

40 CFR Parts 796 and 799

[OPTS-42075; TSH-FRL 2904-2]

Pentabromoethylbenzene; Proposed Test Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: The EPA is proposing that manufacturers and processors of pentabromomethylbenzene (PEB, CAS No. 85-22-3) be required, under section 4 of the Toxic Substances Control Act (TSCA), to perform testing for chemical fate and environmental effects. This proposed rule is in response to the Interagency Testing Committee's (ITC's) designation of PEB for priority consideration for health and environmental effects testing.

DATES: Submit written comments on or before January 13, 1986. If persons request an opportunity to submit oral comment by December 30, 1985, EPA will hold a public meeting on this rule in Washington, D.C.

ADDRESSES: Submit written comments, identified by the document control number (OPTS-42075), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW, Washington, D.C. 20460.

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, D.C. 20460. Toll free: (801-424-8065), In Washington, D.C.: (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 PEB for health 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 recommended to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated PEB (CAS No. 85-22-3) for priority consideration in its 15th Report, which was submitted to EPA on November 8, 1984. The report was published in the Federal Register of November 29, 1984 (49 FR 48931). The ITC recommended that PEB be considered for health effects testing, including chronic effects and teratogenicity, and ecological effects testing, including acute and chronic toxicity to fish, aquatic invertebrates, and plants. The ITC's rationale for health effects testing includes the following: (1) Releases from production and use are expected to result in human exposure, and (2) there is insufficient information on the chronic effects of PEB and toxic effects are observed in compounds having a polyhalogenated aromatic moiety. The chronic bioassay was recommended rather than short-term tests because the latter do not, in general, show a positive association with carcinogenicity for polyhalogenated compounds. Teratogenicity testing was recommended because of lack of information.

The ITC's rationale for ecological effects testing includes the following: (1) PEB may be widely distributed in the environment; (2) PEB is structurally similar to halogenated compounds that have appreciable toxicity; (3) PEB is expected to partition into soils, sediments, and biota after release; and (4) data on a structurally related compound, pentabromomethylbenzene, indicate that although only low levels of PEB may be taken up by aquatic organisms, its residence time in the organisms may be relatively long. The ITC regarded this as presumptive evidence that PEB may have the potential to produce chronic effects.

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 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 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 sections 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 PEB, 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 PEB 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) for PEB; and published and unpublished data available to the Agency. Its evaluation, as described in this proposed rule, leads EPA to propose chemical fate and environmental effects testing requirements for PEB under section 4(a)(1)(A). By this action, EPA is responding to the ITC's designation of PEB for priority testing consideration.

II. Review of Available Data

A. Production

According to the public portion of the TSCA inventory, 1977 production of PEB was 100,000 to 1 million pounds. The public portion of the 1977 TSCA Inventory lists Velsicol Chemical Corp., St. Louis, MO; Great Lakes Chemical Corp., El Dorado, AR and West Lafayette, IN; Hexcel/Fine Organics, Sayreville, NJ; and the Chemical Systems Lab, Aberdeen Proving Grounds, MD as producers of PEB. Neither Great Lakes Chemical Corp. nor Velsicol Chemical Company presently produce PEB (Refs. 1 and 2). The U.S. International Trade Commission listed Ethyl Corp. as the only domestic producer of PEB from 1980 to 1983 (Refs. 3 through 6). Ethyl Corp. currently produces PEB and plans to continue PEB production through 1985 (Ref. 7). Ethyl Corp. submitted production volumes for 1980-1984 and export volumes for 1984 as confidential business information (CBI) (Refs. 8 and 9).

PEB can be prepared in an inert solvent by a Friedel-Crafts catalyzed bromination of ethylbenzene (Ref. 10). Batch processes are used by Ethyl Corp. (Ref. 7) to prepare the compound. Ethyl Corp. (Refs. 7 and 11) packages PEB in 250-lb. capacity fiber drums.

B. Uses

PEB is an additive-type flame retardant (1 to 8 percent w/w) and is suggested for use in thermoset polyester resins for circuit boards, textiles, adhesives, wire and cable coatings, polyurethanes, and thermoplastic resins (Refs. 7, 11, 12, and 13). Ethyl Corp. (Ref. 13) stated that it knew of no PEB uses in any consumer products. They were also unaware of any non-flame retardant PEB uses. According to Ethyl Corp., probable uses by its current customers for PEB as a flame retardant are in adhesives, polyester resins, textiles, and polyurethane foam (Ref. 14). Ethyl Corp. has submitted domestic customer sales volumes, number of U.S. customers, and geographical location of U.S. customers for 1984 as CBI (Refs. 8, 9, and 15).

C. Exposure and Release

Ethyl Corp. (Ref. 13) reported that an analytical method specific for the quantitation of PEB was not available to them. The total dust concentration is, therefore, the only available measure of the compound's concentration in workplace air. Ethyl Corp. (Ref. 13) has reported personal monitoring for total dust of a packer in the PEB packaging area. The result was $<1 \text{ mg/m}^3$ with limits of detection being 1 mg/m^3 to 2 mg/m^3 . OSHA has established limits for nuisance dust of 5 mg/m^3 for respirable fractions and 15 mg/m^3 for total dust (Ref. 18).

Ethyl Corp. (Refs. 8 and 13) submitted worker exposure estimates. During PEB production, one worker per day will be exposed to PEB while digging the product from a nutsche filter (Ref. 13). One operator per shift will be exposed during packaging (Ref. 13). During production, workers are required by Ethyl Corp. to wear body-covering clothing, safety shoes, safety glasses/goggles, gloves, a safety helmet and a respirator (Ref. 13). Packaging operators must also wear this equipment plus a dust cap and disposable coveralls and booties (Ref. 13). Mechanical ventilation is used to limit exposure to PEB by packagers (Ref. 13). Ethyl's Material Safety Data Sheet recommends that protective equipment and clothing be worn when handling PEB (Ref. 18).

Ethyl Corp. (Ref. 13) reports that manufacturing wastes are disposed of at an off-site landfill. Specifically, PEB is disposed of in 55-gallon sealed metal drums, and still bottoms from recycling process solvent are disposed of as waste-flammable liquid, not otherwise specified. EPA Waste No D001 (Ref. 13). Ethyl Corp. has submitted as CBI the amount of these untreated PEB manufacturing wastes (Ref. 8). Ethyl Corp. recommends on its Material Safety Data Sheet to dispose of waste PEB in a "chemically secure" landfill (Ref. 17).

Several possible point sources of PEB release into the environment occur during manufacturing and packaging (Ref. 13). To minimize worker exposure to dust, the packaging of PEB is performed in well-ventilated buildings. Intervening between these buildings and the atmosphere are bag houses designed to collect dust. No information on the efficiency of these bag houses was given. Ethyl Corp. has submitted as CBI estimates of the amount of PEB lost to the environment (Refs. 8 and 9).

According to Ethyl Corp. (Ref. 13), PEB crystals are washed with water during separation from the mother liquor. The wastewater is discharged

into a sewer system and ultimately treated at a publicly-owned treatment works (POTW). It is possible, therefore, that PEB may be released to the aquatic environment and that aquatic organisms may be exposed to PEB. No information on PEB levels in this water was given. However, the low water solubility of PEB suggests that most of the PEB not degraded in the POTW would be adsorbed onto the sludge and not be released in the effluent. The sludge from this particular POTW is dumped into the ocean at a site 12 miles directly off the Southern New Jersey Coast (Ref. 18). In the near future, a site 108 miles out will be used (Ref. 18). Ethyl Corp. has submitted domestic sales volumes, number of U.S. customers and geographical locations of U.S. customers for 1984 as CBI (Refs. 8, 9, and 15). However, information is not available to EPA concerning the quantities of PEB released from these processing sites.

In summary, EPA concludes that based on the available data, human exposure to PEB will be quite limited. However, there is evidence that small quantities of PEB are released to the environment as a result of manufacturing and additional amounts of PEB (which cannot be quantified at this time) can be expected to be released to the environment from processing activities.

D. Health Effects

1. *Pharmacokinetics.* Very few data on the absorption, distribution, metabolism, and elimination of PEB were located in the available literature. In a 28-day feeding study, PEB was administered to male and female Charles River CD rats at 100 and 1,000 ppm (corresponding to 5 and 50 mg/kg bw/day assuming that a rat consumes 0.05 kg food/kg bw/day) in the diet (Ref. 19). At the end of the study, the bromine content of the liver and fat was elevated in a dose-related manner (see Unit II.D.3) indicating absorption of the compound when exposure occurs by the oral route.

2. *Acute toxicity—*a. *Oral Studies.* In a study conducted by Industrial Bio-Test Laboratories in 1978 (Ref. 20), an oral LD_{50} was calculated to be 8,800 mg/kg (range 5,271-8,722 mg/kg), which led these authors to classify PEB as "practically non-toxic."

Great Lakes Chemical Company (Ref. 21) provided data on a study in which PEB as a suspension in corn oil was administered by gavage to male Carworth CFE rats (five/dose level). The dosages employed were 50, 500, and 5,000 mg/kg bw. Normal weight gains

were recorded for all exposed rats during the 14-day observation period.

b. *Inhalation Studies.* Carworth CFE rats (10 males/group) were exposed to two dose levels of PEB dust in air for 1 hour and were observed for 14 days following the single exposure (Ref. 21). Addition of the PEB dust to the atmosphere in the test chamber was controlled by a Wright Dust Feeder. The atmospheric concentrations administered were calculated to be approximately 2 and 200 mg PEB/1 air (2,000 and 200,000 mg/m³; 97.6 and 9,760 ppm). No deaths were reported at either exposure level. Symptoms such as eye squint, changed respiratory rates, prostration, salivation, lacrimation, erythema, and decreased motor activity were noted at both exposure levels during the treatment periods. At 2 mg/l (97.6 ppm) the animals exhibited complete recovery within 24 hours. No additional symptoms were noted over the 14-day observation period. At 200 mg/l (9,760 ppm) dyspnea was also observed. Decreased motor activity persisted throughout the 9th day. Corneal opacity, chemosis, and drying of the corneal surface persisting through the 9th day were also observed. Corneal opacity was reported in one rat on the 10th and 11th day and in one rat on the 14th day. It was not specifically stated whether the same rat was involved each time.

Industrial Bio-Test performed a heated vapor inhalation toxicity study of PEB in which five male and five female Charles River rats were exposed to 0.57 mg PEB/1 air for 4 hours and were subsequently observed for a 14-day period (Ref. 22). The report did not provide any indication of the method of measuring the vapor concentration of PEB. Normal weight gains were reported for all animals. Necropsies performed at the end of the observation period did not reveal any gross pathologic changes.

c. *Dermal Studies.* Industrial Bio-Test applied PEB (3,000 mg/kg) as a slurry in 3 percent (w/v) aqueous methylcellulose to the shaved skin of four New Zealand white rabbits (two males and two females) (Ref. 20). The skin of one animal of each sex was abraded. The application site was covered by securely taped impervious plastic sheeting for 24 hours, at which time the bandages and the residual test material were removed. No deaths occurred during the 14-day observation period. At 24 hours pale red erythema was noted in the treated areas and was still observable at 7 days. At 14 days, it was barely perceptible, and mild desquamation was noted. No gross pathologic changes were noted upon necropsy at 14 days.

Great Lakes (Ref. 21) employed two dosage levels of PEB (200 and 2,000 mg/kg) in a similar experimental protocol using two males and two female New Zealand white rabbits at each dose level. No deaths occurred during the 14-day observation period. One animal at each dose level lost weight, but this was attributed to injuries received during the experiment and was not considered compound related.

Ethyl Corp. (Ref. 23) reported the dermal LD₅₀ of PEB in the New Zealand white rabbit to be > 8,000 mg/kg (the highest dose mechanically feasible); however, no further information was provided.

Great Lakes (Ref. 21) performed skin irritation tests using three male and three female New Zealand white rabbits. The clipped skin of three of the animals was abraded with a scalpel blade. PEB (500 mg/animal) was applied as a grainy powder and was covered for 24 hours by occlusive bandages, after which the bandages and residual test material were removed. The sites were examined and scored for evidence of irritation at 24 and 72 hours. No edema was observed in any test animals. Erythema was noted in one animal with intact skin and one which abraded skin at 24 hours. No erythema was observed at 72 hours. The author concluded that PEB was not a primary skin irritant. In similar tests Industrial Bio-Test classified PEB as moderately irritating (Ref. 20).

d. *Eye Irritation.* Great Lakes (Ref. 21) commissioned an eye irritation test using three male and three female New Zealand white rabbits. Slight to moderate conjunctival redness was observed in five of the six animals at 24 hours. This persisted throughout the 7-day observation period. Very slight chemosis was seen in one animal at 24 and 48 hours, but was not noted at later examinations. No discharge was observed in any of the test animals. The investigators considered PEB a possible slight eye irritant. In similar tests Industrial Bio-Test classified PEB as minimally irritating to rabbit eyes (Ref. 20).

Ethyl Corp. (Ref. 24) performed an eye irritation study in an unspecified animal (probably the rabbit) according to standard techniques in which 100 mg of PEB as a powder was applied to the eye. The treated eyes were left unwashed and were observed at 1, 2, 3, 4, and 7 days after treatment. No irritation or corneal damage was noted in treated or untreated eyes. No further experimental details were provided.

e. *Other acute studies.* Limited data are available on the effects of parenteral

administration of PEB. In a preliminary report on the effects of four times retardants on liver microsomal enzyme systems, an unquantified decrease in the N-demethylation of ethylmorphine was observed after mice were treated with unspecified levels of PEB (by intraperitoneal injection) daily for 3 days (Ref. 25).

3. *Subchronic toxicity.* Great Lakes (Ref. 19) administered PEB to male and female Charles River CD rats at 0, 100, and 1,000 ppm in the diet (10 animals/sex/dose level) for 28 days. Animals were killed and selected organs were weighted. The livers, kidneys, and thyroids were examined microscopically. Liver and fat specimens were analyzed for bromine content. No compound-related changes in behavior or appearance were observed throughout the course of the study. Male rats at both dose levels consumed less food and gained less weight than control animals. The bromine content of the liver and fat was evaluated for all treated groups. Bromine content of the livers of control rats was 2.3 ppm for males and 4.9 ppm for females. Male and female animals that received 100 ppm PEB in the diet had 5.2 and 5.5 ppm bromine, respectively, in their livers; at 1,000 ppm PEB in the diet, they had 24.2 and 40.4 ppm bromine in their livers. Control values for bromine in the fat were 1.0 ppm in males and 1.3 ppm in females. At 100 ppm PEB in the diet, males had 7.7 and females had 7.1 ppm bromine in the fat. The values were 75.5 and 61.9 ppm PEB in the diet. No compound-related gross or microscopic pathologic lesions were observed at necropsy in any of the treated animals.

At the request of Hexcel-Fine Organics Division, Consumer Product Testing Co. performed a skin sensitization study in guinea pigs using a 0.1-percent suspension of PEB in physiological saline (Ref. 26). PEB was injected intradermally into 10 white-male guinea pigs, 10 times over a 21-day period (every other day). The first injection consisted of a volume of 0.05 ml; the other 9 injections were of 0.1 ml each. Two weeks following the tenth injection a retest injection of 0.05 ml was made. Injection sites were examined and scored for the diameter, height, and color of the reaction 24 hours after each injection. Irritation was observed in all animals during the sensitization period following the third injection. One animal died during this period, but the report states that the death was not compound related. No reaction was seen in any animal following the challenge dose. PEB was not considered to be a sensitizing

material to guinea pigs under the conditions of this test.

Ethyl Corp. (Ref. 23) also performed a 21-day dermal toxicity study of PEB using 30 New Zealand white rabbits (15 males and 15 females). PEB (0, 4, or 8 g/kg bw) was applied as a powder to clipped or clipped and abraded skin. The powder was held in place with gauze and adhesive tape for a 6-hour application period, after which the powder was brushed from the sites. Applications were made daily for 21 consecutive days. Hematological, blood chemistry, and urinalysis studies were performed prior to the beginning of dosing and after the 21st application of PEB. A complete necropsy was performed on the 28 animals that were killed following the completion of the study and on the 2 that died (from causes determined to be not treatment related) during the course of the study. Animals showed an apparent dose-related decrease in weight gain (controls gained 0.28 kg in 21 days; animals dosed with 4 g PEB/kg body weight gained 0.13 kg; and animals dosed with 8 g/kg gained 0.07 kg); however, the experimenter was unable to determine whether this observation was compound-related or was caused by the increased handling of the treated animals. No dermal irritation was seen in any animal in any treatment group at any time throughout the course of the study. No treatment related effects were observed in the hematologic, blood chemistry, or urine analyses. No treatment-related effects were observed upon necropsy or histopathological examination.

4. *Chronic toxicity.* No chronic toxicity data for PEB were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

5. *Developmental and reproductive toxicity.* No developmental or reproductive toxicity data for PEB were located in the available literature or were reported under TSCA section 8(d) (49 FR 46741) for this chemical.

A teratological evaluation of a structurally related compound, pentabromomethylbenzene (PMB), is available in abstract form (Ref. 27). The compound was administered orally to rats on gestational days 6 through 15 at 0, 7.5, 150, 300, and 600 mg/kg bw/day. No significant effect of the treatment was noted in any of the parameters studied. These parameters included maternal weight gain, maternal hematology and serum biochemistry, litter size, fetal weight, deciduoma, fetal skeletal and visceral abnormalities, and microscopic tissue changes.

6. *Mutagenicity.*—a. *Gene mutation studies.* Pentabromoethylbenzene has been tested for mutagenicity in *Salmonella typhimurium* and *Saccharomyces cerevisiae* (Refs. 28 and 29). In both studies *Salmonella* strains TA1535, TA1537, TA1538, TA98, and TA100 and *Saccharomyces* strain Dr were employed in a plate incorporation assay both with and without metabolic activation. In one study (Ref. 28), concentrations of PEB were employed ranging from 0.05–50 g/plate. In the other study (Ref. 28), six concentrations (from 0.1–5,000 g/plate) were used. The results of the tests were all negative and PEB was judged to be nonmutagenic under these conditions.

NTP (Ref. 30) performed a series of tests using *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100. PEB in dimethylsulfoxide (0, 333, 1,000, 3,333, 6,666, or 10,000 g/plate) was tested with or without activation by S-9. The results were uniformly negative under these conditions.

b. *Chromosomal aberration studies.* No data on the ability of PEB to cause cytogenetic damage were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

c. *Other studies indicative of genetic damage.* No other data on the ability of PEB to cause genetic damage were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

7. *Oncogenicity.* No data on the oncogenicity of PEB in animals or humans were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

E. Chemical Fate

1. *Water solubility and octanol/water partition coefficient:* A water solubility of 3.96×10^{-3} mg/l (3.96 ppb) and a log of the octanol/water partition coefficient (log P) of 7.83 have been calculated for PEB (Ref. 31). These values indicate that under equilibrium conditions, PEB will partition primarily into the soil/sediment compartment.

2. *Soil mobility.* The sorption properties of PEB to soil have not been reported in the available literature. However, using equations developed by Lyman et al. (Ref. 32) a value for the soil-sorption coefficient (K_{oc}) of 7.42 has been calculated (Ref. 31) for PEB from its calculated log P of 7.83 (Ref. 31). This estimate of log K_{oc} indicates that PEB will substantially partition to organic matter in soil and sediment and be highly immobile in these media.

3. *Persistence.* EPA is not aware of any information on the environmental

persistence of PEB in the available literature. The structure of PEB used by analogy to other halogenated aromatic compounds, that PEB might be extremely persistent, with the aromatic part of the molecule highly resistant to biodegradation and chemical attack. However, the aliphatic side chain can be biodegraded.

F. Environmental Effects

1. *Bioconcentration.* No data were found in the available literature on the bioconcentration of PEB in aquatic organisms. Using the equation ($\log BCF = 0.85 \log P - 0.70$) developed by Veith (Ref. 33), the log of the bioconcentration factor (log BCF) for PEB estimated from its log P value is 5.79. This estimate indicates that PEB may bioconcentrate to a significant degree.

A structurally related compound, pentabromomethylbenzene (PMB), in study with juvenile Atlantic Salmon (Ref. 34), exhibited a fairly low uptake from water (96 hours) and from food (83 days). Depuration half-lives were 32 and 83 days for uptake from water and food, respectively. It should be noted that 96 hours is a fairly short time for evaluating chemical uptake from water, and that extended period of testing might have resulted in much higher accumulation. The relatively long depuration half-life also creates some concern for potential chronic effects.

2. *Acute and chronic effects on aquatic invertebrates, and plants.* No data were located on PEB in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

III. Findings

A. Health Effects

Ethyl Corp. has submitted to EPA occupational exposure information, production volumes for 1980–1984, export data for 1984, and sales volume to its domestic customers for 1984 as CBI (Refs. 8, 9 and 15). On the basis of this information EPA concludes that section 4(a)(1)(B) finding for health effects cannot be supported because of lack of substantial production and because human exposure to PEB is neither significant nor substantial. Furthermore, EPA concludes that the current exposures to PEB, taken together with the existing health effects data discussed in Unit II.D of this notice, do not provide a basis for a section 4(a)(1)(A) finding under TSCA. However, EPA is considering an appropriate followup activity to monitor future increased production or use of

PEB. Should such increases occur, EPA would reconsider the need to propose health effects testing of PEB.

B. Chemical Fate and Environmental Effects

In the area of chemical fate and environmental effects testing, EPA is making a section 4(a)(1)(A) finding.

The section 4(a)(1)(A) findings for chemical fate and environmental effects are as follows:

EPA finds that the manufacture, processing, and disposal of PEB may present an unreasonable risk of injury to the environment because PEB is potentially persistent, PEB may bioconcentrate, and there is potential for release of PEB to the environment.

EPA also finds that there are insufficient chemical fate and environmental effects data to reasonably determine or predict the chemical fate and environmental effects of such PEB releases. The finding of potential unreasonable risk is based on two considerations: (1) The structure of PEB suggests by analogy to other halogenated aromatic compounds that PEB might be extremely persistent. PEB's structure suggests that most of the molecule will be highly resistant to biodegradation and chemical change. Although the ethyl group offers a potential point of attack by microorganisms, only testing can resolve the question of degradability. (2) PEB's estimated log P suggests that PEB may bioconcentrate to a significant degree. Pentabromomethylbenzene (PMB), structurally related to PEB, appears to be poorly absorbed in juvenile Atlantic salmon, but once taken up it is excreted very slowly. PEB may respond similarly. Therefore, because PEB may bioconcentrate and because a structurally related compound shows potential for bioconcentration, EPA is proposing such testing.

EPA finds that additional chemical fate and environmental effects testing of PEB is necessary to develop data to evaluate the chemical fate and environmental effects of PEB. Because wastewater from PEB manufacture goes to a POTW and EPA has no information on concentrations of PEB entering or leaving the POTW, testing is necessary to determine whether PEB entering treatment is completely removed by degradation and absorption onto sludge, or whether POTW effluent may still contain PEB that may pose a risk to aquatic life. EPA encourages manufacturers and processors to submit any available data or to monitor POTW influent and effluent as well as sludge PEB concentrations. Such information could be useful to EPA in determining

the need for chemical fate and environmental effects testing.

EPA is not proposing testing in aquatic plants, algae, or pelagic fish because, on the basis of PEB's extremely low water solubility and high sediment sorption coefficient, the Agency believes PEB would partition to the organic phase of sediment and to lipids in biological tissues and that a benthic organism such as the oyster provides a better test organism to assess the aquatic toxicity and bioconcentration potential of PEB.

IV. Proposed Rule

A. Proposed Testing and Test Standards

On the basis of the findings given above for chemical fate and environmental effects testing (see Unit III.B), the Agency is proposing chemical fate and environmental effects testing of PEB. Test methods under new parts 796 and 797 of 40 CFR were published in the Federal Register of September 27, 1985 (50 FR 39252). Initial testing would consist of chemical fate testing to determine whether PEB would be released to the aquatic environments, and be persistent in soil environments. The initial tests are (1) water solubility, (2) semicontinuous activated sludge biodegradation and physical removal adsorption on sludge and (3) inherent biodegradability in soil. The Agency is proposing that PEB be tested for water solubility using the test specified in 40 CFR 796.1800. Although EPA has estimated PEB's water solubility (see Unit II.E.1), the Agency considers it necessary that an experimentally determined water solubility be obtained for this compound because this information is necessary before other tests on PEB can be conducted. The Agency is proposing that PEB be tested for semicontinuous activated sludge biodegradation and physical removal by adsorption on sludge using the test specified in 40 CFR 796.3341. The Agency is proposing that PEB be tested for inherent biodegradability in soil using the test specified in 40 CFR 796.3400.

The semicontinuous activated sludge and physical removal by adsorption test will allow EPA to evaluate whether releases of PEB to waste water treatment facilities will be removed by such treatment or will potentially be released to the aquatic environment. The Agency is proposing that if any PEB is found in the aqueous phase in the semicontinuous activated sludge and physical removal by adsorption test specified in 40 CFR 796.3341, the following three tests be conducted: (1) Biodegradation rate using the protocol

described in a study by Bourquin et al. (Ref. 35); (2) acute aquatic toxicity in benthic organisms (oyster) using the test specified in 40 CFR 797.1800; (3) bioconcentration in benthic organisms using the test specified in 40 CFR 797.1830.

The Agency is proposing that the above referenced TSCA Chemical Fate and Environmental Effects Test Guidelines and other cited methods be considered the test standards for the purposes of the proposed tests for PEB. The TSCA guidelines for chemical fate and aquatic toxicity testing specify generally accepted minimal conditions for determining chemical fate and aquatic animal toxicities for substances like PEB to which aquatic life is expected to be exposed. The Agency's review of the guidelines, which occurs on a yearly basis as described in 47 FR 41857 (September 22, 1982), has found no reason to conclude that these protocols need to be modified significantly except for the protocol for the semicontinuous activated sludge test. Modifications to this test are necessary because of PEB's limited water solubility. Additionally, the test procedure employed by Bourquin et al. (Ref. 35) specifies, in EPA's judgment, minimal test conditions and practices for acceptable investigations of PEB's rate of biodegradation. Although the Agency has not issued a TSCA testing guideline for biodegradation rate, the testing procedures found in this reference reflect the current state of the science for such testing and is being proposed as an acceptable method for testing PEB's biodegradation rate.

EPA intends to propose shortly in a separate Federal Register notice, certain revisions to these TSCA Test Guidelines to provide more explicit guidance on the necessary minimum elements for each study. These revisions will avoid repetitive chemical-by-chemical changes to the guidelines in their adoption as test standards for chemical-specific test rules. EPA is proposing that these modifications be adopted in the test standards for PEB.

B. Test Substance

EPA is proposing that PEB of at least 95 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 PEB itself. Commercial PEB is 95 percent pure.

C. Persons Required To Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Agency

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 and disposal of PEB on the environment, EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, PEB 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.

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.

When both manufacturers and processors are subject to a test rule, EPA expects that manufacturers will conduct the testing and that processors will ordinarily be exempted from testing. As described in 40 CFR Part 790, processors will be granted an exemption automatically without filing applications if manufacturers perform all of the required testing. Manufacturers 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 test rule.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for PEB. As noted in Unit IV.B, EPA is interested in evaluating the effects attributable to PEB itself and has specified a relatively 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 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 at least 30 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 water solubility test, semicontinuous activated sludge and physical removal by adsorption test, and the inherent biodegradability in soil test shall be completed and the final results submitted to EPA within 1 year of the effective date of the final test rule. Quarterly progress reports shall be submitted beginning 90 days after the effective date of the final rule.

2. The biodegradation rate test, acute aquatic toxicity in oyster test, and bioconcentration in oyster test shall be completed and the final results submitted to EPA within 2 years of the effective date of the final test rule if triggered by results from the semicontinuous activated sludge and physical removal by adsorption test. Quarterly progress reports shall be submitted beginning 120 days after submission of study plans for these tests.

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 (45 FR 82844; December 18, 1980). In brief, as of the effective date of the final test rule, an exporter of PEB must report to EPA the first annual export or intended export of PEB to an one country. EPA will notify the foreign country about 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 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 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 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 consid a testing facility to be a place where a chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audi will be conducted periodically in accordance with the authority and procedures outlined in TSCA section by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for PE. These inspections may be conducted purposes which include verification t testing has begun, that schedule being met, that reports accurat the underlying raw data and interpretations and evaluations, and determine compliance with TSCA GI standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b) of the TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspection 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 may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person v

violates section 15 could be subject to a civil penalty of up to \$25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions. 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 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 environmental effects and chemical fate testing of PEB. 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 PEB. Also regarding testing of PEB, the Agency requests comments on:

1. The adequacy of this testing.
2. The reporting times for the identified chemical fate and environmental effects tests.
3. Whether there are any other testing approaches which should be considered.

VI. Economic Analysis of Proposed Rule

To assess the economic impact of this rule, EPA has prepared an economic analysis that evaluates the potential for significant economic impacts 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 PEB: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations.

Total testing costs for the proposed rule for PEB are estimated to range from \$22,396 to \$68,602. This estimate includes the costs for both the required minimum series of tests as well as the conditional tests. The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from \$5,803 through \$17,776. The cost of the first tier of testing ranges from \$15,646 to \$42,102, or only \$2,137 to \$6,669 on an annualized basis. There should be no adverse economic impact from the first tier tests. Based on the 1984 production volume reported under section 8(a) of TSCA (CBI), and the current list price for PEB of \$2.35 per pound, the annualized total test cost for both the first and second tier tests could represent a significant impact on PEB as a percent of sale price. This conclusion is based on the following observations: (1) The annual unit cost of the testing required in this rule is high relative to expected revenue; (2) the market for PEB appears to be declining; and (3) the likelihood of substitutes among brominated flame retardants indicates that demand for PEB is relatively elastic with respect to price. Therefore, EPA tried to minimize any adverse economic impact by proposing tiered testing requirements and initial tests that are few and inexpensive. Testing beyond this limited first tier may not be necessary. Should the second set of testing be triggered from the results of the semicontinuous activated sludge and physical removal by absorption test, EPA concludes that the importance of the potential adverse environmental effects outweighs the possible adverse economic effects.

Refer to the economic analysis, which is available in the public record for this rulemaking (docket number OPTS-42075), for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

VII. 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) (PB 82-140773) in Springfield, VA. 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.

VIII. 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 in Washington, D.C. after the close of the public comment period. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free (800-424-9085); in Washington, D.C. (554-1404); outside the U.S.A. (Operator—202-554-1404), by December 30, 1985. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. 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.

IX. Public Record

EPA has established a record for this rulemaking, (docket number OPTS-42075). This record contains the basic information considered by the Agency in developing this proposal and appropriate Federal Register notices. The Agency will supplement this record with additional information as received.

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 pentabromoethylbenzene to the Priority List (49 FR 46931; November 29, 1984).
 - (b) Rules requiring TSCA section 8(a) and (d) reporting on pentabromoethylbenzene (49 FR 46739, 49 FR 46741; November 23, 1984).
 - (c) Notice containing TSCA test guidelines as test standards for this rule.

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

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

(f) TSCA GLP Standards (48 FR 53922; Nov. 29, 1983).

(2) Support document consisting of pentabromoethylbenzene economic analysis.

(3) Communications before proposal consisting of:

(a) written public comments and letters.

(b) Contract reports of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished factual materials.

B. References

(1) Nemetz, R. Great Lakes Corp., West Lafayette, IN 47906. Transcribed telephone conversation with S. Beala, Syracuse Research Corp., Syracuse, NY 13210. February 15, 1985.

(2) Velsicol Chemical Corp., Chicago, IL 60611. Letter from A.A. Levin to M. Greif, TSCA Interagency Testing Committee. Washington, D.C. 20460. Nov. 14, 1983.

(3) USITC, U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1980. Publication No. 1183. U.S. Government Printing Office, Washington, D.C. 1981.

(4) USITC, U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1981. Publication No. 1282. U.S. Government Printing Office, Washington, D.C. 1982.

(5) USITC, U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1982. Publication No. 1422. U.S. Government Printing Office, Washington, D.C. 1983.

(6) USITC, U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1983. Publication No. 1588. U.S. Government Printing Office, Washington, D.C. 1984.

(7) Ethyl Corp., Baton Rouge, LA 70801. Letter and enclosures from R.L. Smith to M. Greif, TSCA Interagency Testing Committee. Washington, D.C. 20460. February 1, 1984.

(8) Ethyl Corp., Baton Rouge, LA 70808. 8(a) submission 80823850 Confidential Business Information. February 27, 1985.

(9) Ethyl Corp., Baton Rouge, LA 70808. Letter to J. Harris, Test Rules Development Branch, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 20460. Confidential Business Information. DC No. 40-8560069. February 7, 1985.

(10) Kirk-Othmer, Kirk-Othmer Encyclopedia of Chemical Technology, 3rd ed. Vol. 10. John Wiley and Sons, Inc. New York. p. 384-387. 1980.

(11) Chemycyclopedia. The Annual Manual of Chemicals. VI. An American Chemical Society Publication. p. 124-125. 1982-1983.

(12) Ethyl Corp. Technical bulletin: Saytech flame retardants. Ethyl Tower, 451 Florida Blvd., Baton Rouge, LA 70801. n.d.

(13) Ethyl Corp., Baton Rouge, LA 70808. Letter (with CBI deleted by Ethyl Corp.) to J. Harris, Test Rules Development Branch, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 20460. February 7, 1985.

(14) Ethyl/Saytech, Sayreville, NJ 08872. Letter to J. Harris, Test Rules Development Branch, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 20460. March 15, 1985.

(15) Ethyl/Saytech, Sayreville, NJ 08872. Letter to Document Control Officer, Environmental Protection Agency, Washington, D.C. 20460. Pentabromoethylbenzene: 1984 sales volumes. Confidential Business Information: Document Control No. 40-8500075. March 15, 1985.

(16) OSHA Safety and Health Standards, 29 CFR 1910.1010.1000 Table Z-3. U.S. Dept. of Labor, OSHA. Revised, June 1981.

(17) Ethyl Corp., Ethyl Tower 451 Florida Blvd., Baton Rouge, LA 70808. Saytech 105: Material Safety Data Sheet. May 4, 1984.

(18) Mr. Aiello, Middlesex County Utilities Authority, Sayreville, NJ 08872. Transcribed telephone conversation with J. Robinson, Syracuse Research Corp., Syracuse, NY 13210. May 8, 1985.

(19) Great Lakes Chemical Corp., West Lafayette, IN 47906. TSCA sec. 8(d) submission 878214933. Twenty-eight day toxicity study in rats. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1985.

(20) Velsicol Chemical Corp., Chicago, IL 60611. TSCA sec. 8(d) submission 878214862. Acute toxicity studies with pentabromoethylbenzene, 1978. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1984.

(21) Great Lakes Chemical Corp., West Lafayette, IN 47906. TSCA sec. 8(d) submission 878214931. Acute toxicity studies in rats and rabbits. Pentabromoethylbenzene, 1973. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1985.

(22) Velsicol Chemical Corp., Chicago, IL 60611. TSCA sec. 8(d) submission 878214881. Acute heated vapor inhalation toxicity study with pentabromoethylbenzene in rats, 1978. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1984.

(23) Ethyl Corp., Baton Rouge, LA 70808. TSCA sec. 8(d) submission 878214943. Twenty-one day dermal toxicity study on rabbits, 1976. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1985.

(24) Ethyl Corp., Baton Rouge, LA 70808. TSCA sec. 8(d) submission 878214942. Eye irritation study. Assay No. 174-185, 174-186, 1975. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1985.

(25) Lundberg, P. Effects of some flame retardants on the liver microsomal enzyme system. In: Microsomes, drug oxidation, and chemical carcinogenesis [4th Int. Symp. Microsomes Drug Oxid., Conn MJ, ed. Vol. 2:853-858. 1980.

(26) Ethyl Corp., Baton Rouge, LA 70808. TSCA sec. 8(d) submission 878214941. Guinea

pig sensitization: pentabromoethylbenzene, 1976. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1985.

(27) Ruddick, J.A., Black, W.D., Villeneu- D.C., Valli, V.E. "A teratological evalua- pentachlorotoluene and pentabromotolu- following oral treatment in the rat. (Abstract)." *Teratology* 29(2):56A. 1984.

(28) Velsicol Chemical Corp., Chicago, IL 60611. TSCA sec. 8(d) submission 878214893. Mutagenicity evaluation of 859-74-8. Final report, 1978. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1984.

(29) Great Lakes Chemical Corp., West Lafayette, IN 47906. TSCA sec. 8(d) submission 878214932. Mutagenicity evaluation of pentabromoethylbenzene, 1977. Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1985.

(30) NTP, National Toxicology Program studies on pentabromoethylbenzene referenced in the ITC 15th report, pg. 100, no. 8. Submitted by V. Fung of NTP to J. Harris, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 1985.

(31) Syracuse Research Corporation, Merrill Lane, Syracuse, NY 13210. Draft Final Technical Support Document: Pentabromoethylbenzene. Prepared for Test Rules Development Branch, Office of Toxic Substances, Environmental Protection Agency, Washington, D.C. 20460. Contract No. 88-02-4208. May 28, 1985.

(32) Lyman, W. J., Reehl, W. F. and Rosenblatt, D. H. Handbook of Chemical Property Estimation Methods. New York: McGraw-Hill, Chapters 1, 2, 4, 12, 14, a. 1982.

(33) Veith, G. D.; DeFoe, D. L., and Bergstedt, B.I. "Measuring and estimating the bioconcentration factor of chemicals in fish." *J. Fish Res. Board Can.* 38:1040-1048. 1979.

(34) Zitko, V. and Carson, W. G. "Uptake and excretion of chlorinated diphenyl ethers and brominated toluenes by fish." *Chemosphere* 6:293-301. 1977.

(35) Bourquin, A. W., Hood, M. A., and Garnas, R. L. "An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment." Ch. 11 in Vol. 18 of Developments in Industrial Microbiology. Published by the Society for Industrial Microbiology, 1977.

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 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. enterprises 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 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) They are not expected to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs in securing exemption from testing requirements; and (3) 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 of OMB 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 796 and 799

Testing, Environmental protection; Recordkeeping and reporting requirements, Hazardous substances, Chemical fate, Chemicals.

Dated: November 5, 1985.

John A. Moore,
Assistant Administrator for Pesticides and Toxic Substances.

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

PART 796—[AMENDED]**1. In Part 796:**

a. The authority citation for Part 796 is revised to read as follows:

Authority: 15 U.S.C. 2803, 2811, 2825.

b. By adding new § 796.3341, to read as follows:

§ 796.3341 Inherent biodegradability: Modified SCAS test for chemical substances that are water insoluble or water insoluble and volatile.

(a) *Introductory Information*—(1) *Prerequisites.* (i) Water solubility.

(ii) The organic carbon content of the test material must be established.

(2) *Guidance information.* (i) Information on the relative proportions of the major components of the test material will be useful in interpreting the results obtained.

(ii) Information on the toxicity of the chemical may be useful to the interpretation of low results and in the selection of appropriate test concentrations.

(3) *Standard documents.* This Test Guideline has been based on the paper cited under paragraph (d)(1) and (2) of this section.

(b) *Method*—(1) *Introduction, purpose, scope, relevance, application and limits of test.* (i)(A) The method is an adaptation of the Soap and Detergent Association Semi-Continuous Activated Sludge (SCAS) procedure for assessing the primary biodegradation of alkylbenzene sulphonate. The method involves exposure of the chemical to relatively high concentrations of microorganisms over a long time period (possibly several months). The viability of the microorganisms is maintained over this period by daily addition of a settled sewage feed.

(B) Since the conditions provided by the test are highly favorable to the selection and/or adaptation of microorganisms capable of degrading the test chemical, the procedure may also be used to produce microbial inocula adapted to selected chemicals for use in other tests. The test is applicable to organic chemicals that are water insoluble or water insoluble and volatile and that are not inhibitory to bacteria at the test concentration.

(ii) *Reference substances.* In some cases when investigating a new substance, reference substances may be useful; however, specific reference

substances cannot yet be recommended. Data on several compounds used in ring tests are provided (see Table 1) primarily so that calibration of the method may be performed from time to time and to permit comparison of results when method is employed.

(iii) *Principle of the test method.* (A) Activated sludge from a sewage treatment plant is placed in an aeration (SCAS) unit. The test compound and settled domestic sewage are added, and the mixture is aerated for 23 hours. The aeration is then stopped, the sludge allowed to settle and the supernatant liquor is removed. The sludge remaining in the aeration chamber is then mixed with a further aliquot of test compound and sewage and the cycle is repeated.

(B) This method requires use of a compound-specific analytical technique or ¹⁴C-labeled test compound. The purpose of the method is to determine the fate of the test compound in a conventional activated sludge treatment plant. To this end, a complete mass balance for the test compound is established, by quantifying parent compound in settled effluent sludge, solids (insoluble test compounds whether volatile or not), effluent plus solids (insoluble test compounds whether volatile or not), and off gases (volatile test compounds only). The identification and quantification of degradation products in all phases is recommended, but not required.

(iv) *Quality Criteria*—(A) *Reproducibility.* The reproducibility of this method has not yet been established. When primary biodegradation is considered, very precise data are obtained for materials that are extensively degraded. The results reported in the reference under paragraph (d)(1) of this section suggest 95-percent confidence limits of less than ±3 percent; and this includes interlaboratory tests. As would be expected, wider confidence limits are obtained for less biodegradable chemical substances.

(B) *Possibility of standardization.* Since the method uses a feed of settled sewage, absolute standardization is not possible unless this feed were replaced by synthetic sewage. However, since the method is designed to give an indication of the biodegradability potential of a chemical and is not a simulation test such standardization is unnecessary.

(C) *Possibility of automation.* Automation of this method would be possible but would be expensive. As the method is not labor intensive, the exercise would offer few advantages.

(2) *Description of the test procedure*—(i) *Preparations.* (A) The aeration units

are cleaned and fixed in a suitable support. The air inlet tubes are connected to the supply manifold. A small laboratory-scale air compressor is used to aerate the units, and the air is presaturated with water to reduce evaporation losses from the units.

(B) If the test compound is volatile, exhaust gases from the aeration units should be passed through a suitable trap (such as Amberlite XAD-4, Rohm and Haas, Phila., PA) to remove volatilized organics.

(C) A sample of mixed liquor from an activated sludge plant treating predominantly domestic sewage is obtained. Approximately 150 ml of the mixed liquor are required for each aeration unit.

(D) The organic carbon analyzer is calibrated using potassium hydrogen phthalate.

(E) Stock solutions of the test compounds are prepared: the concentration normally required is 400 mg/L as organic carbon which gives a test compound concentration of 20 mg/L carbon at the start of each aeration cycle if no biodegradation is occurring.

(F) If the test compound is insoluble in water at 400 mg/L it may be necessary to use ultrasound dispersion to obtain a uniform stable suspension.

Alternatively, test compound may be added directly to the aeration units.

(G) The organic carbon content of the stock solutions is measured.

(ii) *Test conditions.* A high concentration of aerobic microorganisms is used, and the effective detention period is 36 hours. The carbonaceous material in the sewage feed is oxidized extensively within 6 hours of the start of each aeration cycle. Thereafter, the sludge respire endogenously for the remainder of the aeration period, during which time the only available substrate is the test compound unless this is also readily metabolized. These features, combined with daily reinoculation of the test when domestic sewage is used as the medium, provide highly favorable conditions for both adaption and biodegradation.

(iii) *Performance of the test.* (A) A sample of mixed liquor from a suitable activated sludge plant is obtained and aerated during transportation to the laboratory. Each aeration unit is filled with 150 ml of mixed liquor and the aeration is started. After 23 hours, aeration is stopped, and the sludge is allowed to settle for 45 minutes. The tap is opened and 100 ml of the supernatant liquor withdrawn. A sample of settled domestic sewage is obtained immediately before use, and 100 ml are added to the sludge remaining in each aeration unit. Aeration is started anew.

At this stage no test materials are added, and the units are fed daily with domestic sewage only until a clear supernatant liquor is obtained on settling. This usually takes up to two weeks, by which time the dissolved organic carbon in the supernatant liquor at the end of each aeration cycle should be less than 12 mg/L.

(B) At the end of this period the individual settled sludges are mixed, and 50 ml of the resulting composite sludge are added to each unit.

(C) One hundred ml of settled sewage are added to the control units and 95 ml of settled sludge plus 5 ml of the appropriate test compound stock solution or suspension (400 mg/l) to the test units. If test compound is added directly to aeration units, 100 ml of settled sewage is added, as in the control units.

(D) The sludge is then allowed to settle for 45 minutes and the supernatant drained off and analyzed for parent compound. Before analysis the liquors are filtered through washed 0.45 micrometer membrane filters and centrifuged. Temperature of the sample must not exceed 40°C while it is in the centrifuge.

(E) If the test compound is insoluble or expected to sorb significantly to sludge solids, settled sludge is also collected by an appropriate means (such as centrifugation) and extracted to remove test compound, and the extract is analyzed for parent compound.

(F) If the test compound is volatile, traps for removing volatile organics from exhaust gases are also extracted and the extracts analyzed for parent compound.

(G) The fill and draw procedure under paragraph (b)(2)(iii) of this section is repeated daily throughout the test.

(H) Before settling, it may be necessary to clean the walls of the units to prevent the accumulation of solids above the level of the liquid. A separate scraper or brush is used for each unit to prevent cross contamination.

(I) The length of the test for compounds showing little or no biodegradation is indeterminate, but experience suggests that this should be at least 12 weeks.

(c) *Data and reporting*—(1) *Treatment of the results.* (i) The concentration of parent compound in settled effluent sludge solids (insoluble test compounds whether volatile or not), effluent plus solids (insoluble test compounds whether volatile or not), and off-gases (volatile test compounds only) is plotted versus time, for both test and control units. As biodegradation is achieved the level found in the test will approach that found in the control. Once the difference between the two levels is found to be

constant over three consecutive measurements, three further measurements are made.

(ii) An example of the application of specific analytical technique to the SCAS test is discussed in paragraph (d)(2) of this section.

(d) *Literature references.* For additional background information on this test guideline the following references should be consulted:

(1) "A Procedure and Standards for the Determination of the Biodegradability of Alkyl Benzene Sulphonate and Linear Alkylate Sulphonate", *Journal of the American Chemical Society*, 42:986, 1935.

(2) Games, L.M., King, J.E., and Larson, R.J. "Fate and distribution of a quaternary ammonium surfactant octadecyltrimethylammonium chloride (OTAC), in wastewater treatment." *Environmental Science and Technology* 16:483-488, 1982.

TABLE 1.—EXAMPLES OF RESULTS OF SCAS TEST ON VARIOUS COMPOUNDS USED IN THE OECD/EEC RING TEST

Test compound	C ₀ (mg/l)	C ₀ -C _t (mg/l)	Percent age biodegradation biomass flow
4-Acetylamino-benzene sulphoxide	17.2	2.0	86
Tetracyclohexene-benzene sulphoxide	17.3	8.4	51
4-Nitrophenol	16.9	0.8	96
Dialkylamine glycol	16.5	0.2	98
Aniline	16.9	1.7	94

Duration of test 40 days.

RESULTS FOUND FOR CYCLOPENTANE TETRACARBOXYLATE

C ₀ (mg/l)	C ₀ -C _t (mg/l)	Percentage biodegradation/biomass flow
17.9	3.2	81

Duration of test 120 days.

PART 799—[AMENDED]

2. In Part 799:

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

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

b. By adding new § 799.3205 to read as follows:

§ 799.3205 Pentabromoethylbenzene.

(a) *Identification of test substance.* (1) Pentabromoethylbenzene (CAS No. 85-22-3) shall be tested in accordance with this section.

(2) Pentabromoethylbenzene of at least 95 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 or process pentabromoethylbenzene other than as an impurity after the effective date of this section, December 27, 1985, to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests in accordance with Part 792 of this chapter, and submit data as specified in this section, Subpart A of this Part, and Part 790 of this chapter for single-phase rulemaking.

(c) *Chemical fate testing—(1) Water solubility—(i) Required testing.* A water solubility test shall be conducted with pentabromoethylbenzene in accordance with the test guideline for water solubility specified in § 796.1860 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The water solubility test shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

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

(2) *Biodegradability and physical removal by adsorption in sludge systems—(i) Required testing.* Biodegradability and physical removal by adsorption tests in sludge systems shall be conducted with pentabromoethylbenzene in accordance with the guideline specified in § 796.3341 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The biodegradability and physical removal by adsorption 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.

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

(3) *Biodegradability in soil—(i) Required testing.* Biodegradability tests in soil shall be conducted with pentabromoethylbenzene in accordance with the test guideline specified in § 796.3400 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The biodegradability test in soils shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

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

(4) *Biodegradation rate—(i) Required testing.* (A) Biodegradation rate tests shall be conducted with pentabromoethylbenzene in accordance with the test guideline described in a study by A. W. Bourquin et al. entitled "An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment" published in *Development in Industrial Microbiology*, Volume 18, Chapter 11, 1977, published and sold by the Society for Industrial Microbiology, POB 12538, Arlington, VA 22206-6534, if any PEB is found in the aqueous phase in the semicontinuous-activated sludge and physical removal by adsorption tests conducted in accordance with paragraph (c) (2) of this section. This test guidelines document is also available for inspection at both the Office of the Federal Register Information Center and the OPTS Reading Room (docket no. OPTS-42075). This incorporation by reference was approved by the Director of the Federal Register. These materials are incorporated as they exist on the effective date of this rule; a notice of any change will be published in the Federal Register.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) If required, the biodegradation rate tests shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 120 days after submission of study plans.

(d) *Environmental effects testing—(1) Aquatic invertebrate acute toxicity—(i) Required testing.* (A) An aquatic invertebrate acute toxicity test shall be conducted with pentabromoethylbenzene using the oyster, *Crassostrea virginica*, in accordance with the test guideline specified in § 797.1800 of this chapter and using modifications of the oyster acute toxicity test for PEB specified in paragraph (d)(1)(i)(B) of this section, if any PEB is found in the aqueous phase in the semicontinuous activated sludge and physical removal by adsorption tests conducted in accordance with paragraph (c)(2) of this section.

(B) *Modifications of the oyster acute toxicity test.* The following modifications for testing PEB are required.

(1) At least five test concentrations shall be used. The highest concentration shall be less than or equal to the solubility limit of PEB as determined under the testing specified in paragraph (c)(1)(i) of this section.

(2) *Concentration of dissolved test chemical.* The requirement under § 797.1800 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(3) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) If required, the oyster acute toxicity test shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 120 days after submission of study plans.

(2) *Biococoncentration—(i) Required testing.* (A) A biococoncentration test shall be conducted with pentabromoethylbenzene using the oyster, *Crassostrea virginica*, in accordance with the test guideline specified under § 797.1830 of this chapter and using modifications of the oyster biococoncentration test for PEB specified in paragraph (d)(2)(i)(B) of this section if any PEB is found in the aqueous phase in the semicontinuous-activated sludge and physical removal by adsorption tests conducted in accordance with paragraph (c)(2) of this section.

(B) *Modifications.* The following modifications for testing PEB are required.

(1) The test concentrations shall be less than the solubility limit of PEB as determined under the testing specified in paragraph (c)(1)(i) of this section.

(2) At least two concentrations shall be tested which are at least a factor of 10 apart.

(3) *Concentration of dissolved test chemical.* The requirement under § 797.1830 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(4) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) If required, the bioconcentration test shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 120 days after submission of study plans. (Information collection requirements have been approved by the Office of Management and Budget under control number 2070-0033.)

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