Each plant emits more than 100 tons of VOC per year from flexographic processes, and as such is subject to Rule 115.201. Based on Arrow's contention that water-based and/or high solids content ink would not be available by the SIP compliance date and that "add-on" control equipment was economically infeasible, on June 10, 1983, the TACB issued two Board Orders to Arrow extending their SIP compliance date for both plants until December 31, 1985. The TACB did not, however, submit the SIP compliance date extensions to EPA for revision to the SIP, and thus the SIP-required compliance date remained December 31, 1982. On January 30, 1984, and October 9, 1985, EPA notified Arrow's Carrollton and Farmers Branch facilities, respectively, under section 113(a)(1) of the Clean Air Act that they were operating in violation of the Texas SIP. Subsequently, the TACB developed the September 20, 1985 DCOs that are now proposed for approval under this notice. The TACB transmitted the DCOs to EPA on September 27, 1985. EPA reviewed the DCOs,[1] and found that they satisfy the requirements of section 113(d) of the Clean Air Act, including public notice and hearing requirements and section 121 of the Clean Air Act regarding consultation with general purpose local governments. The full texts of these orders were published on January 7, 1986, at 51 FR 627.

Since the DCOs are approved by EPA, compliance with their terms preclude federal enforcement action under section 113 of the Clean Air Act against Arrow for violations covered by the Order during the period that the Orders are in effect. Further, enforcement under the citizen suit provision of section 304 of the Clean Air Act are similarly precluded. The approved Orders constitute an addition to the Texas SIP. However, compliance with the Orders will not preclude assessment of any non-compliance penalty under section 120 of the Clean Air Act, unless the source is entitled to an exemption under section 120(a)(2) (B) or (C).

All interested persons were invited to submit written comments on the proposed approval action. No comments were received. The public should be advised that this action will be effective on the date listed in the effective date section of this rulemaking. Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit within 60 days of the date of publication of this notice of final rulemaking. This action may not be challenged later in proceedings to enforce its requirements (See Sec. 307(b)(2)).

Each DCO affects only one entity and involves an "Order", rather than a "Rule", and therefore this action is not subject to the requirements of the Regulatory Flexibility Act or to Executive Order 12291.

The Notice of Approval is issued under the authority of sections 113 and 301 of the Clean Air Act, 42 U.S.C. 7413 and 7601.

List of Subjects in 40 CFR Part 65

Air pollution control.

PART 65—[AMENDED]

Part 65 of Chapter 1, Title 40 of the Code of Federal Regulations is amended as follows:

Subpart SS—Texas

1. The authority citation for Part 65 continues to read as follows:

Authority: 42 U.S.C 7413 and 7601.

2. In § 65.481, two entries are added to the table in alphabetical order as follows:

§ 65.481 EPA approval of State delayed compliance orders issued to major stationary sources.

* * * * *

Source	Location	Order No.	SIP regulations involved	Date of FEDERAL REGISTER proposal	Final compliance date
Arrow Industries, Inc.	Carrollton, TX	TACB No. 85-10	§ 115.201	1/7/86	12/31/85
Arrow Industries, Inc.	Farmers Branch, TX	TACB No. 85-11	§ 115.201	1/7/86	12/31/85

Dated: June 23, 1986.

Lee M. Thomas,

Administrator

[FR Doc 86-15267 Filed 7-7-86; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 799

[OPTS-47002F; FRL-3028-7]

Chlorinated Benzenes; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a final rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring: (1) Manufacturers and processors of 1,2,4-trichlorobenzene (TCB) to conduct oncogenicity testing of 1,2,4-TCB (CAS No. 120-82-1), (2) manufacturers and processors of monochlorobenzene (MCB) to conduct reproductive effects testing of MCB (CAS No. 108-90-7), (3) manufacturers and processors of ortho- and para-dichlorobenzenes (1,2- and 1,4-DCBs) to conduct reproductive effects testing of 1,2- and 1,4-DCBs (CAS Nos. 95-50-1 and 106-46-7, respectively), and (4) manufacturers and processors of 1,2,4,5-tetrachlorobenzene (1,2,4,5-TCB; CAS No. 95-94-3) to conduct reproductive effects and developmental toxicity testing of 1,2,4,5-TCB. This rule requires that the health effects testing for these chlorinated benzenes be performed according to the TSCA Health Effects Testing Guidelines in 40 CFR Part 798 for the required health effects. EPA is also terminating its rulemaking process for subchronic/chronic and oncogenicity testing of 1,2,4,5-TCB.

DATES: In accordance with 40 CFR Part 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1:00 eastern daylight time on July 22, 1986. These regulations shall become effective on August 21, 1986.

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: (800-424-9065). In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA in response to the Interagency Testing Committee's (ITC) 1977 and 1978 designations of the chlorinated benzenes for health effects testing consideration and to satisfy a 1984 court order requiring the Agency to take final action on its July 18, 1980 proposed test rule (45 FR 48524) for the chlorobenzenes by June 1986.

I. Introduction

A. Test Rule Development Under TSCA

This notice is part of the overall implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*) which contains authority for EPA to require the

[1] "EPA Review of Texas State Delayed Compliance Orders for Arrow, Incorporated, Dallas County, Texas, September 20, 1985: October-November 1985". This evaluation is available at the Region 6 address given previously in this notice.

development of data relevant to assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

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

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

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

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

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

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

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

For a more complete understanding of the statutory section 4 findings, the reader is directed to the Agency's first proposed test rule package published July 18, 1980 (45 FR 48510) for in-depth discussions of the general issues applicable to this action.

B. Regulatory History

In the **Federal Register** of October 12, 1977 (42 FR 55026), the Interagency Testing Committee (ITC) designated monochlorobenzene and the dichlorobenzenes for health and environmental effects testing consideration. On October 30, 1978 (43 FR 50630), the ITC also designated tri-, tetra- and pentachlorobenzenes for health and environmental effects testing consideration. The Agency responded to the ITC's health effects testing recommendations by issuing in the **Federal Register** of July 18, 1980 (45 FR 48524), a proposed health effects test rule for the chlorobenzenes chemical category requiring testing of specific members of both groups of chlorinated benzenes.

During October 1980 EPA held several public meetings to hear and respond to oral comments presented on various aspects of the proposed rule. The minutes for these meetings are contained in the record for this action.

In the **Federal Register** of December 7, 1983 (48 FR 54836), EPA issued a proposed rule-related notice and request for comments on a proposed negotiated testing agreement for reproductive effects testing of certain chlorinated benzenes, and a tentative decision to withdraw a number of the health effects testing requirements the Agency previously had proposed.

In late 1983, however, the Natural Resources Defense Council (NRDC) and the Industrial Union Department of the American Federation of Labor-Congress of Industrial Organizations (AFL–CIO) filed an action under TSCA section 20 which challenged, among other things, EPA's utilization of negotiated testing agreements in lieu of initiating rulemaking under TSCA section 4(a) for four ITC-designated chemical substances. In an August 23, 1984 Opinion and Order, the district court found that in EPA's responses to chemicals designated by the ITC, non-enforceable negotiated agreements may not be adopted by EPA in lieu of requiring testing through enforceable section 4(a) test rules [see *NRDC and AFL–CIO* v. *EPA*, 595 F. Supp. 1255 (S.D.N.Y. 1984)].

The Court also agreed with another NRDC complaint against the length of time EPA had taken to issue the final decision on the health effects testing of the chlorinated benzenes. In the court's Final Judgment and Order of October 30, 1984, EPA was directed to issue its final decision on the chlorinated benzenes health effects testing by June 1986.

In accordance with the court's opinion, EPA decided not to adopt the industry testing program discussed in its December 7, 1983 notice, and announced this decision in the **Federal Register** issue of December 28, 1984 (49 FR 50408).

Also in the **Federal Register** of December 28, 1984 (49 FR 50408), EPA issued a notice withdrawing several portions of the July 1980 proposed test rule on the basis of insufficient exposure, adequate testing in progress, or the availability of data to reasonably predict the risk of certain health effects that those chlorinated benzenes may present to humans. This removed from further consideration the following health effects testing: (1) Structural teratogenicity (developmental toxicity) testing for MCB, 1,2-DCB, 1,4-DCB, and 1,2,4-TCB; (2) subchronic/chronic effects testing of MCB, 1,2-DCB, 1,4-DCB and 1,2,4-TCB; and (3) oncogenicity and reproductive effects testing of pentachlorobenzene.

Having decided to withdraw certain portions of the health effects test rule proposal and not to adopt a negotiated testing program, the Agency continued with the rulemaking process for the following portions of the chlorinated benzenes health effects testing proposal: (1) Oncogenicity testing of 1,2,4-TCB; (2) chronic/subchronic toxicity, oncogenicity, teratogenicity (developmental effects), and reproductive effects testing of 1,2,4,5-tetrachlorobenzene; and (3) reproductive effects testing of MCB and 1,2- and 1,4-DCBs.

EPA also stated in its December 28, 1984 notice, that the final rule concerning the chlorobenzene health effects testing requirements would be promulgated in a single phase, such that the rule would include test standards and reporting requirements. In the proposed rule, EPA set forth proposed reporting requirements and data submission deadlines and proposed that the testing should be done in accordance with the applicable proposed test standards, with possible chemical-specific modifications (45 FR 48565; July 18, 1980). In the **Federal Register** of November 27, 1985 (50 FR 48805), the EPA issued a notice revising its proposed rule of July 18, 1980, by updating the proposed health effects testing requirements to reflect the incorporation of current TSCA test guidelines issued by EPA's Office of Toxic Substances. In the updated notice, EPA proposed that the remaining health effects tests for the chlorinated benzenes would be performed in accordance with the methodologies cited in the TSCA Health Effects Test Guidelines in 40 CFR Part 798. By doing so the testing requirements would follow current Agency policy and ensure current and generally accepted minimal conditions for determining the health effects of test substances like the chlorinated benzenes.

The Agency has also published a final rule and an advance notice of proposed rulemaking for environmental effects testing of these chlorinated benzenes (51 FR 11728, April 7, 1986 and 49 FR 1760, January 13, 1984, respectively). This final rule addresses only the health effects decisions for the chlorinated benzenes.

Therefore, in accordance with the Final Order and Judgment in NRDC and AFL–CIO v. EPA, the Agency is taking this final action on the remaining portions of the chlorinated benzenes proposed health effects test rule to comply with the court's order.

II. Public Comment

The comments received by the Agency in response to the proposed rule for the chlorinated benzenes were from the affected industry and several trade associations. The Agency did not receive any comments which, in the Agency's judgment, rebutted the findings of potential unreasonable risk and insufficient data for reproductive effects for MCB and 1,2- and 1,4-DCBs, oncogenic effects for 1,2,4-TCB, and reproduction and developmental toxicity testing of 1,2,4,5-TCB.

In the proposed rule, the Agency raised a number of issues for comment. Several of the issues are no longer applicable to this rulemaking in light of additional data received and the withdrawal of portions of the proposed rule. Major issues relevant to the remaining rulemaking and comments received are discussed below.

1. Should any additional chlorinated benzenes be incorporated in the sample designated for testing? Should any be deleted? Alternatively, should all chlorinated benzenes that are members of the category, as defined by EPA, be tested?

Many comments were received on this issue. However, when considering: (1) The withdrawal of the proposed testing requirements in this notice together with those withdrawn in December 1984, (2) that much of the proposed testing has now been conducted, and (3) that very little of the originally designated representative test sample and proposed test requirements remain, EPA has decided not to require testing under a category-based approach for the remaining testing requirements.

2. Is the Agency's requirement that the chlorinated benzene test chemicals be 99.9 percent pure with no more than 0.05 percent benzene and 0.05 percent hexachlorobenzene appropriate?

The Chlorobenzene Producers Association (CPA) commented that the most appropriate approach to purity of materials to be tested is to select the purest material that is representative of that which is available in commercial quantities, rather than using laboratory-pure, 99.9 percent material. CPA indicated that commercial grades of high purity MCB, 1,2-DCB, 1,4-DCB, 1,2,4-TCB, and 1,2,4,5-TCB are (or recently have been) available. All of these products contain less than 0.05 percent hexachlorobenzene and less than 0.05 percent benzene. However, CPA felt that requiring purities of 99.9 percent is not practical for several of these products, nor representative of economically feasible purities in commercial products.

The Agency believes that in most instances testing should be required for a "representative" commercial grade of a test substance. However, the EPA believes that testing of a purer grade may be appropriate when a known impurity or contaminant in a commercial product is a suspected cause of adverse effects and is itself being characterized by other tests, or when the test substance is being tested as representative of a large group and test data on a purer form would better insure reliable extrapolation to other group members.

EPA will designate the purity of the test chemicals selected which will generate data expected to reasonably define the likely toxicological effects of the commercial variations of the test chemical in the market place. EPA initially believed that a 99.9 percent pure MCB, 1,2- and 1,4-DCB, 1,2,4-TCB and 1,2,4,5-TCB would best define the likely toxic effects of the commercially available chlorinated benzenes. However, on the basis of industry comments and the National Toxicology Program's (NTP) use of a test material characterized as having purities greater than 99 percent for its oncogenicity studies of MCB, 1,2- and 1,4-DCB, EPA is revising its purity requirement to be similar to that of NTP's, which the Agency believes is acceptable.

3. Are there significant studies that have not come to the attention of EPA which would provide sufficient data and experience for evaluation of the chlorinated benzenes?

Commenters suggested that EPA failed to cite numerous data from the existing literature which are of critical importance in evaluating the chlorobenzene compounds. The Agency has received the data cited by the commenters and finds that the data are insufficient for evaluation of the chlorinated benzenes. For the most part, the following studies either had deficiencies in performance or insufficient information reported to fully evaluate the study:

a. One commenter noted a Dow Chemical U.S.A. study in dogs with 1,2,4,5-tetrachlorobenzene. The chemical was administered in the diet at 5 mg/kg/day for 2 years. No citation was given. EPA believes that this study was deficient in that it was not conducted at the maximum tolerated dose, only one dose was used, the pathology data were not submitted for evaluation by the EPA, and insufficient information was provided on methodology and results for the EPA to properly assess its significance.

b. Cragg, S.T., Wolfe, G.F., and Smith, C.C. "Toxicity of 1,2,4-trichlorobenzene in Rhesus monkeys: Comparison of two *in vivo* methods for estimating P-450 activity." *Toxicology and Applied Pharmacology*. 45(1):340. 1978.

This study was only reported as an abstract. There was not enough information given for an extrapolation of risk to humans.

c. Gage, J.C. "The subacute inhalation toxicity of 109 industrial chemicals." *British Journal of Industrial Medicine*. 27:1–18. 1970.

This study used far too few animals (two to four males and females at three dose levels) and there was up to a 20 percent impurity of 1,2,3-trichlorobenzene in the 1,2,4-trichlorobenzene sample. In addition, no microscopic examinations were performed.

d. Powers, M.B. *et al.* "Repeated topical applications of 1,2,4-trichlorobenzene." *Archives of Environmental Health*. 30:165–167. 1975.

In this study histopathology was only done on five organ systems, the number of animals (rabbits) per sex was not reported, and prevention of licking or rubbing the chemical off the ear was not done. In addition, no clinical chemistry or hematology examinations were performed. Therefore, based on this study, it would be difficult for the Agency to perform an adequate risk estimate for humans.

e. Smith, C.C., Cragg, S.T., and Wolfe, G.F. "Subacute toxicity of 1,2,4-trichlorobenzene in subhuman primates." *Federal Proceedings*. 36:248, 1978.

This study was only reported as an abstract. There was no indication of microscopic examination and there was not enough information given for an adequate risk estimate for humans.

f. Watanabe, P.G., Yakel, H.O., and Kociba, R.J. "Subchronic toxicity study of inhaled 1,2,4-trichlorobenzene in rats". Dow Chemical Company. 1978.

This was not a complete subchronic study because no microscopic examinations were performed. The observations were mainly concerned with porphyrin metabolism.

g. ICI Americas Inc. 1980.

The long-term inhalation studies of 1,4-DCB have been reviewed. In these studies, the 1,4-DCB was administered at two dose levels (75 and 500 ppm) for 15 months to mice and 20 months for rats. The studies did not indicate significant toxicity of 1,4-DCB in either rats or mice at 500 ppm. Therefore, EPA cannot characterize the dose-response curve from the information submitted. Since previous studies have indicated toxicity to the kidneys and liver from this chemical, it is reasonable to assume

that 1,4-DCB does induce damage to these organs at a higher level of exposure and that the authors were not sufficiently dosing the test animals to elicit a toxic response. In addition, EPA cannot analyze the very slight indications of toxicity at 500 ppm in rats because only five animals/sex/dose group were sacrificed at the most significant times (i.e. at 26, 52 and 76 weeks). Although the authors stated that the studies were conducted to evaluate potential oncogenicity of 1,4-DCB, EPA believes that these studies are too short to be considered as adequate negative oncogenicity studies.

In summary, these studies are not adequate either in themselves or in combination with other subchronic data to reasonably predict the chronic/subchronic effects of 1,2,4-TCB. Nor are the studies sufficient to eliminate EPA's concern for 1,2,4-TCB's oncogenic potential.

4. What strain(s) of rat is (are) most appropriate for assessing the oncogenic effects of the chlorinated benzenes?

Most commenters felt that EPA should not specify species or strains for these tests. They felt that selection of species for assessing any toxicologic response is best made by the investigators who will conduct the study because experience with the species and strain is critical to the appropriate interpretation of data from any study.

EPA realizes that investigators have substantial experience with the species they use. Nevertheless, for uniformity of experimental design, for the proper conduct of oncogenicity studies by several laboratories, and for the meaningful interpretation of oncogenicity studies conducted between laboratories, the Agency issues guidelines for the conduct of oncogenicity studies and believes it is appropriate in certain instances to specify the species and strains to be used. These guidelines and specifications are based on a thorough review of the literature, consultations with appropriate scientists, and input from public comments.

EPA originally considered requiring the use of the Sprague-Dawley rat in the oncogenicity testing of 1,2,4-TCB. This was based on a study by Maltoni *et al.* (Ref. 1) which indicated a significant tumorigenic effect by benzene in the rat. This study provided in EPA's estimation sufficient evidence to suggest the rodent (Sprague-Dawley rat) as the test species for an oncogenic study with chlorinated benzenes. However, EPA now believes that because oncogenicity testing conducted by NTP on MCB, 1,2- and 1,4-DCB utilized the Fischer-344 rat, the required oncogenicity testing for 1,2,4-TCB should also use the Fischer-344 rat as one of the 2 test species. EPA believes this test species will provide a stronger basis on which to make a comparative analysis.

5. Should testing for reproductive effects be required for chlorinated benzenes?

Commenters suggested that the testicular effects observed in dogs and the increased ovarian weights in rats exposed to MCB, as cited by EPA in its findings for proposed reproductive effects testing (45 FR 48544), do not provide sufficient evidence suggesting an unreasonable risk of reproductive effects.

EPA disagrees. EPA believes both effects are suggestive of a potential reproductive hazard which cannot be ignored or postponed for future consideration. The Agency believes this hazard potential must be elucidated by full reproductive effects testing of the appropriate chlorobenzenes.

6. Has EPA overlooked a test that could be more informative in the assessment of reproductive problems associated with the proposed test chemicals?

Commenters suggested that a monitoring program for male fertility and chromosomal breakage in humans occupationally exposed to the chlorinated benzenes be run in parallel with tests for the same endpoints in laboratory animals.

EPA believes the reproductive effects studies being required will generate adequate information on the potential reproductive effects these chemicals may cause. The need for further studies as suggested in the comment will be considered upon evaluation of the required testing results.

III. Decision To Terminate Rulemaking Process for Subchronic and Oncogenicity Testing Requirements for 1,2,4,5-Tetrachlorobenzene

After proposing health effects testing for 1,2,4,5-tetrachlorobenzene (1,2,4,5-TCB), the Agency received additional information which indicated that production of the tetrachlorobenzenes was performed in a closed process. EPA learned that the chemicals were used as chemical intermediates, primarily in the production of pentachloronitrobenzene. The potential for exposure in this system was estimated to be less than 100 workers. After reviewing this information, EPA considered terminating its rulemaking process for 1,2,4,5-TCB.

However, during the Fall of 1983, EPA received information concerning the use of tetrachlorobenzenes as a temporary transformer retrofilling dielectric fluid in railroad equipment which was being operated by the Southeastern Pennsylvania Transit Authority (SEPTA). EPA began a review of this use to determine whether human exposure to the chemicals was significantly increased over that already known. Early in 1984, EPA received information about further use of tetrachlorobenzenes in retrofilling electrical transformers other than railroad equipment. When reviewing this information, together with that for railroad use, EPA concluded the potential existed for a greater number of people to be exposed to the tetrachlorobenzenes, and that exposures would be to a more general population: i.e., satisfying the risk findings under TSCA section 4(a)(1)(A).

Meanwhile, the National Toxicology Program (NTP) initiated activity to test the chemical for oncogenicity. Because NTP has initiated its pre-chronic testing program for 1,2,4,5-TCB, EPA has decided to terminate its rulemaking process for subchronic/chronic effects and oncogenic effects testing and is notifying the public of this decision in this notice at this time. EPA remains concerned about the reproductive and teratogenic (developmental) hazard potential, 1,2,4,5-TCB may pose to human health and is requiring this testing as described below.

IV. Final Test Rule for MCB, 1,2,- and 1,4-DCB, 1,2,4-TCB, and 1,2,4,5-TCB

A. Findings

1. *1,2,4-Trichlorinated benzene.* The EPA is basing the final oncogenicity testing requirement for 1,2,4-TCB on the authority of section 4(a)(1)(A) of TSCA. EPA finds that the manufacture, processing, use and disposal of 1,2,4-TCB may present an unreasonable risk of cancer to humans, that there are insufficient data to reasonably determine or predict the effects of such activities on human health, and that testing is necessary to develop these data. The bases for these findings, which are summarized in the following paragraphs in IV.A., are set forth in the Agency's chlorinated benzenes support document.

Approximately 10 to 20 million pounds of 1,2,4-trichlorobenzene are produced annually in the United States. 1,2,4-TCB is used as a dye carrier, synthetic intermediate, dielectric fluid, and as a solvent. NIOSH estimated that these uses could result in 86,340 workers being exposed to 1,2,4-TCB each year (Ref. 2). An industry survey indicated approximately 40,000 workers are potentially exposed to 1,2,4-TCB (Ref. 3).

The Agency has received no additional information which would contradict the exposure estimates discussed here. EPA believes that either figure represents sufficient human exposure to make a "may present an unreasonable risk" finding under TSCA 4(a)(1)(A).

After reviewing available literature for individual members of the chlorobenzenes group, EPA has concluded that there is sufficient information to indicate that 1,2,4-TCB may present an oncogenic hazard to humans. Monochlorobenzene was reported to induce a significant increase in neoplastic nodules of the liver in high dose (120 mg/kg) male rats when administered by gavage in corn oil to both rats and mice (Ref. 4). Studies reviewed by EPA in its 1980 Chlorinated Benzene Support Document (Ref. 5) have shown that hexachlorobenzene (HCB) will induce hepatomas, liver haemangioendotheliomas, and thyroid alveolar adenomas in hamsters; hepatomas in mice; and liver, kidney, adrenal, and parathyroid tumors in rats. It was concluded that the NTP bioassay on 1,2-DCB showed no evidence of carcinogenicity in male or female rats and mice (Ref. 9). However, EPA believes the NTP study results, particularly on the dose-related increase in malignant histiocytic lymphomas found in this study, may suggest that their significance in the study may be underestimated when compared with the NTP study results for 1,4-DCB. The NTP bioassay on 1,4-DCB was positive for rats and mice (Ref. 7). EPA believes that these data substantiate a concern for the oncogenic potential of 1,2,4-TCB.

Other chronic studies for 1,4-DCB concluded that it was not oncogenic to both rats and mice under the conditions of the study (Refs. 8 and 9). However, EPA believes these studies are of limited value because of the shortened exposure periods, the abbreviated histopathological examinations, and a background incidence of respiratory disease in many of the test animals. Viewed in the light of the positive NTP bioassay for 1,4-DCB, they do not alleviate EPA's concern for the oncogenicity potential of 1,2,4-TCB.

Positive results from testing 1,2,4-TCB in a cell transformation bioassay (one with uncertain correlation to oncogenicity because of the low number of chemicals that have been tested in the assay) (Ref. 10) also increase suspicion for its potential oncogenic hazard. Although short-term mutagenicity testing has produced mixed results with a high number of negative results for all the chlorobenzenes examined, the correlation between the negative findings for these tests for this class of chemicals and their potential oncogenicity is unknown. Therefore, prediction of potential oncogenic activity from short-term tests is severely limited for the chlorobenzenes and oncogenicity testing is necessary to determine the oncogenic potential.

EPA concludes on the basis of occupational exposure, the cell transformation results for 1,2,4-TCB, and the oncogenicity of structurally related chlorinated benzenes, that 1,2,4-TCB may present an oncogenic risk to humans.

2. *Mono- and dichlorinated benzenes.* The EPA is also promulgating a final reproductive effects testing requirement for MCB and 1,2- and 1,4-DCBs based on the authority of section 4(a)(1)(A) of TSCA. EPA finds that the manufacture, processing, use and disposal of MCB and 1,2- and 1,4-DCBs may present an unreasonable risk of reproductive effects to humans, that there are inadequate data to reasonably determine or predict the effects of such activities on human health, and that testing is necessary to obtain this data. Approximately 200 to 300 million pounds of MCB, and 100 to 150 million pounds of DCBs are produced annually. EPA believes the uses of the chemicals, which are set forth in the Agency's chlorinated benzene support document provide for sufficient human exposures to these chemicals. EPA also believes that adequate evidence for a potential reproductive effect in humans exposed to MCB exists because studies have demonstrated MCB's ability to affect the reproductive organs of rats and dogs (Ref. 11). For DCBs, EPA believes the close structural similarity between MCB and the DCB's provided a reasonable basis on which to conclude they too may present a reproductive hazard.

EPA acknowledges that the combined reproductive effects studies and embryo/fetal teratology screen on 1,2,4-TCB (Ref. 12), which produced negative results as discussed in the December 1984 notice (48 FR 54842), does present some question regarding the DCBs' potential for causing a reproductive hazard in humans. However, because the data provide suggestive evidence which conflicts with available suggestive data on the reproductive effects potential of MCB, EPA believes that only by actual study can the potential of MCB and the DCB's to cause this effect be satisfactorily established.

EPA is also aware of a reproductive effects study for MCB that has recently been conducted under the sponsorship of the chlorobenzene producers (Ref. 13). At this time EPA has received interim data from this study describing histopathological changes in the testes of male Sprague-Dawley rats exposed to 450 ppm MCB. If the study complies with the test standards established under this rule it may be submitted in satisfaction of the rule's test requirements for MCB. Should the study not meet the test standards described for MCB reproductive effects testing under this rule, but the manufacturers believed it provides adequate data to reasonably determine or predict the reproductive effects of the manufacturer, processing, use, and disposal of MCB, such manufacturers may petition EPA to withdraw the test rule. Similarly, if the manufacturers believe the MCB study results substantially alter the Agency's basis for requiring reproductive effects testing of 1,2- or 1,4-DCB, they may petition for reconsideration of those requirements.

EPA concludes that on the basis of the high occupational exposures to MCB, 1,2- and 1,4-DCBs, the suggestive evidence of MCB's potential to cause reproductive effects, and the close structural similarity between MCB and DCBs, both MCB and 1,2- and 1,4-DCBs may present an unreasonable risk of reproductive effects to humans.

3. *1,2,4,5-Tetrachlorinated benzene.* The Agency is basing the final reproductive and teratogenic (developmental) effects testing requirements for 1,2,4,5-TCB on the authority of section 4(a)(1)(A). EPA finds that the use of 1,2,4,5-TCB may present an unreasonable risk of reproductive and teratogenic (developmental) effects to humans, that there are insufficient data to reasonably determine or predict such effects on humans, and that testing is necessary to develop these data. The bases for these findings are summarized in the following paragraphs.

a. *Exposure.* EPA believes a liquid solution containing 1,2,4,5-TCB, which is being used as a temporary dielectric retrofilling fluid for use in PCB-containing electrical transformers, poses a significant source of potential 1,2,4,5-TCB exposure to humans. Electrical transformers can contain hundreds to thousands of gallons of dielectric fluid. PCB transformers typically contain about 500 gallons of PCBs, although they can contain up to 1,650 gallons. Currently, there are an estimated 140,000 PCB transformers in use in the United States. There are also an estimated 34 million transformers containing mineral oil that are contaminated with PCBs to varying degrees. EPA believes all of the 140,000 PCB transformers and many of the mineral oil transformers containing

over 50 ppm PCBs are potential candidates for retrofilling with the 1,2,4,5-TCB containing fluid. EPA believes that because of the typical liquid volume of these transformers, sufficient quantities of 1,2,4,5-TCB are present for human exposure.

EPA believes there are four population groups potentially at risk of exposure from the use 1,2,4,5-TCB as a temporary dielectric fluid: (1) Persons involved in the actual retrofill of existing equipment, (2) persons involved in the servicing/maintenance of the equipment, (3) other workers (recognizing that transformers in other than electrical substations are for the most part used exclusively in "commercial" areas including manufacturing plants), and (4) members of the general population (considering transformer locations near office buildings, shopping malls, and apartment buildings).

EPA's experience with the use, servicing, and retrofilling of PCB transformers and PCB contaminated transformers suggests that these activities have resulted in widespread human exposure to PCBs and that it is reasonable to assume the same exposure potential that exists for PCBs will also exist for 1,2,4,5-TCB. Although current controls exist to reduce the PCB exposure to humans via inspection of transformers, recordkeeping, and required removal programs, EPA believes that because insufficient health effects data exist for 1,2,4,5-TCB to support the need for continued safe handling of "retrofilled transformers, once the PCBs are removed, the care exhibited in servicing PCB containing or contaminated transformers can reasonably be expected to be relaxed, if not eliminated.

b. *Reproductive effects.* Although there are no reproductive effects studies for the tetrachlorobenzenes, EPA believes that reproductive effects may occur from sufficient exposure to the tetrachlorobenzenes. EPA anticipates antifertility effects will not occur except possibly at dose levels causing other toxic symptoms, and that there is a high probability that effects on the neonate will result from in utero dosing and/or on postnatal growth and development through excretion of the tetrachlorobenzenes through the mother's milk. Subsequent effects on growth and development of the young adult are also possible.

The fetal effects demonstrated to date have been reduced litter size with a few other equivocal effects on surviving embryos as seen in the following non-reproductive effects studies (Refs. 14, 15 and 16). Although evidence of effects on the surviving embryo/fetus is limited to 1,2,3,4-TCB exposure only (Ref. 16), the observation that the other two isomers (1,2,4,5,- and 1,2,3,5-TCB) cause reduced litter sizes and accumulate in the fetus and the mother (Ref. 14), indicate that a potential risk of effects on growth and development postnatally may occur given sufficient exposure.

The chlorinated hydrocarbons are known to gain access to the fetus via the placenta and to the neonate via the placenta and the milk supply. In the case of the tetrachlorobenzenes, pasage into the fetus has been demonstrated with effects (Refs. 14 and 16).

Kacew et al. (Ref. 14) analyzed tetrachlorobenzene residues in organs and tissue from Sprague-Dawley rat fetuses and dams dosed during days 6–15 of gestation. The isomer 1,2,4,5-TCB was found to accumulate to the greatest degree. Accumulation of 1,2,3,5-TCB was found to be approximately 100–200 times less in fetal and maternal tissue. There was no evidence that 1,2,3,4-TCB accumulated in either the fetus or the dam.

Two more highly chlorinated benzenes, penta- and hexachlorobenzenes, have been shown to cause fetal effects (Refs. 17 and 18). Although accumulation of these two analogs would probably be greater, tetrachlorobenzenes may be expected to behave in a similar manner.

These data indicate a potential risk of effects on growth and development for tetrachlorobenzenes. However, EPA concludes because there are no reproductive effects studies for 1,2,4,5-TCB or other tetrachlorobenzene isomers to characterize their potential effects on growth and development, reproductive effects testing is necessary. EPA believes that sufficient human exposure to 1,2,4,5-TCB exists from its use as a temporary dielectric retrofilling fluid to support a TSCA section 4(a)(1)(A) finding to require testing. At this time EPA is requiring that only 1,2,4,5-TCB be tested for reproductive effects according to the TSCA test guidelines because available data indicate that 1,2,4,5-TCB accumulates in body tissues to a greater degree than the other tetrachlorobenzene isomers. Based on the data resulting from these studies, EPA will reevaluate the need for reproductive testing of the other tetrachlorobenzene isomers.

c. *Developmental toxicity.* Although none of the tetrachlorobenzene isomers have demonstrated unequivocal potential to cause terata, developmental effects from in utero dosing have been demonstrated for all three isomers. Kacew et al. (Ref. 14) administered each isomer at 0, 50, 100 or 200 mg/kg body weight in corn oil to 8–10 rats per group from day 6–15 of gestation. Fetal effects were demonstrated in reduced litter sizes when the rats were dosed with 1,2,3,4, or 1,2,3,5-TCB at 200 mg/kg. The fetal effects from 1,2,4,5-TCB could not be determied because only one dam survived at this dose level. However, Kitchin and Ebron (Ref. 15) found a reduced number of implantations in rats exposed to the same isomer, 1,2,4,5-TCB.

In the 1,2,3,4-TCB group at 200 mg/kg, not only reduced litter size occurred but retarded ossification and an extra 14th rib was found. Although litter size reduction was the only statistically significant fetal effect noted, only 5 litter were seen at this dose level (Ref. 14). If more litters have been examined, terata and/or retarded growth may have been detected.

In the 1,2,3,5-TCB group dosed at 200 mg/kg, only one malformation occurred in 6 litters, but delayed osteogenesis in the cranium and sternebrae, small pup sizes and the presence of a 14th rib and clubbed foot led to the conclusion that if more litters had been examined, statistical significance in some of these parameters may have been found in addition to the reduced litter sizes (Ref. 14).

In the 1,2,4,5-TCB group dosed at 200 mg/kg, no fetal effects could be determined because all but one of the dams died approximately 6.5 days (mean time to deaths) after the beginning of dosing. An adequate NOEL may not have been demonstrated by the less than 10 litters per dose level used in these studies.

Kitchin and Ebron (Refs. 15 and 16) studied the effects of two of the isomers 1,2,3,4,-TCB and 1,2,3,5-TCB on maternal enzyme induction and embryonic growth at 0, 30, 100, 300 or 1000 mg/kg body weight on 10 rats per group from day 6–13 of gestation. The TCB was administered in gum tragacanth instead of the corn oil used by Kacew et al. (Ref. 14). Embryos were examined at day 14 of gestation.

The isomer 1,2,3,4-TCB demonstrated a reduction in crown-rump length and head length at 300 mg/kg. Except for enzyme induction, no other maternal toxicity occurred at this dose level. At 1000 mg/kg, 37 percent of the dams died and no fetal determinations were made (Ref. 16).

Exposure to 1,2,4,5-TCB demonstrated a reduced number of implants at 1000 mg/kg; reduced maternal weight gain also occurred at this dose level, and liver enzyme induction occurred at all dose levels (Ref.15).

The studies by Kacew et al. and Kitchin and Ebron are adquate to

indicate that fetal effects may be produced by all of the TCB isomers.

The teratological data available for the tetrachlorbenzenes demonstrate effects on development. However, EPA believes that the available studies are not adequate to reasonably predict the risk of developmental effects that 1,2,4,5-TCB, or other tetrachlorobenzenes, may present to humans and that developmental toxicity testing is necessary. EPA believes sufficient human exposure exists through 1,2,4,5-TCB's use as a temporary dielectric retrofilling fluid to support a TSCA section 4(a)(1)(A) finding to require testing. At this time EPA is requiring that only 1,2,4,5-TCB be tested for developmental toxicity according to the TSCA test guidelines because available data indicate that 1,2,4,5-TCB accumulates in body tissues to a greater degree than the other tetrachlorobenzene isomers. Based on the data resulting from these studies, EPA will reevaluate the need for developmental effects testing of the other tetrachlorobenzene isomers.

B. Test Standards

On November 27, 1985 (50 FR 48805), EPA issued a notice proposing the use of the TSCA guidelines in place of the proposed test standards, issued in the **Federal Register** on May 9, 1979 (44 FR 27334), and July 26, 1979 (44 FR 44054), for the required health effects testing of the chlorinated benzenes. As described in the November 27, 1985 notice, EPA had previously issued a change in its test standards policy (March 26, 1982; 47 FR 13012) that eliminated the use of rigid generic testing requirements or standards, as proposed on July 18, 1980, for the health effects testing of the chlorinated benzenes. EPA believes that public comments addressing the original generic test standards as well as those provided during the public comment period for this action, addressing their applicablity to the required testing for the chlorinated benzenes, have been adequately considered in the preparation of the TSCA guidelines. EPA believes that because of this effort, and the annual reviews of the guidelines by EPA, the original proposed test standards have been modified to a point where the resulting test data will reflect state-of-the-art toxicological procedures, and ensure current and generally acceptable minimal conditions for determining the health effects of the chlorinated benzenes. Therefore, the remaining health effects tests for the chlorinated benzenes shall be performed in accordance with the methodologies cited in the TSCA Health Effects Test Guidelines in 40 CFR Part 798, published in the **Federal Register** on September 27, 1985 (50 FR 39252).

At this time the Agency is requiring that oncogenicity testing for 1,2,4-TCB be conducted by testing 1,2,4-TCB in two mammalian species (the mouse and the Fischer-344 rat). The Agency is requiring that the oncogenicity testing be performed in accordance with the methodology cited in the TSCA Health Effects Test Guideline at 40 CFR Part 798.3300 and the TSCA Good Laboratory Practice Standards in 40 CFR Part 792. EPA is requiring that 1,2,4-TCB be administered in the feed.

EPA also is requiring that reproductive effects testing for MCB and 1,2- and 1,4-DCBs be conducted by testing MCB, 1,2- and 1,4-DCBs in the 2-generation reproductive and fertility study in the Sprague-Dawley rat. The Agency is requiring that the reproductive and fertility effects testing be performed in accordance with the methodology cited in the TSCA Health Effects Test Guideline at 40 CFR Part 798.4700. EPA is requiring that the route of administration for MCB, and 1,2- and 1,4-DCBs be inhalation.

EPA is also requiring that reproductive effects and developmental effects testing for 1,2,4,5-TCB be conducted. The Agency is requiring that the reproductive and fertility effects testing be performed in accordance with the methodology cited in the TSCA Health Effects Test Guidelines at 40 CFR Part 798.4700. The Agency is requiring that the developmental effects testing be performed in accordance with the methodology cited in the TSCA Health Effects Test Guidelines at 40 CFR Part 798.4900. EPA is requiring that the reproductive and fertility effects testing be conducted using the Sprague-Dawley rat and that the developmental effects testing be done in the Fischer 344 rat and the New Zealand White rabbit (both species were previously used in the developmental effects testing of MCB, 1,2- and 1,4-DCB). 1,2,4,5-TCB shall be administered in the feed in the reproductive and fertility effects study and shall be administered by oral gavage in the developmental effects study. Developmental effects testing of the tetrachlorobenzenes by Kacew, et al. (Ref. 14) demonstrated the effective use of this route of administration.

C. Test Substance

EPA is requiring that MCB, 1,2- and 1,4-DCB, 1,2,4-TCB, and 1,2,4,5-TCB, containing no more than 0.05 percent benzene and 0.05 percent hexachlorobenzene, be used as the test substances for the tests required by this rule. The purity of the test substances must be at least 99 percent. EPA is aware that commercially available chlorinated benezenes have been offered at a 99.9 percent level of purity. However, because NTP oncogenicity testing has utilized purities specified as greater than 99 percent, EPA believes requiring a similar purity for the required testing in this rule will be acceptable.

D. Persons Required To Test

Section 4(b)(3)(B) specifies that the activities for which the EPA makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal.

Because EPA has found that insufficient data exist to reasonably determine the effects on human health from the manufacture, processing, use, and disposal of MCB, 1,2- and 1,4-DCBs and 1,2,4-TCB, and the use of 1,2,4,5-TCB, EPA is requiring that persons who manufacture (or import) and/or process MCB, 1,2- or 1,4-DCB, 1,2,4,-TCB, or 1,2,4,5-TCB, 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 rule for each of the chemicals they manufacture (or import) and/or process. The end of the reimbursement period will be 5 years after the last final report is submitted for a given chemical or an amount of time equal to that which was required to develop data if more than 5 years after the submission of the last final report required under the test rule.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to

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

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing, unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the **Federal Register** to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for MCB, 1,2- or 1,4-DCB, 1,2,4-TCB, or 1,2,4,5-TCB. As noted in Unit IV.C, EPA is interested in evaluating the effects attributable to these chlorinated benzenes 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.

E. Reporting Requirements

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

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

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is requiring that manufacturers and processors responsible for the oncogenicity testing of 1,2,4-TCB report the study results within 53 months after the effective date of this rule. Manufacturers and processors responsible for the reproductive effects testing of MCB, or 1,2- or 1,4-DCB, or 1,2,4,5-TCB must report these study results within 29 months after the effective date of this rule. Manufacturers and processors responsible for the developmental effects testing of 1,2,4,5-TCB must report the study results within 12 months after the effective date of this rule.

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). In brief, as of the effective date of this test rule, and exporter of MCB, 1,2- or 1,4-DCB, 1,2,4-TCB, or 1,2,4,5-TCB must report to EPA the first annual export or intended export of any of these chemicals to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

F. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substance or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce . . ." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for MCB, 1,2,- and 1,4-DCBs, 1,2,4-TCB, and 1,2,4,5-TCB. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of the TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions.

This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.28(b)). Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. 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. Economic Analysis of Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (Ref. 14) 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 these chlorinated benzenes: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If these indications are negative, no further economic analysis is performed; however, if the first level of analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted which more precisely predicts the magnitude and distribution of the expected impact.

Total direct testing costs for the final rule for MCB, 1,2-DCB and 1,4-DCB are projected to range from $590,229 to $768,141. Since the three chemicals are produced jointly, the direct costs of testing have been dispersed over the total production of the three chlorobenzenes. Including the costs for environmental effects testing which EPA has proposed in a prior rule (Ref. 14), the total costs of testing MCB, 1,2-DCB and 1,4-DCB range from $595,021 to $774,551.

The total direct costs testing 1,2,4-TCB range from $562,627 to $747,009. Because 1,2,4-TCB is commercially manufacturered as a joint product with 1,2,3-TCB, the direct costs of testing have been dispersed over the total production for both trichlorobenzenes. Including the costs for environmental effects testing for 1,2,4-TCB and 1,2,3-TCB which EPA has previously proposed, raises the total testing costs for 1,2,4-TCB to $587,064 to $779,348.

The estimated range of test costs for 1,2,4,5-tetrachlorobenzene is from $181,000 to $240,000. Because the production level of tetrachlorobenzene is Confidential Business Information (CBI), the quantitative impact projected by EPA must remain CBI.

The annualized tests costs (using a costs of capital of 25 percent over a period of 15 years) range from $154,194 to $200,717 for MCB, 1,2-DCB and 1,4-DCB and from $152,132 to $201,960 for 1,2,4-TCB. Based upon the most recent production data, the unit test costs for the mono- and dichlorobenzenes range from 0.04 to 0.05 cents per pound. These costs are equivalent to 0.11 to 0.12 percent of the list price of MCB, 0.11 to 0.14 percent of the unit sales value of 1,2-DCB, and 0.10 to 0.13 percent of the unit sales value of 1,4-DCB.

Unit test costs for 1,2,4-TCB range from 0.94 to 1.24 cents per pound after adjusting for upstream testing costs. These costs represent from 1.5 to 2.0 percent of 1,2,4-TCB price.

Based on these costs and the uses of these chlorinated benzenes, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is extremely low. For MCB, DCBs and TCBs, this conclusion is based upon the following observations:

1. The estimated unit test costs are low and should not affect demand, and

2. The demand for these compounds as chemical intermediates is dispersed over numerous end markets.

The potential for significant adverse economic impact on tetrachlorobenzene production is low. This conclusion is based upon the following observation.

1. Production of tetrachlorobenzene is expected to be substantial in the near-term; and

2. Review of the industry structure and cost characteristics of tetrachlorobenzene manufacture indicates that the manufacturer is collecting monopoly profits which will not be significantly affected by the testing costs.

Refer to the economic analysis (Ref. 14) for a complete discussion of test costs estimation and the potential for economic impact resulting from these costs.

VI. 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 NTIS (PB 82-140773). On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this rule.

VII. Rulemaking Record

EPA has established a public record for this rulemaking proceeding [docket number OPTS-47002F]. This record includes:

A. Supporting Documentation

(1) **Federal Register** notices designating the chlorinated benzenes to the priority list (42 FR 55026 and 43 FR 50630) and all comments received on the chlorinated benzenes.

(2) **Federal Register** notice of EPA's proposed health effects test rule on chlorinated benzenes (45 FR 48424) and all comments received on the proposed testing.

(3) **Federal Register** notice (48 FR 54836) requesting comment on the negotiated testing program and proposed decision to withdraw certain proposed testing requirements, and comments, received.

(4) **Federal Register** notice (49 FR 50408) announcing its final decision to withdraw several proposed testing requirements.

(5) **Federal Register** notice (50 FR 48805) announcing a revision to the proposed test standards, and comments received.

(6) Communications consisting of letters, contact reports of telephone conversations, and meeting summaries.

(7) Proposed test standards for oncogenicity, reproductive effects (44 FR 44054 and 27334) and comments submitted on those standards which may be found in public dockets Nos. OPTS-46005 and 46003.

(8) Transcript of September 25, 1984 Public Meeting.

B. References

(1) Maltoni, C., and Scarnato, C. "First experimental demonstration of the carcinogenic effects of benzene. *Med. Lavoro.* 5: 352-357. 1979.

(2) National Institute of Occupational Safety, and Health. National Occupational Hazard Survey Data Base. Washington, D.C. U.S. Department of Health, Education, and Welfare. 1979.

(3) Hull and Company. "Employee exposure to trichlorobenzene products." Prepared by Hull and Company of Greenwich, Connecticut for the Chlorobenzene Producers Association. October 22, 1980.

(4) National Toxicology Program. "NTP technical report on the toxicology and carcinogenesis studies of chlorobenzene." U.S. Department of Health and Human Services. October 1985. NIH Publication Number 86-2517.

(5) U.S. Environmental Protection Agency. "Assessment of testing needs: chlorinated benzenes." Office of Pesticides and Toxic Substances. U.S. Environmental Protection Agency. July 1980.

(6) National Toxicology Program. "NTP technical report on the toxicology and carcinogenesis studies of 1,2-

dichlorobenzene." U.S. Department of Health and Human Services. October 1985. NIH Publication Number 86-2511.

(7) National Toxicology Program. "NTP draft technical report on the toxicology and carcinogenesis studies of 1,4-dichlorobenzene." U.S. Department of Health and Human Services. March 1986. NIH Publication Number 86-2575.

(8) Imperial Chemical Industrial Limited. "Para-dichlorobenzene: long term inhalation study in the rat." Report Number CTL/P/447. Received by the Test Rules Development Branch of the U.S. Environmental Protection Agency, Washington, D.C., on March 23, 1982.

(9) Imperial Chemical Industries Limited. "Para-dichlorobenzene: long term inhalation study in the mouse." Report Number CTL/P/478. Received by the Test Rules Development Branch of the U.S. Environmental Protection Agency, Washington, D.C., on March 23, 1982.

(10) Shimada, T., *et al.* "Study of effects on cultured liver cells of three chlorinated benzenes." Final report. Naylor Dana Institute. American Health Foundation. Valhalla, New York. December 5, 1983.

(11) Monsanto Company. TSCA Section 8(d) submission 8DHQ-1078-0212 (1). "Industrial bio-test draft report of 90-day subacute vapor inhalation toxicity study with monocholorobenzene, in beagle dogs and albino rats. Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C., 1978.

(12) Robinson, S., *et al.* "Multigeneration study of 1,2,4-trichlorobenzene in rats." *Journal of Toxicology and Environmental Health.* 8:489-500. 1981.

(13) Chlorobenzene Producers Association. Letter from Alan W. Rautio to Don R. Clay. May 8, 1986.

(14) Kacew, S., Ruddick, J.A., Parulekar, V.E., *et al.* "A teratological evaluation and analysis of fetal tissue levels following administration of tetrachlorobenzene isomers to the rat." *Teratology.* 29:21-27. 1984.

(15) Kitchin, K. T. and Ebron, M.T. "Maternal hepatic effects of 1,2,4,5-tetrachlorobenzene in the rat." *Environmental Research.* 32:134-144. 1983a.

(16) Kitchin, K.T. and Ebron, M.T. "Maternal hepatic and embryonic effects of 1,2,3,4-tetrachlorobenzene in the rat." *Toxicology.* 26:243-256. 1983b.

(17) Khera, K.S. and Villeneuve, D.C. "Teratogenicity studies on halogenated benzenes (pentachloro-, pentachloronitro-, hexabromo- in rats." *Toxicology.* 5:117:122. 1975.

(18) Courtney, K.D. "Hexachlorobenzene (HCB)." A review. *Environmental Research* 20:225-266. 1979.

(19) U.S.EPA. "Economic impact analysis of final health effects rule for chlorobenzenes." Office of Pesticides and Toxic Substances, U.S.EPA. Contract No. 68-02-4235. March 11, 1986.

The record, containing the information considered by the Agency in developing this decision, is available for inspection from 8 a.m. to 4 p.m., Monday through Friday except legal holidays, in Rm. E-107, 401 M St., SW., Washington, D.C. 20460.

VIII. Other Regulatory Requirements

A. Classification of Rule

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

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

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.* Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule will not have a significant impact on a substantial number of small businesses because: (1) They are not likely to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, if any, in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

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

List of Subjects in 40 CFR Part 799

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

Dated: June 24, 1986.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

Therefore, 40 CFR Part 799 is amended as follows:

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

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

2. Part 799 is amended in Subpart B as follows:

a. By adding § 799.1051 to read as follows:

§ 799.1051 Monochlorobenzene.

(a) *Identification of test substance.* (1) Monochlorobenzene (CAS Number 108-90-7) (hereinafter "MCB") shall be tested in accordance with this section.

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

(3) The test substance shall not contain more than 0.05 percent benzene and 0.05 percent hexachlorobenzene.

(b) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture (import) or process monochlorobenzene other than as an impurity after the effective date of this rule (August 21, 1986) to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests, and submit data as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this Chapter for single-phase rulemaking.

(c) *Health effects testing*—(1) *Reproductive and fertility effects*—(i) *Required testing.* (A) A test for reproductive and fertility effects shall be conducted with MCB in accordance with § 798.4700 of this chapter.

(B) The route of administration for the reproductive and fertility effects testing of MCB shall be inhalation.

(C) The test species shall be the Sprague-Dawley Rat.

(ii) *Reporting requirements.* (A) The reproductive and fertility effects test shall be completed and the final results submitted to the Agency within 29 months of the effective date of this rule.

(B) Progress reports shall be submitted to the Agency every 6 months after the effective date of the final rule.

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

b. By adding paragraphs (a)(3), (b)(5), (d) and an OMB control number to § 799.1052 to read as follows:

§ 799.1052 Dichlorobenzenes.

(a) * * *

(3) For health effects testing required under (e), both test substances shall not contain more than 0.05 percent benzene and 0.05 percent hexachlorobenzene.

(b) * * *

(5) For health effects testing required under (e), all persons who manufacture (import) or process 1,2- and/or 1,4-dichlorobenzene, other than as an impurity, after the effective date of this rule (August 21, 1986) to the end of the reimbursement period, for each of these chemicals that they manufacture and/or process, shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests, and submit data as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

* * * * *

(d) *Health effects testing*—(1) *Reproductive and fertility effects*—(i) *Required testing.* (A) A test for reproductive and fertility effects shall be conducted with both 1,2- and 1,4-DCBs in accordance with § 798.4700 of this chapter.

(B) The route of administration for the reproductive and fertility effects testing of both 1,2- and 1,4-DCB shall be inhalation.

(C) The test species shall be the Sprague-Dawley rat.

(ii) *Reporting requirements.* (A) Both reproductive and fertility effects tests shall be completed and the final results submitted to the Agency within 29 months of the effective date of this final rule.

(B) Progress reports for both studies shall be submitted to the Agency every 6 months after the effective date of the final rule.

(Approved by the Office of Management and Budget under control number 2070–0033)

c. By adding paragraphs (a)(3), (b)(5), and (e) to § 799.1053 to read as follows:

§ 799.1053 1,2,4-Trichlorobenzene.

(a) * * *

(3) For health effects testing required under (e), the test substance shall not contain more than 0.05 percent benzene and 0.05 percent hexachlorobenzene.

(b) * * *

(5) For health effects testing required under (e), all persons who manufacture (import) or process 1,2,4-trichlorobenzene, other than as an impurity, after the effective date of this rule (August 21, 1986) to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests, and submit data as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

* * * * *

(e) *Health effects testing*—(1) *Oncogenicity*—(i) *Required testing.* (A) A test for oncogenic effects shall be conducted with 1,2,4-TCB in accordance with § 798.3300 of this chapter.

(B) The route of administration for the oncogenicity testing for 1,2,4-TCB shall be via the animal feed.

(C) Two rodent species shall be used and one shall be the Fischer-344 rat.

(ii) *Reporting requirements.* (A) The oncogenicity test shall be completed and the final results submitted to the Agency within 53 months of the effective date of this final rule.

(B) Progress reports shall be submitted to the Agency every 6 months after the effective date of the final rule.

d. By adding § 799.1054 to read as follows:

§ 799.1054 1,2,4,5-Tetrachlorobenzene.

(a) *Identification of test substances.* (1) 1,2,4,5-Tetrochlorobenzene (CAS Number 95–94–3) (hereinafter "1,2,4,5-TCB") shall be tested in accordance with this section.

(2) 1,2,4,5-TCB of at least 99 percent purity shall be used as the test substance.

(3) The test substance shall not contain more than 0.05 percent benzene and 0.05 percent hexachlorobenzene.

(b) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture (import) or process 1,2,4,5-tetrochlorobenzene, other than as an impurity, after the effective date of this rule (August 21, 1986) to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests, and submit data as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Health effects testing.*—(1) *Reproduction and fertility*—(i) *Required testing.* (A) A test for reproduction and fertility effect shall be conducted with 1,2,4,5-TCB in accordance with § 798.4700 of this chapter.

(B) The route of administration for the reproduction and fertility testing for 1,2,4,5-TCB shall be dietary.

(C) A rodent test species shall be used and shall be the Sprague-Dawley rat.

(ii) *Reporting requirements.* (A) The reproduction and fertility test shall be completed and the final results submitted to the Agency within 29 months of the effective date of this final rule.

(B) Progress reports shall be submitted to the Agency every 6 months after the effective date of the final rule.

(2) *Developmental toxicity.*—(i) *Required testing.* (A) A test of developmental toxicity shall be conducted with 1,2,4,5-TCB in accordance with § 498.4900 of this chapter.

(B) The route of administration for the developmental toxicity testing for 1,2,4,5-TCB shall be via oral gavage.

(C) Two rodent species shall be used in the study. One shall be the Fischer-344 rat and the second the New Zealand white rabbit.

(ii) *Reporting requirements.* (A) The developmental toxicity testing shall be completed and the final results submitted to the Agency within 12 months of the effective date of this final rule.

(B) Progress reports shall be submitted to the Agency every 6 months after the effective date of the final rule.

(Approved by the Office of Management and Budget under control number 2070–0033)

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GENERAL SERVICES ADMINISTRATION

48 CFR Parts 508 and 525

[APD 2800.12 CHGE 28]

General Services Administration Acquisition Regulation; Required Sources of Supply and the Trade Agreements Act

AGENCY: Office Acquisition Policy, GSA.

ACTION: Final rule.

SUMMARY: The General Services Administration Acquisition Regulation (GSAR), Chapter 5, is revised to incorporate the substance of GSAR Acquisition Circulars AC–85–5 and AC–86–3. This change amends section 508.705–73 to eliminate the prohibition against requesting a price reduction when negotiating adjustments to delivery schedules for delinquent orders under contracts with workshops for the blind or other severely handicapped. Section 525.402 is amended to reflect the current dollar threshold for applicability of the Trade Agreements Act. Miscellaneous other changes are made in Part 508 to reflect current organization and document titles.

EFFECTIVE DATE: June 17, 1986.

FOR FURTHER INFORMATION CONTACT: Ms. Ida M. Ustad, Office of GSA