

28. Section 100.302 is redesignated § 100.503, and paragraph (b) is revised to read as follows:

§ 100.503 Barnegat Bay Air Brook Classic, Tom's River, NJ.

(b) *Effective period.* This regulation will be effective from 10:00 a.m. to 3:00 p.m. annually on the fourth Saturday in August unless otherwise specified in the Coast Guard Local Notice to Mariners and a Federal Register Notice. In case of postponement, this regulation will be in effect the following day.

29. Section 100.303 is redesignated § 100.504, and paragraph (b) is revised to read as follows:

§ 100.504 Night in Venice, Great Egg Harbor Bay, City of Ocean City, NJ.

(b) *Effective period.* This regulation will be effective from 4:30 p.m. to 11:45 p.m. annually on the fourth Saturday in July unless otherwise specified in the Coast Guard Local Notice to Mariners and a Federal Register Notice.

30. Section 100.304 is redesignated as § 100.101, and paragraph (b) is revised to read as follows:

§ 100.101 Harvard-Yale Regatta, Thames River, New London, CT.

(b) *Effective period.* This regulation will be effective from 10:00 a.m. to 1:30 p.m. annually on the first or second Saturday in June as published in the Coast Guard Local Notice to Mariners and a Federal Register Notice. In case of postponement, this regulation will be in effect the following day.

31. Section 100.305 is redesignated § 100.102, and paragraph (b) is revised to read as follows:

§ 100.102 Connecticut River Raft Race.

(b) *Effective period.* This regulation will be effective from 9:00 a.m. to 2:00 p.m. annually on the first Saturday in August unless otherwise specified in the Coast Guard Local Notice to Mariners and a Federal Register Notice.

32. Section 100.306 is redesignated § 100.505 and paragraph (b) is revised to read as follows:

§ 100.505 New Jersey Offshore Grand Prix.

(b) *Effective period.* This regulation will be effective from 8:00 a.m. to 5:00 p.m. annually on the third Wednesday in

July unless otherwise specified in the Coast Guard Local Notice to Mariners and a Federal Register Notice.

33. Section 100.307 is redesignated § 100.103 and paragraph (b) is revised to read as follows:

§ 100.103 National Sweepstakes Regatta, Redbank, N.J.

(b) *Effective period.* This regulation will be effective from 8:00 a.m. to 6:00 p.m. annually on the third weekend (Saturday and Sunday) in August unless otherwise specified in the Coast Guard Local Notice to Mariners and a Federal Register Notice.

34. Section 100.308 is redesignated § 100.104, and paragraph (b) is revised to read as follows:

§ 100.104 Empire State Regatta, Albany, N.Y.

(b) *Effective period.* This regulation will be effective from 6:00 a.m. Friday through 6:00 a.m. Monday, annually on the first or second weekend (Friday, Saturday, Sunday and early Monday) in June unless otherwise specified in the Coast Guard Local Notice to Mariners and a Federal Register Notice.

§ 100.1201 and 100.1202 [Redesignated as § 100.1103 and 100.1104 Respectively]

35. Sections 100.1201 and 100.1202 are redesignated § 100.1103 and 100.1104, respectively.

#### PART 174—STATE NUMBERING AND CASUALTY REPORTING SYSTEMS

36. The authority citation for Part 174 is revised to read as follows:

Authority: 46 U.S.C. 4302, 12302; 49 CFR 1.46.

37. Section 174.121 is revised to read as follows:

#### § 174.121 Forwarding of casualty or accident reports.

Within 30 days of the receipt of a casualty or accident report, each state that has an approved numbering system must forward a copy of that report to the Commander of the Coast Guard District in which the state capitol is located, except that Ohio and Minnesota must forward reports to Commander, Ninth Coast Guard District, Cleveland, Ohio.

Dated: June 29, 1987.

R.E. Kramek,

CAPT., U.S. Coast Guard, Chief of Staff, Acting.

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#### ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42063A; FRL-3228-9]

Tetrabromobisphenol A; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** EPA is issuing a final test rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring manufacturers and processors of tetrabromobisphenol A (TBBPA, CAS No. 79-94-7) to perform testing for chemical fate and environmental effects. The testing requirements include biodegradation studies in sediment/water and soil, an acute toxicity study in a freshwater alga, acute and early life stage toxicity studies in fish, a partial life-cycle toxicity study in a benthic invertebrate, a chronic toxicity study in an aquatic invertebrate, and bioconcentration studies in fish and invertebrates.

**DATES:** In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern (daylight or standard as appropriate) time on July 20, 1987. These regulations shall become effective on August 19, 1987. The incorporation by reference in the regulations is approved by the Director of the Federal Register as of July 6, 1987.

**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, (202) 554-1404.

**SUPPLEMENTARY INFORMATION:** EPA is issuing a final test rule under section 4(a) of TSCA to require chemical fate and environmental effects testing of TBBPA.

#### I. Introduction

##### A. Test Rule Development Under TSCA

This final rule is part of the overall implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require the development of data relevant to assessing the risk to health and the environment posed by exposure to particular chemical substances or mixtures (chemicals).

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical to

develop health or environmental data if the Administrator finds that:

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

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

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

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

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

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

A more complete discussion of the statutory section 4 findings is provided in the Agency's first proposed test rule published in the *Federal Register* of July 18, 1980 (45 FR 48510).

### B. Regulatory History

The Interagency Testing Committee (ITC) designated TBBPA for priority testing consideration in its 16th Report, published in the *Federal Register* on May 21, 1985 (50 FR 20930). It was recommended by the ITC that TBBPA be considered for chemical fate testing, including water solubility, soil adsorption coefficient, and persistence; environmental effects testing, including acute and chronic toxicity to fish, aquatic invertebrates and algae; and bioconcentration potential in fish.

EPA responded to the ITC's recommendations for TBBPA by issuing a proposed rule, published in the *Federal Register* of May 15, 1986 (51 FR 17872), which would require that TBBPA be tested for biodegradation in sediment/water, soil, and sludge, acute toxicity in freshwater algae, fish, and invertebrates, early life stage toxicity in fish, chronic toxicity to invertebrates, and bioconcentration potential in fish and invertebrates. In addition, the Agency proposed to include tests to determine the toxicity of TBBPA to benthic organisms in the final rule for TBBPA if any of the sediment bioassay

methods referenced in the proposed rule were determined to be appropriate or if the comments received on the proposed rule indicated the availability of other appropriate sediment bioassay methods.

The proposed rule contained a chemical profile of TBBPA, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards to be used.

### II. Response to Public Comments

The Agency received written comments on the TBBPA proposed rule from the Brominated Flame Retardant Industry Panel (BFRIP or the Panel) on July 14, 1986 (Ref. 1). Ameribrom Inc., Ethyl Corporation, Great Lakes Chemical Corporation, and Dow Chemical Company are members of BFRIP. Ethyl and Great Lakes are the only manufacturers of TBBPA in the U.S.; Ameribrom is the only known importer of TBBPA; and Dow is one of the many U.S. processors of TBBPA. A public meeting was also requested by BFRIP and was held on August 21, 1986. The comments received by the Agency in response to the TBBPA proposed rule are discussed below.

#### A. The "May Present an Unreasonable Risk" Finding

The Great Lakes Chemical Company commented that the Agency has used outdated and flawed information, monitoring data from Research Triangle Institute (RTI), to reach decisions on the proposed tests, and therefore, has not satisfied the statutory requirement of section 4(a)(1)(A)(i) of TSCA (Refs. 2 and 3). Great Lakes claims that, in the 9 years since the RTI data were generated, it has made many improvements in the handling of process wastes, and procedures are now employed to either contain or recycle all byproducts and process wastes.

The Agency disagrees with the comments from Great Lakes that the statutory requirement of section 4(a)(1)(A)(i) of TSCA has not been satisfied. The Agency 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 substance may present an unreasonable risk. The stronger the Agency's scientific basis for suspecting potential toxicity, the fewer exposure data are needed to support the potential risk finding. In the case of TBBPA, the Agency believes that the monitoring data from RTI (Ref. 3) and the limited set of current monitoring data from Great Lakes (Ref. 4), received following submission of comments on the proposed rule, provide evidence that

TBBPA has been released and continues to be released to the environment. The RTI study reported detection of TBBPA in sediments at levels up to 330 parts per million (ppm) and soils at levels up to 150 ppm near a TBBPA production site. The Great Lakes monitoring data represent results from analysis of TBBPA in five soil/sediment samples obtained from locations that were either a part of the earlier RTI study or from some undisclosed locations. TBBPA was detected in four of the five samples from Great Lakes at levels ranging between 5.4 ppm and 106 ppm. Although data from Great Lakes show reduced levels of TBBPA, in comparison to the levels reported by RTI in 1978, at two sampling locations, this information is too sparse and does not significantly alleviate the Agency's concern for release of TBBPA into the environment considering TBBPA's high aquatic toxicity. TBBPA is likely to enter the environment as a result of inadequate treatment and disposal of wastes generated from the TBBPA manufacturing process, from drying and packaging operations, from transport of TBBPA and wastes containing TBBPA, and from 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). The available physical/chemical data (i.e., low water solubility and log P of 4.5) and the available data for acute toxicity to marine algae, invertebrates and fish (i.e., EC<sub>50</sub> or LC<sub>50</sub> < 1 mg/L) demonstrate the potential for TBBPA to bioconcentrate and to cause chronic toxicity in aquatic organisms.

#### B. Notification to Foreign Governments

Great Lakes Chemical Company commented that EPA should interpret section 12(b) of TSCA to require no notification to foreign governments until test data are available (Ref. 2).

Section 12(b) of TSCA requires any person who exports or intends to export a chemical substance or mixture to notify EPA of such exportation to a particular country if data are required under section 4 for that chemical. EPA is required to send the importing country a notice to identify the regulated chemical and indicate the availability of the test data on the chemical. The Agency has interpreted section 12(b) of TSCA to apply at the time a final rule is promulgated under section 4 of TSCA, since this represents the Agency's commitment to proceed with data collection with respect to specific chemicals. While the results of required testing may not be available for some

time, a notice to the foreign government about the export of such a chemical serves to alert it to the Agency's interest in the chemical. It gives the government the opportunity to request data that the Agency may currently possess plus whatever data may become available as a result of section 4 testing activities. EPA is continuing to review issues relating to the application of section 12(b) requirements to exporters of section 4 chemicals. However, EPA is not prepared to change its interpretation in the context of this rule.

### C. Chemical Fate

#### 1. Biodegradability Test in Water

The Panel commented that because of TBBPA's tendency to partition from water into sediment, testing for biodegradability in water will provide only limited useful information on the chemical fate of TBBPA.

The test methodology proposed by the Agency for this test (Core-Chamber Method by Bourquin et al.), however, provides data on biodegradability (i.e., rate of carbon dioxide evolution and extent of transformation) of the chemical in a combined sediment/water environment (Ref. 5).

#### 2. Inherent Biodegradability: Modified Semi-continuous Activated Sludge (SCAS) Test

The Panel recommended using the results to be obtained from the inherent biodegradability in soil test to predict biodegradation of TBBPA in activated sludge because biodegradation is due to the same types of bacteria in both.

EPA believes many differences exist between soil and activated sludge which influence their bacterial composition and activity (i.e., moisture, temperature, pH, etc.). However, the review of information collected following the proposed rule shows that activated sludge is not currently being used in treatment of TBBPA process wastes. Therefore, the modified SCAS test, which provides data on biodegradability of a chemical substance in activated sludge, is not being required in this final rule.

### D. Environmental Effects

#### 1. Activated Sludge Respiration Inhibition Test

The Agency is not requiring this test in the final rule because there is no need to determine the inhibitory concentration in sludge if activated sludge is not being used in the treatment of TBBPA wastes and the SCAS test is not being performed.

#### 2. Algal Acute Toxicity Test for Freshwater Algae

The Panel recommends using the marine algae data generated by the Agency at its Gulf Breeze facility to make an assessment of the toxicity to freshwater algae (Ref. 6).

The Agency disagrees with the Panel's recommendation because there are insufficient comparative toxicology data available for organic chemicals structurally related to TBBPA to demonstrate that the sensitivities of marine and freshwater algae are similar.

#### 3. Gammarus Acute Toxicity Test

The Panel claims that acceptable culturing and testing guidelines are not available for *Gammarus* and that lack of published data on *Gammarus* will not allow for the relative assessment of the toxicity results.

The Agency has published an adequate test guideline for *Gammarus* and published data on *Gammarus* are also available. However, following the publication of the TBBPA proposed rule, the Agency received data on acute toxicity of TBBPA to mysid shrimp (*Mysidopsis bahia*) from its Gulf Breeze facility (Ref. 7) and, therefore, does not see any further need to require another acute toxicity test with an invertebrate at this time.

#### 4. Daphnid Chronic Toxicity Test

The Panel agrees that a daphnid chronic toxicity study will provide useful information in evaluating the environmental effects of TBBPA. However, it recommends the test be performed by a static renewal method instead of in a flow-through system because of the difficulty in providing adequate algal food for the daphnids in a flow-through system.

The Agency believes that a static renewal method can provide reliable information as long as the TSCA test guideline is followed and the test substance (TBBPA) is maintained at the desired concentration within the test chambers through periodic measurements of its concentration between the renewal periods. While EPA prefers that this test be performed in a flow-through system, the final rule permits use of either flow-through or static renewal method.

#### 5. Fish Early Life Stage Toxicity Test

The Panel commented that EPA provides no justification for its proposal to use a 96-hour LC<sub>50</sub> of 0.40 mg/L as the point for deciding whether fathead minnows or rainbow trout are to be used to conduct the fish early life stage toxicity test. The Panel recommends

that fathead minnows be used in any fish early life stage toxicity testing, even if the 96-hour LC<sub>50</sub> is greater than 0.40 mg/L, because testing laboratories have experienced considerable difficulty in reaching the percent hatchability of green eggs required for the rainbow trout test to be valid.

The Agency cited the LC<sub>50</sub> value of rainbow trout (0.40 mg/L) as a means to ensure that a sensitive fish species is tested for chronic toxicity (Ref. 8). It is possible that there can be substantial variation in LC<sub>50</sub>'s as a result of minor differences in test water, procedures, fish stock, and other variables between laboratories. Therefore, the final rule provides that if the fathead minnow LC<sub>50</sub> is any value in the range between 0.08–2.0 mg/L, five times below or above the LC<sub>50</sub> value for rainbow trout, either species may be used for the early life stage toxicity test. If the LC<sub>50</sub> value for fathead minnow is equal to or greater than 2.0 mg/L, then rainbow trout must be used in this test in accordance with the stated guideline.

#### 6. Bioconcentration Test in Fish (Fathead Minnows)

The Panel commented that the study with bluegill sunfish submitted to EPA in the TSCA section 8(d) data reporting provides a sound basis for evaluating the bioconcentration potential of TBBPA in fish (Ref. 9).

The Agency finds the bioconcentration study with bluegill submitted by the Panel to be unreliable (i.e., loading was very high, environmental variables were not reported, etc.). The Agency's concerns with this study were communicated to a Panel member along with a request for submission of any additional information that could eliminate these concerns. There was no response from the Panel member on this matter. Therefore, a bioconcentration study in fish is included as a requirement in the final rule.

#### 7. Bioconcentration Test in Oysters

The Panel commented that the proposed 1-year reporting requirement will not allow sufficient time to conduct the testing because the study for bioconcentration in oysters requires the acute toxicity test with oysters as a range-finding study, and because oyster studies usually can be performed only from April to September without supplementing food. The Panel recommends that 2 years be permitted for this study.

The Agency believes that adding 6 months to the proposed 1-year reporting

requirement will be sufficient to conduct the testing.

### III. Final Test Rule for TBBPA

#### A. Findings

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

EPA finds that the manufacture, processing, use, and disposal of TBBPA may present an unreasonable risk of injury to the environment because TBBPA has the potential to persist in the environment, bioconcentrate in aquatic organisms, and cause adverse effects in aquatic and benthic organisms. These findings are based on the evidence of exposure, available physical/chemical data, and available toxicity data discussed in Unit II of this preamble and in Unit II of the preamble to the proposed rule.

EPA also finds that the available data on TBBPA are inadequate to fully characterize the chemical fate and environmental effects following release of TBBPA to the environment.

The structure of TBBPA suggests, by analogy to other polyhalogenated compounds, that TBBPA may be persistent. Biodegradation studies in sediment/water and soil are needed to reasonably determine TBBPA's persistence in the environment.

There is also the potential, based on its estimated bioconcentration factor of 1,300, for TBBPA to bioconcentrate in aquatic organisms. Tests with aquatic organisms are required to accurately measure TBBPA's ability to bioconcentrate.

As discussed in the preamble to the proposed rule, the existing acute toxicity data for aquatic organisms experimentally exposed to TBBPA demonstrate that TBBPA can be expected to be acutely toxic to aquatic organisms at low to moderate concentrations and to be chronically toxic to fish and aquatic invertebrates at very low concentrations. From EPA's evaluation of the available toxicity data, the experimental acute toxicity data for freshwater algae and one additional fish species exposed to TBBPA are necessary to determine whether freshwater algae are more sensitive than marine algae and to determine the relative sensitivity of different fish species. EPA also finds that there are no toxicity data on benthic organisms and no chronic effects data on fish and aquatic invertebrates.

EPA finds that sufficient data are available for water solubility, log K<sub>ow</sub>, log K<sub>oc</sub>, and acute toxicity to marine unicellular algae and aquatic

invertebrates to reasonably determine or predict these characteristics for TBBPA.

Finally, EPA finds that testing is necessary to develop the chemical fate and environmental effects data described above. EPA believes that the data resulting from this testing will be relevant to a determination as to whether the manufacture, processing, use, or disposal of TBBPA does or does not present an unreasonable risk of injury to the environment.

#### B. Required Testing and Test Standards

On the basis of these findings, the Agency is requiring chemical fate and environmental effects testing be conducted for TBBPA in accordance with specific test guidelines set forth in 40 CFR Parts 796, 797, and 798. Revisions to these guidelines were proposed in the Federal Register of January 14, 1986 (51 FR 1522), and were promulgated in the Federal Register of May 20, 1987 (52 FR 19056).

In the aquatic environment, TBBPA is expected to partition strongly to sediment based on its log P value of 4.5. Therefore, the Agency believes that determining the toxicity of TBBPA to benthic organisms is important in characterizing the environmental effects of TBBPA. Since the Agency did not receive any comments on the sediment bioassay methods referenced in the proposed rule or on the availability of alternate sediment bioassay methods, the Agency is requiring that testing the toxicity of TBBPA to benthic organisms be conducted in accordance with the method it has selected as being appropriate from those referenced in the proposed rule.

1. Chemical fate tests to be conducted for TBBPA are: (a) biodegradability in sediment/water, using the Core-Chamber Method described by Bourquin et al. (Ref. 5) and (b) aerobic and anaerobic biodegradability in soil, using the guideline at 40 CFR 796.3400.

2. Environmental effects tests to be conducted for TBBPA are: (a) acute toxicity to freshwater algae, *Selenastrum capricornutum*, using the test guideline at 40 CFR 797.1050; (b) acute toxicity to *Pimephales promelas* (fathead minnow) in a flow-through system, using the guideline at 40 CFR 797.1400; (c) partial life-cycle toxicity to the midge (*Chironomus tentans*) conducted in a flow-through system using TBBPA-spiked clean, freshwater sediments having low, medium, and high organic carbon content in accordance with the method described by Adams et al. (Ref. 10); (d) chronic toxicity to the invertebrate *Daphnia*, tested in a renewal or a flow-through system, using

the guideline at 40 CFR 797.1330; (e) early life stage toxicity to fish conducted in a flow-through system, using the guideline at 40 CFR 797.1600 (the test species for the fish early life stage test is fathead minnow (*Pimephales promelas*) if the LC<sub>50</sub> value for fathead minnow is equal to or less than 0.08 mg/L, either fathead minnow or rainbow trout if the 96-hour LC<sub>50</sub> for fathead minnow is in the range between 0.08–2.0 mg/L, and rainbow trout if the 96-hour LC<sub>50</sub> for fathead minnow is greater than or equal to 2.0 mg/L); (f) bioconcentration in the fathead minnow (*Pimephales promelas*) using the guideline at 40 CFR 797.1520; and (g) bioconcentration in the oyster (*Crassostrea virginica*) using the guideline at 40 CFR 797.1830.

The Agency is requiring that the above referenced TSCA Chemical Fate and Environmental Effects Test Guidelines and revisions and other cited methods be the test standards for the purposes of the required tests for TBBPA. The TSCA test guidelines for chemical fate and aquatic toxicity testing specify generally accepted minimum conditions for determining chemical fate and aquatic organism toxicities for substances like TBBPA to which aquatic life is expected to be exposed.

The required methods of Bourquin et al. (1977) for investigating the biodegradation rate of TBBPA in sediment/water and Adams et al. for investigating the toxicity of TBBPA to benthic organisms specify generally accepted minimum conditions (Refs. 5 and 10). The Agency believes that these test methods reflect the current state-of-the-science for testing the fate and effects of chemicals such as TBBPA in sediment/water systems.

#### C. Test Substance

EPA is requiring that TBBPA of greater than 98 percent purity shall be used as the test substance. TBBPA of such purity is available according to comments received from the Panel (Ref. 1).

#### D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which the Agency makes section 4(a) findings (manufacture, processing, distribution in commerce, use, and/or disposal) determine who bears the responsibility for testing a chemical. 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 in commerce, or disposal.

Because EPA has found that manufacturing, processing, use, and disposal of TBBPA give rise to exposure that may lead to an unreasonable risk, EPA is requiring that persons who manufacture or process, or who intend to manufacture or process, TBBPA, other than as an impurity, at any time from the effective date of the final test rule to the end of the reimbursement period are subject to the testing requirements contained in this final rule. The end of the reimbursement period will be 5 years after the last final report is submitted or an amount of time equal to that which was required to develop data if more than 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 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 of 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 other 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 requiring the submission of equivalence data as a condition for exemption from the required testing for TBBPA. As noted in Unit III.C., EPA is interested in evaluating the effects attributable to TBBPA and has specified a relatively pure substance for testing.

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

#### *E. Reporting Requirements*

EPA is requiring that all data developed under this rule be reported in accordance with its TSCA 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 within 45 days before 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. Specific reporting requirements for each of the required test follow:

The biodegradation studies in sediment/water and soil, the acute toxicity studies in freshwater algae and fish, and the bioconcentration study in fish shall be completed and the final results submitted to EPA within 1 year of the effective date of the final test rule. An interim progress report for each of these studies shall be provided to the Agency 6 months after the effective date of this rule.

The bioconcentration study in oyster shall be completed and the final results submitted to EPA within 18 months of the effective date of the final test rule. The fish early life stage toxicity study, the midge partial life-cycle toxicity study in sediments, and the daphnid chronic toxicity study shall be completed and the final results submitted to EPA within 2 years of the effective date of the final test rule. Interim progress reports for each of these studies shall be provided to the Agency at 6 month intervals after the effective date of this rule, until the final report is submitted to EPA.

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 this 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.

#### *F. 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 TSCA 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 the purpose of determining compliance with the final rule for TBBPA. These inspections may be conducted for purposes which include verification that testing has begun, schedules are being met, and reports accurately reflect the underlying raw data, 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 TSCA which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that

laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties 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 of TSCA 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 790.48(b)). 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 TSCA 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. Sections 15 and 16 of TSCA apply to "any person" who violates 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.

#### IV. Economic Analysis of Final Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (Ref. 11) that evaluates the potential for significant economic impact on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of TBBPA: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If

there is no indication of adverse effect, no further economic analysis will be performed; however, if the first level of analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted which more precisely predicts the magnitude and distribution of the expected impact.

Total testing costs for the final rule for TBBPA are estimated to range from \$141,790 to \$184,640. In order to predict the financial decisionmaking practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period in order to finance the testing expenditure in the first year.

The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from \$35,448 to \$46,160. Based on the lower bound of the 1984 estimated production volume for TBBPA of 59.8 million pounds to 83.7 million pounds, the unit test costs will range from about 0.06 to 0.08 cents per pound. In relation to the selling price of \$1.16 per pound for TBBPA, these costs are equivalent to 0.05 to 0.07 percent of price.

Based on these costs and the uses of TBBPA, the economic analysis indicates that the potential for significant adverse economic impact as a result of this testing rule is low. This conclusion is based on the following observations:

1. The estimated unit test costs are very low, 0.07 percent of current price in the upper-bound case;
2. The overall demand for TBBPA appears relatively inelastic;
3. Producers of TBBPA may exercise a degree of control over price; and
4. The market expectations for TBBPA end use products appear favorable.

Refer to the economic analysis for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

#### V. 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. Copies of the study, *Chemical Testing Industry: Profile of Toxicological Testing*, can be obtained

through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (PB 82-1407730). On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this rule.

#### VI. Rulemaking Record

EPA has established a record for this rulemaking proceeding [docket number OPTS-42083A]. This record includes:

##### 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) Notice of EPA's proposed test rule on TBBPA (51 FR 17872; May 15, 1986).

(d) TSCA test guidelines final rule (40 CFR Parts 796, 797, and 798; September 27, 1985).

(e) Notice of final rulemaking on data reimbursement (48 FR 31786; July 11, 1983).

(f) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(g) TSCA GLP standards (48 FR 53992; November 29, 1983).

(2) Support documents consisting of:

(a) TBBPA technical support document for proposed rule (Syracuse Research Corporation; November 15, 1985).

(b) Economic impact analysis of final test rule for TBBPA.

(3) Communications consisting of:

(a) Written public comments.

(b) Transcripts of public meeting.

(c) Summaries of phone conversations.

(4) Reports—published and unpublished factual materials.

##### B. References

(1) Comments from the Brominated Flame Retardant Industry Panel (BFRIP) on EPA's Proposed Test Rule for Tetrabromobisphenol A to Public Information Office, USEPA (July 14, 1986).

(2) Copy of comments presented by David L. McAllister of Great Lakes Chemical Corporation on EPA's Proposed Test Rule for Tetrabromobisphenol A at a public meeting. (August 21, 1986).

(3) 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).

(4) Great Lakes Chemical Corp., West Lafayette, IN 47906. Report on soil analysis for Tetrabromobisphenol A from Great Lakes Chemical Corp. Letter with results on sample analysis from D.L. McAllister to Narendra Chaudhari, Washington, DC, Office of Toxic Substances, USEPA (March 4, 1987).

(5) Bourquin, A.W., Hood, M.A., and Gernas, R.I. "An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment."

*Developments in Industrial Microbiology*  
18:185-191 (1977).

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

(7) U.S. Environmental Protection Agency, Environmental Research Laboratory, Gulf Breeze, FL 32561. Acute toxicity of tetrabromobisphenol A to mysids. Memorandum from L.R. Goodman to Narendra Chaudhari, Washington, DC, Office of Toxic Substances, USEPA (September 22, 1986).

(8) 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, Washington, DC, Office of Toxic Substances, USEPA (August 1, 1985).

(9) Great Lakes Chemical Corp., West Lafayette, IN 47906. The bioaccumulation of tetrabromobisphenol A in the bluegill sunfish. Letter with attached studies from D.L. McFadden to Narendra Chaudhari, Washington, DC, Office of Toxic Substances, USEPA (August 1, 1985).

(10) 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. 429-453 (1985).

(11) U.S. Environmental Protection Agency, Economic Impact Analysis of Final Test Rule for Tetrabromobisphenol A. Washington, DC, Office of Toxic Substances, USEPA (March 24, 1987).

**VII. Other Regulatory Requirements****A. 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. 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 an 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 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 will not have a significant impact on a substantial number of small businesses because: (1) They are not likely to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, if any, in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

**C. Paperwork Reduction Act**

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070-0033.

**List of Subjects in 40 CFR Part 799**

Testing, Environmental protection, Hazardous substances, Chemicals, Reporting and recordkeeping requirements, Incorporation by reference.

Dated: June 26, 1987.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

**PART 799—[AMENDED]**

Therefore, 40 CFR Part 799 is amended as follows:

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

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

2. Section 799.4000 is added 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 98 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 (including import) or process or intend to manufacture or process tetrabromobisphenol A, other than as an impurity, after August 19, 1987, to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data or submit exemption applications as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Chemical fate*—(1) *Biodegradability in sediment/water*—(i) *Required testing.* Biodegradation testing

in sediment/water shall be conducted with TBBPA using clean, freshwater sediments in accordance with the method described in an A.W. Bourquin article entitled "An Artificial Microbial Ecosystem for Determining Effects and Fate of Toxicants in a Salt-Marsh Environment", published in *Developments in Industrial Microbiology*, Vol. 18, Chapter 11, 1977, which is incorporated by reference. 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. G-004 Northeast Mall, 401 M St., SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. The method is incorporated as it exists on the effective date of the final 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 sediment/water shall be completed and the final report submitted to EPA within 1 year of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6 months 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 EPA within 1 year of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final rule.

(d) *Environmental effects*—(1) *Algal acute toxicity*—(i) *Required testing.* Algal acute toxicity testing shall be conducted with TBBPA using *Selenastrum capricornutum* in accordance with § 797.1050 of this chapter.

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

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final rule.

(2) *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 EPA within 1 year of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final rule.

(3) *Midge partial life-cycle toxicity in sediments—(i) Required testing.* A 14-day toxicity test in a flow-through system shall be conducted with the midge (*Chironomus tentans*) using TBBPA-spiked clean, freshwater sediments having low, medium, and high organic carbon content in accordance with the American Society for Testing and Materials Special Technical Publication 854 (ASTM STP 854), entitled "Aquatic Safety Assessment of Chemicals Sorbed to Sediments," by W.J. Adams et. al., and published in *Aquatic Toxicology and Hazard Assessment: Seventh Symposium*, ASTM STP 854, pp. 429-453, R.D. Cardwell et. al., Eds. 1985, which is incorporated by reference. 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 G-004 Northeast Mall, 401 M St., SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. 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 14-day toxicity test with midge using sediments shall be conducted and the final report submitted to EPA within 2 years of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(4) *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 EPA within 2 years of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective

date of the final rule, until the final report is submitted to EPA.

(5) *Fish early life stage toxicity—(i) Required testing.* A fish early life stage toxicity test shall be conducted with TBBPA. The test species shall be fathead minnow (*Pimephales promelas*) if the 96-hour LC<sub>50</sub> for fathead minnow conducted in accordance with paragraph (d)(2) of this section is equal to or less than 0.08 mg/L; the test species shall be either fathead minnow or rainbow trout if the 96-hour LC<sub>50</sub> for fathead minnow is between 0.08-2.0 mg/L; the test species shall be rainbow trout if the 96-hour LC<sub>50</sub> for fathead minnow is greater than or equal to 2.0 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 EPA within 2 years of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(6) *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 EPA within 1 year of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6-months after the effective date of the final rule.

(7) *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 EPA within 18 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(e) *Effective date.* The effective date of the final rule is August 19, 1987.

(Information collection requirements have

been approved by the Office of Management and Budget under control number 2070-0033)

[FR Doc. 87-15241 Filed 7-2-87; 8:45 am]

BILLING CODE 6560-50-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[MM Docket No. 86-348; RM-5357]

### Radio Broadcasting Services; Laurel, DE

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 237A to Laurel, Delaware, as a first FM channel at the request of Troy D. Hill. With this action, this proceeding is terminated.

**DATES:** August 13, 1987. The window period for filing applications will open on August 14, 1987, and close on September 14, 1987.

**FOR FURTHER INFORMATION CONTACT:** Montrose H. Tyree, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, MM Docket No. 86-348, adopted June 11, 1987, and released June 29, 1987. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

### List of Subjects in 47 CFR Part 73

Radio broadcasting.

### PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

#### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments, in the entry for Laurel, Delaware, Channel 237A is added.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 87-15208 Filed 7-2-87; 8:45 am]

BILLING CODE 6712-01-M