

in that paragraph must submit a notice to the EPA Office of Toxic Substances in Washington, D.C. under the provisions of section 5(a)(1)(B) of the Act, Part 720 of this Chapter, and this section. Any notice of import must be submitted by the principal importer.

(d) *Notice requirements and procedures.* Each person who is required to submit a significant new use notice under this section must submit the notice at least 90 calendar days before commencing the significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be submitted on the notice form in Appendix A to Part 720 of this Chapter and must comply with the requirements of Part 720, except to the extent that they are inconsistent with this section. EPA will process the notice in accordance with the procedures in Part 720 of this Chapter, except to the extent that they are inconsistent with this section.

(e) *Exemptions and exclusions.* The chemical substance listed in paragraph (a) of this section is not subject to the notification requirements of this section if:

(1) The substance is manufactured or processed only in small quantities solely for research and development, and the substance is manufactured or processed in accordance with the provisions of § 720.36 of this chapter.

(2) The substance is manufactured or processed only as an impurity or byproduct.

(f) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit access to or copying of records, as required by section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to permit entry or inspection, as required by section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(5) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirement of any provision of this

section may be subject to penalties calculated as if they never filed their notices.

(6) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section or act to seize any chemical substance manufactured or processed in violation of this section or take other actions under the authority of sections 7 or 17 of the Act (15 U.S.C. 2606 or 2616).

(g) *Recordkeeping.* Processors who process the substance identified in paragraph (a) of this section must maintain the following records for five years from the date of their creation:

(1) The names of persons required to use protective equipment.

(2) Records of specifications evaluated or tests performed on the prescribed protective equipment.

(Approved by the Office of Management and Budget under control number 2070-0012)

[FR Doc. 84-971 Filed 1-12-84; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 799

[OPTS-42050; TSH-FRL 2483-1]

Mono-, Di-, and Trichlorinated Benzenes; Proposed Environmental Effects Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under section 4 of the Toxic Substances Control Act (TSCA), EPA is proposing that manufacturers and processors of mono-, di-, and trichlorinated benzenes conduct certain chemical fate and environmental effects tests on these chemicals. The testing being proposed will be performed according to protocols adopted by the Agency. EPA is not proposing chemical fate or environmental effects testing of the tetrachlorobenzenes or pentachlorobenzene at this time. However, in view of recently obtained information indicating production and environmental release of the tetrachlorobenzenes, the Agency is issuing an Advance Notice of Proposed Rulemaking (ANPR) for the tetrachlorobenzenes and is soliciting comments on the possible need to issue a proposed test rule for one or more of the tetrachlorobenzene isomers. This notice constitutes EPA's response to the Interagency Testing Committee's (ITC) designation of mono-, di-, tri-, tetra- and pentachlorinated benzenes as priority candidates for environmental effects testing consideration.

DATES: Submit written comments on or

before March 13, 1984. If persons request an opportunity for oral comment by February 27, 1984, EPA will hold a public meeting on March 28, 1984, on this rule in Washington, D.C. For further information on arranging to speak at the meeting see Unit VI of this preamble.

ADDRESS: Submit written comments in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460. Include the document control number [OPTS-42050] on all submissions.

FOR FURTHER INFORMATION CONTACT:

Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St. SW., Washington, D.C. 20460. Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act. The ITC may designate substances on the list for priority consideration for testing under section 4(a) of the Act.

The ITC designated the chlorinated benzenes for priority consideration in its Initial (mono-, di-, and trichlorinated benzenes) and Third (tetra-, and pentachlorinated benzenes) Reports, published in the *Federal Register* of October 12, 1977 (42 FR 55026) and October 30, 1978 (43 FR 50630), respectively. The ITC recommended that mono-, di-, tri-, tetra- and pentachlorinated benzenes be considered for health and environmental effects testing. EPA's response to the ITC's health effects testing recommendations for these chlorinated benzenes was published in the *Federal Register* of July 18, 1980 (45 FR 48524). This notice constitutes EPA's response to the ITC's designation of chlorobenzenes as priority candidates for consideration for environmental effects testing, with particular emphasis on long-term environmental studies on freshwater and marine organisms or populations.

The ITC's testing recommendations for mono- and dichlorinated benzenes were based on the reported large U.S. production volumes of these compounds. The ITC's Initial Report stated that the U.S. production of monochlorobenzene

was over 300 million pounds/year. Production of 1,2- and 1,4-dichlorobenzene was estimated by the ITC at 50 million pounds each. In addition, the ITC was concerned that the manufacture of mono- and dichlorobenzenes and their use alone and in products could present an environmental hazard, particularly in light of the high release rate of mono- and dichlorobenzenes and their anticipated persistence in the environment.

The ITC's recommendations for tri-, tetra- and penta-chlorinated benzenes were based on reports of contamination of air, water, soil and food chains by chlorinated benzene compounds. The ITC cited several possible sources of contamination, which included the use of chlorinated benzenes as chemical intermediates, as solvents in the manufacture of dyes, as lubricants and pesticides, and as transformer oils. The ITC also speculated that a reduction in the use of polychlorinated biphenyls may result in increased use of trichlorobenzenes as transformer oils.

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

EPA uses a weight of evidence approach in making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the finding that the

chemical may present an unreasonable risk. For the section 4(a)(1)(B)(i) finding, EPA considers only production, exposure, and release information to determine if there is substantial exposure or release. For the second finding under both sections 4(a)(1)(A) and 4(a)(1)(B), EPA examines toxicity and fate studies to determine if existing information is adequate to determine or reasonably predict the effects of human exposure to, or environmental release of, the chemical. In making the third finding, that testing is necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings can be made is described in detail in EPA's first and second proposed test rules as published in the *Federal Register* of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300), respectively. The section 4(a)(1)(A) findings are discussed in (45 FR 48528), and the section 4(a)(1)(B) findings are discussed in (46 FR 30300).

In evaluating the ITC's testing recommendations concerning the chlorinated benzenes, EPA considered all available relevant information, which included the following: Information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of the chlorinated benzenes under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); health and safety studies submitted by the manufacturers of the chlorinated benzenes under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716); and published and unpublished data available to the Agency. On the basis of its evaluation, as described in this preamble and the accompanying technical support document, EPA is proposing environmental effects and chemical fate testing requirements for the mono-, di-, and trichlorinated benzenes under either section 4(a)(1)(A) or 4(a)(1)(B), as appropriate. EPA also is soliciting comments on the need for environmental effects and chemical fate testing of tetrachlorobenzenes through an Advance Notice of Proposed Rulemaking (ANPR) contained in this Notice. The Agency is not proposing testing for pentachlorobenzene because available information indicates that pentachlorobenzene is not produced in or imported into the United States. By these actions, EPA is responding to the ITC's designations of mono-, di-, tri-,

tetra- and pentachlorinated benzenes for testing consideration.

II. Chlorinated Benzenes

A. Profile

The eleven chlorinated benzenes listed in Table 1 are those considered in this response to the ITC. For membership in the category, a substance must be a benzene ring in which one to five hydrogen atoms are replaced by a chlorine.

TABLE 1.—IUPAC NAMES, CAS NUMBERS AND SYNONYMS OF THE CHLORINATED BENZENES

IUPAC name	CAS No.	Synonyms
Chlorobenzene.....	108-90-7	Monochlorobenzene. benzene chloride
1,2-Dichlorobenzene.....	95-50-1	ortho or o-Dichlorobenzene.
1,3-Dichlorobenzene.....	541-73-1	meta- or m-Dichlorobenzene
1,4-Dichlorobenzene.....	106-46-7	para- or p-Dichlorobenzene.
1,2,3-Trichlorobenzene.....	87-61-6	vic-Trichlorobenzene.
1,2,4-Trichlorobenzene.....	120-82-1	unsym-Trichlorobenzene.
1,3,5-Trichlorobenzene.....	106-70-3	sym-Trichlorobenzene
1,2,3,4-Tetrachlorobenzene.....	634-66-2	1,2,3,4-Tetrachlorobenzol.
1,2,3,5-Tetrachlorobenzene.....	634-90-2	1,2,3,5-Tetrachlorobenzol.
1,2,4,5-Tetrachlorobenzene.....	95-94-3	1,2,4,5-Tetrachlorobenzol.
1,2,3,4,5-Pentachlorobenzene.....	608-93-5	Quintochlorobenzene.

Ranges of chlorinated benzene production in and/or import into the United States are presented in Table 2. These figures were derived from information reported under the TSCA section 8(a) Preliminary Assessment Information Rule published in the *Federal Register* of June 22, 1982 (47 FR 26992), using the techniques for aggregating data as described in the *Federal Register* of June 13, 1983 (48 FR 27041), and rounding off to three significant figures.

TABLE 2.—UNITED STATES PRODUCTION AND/OR IMPORT OF THE CHLORINATED BENZENES

Chlorinated benzene	Production and/or import volume (lbs/year)*
Monochlorobenzene.....	195,000,000 to 284,000,000.
1,2-Dichlorobenzene.....	40,300,000 to 47,300,000.
1,3-Dichlorobenzene.....	323,000 to 1,010,000.
1,4-Dichlorobenzene.....	62,300,000.
1,2,3-Trichlorobenzene.....	51,300 to 163,000.
1,2,4-Trichlorobenzene.....	2,750,000 to 8,070,000.
1,3,5-Trichlorobenzene.....	244,000 to 462,000.
Tetrachlorobenzene.....	Unknown.*
Pentachlorobenzene.....	None.

* Data were derived from information reported under the TSCA Section 8(a) Preliminary Assessment Information Rule (47 FR 26992) using the techniques for aggregating data described in 48 FR 27041 and EPA communications with the chlorobenzene manufacturers.

* The single tetrachlorobenzene manufacturer that reported under the TSCA Section 8(a) Preliminary Assessment Information Rule (47 FR 26992) informed the Agency that it no longer produced tetrachlorobenzene. However, recent information now indicates that potentially significant levels of tetrachlorobenzene may now or soon will be produced by another chlorobenzene manufacturer (CBI 1983).

The principal uses of the chlorobenzenes are summarized in table 3.

TABLE 3.—PRINCIPAL USES OF CHLOROBENZENES*

Chlorinated benzene	Principal uses
Monochlorobenzene.	Intermediate in dye and herbicide manufacture; solvent in pesticide* and degreasing formulations.
1,2-Dichlorobenzene.	Production of 3,4-dichloroaniline; intermediate in manufacture of herbicides, dyes, polymers, and epoxy resins; organic solvent.
1,4-Dichlorobenzene.	Space deodorants and moth-control.*
Trichlorobenzenes	Organic intermediates; solvents, dye carriers; transformer and dielectric fluids.
Tetrachlorobenzenes.	Intermediate in production of dielectric fluids, pesticides, herbicides, and pentachlorobenzene.
Pentachlorobenzene	Production of pentachloronitrobenzene.

*Use of chlorinated benzenes as pesticide products or as solvents in such pesticides is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act and was not considered in this rulemaking.

B. Findings

1. *TSCA Section 4(a)(1)(B)*. The EPA is basing its proposed testing of monochlorobenzene, 1,2- and 1,4-dichlorobenzenes and 1,2,4-trichlorobenzene on the authority of section 4(a)(1)(B) of TSCA. EPA has concluded that monochlorobenzene, 1,2- and 1,4-dichlorobenzenes and 1,2,4-trichlorobenzene are produced in substantial quantities, and may enter the environment in substantial quantities. Furthermore, EPA has concluded that there are insufficient data available to either reasonably determine or predict the results of this exposure in the areas of chemical fate and environmental effects and that testing is necessary to develop such data.

EPA has reached these conclusions for the following reasons: (1) Available information indicates that the annual United States production and/or import volumes for monochlorobenzene, 1,2- and 1,4-dichlorobenzenes and 1,2,4-trichlorobenzene are substantial (see Table 2), based on information reported under the TSCA section 8(a) Preliminary Assessment Information Rule (47 FR 26992), aggregated using the techniques described in 48 FR 27041 and rounded off to three significant figures. (2) Available information indicates that there are substantial amounts of monochlorobenzene, 1,2- and 1,4-dichlorobenzenes and 1,2,4-trichlorobenzene released to the environment each year via manufacturing, processing and/or use activities. Table 4, presents aggregated

environmental release estimates of the chlorinated benzenes resulting from their manufacture, based on information reported under the TSCA section 8(a) Preliminary Assessment Information Rule (47 FR 26992) and rounded off to three significant figures. In addition, available data indicate that the uses of these chlorinated benzenes may result in substantial release of monochlorobenzene, 1,2- and 1,4-dichlorobenzenes and 1,2,4-trichlorobenzene into the environment. Johnston et al. (1980) and Mattech (1983) estimated the following environmental releases from use: monochlorobenzene—2 million pounds released to air, and 70 million pounds released to water; 1,2-dichlorobenzene—<0.1 million pounds released to air, 9.1 million pounds released to water, and <0.1 million pounds released to land; 1,4-dichlorobenzene—15.7 million pounds released to air, 11.8 million pounds released to water, and 0.6 million pounds released to land; and 1,2,4-trichlorobenzene—3.2 million pounds released to water (Refs 1 and 2). (See section 2.1 of the technical support document for additional information on the environmental release of the chlorinated benzenes.) (3) EPA has concluded that there are insufficient data on the chemical fates and environmental effects of monochlorobenzene, 1,2- and 1,4-dichlorobenzenes and 1,2,4-trichlorobenzene to reasonably determine or predict the results of their environmental releases, and that testing is necessary to develop such data.

TABLE 4.—ANNUAL ENVIRONMENTAL RELEASE ESTIMATES DURING THE MANUFACTURE OF FOUR CHLORINATED BENZENES

Chlorinated benzene	Annual release estimate in pounds
Monochlorobenzene.....	420,000-805,000
1,2-Dichlorobenzene.....	65,800
1,4-Dichlorobenzene.....	365,000-592,000
1,2,4-Trichlorobenzene.....	801-2,093

2. *TSCA Section 4(a)(1)(A)*. EPA is basing its proposed testing of 1,2,4-trichlorobenzene on the authority of TSCA section 4(a)(1)(A), because EPA has concluded that 1,2,3-trichlorobenzene may present an unreasonable risk of injury to organisms in the aquatic environment. EPA has reached this conclusion for the following reasons: (1) Existing toxicity data indicate that among the mono-, di-, and trichlorobenzenes, 1,2,3-trichlorobenzene is the most toxic chlorinated benzene to aquatic organisms (Ref. 3). Toxicity

measurements include reported 48-hr LC₅₀s of 0.71 mg/L and 3.1 mg/L for rainbow trout and zebra danios, respectively, and a 24-hr daphnid LC₅₀ of 3.35 mg/L (Ref. 3). In addition, chronic toxicity data on daphnids show significant effects at concentrations as low as 0.1 mg/L (Ref. 3). (2) Available information indicates that the manufacture and uses of 1,2,3-trichlorobenzene (dye carrier, organic solvent, intermediate and dielectric fluid) are the principal sources of its environmental release. Ware and West (1977) reported levels of 21-46 mg/L 1,2,3-chlorobenzene in municipal discharge, measured using flame-ionization gas chromatography (Ref. 5). Using these measured levels of 1,2,3-trichlorobenzene of 1200-2600× in rainbow and its trout (Ref. 4) the potential concentration of 1,2,3-trichlorobenzene in fish is in the range of 25-126 mg/L (measured levels in water×BCF's for rainbow trout=potential concentration of 1,2,3-trichlorobenzene in fish). Due to this potential bio-concentration of 1,2,3-trichlorobenzene, and its reported LC₅₀ of 0.71 ml/l for rainbow trout, the Agency has determined that 1,2,3-trichlorobenzene may present an unreasonable risk to aquatic organisms. (3) EPA has concluded that there are insufficient data on the environmental effect of 1,2,3-trichlorobenzene to reasonably determine or predict the result of its environmental release and that testing is necessary to develop such data.

On the basis of these findings, the agency is proposing the testing requirements summarized in Tables 5 and 6 as a basis for determining the chemical fate and/or environmental effects of monochlorobenzene, 1,2- and 1,4-dichlorobenzenes, 1,2,4-trichlorobenzene and 1,2,3-trichlorobenzene.

TABLE 5.—PROPOSED TESTING REQUIREMENTS FOR MONO-, 1,2-DI-, 1,4-DI- AND 1,2,4-TRICHLORINATED BENZENE

Chlorinated benzene	Proposed testing
Monochlorobenzene.	Chemical fate: Atmospheric oxidation via hydroxyl radical. Environmental effects: Speed germination, root elongation and early seedling growth in terrestrial macrophytes.
1,2- and 1,4-Dichlorobenzenes.	Chemical fate: Atmospheric oxidation via hydroxyl radical, and soil adsorption coefficient. Environmental effects: Speed germination, root elongation and early seedling growth in terrestrial macrophytes.
1,2,4-Trichlorobenzene.	Chemical fate: Atmospheric oxidation via hydroxyl radical, and soil adsorption coefficient.

TABLE 5.—PROPOSED TESTING REQUIREMENTS FOR MONO-, 1,2-DI-, 1,4-DI- AND 1,2,4-TRICHLORINATED BENZENE—Continued

Chlorinated benzene	Proposed testing
	Environmental effects: Acute and chronic toxicity to mysid shrimp, acute toxicity to the aquatic macrophyte <i>Lemna gibba</i> , seed germination, root elongation and early seedling growth in terrestrial macrophytes.

TABLE 6.—PROPOSED TESTING REQUIREMENTS FOR 1,2,3-TRICHLOROBENZENE

Environmental effects
96-hr LC ₅₀ for fathead minnow; 96-hr EC ₅₀ for one species of <i>Gammarus</i> ; acute toxicity to the aquatic macrophyte <i>Lemna gibba</i> ; acute toxicity to mysid shrimp and silversides; chronic toxicity to mysid shrimp if LC ₅₀ is <1 ppm.

3. *No Further Testing.* For 1,3-dichlorobenzene, the Agency has concluded that no further testing should be proposed at this time. Existing data for 1,3-dichlorobenzene adequately characterize its toxicity to aquatic organisms. In addition, available information provides no basis for believing that 1,3-dichlorobenzene may present an unreasonable risk to the terrestrial environment.

For 1,3,5-trichlorobenzene, the Agency has concluded that no further testing should be proposed under either TSCA section 4(a)(1)(B) or 4(a)(1)(A) at this time. This conclusion is based on the following factors: (1) Data submitted under TSCA section 8(a) indicate that 1,3,5-trichlorobenzene is not currently produced in the United States; (2) the primary uses of 1,3,5-trichlorobenzene, for which it is imported into the United States, are expected to result in low environmental releases and exposures; and (3) in view of the level of exposure, currently available, albeit limited, data on the chemical fate and environmental effects of 1,3,5-trichlorobenzene do not support a finding that this compound may pose an unreasonable risk of injury to organism in the aquatic and terrestrial environments.

For pentachlorobenzene, the Agency concludes that no additional testing should be proposed at this time. This conclusion is based on the fact that pentachlorobenzene is neither produced in nor imported into the United States at this time. The only former U.S. pentachlorobenzene manufacturer and/or importer has notified EPA that it no longer manufactures and/or imports pentachlorobenzene.

4. *Advance Notice of Proposed Rulemaking.* For the tetrachlorobenzenes, this Notice

constitutes an Advance Notice of Proposed Rulemaking. The Agency decided to issue an ANPR for tetrachlorobenzenes based on the following factors: (1) Information submitted to the EPA under the June, 1982, TSCA section 8(a) Preliminary Assessment Information Rule (47 FR 26992) indicated that only one manufacturer produced 1,2,4,5- and 1,2,3,5-trichlorobenzenes in the U.S., and that no tetrachlorobenzene was imported into the country. On May 2, 1983, this sole manufacturer notified the Agency that it no longer produced 1,2,4,5- and 1,2,3,5-trichlorobenzenes. Because these chlorobenzenes were neither produced in nor imported into the United States, the Agency had initially decided not to propose environmental effects testing for 1,2,4,5- and 1,2,3,5-tetrachlorobenzenes under TSCA section 4(a). (2) In September 1983, EPA was informed that a chlorinated benzene manufacturer in the United States had received and accepted an order for a mixture of tri- and tetrachlorinated benzenes to be used as a substitute for polychlorinated biphenyls (PCBs) in transformers. On September 27, 1983, the Agency received information, claimed as confidential business information (CBI), as to which isomer or isomers of tri- and tetrachlorinated benzenes make up this mixture and in what percentages. (3) EPA believes that the use of tetrachlorobenzene in transformers may result in environmental release and exposure similar to that demonstrated with polychlorinated biphenyls (PCBs). However, EPA does not know the potential production/importation volume of tetrachlorobenzenes for this use and cannot estimate potential release of tetrachlorobenzenes to the environment at this time.

EPA believes that an ANPR is an appropriate mechanism to obtain information on the potential production, use, and environmental release of tetrachlorobenzene as a PCB substitute. The Agency is asking for public comment on the need to test the tetrachlorobenzenes for environmental effects. (See Unit II. I). If EPA determines that there is a significant potential for environmental release from the manufacturing, processing, use or disposal of tetrachlorobenzenes, EPA will propose that they be tested for chemical fate and/or environmental effects.

The analyses on which the above findings are based are presented in the Chlorinated Benzenes Support Document, which is available from the TSCA Assistance Office (TAO).

C. Test Substance

EPA is proposing that chlorinated benzenes of 99 percent purity be used as the test substances for the chemical and environmental effects testing. This stipulation increases the likelihood that any toxic effects observed are related to the chlorinated benzenes and not to any impurities.

D. Persons Required to Test

Section 4(b)(3)(B) 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.

EPA has found that (a) mono-, 1,2-di-, 1,4-di-, and 1,2,4-trichlorinated benzenes are produced in substantial quantities and that their manufacture, processing, and use are likely to result in significant or substantial exposure to the environment, and (b) for 1,2,3-trichlorobenzene, manufacture, processing and use may lead to unreasonable risk to organisms in the aquatic environment. Thus, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process monochlorobenzene, 1,2- and 1,4-dichlorobenzenes, and 1,2,4- and 1,2,3-trichlorobenzenes at any time from the effective date of this test rule to the end of the reimbursement period be subject to the requirements of the rule for the chlorinated benzene(s) that they manufacture or process. The end of the reimbursement period ordinarily will be 5 years after the submission of the last final report required under the test rule.

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 as discussed in Unit II.E. below.

E. Exemptions

EPA's proposed policy on application exemptions from section 4 testing requirements was published in the *Federal Register* of July 18, 1980 (45 FR 48512). EPA intends to promulgate its final procedures for exemptions in 40 CFR Part 770. The exemption procedures described below and included in the proposed rule language are consistent with EPA's current thinking on exemption procedures. If the general rule is promulgated before this proposal becomes final, the chlorinated benzenes rule will be modified to comport with the general procedural provisions.

Any manufacturer or processor of the chlorinated benzenes identified in paragraph (a) of this proposed rule would be able to apply for an exemption. Any person who has applied for an exemption would not be in violation of the rule until such time as EPA denies the application.

If manufacturers perform all the required testing, processors would be granted exemptions automatically without having to file applications.

When EPA has received a proposed study plan for a test set and has adopted the plan as the test standard, EPA would conditionally grant all exemption applications for that test set. If the test sponsor later fails to perform the testing, EPA would notify all persons who had submitted exemption applications for that test set that the exemptions would be denied unless within 30 days a manufacturer or processor notified EPA of its intent to perform the testing in accordance with the adopted test standards.

F. Approach to Adoption of Test Rules

1. *General process.* EPA announced a new approach to adoption of test rules published in the *Federal Register* of March 26, 1982 (47 FR 13012). EPA intends to promulgate a general procedural rule in 40 CFR Part 770 which will contain the procedural requirements for this approach. However, because that procedural rule is not in effect, this proposed rule contains specific procedures for adoption of this test rule. If the general rule is promulgated before this proposal becomes final, the chlorinated benzenes final rule will be modified to comport with the general procedural provisions.

Under the approach being followed for chlorinated benzenes, test rule development will be a two-phase process. In phase I, EPA is proposing that specific testing be required for chlorinated benzenes. This phase of the rulemaking will allow the public to comment on the decision to require

testing and the specific types of tests to be required. Phase II begins after promulgation of the phase I test rule. In phase II, EPA will propose study plans submitted by test sponsors for public comment. After comment, the Agency will adopt the study plans, as proposed or modified, as specific test standards for the tests required by the phase I rule. Persons who submit the study plans will be obligated to perform the tests in accordance with the test standards adopted.

2. *Letter of intent to test or exemption application.* The proposed rule would require manufacturers and processors of chlorinated benzenes to perform certain tests. Once the rule is in effect, 30 days after publication in the *Federal Register*, each current manufacturer of monochlorobenzene, 1,2-dichlorobenzene, 1,4-dichlorobenzene, 1,2,4-trichlorobenzene, and 1,2,3-trichlorobenzene would have 30 days to submit for each required test set (see paragraphs (j) (1) through (9) of the proposed rule) either a letter of intent to perform the test set or an application for exemption. Each manufacturer who submitted a letter of intent to perform a specific test set would be obligated, first to submit, within 90 days of the effective date, a proposed study plan for the test set and, ultimately, to perform the testing.

Because EPA is making findings on individual chlorinated benzenes, the exemption procedures for the chlorobenzenes are the same as the procedures for individual chemicals discussed in Unit II.E. If manufacturers of a chlorinated benzene performed all the required test sets, processors of that chlorinated benzene would not be required to test or to submit exemption applications. EPA would automatically grant them exemptions from the requirements of the rule.

If no manufacturer of a given chlorinated benzene submitted a letter of intent to perform a particular test set within the 30-day period, EPA would publish a notice in the *Federal Register* to notify all processors of that chlorinated benzene. The notice would state that EPA had not received letters of intent to perform certain test sets and that current processors would have 30 days to submit, for each test set remaining, either a letter of intent to perform the test set or an exemption application for that test set. Each processor who submitted a letter of intent to perform a specific test set would be obligated, first, to submit, within 90 days of the publication of the *Federal Register* notice, a proposed study plan for the test set and, ultimately, to perform the testing.

If no manufacturer or processor submitted a letter of intent to perform a particular test set, EPA would notify all manufacturers and processors, by letter or through the *Federal Register*, that all exemption applications for that chlorinated benzene would be denied and that all manufacturers and processors of that chlorinated benzene would be in violation of the rule until a proposed study plan is submitted for that test set.

Any person not manufacturing chlorinated benzenes subject to testing requirements in effect, who later begins manufacturing before the end of the reimbursement period, would be required to submit a letter of intent to test or an exemption application for each required test set by the day the person begins manufacture. If EPA has published a notice in the *Federal Register* telling processors to submit letters of intent or exemption applications for certain test sets, any person not processing chlorinated benzenes at the time the rule goes into effect, who later begins processing before the end of the reimbursement period, would be required to submit a letter of intent to test or an exemption application for each test set specified in the *Federal Register* notice by the day the person begins processing.

3. *Submission and adoption of study plans.* Any manufacturer of chlorinated benzenes who submitted a letter of intent to perform a test set would have to submit, within 90 days after the effective date of the rule, a proposed study plan for that test set. In the event manufacturers do not submit letters of intent for all the required test sets, any processor who submits a letter of intent to perform a specific test set would have to submit, within 90 days of the publication of the *Federal Register* notice notifying processors, a proposed study plan for that test set. Paragraph (e) of the rule describes the contents of a proposed study plan.

EPA proposed generic test methodology requirements (generic test standards) in the *Federal Register* of May 9, 1979 (44 FR 27334), July 26, 1979 (44 FR 44054), and November 21, 1980 (45 FR 77332). In response to concerns about the rigidity of generic test methodology requirements, EPA has changed its approach for providing test standards for TSCA section 4 test rules. It has issued generic test methodology guidelines to replace the previously proposed generic test methodology requirements. The TSCA guidelines have been published by the National Technical Information Service (NTIS) for health effects (PB 82-232904).

environmental effects (PB 82-232992), and chemical fate (PB 82-233008). Good Laboratory Practice (GLP) standards for development of data on physical and chemical properties, persistence, and ecological effects of chemical properties, persistence, and ecological effects of Chemical Substances under TSCA were proposed in the *Federal Register* of November 21, 1980 (44 FR 77357). These GLP standards will be promulgated as generic requirements. These final TSCA GLP regulations will apply to the chlorinated benzenes test rule.

For guidance in preparing study plans, EPA recommends that test sponsors consult the TSCA Test Guidelines and the TSCA GLP standards as referenced above: the Organization for Economic Cooperation and Development's (OECD) Guidelines, as adopted by the OECD Council on May 12, 1981; or the FIFRA Pesticide Registration Guidelines: Proposed Data Requirements published by the National Technical Information Service (see the *Federal Register* of November 24, 1982 (47 FR 53192), for a list of these guidelines).

Failure to submit a study plan would be a violation of the rule.

EPA would review the proposed study plans. If they are incomplete, the manufacturer or processor would be notified of the deficiency and would have 15 days to provide appropriate information to make the plan complete. If the information is not provided in 15 days, the manufacturer or processor would be in violation of the rule. In addition, EPA would return to the appropriate stage of the process and require manufacturers or processors, as appropriate, to submit letters of intent, exemption applications, and study plans.

If the proposed study plan is complete, EPA would propose the study plan for public comment. In particular, the request for comments would focus on whether the study plan will ensure that data from the test set will be reliable and adequate. There would be a 45-day comment period and the opportunity to present views orally upon request. After considering the public comment, EPA would adopt the study plan as proposed, or as modified in response to comment, as the test standard for the required test set.

The person who submitted the proposed study plan would be required to perform the testing according to that standard. Failure to perform the testing would be in violation of the rule.

G. Reporting Requirements

EPA is proposing that all data be reported in accordance with the EPA GLP Standards to appear in 40 CFR Part

792. EPA has reviewed public comment on the proposed GLP Standards and is now developing final GLP standards. The final GLP Standards will 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 phase II rulemaking in which study plans are approved, or in a subsequent FR notice if EPA changes its policy as described in Unit II.E.

TSCA section 4(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).

H. 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 rule 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 authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for chlorinated benzenes. These inspections may be conducted for purposes 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 EPA GLP standards and the test standards established in the phase II rule.

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) 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 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 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent to perform testing or an exemption request. Continued manufacturing or processing after the deadlines for such submissions would be a violation of the rule. Knowing or willful violations could lead to the imposition of criminal penalties of up to \$25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking and 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.

I. Issues

The decision to defer environmental testing of the tetrachlorobenzenes is one for which further input by interested parties will be particularly useful. Therefore, EPA is soliciting public comment on the following information needs: (1) Production in and/or import

into the United States of tetrachlorobenzenes. (2) anticipated environmental release from production, use, distribution, or disposal of tetrachlorobenzenes. (3) ratios and isomer specific chemical components of mixtures of the chlorinated benzenes, including impurities, for use as a polychlorinated biphenyls substitute, and (4) the potential production of chlorinated benzenes (isomer specific) for use as a substitute for polychlorinated biphenyls.

The public comments received in response to this ANPR for the tetrachlorobenzenes will be instrumental in assisting the Agency in its determination on whether to require environmental effects testing of these chlorinated benzenes. If, after public comments are reviewed and evaluated, the Agency is unable to obtain specific information concerning tetrachlorinated benzene production in and/or importation into the United States, and their potential environmental release from use as a substitute for polychlorinated biphenyls, then the Agency may issue a TSCA section 8(a) rule requiring this specific information. In addition, the Agency may issue a TSCA section 5 Significant New Use Rule (SNUR) on 1,3-dichlorobenzene, 1,3,5-trichlorobenzene, and/or pentachlorobenzene.

Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis. This consists of evaluating each chemical group on four principal market characteristics: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis, along with the consideration of the costs of the required tests, indicate whether the possibility of a significant adverse economic impact exists. Where the indication is negative, no further economic analysis is done for that chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for a significant economic impact, a more comprehensive and detailed analysis is conducted. This Level II analysis attempts to predict more precisely the magnitude of the expected impact.

Total testing costs for the proposed rule for the chlorinated benzenes are estimated to range from \$100,900 to \$210,600. The annualized cost range is \$76,100 to \$54,600, based on a 25 percent rate of capital over 15 years; the estimated unit costs range from 0.01 to

0.03 cents per pound. These estimates indicate that the economic impact of the proposed testing will not be significant. Moreover, on the basis of its Level I assessment, EPA believes that this proposed test rule will not result in a loss to society of the benefits of the chlorinated benzenes.

A detailed discussion of the methodology used to conduct the economic analysis for this test rule, the "Level I Economic Impact Analysis for Chlorobenzenes" (EPA Contract No. 68-01-6630), is available from the TSCA Assistance Office (TAO)¹ and is part of the public docket for this rulemaking.

IV. 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 (PB 82-140773).

On the basis of this study, the Agency believes that there will be available resources to perform the testing in this proposed rule.

V. Guidelines and Study Plans

The following guidelines and/or study plans cited in this proposed test rulemaking are available from: National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703) 487-4650.

NTIS publication No.	Title	Price
PB 82-140773	Chemical Testing Industry: Profile of Toxicological Testing.	\$16.00
PB 82-232992	TSCA Environmental Effects Test Guidelines for Acute Toxicity Testing.	60.00
PB 83-153908	OECD Test Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms.	11.50
PB 83-153916	FIFRA Pesticides Registration Guidelines: Proposed Data Requirements for Hazard Evaluation: Humans and Domestic Animals.	11.50

VI. Public Meetings

If persons indicate to EPA that they wish to present comments on this

¹ TSCA Assistance Office, EPA, Rm. E-543, 401 M St., SW., Washington, D.C. 20460. Toll Free: (800-424-9065). In Washington, D.C. (554-1404). Outside USA: (Operator-202-554-1404).

proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting on March 28, 1984 in Washington, D.C. Persons who wish to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free: (800-424-9065); In Washington, D.C.: (554-1404); Outside the U.S.A. (Operator-202-554-1404), by February 27, 1984. The meeting will not be held if members of the public do not indicate that they wish to make oral presentations. This meeting is scheduled after the deadline for submission of written comments, so that issues raised in the written comments can be discussed by EPA and the public commenters. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to check whether the meeting will be held.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

VII. Public Record

EPA has established a record for this rulemaking docket number [OPTS-4250]. This record includes the basic information the Agency considered in developing this proposal, and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received. The Record includes the following information:

- (1) Federal Register notices pertaining to this rule consisting of:
 - (a) Notice of proposed rule on the chlorinated benzenes.
 - (b) Notice containing the ITC designation of the chlorinated benzenes to the Priority List [42 FR 55026, October 12, 1977 and 43 FR 50630, October 30, 1978].
 - (c) Notices relating to EPA's environmental effects test guidelines and EPA Good Laboratory Practice Standards.
 - (d) Notice of proposed rule on exemption policy and procedures.
 - (e) Notice of final rule on reimbursement policy and procedures.
- (2) Support Documents consisting of:
 - (a) Chlorinated Benzenes Technical Support Document.
 - (b) Economic Analysis Support Document.
 - (3) Minutes of informal meetings.
 - (4) Communications before proposal consisting of:

- (a) Written public and intra- or interagency memoranda and comments.
- (b) Summaries of telephone conversations.
- (c) Meeting summaries.
- (d) Reports—published and unpublished factual materials, including contractors' reports.

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 in the OPTS Reading Room, Rm. E-107, 401 M St. SW., Washington, D.C. from 8:00 a.m. to 4:00 p.m., Monday through Friday except legal holidays:

VIII. 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. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the actual annual cost of the testing prescribed for the chlorinated benzenes is less than \$55,000 over the testing and reimbursement period. 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 these chemicals. Finally, taking into account the nature of the market for these chemicals, 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 proposed 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.

IX. 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 because: (1) They will not perform testing themselves and will not participate in the organization of the testing effort; (2) they will experience only minor costs in securing exemptions from testing requirements; and (3) they are unlikely to be significantly affected by reimbursement requirements.

X. Paperwork Reduction Act

The information collection requirements in the proposed rule will be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB mailed Attention: Desk Officer for EPA.

XI. References

- (1) Johnston P, Hodge V, Slimak K. 1980. Materials Balance—Task # 4—Chlorobenzenes. Prepared by J.R.B. Associates, Inc. for Office of Pesticides and Toxic Substances. U.S. Environmental Protection Agency. Report 560/13-80-001.
- (2) Mathtech, Inc. 1983. Draft Report Level I Economic Evaluation Chlorobenzenes. Prepared for Economics and Technology Division, Office of Pesticides and Toxic Substances. U.S. Environmental Protection Agency. Contract No. 68-01-6630.
- (3) Calamari D, Galassi S, Setti F, Vighi M. 1983. Toxicity of Selected Chlorobenzenes to Aquatic Organisms. *Chemosphere* 12(2): 253-262.
- (4) Oliver BC, Niimi AJ. 1983. Bioconcentration of Chlorobenzenes From Water by Rainbow Trout: Correlations
- (5) Ware SA, West WL. 1977. Investigation of Selected Potential Environmental Contaminants: Halogenated Benzenes. Report 560/2-77-004. U.S. Environmental Protection Agency, Office of Toxic Substances.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection. Hazardous material, Chemicals.

(Sec. 4, Pub. L. 94-469, 90 stat. 2003; (15 U.S.C. 2061))

Dated: December 23, 1983.

Alvin L. Alm.

Acting Administrator.

PART 799—[AMENDED]

Therefore, it is proposed that a new § 799.2900 be added to Subpart B of the proposed Part 799 to read as follows:

§ 799.2900 Monochlorobenzene; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,2,4-trichlorobenzene and 1,2,3-trichlorobenzene.

(a) *Identification of test substance.* (1) Monochlorobenzene (CAS No. 108-90-7); 1,2-dichlorobenzene (CAS No. 95-50-1); 1,4-dichlorobenzene (CAS No. 106-46-7); 1,2,4-trichlorobenzene (CAS No. 120-82-1); and 1,2,3-trichlorobenzene (CAS No. 87-61-6) each shall be tested in accordance with this section.

(2) Monochlorobenzene; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,2,4-trichlorobenzene and 1,2,3-trichlorobenzene of 99 percent purity shall be used as the test substance in all tests.

(b) *Persons required to submit study plans, conduct tests and submit data.* (1) all persons who manufacture or process monochlorobenzene; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,2,4-trichlorobenzene; or 1,2,3-trichlorobenzene or any mixture of these chlorinated benzenes from the effective date of this rule February 13, 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 paragraphs (c), (d), (e), (h), (j), and (k) of this section.

(2) Any person subject to the requirements of this section may apply to EPA for an exemption from study plan submission and testing requirements. Any such application shall be in accordance with paragraph (h) of this section.

(c) *Submission of notice of intent to test or exemption application.* (1) No later than 30 days after the effective date of this rule, each person manufacturing monochlorobenzene, 1,2-dichlorobenzene, 1,4-dichlorobenzene, 1,2,4-trichlorobenzene, and 1,2,3-trichlorobenzene, or any mixture thereof, as of the effective date of this rule must, for each test or test set required by paragraphs (j)(1) through (j)(9) of this section, either notify EPA by letter of its intent to perform the test set or submit an application for an exemption from the study plan submission and testing requirements for the test set.

(2) If, by the date specified in paragraph (c)(1) of this section, for each of the chlorinated benzenes identified in paragraph (a) of this section, no manufacturer has notified EPA of its intent to perform testing for each test set required by paragraph (j) of this section, EPA will publish a notice in the **Federal Register** of this fact specifying the chlorobenzene and the testing for which no notice of intent has been submitted. No later than 30 days after publication of such a notice, each person processing the chlorinated benzenes identified in the notice as of the effective date of this section must, for each test set specified in the **Federal Register** notice, either notify EPA by letter of its intent to perform the test set or submit an application for an exemption from the study plan submission and testing requirements for the testing.

(3) Any person not manufacturing the chlorinated benzenes identified in paragraph (a) of this section as of the effective date of this rule who, before the end of the reimbursement period, manufactures any one of them must comply with the requirements of

paragraphs (c)(1) and (d)(1) of this section. For the purpose of paragraph (c) of this section, the manufacturer must submit the notice of intent to test or exemption application required by paragraph (c)(1) of this section by the date manufacture begins and must submit any proposed study plan required by paragraph (d)(1) of this section within 60 days of the date manufacture begins.

(4) If a Federal Register notice has been published under paragraphs (c)(2) or (d)(4) of this section, any person not processing the chlorinated benzenes identified in the notice described in paragraph (c)(2) of this section, as of the effective date of this rule who, before the end of the reimbursement period, begins processing the chlorobenzenes must comply with the requirements of paragraphs (c)(2) and (d)(2) of this section. For purposes of paragraph (c) of this section, the processor must submit the notice of intent to test or exemption application required by paragraph (c)(2) of this section by the date processing begins and must submit any proposed study plan required by paragraph (d)(2) of this section within 60 days of the date processing begins.

(5) Any manufacturer or processor of the chlorinated benzenes identified in paragraph (a) of this section, which has notified EPA under paragraphs (c)(1), (c)(2), (c)(3), or (c)(4) of this section of its intent to perform testing for a test set required by paragraph (j) of this section, must submit a proposed study plan for the test set and must perform that test set in accordance with the test standards in paragraph (k) of this section.

(d) *Submission of proposed study plans.* (1) Manufacturers of the chlorinated benzenes identified in paragraph (a) of this section which notify EPA under paragraph (c)(1) of this section that they intend to perform a test set must submit a proposed study plan for the test set in accordance with paragraph (e) of this section no later than 90 days after the effective date of this rule. Manufacturers may jointly submit a single proposed study plan if they plan to sponsor or perform the test set jointly. Any manufacturer which, having notified EPA of its intent to perform a test set, fails to submit a proposed study plan for that test set will have been in violation of this section as if no letter of intent to perform the test had been submitted.

(2) Processors of the chlorinated benzenes identified in paragraph (a) of this section which notify EPA under paragraph (c)(2) of this section that they intend to perform a test set must submit a proposed study plan for the test set in

accordance with paragraph (e) of this section no later than 90 days after the publication of the notice specified in paragraph (c)(2) of this section. Processors may jointly submit a single proposed study plan if they plan to sponsor or perform the test set jointly. Any processor which, having notified EPA of its intent to perform a test set, fails to submit a proposed study plan for that test set will have been in violation of this section as if no letter of intent to perform the test set had been submitted.

(3) If EPA determines in accordance with paragraph (f)(1)(i) of this section that a proposed study plan is incomplete and the manufacturer or processor has not, after notice from EPA, submitted appropriate information to make the study plan complete within 15 days, the manufacturer or processor will have been in violation of this section as if no letter of intent to perform the test set had been submitted.

(4) If either by:

(i) The date specified in paragraph (d)(1) of this section a manufacturer of the chlorinated benzenes identified in paragraph (a) of this section, which notified EPA of its intent to perform a test set, has failed to submit a proposed study plan for that test set; or

(ii) A proposed study plan submitted under paragraph (d)(1) of this section has been found to be incomplete under paragraph (f)(1)(i) of this section and the manufacturer has not submitted appropriate information to make the study plan complete within 15 days, EPA will publish a notice in the Federal Register of this fact specifying the test set. The requirements of paragraphs (c)(2) and (d)(2) of this section for processors to submit letters of intent to perform testing, applications for exemption and proposed study plans will apply.

(5) If either:

(i) By the date specified in paragraph (c)(2) of this section no processor of the chlorinated benzenes has notified EPA of its intent to perform testing for any test set identified in a Federal Register notice published under paragraphs (c)(2) or (d)(4) of this section.

(ii) The date specified in paragraph (d)(2) of this section any processor of the chlorinated benzenes identified in paragraph (a) of this section, which notified EPA of its intent to perform a test set, has failed to submit a proposed study plan for that test set; or

(iii) A proposed study plan submitted under paragraph (d)(2) of this section has been found to be incomplete under paragraph (f)(1)(i) of this section and the processor has not submitted appropriate information to make the study plan complete within 15 days, all applications

for exemption from the requirements to submit study plans and to perform tests for the specified test set involved will automatically be denied. EPA will notify each manufacturer and processor of the chlorinated benzenes identified in paragraph (a) of this section, which applied for an exemption for the specific test set involved, of this automatic denial either by letter or by notice in the Federal Register. Each manufacturer or processor of the chlorinated benzenes identified in paragraph (a) of this section for whom an exemption application has been automatically denied will be in violation of this section 30 days from the time that it receives the notice letter or 30 days from the time that the notice is published in the Federal Register, whichever comes first. The violation will continue until a manufacturer or processor of the chlorinated benzenes identified in paragraph (a) of this section, submits a proposed study plan for each test set involved.

(6) Any manufacturer or processor of the test substance specified in paragraph (a) of this section may submit a proposed study plan for any test set required by this section at any time, regardless of whether the manufacturer or processor submitted an application for exemption from testing that test set.

(e) *Content of study plans.* (1) All study plans are required to contain the following information:

(i) A citation to this section.

(ii) The specific test set covered by the study plan.

(iii) (A) The names and addresses of the test set sponsors.

(B) The names, addresses, and telephone numbers of the responsible administrative officials and project manager(s) in the principal sponsor's organization.

(C) The name, address, and telephone number of the appropriate individual(s) for oral and written communication with EPA.

(D)(1) The name and address of the testing facility(ies) and the names, addresses, and telephone numbers of the testing facility's administrative officials and project managers responsible for the testing.

(2) Brief summaries of the training and experience of each professional involved in the study, including study director, veterinarian(s), toxicologist(s), pathologist(s) and laboratory assistants.

(iv) Identity and data on the substances or mixtures being tested, including appropriate physical constants, spectral data, chemical analysis and stability under test and storage conditions.

(v) Study protocols, including rationales for: species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; a description of diet to be used and its source, including nutrients and contaminants and their concentrations; for *in vitro* test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic disease (including tumors), genealogy, and life span.

(vi) Schedule for initiation and completion of major phases of long-term tests; schedule for submission of interim progress and final reports to EPA.

(2) Information specified under paragraph (e)(1)(iii)(D) of this section is not required in proposed study if the information is not available at the time of submission; however, the information must be submitted before the initiation of testing.

(f) *Review and adoption of study plans.* (1) Upon receipt of a proposed study plan, EPA will review the study plan to determine whether it complies with paragraph (e) of this section.

(i) If EPA determines that the proposed study plan does not comply with paragraph (e) of this section, EPA will notify the submitter that the submission is incomplete and identify the deficiencies and the steps necessary to complete the submission. The submitter will have 15 days from the day it receives this notice to submit appropriate information to make the study plan complete. If the submitter fails to provide appropriate information to complete the study plan within this time, the submitter will have been in violation of this section as if no study plan had been submitted.

(ii) If EPA determines the proposed study plan complies with paragraph (e) of this section, EPA will publish a notice in the **Federal Register** requesting comments on the ability of the study plan to ensure that data from the test set will be reliable and adequate. EPA will provide a 45-day comment period and will provide an opportunity for an oral presentation upon request of any person. EPA may extend the comment period if it appears from the nature of the issues raised by EPA's review or from public comments that further comment is warranted.

(2) After receiving and considering public comment, EPA will adopt the study plan, including time deadlines and reporting schedules, as proposed or as modified in response to EPA review and public comments, as test standards for the testing of the chlorinated benzenes in paragraph (k) of this section.

(g) *Modification of study plans during conduct of study*—(1) *Application.* Any

test set sponsor who wishes to modify the adopted study plan for any test set or study required under this rule must submit an application in accordance with this section. Application for modification shall be made in writing to the Chief, Test Rules Development Branch, Office of Toxic Substances, or by phone, with written confirmation to follow as soon as feasible. Applications must include appropriate explanations of why the modification is necessary.

(2) *Adoption.* To the extent feasible, EPA will seek public comment on all substantive changes in study plans. EPA will issue a notice in the **Federal Register** requesting comments on requested modifications. However, EPA will act on the requested modification without seeking public comment:

(i) If EPA believes that an immediate modification to a study plan is necessary in order to preserve the accuracy or validity of an on-going study; or

(ii) if EPA determines that a modification clearly does not pose any substantive issues. EPA will notify the sponsor of the Agency's approval or disapproval. When the Agency approves a modification, it will publish a notice in the **Federal Register** indicating that the study plan has been modified.

(h) *Exemption applications.* (1) Any manufacturer or processor of the chlorinated benzenes identified in paragraph (a) may submit an application to EPA for an exemption from submitting proposed study plans for and from performing any or all of the test sets specified in paragraph (j) of this section. The application must include the name and address of the manufacturer or processor and must identify the specific requirements of this section from which the exemption is sought.

(2) No manufacturer or processor of the chlorinated benzenes identified in paragraph (a) of this section will be in violation of the requirement to perform a specific test set under paragraph (j) of this section if it has submitted a timely application for an exemption for that test set and the application has not been denied by EPA.

(3) EPA will conditionally grant any requested exemption for a specific test set required by paragraph (j) of this section if EPA has received a complete proposed study plan for that test set in accordance with paragraph (e) of this section and has adopted the study plan in accordance with paragraph (f)(2) of this section.

(4) EPA will deny any exemption for a specific test set in paragraph (j) of this section if the study sponsor fails to perform the test set or to submit data as

required in the test standards adopted under paragraph (k) of this section.

(5) If manufacturers of the chlorinated benzenes identified in paragraph (a) of this section perform all the tests required by paragraph (j) of this section, processors of the chlorinated benzenes identified in paragraph (a) of this section will automatically be granted an exemption from the study plan submission and testing requirements without the need to file an application for exemption.

(i) *Test results.* Except as set forth in paragraph (j) of this section, a positive or negative test result in any of the environmental health effects or chemical fate tests enumerated in paragraph (j) of this section is defined as specified in the TSCA Environmental Effects Test Guidelines or the TSCA Chemical Fate Guidelines published by the National Technical Information Service (NTIS).

(j) *Environmental Effects Testing.*—(1) *Aquatic macrophyte acute toxicity testing.*—(i) *Required testing.* Testing using measured concentrations, flow through or static renewal systems and systems that control for evaporation of the test substance, shall be conducted for 1,2,4-trichlorobenzene and 1,2,3-trichlorobenzene. Testing shall be conducted with *Lemna gibba* to develop data on the acute toxicity of the above chlorobenzene isomers to aquatic plants.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for *Lemna* acute toxicity testing (EG-23), available in the public record for this rulemaking, be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908).

(2) *Marine invertebrate acute toxicity testing.*—(i) *Required testing.* Testing using measured concentrations, flow through or static renewal systems, and systems that control for evaporation of the test substance, shall be conducted for 1,2,4-trichlorobenzene and 1,2,3-trichlorobenzene. Testing shall be conducted with mysid shrimp (*Mysidopsis bahia*) to develop data on the acute toxicity of the above chlorobenzene isomers to marine invertebrates.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for mysid shrimp acute toxicity testing (EG-3), available in the public record for this rulemaking, be consulted.

(3) *Marine fish acute toxicity testing*—(i) *Required testing.* Testing using measured concentrations, flow through systems, and systems that control for evaporation of the test substance shall be conducted for 1,2,3-trichlorobenzene. Testing shall be conducted with Silversides (*Menidia menidia*) to develop data on the acute toxicity of 1,2,3-trichlorobenzene to saltwater fish.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the American Society for Testing and Materials (ASTM) publication "Conducting Acute Toxicity Tests With Fishes, Macroinvertebrates, and Amphibians" be consulted (ASTM Designation E729-80). Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908) and the Ecological Research Series, "Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians" (EPA-660/3-75-009).

(4) *Freshwater fish acute toxicity testing*—(i) *Required testing.* Testing using measured concentrations, flow through systems, and systems that control for evaporation of the test substance shall be conducted for 1,2,3-trichlorobenzene. A 96-hr LC50 test shall be conducted with the fathead minnow to develop data on the acute toxicity of 1,2,3-trichlorobenzene to freshwater fish.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for fish acute toxicity testing (EG-9), available in the public record for this rulemaking, be consulted. Additional guidance may be obtained by consulting the Organization for Economic Cooperation and Development's (OECD) test guideline for fish acute toxicity testing (EG-20) available in the public record for this rulemaking.

(5) *Freshwater invertebrate acute toxicity testing*—(i) *Required testing.* Testing using measured concentrations, flow through or static renewal systems, and system that control for evaporation of the test substance shall be conducted for 1,2,3-trichlorobenzene. A 96-hr EC50 test shall be conducted for one species of *Gammarus* to develop data on the acute toxicity of 1,2,3-trichlorobenzene to aquatic freshwater invertebrates.

(ii) *Study plans.* For guidance in preparing study plans it is recommended that the American Society For Testing and Materials (ASTM) publication, "Conducting Acute Toxicity Tests With Fishes, Macroinvertebrates, and Amphibians," be consulted. Additional guidance may be obtained by consulting

the Ecological Research Series, "Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians" (EPA-660/3-75-009).

(6) *Mysid shrimp chronic toxicity testing*—(i) *Required testing.* Testing using measured concentrations, flow through or static renewal systems, and systems that control for evaporation of the test substance shall be conducted for 1,2,3-trichlorobenzene. Testing shall be conducted with mysid shrimp (*Mysidopsis bahia*) to develop data on the chronic toxicity of 1,2,4-trichlorobenzene to marine invertebrates. The above testing shall also be conducted for 1,2,3-trichlorobenzene, should the acute LC50 of this chemical for mysid shrimp be determined to be 1 ppm or less.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for mysid shrimp chronic toxicity testing (EG-4), available in the public record for this rulemaking, be consulted.

(7) *Seed germination, root elongation and early seedling growth in terrestrial macrophytes*—(i) *Required testing.*

Testing, using measured concentrations and systems that control for evaporation of the test substance, shall be conducted for monochlorobenzene, 1,2-dichlorobenzene, 1,4-dichlorobenzene, and 1,2,3-trichlorobenzene. Testing shall be conducted with terrestrial macrophytes to develop data on the acute toxicities of the above chlorobenzenes to terrestrial plants.

(ii) *Study Plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for seed germination/root elongation (EG-12) and early seedling growth (EG-13), available in the public record for this rulemaking, be consulted. Additional guidance may be obtained by consulting the proposed Organization for Economic Cooperation and Development (OECD) plant toxicity test guideline, available in the public record of this rulemaking.

(8) *Atmospheric oxidation*—(i) *Required testing.* Testing shall be conducted for monochlorobenzene; 1,2-dichlorobenzene; 1,4-dichlorobenzene, and 1,2,4-trichlorobenzene to develop data on the rate of atmospheric oxidation via the hydroxyl radical.

(ii) *Study Plans.* For guidance in preparing study plans it is recommended that the "Experimental Protocol for Determining Hydroxyl Radical Reaction Rate Constants" (EPA 600/3-82-038), available in the public record for this rulemaking, be consulted.

(9) *Soil adsorption coefficient test*—(i) *Required testing.* Testing, using systems that control for evaporation of the test substance, shall be conducted for 1,2-dichlorobenzene; 1,4-dichlorobenzene, and 1,2,4-trichlorobenzene to develop data on the adsorption of the above chlorobenzenes to sediments.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Chemical Fate Guidelines for sediment and soil adsorption isotherms (CG-1710), available in the public record for this rulemaking, be consulted.

(k) *Test Standards.* (1) All data must be developed and reported in accordance with the EPA Good Laboratory Practice Regulations in 40 CFR Part 792.

(2) [reserved].

(l) *Enforcement.* (1) If a manufacturer or processor, which notified EPA under paragraph (c) (1), (2), (3) or (4) of this section of its intent to perform testing for a test set required by paragraph (j) of this section, fails to perform the test set in accordance with the test standards in paragraph (k) of this section, that failure will be in violation of this rule.

(2) EPA will publish a notice in the Federal Register to inform all manufacturers and processors that all exemptions for performance of the test set will be denied unless, within 30 days of the publication of the notice, a manufacturer or processor of the chlorobenzenes notifies EPA by letter that it intends to perform the test set in accordance with the test standards in paragraph (k) of this section.

(3) Any person who fails or refuses to comply with any aspect of this rule is in violation of section 15 of TSCA.

(m) *Sources of study plans/guidelines.* The various study plans/guidelines given in this proposed rulemaking are available from the following source. Address and telephone number: National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703) 477-4650.

[FR Doc. 84-936 Filed 1-12-84 8:45 am]
BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA-6561]

**National Flood Insurance Program;
Proposed Flood Elevation
Determinations; Connecticut, et al.**

AGENCY: Federal Emergency
Management Agency.