

take final action on the District's 1982 SIP revision.

Proposed Action: EPA proposes to approve the I/M portion of the SIP for the District of Columbia; however, EPA will not take final action on this portion of the plan until the District submits its audit and surveillance procedures and sticker issuance procedures.

II. Carbon Monoxide

Transportation sources, especially automobiles, are responsible for 93 percent of CO emissions in this area. CO is monitored at 10 sites throughout the region. Violations of the 8-hour standard have been recorded in areas of high traffic density. The entire District of Columbia is currently designated as nonattainment for CO. The attainment date for the District is December 31, 1987.

CO concentrations are expected to decrease significantly by 1987 due to a continuation of the Federal Motor Vehicle Control program and implementation of vehicle I/M. In order to determine expected concentrations of CO in 1987, the District performed several analyses of CO emissions. These included use of several techniques for modeling highway CO concentrations, and a modeling analysis of the primary point source of CO emissions (the Solid Waste Reduction Center). These analyses, which were submitted as part of the SIP, demonstrate that the standards for CO will be attained by 1987. The plan also contains an adequate demonstration of Reasonable Further Progress (RFP). This material satisfies EPA criteria, and the District's submittal included all items necessary for an approval CO plan.

Proposed Action: EPA proposes to approve the CO portion of the SIP.

C. Additional Requirements—1. Conformity of Federal Actions.

Compliance with Section 176(c) of the Clean Air Act requires a close cooperative effort between all agencies granted Federal funding.

Routine procedures which are part of the basic planning process performed by COG and the State and local governments will ensure that no projects will be constructed or implemented which will produce emissions that are inconsistent with the adopted SIP. Compliance with Sections 176(c) and 316 also requires the use of consistent population projections in all Federal planning activities. COG has developed a "Cooperative Forecasting Process" which fills this need.

Proposed Action: EPA proposes to approve this portion of the SIP.

2. Consultation with State and Local Officials. During the preparation of the

1982 SIP, the District, via the COG planning process, insured the continued involvement of the public and all appropriate government agency officials. Opportunity was given for all interested parties to participate in the development of the transportation plan and other elements of the SIP.

Proposed Action: EPA proposes to approve this portion of the SIP.

3. Conformance with Other Requirements of Section 172 of the Clean Air Act. Section 172(b) of the Clean Air Act requires that certain items be included in all SIP revisions. Most of these requirements have been addressed above. Following is a discussion of the remaining requirements.

a. Commitment of Financial and Manpower Resources—The District has committed adequate financial and manpower resources to carry out the programs established in the 1982 SIP.

b. Analysis of Effects—The District submitted an analysis of the effects the SIP will have on air quality, health, welfare, the economy, energy and society. In general, there are few negative effects, and these will be minimal. The majority of the effects of the plan on each of the above-mentioned criteria will be neutral or positive.

c. Contingency Plan—EPA's January 1981 policy also requires States to develop a process for identifying and implementing additional transportation control measures that can be used in the event that there is an unanticipated shortfall in emission reductions. The COG plan includes a list of measures which will be considered in each circumstance and describes the process which will be used to make up any future shortfalls.

Proposed Action: EPA proposes to approve this portion of the SIP.

EPA Action

Proposed Action: Based on the above information, EPA is proposing to approve the 1982 State Implementation Plan for ozone for the District of Columbia, submitted on December 28, 1982 and April 15, 1983. However, prior to final approval, the District must submit schedules for the control of two graphic arts sources. EPA is soliciting public comment on this notice and any related matters. Interested parties may participate in the Federal rulemaking procedures by submitting written comments to the address above.

The Administrator's decision to approve or disapprove the plan revision will be based on whether it meets the requirements of Sections 110(a)(2)(A)-(K) and 110(a)(3) of the Clean Air Act, as amended, and EPA regulations in 40 CFR Part 51.

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant impact on a substantial number of small entities. (See 46 FR 8709).

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Intergovernmental relations, Lead, Particulate matter, Carbon monoxide, Hydrocarbons.

Authority: Secs. 110(a), 172 and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410(a), 7502, and 7601(a)).

Dated: August 23, 1983.

Thomas P. Eichler,

Regional Administrator.

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40 CFR Part 773

[OPTS-47002B BH-FRL 2395-4]

Chlorinated Benzenes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule related notice; request for comments.

SUMMARY: On July 18, 1980, EPA issued a proposed test rule for health effects testing of monochlorobenzene, specific isomers of di-, tri-, and tetrachlorobenzenes, and pentachlorobenzene. EPA now intends to withdraw the proposed test requirements, except for the proposed requirement for oncogenicity testing of 1,2,4-trichlorobenzene and the proposed health effects tests for 1,2,4,5-tetrachlorobenzene, based on EPA's analysis of data received during, and subsequent to, the public comment period for the proposal and on testing being conducted by the manufacturers of chlorobenzenes. An industry-proposed testing program, sponsored by the Chlorobenzene Producers Association, should generate sufficient data to reasonably determine or predict the reproductive effects of monochlorobenzene and *ortho*- and *para*-dichlorobenzene. The need for oncogenicity testing of 1,2,4-trichlorobenzene will be determined based on data being developed by the National Toxicology Program and the Chlorobenzene Producers Association, and will be the subject of later public meeting.

DATE: Written comments should be received by February 6, 1984.

ADDRESS: Written comments should bear the document control number [OPTS-47002B] and should be submitted in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

The Administrative record supporting this action is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460, toll free: (800-424-9065), in Washington, DC: (554-1404), Outside the USA: (operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2003; 15 U.S.C. 2601 *et seq.*) authorizes the EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to human health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to the EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC designated monochlorobenzene and the dichlorobenzenes for health and environmental effects testing, as published in the Federal Register of October 12, 1977 (42 FR 55026). Tri-, tetra-, and pentachlorobenzenes were designated later by the ITC for similar testing, as published in the Federal Register of October 30, 1978 (43 FR 50630). The specific recommendations for the lower (mono- and di-) chlorinated benzenes were carcinogenicity, mutagenicity, teratogenicity, other chronic effects, environmental effects testing, and epidemiology studies. The test recommendations for the higher chlorinated benzenes were similar except for modifying the "other chronic effects" testing recommendation to include testing for "other toxic effects", particularly effects on the neurological and hematopoietic systems.

The Agency issued a proposed health effects test rule for both groups of

chlorinated benzenes designated by the ITC which was published in the Federal Register of July 18, 1980 (45 FR 48524). The proposed rule was based upon a finding that there may be an unreasonable health risk as described under TSCA section 4(a)(1)(A). Although the finding was made for the category of chlorobenzenes as a whole, EPA proposed that manufacturers and processors of the chlorinated benzenes would be required to conduct oncogenicity, structural teratogenicity, reproductive effects and subchronic/chronic effects testing of only certain members of the category.

The specific test requirements proposed on July 18, 1980, are designated with an "X" in Table 1 below. The numerical superscripts in the table summarize EPA's reasons for not proposing certain test for specific chlorobenzenes as discussed in the July 18, 1980, proposal and give EPA's subsequent conclusions concerning the proposed test requirements. The bases for these latter conclusions are presented in Units II and III of this notice.

TABLE 1.—SUMMARY OF TEST NEEDS ADDRESSED IN THE 7-18-80 PROPOSED RULE* AND RATIONALES FOR TENTATIVE DECISIONS NOT TO PURSUE SUCH TESTING THROUGH RULEMAKING

	Oncogenicity	Structural teratogenicity	Reproductive effects	Subchronic
Monochlorobenzene.	— ⁵	X ²	X ⁴	X ²
Orthodichlorobenzene.	— ⁵	X ²	X ⁴	X ²
Paradichlorobenzene.	— ⁵	X ²	X ⁴	X ²
1,2,4-Tri-	X ⁶	X ²	— ⁸	X ²
1,2,4,5-Tetra-	X ¹⁰	X ¹⁰	X ¹⁰	X ¹⁰
Pentachlorobenzene.	X ⁷	— ⁷	X ¹	— ⁸

* Neurotoxicity and behavioral teratogenicity testing were deferred pending development of test standards for each. X=Testing proposed 7-18-80.

—=Testing not proposed 7-18-80.
¹=Lack of sufficient TSCA exposure to support testing; this exposure does not include that resulting from FIFRA uses of the chemical.

²=Adequate data submitted subsequent to proposal or appropriate testing in progress.

³=Sufficient data available to reasonably predict low risk at anticipated exposure levels.

⁴=Negotiated testing program.

⁵=Bioassay testing in the National Toxicology Program (NTP).

⁶=Decision deferred pending review of ongoing NTP bioassays and short-term tests.

⁷=Sufficient data available prior to proposed rule to reasonably predict health risk.

⁸=Adequate reproductive effects study has been performed.

⁹=Sufficient data available prior to proposed rule to characterize subchronic toxicity.

¹⁰=Data provided in response to proposed rule indicate lack of sufficient TSCA exposure to support testing; however, data recently provided to the Agency indicate new production that may justify testing of 1,2,4,5-tetrachlorobenzene and/or other tetrachlorobenzene isomers.

Although the Agency did propose structural teratogenic effects testing of 1,2,4-trichlorobenzene, EPA stated that it would reconsider the need to include teratogenic testing requirements for

1,2,4-trichlorobenzene in a final test rule upon evaluation of the test data from an Agency-sponsored teratogenicity screening study being conducted at Research Triangle Park, N.C.

Also in its proposed rule, the Agency solicited comments on additional health effects testing which included neurotoxicity, behavioral teratogenicity, mutagenicity, and metabolism testing of the chlorobenzenes. However, the Agency indicated it intended to defer requiring such testing because (1) EPA was not prepared to specify test standards for neurotoxicity, behavioral teratogenicity, or metabolism testing, and (2) EPA had not yet developed mutagenicity testing sequence criteria. Subsequently, the Agency has published test guidelines for some neurotoxicity and metabolism testing (Ref. 1) and has itself initiated lower tiered mutagenicity testing of several of the industrially and commercially important isomers of the chlorinated benzenes (Ref. 2). The EPA believes that information generated by ongoing testing may bear on the determination of the need for neurotoxicity testing and has therefore decided not to propose neurotoxicity testing at this time. Guidelines are still not available for behavioral teratogenicity testing. The Agency will reevaluate the need for neurotoxicity and behavioral teratogenicity testing of the chlorobenzenes after it has assessed data from existing, ongoing, and proposed testing addressed later in this notice. The Agency does not consider these testing concerns to be dismissed by this action and intends to resolve the need to require neurotoxicity and behavioral teratogenicity testing through further analysis in calendar year 1984.

The Agency did not propose testing for oncogenicity of monochlorobenzene, *ortho*- and *para*-dichlorobenzenes, and teratogenicity and subchronic/chronic effects of pentachlorobenzene because adequate testing appeared to be underway or completed to characterize all these effects. Nor did it propose reproductive effects testing of 1,2,4-trichlorobenzene because an Agency-sponsored test was then in progress. Epidemiology studies were not proposed because the Agency was unable to identify a suitable cohort. To date no epidemiological information is known to exist for the chlorobenzenes.

The Agency did not include environmental effects testing in its July 18, 1980, proposal because environmental effects test standards development had not progressed at the same rate as that for some health effects and, therefore, test standards were unavailable for supporting an

environmental effects test rule. Environmental effects testing needs for the chlorobenzenes are currently being assessed and will be addressed by the Agency in a future Federal Register notice in this calendar year.

II. Events Subsequent to Proposal

In its July 18, 1980, proposed health effects test rule for chlorinated benzenes, EPA asked commenters to provide any other relevant health effects studies or data that were not referenced by the testing support document and which might cause the Agency to revise its evaluation of testing needs for the chlorobenzenes. A considerable amount of voluntarily submitted information was received after publication of the proposal. As a result EPA reevaluated the testing it had proposed and concluded that, with the exceptions of the oncogenicity testing of 1,2,4-trichlorobenzene and the reproductive effects testing of monochlorobenzene and *ortho*- and *para*-dichlorobenzenes, the testing as originally proposed is either already being performed or no longer necessary. This information is in the public record of this proceeding and may be commented upon during the public comment period established by this notice. Some information was received in responses to the TSCA section 8(d) Health and Safety Data Reporting rule (September 2, 1982, 47 FR 38780) and the TSCA section 8(a) Preliminary Assessment Information rule (June 22, 1982, 47 FR 26992).

After evaluating the available exposure information the chlorobenzene manufacturers had submitted after issuance of the proposed rule, the Agency had determined initially that there was insufficient human exposure to tetra- and pentachlorobenzenes to present an unreasonable risk to human health. However, more recent information on production and use of tetrachlorobenzenes was submitted to the Agency (see Unit III.A.). This new information has prompted the Agency to reconsider its initial determination for not requiring health effects testing of tetrachlorobenzenes while proceeding to publish its testing decisions regarding the other chlorobenzenes. Consequently, the Agency is deferring its final decision on the need for testing of tetrachlorobenzenes until the potential for exposure through the new production and use of tetrachlorobenzenes can be assessed adequately.

In June, 1981, EPA informed the Chlorobenzene Producers Association (PA) of the results of its tentative assessment of testing needs and over the next 8 months, began discussions with industry about additional testing.

Generally, EPA does not negotiate testing with industry after it has proposed a test rule. The policy of not negotiating after proposal was adopted because the advantages of negotiations, *i.e.*, saving time and Agency resources, are less if the Agency has already issued a proposed test rule. However, the chlorobenzenes were treated as an exception to this policy because negotiations with industry were well underway at the time the policy was adopted. On February 26, 1982, the CPA proposed a test program for the chlorobenzenes for the remaining health effects of concern (Ref. 3). EPA delayed publishing this notice because of the Agency's need to give highest priority to complying with the court-ordered test rule actions for calendar year 1982 (*Costle vs NRDC*; 79 Civ 2411, U.S. District Court, January 9, 1981). Meanwhile, the CPA decided not to initiate its proposed testing until EPA formally accepted the test program through a published Federal Register notice and public comment was received on the CPA test proposal.

A. Reproductive Effects Testing of mono- and Dichlorobenzenes

The CPA proposes to conduct reproductive effects testing of monochlorobenzene, and *ortho*- and *para*-dichlorobenzenes under a "decision tree" or tiered approach. Testing on monochlorobenzene will be performed first because (1) evidence suggesting reproductive toxicity is available for monochlorobenzene (see Chlorinated Benzenes Support Document for the proposed rule) and (2) reproductive effects test data on monochlorobenzene, in combination with that now available for 1,2,4-trichlorobenzene will be most useful for making reproductive effects testing decisions about the dichlorobenzenes since these chlorobenzene isomers structurally bracket the dichlorobenzenes.

If the test on monochlorobenzene fail to show a biologically significant adverse reproductive effect, no further reproductive effects testing will be necessary for the dichlorobenzenes. As stated in Unit III. D. 2. below, EPA believes that if reproductive effects testing of monochlorobenzene fails to yield a biologically significant adverse reproductive effect, this when combined with negative reproductive effects for 1,2,4-trichlorobenzene and other available information will mean there is no basis for believing that these chemicals are likely to pose an unreasonable risk of reproductive effects to humans. If, however, the monochlorobenzene study does show a

biologically significant adverse reproductive effect, the producers, in consultation with EPA, will select either *ortho*- or *para*-dichlorobenzene for consideration for reproductive effects testing. Together with EPA, the producers will then evaluate all other data available at the time regarding the dichlorobenzene selected, including exposure data and toxicity data, to determine whether a reproductive effect study on either *ortho*- or *para*-dichlorobenzene is needed. If, after that evaluation, there remains a need for a reproductive effect study on the first dichlorobenzene as determined by EPA, the producers will conduct such a study.

Upon the completion of the first dichlorobenzene study, the producers, together with EPA, will evaluate all other data available at the time, including available exposure and toxicity data and the results of the monochlorobenzene and dichlorobenzene studies, to determine whether the second dichlorobenzene should be tested for reproductive effects. If after that evaluation, there remains a need for a reproductive effects study on the second dichlorobenzene as determined by EPA, the producers will conduct such a study.

Reproductive effects testing protocols will be submitted to the Agency in advance of each study. The protocols for the monochlorobenzene study will be consistent with those proposed by the Agency on July 28, 1979 (44 FR 44087), with appropriate modification for the inhalation route of exposure. Subsequent protocols may vary depending upon the state of the art at the time the study is undertaken.

The complete reproductive effects testing proposal is contained in the public record for the chlorobenzenes and is part of the comprehensive test agreement package contained in (Ref. 3) of Unit V of this notice.

Persons interested in reviewing the reproductive effects test data for the individual chlorobenzenes being proposed for testing and assisting the Agency in determining whether additional reproductive effects testing will be necessary, should notify the Agency at the address given above.

B. DNA Repair and Cell Transformation Tests on Monochlorobenzene, ortho-Dichlorobenzene and 1,2,4-Trichlorobenzene

In discussing the question of oncogenicity testing for 1,2,4-trichlorobenzene, CPA suggested that a testing decision should be based on the results from the National Toxicology Program's (NTP's) chronic toxicity

bioassays on monochlorobenzene and *ortho*-dichlorobenzene. The Agency agreed that the results of the bioassays would be useful, but suggested that additional *in vitro* cell transformation data also might be useful in making a priority decision concerning the need for oncogenicity testing of 1,2,4-trichlorobenzene. As a result of these discussions, the CPA initiated DNA repair and cell transformation assays for each of the following: monochlorobenzene, *ortho*-dichlorobenzene, and 1,2,4-trichlorobenzene.

The DNA repair study is in a primary hepatocyte cell culture from adult male F-344 rats. The major advantage proposed for this test system is that the liver has the broadest capability for biotransformation of xenobiotics, and in this test system cultured hepatocytes will provide this same metabolic capability but in an intact cell system. This test has been conducted according to a method developed by Dr. Gary Williams, (Refs. 4,5). This test protocol was reviewed by EPA prior to initiation of the study. The DNA repair test proposal is attachment B-1 of the February 26, 1982, comprehensive test proposal (Ref. 3), and is available for inspection in the public record. This study will follow the proposed testing guidelines for detecting effects on DNA repair or recombination (the guidelines first proposed as test standards in 40 CFR 772.114-4).

The DNA repair assay is currently being performed. A copy of the final test report including study results will be incorporated into the public record for this action when it is made available to the Agency by the CPA later this year.

Attachment B-2 of the CPA test program (Ref. 3) contains the protocol for a cell transformation assay in adult Fischer F-344 rat liver epithelial cells. The assessment of neoplastic transformation by chemicals in adult rat epithelial cell lines (ARL) involves assay for five markers of transformation. Growth on soft agar, growth in low calcium medium, increase in cell density at confluency, presence of cytochemical activity of gamma-glutamyl transpeptidase, and increase in 2-deoxyglucose uptake have established by San, *et al.*, 1979 (Ref. 6) as objective and quantifiable markers of transformation in liver cells. These markers were shown to be induced by chemical carcinogens (Shimada, *et al.*, 1980) (Ref. 7).

The advantages cited by CPA for the ARL transformation assay are that these lines are of epithelial origin, producing carcinomas upon implantation in animals after transformation (Williams

et al., 1973) (Ref. 8); and, being derived from liver, they retain a broad capability for intact cell carcinogen metabolism as shown in mutagenesis studies (Tong and Williams, 1978 and 1980) (Refs. 9, 10)

The reliability of these cell transformation and DNA repair assays for predicting the oncogenic potential of untested chemicals has not been fully established. EPA has sponsored testing of known chemical carcinogens and non-carcinogens in these assays in an attempt to validate the usefulness of the test systems for predicting chemically-induced oncogenicity. However, these studies were never completed and the assays were never fully validated by EPA for general use. (Final reports for the completed test results are available for inspection in the public docket.) Nevertheless, EPA believes that test data resulting from the CPA program specifically using the chlorobenzenes, when assessed with EPA's own mutagenicity test data and the results from NTP's chronic toxicity bioassays, will provide information relevant to determining the need for 1,2,4-trichlorobenzene oncogenicity testing. EPA plans to re-open the comment period and hold a public meeting in the first quarter of 1984 to discuss the results from all these tests and establish their usefulness in determining the need for the oncogenicity testing of 1,2,4-trichlorobenzene.

C. Interactive Process

EPA and the manufacturers have agreed, that as each necessary sequence of the reproductive effects testing is completed, they will meet to discuss whether the test data will enable the Agency to assess the health risk for the test chemical.

1. CPA has agreed to furnish EPA with the names and addresses of the laboratories conducting the tests described above as soon as they are available. The specific test being performed by each laboratory shall be indicated.

2. CPA has agreed to adhere to the Good Laboratory Practice Standards adopted by the Food and Drug Administration (FDA) in 43 FR 59986 (December 22, 1978).

3. CPA has agreed to permit laboratory audits/inspections by the EPA or FDA in accordance with the authority and procedures outlined in TSCA Section 11. 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 that the studies are being conducted according to either

TSCA or FDA Good Laboratory Practices.

4. CPA has agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of a study and required to be retained by proposed TSCA Good Laboratory Practice Standards or FDA Good Laboratory Practices, at CPA's option, will be retained for a period of ten years after completion of a study and made available to EPA during an inspection, or submitted to EPA if requested by EPA.

5. TSCA section 14(b)(1)(A)(i) governs Agency disclosure of all test data submitted pursuant to this negotiated agreement. The Agency plans to publish quarterly notices in the *Federal Register* of the receipt of all test data submitted under this agreement. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, such data will be made available by EPA for examination by any person.

6. Finally, failure to conduct the testing according to the specified protocol(s) or failure to follow Good Laboratory Practices as indicated above may invalidate the tests. In such cases, a data gap may still exist and the Agency may decide to require testing through a rule.

D. Timing of Testing

CPA anticipates starting the reproductive effects testing within 3 months of final acceptance of the proposal by EPA and completion of dosing for these studies 12 months after the start date (Ref. 3).

Quarterly status reports of study progress will be submitted to the Agency while testing is being conducted and will be available for review in the public record. A final report will be issued upon evaluation of the data and released by the Chemical Manufacturers Association (CMA) which will be providing administrative and technical support to the CPA for the test program. This is anticipated to occur 12 months after sacrificing the test animals for the study. The total time from initiation to report submission to EPA is 24 months, somewhat less than the initiation to submission time proposed by EPA in the July 18, 1980, notice (45 FR 48536). If one or both of the dichlorobenzenes are required to be tested, testing will begin as soon as practical following the decision to test. The same dosing periods and reporting schedules set forth for monochlorobenzene will be followed. Should CPA fail to make a good faith effort to adhere to its testing

schedule, EPA will initiate rulemaking to require testing.

As indicated in Unit II.B., the cell transformation and DNA repair studies have been initiated. Test completion is expected in September, 1983, with report submission to EPA by December 31, 1983. EPA will include these test results in the public record as soon as they are made available to the Agency.

III. Proposed Decision to Terminate Rulemaking

For the reasons described below, the Agency has tentatively accepted the CPA reproductive testing program, concluding that the proposed reproductive effects testing will adequately characterize the reproductive health hazards for the lower chlorinated benzenes. In addition, EPA has concluded that CPA's cell transformation and DNA repair testing for the chlorinated benzenes, together with other relevant test data discussed in Unit III.C. below, is likely to provide information relevant to evaluating the oncogenic potential of 1,2,4-trichlorobenzene and does not believe that immediately beginning a 2-year bioassay would be necessary. EPA also believes that: (1) The teratogenic effects testing results for monochlorobenzene, *ortho*- and *para*-dichlorobenzenes, and 1,2,4-trichlorobenzene, received after the July 18, 1980, proposal, are adequate to reasonably determine or predict the potential teratogenic risk of these substances; (2) ongoing or completed studies will provide adequate data to reasonably predict the subchronic/chronic toxicity of the above-mentioned substances; (3) that exposure data received subsequent to the July 18, 1980, proposal indicate that there is insufficient exposure to pentachlorobenzene to support section 4(a)(1)(A) findings to require the health effects testing previously proposed for this chemical, and (4) that the exposure profile of the tetrachlorobenzenes is highly uncertain at the current time.

Therefore, on the basis of the information now available to the Agency and the proposed CPA testing program, EPA has tentatively decided not to issue a final rule for any of the previously proposed health effects tests for any of the chlorinated benzenes at this time and will, therefore, withdraw its proposed test rule except for testing of 1,2,4,5-tetrachlorobenzene and oncogenicity testing of 1,2,4-trichlorobenzene. In the latter case, EPA will determine the need to promulgate a final test rule upon review of the data from the ongoing NTP oncogenicity tests and the CPA's DNA repair and cell transformation tests.

Should the test results indicate to EPA the need for a long-term oncogenicity bioassay for this substance, the Agency can proceed with issuing a final rule under section 4(a) of TSCA. This decision will be the subject of subsequent public comment and a public meeting. The reasons for the Agency's decision with respect to each of the chlorobenzenes are presented below.

A. Exposure Data: *meta*-Dichlorobenzene, 1,2,3- and 1,3,5-Trichlorobenzenes, and *Tetra*- and *Penta*-Chlorobenzenes

In the fall of 1980, the CPA submitted to the Agency two occupational exposure survey reports, one for trichlorobenzenes (Ref. 11) and a second for *tetra*- and *pentachlorobenzenes* (Ref. 12). Occupational survey reports for monochlorobenzene and the dichlorobenzenes were submitted in February 1980 (Ref. 13). The exposure estimates used by the Agency in its July 18, 1980, proposal and the industry estimates of exposure to these chlorinated benzenes appear in Table 2.

TABLE 2—ESTIMATED OCCUPATIONAL EXPOSURES TO CHLOROBENZENES

	Total potential 1978 production (million pounds) (Ref. 14)	Worker exposure (NOHS 1979) (Ref. 15)	CPA**
Monochlorobenzene	300-325	1,092,522	3,146 (Ref. 13)
<i>o</i> -Dichlorobenzene	50	1,977,529	1,311 (Ref. 13)
<i>p</i> -Dichlorobenzene	70	544,000	821 (Ref. 13)
Trichlorobenzenes (1,2,4 & 1,2,3)*	20*	1,080,825	47,995 (Ref. 11)
Tetrachlorobenzenes (all three isomers)	6.5	N/A	82 (Ref. 12)
Pentachlorobenzene	5	N/A	33 (Ref. 12)

*Includes imports

**The CPA surveys did not take into account workers exposed through most processing and uses of the surveyed chemicals. N/A=Not Available.

* 1,2,3-Trichlorobenzene was only a minor component in a trichlorobenzene product mix.

The Agency concludes from the CPA information (Refs. 11, 12, 13 and 14) that there is insufficient human exposure to several chlorinated benzenes, namely *meta*-dichlorobenzene, and 1, 2, 3-, and 1, 3, 5-trichlorobenzenes, because these chemicals are low volume incidental contaminants occurring during the manufacture of the industrially and commercially important isomers. Therefore, EPA believes there is no reason to require testing of these isomers under TSCA section 4(a).

The CPA information indicated that 100 percent of the 6.5 million pounds of tetrachlorobenzenes (all three isomers) produced in 1978 was consumed in the manufacture of pentachlorobenzene.

The information further showed that all of the pentachlorobenzene then was used to produce pentachloronitrobenzene, whose uses are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and are outside of the coverage of TSCA. The data also showed that while there were 82 workers exposed to tetrachlorobenzenes and 33 to pentachlorobenzene, the total number of workers exposed to either or both materials together was 82 because the tetrachlorobenzene to pentachloronitrobenzene conversion process was operated by the same 33 workers. The CPA also pointed out that there was virtually no TSCA-covered consumer or significant general population exposures to either the tetrachlorobenzenes or pentachlorobenzene. The Agency found no contradictory evidence in the information reported by chlorobenzene manufacturers and importers under the TSCA section 8(a) Preliminary Assessment Information rule (June 22, 1982, 47 FR 26992) with respect to these substances.

More recently, several of the chlorobenzene manufacturers have voluntarily notified the Agency, via written correspondence which is available for inspection in the public docket for this action, that they have ceased production of all chlorobenzenes. Some of these manufacturers were the only domestic producers of *tetra*- and *pentachlorobenzenes*. There is no indication of importation. Consequently, EPA has tentatively decided to withdraw the proposed health effects testing requirements for pentachlorobenzene because it is unable to conclude that there is sufficient exposure which, if combined with effects data, might indicate a potential for unreasonable risk. However, CPA has informed the Agency (Ref. 16) that one manufacturer has just begun to produce a substance composed of trichlorobenzenes and tetrachlorobenzenes for use as a substitute for PCB's in electric transformers. This new use information for tetrachlorobenzenes raises concerns regarding potential human exposure which were controlled during the manufacture of pentachlorobenzene and pentachloronitrobenzene. The Agency intends to study this recently reported information in detail and determine the potential for human exposures during production and use, and reassess the need for health effects testing of tetrachlorobenzenes. The Agency plans to complete this analysis during 1984, and hold a public meeting to discuss its

findings. Notification of this public meeting will be included in a Federal Register notice announcing a public meeting for EPA's testing decision regarding 1, 2, 4-trichlorobenzene (see Unit III.C. below).

B. Chronic/Subchronic Toxicity Studies

1. *Monochlorobenzene, ortho- and para-dichlorobenzenes.* In June, 1981, EPA received data from prechronic and subchronic toxicity testing being performed by the NTP with rats and mice for monochlorobenzene, *ortho-* and *para-dichlorobenzenes* (Refs. 17, 18, 19 and 20). For all three compounds, a dose-response relationship was observed and a subchronic no-effect level was established. EPA's examination of the subchronic studies conducted with these chlorobenzenes has found that they contain sufficient information to characterize the subchronic toxicity of these three substances and generally produce sufficient data under TSCA section 4(a) to reasonably predict chronic effects in humans at expected exposure levels.

2. *1,2,4-Trichlorobenzene.* The Agency also received in June, 1981, a published scientific paper by Kociba, *et al.*, 1981 (Ref. 21) which contained subchronic inhalation toxicity data for 1,2,4-trichlorobenzene in the rat, rabbit, and Beagle dog. EPA has found that this study was too short (30 exposures in 44 days) for an adequate subchronic study and that the administered doses were not high enough to totally characterize the toxicity. However, there were indications of an effect at 100 ppm when inhaled for 7 hours/day, 5 days/week for a total of 30 exposures. At this dose, increases in liver weights were observed in dogs and rats, increases in kidney weights were observed in rats, and increases in blood urea nitrogen (BUN) were observed in rabbits. The results of the Kociba study supplement those of Dow Chemical Company, 1977 (Ref. 22), Gage, 1970 (Ref. 23) and Coate *et al.*, 1977 (Ref. 24), previously contained in the public record. In the Dow study, groups of male and female rats inhaling 10 ppm 1,2,4-trichlorobenzene for 6 hours per day, 5 days per week for 3 months showed an increase in the urinary excretion of both copro- and uroporphyrin. These levels returned to normal 4 months after cessation of exposure. Gage showed that no toxicity resulted from the inhalation of 20 ppm of 1,2,4-trichlorobenzene for twenty 6-hour exposures. However, at higher doses (i.e. fifteen 6-hour exposures of 200 and 70 ppm) lethargy and retarded weight gain were observed. The Coate *et al.* study found that inhalation of 25, 50, and 100 ppm 1,2,4-trichlorobenzene for 4 and

13 weeks at 7 hours per day and 5 days per week resulted in microscopic changes to the livers and kidneys of exposed rats. However, no exposure-related effects were seen after 26 weeks of exposure in any species.

Based upon the results of these 4 studies, and the subchronic results for the lower chlorinated benzenes, generated by NTP (Ref. 25), EPA tentatively has concluded that there is sufficient information to reasonably predict that at expected exposure levels (at or below 5 ppm TLV), the risk of chronic effects to humans of exposure to 1,2,4-trichlorobenzene would be minimal. Therefore, the Agency finds that no further testing of this chemical under TSCA section 4 for chronic or subchronic effects is necessary at this time.

C. Oncogenic Effects Testing of 1,2,4-trichlorobenzene

The CPA proposed testing program for DNA repair and cell transformation studies (Unit II.B.) is premised on the belief that a correlation can be made between the results of the proposed short-term assays and the ongoing NTP 2-year chronic toxicity bioassays which will allow reasonable prediction of 1,2,4-trichlorobenzene's oncogenic potential. The NTP long-term bioassays on monochlorobenzene and *ortho-dichlorobenzene* would provide a total of five data points, when combined with the CPA's short-term test results for monochlorobenzene, *ortho-dichlorobenzene*, and 1,2,4-trichlorobenzene. *Together, these data would be used to determine the need to require oncogenicity testing of 1,2,4-trichlorobenzene. (In the CPA short-term testing program (Unit II.B.), ortho-dichlorobenzene was used because the NTP long-term study results on this isomer will precede those of para-dichlorobenzene which are expected in 1984.)*

Other data are or soon will become available to the Agency to include in its considerations when making the oncogenicity priority testing determination for 1,2,4-trichlorobenzene. These are: (1) the final results of the National Institute of Environmental Health Sciences (NIEHS) and the NTP mutagenesis testing showing that monochlorobenzene, 1,2,4-trichlorobenzene and pentachlorobenzene are all negative in the *S. typhimurium* assay (Ref. 26); (2) the negative results of NIEHS/NTP mutagenicity testing in the *S. typhimurium* assay for 1,2,4,5-tetrachlorobenzene (Ref. 26); and (3) the mutagenicity test data on mono-, *ortho-di-*, *para-di-*, 1,2,4-tri- and 1,2,4,5-

tetrachlorobenzenes that will become available this year from an EPA contract with Bioassay Systems, Inc., Woburn, Mass. (Ref. 2). (The later testing provides for the tiered mutagenicity testing sequences as outlined in the July 18, 1980, proposed rule and includes *Drosophila* sex-linked recessive lethal, *in vitro* gene mutation, *Aspergillus* reverse mutation, unscheduled DNA repair, *in vitro* and *in vivo* cytogenetics, and dominant lethal assays.)

The Agency believes that if the short-term assays are clearly negative, and if the NTP long-term bioassay results on monochlorobenzene and *ortho-dichlorobenzene* are also negative, sufficient data and experience will be available to reasonably predict that 1,2,4-trichlorobenzene will present so low a likelihood of oncogenicity as not to constitute an unreasonable risk. The Agency would not interpret such data to mean that this chemical is proven not to be an oncogen, but rather that the likelihood of its being a potent oncogen would be slight given such results.

In the event that results from the CPA short-term assays and the NTP long-term studies are positive or mixed, the Agency will require oncogenicity testing of 1,2,4-trichlorobenzene unless comments indicate that such testing is unnecessary. In the event that EPA concludes that an oncogenicity test for 1,2,4-trichlorobenzene is needed, the Agency will require such additional testing by a final rule unless the manufacturers promptly initiate the appropriate testing. EPA expects to receive all of the data from the CPA short-term assays and the NTP long-term studies by the end of the current calendar year. At that time EPA will re-open the record for public comment and schedule a public meeting through a notice in the Federal Register in which discussions will focus on the interpretation of the available data in making a TSCA section 4 test decision regarding 1,2,4-trichlorobenzene.

D. Teratology and Reproductive Effects

1. *Teratology studies on monochlorobenzene, ortho-, and para-dichlorobenzenes.* In its comments to the Agency on the two ITC recommendations, the Dow Chemical Company reported that the chlorobenzene producers were planning to jointly sponsor teratology studies on monochlorobenzene and *ortho-* and *para-dichlorobenzenes*. At the time of the proposal, the CMA was preparing to initiate this test program; however, because test protocols were not available to EPA until after the proposed rule was published, the

Agency could not review and evaluate them.

In July, 1980, CMA submitted its proposed protocols for inhalation teratology testing of monochlorobenzene and *ortho*- and *para*-dichlorobenzenes in rats and rabbits (Refs. 27, 28, and 29). Nearly 1 year later, EPA had received an interim study report for monochlorobenzene in both species (Ref. 30), a final testing protocol for a repeat of the rabbit teratology study (or Phase II) of monochlorobenzene (Ref. 31), and an interim report for the second rabbit teratology study (Ref. 32).

On February 24, 1982, CMA submitted a final report of the monochlorobenzene teratology studies (Ref. 33). Exposure of pregnant rats to 75, 210, or 590 ppm of monochlorobenzene for 6 hours/day on days 6 through 15 of gestation produced maternal toxicity only at the highest exposure level. No evidence was found of any embryotoxicity or increased incidence or external or soft-tissue abnormalities in rats at any exposure level. Exposure of pregnant rabbits to the same regimen as that used for rats, but on days 6 through 18 of gestation, produced elevated maternal liver weights in the 210 and 590 ppm exposure groups and a slightly, but not statistically significant, increased incidence in external and soft-tissue malformations at all exposure levels. The incidence of fetal malformations did not increase in a dose-related manner. The CMA concluded that the data indicated a need for further monochlorobenzene inhalation exposure studies because of inconsistencies in the results from the two species studied. Consequently, they continued with a second study in rabbits with exposure levels of 0, 10, 30, 75 and 590 ppm (Phase II). The results of the Phase II study (Ref. 33) showed that although a variety of external, soft-tissue, and skeletal malformations were observed in the rabbit at all exposure levels including controls, the incidences of major malformations in offspring of the exposed groups were not significantly increased, compared to their respective control groups. The Agency believes these data are sufficient to assess the human teratogenic risk from exposure to monochlorobenzene.

The CMA has provided EPA with a copy of their *ortho*-dichlorobenzene teratology probe study report (Ref. 34). This report describes various maternal and embryotoxic effects in pregnant rats exposed to 400 or 500 ppm for 6 hours/day on days 6 through 15, and toxic effects in pregnant rabbits at 500 ppm on days 6 through 10. The full teratology

study was then initiated and employed the testing protocol given in (Ref. 35).

A final report of this study received by EPA in July 1982, showed that when exposed to 100, 200, and 400 ppm for 6 hours/day there were low incidences of malformations observed among fetuses for each test species from all test groups, including controls. The incidences of major malformations were not significantly increased over controls in either species. Maternal toxicity, as evidenced by depressed body weight gain, was observed in both species, and liver weights were significantly elevated among pregnant rats exposed to 400 ppm of *ortho*-dichlorobenzene. Exposure to this chlorobenzene was described as not being embryotoxic or teratogenic in either species at the concentrations tested (Ref. 36). EPA believes that this information is sufficient to assess the human teratogenic risk from exposure to *ortho*-dichlorobenzene.

On May 28, 1981, Imperial Chemical Industries Limited (ICI) provided to EPA results of a rat inhalation teratology study on *para*-dichlorobenzene (Ref. 37). The Agency has reviewed these results and has found the test data to be sufficient for characterizing *para*-dichlorobenzene's teratogenic effects in rats. The test results demonstrate that *para*-dichlorobenzene is not embryotoxic, fetotoxic, or teratogenic in the rat at levels up to and including 500 ppm. However, because EPA believes that data from two test animal species generally are necessary to assess the potential teratogenic risk of a chemical to humans, CPA/CMA agreed to continue with its original plan to conduct teratogenicity testing in rabbits on *para*-dichlorobenzene. Results for the probe inhalation teratology study in rabbits using *para*-dichlorobenzene were submitted by the CMA on April 2, 1982 (Ref. 38). These results indicate that slight maternal toxicity was occurring in the 1,000 ppm probe test group. Consequently, inhalation exposure levels of 100, 300, and 800 ppm were selected for the teratology study. In a final report submitted to the Agency in October 1982, 6 hours/day exposures during the period of major organogenesis was not embryotoxic or teratogenic in rabbits. Slight maternal toxicity, as evidenced by a decrease in body weight gain on days 6 through 8 of gestation, was observed only in the 800 ppm group (Ref. 39). EPA believes that this data, when combined with the ICI data, is sufficient to assess the human teratogenic risk of *para*-dichlorobenzene.

EPA's review of the proposed and final teratology testing protocols for rats

and rabbits and final test data resulting from the testing on monochlorobenzene and *ortho*- and *para*-dichlorobenzenes has convinced it of the adequacy of the testing approach and sufficiency of test data to allow a reasonable prediction of the teratogenic potential to human health of these substances. Based upon this data, the Agency finds no need to require further teratology testing on these compounds. This notice sets forth EPA's tentative decision to withdraw its proposed teratology testing requirement for these three substances.

2. *Reproductive effects testing on monochlorobenzene and ortho- and para-dichlorobenzene.* The CPA-proposed tiered reproductive effects testing of monochlorobenzene and *ortho*- and *para*-dichlorobenzenes was described in Unit II.A. EPA believes that a negative result on monochlorobenzene, when combined with the negative result on 1,2,4-trichlorobenzene described in Unit III.D.3. below, is sufficient to reasonably predict a low likelihood of reproductive effects potential of the two dichlorobenzenes. If, however, the monochlorobenzene study is positive and the CPA does not demonstrate that additional testing of one of the dichlorobenzenes is unnecessary, then one of the dichlorobenzenes will be tested. A weight-of-evidence judgment will be made as to whether the second dichlorobenzene needs to be tested.

This study plan appears to EPA to be acceptable for generating sufficient data for predicting the reproductive effects of the chlorinated benzenes. Therefore, EPA intends to withdraw its proposed requirement for reproductive effects testing for monochlorobenzene and the dichlorobenzenes.

3. *Teratogenicity testing of 1,2,4-trichlorobenzene.* EPA, at its Health Effects Research Laboratory in Research Triangle Park, N.C., has performed reproductive effects studies and an embryo/fetal teratology screen on 1,2,4-trichlorobenzene (Ref. 40). The embryo/fetal teratology screen was performed in the mouse and the reproductive effects study was performed in the rat. The test data, indicating negative effects in both these studies, became available in August, 1980, just subsequent to publication of the proposal.

Because the screening test has not yet been fully validated, the Agency finds the use of these results alone is not adequate for fully assessing 1,2,4-trichlorobenzene teratogenicity. However, there are other data which EPA considered in making a decision regarding teratology of 1,2,4-trichlorobenzene. For example, no

effects on fertility, growth, viability, locomotion activity, or blood chemical analyses were shown in the reproductive effects study of 1,2,4-trichlorobenzene where rats were continuously exposed to 25, 100, and 400 ppm of 1,2,4-trichlorobenzene through their drinking water. Adrenal gland enlargement was observed, however, in both the F_0 and F_1 animals at 95 days of age.

In further study of the adrenal gland enlargement phenomenon, immature females given interperitoneal injections of 250 or 500 mg/kg 1,2,4-trichlorobenzene on 3 consecutive days showed no estrogenic activity but did show significant enlargement of livers and adrenals over those of controls. Rather than being estrogenic, 1,2,4-trichlorobenzene in this treatment regimen resulted in decreased uterine weights (Ref. 40). Although uterine weights were decreased and could indicate a shift in the estrogen to progesterone ratio, this shift is not considered reproductively significant to the rat study since no other reproductive effect was found in the rat.

EPA has determined that the negative results of the teratology screening, including the absence of embryo/fetal or neonatal wastage, when combined with the negative teratology findings emerging from the CMA and the ICI teratology programs on monochlorobenzene and the dichlorobenzenes, and the lack of observed teratogenic effects seen in EPA's reproductive effects study, indicate that the teratogenic potential of 1,2,4-trichlorobenzene is very small. Thus, EPA believes that testing 1,2,4-trichlorobenzene for teratogenic effects is no longer needed since the Agency can reasonably predict the teratogenic potential of 1,2,4-trichlorobenzene.

IV. Public Comment

EPA is herein soliciting public comment on its tentative decision not to proceed with promulgating a health effects test rule for the chlorinated benzenes except possibly for 1,2,4-trichlorobenzene and 1,2,4,5-tetrachlorobenzene. Comments should bear the identifying docket number [OPTS-47002B].

Comments especially are sought on the need for EPA to require health effects testing of 1,2,4,5-tetrachlorobenzene and/or other tetrachlorobenzene isomers in the light of recently increased production of these chlorobenzenes for uses subject to TSCA, e.g., substitute for PCBs. Commenters are requested to provide any data relevant to the potential for human exposure to tetrachlorobenzenes

resulting from this increased production, and to address the need to develop further test data on 1,2,4,5-tetrachlorobenzene and/or other tetrachlorobenzenes to evaluate any risks associated with such exposures.

V. References

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- (2) Bioassay Systems Corporation, "Chloromethane/Chlorobenzenes Testing Project—Monthly Project Reports for Project Number 10506." Washington, D.C.: Office of Toxic Substances, U.S. Environmental Protection Agency. Contract No. 68-02-3173.
- (3) "Chlorobenzene Producers Association Proposed Voluntary Health Effects Test Program for Chlorobenzenes," Chlorobenzene Producers Association, February 26, 1982.
- (4) Williams, G.M., "Detection of Chemical Carcinogens by Unscheduled DNA Synthesis in Rat Liver Primary Cell Cultures." *Cancer Research*, Vol. 37, pp. 1845-1851, 1977.
- (5) Williams, G.M., In: *Chemical Mutagens*, Vol. VI ed., F.J. de Serres and A. Hollaender, Plenum Press, New York, pp. 61-79, 1980.
- (6) San, R.H.C. et al., "A Survey of Growth in Soft Agar and Cell Surface Properties as Markers for Transformation in Adult Rat Liver Epithelial-Like Cell Cultures." *Cancer Research*, Vol. 39, pp. 4441-4448, 1979.
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- (12) "Employee Exposure to Tetrachlorobenzene and Pentachlorobenzene Products," prepared by Hull & Co. of Greenwich, Connecticut, for The Chlorobenzene Producers Association of The Synthetic Organic Chemical Manufacturers' Association, Inc., June 1980.
- (13) "Employee Exposure to Chlorobenzene Products," prepared by Hull & Co. of Greenwich, Connecticut, for the Chlorobenzene Producers Association of the Synthetic Organic Chemical Manufacturers' Association, Inc., February 1980.
- (14) "Proceedings from Public Meetings Held October 24, 1980, at 1:10 p.m., re: Section Four Proposed Rules—Chlorobenzene Producers Association," Prepared by Hunt Reporting Company, Severna Park, Maryland.
- (15) NIOSH, 1979. National Institute for Occupational Safety and Health. National Occupational Hazard Survey Data Base. Washington, D.C. U.S. Department of Health, Education, and Welfare.
- (16) General Contact Report: Chlorinated Benzenes. Phone conversation between Steven Newburg-Rinn (EPA) and R. Bruce Dickson (CPA), August 30, 1983.
- (17) "Subchronic Toxicity Studies in Mice and Rats: Chlorobenzene, a Report;" Battelle Columbus Laboratories, Columbus, Ohio. Subcontract No. 76-34-106002; October 25, 1978.
- (18) "Subchronic Toxicity Studies in Mice and Rats: *ortho*-Dichlorobenzene, a Report;" Battelle Columbus Laboratories, Columbus, Ohio. Subcontract No. 76-34-106002; December 21, 1978.
- (19) "Subchronic Toxicity Study in Mice and Rats: *para*-Dichlorobenzene, a Report;" Battelle Columbus Laboratories, Columbus, Ohio. Subcontract No. 76-34-106002; March 20, 1979.
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- (26) National Toxicology Program. Technical Bulletin, Vol. 1, Issue 3, December 1980.
- (27) "Monochlorobenzene: Inhalation Teratology Study in Fischer 344 Rats and New Zealand White Rabbits Proposed Probe and Teratology Protocols;" Chemical Manufacturers' Association, July 1980.
- (28) "Orthodichlorobenzene: Inhalation Teratology Study in Fischer 344 Rats and New Zealand White Rabbits Proposed Probe and Teratology Protocols;" Chemical Manufacturers' Association, July 1980.
- (29) "Paradichlorobenzene: Inhalation Teratology Study in Fischer 344 Rats and New Zealand White Rabbits, Proposed Probe and Teratology Protocols;" Chemical Manufacturers' Association, July 1980.
- (30) "Monochlorobenzene: Inhalation Teratology Study in Fischer 344 Rats and New Zealand White Rabbits, an Interim

Report: "Dow Chemical Company, Midland, Michigan; February 16, 1981.

(31) "Monochlorobenzene: Inhalation Teratology Study in New Zealand White Rabbits, a Final Protocol;" Chemical Manufacturers' Association, February 24, 1981.

(32) "Monochlorobenzene: Inhalation Teratology Study in New Zealand White Rabbits, an Interim Report;" Dow Chemical Company, Midland, Michigan; June 12, 1981.

(33) "Monochlorobenzene: Inhalation Teratology Study in Rats and Rabbits, a Final Report;" Chemical Manufacturers' Association, January 1982.

(34) "Orthodichlorobenzene: Inhalation Teratology Probe Study in Rats and Rabbits, a Study Report;" Chemical Manufacturers' Association, June 8, 1981.

(35) "Orthodichlorobenzene: Inhalation Teratology Study in Fisher 344 Rats and New Zealand White Rabbits, a Final Protocol;" Chemical Manufacturers', June 1, 1981.

(36) Orthodichlorobenzene: Inhalation Teratology Study in Rats and Rabbits, a Final Report;" Chemical Manufacturers' Association, June 7, 1982

(37) "Paradichlorobenzene: Teratology Study in Rats, a Final Report;" Imperial Chemical Industries Limited, July 27, 1977.

(38) "Paradichlorobenzene: Inhalation Teratology Probe Study in Rabbits, a Report;" Chemical Manufacturers' Association, February 16, 1982

(39) "Paradichlorobenzene: Inhalation Teratology Study in Rabbits, a Final Report;" Chemical Manufacturers' Association, September 15, 1982

(40) Robinson K. S., Kavlock R. J., Chernoff N., and Gray E., "Multigeneration Study of 1,2,4-Trichlorobenzene in Rats," Journal of Toxicology and Environmental Health, Vol. 8, pp. 489-500, 1981.

VI. Public Record

EPA has established a public record for this rulemaking decision under TSCA section 4, docket number [OPTS-47002B]. This record includes basic information considered by the Agency in developing this decision. The Agency will supplement the record with additional relevant information as it is received. The record includes the following information:

- (1) Federal Register notices containing the designation of the chlorinated benzenes to the Priority List.
- (2) Federal Register notices containing the proposed test rule.
- (3) Communications before proposal.
- (4) Comments on the proposed rule.
- (5) Public and intra-agency or interagency memoranda, comments, and proposals.
- (6) Contact reports of telephone conversations.
- (7) Meeting summaries.
- (8) Public comments on the ITC reports.
- (9) Reports—published and unpublished data.

(10) Study reports from EPA-sponsored mutagenicity testing and the National Toxicology Program testing as they become available.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: November 28, 1983.

William D. Ruckelshaus,
Administrator.

[FR Doc. 83-32434 Filed 12-6-83; 8:45 am]

BILLING CODE 6560-50-M

INTERSTATE COMMERCE COMMISSION

49 CFR Ch. X

[Ex Parte No. MC-172]

Withdrawal of Antitrust Immunity for Collective Ratemaking on Small Shipments

AGENCY: Interstate Commerce Commission.

ACTION: Extension of time to file comments to notice of proposed rulemaking.

SUMMARY: This proceeding was instituted by a notice opening the proceeding to request comments, served October 6, 1983, and published at 48 FR 46399, October 12, 1983. Comments on the proposal to withdraw antitrust immunity from collective ratemaking activities applicable to small shipments were originally due November 16, 1983. In a decision served November 8, 1983, and published at 48 FR 51664, November 10, 1983, the deadline for filing all comments was set at December 12, 1983. In response to a request for extension, this notice extends the time for filing these comments 19 days, until December 31, 1983.

DATES: Comments must be received by December 31, 1983.

ADDRESSES: Send comments (original and 10 copies) to: Ex Parte No. MC-172, Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Thomas T. Vining (202) 275-7426, or Howell I. Sporn (202) 275-7691.

SUPPLEMENTARY INFORMATION: Comments on the proposals in this proceeding to withdraw antitrust immunity for some or all collective ratemaking activities by motor carriers are currently due by December 12, 1983. In a letter dated November 10, 1983, the Honorable James J. Howard, Chairman, Committee on Public Works and Transportation, U.S. House of Representatives, has requested that the deadline for filing comments be

extended to December 31, 1983. Chairman Howard states that this extension will permit Committee members to review the record of the oversight hearings held by the Subcommittee on Surface Transportation on November 16, 1983, and to file comments on the proposals if they so choose.

An extension of the comment period to December 31, 1983, is warranted. The extension will allow adequate time for Committee members to prepare and submit any comments without unduly delaying the proceeding or otherwise prejudicing the interests of any party.

It is ordered:

The request for an extension of time for filing of comments is granted. All comments in this proceeding must be received by December 31, 1983.

Decided: November 30, 1983.

By the Commission, Reese H. Taylor, Jr.,
Chairman.

James H. Bayne,
Acting Secretary.

[FR Doc. 83-32583 Filed 12-6-83; 8:45 am]

BILLING CODE 7035-01-M

49 CFR Part 1056

[Ex Parte No. MC-19 (Sub-36A)]

Practices of Motor Common Carriers of Household Goods; Performance Standards

AGENCY: Interstate Commerce Commission.

ACTION: Withdrawal of proposed rule; discontinuance of rulemaking.

SUMMARY: The Commission has determined that it would be inappropriate to adopt performance standards for the household goods moving industry. The Commission had proposed standards governing estimating practices, timely pickup and delivery, and timely complaint handling. On further consideration, the Commission believes that the adoption of standards at this time would be contrary to consumer interests, impractical and counterproductive, and that the benefits of performance standards to consumers are outweighed by the costs of compliance.

DATE: The proposed rule is withdrawn, effective December 7, 1983.

FOR FURTHER INFORMATION CONTACT:

W. F. Sibbald, Jr., (202) 275-7148;
P. M. Schulze, (202) 275-7841.