

**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Parts 721 and 799

[OPTS-420758 and OPTS-50568; FRL-3480-2]

Pentabromoethylbenzene; Withdrawal of Proposed Test Rule; Proposed Significant New Use of Chemical Substance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed rule and proposed rule.

SUMMARY: This document withdraws a proposed rulemaking to require testing of pentabromoethylbenzene (PEB, CAS Number 85-22-3) for chemical fate and environmental effects under section 4 of the Toxic Substances Control Act (TSCA). Data received by EPA since proposal of the test rule indicate that there is currently no ongoing or intended manufacture or processing of the chemical substance. Additionally, EPA is herein proposing a significant new use rule (SNUR) under section 5(a)(2) of TSCA which would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of PEB for any use. EPA believes that PEB may be hazardous to human health and the environment, and that any use of PEB and activities associated with such use may result in significant human and environmental exposure. The required notice would provide EPA with the information needed to evaluate the intended use and associated activities, and an opportunity to protect against potentially adverse exposure to PEB before it can occur.

DATE: Written comments regarding the proposed SNUR should be submitted to EPA by December 22, 1988.

ADDRESS: Since some comments may contain confidential business information (CBI), all comments should be sent in triplicate to: TSCA Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, Rm. L-100, 401 M St. SW., Washington, DC 20460.

Comments regarding the proposed SNUR should include the docket control number OPTS-50568. Nonconfidential comments on this proposed rule will be placed in the rulemaking record and will be available for public inspection. Unit XI of this preamble contains additional information on submitting comments containing CBI.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental

Protection Agency, Rm. EB-44, 401 M St. SW., Washington, DC 20460. Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: The proposed SNUR for PEB would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of PEB for any use. The required notice would provide EPA with the information needed to evaluate an intended use and associated activities, and an opportunity to protect against potentially adverse exposure to PEB before it can occur.

Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

L Background of Proposed Test Rule Withdrawal

Section 4(a) of TSCA authorizes EPA to promulgate rules which require manufacturers and processors to test chemical substances and mixtures (chemicals) they manufacture or process. Data developed through these test programs are used by EPA in assessing the risks that the chemicals may present to human health and the environment.

Section 4(e) of TSCA established the Interagency Testing Committee (ITC) to recommend chemicals for priority testing consideration by EPA under section 4(a) of TSCA. The ITC designated PEB for priority consideration in its 15th Report, which was published in the Federal Register of November 29, 1984 (49 FR 46931), the ITC based its recommendation for health effects testing on the following factors: (1) Releases from production and use were expected to result in human exposure; and (2) there was insufficient information on the chronic effects of PEB, and toxic effects were observed in other substances having a polyhalogenated aromatic moiety. Teratogenicity testing was recommended because of lack of information.

The ITC also recommended PEB for ecological effects testing. The ITC's rationale was based on the following: (1) The purported and potential uses of PEB were evidence of its probable wide distribution; (2) PEB is structurally similar to halogenated substances that have appreciable toxicity; (3) PEB is expected to partition into soils, sediments, and biota after release; and (4) data on a structurally related substance, pentabromomethylbenzene, indicate that it is taken up by aquatic organisms and 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.

EPA's response to this designation was published in the *Federal Register* of November 13, 1985 (50 FR 46785) as a proposed test rule on PEB under proposed § 799.3205. EPA proposed, pursuant to TSCA section 4(a)(1)(A) findings, that chemical fate and environmental effects testing be performed on PEB by manufacturers and processors of the substance. For a full discussion of test rule development under TSCA, and the rationale on which EPA based the proposed chemical fate and environmental effects testing, refer to the proposed test rule.

II. Decision Not To Require Testing

EPA has decided not to promulgate a rule to require testing of PEB because data available to EPA indicate that there is currently no ongoing or intended manufacture or processing of PEB. Therefore, there exist no entities that would be subject to the test rule should it be promulgated. However, to ensure that resumption of PEB production is monitored, under the authority of section 5(a)(2) of TSCA, EPA is proposing a SNUR for PEB, as described below.

III. Authority for Proposed SNUR

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Persons subject to this SNUR would comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under

section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR Part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the *Federal Register* its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR Part 707.

IV. Applicability of General Provisions to SNURs

In the *Federal Register* of September 5, 1984 (49 FR 35011), EPA promulgated general regulatory provisions applicable to SNURs (40 CFR Part 721, Subpart A). The general provisions are discussed in detail in that *Federal Register* notice, and interested persons should refer to that document for further information. On July 27, 1988, EPA published final amendments to the general provisions (53 FR 28354) which would apply to this proposed SNUR, except as provided in proposed § 721.1515(b)(1). The entire text of Subpart A was published in that document; interested parties should refer to it for further information.

V. Summary of this Proposed Rule

The chemical substance which is the subject of this proposed SNUR is PEB. EPA is proposing to designate any use of PEB as a significant new use. Thus, this proposed rule would require persons who intend to manufacture, import, or process PEB for any use to notify EPA at least 90 days before such manufacture, import, or processing.

VI. Background Information on PEB

A. Production and Use Data

PEB (listed as benzene, pentabromoethyl) on the TSCA Chemical Substance Inventory) has been used in the past as an additive-type flame retardant and was suggested for use in thermoset polyester resins for circuit boards, textiles, adhesives, wire and cable coatings, polyurethanes, and thermoplastic resins.

EPA reviewed the TSCA Chemical Substance Inventory Data Base and other information sources to identify current manufacturers, importers, and processors of PEB. The review indicates that all production and importation of

PEB in the U.S. has been discontinued as of August 1986. It is therefore unlikely that any PEB has been processed or used since 1987.

B. Human Health Effects

A 28-day feeding study submitted to EPA pursuant to TSCA section 8(d) by a former manufacturer of PEB indicates that absorption of PEB occurs when exposure is through the oral route. In this study, PEB was administered to male and female Charles River CD rats at 100 and 1,000 parts per million in the diet. At the end of the study, the bromine content of the liver and fat was elevated in a dose-related manner (Ref. 1). Very few other data on the absorption, distribution, metabolism, and elimination of PEB were located in the available literature. However, because toxic effects (e.g., carcinogenicity) are observed in other substances having a polyhalogenated aromatic moiety, and there are no available data on the chronic toxicity of PEB, EPA is concerned that PEB may cause adverse effects in humans.

C. Environmental Effects

EPA is not aware of any information on the environmental persistence of PEB in the available literature. The structure of PEB suggests, however, by analogy to other halogenated aromatic substances, that PEB may be extremely persistent, with the aromatic part of the molecule highly resistant to biodegradation/chemical attack.

No data were found in the available literature on bioconcentration of PEB in aquatic organisms. However, estimates indicate that PEB may bioconcentrate to a significant degree (Ref. 2).

A structurally related substance, pentabromomethylbenzene, in a study with juvenile Atlantic Salmon, exhibited a fairly low uptake from water (96 hours) and from food (42 days) (Ref. 3). 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 an extended period of testing might have resulted in much higher accumulation. The relatively long depuration half-lives also create some concern for potential chronic effects. No data were located from the available literature on the acute and chronic effects of PEB on fish, aquatic invertebrates, or plants.

Based on the foregoing data which indicate a potential for persistence and bioconcentration, the lack of data on potential chronic environmental effects, and PEB's structural similarity to substances of known toxicological

effect. EPA is concerned that PEB may cause adverse effects to the environment.

D. Past and Current Exposure Data

EPA has little data on actual numbers of persons who have been exposed to PEB or at what levels. Current known exposures are limited to those resulting from any residues of previously manufactured or imported PEB in the environment.

VII. Objectives and Rationale for the Rule

To determine what would constitute a significant new use of PEB, EPA considered relevant information on the toxicity of the substance, likely exposures and releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new use that is designated in this proposed rule:

1. EPA wants to ensure that it would receive notice of any company's intent to manufacture, import, or process PEB for any use before that activity begins.

2. EPA wants to ensure that it would have an opportunity to review and evaluate data submitted in a significant new use notice before the notice submitter begins manufacturing, importing, or processing PEB for any use.

3. EPA wants to ensure that it would be able to regulate prospective manufacturers, importers, or processors of PEB before any manufacturing, importing, or processing of PEB occurs, provided that the degree of potential health and environmental risk is sufficient to warrant such regulation.

PEB is structurally related to known and suspected carcinogenic substances. Data indicate that absorption occurs when PEB is administered orally. Additionally, evidence exists that PEB persists in the environment and may bioconcentrate. Currently, PEB is not subject to any Federal regulation that would notify the Federal Government of activities that might result in adverse exposures or releases, or provide a regulatory mechanism that could protect human health from potentially adverse exposures or protect the environment from potentially adverse releases before they occur.

EPA believes that the resumption of any use of PEB, and its related manufacture, import, or processing, has a high potential to increase the magnitude and duration of exposure to PEB as well as increasing the probability of environmental release. Given the potential toxicity of PEB, the

reasonably anticipated situations that could result in exposure or release, and the lack of sufficient regulatory controls, individuals and/or the environment could be exposed to PEB at levels which may result in adverse effects.

Because EPA is concerned about potential exposure during the entire life cycle of PEB, EPA is proposing to modify § 721.5(a)(2) to require any prospective manufacturer, importer, or processor of PEB who intends to distribute the substance in commerce to submit a significant new use notice.

VIII. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory actions for PEB.

1. Promulgate a TSCA section 4(a)(1)(A) test rule to require any future manufacturers and processors of PEB to perform chemical fate and environmental effects testing. The data generated from such testing could supply EPA with the information relevant to a determination as to whether the manufacture, processing, or disposal presents an unreasonable risk of injury to human health or the environment. However, the promulgation of a test rule of this type may present a significant and potentially unwarranted economic barrier to the resumption of the chemical's production or importation. Alternatively, EPA believes that a SNUR notice would provide EPA with an opportunity to evaluate the intended use and associated activities before they occur, including the extent of potential environmental and human exposure for that use scenario. Thereafter, if environmental and health concerns persist, and data are still unavailable for a thorough risk assessment, EPA could regulate the proposed activities under TSCA section 5(e).

2. Promulgate a TSCA section 6(a) reporting rule for this substance. Under such a rule, EPA could require any person to report information to EPA when they intend to manufacture, import, or process PEB for any use. However, for this particular substance, the use of section 6(a) rather than SNUR authority would have several drawbacks. First, EPA would not receive sufficient advance notification of the intended activity, nor would it be able to take immediate follow-up regulatory action under section 5(e) or 5(f) to prohibit or limit the activity. In addition, EPA may not receive important information from small businesses, because such firms are exempt from section 6(a) reporting requirements. In view of the level of health and environmental concern for PEB, EPA

believes that a section 6(a) rule for PEB would not meet EPA's regulatory objectives.

IX. Applicability of Proposed Rule to Uses Occurring Before Promulgation of Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of the SNUR rather than as of the promulgation of the final rule. If uses begun during the proposal period of a SNUR were considered ongoing as of the date of promulgation, it would be difficult for EPA to establish SNUR notice requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became final; this interpretation of section 5 would make it extremely difficult for EPA to establish SNUR notice requirements.

Persons who begin commercial manufacture, importation, or processing of PEB for a significant new use designated in this proposed rule between proposal and promulgation of the SNUR may comply with this proposed SNUR before it is promulgated. If a person were to meet the conditions of advance compliance as codified at § 721.45(h) (53 FR 28354, July 17, 1988), the person will be considered to have met the requirements of the final SNUR for those activities. If persons who begin commercial manufacture, importation, or processing of the substance between proposal and promulgation of the SNUR do not meet the conditions of advance compliance, they must cease that activity before the effective date of the rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. EPA recognizes that this interpretation of TSCA may disrupt the commercial activities of persons who begin manufacturing, importing, or processing PEB for a significant new use during the proposal period of this SNUR. However, this proposed rule constitutes notice of that potential disruption, and persons who commence the proposed significant new use prior to promulgation of the SNUR do so at their own risk.

X. Economic Analysis

EPA has evaluated the potential costs of establishing significant new use notice requirements for potential manufacturers, importers, and processors of PEB. EPA's complete economic analysis is available in the

public record for this proposed rule (OPTS-50568).

XI. Comments Containing Confidential Business Information

Any person who submits comments claimed as confidential business information must mark the comments as "confidential," "trade secret," or other appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR Part 2. EPA requests that any party submitting confidential comments prepare and submit a public version of the comments that EPA can place in the public file.

XII. Rulemaking Records

EPA has established a record for the TSCA section 4 proposed test rule (document control number OPTS-42075). Interested persons should refer to the proposed test rule for a listing of the record (50 FR 46785, November 13, 1985). Additionally, the record contains the following:

1. Letter from Ethyl Corporation, dated May 30, 1986, informing EPA of their concerns regarding the economic impact of the proposed tests on their production of PEB.
2. Letter from Ethyl Corporation, dated August 18, 1986, informing EPA of their decision to cease production of PEB.

EPA has established a record for the SNUR rulemaking (Document control number OPTS-50568). This record contains basic information considered by EPA in developing the proposed SNUR. EPA will supplement the record with additional information as it is received. The record now includes the following:

1. This proposed rule.
2. The economic analysis of this proposed rule.
3. The three documents listed under References (Unit XIII of this preamble).
4. Letter from Ethyl Corporation, dated August 18, 1986, informing EPA of their decision to cease production of PEB.
5. ITC report on PEB.

EPA will accept additional materials for inclusion in the SNUR record at any time between this proposal and designation of the complete record. EPA will identify the complete rulemaking record by the date of promulgation.

Public versions of these records containing nonconfidential materials are available for reviewing and copying from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays in the

TSCA Public Docket Office, located at Rm. NE-G004, 401 M St., SW., Washington, DC

XIII. References

1. TSCA section 8(d) submission 878214933.
2. Veith, G.D., DeFoe, D.L., and Bergstedt, B.J. "Measuring and Estimating the Bioconcentration Factor of Chemicals in Fish." *Journal of the Fishery Research Board of Canada*. 38:1040-1048, 1979.
3. Zitko, V. and Carson, W.G. "Uptake and Excretion of Chlorinated Diphenyl Ethers and Brominated Toluenes by Fish." *Chemosphere*. 6:293-301, 1977.

XIV. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this proposed SNUR would not be a "major" rule because it would not have an effect on the economy of \$100 million or more, and it would not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this rule, EPA estimates that the reporting cost for submitting a significant new use notice would be approximately \$1,400 to \$8,000. EPA believes that, because of the nature of the rule and the substance involved, there would be few significant new use notices submitted. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovation, that impact would be limited because such factors are unlikely to discourage an innovation that has high potential value.

This proposed rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this proposed rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA expects to receive few SNUR notices for the substance. Therefore, EPA believes that the number of small businesses affected by this proposed rule would not be substantial, even if all of the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act, 44 U.S.C.

3501 *et seq.*, and has assigned OMB control number 2070-0038 to this proposed rule.

Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information requirements contained in this proposal.

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: November 1, 1988.

Susan F. Vogt,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for Part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604 and 2607.

2. By adding new § 721.1515 to read as follows:

§ 721.1515 Pentabromoethylbenzene.

(a) *Chemical substance and significant new use subject to reporting.*

(1) The chemical substance pentabromoethylbenzene (CAS Number 85-22-3) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Any use.

(b) *Special requirements.* The provisions of Subpart A of this Part apply to this section except as modified by this paragraph:

(1) *Persons who must report.* Section 721.5 applies to this section except for § 721.5(a)(2). A person who intends to manufacture, import, or process for

commercial purposes the substance identified in paragraph (a)(1) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) [Reserved]

(Approved by the Office of Management and Budget under OMB control number 2070-0038)

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