(C)(*1*) A sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with commercial hexane in accordance with § 798.5275 of this chapter and as modified in paragraph (c)(6)(i)(C)(*2*) of this section unless the results of both the *Salmonella typhimurium* test conducted pursuant to paragraph (c)(6)(i)(A) of this section and the mammalian cells in the culture gene mutation test conducted pursuant to paragraph (c)(6)(i)(B) of this section, if required, are negative.

(*2*) Test standard modifications. The requirement under § 798.5275 of this chapter is modified so that the route of administration shall be inhalation.

(D)(*1*) A mouse specific locus test shall be conducted with commercial hexane by inhalation in accordance with § 798.5200 of this chapter and as modified in paragraph (c)(6)(i)(D)(*2*) of this section if the results of the sex-linked recessive lethal test conducted pursuant to paragraph (c)(6)(i)(C) of this section are positive.

(*2*) Test standard modifications. The requirement under § 798.5200 of this chapter is modified so that the duration of exposure shall be for 6 hours per day.

(ii) *Reporting requirements.* (A) The study plans for each gene mutation test must be submitted at least 45 days before the initiation of testing.

(B) Gene mutation tests shall be completed and final results submitted as follows: *Salmonella typhimurium*, 4 months; mammalian cells in culture, 12 months; *Drosophila* sex-linked recessive lethal, 24 months; and mouse specific locus, 48 months.

(C) Except for the *Salmonella typhimurium* test, progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule.

(7) *Mutagenic effects—chromosomal aberrations*—(i) *Required testing.* (A)(*1*) An *in vitro* cytogenetics test shall be conducted with commercial hexane in accordance with § 798.5375 of this chapter and as modified in paragraph (c)(7)(i)(A)(*2*) of this section.

(*2*) Test standard modifications. The requirement under § 798.5375 of this chapter is modified so that the assay shall be performed using flasks flushed with commercial hexane vapors, then closed with a cap with a rubber septum.

(B)(*1*) An *in vivo* cytogenetics test shall be conducted with commercial hexane by inhalation in accordance with § 798.5385 of this chapter and as modified in paragraph (c)(7)(i)(B)(*2*) of this section if the *in vitro* test conducted pursuant to paragraph (c)(7)(i)(A) of this section is negative.

(*2*) Test standard modifications. The requirement under § 798.5385 of this chapter is modified so that the duration of exposure shall be for 6 hours per day for 5 consecutive days.

(C)(*1*) A dominant lethal assay shall be conducted with commercial hexane by inhalation in accordance with § 798.5450 of this chapter and as modified in paragraph (c)(7)(i)(C)(*2*) of this section unless both the *in vitro*. and *in vivo* cytogenetics tests conducted pursuant to paragraphs (C)(7)(i) (A) and (B) of this section are negative.

(*2*) Test standard modifications. The requirement under § 798.5450 of this chapter is modified so that the duration of exposure shall be for 6 hours per day for 5 consecutive days.

(D) A heritable translocation test shall be conducted with commercial hexane by inhalation in accordance with § 798.5460 of this chapter if the results of the dominant lethal assay conducted pursuant to paragraph (c)(7)(i)(C) of this section are positive.

(ii) *Reporting requirements.* (A) The study plans for each chromosomal aberration test must be submitted at least 45 days before the initiation of testing.

(B) Chromosomal aberration tests shall be completed and final results submitted as follows: *in vitro* cytogenetics, 4 months; *in vivo* cytogenetics, 12 months; dominant lethal assay, 24 months; and heritable translocation assay, 48 months.

(C) Except for the *in vitro* cytogenetics test, progress reports shall be submitted beginning 6 months after the effective date of the final rule.

(8) *Neurotoxicity*—(i) *Required testing.* Neurotoxicity tests shall be conducted with commercial hexane in accordance with §§ 798.6050, 798.6200, 798.6400, and 798.6500 of this chapter.

(ii) *Reporting requirements.* (A) The study plan for the neurotoxicity tests must be submitted at least 45 days before the initiation of testing.

(B) The neurotoxicity tests shall be completed and the final results submitted to the Agency within 12 months of the effective date of the final rule.

(C) Progress reports shall be submitted 6 months from the effective date of the final rule.

(9) *Inhalation and dermal pharmacokinetics*—(i) *Required testing.* (A) An inhalation and dermal pharmacokinetics test shall be conducted with commercial hexane in accordance with § 795.232 of this chapter.

(B) Test standard modifications. The requirement under § 795.232 (c)(2)(i) of this chapter is modified to read as follows:

(2) *Administration of test substance*—(i) *(test substance.* Since the test substance is a mixture of *n*-hexane; MCP; 3-MP; 2-MP; benzene; cycolohexane; 2,2- and 2,4-DMp; 2,3-DMB; and sulfur, the experiments shall be conducted in groups using ^{14}C and ^{3}H labeled components. This type of labeling can be conducted in groups of 2 components. For example, in the first groups, *n*-hexane may be labeled with ^{14}Cv and MCP with tritium with the remaining components unlabeled. The kinetic and metabolic studies would then be run on the test substance and analyzed for *n*-hexane and MCP as described below. In the second group, 3-MP may be labeled with tritium and 2-MP labeled with ^{14}C. The third group would have benzene labeled with ^{14}C and cyclohexane labeled with tritium, etc. If it is feasible from an analytical standpoint, one of the higher liquid volume percent components (*n*-hexane, MCP, or 3-MP) could be labeled with deuterium and a gas chromatograph/mass spectrometer (GC/MS) used to follow the disposition of the deuterium-labeled component of the test substance. This procedure would permit the investigators to use fewer experimental groups to obtain the same amount of information.

(ii) *Reporting requirements.* (A) The study plan for the inhalation and dermal pharmacokinetics test must be submitted at least 45 days before the initiation of testing.

(B) The inhalation and dermal pharmacokinetics test shall be completed and the final results submitted to the Agency within 12 months of the effective date of the final rule.

(C) Progress reports shall be submitted 6 months from the effective date of the final rule.

(Information collection requirements have been approved by the Office of Management and Budget under control number 2070-0033)

[FR Doc. 86-10711 Filed 5-14-86; 8:45 am]
BILLING CODE 6560-50-M

---

40 CFR Parts 795 and 799

[OPTS-42083; FRL-2998-5]

Tetrabromobisphenol A; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing that manufacturers and processors of tetrabromobisphenol A (TBBPA, CAS No. 79-94-7) be required, under section

4 of the Toxic Substances Control Act (TSCA), to perform testing for chemical fate and environmental effects. The proposed testing includes biodegradation studies and a number of environmental effects studies including a study to determine the effects of TBBPA on microorganisms in activated sludge, acute toxicity studies in freshwater algae, fish, and invertebrates, chronic toxicity studies in fish and invertebrates, and bioconcentration potential studies in fish and invertebrates. This proposed rule is in response to the Interagency Testing Committee's (ITC's) designation of TBBPA for priority consideration for chemical fate and environmental effects testing.

DATES: Submit written comments on or before July 14, 1986. If persons request an opportunity to submit oral comment by June 30, 1986, EPA will hold a public meeting on this rule in Washington, DC. For further information on arranging to speak at the meeting see Unit VII of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42083), 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, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460, Toll free: (800-424-9065); In Washington, DC: (554-1404), Outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the ITC's designation of TBBPA for chemical fate and environmental effects testing consideration.

I. Introduction

A. ITC Recommendation

TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established the ITC under section 4(e) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated TBBPA (CAS No. 79-94-7) for priority consideration in its 16th Report submitted to EPA on May 2, 1985. The report was published in the Federal Register of May 21, 1985 (50 FR 20830). The ITC recommended that TBBPA be considered for chemical fate testing, including water solubility, soil adsorption coefficient, and persistence; and environmental effects testing, including acute and chronic toxicity to fish, aquatic invertebrates and algae, and bioconcentration potential in fish.

ITC's rationale for chemical fate testing was the lack of definitive data to characterize the effects of concern for TBBPA in the environment.

The ITC's rationale for ecological effects testing was: (1) TBBPA is highly toxic to fish under acute conditions; (2) there is a lack of acute data for invertebrates and algae; (3) TBBPA is expected to be chronically toxic to fish and aquatic invertebrates at very low concentrations (i.e., <0.10 mg/L), and (4) there is the potential for TBBPA to bioconcentrate based on its high log P value of 4.5.

No health effects tests were recommended by the ITC. According to the ITC, TBBPA has been found to have a low level of toxicity to animals by the oral and inhalation routes, microbial genotoxicity tests with TBBPA have been negative, and the potential for human exposure is low.

B. Test Rule Development Under TSCA

Under section 4(a) of TSCA, EPA shall by rule require testing of a chemical substance or mixture to develop appropriate test 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; both exposure and toxicity information are considered in determining whether available data support a finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure and release information to determine whether there is or may be substantial production and significant or substantial human exposure or substantial release to the environment. For the findings under section 4(a)(1) (A)(ii) and (B)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the finding under section 4(a)(1) (A)(iii) or (B)(iii) that testing is necessary, EPA considers whether 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 apply 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 48524) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) findings are discussed at 45 FR 48524 and 46 FR

30300 and the section 4(a)(1)(B) findings are discussed at 46 FR 30300.

In evaluating the ITC's testing recommendations for TBBPA, EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing consideration and any public comments on the ITC's recommendations; production volume, use, exposure, and release information reported by manufacturers of TBBPA under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); health and safety studies submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716) concerning TBBPA; and published and unpublished data available to the Agency. From its evaluation, as described in this proposed rule, EPA is proposing chemical fate and environmental effects testing requirements for TBBPA under section 4(a)(1)(A). By this action, EPA is responding to the ITC's designation of TBBPA for priority testing consideration.

II. Review of Available Data

A. Profile

TBBPA is a white, free-flowing or crystalline powder that is soluble in many organic solvents but has a low solubility in water (Refs. 1 and 2). The experimentally determined water solubility values for TBBPA at 15 °C, 25 °C, and 35 °C are 0.72 ppm, 4.16 ppm, and 1.77 ppm respectively (Ref. 3). At 25 °C, TBBPA has an estimated vapor pressure of 4.15×10^{-5} mm Hg and an estimated Henry's Law constant of 4.46×10^{-5} atm-m^3/mole (Ref. 4). Its experimentally determined log octanol-water partition coefficient (K_{ow}) value is 4.5 (Ref. 5). The estimated log soil adsorption coefficient (K_{oc}) value is 4.29 (Ref. 4).

B. Production

TBBPA is manufactured by reacting gaseous bromine with bisphenol A in a low molecular weight solvent; it is then crystallized by adding water. The solvent can be an alcohol, aqueous acetic acid, a non-polar solvent, or a two-phase water-organic system (Ref. 6). Ethyl Corporation uses a continuous batch operation which involves a closed vessel procedure during the reaction and drying cycles (Ref. 2).

TBBPA is produced domestically by two corporations, Ethyl Corporation and Great Lakes Chemical Corporation, with a combined production capacity of 85 million pounds per year (Ref. 7). The actual production volumes for 1984 have been submitted by the two companies under section 8(a) of TSCA as confidential business information (CBI). Importation of the compound from 1979 to 1983 ranged from approximately 1.3 to 2.6 million pounds per year (Ref. 8). At the present time, Ameribrom appears to be the only importer of TBBPA (Ref. 9).

C. Uses

TBBPA is used primarily as a reactive flame retardant and to a lesser extent as an additive flame retardant. In general, when used as a reactive flame retardant, TBBPA reacts chemically with other compounds to form a polymer, leaving little opportunity for the TBBPA to be released once it has been incorporated into the polymer. TBBPA is used as a reactive flame retardant in the manufacture of epoxy resins, polycarbonates, and unsaturated polyesters (Refs. 1 and 2). A principal use of TBBPA epoxy resins, where the TBBPA content may be 34 percent, is in printed circuit boards (Ref. 10). Polycarbonates are used in communication and electronics equipment, lighting fixtures and signs (Ref. 11). Unsaturated polyesters are used for making simulated marble, floor tiles, bowling balls, furniture parts, sewer pipe coupling compound, automotive patching compounds, buttons, and for encapsulating electrical devices (Ref. 12).

TBBPA is coated on or mixed with other compounds when used as an additive flame retardant. Approximately six to eight million pounds of TBBPA is believed to be used annually as an additive flame retardant (Ref. 7). Because TBBPA does not chemically react with the other compounds when used in this manner, it may leach out of the finished products when they are in use and/or following disposal of these products. No information is available on whether TBBPA leaches out of products or the extent of leaching. Ethyl Corporation, in response to Agency questions concerned with leaching of TBBPA, submitted the statements that no leaching of TBBPA is expected for products containing TBBPA and that there is no consumer exposure from using products containing TBBPA (Ref. 13). TBBPA is used as an additive in ABS (acrylonitrile-butadiene-styrene) thermoplastics, in polystyrene, and in phenolic resins (Ref. 2). Recommended starting levels of TBBPA in ABS (medium to high impact) are 17.6 to 22 percent and 14 percent in high impact polystyrene (Ref. 14). ABS resins are used in automotive parts, pipe and fittings, refrigerators, other appliances, business machines, and telephones (Ref. 15). Polystyrene is used in packaging, consumer products, disposables, electrical and electronics equipment, furniture, and building and construction materials (Ref. 16). TBBPA is also reportedly used as a flame retardant in paper and textile applications, and as a plasticizer (Refs. 17 and 18).

D. Release and Exposure

TBBPA is expected to enter the environment mainly as a result of wastewater released from processes where TBBPA is made and used. A limited amount of TBBPA is likely to enter the environment as a result of its release into the atmosphere from activity in the packaging area of plants and from the use of TBBPA as an additive flame retardant. Release levels have been submitted by the manufacturers of TBBPA under section 8(a) of TSCA as confidential business information (CBI).

According to one process described for manufacturing TBBPA, bisphenol A is brominated in an anhydrous methanol solvent and then crystallized by adding water. The crystals are filtered, washed, and dried. Wastewater generated from the crystallization and washing steps may be treated to recover the excess bromide and solvent. The methanol solvent may be recovered by neutralizing the waste stream and then distilling. The still bottoms contain polyhalongenated phenolics such as TBBPA. An oxidizing agent can be used to initiate a polymerization reaction among polyhalogenated phenolic compounds present in the waste liquid. The polymerized product settles rapidly in the waste liquid and may be disposed of in a sanitary landfill. However, the efficiency of this process to polymerize the polyhalogenated phenolics and the precent of the total wastewater being treated in this manner has not been reported (Ref. 6).

Evidence of TBBPA exposure to the environment has been found in sediment, soil, and air samples collected in the vicinity of a company manufacturing the compound. The concentrations reported at these sites were from 0.03 to 330 ppm in the sediments, 2 to 150 ppm in the soil, and 28 to 1800 ng/m^3 in the air (Ref. 19). Although levels of TBBPA as high as 150 ppm in the soil have been reported, on the basis of sampling locations information provided in the monitoring study, it is very likely that the presence of TBBPA in the soil is limited to the area surrounding the production facility and may result from releases during packaging and loading operations. Therefore, it does not appear to the Agency at this time that terrestrial exposure to TBBPA presents a concern.

E. Chemical Fate

Based on its high log K_{oc} and log K_{ow} values and low water solubility, TBBPA is expected to partition to compartments with high concentrations of organic matter or lipids. In water, TBBPA will partition to sediments or biological tissues; on land, it will partition to soils. Volatilization of TBBPA is expected to be fairly slow and partitioning from soil and water to air is not expected to be important because of the low estimated values for the vapor pressure and the Henry's law constant (Refs. 4, 9 and 20).

The Environmental Partitioning Model (ENPART) and the Exposure Analysis Model (EXAMS 2) were used to estimate the relative partitioning of TBBPA between air, water, soil and sediment. The ENPART results show that the highest concentration of TBBPA will be in soil but the largest mass will be in water (this is due to the much greater volume of water in comparison to the volume of soil). Ambient monitoring data for TBBPA in the sediment are available. For a sediment concentration of 24 ppm, TBBPA concentrations in the water column are estimated to be 125 ppb by the EXAMS 2 model. Partitioning of TBBPA to the atmosphere will be insignificant. The estimated atmospheric half-life for TBBPA, using the Fate of Atmospheric Pollutants (FAP) model, is 1.79 days (Refs. 4 and 9).

The persistence of TBBPA trapped in soils, sediments and sludges is not well defined. One study from Japan classified TBBPA as not very biodegradable; however, no experimental details were available (Ref. 21). The ENPART estimate for 50 percent mass reduction of TBBPA present in the environment at steady state, after loading ceases, is 3 months (Ref. 4).

F. Environmental Effects

1. *Acute toxicity*—a. *Fish and aquatic invertebrates.* Static studies (96-hr) are available for bluegill sunfish (*Lepomis macrochirus*) and rainbow trout (*Salmo gairdneri*) using nominal concentrations of TBBPA (Ref. 22). The 96-hour LC_{50} values for bluegill sunfish and rainbow trout are reported to be 0.51 mg/L and 0.40 mg/L respectively. These values indicate a high order of acute toxicity towards freshwater fish. The no-effect levels (based on the lack of abnormal behavioral observations) were reported as 0.18 mg/L for bluegill and 0.10 mg/L for trout.

Static acute toxicity of TBBPA to *Daphnia magna* has been investigated using a range of nominal test concentrations (Ref. 23). The 48-hour LC_{50} value for *Daphnia* is reported to be 0.96 mg/L. The no effect level (based on zero deaths) was observed to be <0.32 mg/L.

The static test conditions used for the above studies are satisfactory because TBBPA has an extremely low volatility and the biological loading in the test vessels is well below a maximum loading of 1.0 g/L recommended in EPA's TSCA test guidelines. Although the use of nominal concentrations may have actually underestimated the acute toxicity of TBBPA, the Agency believes that these data are adequate to reasonably predict the high acute toxicity of TBBPA towards the two freshwater fish (bluegill sunfish and rainbow trout) and *Daphnia*. However, when a high order of acute toxicity is demonstrated from initial static acute tests, as is the case of existing data on TBBPA, the Agency believes that further acute testing also appears to be indicated in alternate species for making a final assessment of the acute safety hazard.

b. *Marine algae.* Preliminary data for effects of TBBPA on growth of three species of marine unicellular algae in several different media were received from an EPA lab (Ref. 24). The 72-hour EC_{50} values of two species, *Skeletonema costatum* and *Thalassiosira pseudonana*, were, in most instances, well below 1 mg/L. The EC_{50} values of less than 1 mg/L indicate that TBBPA is highly toxic to these species. No EC_{50} values could be calculated for TBBPA when tested with *Chlorella*. The highest concentration, 1.5 mg/L, did not inhibit growth of *Chorella* by 50 percent in any medium.

2. *Chronic toxicity.* No information was found on the chronic toxicity of TBBPA to aquatic organisms. However, the available data on the compound's acute toxicity to aquatic organisms indicate that TBBPA is highly toxic under acute conditions. In the acute study with rainbow trout, fish mortality increased throughout the duration of the study suggesting that, if the study had continued, mortalities may have occurred at even lower concentrations. On the basis of this information and the reported high log k_{ow} value, TBBPA is expected to be chronically toxic to fish at very low concentrations.

3. *Bioconcentration.* No useful experimental data were located on the bioconcentration of TBBPA in aquatic organisms. Using the equation (log BCF=0.85 log P-0.70) developed by Veith (Ref. 25), the bioconcentration factor (BCF) for TBBPA in fish was estimated to be approximately 1,300. This estimate indicates that TBBPA may bioconcentrate to a significant degree.

III. Findings

EPA is basing its proposed chemical fate and environmental effects testing for TBBPA on the authority of section 4(a)(1)(A) of TSCA.

EPA finds that the release of TBBPA which likely results from its manufacture, processing, use and disposal may present an unreasonable risk of exposure and injury to the organisms in the environment, on the basis of information presented in Unit II above showing that TBBPA has the potential to be persistent, it may bioconcentrate, and it is highly toxic under acute conditions to aquatic organisms. Studies performed to determine acute toxicity of TBBPA to fish, *Daphnia*, and marine unicellular algae show that it is highly toxic (i.e., LC_{50} less than 1 mg/L or ppm). The reported high log k_{ow} of 4.5 and the high acute toxicity data reported for fish and *Daphnia* suggest that TBBPA can be expected to be chronically toxic to fish and aquatic invertebrates at very low concentrations. TBBPA concentrations up to 330 ppm in sediment samples have been detected in the vicinity of a company manufacturing the compound.

In addition, modeling indicates that TBBPA may be present in the water column in ppb levels, which could be of concern. The primary release of TBBPA to the environment is expected to be via wastewater generated from processes where TBBPA is made and used. In the aquatic environment, TBBPA partitions mainly to sediments. The Agency is particularly concerned with the effects of TBBPA on benthic organisms, i.e., organisms which remain in intimate contact with the sediments.

There is also the potential for TBBPA to bioconcentrate in aquatic organisms based on its estimated bioconcentration factor of 1,300.

The structure of TBBPA suggests by analogy to other polyhalogenated compounds that TBBPA might be persistent. As noted in Unit II.E., one study from Japan, with no experimental details provided, classified TBBPA as not very biodegradable.

Based on EPA's evaluation, the experimental data available for water solubility, log K_{ow}, and acute toxicity to marine unicellular algae appear to be adequate to reasonably determine or predict these characteristics for TBBPA. The log K_{oc} can be estimated reasonably well if the experimental value for the log K_{ow} is available. The Agency has further determined that data are inadequate to fully characterize the degradability of TBBPA present in soils, sediments, sludges, and water; toxicity

of TBBPA to microorganisms in activated sludge; toxicity of TBBPA to freshwater algae under acute conditions; chronic toxicity of TBBPA to fish and invertebrates and bioconcentration potential of TBBPA in fish and invertebrates. In addition, because acute toxicity values below 1 mg/L (ppm) have been found for the two fish (bluegill Sunfish and rainbow trout) and *Daphnia*, additional acute tests with alternate species of fish and invertebrates are required for making a final assessment of the acute hazard. Testing is necessary to develop these data.

IV. Proposed Rule

A. Proposed Testing and Test Standards

On the basis of the findings given in Unit III, EPA is proposing chemical fate and environmental effects testing for TBBPA. The tests are to be conducted in accordance with EPA's TSCA Good Laboratory Practice standards in 40 CFR Part 792 and specific TSCA test guidelines as enumerated in 40 CFR Parts 796 and 797, published in the **Federal Register** of September 27, 1985 (50 FR 39252), or other published test methods as specified in this test rule for TBBPA. Proposed revisions to the TSCA test guidelines were published in the **Federal Register** of January 14, 1986 (51 FR 1522); the Agency is proposing that these revisions be adopted in the test standards for TBBPA.

The chemical fate tests to be conducted for TBBPA are: (1) Biodegradability in water, using the eco-core method described by Bourquin *et al.* (Ref. 26); (2) the aerobic and anaerobic biodegradability in soil, using the guideline at 40 CFR 796.3400; and (3) the biodegradability in sludge systems, using the guideline at 40 CFR 796.3341.

Environmental effects tests to be conducted for TBBPA are: (1) The effect of test substance on activated sludge, using the guideline entitled "Activated Sludge, Respiration Inhibition Test" proposed at 40 CFR 795.170, and published with this rule. (2) The acute toxicity to freshwater alga, *Selenastrum capricornutum*, using the test guideline at 40 CFR 797.1050, and as modified under § 799.4000(d)(2)(i)(B). (3) The acute toxicity to the amphipod *Gammarus*, using the guideline at 40 CFR 797.1310. (4) The acute toxicity to *Pimephales promelas* (fathead minnow) in a flow-through system, using the guideline at 40 CFR 797.1400.

EPA is also proposing that: (5) The invertebrate *Daphnia* shall be tested in a flow-through system to determine the chronic toxicity of TBBPA using the guideline at 40 CFR 797.1330. (6) The testing for early life stage toxicity to fish be conducted in a flow-through system using the guideline at 40 CFR Part 795. The test species shall be fathead minnow (*Pimephales promelas*) if the 96-hour LC_{50} for fathead minnow is equal to or less than 0.40 mg/L; the test species shall be rainbow trout if the 96-hour LC_{50} for fathead minnow is greater than 0.40 mg/L.

EPA further proposes that: (7) A bioconcentration test in the fathead minnow (*Pimephales promelas*) be conducted using the guideline at 40 CFR 797.1520, and (8) a bioconcentration test in the oyster (*Crassostrea virginica*) be conducted using the guideline at 40 CFR 797.1830.

The Agency is proposing that the above referenced chemical fate and environmental effects test guidelines and modifications and other cited methods be considered the test standards for the purposes of the proposed testing for TBBPA. The TSCA test guidelines for chemical fate and aquatic toxicity testing specify generally accepted minimal conditions for determining chemical fate and aquatic animal toxicities for substances like TBBPA to which aquatic life is expected to be exposed.

The proposed eco-core method of Bourquin *et al.* (1977) for testing the biodegradability of TBBPA in water specifies generally accepted minimal conditions. The Agency believes that this test reflects the current state-of-the-art methodology for testing the fate of chemicals such as TBBPA in aquatic systems.

B. Test Substance

EPA is proposing that TBBPA of at least 99 percent purity be used as the test substance; EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to TBBPA itself. In a separate rulemaking, EPA is proposing to require testing and submission of data on the presence of dioxins and furans in TBBPA (50 FR 51794; December 19, 1985). If contamination of TBBPA with these substances is confirmed, the purity of the test substance for this test rule may need to be further defined to limit levels of contamination.

C. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which the EPA 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 findings are based on distribution, use, or disposal.

Because EPA has found that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, processing, use and disposal of TBBPA on the environment, EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, TBBPA at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements contained in this proposed rule. The end of the reimbursement period will be 5 years after the last final report is submitted or an amount of time after the submission of the last final report required under the test rule equal to that which was required to develop data, if more than 5 years.

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 the 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 the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of

intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for TBBPA. As noted in Unit IV.B, EPA is interested in evaluating the effects attributable to TBBPA itself and has specified a highly pure substance for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

D. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with its TCSA Good Laboratory Practice (GLP) standards which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 45 days prior to the initiation of each study.

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. The Agency is proposing specific reporting requirements for each of the proposed test standards as follows:

1. The biodegradation tests, the test for toxicity to microorganisms in activated sludge, the acute toxicity tests in fresh water algae, fish, and invertebrates, and the bioconcentration tests in fish and invertebrates shall be completed, and the final reports submitted to EPA within 1 year of the effective date of the final test rule. Quarterly progress reports shall be required.

2. The early life stage toxicity test in aquatic vertebrates and a chronic toxicity test in invertebrates shall be completed, and the final reports submitted to EPA within 2 years of the effective date of the final test rule. Quarterly progress reports shall be required.

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).

Persons who export a chemical substance or mixture which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707. In brief, as of the effective date of the final test rule, an exporter of TBBPA must report to EPA the first annual export or intended export of TBBPA to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

E. 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 or 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 inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for purpose of determining compliance with any final rule for TBBPA. 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, and to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of the 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 to include 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 which may be calculated as if they never submitted their data. Under the penalty provisions 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 that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions.

This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.28(b)). 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 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 the other factors listed in section 16. Other remedies are available to EPA under section 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. Section 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. Issues for Comment

This proposed rule specifies TSCA test guidelines and independent, published test methods as the test standards for chemical fate and environmental effects. The Agency is soliciting comments as to whether the chemical fate and environmental effects test guidelines and the independent methods are appropriate and applicable for the testing of TBBPA. Also regarding the testing of TBBPA, the Agency requests comments on:

1. The availability of appropriate test methods and facilities for testing the toxicity of this chemical to benthic organisms (i.e. organisms which remain

in intimate contact with the sediment). Because TBBPA is expected to partition strongly to sediment, the Agency believes that determining the toxicity of TBBPA to benthic organisms is important in characterizing the environmental effects of aquatic releases of TBBPA. The Agency believes that sediment bioassay methods using freshwater invertebrates, such as those published by Nebeker *et al.* (Ref. 27) and Adams *et al.* (Ref. 28) or, as an alternative, relevant microcosm test protocols (Refs. 29 and 30) may be useful for characterizing the effects of TBBPA on benthic organisms. The Agency is requesting comments on the effectiveness and availability of these or other methods and which, if any, would be most appropriate for testing of TBBPA. If the comments indicate the appropriate test methods and facilities are available, the Agency is proposing that it will include tests to determine the toxicity of TBBPA to benthic organisms in the final rule for TBBPA.

2. The adequacy of the proposed testing to characterize the environmental fate and environmental effects of TBBPA.

3. The reporting times for the identified chemical fate and environmental effects tests.

4. The purity of the test substance to be used in light of the possible presence of the dioxin/furan contamination.

5. Whether there are any other testing approaches which should be considered.

VI. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for the test rules go through a Level I analysis. This consists of evaluating each chemical or 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 the chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for 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 TBBPA are estimated to range from $59,520 to $144,580. This estimate includes the costs for both the required minimum series of tests as well as any conditional ones. The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from $15,400 to $37,500. Based on an estimated production volume range of 59.8 million pounds to 83.7 million pounds the unit test costs range from 0.026 to 0.063 cents per pound. In relation to the current list price of $1.15 per pound (99 percent purity) of TBBPA, these costs are equivalent to 0.02 to 0.05 percent of price.

Based on these costs and market characteristics of TBBPA, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is low. This conclusion is based on the following observations: (1) The annual unit cost of the testing required in this rule is very low; and (2) the market expectations for TBBPA are optimistic.

Refer to the economic analysis which is contained in the public record for this rulemaking for a complete discussion of test cost estimation and potential for economic impact resulting from these costs.

VII. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting subsequent to the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free: (800-424-9065); In Washington, DC: (554-1404); Outside the U.S.A. (Operator—202-554-1404), by June 30, 1986. A meeting will not be held if members of the public do not indicate they they wish to make oral presentation. 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 verify whether a 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.

VIII. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonbly 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. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the NTIS (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 in this proposed rule.

IX. Public Record

EPA has established a record for this rulemaking, (docket number OPTS-42083). This record contains the basic information considered by the Agency in developing this proposal and appropriate Federal Register notices.

This record includes the following information:

A. Supporting Documentation

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

(a) Notice containing the ITC designation of TBBPA to the Priority List (50 FR 20930; May 21, 1985).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on TBBPA (50 FR 20910; May 21, 1985).

(c) TSCA test guidelines cited as test standards for this rule.

(d) Notice containing revision of TSCA test guidelines cited as test standards for this rule.

(2) Communications before proposal consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(3) Reports—published and unpublished factual materials.

B. References

(1) Great Lakes Chemical Corp. West Lafayette, IN 47906. Product information and material safety data sheet for TBBPA submitted by D.L. McFadden to Dynamac Corp. (August 10, 1983).

(2) Ethyl Corp. Baton Rouge, LA 70820. Letter and enclosures from R.L. Smith to M. Grief, TSCA Interagency Testing Committee, Washington, DC 20460. (February 29, 1984).

(3) Great Lakes Chemical Corp. West Lafayette, IN 47906. "Water solubility of several flame retardants and industrial chemicals." Letter with attached studies from D.L. McFadden to Narendra Chaudhari, Environmental Protection Agency. (August 1, 1985).

(4) U.S. Environmental Protection Agency, Computer Printout: "Chemical property and

environmental behavior estimates." Washington, DC, Office of Toxic Substances, USEPA. (1985).

(5) Great Lakes Chemical Corp. West Lafayette, IN 47906. "Partition coefficient of several flame retardants and industrial chemicals." Letter with attached studies from D.L. McFadden to Narendra Chaudhari, Environmental Protection Agency. (August 1, 1985).

(6) Bossier, J.A., and J.J. Vega "Method for removing brominated phenolic waste." United States Patent 4431847 A. (February 14, 1984).

(7) Stanford Research Institute International. Menlo Park, CA. "Tetrabromobisphenol A". In: *Chemical Economics Handbook*. (1985).

(8) USITC. U.S. International Trade Commission. "Imports of benzenoid chemical and products, 1979–1983". USITC Publications 1083, 1163, 1277, 1401, and 1548. (1980–1984).

(9) Syracuse Research Corp. Merrill Lane, Syracuse, NY 13210. Draft Final Technical Support Document: "Tetrabromobisphenol A". Prepared for Test Rules Development Branch, Office of Toxic Substances, Environmental Protection Agency, Washington, DC 20460. Contract No. 68–02–4209. (1985).

(10) Kirk-Othmer. *Kirk-Othmer Encyclopedia of Chemical Techology*. 3rd ed. Vol. 9. John Wiley and Sons, Inc. New York, p. 276. (1980).

(11) "Chemical profile: Polycarbonate resins". *Chemical Marketing Reporter*. (May 14, 1984).

(12) Kirk-Othmer. *Kirk-Othmer Encyclopedia of Chemical Technology*, 3rd ed. Vol. 18. John Wiley and Sons, Inc. New York. pp. 588–589. (1982).

(13) Ethyl Corp. Baton Rouge, LA 70820. Letter with attached responses to Agency questions from R.L. Smith to Narendra Chaudhari, Environmental Protection Agency. (September 18, 1985).

(14) Great Lakes Chemical Corp., West Lafayette, IN 47906. Letter with attached information on BA–59 from Rebecca Ball to Susan Beals, Syracuse Research Corp. (June 25, 1985).

(15) "Chemical profile: ABS resins." *Chemical Marketing Reporter* (July 1, 1985).

(16) "Chemical profile: Polystyrene." *Chemical Marketing Reporter* (June 17, 1985).

(17) Hawley, G.G. *The Condensed Chemical Dictionary*, 10th ed. Van Nostrand Reinhold Co., New York (1981).

(18) Tsuchida, A., and M. Fujii. Hokuetsu Paper Mfg. Co., Ltd. Japan. (1975).

(19) U.S. Environmental Protection Agency. Environmental Monitoring Near Industrial sites: Brominated Chemicals (Part I). Washington, DC, Office of Toxic Substances, USEPA. Contract 68–01–1978. EPA–560/6–78–002. (1978).

(20) CRCS, Inc. in collaboration with Dynamac Corp. Reston, VA 22090. Information Review: Tetrabromobisphenol A. Prepared for TSCA Interagency Testing Committee. Contract No. 68–01–5789. (February 15, 1984).

(21) Sasaki, S. "The scientific aspects of the chemical substance control law in Japan" *In: Aquatic Pollutants: Transformation and Biological Effects*. Hutzinger, O., L.H. Von Letyoeld, and B.C.J. Zoeteman, eds. Pergamon Press. Oxford. pp. 283–298. (1978).

(22) Great Lakes Chemical Corp., West Lafayette, IN 47906. Acute toxicity of TBBPA to bluegill sunfish (Project #11506–03–50) and rainbow trout (Project #11506–03–51). Letter with attached studies from D.L. McFadden to Narendra Chaudhari, Environmental Protection Agency. (August 1, 1985).

(23) Great lakes Chemical Corp., West Lafayette, IN 47906. Acute toxicity of TBBPA to *Daphnia magna* (Project #11506–03–52). Letter with attached studies from D.L. McFadden to Narendra Chaudhari, Environmental Protection Agency. (August 1, 1985).

(24) U.S. Environmental Protection Agency. Environmental Research Laboratory, Gulf Breeze, Florida 32561, Preliminary report on effects of TBBPA on marine unicellular algae. Memorandum from G.E. Walsh to Steve Ells, Washington, DC, Office of Toxic Substances, USEPA. (August 9, 1985).

(25) Veith, G.D., Defore, D.L., and Bergstedt, B.J. "Measuring and estimating the bioconcentration factor of chemicals in fish." *Journal of Fish Research Board Canada* 36: 1040–1048. (1979).

(26) Bourquin, A.W., Hood, M.A. Garnas, R.L., "An artifical microbial exosystem for determining effects and fate of toxicants in a salt-marsh environment." *Developments in Industrial Microbiology* 18: 185–191. (1977).

(27) Nebeker, A.V. *et al.* "Biologoical methods for determining toxicity of contaminated freshwater sediments to invertebrates." *Environmental Toxicology and Chemistry*. 3:617–630. (1984).

(28) Adams, W.J. Kimerle, R.A., and Mosher, R.G., "Aquatic safety assessment of chemicals sorbed to sediments," *Aquatic Toxicology and Hazard Assessment: Seventh Symposium*, ASTM STP 854. R.D. Cardwell. R. Purdy, and R.C. Bahner, Eds., American Society for Testing and Materials, Philadelphia. pp. 329–453. (1985).

(29) Hendrix, P.R. *et al.* "Microcosm as test systems for the ecological effects of toxic substances: an appraisal with cadmium." Prepared for Environmental Research Laboratory, USEPA, Athens, Georgia 30613. NTIS, Springfield, Virginia 22161. PB81–209595. (1981).

(30) U.S. Environmental Protection Agency. Environmental Research Laboratory, Narragansett, Rhode Island 02882. "Experimental marine microcosm test protocol and support document." Prepared for Office of Toxic Substances, USEPA, Washington, DC 20460. EPA–600/3–83–055. (1983).

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 Rm. E–107, 401 M St., SW., Washington, D.C., from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Agency will supplement this record periodically with additional relevant information received.

X. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it will not have any annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprise to compete with foreign enterprises.

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

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) There are no known small manufacturers, (2) any small processors are not expected to perform testing themselves or to participate in the organization of the testing effort, (3) they will experience only very minor cost in securing exemption from testing requirements, and (4) they are unlikely to be affected by reimbursement requirements.

C. 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. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs; OMB; 726 Jackson Place, NW., Washington, DC 20503 marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Parts 795 and 799

Testing, Environmental protection, Hazardous substances, Chemicals,

Environmental effects, Recordkeeping and reporting requirements.

Dated: May 2, 1986.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

PART 795—[AMENDED]

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

1. In proposed Part 795:

a. The authority citation of Part 795 continues to read as follows:

Authority: 15 U.S.C. 2603.

b. By adding § 795.170 to read as follows:

§ 795.170 Activated sludge, respiration inhibition test modified test for chemical substances that have low water solubility.

(a) *Introductory information.*—(1) *Prerequisites.*

(i) Water solubility.

(ii) Vapor pressure.

(2) *Guidance information.* (i) Information on the structural formula of the test substance will be useful.

(ii) Purity of the test substance shall be specified in the test rule in 40 CFR Part 799.

(3) *Recommendation.* Activated sludge may contain potentially pathogenic organisms and should be handled with care.

(4) *Standard documents.* This test guideline has been based on the references in (d) (1) thru (6) of this section.

(b) *Method*—(1) *Introduction, purpose, scope, relevance, application and limits of test.* (i) *Introduction.* (A) The method described in this test guideline assesses the effect of a test substance on microorganisms by measuring the respiration rate under defined conditions in the presence of different concentrations of the test substance. The method is based on that described by the Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry, in which activated sludge obtained from a sewage treatment plant is used as the microbial source.

(B) The purpose of this test guideline is to provide a rapid screening method whereby substances which may adversely affect aerobic microbial treatment plants can be identified and to indicate suitable non-inhibitory concentrations of test substances to be used in biodegradability tests.

(C) A range-finding test may precede a definitive test. It provides information about the range of concentrations to be used in the main test.

(D) Two controls without test substance are included in the test design, one at the start and the other at the end of the test series. Each batch of activated sludge should also be checked using a reference substance.

(ii) *Definitions*—(A) *Respiration rate.* The oxygen consumption of aerobic sludge or wastewater microorganisms, generally expressed as mg O_2 per liter per hour.

(B) *Effective concentration* (EC_{50}). In this test guideline, the concentration of the test substance at which the respiration rate is 50 percent of that shown by the control under conditions in this guideline.

(iii) *Reference substances.* 3,5-dichlorophenol (a known inhibitor of respiration) shall be used as a reference substance and tested for EC_{50} on each batch of activated sludge as a means of checking that the sensitivity of the sludge is not abnormal.

(iv) *Principal of the test method.* The respiration rate of an activated sludge fed with a standard amount of synthetic sewage feed is measured after a contact time of 30 minutes or 3 hours, or both. The respiration rate of the same activated sludge in the presence of various concentrations of the test substance under otherwise identical conditions is also measured. The inhibitory effect of the test substance at a particular concentration is expressed as a percentage of the mean respiration rates of two controls. An EC_{50} value is calculated from determinations at different concentrations.

(v) *Conditions for the validity of the test.* (A) The test results are valid if the two control respiration rates are within 15 percent of each other.

(B) The EC_{50} (3 hours) of 3,5-dichlorophenol must be in the accepted range 5 to 30 mg/L.

(2) *Description of the test procedure*—(i) *Preparations*—(A) *Equipment.* Normal laboratory equipment and especially the following is necessary:

(1) Measuring apparatus (flat bottom flask, stirrer bar, magnetic stirrer, oxygen electrode, and recorder).

(2) Aeration device.

(3) pH-Electrode and measuring equipment.

(4) O_2-Electrode.

(B) *Solutions of the test substance.* (1) Solutions of the test substance are freshly prepared at the start of the study using a stock solution. A stock solution concentration of 0.5 g/L is appropriate if the procedure recommended below is followed. [Note: A solution of 3,5-dichlorophenol can be conveniently prepared by dissolving 0.5 g 3,5-dichlorophenol in 10 ml of 1N NaOH, diluting to approximately 30 ml with distilled water, adding under stirring 1N H_2SO_4 to the point of incipient precipitation—and finally diluting the mixture to one liter with distilled water. The pH should then be in the range 7 to 8].

(2) If the test substance is not sufficiently soluble to allow preparation of a concentrated stock solution in water, it should be added directly to test vessels or, alternatively, as a concentrated stock solution in an organic solvent. Direct addition is recommended. If an organic solvent is used, the solvent must neither significantly inhibit nor contribute to respiration. Further, a control containing activated sludge and solvent but no test substance is required.

(C) *Test concentrations.* At least five concentrations, spaced by a constant factor preferably not exceeding 3.2, should be used.

(D) *Synthetic sewage feed.* (1) A synthetic sewage feed is made by dissolving the following amounts of substances in 1 liter of water:

(*i*) 16 g peptone.

(*ii*) 11 g meat extract.

(*iii*) 3 g urea.

(*iv*) 0.7 g NaCl.

(*v*) 0.4 g $CaCl_2.2\ H_2O$.

(*vi*) 0.2 g $MgSO_4.7\ H_2O$.

(*vii*) 2.8 g K_2HPO_4.

(2) This synthetic sewage is a 100-fold concentrate of that described in the OECD Technical Report "Proposed method for the determination of the biodegradability of surfactants used in synthetic detergents" June 11, 1976, with dipotassium hydrogen phosphate added.

(ii) *Test system.* Activated sludge from a sewage treatment plant is normally used as the microbial innoculum for the test. Where possible, activated sludge should be obtained from a sewage work treating predominantly domestic sewage. If this is not possible, the activated sludge may be obtained from sewage works treating predominantly industrial waste water but used only following deadaptation. Even so, results obtained with activated sludge from works treating industrial waste waters may be atypical. On return to the laboratory the sludge is washed, if necessary, with tap water or an isotonic solution. After centrifuging the supernatant is decanted. This procedure is repeated three times. A small amount of the washed sludge is weighed and dried. From this result the amount of wet sludge can be calculated which must be suspended in water in order to obtain an activated sludge with a mixed liquor suspended solids level of 4 g/L(±10 percent). This level gives a concentration of 1.6 g/L in the test medium if the procedure recommended below is followed. If the sludge cannot

be used on the day of collection, 50 ml synthetic sewage is added to each liter of the activated sludge prepared as described above; this is then aerated overnight at 20±2°C. It is then kept aerated for use during the day. Before use the pH is checked and buffered, if necessary to pH 6.0 to 8.0 using sodium bicarbonate solution. The mixed liquor suspended solids should be determined as described in the preceeding paragraph. If the same batch of sludge is required to be used on subsequent days (maximum 4 days), a further 50 ml of synthetic sewage feed is added at the end of each working day.

(iii) *Test conditions.* The following conditions apply to the test system.

(A) Duration/contact time: 30 minutes and/or 3 hours, during which aeration takes place.

(B) Vessels: Beakers are suitable.

(C) Water: Drinking water (dechlorinated if necessary).

(D) Air supply: Clean oil-free air. Air flow 0.5 to 1 liter/minute.

(E) Measuring apparatus: Flat bottom flask such as a BOD-flask.

(F) Oxygen meter: Polarographic oxygen electrode, connectable to a potentiometric recorder. (200 mv range).

(G) Nutrient solution: Synthetic sewage feed (see above).

(H) Test substance: The test solution is freshly prepared at the start of the test.

(I) Reference substance: e.g. 3,5-dichlorophenol (at least 3 concentrations).

(J) Controls: Innoculated sample without test substance.

(K) Temperature: 20± 2°C.

(iv) *Performance of the test.* A suggested experimental procedure which may be followed for both the test and reference substance for the 3-hour contact period is given below:

(A) Several vessels (e.g. 1-liter beakers) are used.

(B) At time "0", 16 ml of the synthetic sewage feed are made up to 300 ml with water. Two hundred ml of microbial innoculum are added and the total mixture (500 ml) poured into a first vessel (first control C_1). Aeration at 0.5 to 1 liter per minute is commenced using a Pasteurpipete as aeration device.

(C) (*1*) At time "15 min" (15 minutes is an arbitrary, but convenient, interval) the above is repeated, except that 100 ml of the test substance stock solution are added to the 16 ml of synthetic sewage before adding water to 300 ml and microbial innoculum to make a volume of 500 ml. This mixture is then poured into a second vessel and aerated as described in (B) above. This process is repeated at 15-minute intervals with different volumes of the test substance stock solution to give a series of vessels containing different concentrations of the test substance. Finally, a second control (C_2) is prepared.

(*2*) If the test substance is not sufficiently soluble to allow addition from a stock solution in water, the appropriate proportion of the 100 ml-volume of test substance stock solution referred to above is replaced with water. For example, if 10 ml of an insoluble liquid test substance or solvent containing test substance is added directly to the test vessels, 90 ml of water is added. If insoluble solid test substance is added to the test vessel, 100 ml of water is added. If test substance is added as a stock solution in an organic solvent, a third control, containing the appropriate amount of solvent plus water to a total of 100 ml, is required, in addition to the series of test vessels containing different concentrations of the test substances.

(D) After 3 hours the contents of the first vessel are poured into the measuring apparatus and the respiration rate is measured over a period of up to 10 minutes; the measuring can also be carried out directly in the vessel.

(E) This determination is repeated on the contents of each vessel at 15-minute intervals, in such a way that the contact time in each vessel is three hours.

(*1*) The reference substance is tested on each batch of microbial innoculum in the same way. A different regime (e.g. more than one oxygen meter) will be necessary when measurements are to be made after 30 minutes of contact.

(*2*) If measurement of the chemical oxygen consumption is required, further vessels are prepared containing test substance, synthetic sewage feed and water, but no activated sludge.

(v) *Observations.* Oxygen consumption is measured and recorded after an aeration time of 30 minutes and/or 3 hours contact time.

(c) *Data and reporting*—(1) *Treatment of results.* (i) The respiration rate is calculated from the recorder trace as mg O_2/L.h between approximately 6.5 mg O_2/L and 2.5 mg O_2/L, or over a 10-minute period when the respiration rate is low. The portion of the respiration curve over which the respiration rate is measured should be linear. In order to calculate the inhibitory effect of a test substance at a particular concentration, the respiration rate is expressed as a percentage of the mean of the two control respiration rates:

Formula:

$$\left(1-\frac{2R_s}{Rc_1+Rc_2}\right)\bullet 100=\text{percent inhibition}$$

where

R_s = oxygen-consumption rate at tested concentration of test substance

R_{c1} = oxygen-consumption rate, control 1

R_{c2} = oxygen-consumption rate, control 2

(ii) If the respiration rates of the two controls are not within 15 percent of each other or the EC_{50} (3h) of the reference substance is not in the accepted range (5 to 30 mg/L for 3,5-dichlorophenol), the test is invalid and must be repeated. The percent inhibition is calculated at each test concentration using the formula shown above. The percent inhibition is plotted against concentration on log-normal (or log-probability) paper and an EC_{50} value derived. Ninety five percent confidence limits for the EC_{50} values can be determined using standard procedures. In view of the variability often observed in the results, it is recommended that the results be expressed in orders, of magnitude, e.g. less than 1, 1 to 10, 10 to 100, etc. (in mg/L).

(2) *Interpretation of results.* The EC_{50} value should be regarded merely as a guide to the likely toxicity of the test substance either to activated sludge sewage treatment or to wastewater microorganisms, since the complex interactions occurring in the environment cannot be accurately simulated in a laboratory test.

(3) *Test report.* The test report should include the following information.

(i) Test substance: Chemical identification data.

(ii) Test system: Source, concentration and any pretreatment of the activated sludge.

(iii) Test conditions: Test temperature, test duration, reference substance and its measured EC_{50}, and abiotic oxygen uptake, if any.

(iv) Results: All measured data; inhibition curve and method for calculation of EC_{50}; EC_{50}, and if possible, 95 percent confidence limits; EC_{20} and EC_{80}; all observations and any deviations from this test guideline which could have influenced the result.

(d) Literature references. (1) International Standard ISO/TC 147/SC 5/WC 1, N53 No. D (June 1981).

(2) Broecker, B. and Zahn, R., *Water Research, 11*, 165 (1977).

(3) Brown, D., Hitz, H.R. and Schaefer, L., *Chemosphere, 10*, 245 (1981).

(4) ETAD (Ecological and Toxicological Association of Dyestuffs Manufacturing Industries) Recommended Method No. 103, also described by:

(5) Robra, B., *Wasser/Abwasser, 117*, 80 (1976) and

(6) Schefer, W., *Textilveredlung, 6*, 247 (1977).

PART 799—[AMENDED]

2. Part 799 is amended as follows:

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

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

b. By adding § 799.4000 to read as follows:

§ 799.4000 Tetrabromobisphenol A.

(a) *Identification of test substance.* (1) Tetrabromobisphenol A (TBBPA CAS No. 79-94-7) shall be tested in accordance with this section.

(2) Tetrabromobisphenol A of at least 99 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (import) or process tetrabromobisphenol A, other than as an impurity, after the effective date of this rule (44 days after publication of the final rule in the **Federal Register**) to the end of the reimbursement period submit exemption applications, submit study plans, conduct tests, and submit data as specified in this section, Subpart A of this Part, Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Chemical fate*—(1) *Biodegradability in water*—(i) *Required testing.* Biodegradation testing in water shall be conducted with TBBPA in accordance with the method described in Bourquin *et al.* "Developments in Industrial Microbiology" 18, 185-191, 1977. The method is available from the Office of the Federal Register Information Center, 11th and L St., NW., Washington, DC 20408, and in the EPA OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Federal Register on [date]. The method is incorporated as it exists on the effective date of this rule and a notice of any change to the method will be published in the **Federal Register**.

(ii) *Reporting requirements.* (A) The biodegradation test in water shall be completed and the final report submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final rule.

(2) *Inherent biodegradability in soil*—(i) *Required testing.* Inherent biodegradability in soil tests to assess aerobic and anaerobic biodegradability shall be conducted with TBBPA in accordance with § 796.3400 of this chapter.

(ii) *Reporting requirements.* (A) The inherent biodegradability in soil tests shall be completed and the final report submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(3) *Biodegradability in sludge systems*—(i) *Required testing.* Biodegradability tests in sludge systems shall be conducted with TBBPA in accordance with § 796.3341 of this chapter.

(ii) *Reporting requirements.* (A) The biodegradability tests in sludge systems shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(d) *Environmental effects*—(1) *Respiration inhibition in activated sludge*—(i) *Required testing.* A respiration inhibition test in activated sludge system shall be conducted with TBBPA in accordance with the guideline specified in § 795.170 of this chapter.

(ii) *Reporting requirements.* (A) The respiration inhibition test in activated sludge system shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(2) *Algal acute toxicity*—(i) *Required testing.* (A) Algal acute toxicity testing shall be conducted with TBBPA using *Selenastrum capricornutum* in accordance with § 797.1050 of this chapter and the modification specified in paragraph (d)(2)(i)(B) of this section.

(B) Modification. The requirements under § 797.1050 (c)(1)(ii) and (c)(6)(i)(B) of this chapter are modified to require that the agal cells at the end of 24, 48, and 72 hours also be enumerated and that the algal cells at the end of 24, 48, cells from the test solution be done using an ultrafiltration (e.g. 0.45 micrometer pore size) technique.

(ii) *Reporting requirements.* (A) The algal acute toxicity test shall be completed and the final report submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(3) *Gammarus acute toxicity*—(i) *Required testing. Gammarus* acute toxicity testing shall be conducted with TBBPA using *G. lacustris, G. fasciatus.* or *G. pseudolimnaeous* in accordance with § 797.1310 of this chapter.

(ii) *Reporting requirements.* (A) The *Gammarus* acute toxicity test shall be completed and the final report submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(4) *Fish acute toxicity*—(i) *Required testing.* Fish acute toxicity testing shall be conducted with TBBPA using *Pimephales promelas* (fathead minnow) in accordance with § 797.1400 of this chapter.

(ii) *Reporting requirements.* (A) The fish acute toxicity test shall be completed and the final report submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(5) *Daphnid chronic toxicity*—(i) *Required testing.* Daphnid chronic toxicity testing shall be conducted with TBBPA using *Daphnia magna* or *D. pulex* in accordance with § 797.1330 of this chapter.

(ii) *Reporting requirements.* (A) The daphnid chronic toxicity test shall be completed and the final report submitted to the Agency within 2 years of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(6) *Fish early life stage toxicity*—(i) *Required testing.* A fish early life stage toxicity test shall be conducted with TBBPA using fathead minnow (*Pimephales promelas*) if the 96-hour LC_{50} for fathead minnow conducted in accordance with paragraph (d)(4) of this section is equal to or less than 0.40 mg/L; the test species shall be rainbow trout if the 96-hour LC_{50} for fathead minnow is greater than 0.40 mg/L. The fish early life stage toxicity test shall be conducted in accordance with § 797.1600 of this chapter.

(ii) *Reporting requirements.* (A) The fish early life stage toxicity test shall be completed and the final report submitted to the Agency within 2 years of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(7) *Bioconcentration in fish*—(i) *Required testing.* A bioconcentration test shall be conducted with TBBPA using *Pimephales promelas* (fathead minnow) in accordance with § 797.1520 of this chapter.

(ii) *Reporting requirements.* (A) The bioconcentration test in fish shall be completed and the final report submitted to the Agency within 1 year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(8) *Bioconcentration in oyster*—(i) *Required testing.* A bioconcentration test shall be conducted with TBBPA using *Crassostrea virginica* (oyster) in accordance with § 797.1830 of this chapter.

(ii) *Reporting requirements.* (A) The bioconcentration test in oyster shall be completed and the final report submitted to the Agnecy within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(Information collection requirements have been approved by the Office of Management and Budget under Control Number 2070-0033)

[FR Doc. 86-10705 Filed 5-14-86; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 799

[OPTS-42080; FRL-3001-9]

Triethylene Glycol Monomethyl, Monethyl, and Monobutyl Ethers; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing that manufacturers and processors of triethylene glycol monomethyl ether (CAS No. 112-35-6), triethylene glycol monomethyl ether (CAS No. 112-50-5), and triethylene glyclo monobutyl ether (CAS No. 143-22-6) be required, under section 4 of the Toxic Substances Control Act (TSCA), to perform testing for these three chemicals for subchronic toxicity, developmental toxicity, neurotoxicity and developmental neurotoxicity, mutagenicity, reproductive toxicity, and onoogenicity. This is a two-stage rule. The subchronic toxicity, developmental toxicity and developmental neurotoxicity, the neurotoxicity and the lower-tier mutagenicity are in the first stage. Following the receipt of the first-stage data, EPA will review it and decide what further testing needs to be done in stage two. This proposed rule responds to the Interagency Testing Committee's (ITC's) designation of these three compounds for priority consideration for health effects testing.

DATES: Submit written comments on or before July 14, 1986. If persons request an opportunity to submit oral comment by June 30, 1986, EPA will hold a public meeting on this rule in Washington, DC. For further information on arranging to speak at the meeting see Unit VIII of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42080), 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, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Wasington, DC 20460. Toll free: (800-424-9065); In Washington, DC: (554-1404); Outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the ITC's designation of triethylene glycol monomethyl, monoethyl, and monobutyl ether for health effects testing consideration.

I. Introduction

A. ITC Recommendation

TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established ITC under section 4(e) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

ITC designated the three triethylene glycol ethers for priority testing consideration in its Sixteenth Report, published in the Federal Register of May 21, 1985 (50 FR 20930). ITC recommended pharmacokinetic and metabolic studies. Dependent upon the results of the pharmacokinetic and metabolic work, subchronic studies with emphasis on hematologic effects, as well as reproductive and developmental toxicity studies, should be performed. This document responds to ITC's designation.

B. Test Rule Development Under TSCA

Under section 4(a) of TSCA, EPA shall by rule require testing of a chemical substance or mixture to develop appropriate test data if it 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.