibility that the conceptus may be uniquely susceptible to adverse effects of TCEA. None of these studies reported evidence of biologically significant teratogenic effects; however, maternal toxicity at the highest dose level, a requirement of an adequate teratogenicity of developmental toxicity test according to the TSCA Guidelines (Ref. 17), was not demonstrated in any of the studies.

With regard to their comments on CNS depression, the Agency believes that Dow and Vulcan have failed to demonstrate that signs of CNS depression will indeed occur prior to other indications of maternal toxicity, such as weight loss. In none of the three available developmental toxicity studies which the Agency has reviewed was there any evidence that adverse CNS effects would occur prior to other signs of maternal toxicity. In fact, there were no indications of CNS depression or maternal toxicity in any of the three studies.

The Agency also disagrees with the commentors' position that the studies have been conducted at sufficiently high dose levels. In general, the Agency believes that the highest dose level delivered to an animal in a developmental toxicity study should produce maternal toxicity; this is to ensure that a chemical has been tested at a high enough exposure level. If the highest dose delivered to an animal produces neither maternal toxicity nor development toxicity, one would not be able to determine if the chemical would be a hazard to the developing embryo or fetus at some higher exposure level in the absence of maternal effects. Most teratology/developmental toxicity guidelines (i.e. TSCA, OECD, FDA's Segment II) recommend testing of a substance at at least three dose or exposure levels with the highest producing some degree of maternal toxicity and the lowest producing no effect on either the embryo/fetus or the dam. This view is in agreement with recognized developmental toxicologists who have conducted state-of-the-art studies (Refs. 13 and 14). This approach allows for assessment of the relationship between the concentration needed to adversely affect the dam and that needed to adversely affect the developing organism and, as such, enables the identification of those agents to which the embryo/fetus is more susceptible than the dam. This dose regimen not only establishes potential developmental effects which may occur independent of adult toxicity, but also establishes a no effect level for developmental effects.

There may be some instances where the Agency will not need to require testing at a dose level that produces maternal toxicity. If developmental effects have been identified at doses below the maternally toxic dose of the chemical, then higher dose levels that would exhibit some form of maternal toxicity are not essential because exposure reduction would be based on developmental toxicity rather than on maternal toxicity. There is uncertainty that the effects observed in the York et al. study indicate biologically significant developmental toxicity. The Agency does not believe the York et al. study or the other studies discussed above are sufficient to reasonably determine or predict the developmental toxicity of TCEA. Another instance where the Agency may not need to require maternal toxicity is when the no observed effect levels are well above those levels identified for human exposure. However, in this particular case, the Agency believes that the difference between the levels of TCEA workplace exposures (Refs. 16 and 18) and the highest dose levels of TCEA utilized in the existing teratogenicity studies (Refs. 1, 5, and 7) do not enable EPA to reasonably predict that offspring of female workers exposed to TCEA would be adequately protected from adverse developmental effects. Therefore, EPA finds that further testing of TCEA for developmental toxicity is necessary.

2. *Chronic effects and oncogenicity.* The Agency identified two chronic studies when preparing the proposed rule: NCI (Ref. 2) and Quast et al. (Ref. 4). EPA concluded that neither study was adequate to characterize the chronic effects of TCEA. However, EPA did not propose chronic effects or oncogenicity testing for TCEA because a National Toxicology Program (NTP/NCI) oncogenicity study underway at the time was expected to be sufficient to reasonably determine or predict the chronic effects and oncogenicity of TCEA. The NTP study has since been completed. The results are still being evaluated and the final report has not yet been released by NTP.

Dow commented that the NTP study could suffer from shortcomings such as grossly high exposure levels which would make it inappropriate for assessing chronic effects. Dow noted that it is currently conducting a "state of the art" study which should more adequately characterize the chronic effects of 1,1,1-trichloroethane. According to Dow, they are in the final stages of a 2-year chronic toxicity/oncogenicity study of TCEA in rats and mice. Both species were exposed using the inhalation route to 150, 500, or 1,500 ppm of TCEA for 6 hours/day, 5 days/week for 24 months. Dow Chemical Company has submitted to the Agency a final report on the chronic inhalation toxicity and oncogenicity of a commercial preparation containing greater than 90% TCEA (Ref. 23). The Agency is currently evaluating the study and the evaluation will be placed into the public docket when completed. The Agency is awaiting the final report from the NTP study. Should the Agency decide that a data insufficiency exists after Agency review of the final NTP report then EPA reserves the right to require an additional oncogenicity study.

3. *Mutagenicity.* Industry commentors stated that the preponderance of available data support the position that 1,1,1-trichloroethane lacks any significant genetic activity and,

therefore, mutagenicity testing is unnecessary. The Agency did not believe existing data were sufficient to predict the mutagenicity of TCEA and has gone forward with its own testing as outlined in the notice of proposed rulemaking (46 FR 30300).

EPA has examined 1,1,1-trichloroethane (Aldrich Chemical Co., 97 percent pure) in a number of *in vitro* assays for genotoxicity. Specifically, TCEA was found to be non-mutagenic under the conditions of the test for Salmonella tester strains TA1535, TA1537, and TA100 in the Ames test in the presence and absence of S-9 activation systems. When examined in the hepatocyte primary culture/DNA repair test, TCEA elicited a positive response at $10^{-6}$ to $10^{-3}$M (noncytotoxic doses) using hepatocytes from male B6C3F1 mice, but did not affect DNA repair when hepatocytes from Osborne Mendel rats were used. TCEA was also able to transform BALB/C-3T3 cells, *in vitro*, at noncytotoxic doses of 20 μg/ml to 250 μg/ml. In addition, TCEA significantly enhanced transformation of Syrian hamster embryo cells by SA7 adenovirus (Refs. 19, 20, 21, and 22).

Experiments to test TCEA in the Drosphila sex-linked recessive lethal assay are currently underway and results from this assay are expected to be available to the Agency in October, 1984. The Agency reserves the right to initiate rulemaking to require higher-tiered mutagenicity studies after it has completed a review of all the ongoing lower-tiered study results (see Unit III. D).

*B. Environmental Effects Testing*

A number of industry commentors addressed issues involving environmental testing of 1,1,1-trichloroethane. Although the commentors agreed that TCEA is produced in substantial quantities, they believed that the volatility (vapor pressure equals 99.75 mm Hg at 20 °C) of TCEA would not allow TCEA to be found in the environment in concentrations sufficient to produce adverse environmental effects. The commentors further maintained that the environmental information submitted to the Agency is sufficient to reasonably determine or predict the risk that TCEA may present to the environment. In support of their contention, the commentors supplied the Agency with information on the environmental concentrations of TCEA, the chemical fate of TCEA, and the aquatic and avian toxicity of TCEA.

Subsequent to the proposed rule, the Agency has performed a materials balance analysis for TCEA, has reevaluated the chemical and physical properties of TCEA, and has reexamined the toxicity data in relation to both the monitoring and environmental fate data. In addition, the Agency has reviewed and evaluated the comments and data submitted by industry. Based on its review of industry comments and the evaluation of the available data, the Agency now believes that sufficient data are available to reasonably predict the environmental effects of TCEA.

EPA agrees with the comments noted above which state that TCEA's volatility make it unlikely that substantial concentrations of the chemical will be found in the aquatic or terrestrial environments. Available monitoring data confirm that environmental concentrations are quite low. Most of these reported levels are in the low ppb range (water=8-17 ppb, soil/sediments=3-6 ppb, air=10-15 ppb) (Ref. 6).

Moreover, these measured concentration levels of TCEA are far below those concentrations which cause acute toxicity in mammalian, aquatic, avian and terrestrial species. For example, the acute oral toxicity ($LD_{50}$'s) for TCEA in the mouse and rat are between 11 to 12 g/kg. Acute toxicity tests performed on aquatic vertebrates and invertebrates yielded $LC_{50}$ values of 9.7 to 52.8 mg/l (9.7 to 52.8 ppm) in flow-through experiments or in experiments where procedures to limit losses due to volatilty were followed (Ref. 6). Studies done on species of algae gave $EC_{50}$'s greater than 669 mg/l (669 ppm). Acute toxicity in avian species produced an oral $LD_{50}$ greater than 2,510 mg/kg. As shown above, levels of TCEA in water, air and soil are in the low ppb range. Because TCEA produces toxicity in a large variety of sensitive species only at doses which are far above (by a factor of 500 or greater) the levels found in the environment, the Agency has concluded that it can reasonably predict that the chemical (at present levels of environmental exposure) does not pose an unreasonable risk to mammalian, aquatic, avian, or terrestrial species.

Finally, the materials balance analysis and environmental fate data (Ref. 12) also allow the Agency to predict TCEA's fate and distribution in the environment. These data provide additional support for the belief that the concentrations of TCEA found in the environment are low.

Therefore, taking all of these data into consideration, EPA believes that sufficient data are now available to reasonably determine or predict the environmental effects of TCEA. Thus, EPA is withdrawing its proposal to require environmental effects testing of TCEA.

*C. Test Substance*

Bendix Environmental Research stated that a test substance stabilized with 0.5 percent butylene oxide is not appropriate because if positive results are seen in any test it will have to be repeated to find out whether TCEA or butylene oxide is responsible for the effect observed. The Agency agrees that this is a problem encountered when testing mixtures. However, the Agency has chosen TCEA stabilized with butylene oxide because of the difficulty in obtaining and working with the pure chemical. Based on the NTP testing experience, the Agency has decided to require that testing be conducted utilizing a TCEA of purity greater than 99.7 percent and stabilized with less than 0.1 percent butylene oxide. NTP obtained this formulation from the Dow Chemical Company.

*D. EPA Testing*

Both Proctor and Gamble and Atlantic Richfield noted that EPA intended to perform certain tests (i.e., mutagenicity) for which test standards had not yet been adopted by EPA. They questioned how the Agency will be able to perform the tests itself if it is unable to provide suitable guidance to others.

Subsequent to the proposal, the Agency developed guidelines for conducting mutagenicity testing, including triggers to go from lower to higher tier testing. However, in the case of TCEA a separate proposal would be required if the Agency wanted to have industry conduct the mutagenicity testing. Because it wanted at least preliminary mutagenicity results sooner than would be possible through rulemaking, the Agency decided to proceed with EPA-sponsored testing. After the Agency has evaluated the results of the lower-tiered mutagenicity tests, EPA may propose a test rule to require higher tiered mutagenicity tests if needed.

## IV. Final Test Rule for 1,1,1-Trichloroethane

*A. Findings*

The EPA is basing the final testing requirements for TCEA on the authority of section 4(a)(1)(B). of TSCA. EPA finds 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. The bases for these findings, which are summarized below, are set forth in the Agency's TCEA support document (Ref. 6), which is hereby incorporated by reference.

Approximately 586 million pounds of TCEA were produced in the United States in 1983 (Ref. 8). TCEA is used in the metal cleaning industry which provides the potential for a large number of people to be exposed to TCEA. In the National Occupational Hazard Survey (NOHS) approximately 2.6 million workers were estimated to be exposed to TCEA (Ref. 3). TCEA has been identified in a substantial number of consumer products with the potential for many millions of people exposed to TCEA as a consequence of consumer use (Ref. 6).

In addition, the Agency believes that available data are insufficient to reasonably predict or determine the developmental toxicity of TCEA and that testing is necessary to develop such data. (See Unit III.A.1)

*B. Required Testing*

The Agency believes that adequate developmental toxicity tests for TCEA should be done in two mammalian species (a rat and a non-rodent species). It is well documented that various animal species have differing sensitivities to chemicals being tested for developmental toxicity (Refs. 9, 10, and 11). Thus, a negative developmentally toxic response in a single mammalian species does not necessarily mean that the chemical being tested is not a developmental hazard. The Agency believes that multispecies testing is a more sensitive means of detecting developmental hazards than single species testing (Refs. 9. 10 and 11). Testing TCEA in the rat and a non-rodent mammalian species will provide the Agency with the data needed to reasonably determine or predict whether TCEA poses a risk of developmental toxicity to humans.

Therefore, the Agency believes that developmental toxicity testing should be performed via inhalation in the rat and a non-rodent mammalian species and that some sign of maternal toxicity should be demonstrated at the highest dose in each species.

The EPA is requiring that a developmental toxicity study or studies on TCEA be conducted by the inhalation route. Although the Agency is currently preparing a guideline for inhalation developmental toxicity, which is expected to be available by Fall, 1984, at the present time there is no TSCA Guideline for this test and EPA suggests using a modified version of the protocol submitted by the Chemical Manufacturers Association (CMA) for inhalation teratogenicity of isophorone in the rat and mouse. A copy of this protocol is in the public record for this rulemaking, docket number [OPTS-42029]. The Agency believes that two modifications should be made to this protocol:

1. Rats and a non-rodent mammalian species should be utilized instead of rats and mice. EPA recommends, but does not require, rabbits as the non-rodent species.

2. EPA does not specify the strains or precise ages of the animals to be used; it recommends only that young adult rats and rabbits be used. The CMA protocol can be easily revised to reflect developmental toxicity protocols for TCEA and test sponsors will need to specify species, age, strain and number of animals used, dose delivery system for inhalation exposure, and chamber monitoring procedures. All data must be developed and reported in accordance with the TSCA Good Laboratory Practice Standards in 40 CFR Part 792.

Should the TSCA Guideline for inhalation developmental toxicity become available at a time consistent with the time requirements for submission of study plans, then the Guideline should also be consulted for appropriate study design.

*C. Test Substance*

EPA is requiring a 1,1,1-trichloroethane test substance containing less than 0.1 percent butylene oxide stabilizer for use in the test required in this rule. This product is 99.7 percent pure and contains the least amount of stabilizer of any product available. It is similar to the formulation used in NTP's oncogenicity bioassay on 1,1,1-trichloroethane and can be obtained from the Dow Chemical Company.

*D. Persons Required To Test*

Several industry commentors stated that only manufacturers and not processors should be required to conduct the tests. One commentor recommended that the Agency categorically exclude "downstream or indirect processors."

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Administrator makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal. Because EPA has found that the manufacturing, processing, and use of 1,1,1-trichloroethane give rise to substantial human exposure to TCEA, EPA is requiring that persons who manufacture or process, or who intend to manufacture or process this chemical, at any time from the effective date of this test rule to the end of the reimbursement period, be subject to the rule. The end of the reimbursement period will be 5 years after the final TCEA developmental toxicity report is submitted. As discussed in the Agency's test rule and exemption procedures (40 CFR Part 790), EPA expects that manufacturers will conduct testing and that processors will ordinarily be exempted from testing.

EPA is, however, exempting those manufacturers and processors which produce and process TCEA only as an impurity from these testing requirements. "Impurity" is defined in 40 CFR 790.3 to mean "a chemical substance which is unintentionally present with another chemical substance." The Agency is exempting those manufacturers and processors because the EPA's findings under section 4(a)(1)(B) are based on exposures to TCEA which are a result of intentional manufacture, processing, and use. In addition, it will be difficult for both EPA and manufacturers and processors to identify with complete assurance all chemical substances which contain TCEA as an impurity. Finally, the Agency would find it difficult to apply both the exemption and reimbursement processes to those who manufacture and/or process TCEA as an impurity. In fact, the Agency's reimbursement regulations issued pursuant to section 4(c) state that those who manufacture or process chemical substances as impurities will not be subject to test requirements unless the rule specifically states otherwise (40 CFR 791.48b).

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to a test rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from that requirement. The Agency anticipates that the current manufacturers of 1,1,1-trichloroethane will form the reimbursement pool and sponsor the testing required. Manufacturers and processors who are subject to the testing requirements of

this rule must comply with the test rules and exemption procedures in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing. As noted in Unit IV. C, EPA is interested in evaluating the effects attributable to TCEA itself and has specified a relatively pure substance for testing.

*E. Test Rule Development*

Under the regulations in 40 CFR Part 790, test rule development for TCEA will be a two-phase process. In the two-phase process, Phase I test rules will be promulgated for individual chemicals specifying the health and environmental effects and other characteristics for which test data are to be developed. In Phase II, following promulgation of the Phase I test rule, those persons subject to the rule will be required to develop study plans for the development of data pertaining to the effects and characteristics specified in the Phase I rule. Within 30 days from the effective date of the final Phase I test rule, manufacturers must submit to EPA a letter stating their intention to sponsor testing or an application for exemption. Test sponsors must submit their study plans to EPA within 90 days from the effective date of the Phase I test rule. After an opportunity for public comment, EPA will promulgate a rule adopting the study plans, as proposed or modified, as the chemical-specific test standards and schedules for the tests required by the Phase I rule. Testing would also be subject to EPA's generic TSCA GLP standards. Persons who submit the study plans will be obligated to perform the tests in accordance with the test standards and schedules developed. Modification to the adopted study plans can be made only with EPA approval.

Processors of TCEA will not be required to submit letters of intent, exemption applications and study plans and to conduct testing unless manufacturers fail to sponsor the required tests. The basis for this decision is that manufacturers are expected to indirectly pass the costs of testing on to processors through any price increase of TCEA.

*F. Reporting Requirements*

EPA is requiring that all data developed under this rule be reported in accordance with the TSCA Good Laboratory Practice (GLP) standards which were published in 40 CFR Part 792 (See 48 FR 53922, November 29, 1983). These final GLP standards apply to this rule.

EPA 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. These deadlines will be established in the second phase of this rulemaking in which study plans are approved. The procedures for the second phase rulemaking are described in 40 CFR Part 790.

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).

*G. Enforcement Provisions*

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce . . . ." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory audits/inspections will be conducted periodically in accordance with the procedures outlined in TSCA section 11 by designated representatives of the EPA for the purpose of determining compliance with the final rule for 1,1,1-trichloroethane. These inspections may be conducted for purpsoes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to the TSCA GLP standards and the test standards established in the second phase of this rulemaking.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties calculated as if they had never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 per day for each violation. Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to one year. Other remedies are available to EPA under sections 7 and 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

## V. Economic Analysis of Rule

To assess the economic impact of this rule, EPA has prepared an economic evaluation (Ref. 8) that examines the cost to the required testing and analyzes four market characteristics of TCEA: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. The costs of conducting the developmental toxicity test are estimated to range from $62,134 to $186,403, with annualized costs ranging from $16,000 to $48,300 (Ref. 8). Based on these test costs and an analysis of the four market characteristics of TCEA, the economic evaluation indicates that the potential for a significant adverse economic impact as a result of this test rule is low. This conclusion is based on the following observations (Ref. 8):

1. The demand for 1,1,1-trichloroethane is relatively inelastic due to select performance advantages in its major uses.

2. The market expectations for 1,1,1-trichloroethane are generally favorable.

3. The relative magnitude of the test cost is negligible (i.e., an estimated 0.008 cents per pound in the upper bound case); this represents 0.03% of the sales value of TCEA.

## VI. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs negotiated with industry in place of rulemaking. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," October, 1981, can be obtained through the NTIS under publication number PB 82-140773.

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing required in this test rule.

## VII. Judicial Review

Judicial review of this final rule may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so-called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review two weeks after publication in the Federal Register, as reflected in "DATES" in this notice. The effective date has, in turn, been calculated from the promulgation date.

## VIII. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-42059). This record includes the basic information the Agency considered in developing this rule, and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received. Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Room E-107, 401 M Street, SW, Washington, D.C.

This record includes the following information:

(1) Federal Register notices pertaining to this rule consisting of:

(a) Notice of final rule on 1,1,1-trichloroethane.

(b) Notice of proposed rule on 1,1,1-trichloroethane (46 FR 30300).

(c) Notice containing the ITC designation of 1,1,1-trichloroethane to the Priority List (43 FR 16684).

(d) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922).

(e) Notice of final rule on test rule development and exemption procedures.

(f) Notice of final rule concerning data reimbursement.

(2) Supports documents consisting of:

(a) 1,1,1-trichloroethane support document.

(b) Economic impact analysis of final test rule for 1,1,1-trichloroethane.

(3) Communications consisting of:

(a) Written public comments.

(b) Summaries of telephone conservations.

(c) Meeting summaries.

(d) Reports—published and unpublished factual materials, including contractors' reports.

(4) Test protocol for an inhalation teratogenicity study.

## IX. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. The regulation for this chemical substance is not major because it does not meet any of the criteria set forth in section 1(b) of the order. First, the annual costs of testing are less than $50,000 over the expected market life of TCEA. Second, because the cost of the required testing will be distributed over a large production volume, the rule will have only very minor effects on producers' costs or users' prices for this chemical substance. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic impact of any type as a result of this rule.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments, are included in the public record.

## X. Regulatory Flexibility Act

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

1. There are no small manufacturers of 1,1,1-trichloroethane.

2. Small processors will not perform testing themselves, or will not participate in the organization of the testing effort.

3. Small processors will experience only minor costs if any in securing exemption from testing requirements.

4. Small processors are unlikely to be affected by reimbursement requirements.

## XI. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB number 2070-0033.

## XII. References

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List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

(Sec. 4, Pub. L. 94–469. 90 Stat. 2006; 15 U.S.C. 2603)

Dated: September 14, 1984.

William D. Ruckelshaus,

*Administrator.*

Therefore, Chapter I of 40 CFR is amended by adding Part 799 to read as follows:

## PART 799—IDENTIFICATION OF SPECIFIC CHEMICAL SUBSTANCE AND MIXTURE TESTING REQUIREMENTS

### Subpart A—General Provisions



### Subpart B—Specific Chemical Test Rules



Authority: Section 4, Section 12, and Section 26, Toxic Substances Control Act (TSCA, 90 Stat. 2006, 2033, 2047; 15 U.S.C. 2603, 2611, 2625).

### Subpart A—General Provisions

#### § 799.1 Scope and purpose.

(a) This part identifies the chemical substances, mixtures, and categories of substances and mixtures for which data are to be developed, specifies the persons required to test (manufacturers, including importers, and/or processors), specifies the test substance(s) in each case, prescribes the tests that are required including the test standards, and provides deadlines for the submission of reports and data to EPA.

(b) This part requires manufacturers and/or processors of chemical substances or mixtures ("chemicals") identified in Subpart B to submit letters of intent to test, exemption applications, and study plans in accordance with EPA test rule development and exemption procedures contained in Part 790 of this chapter and any modifications to such procedures contained in this part.

(c) This part requires manufacturers and/or processors of chemicals identified in Subpart B to conduct tests and submit data in accordance with the test standards contained in this part in order to develop data on the health and environmental effects and other characteristics of these chemicals. These data will be used to assess the risk of injury to human health or the environment presented by these chemicals.

#### § 799.2 Applicability.

This part is applicable to each person who manufactures or intends to manufacture (including import) and/or to each person who processes or intends to process a chemical substance or mixture identified in Subpart B for testing during the period commencing with the effective date of the specific chemical test rule until the end of the reimbursement period. Each set of testing requirements in Subpart B specifies whether those requirements apply to manufacturers only, to processors only, or to both manufacturers and processors.

#### § 799.3 Definitions.

The definitions in section 3 of the Toxic Substances Control Act (TSCA) and the definitions of § 790.3 of this chapter apply to this part.

#### § 799.5 Submission of information.

Information (letters, study plans, reports) submitted to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule (e.g. § 799.4400 for 1,1,1-trichloroethane) and must be addressed to: Document Control Office (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, D.C. 20460.

#### § 799.10 Test standards.

Testing required under Subpart B must be performed using a study plan prepared according to the requirements of Parts 790 and 792 of this chapter unless modified in specific chemical test rules in Subpart B. All raw data, documentation, records, protocols, specimens and reports generated as a result of a study under Subpart B must be developed, reported, and retained in accordance with TSCA Good Laboratory Practice Standards (GLP's) in Part 792 of this chapter. These items must be made available during an inspection or submitted to EPA upon request by EPA or its authorized representative. Laboratories conducting testing for submission to the Agency in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA GLP's. Sponsors must notify the laboratory that the study is being conducted pursuant to TSCA § 4. Sponsors are also responsible for ensuring that laboratories conducting the test abide by the TSCA GLP standards. In accordance with § 792.12 of this chapter, a certification concerning adherence to the TSCA GLP's must be submitted to EPA.

§ 799.11 Availability of test guidelines.

The TSCA and FIFRA guidelines for the various study plans are available from the National Technical Information Service (NTIS). Address and telephone number: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–487–4650).

The OECD guidelines for the various study plans are available from the following address: OECD Publication and Information Center, 1750 Pennsylvania Ave., NW., Washington, D.C. 20006 (202–724–1857).

§ 799.12 Test results.

Except as set forth in specific chemical test rules in Subpart B of this part, a positive or negative test result in any of the tests required under Subpart B is defined in the TSCA test guidelines published by NTIS.

§ 799.17 Effects of non-compliance.

Any person who fails or refuses to comply with any aspect of this part or Part 790 is in violation of section 15 of TSCA. EPA will treat violations of Good Laboratory Practice Standards as indicated in § 792.17 of this chapter.

## Subpart B—Specific Chemical Test Rules

§ 799.4400 1,1,1-Trichloroethane.

(a) *Identification of chemical test substance.* 1,1,1-Trichloroethane (CAS No. 71–55–6, also known as methyl chloroform) shall be tested in accordance with this part.

(b) *Identification of test substance.* 1,1,1-Trichloroethane stabilized with less than 0.1 percent butylene oxide shall be used as the test substance in all tests.

(c) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture or process 1,1,1-trichloroethane, other than as an impurity, from November 23, 1984, to the end of the reimbursement period shall submit letters of intent to test, exemption applications, and study plans and shall conduct tests and submit data as specified in this section, Subpart A of this part and Part 790 of this chapter (Test Rule Development and Exemption Procedures). (Information collection requirements approved by the Office of Management and Budget under control number 2070–0033.)

(d) *Health effects testing*—(1) Developmental toxicity—(i) *Required testing.* A test for developmental toxicity shall be conducted with 1,1,1-trichloroethane.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the inhalation teratogenicity study design submitted by the Chemical Manufacturers Association (CMA) for inhalation teratology of isophorone in the rat and mouse be consulted. A TSCA Guideline for inhalation developmental toxicity is currently being prepared by the Agency and is expected to be available by Fall, 1984. If available, it should also be consulted for appropriate study design. A copy of the CMA protocol is available in the public record for this rulemaking, docket number (OPTS–42059). Testing should, however, be conducted on the rat and a non-rodent mammalian species.

(2) [Reserved].

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