

**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Part 799

[OPTS-42031; TSH-FRL 2338-7]

Biphenyl; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In the Tenth Report of the Interagency Testing Committee (ITC), submitted to the Administrator on May 10, 1982 and published in the Federal Register of May 25, 1982 (47 FR 22585), the ITC designated biphenyl for priority consideration for environmental effects and chemical fate testing. Under section 4 of the Toxic Substances Control Act (TSCA), EPA is proposing that manufacturers and processors of biphenyl test this chemical for acute toxicity to aquatic macrophytes and oysters, chronic toxicity and bioconcentration in oysters, chronic toxicity to aquatic vertebrates and invertebrates, and aerobic and anaerobic sediment biodegradation. Testing would be performed according to test standards prescribed in a subsequent rulemaking. This notice constitutes EPA's response to the ITC's designation of biphenyl as a priority candidate for testing.

DATES: The public is invited to submit written comments on or before July 22, 1983. If persons request time for oral comment by July 7, 1983, EPA will hold a public meeting on August 8, 1983 on this rule in Washington, D.C. For further information on arranging to speak at the meeting see Unit VI of this preamble.

ADDRESS: Address written comments identified by the document control number (OPTS-42031) 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 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

For exact time and place of meeting contact Jack P. McCarthy (See "For Further Information Contact").

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, Industry Assistance Office (TS-799), Office of Toxic Substance, Environmental Protection Agency, Rm. E-511, 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:

I. Introduction

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals for priority consideration and for testing under section 4(a) of the Act.

The ITC designated biphenyl for priority consideration in its Tenth Report, published in the Federal Register of May 25, 1982 (47 FR 22585). The ITC recommended that biphenyl be tested for chronic toxicity to fish and invertebrates, acute toxicity to aquatic macrophytes, and chemical fate. The ITC based its designation of biphenyl on substantial production, on the reported use/disposal pattern of biphenyl in dye-carrier applications, and on the potential persistence of biphenyl and biphenyl byproducts in the aquatic environment.

(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.

EPA uses a weight of evidence approach in making section 4(a)(1)(A) findings in which both exposure and toxicity information are considered to make the finding that the chemical may present an unreasonable risk. For the first finding under section 4(a)(1)(B), EPA considers only production, exposure, and release information to determine if there is substantial exposure or release. For the second finding under both sections 4(a)(1)(A) and 4(a)(1)(B), EPA examines toxicity and fate studies to determine if existing information is adequate to determine or reasonably predict the effects of human exposure to, or environmental release of, the chemical. In making the third

The ITC was concerned about the use of biphenyl as a fungicide. Use of biphenyl as a fungicide is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and cannot be regulated under TSCA [see TSCA section 3(2)(B)(ii)].

The ITC was also concerned that mono- and dichlorobiphenyls might be released from the chlorination of biphenyl at dye-carrier waste treatment facilities. EPA has concluded that release of mono and dichlorobiphenyls resulting from the chlorination of biphenyl at dye-carrier waste treatment facilities is likely to be insignificant. The EPA has reached this conclusion based on existing data on effluent concentrations of biphenyl from dye-carrier facilities and on chlorination of biphenyl under simulated wastewater treatment conditions.

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

finding that testing is necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules. The section 4(a)(1)(A) finding is discussed in the Federal Register of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300) and the section 4(a)(1)(B) finding is discussed in the Federal Register of June 18, 1981 (46 FR 30302).

In evaluating the ITC's testing recommendations concerning biphenyl,

EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing, considerations production volume, use, exposure, and release information reported by manufacturers of biphenyl under the TSCA section 8(e) Preliminary Assessment Information Rule (40 CFR Part 712); unpublished health and safety studies voluntarily submitted by some (but not all) manufacturers and processors of biphenyl under the TSCA section 8(d) Health and Safety Data reporting Rule (40 CFR Part 716); and other published and unpublished data available to the Agency. Based on its evaluation, as described in this proposed rule and the accompanying technical support document, EPA is proposing environmental effects and chemical fate testing requirements for biphenyl under section 4(a)(1)(A) of TSCA.

II. Proposed Rule

A. Profile

Biphenyl (CAS No. 92-52-4) is a solid organic compound at ambient temperature and pressure. Between 37 and 47 million pounds of biphenyl (42 million pounds average) were domestically produced in 1981. Biphenyl is used to produce dye carriers, heat transfer fluids, and alkylated biphenyls. The use/disposal pattern for biphenyl suggests that biphenyl has the potential to be released into the environment at significant concentrations from dye-carrier applications through wastewater discharge or from leakage of heat-transfer fluids.

B. Findings

EPA is basing its proposed testing on the authority of section 4(a)(1)(A) of TSCA. The analyses on which these findings are based are presented in the biphenyl technical support document for this rulemaking which is available from the Industry Assistance Office.

1. EPA has concluded that the use and disposal of biphenyl may present an unreasonable risk of injury to organisms in the aquatic environment. EPA has reached this conclusion because: (1) Available information indicates that use and disposal of biphenyl-containing dye carriers and heat transfer fluids are the principal sources of release of this compound to the aquatic environment; (2) monitoring studies report measurable concentrations of biphenyl in the water and sediment of several U.S. rivers; and (3) existing toxicity data indicate that biphenyl may be toxic to organisms in the aquatic and sediment environment at the measured concentrations and may persist in the sediment environment.

2. EPA has concluded that there are

insufficient data to reasonably determine or predict the acute effects of biphenyl for aquatic plants and that testing is necessary to develop such data. EPA has reached this conclusion because existing algae acute toxicity data for biphenyl, measured concentrations of biphenyl in the aquatic environment and existing data on the sensitivity of aquatic plants versus algae to detect acute effects of chemicals suggest, but are not sufficient to conclude, that biphenyl is acutely toxic to aquatic plants.

3. EPA has concluded that there are insufficient data to reasonably determine or predict the chronic effects of biphenyl for aquatic vertebrates and invertebrates and that testing is necessary to develop such data. EPA has reached this conclusion because existing biphenyl acute toxicity data for vertebrates and invertebrates and measured concentrations of biphenyl in the aquatic environment suggest, but are not sufficient to conclude, that biphenyl is chronically toxic to aquatic vertebrates and invertebrates.

4. EPA has concluded that there are insufficient data to reasonably determine or predict the biodegradation of biphenyl in sediments and the acute and chronic toxicities and bioconcentration of biphenyl for and in benthic (sediment-dwelling) organisms. EPA has reached this conclusion because existing data on biphenyl sorption to sediments and measured concentrations of biphenyl in sediments suggest, but are not sufficient to conclude that biphenyl will persist in sediments and may be acutely or chronically toxic to or will bioconcentrate in benthic organisms.

The ITC's recommendations and EPA's proposed tests are summarized in Table 1. EPA concurs with the ITC's recommendations and in addition believes that acute, chronic and bioconcentration testing in the oyster is necessary because biphenyl may sorb to sediments and persist or accumulate to levels potentially toxic to such benthic invertebrates.

TABLE 1.—BIPHENYL TEST SUMMARY

Test	ITC recommendation	EPA proposed test
Acute aquatic macrophytes	Yes	Yes
Chronic fish	Yes	Yes
Chronic daphnia	Yes	Yes
Acute oyster	No	Yes
Bioconcentration and chronic oyster	No	Yes
Chemical fate	Yes	Yes

C. Test Substance

EPA is proposing that biphenyl of 99 percent purity be used as the test

substance because biphenyl of this purity is readily available commercially and may provide more definitive information on biphenyl toxicity than biphenyl of lower purity.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which the Administrator 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 the use and disposal of biphenyl may present an unreasonable risk to the environment, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process, biphenyl at any time from the effective date of this test rule to the end of the reimbursement period be subject to the rule. The end of the reimbursement period ordinarily will be 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 that requirement (as discussed in Unit II.F. below).

E. Development and Adoption of Study Plans

EPA proposed generic test methodology requirements (generic test standards) in the Federal Register of May 9, 1979 (44 FR 27334), July 26, 1979 (44 FR 44054), and November 21, 1980 (45 FR 77332). In response to concerns about the rigidity of generic test methodology requirements, EPA has changed its approach for providing test standards for TSCA section 4 test rules. It has issued generic test methodology guidelines to replace the previously proposed generic test methodology requirements. The TSCA guidelines have been published by the National Technical Information Service (NTIS)

for health effects (PB 82-232984), environmental effects (PB 82-232992), and chemical fate (PB 82-233008). Good Laboratory Practice (GLP) standards for development of data on health effects of chemical substances were proposed in the Federal Register of May 9, 1979 (44 FR 27334) and July 26, 1979 (44 FR 44054). GLP standards for development of data on physical, chemical, persistence, and ecological effects of chemical substances were proposed in the Federal Register of November 21, 1980 (45 FR 77353). These GLP standards will continue to be promulgated as generic requirements.

Under the new approach, test rule development will be a two-phase process. In Phase I, test rules will be promulgated for individual chemicals, specifying the health and/or environmental characteristics and the reporting requirements for which test data are to be developed. In Phase II, following promulgation of a test rule, those persons subject to the rule will be required to provide study plans for the development of data pertaining to the effects and characteristics specified in the rule. For guidance in preparing study plans, it is recommended that test sponsors consult the TSCA Test Guidelines as referenced above; the Organization for Economic Cooperation and Development's (OECD) Guidelines, as adopted by the OECD Council on May 12, 1981; or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Pesticide Registration Guidelines: Proposed Data Requirements published by NTIS (see the Federal Register of November 24, 1982 [47 FR 53192] for a list of these guidelines). Pesticide Assessment Guidelines related to this rulemaking include Subparts E (Hazard Evaluation: Wildlife and Aquatic Organisms; PB 83-153909), J (Hazard Evaluation: Nontarget Plants; PB 83-153940), and N (Chemistry Requirements: Environmental Fate; PB 83-153973).

Sponsors must submit their study plans to EPA within 90 days from the effective date of the test rule. After an opportunity for public comment, EPA will issue a final rule adopting the study plans as proposed or modified. The approved and adopted study plans will become the enforceable test requirements and will serve as the chemical specific test standards for the test rule. Testing will also be subject to EPA's generic GLP standards. Modifications to the adopted study plans may be made only with EPA approval; see Federal Register of March 26, 1982 (47 FR 13012) for a more detailed explanation of the new approach to providing generic test methodology guidelines.

EPA intends to issue a procedural rule which will set out the details of the two-phase rulemaking process. That procedural rule will apply to the test rule for biphenyl and all other test rules. Information on this proposed procedure appears in the July 18, 1980 Federal Register (45 FR 48512), which describes the proposed exemption policy and procedures, in the March 26, 1982 Federal Register (47 FR 10312) which provides the policy statement on the test rules development process; and in the proposed test rule for diethylenetriamine, see the April 29, 1982 Federal Register (47 FR 18390). The final procedural rule will be issued before the biphenyl rule is promulgated. If there are significant changes in the final procedural rule, EPA may allow a short period of supplementary comment on the biphenyl proposal.

F. Exemption Procedures

Within 30 days after the effective date of the final rule, each biphenyl manufacturer or group of biphenyl manufacturers must either: (1) Notify EPA that it intends to conduct or sponsor testing and to submit study plans for the required tests, or (2) apply for an exemption on a belief that testing will be performed by others. Study plans must be submitted 90 days after the effective date of this rule.

If no manufacturer notifies EPA of its intent to sponsor testing, EPA will inform manufacturers that their exemptions will not be granted and will give them an opportunity to submit study plans in compliance with this rule.

Processors of biphenyl will not be required to apply for an exemption, submit study plans or conduct testing unless manufacturers fail to sponsor the required tests. If manufacturers do not submit study plans and conduct testing, EPA will issue a notice in the Federal Register requiring processors to submit notices of intent to test or apply for an exemption, submit study plans and conduct testing. No exemptions will be granted until a study plan for each of the required tests is received and approved.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for biphenyl. As noted in Unit II.C. above, EPA is interested in evaluating the effects attributable to biphenyl itself and has specified a relatively pure substance for testing.

EPA proposed exemption procedures for section 4 test rules in the Federal Register of July 18, 1980 (45 FR 48512). EPA intends to issue these procedures as a final rule shortly. If there are significant changes in the exemption procedures, EPA may allow a short

period of supplementary comment on the biphenyl proposal.

G. Reporting Requirements

EPA is proposing that all data be reported in accordance with its proposed GLP Standards to appear in 40 CFR Part 792. EPA has reviewed public comments on the proposed GLP Standards and is now developing final GLP Standards. The final GLP Standards will apply to this rule.

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. These deadlines will be established in the Phase II rulemaking in which study plans are approved.

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).

H. Enforcement Provisions

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. The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of 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 substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *". The Agency considers testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory audits/inspections 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 any final rule for biphenyl. 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 thereof, and that the studies

are being conducted according to EPA GLP standards and the protocols established in the Phase II rule.

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. Knowing or willful violations could lead to the imposition of criminal penalties of up to \$25,000 for each day of violation and imprisonment for up to one year. Other remedies are available to EPA under sections 7 and 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4 and the seizure of chemical substances manufactured or processed in violation of the rule.

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.

III. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis. This consists of evaluating each chemical or chemical group on four principal market characteristics: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis, along with the consideration of the costs of the required tests, indicate whether the possibility of a significant adverse economic impact exists. Where the indication is negative, no further economic analysis is done for that chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted. This Level II analysis attempts to predict more precisely the magnitude of the expected impact.

For a more complete and thorough discussion of the methodology used to conduct the economic analysis of this test rule, see the *Level I Economic Impact Analysis for Biphenyl* (EPA Contract No. 88-01-8630).

Total testing costs for the proposed rule for Biphenyl are estimated to range from \$27,500 to \$90,300. The annualized cost range is \$7,100 to \$23,400 based on a 25 percent cost of capital over 15 years; the estimated unit costs range from 0.02 to 0.08 cents per pound.

The Level I analysis of the biphenyl industry indicates that, despite relatively high price elasticity and declining markets, the potential for adverse economic effects due to the estimated testing costs is low. This conclusion is based on the following observations: (1) The estimated test cost is very low (i.e., from 0.02 to 0.08 cents per pound or 0.06 to 0.2 percent of the 1981 selling price of 36 cents per pound). (2) Biphenyl is a secondary product that is manufactured at large petrochemical plants. Minor adjustments in its production can occur without disrupting overall plant operations.

IV. Availability of Test Facilities and Personnel

Section 4(b)(1) 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 and test programs negotiated with industry in place of rulemaking. 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 proposed rule.

V. Environmental Impact Statement

EPA is not required to prepare Environmental Impact Statements (EISs), under the National Environmental Policy Act (NEPA), 41 U.S.C. 4321, for test rules. EPA has determined that voluntary preparation of an EIS is not appropriate for regulations issued under section 4 of TSCA. See the preamble to the Agency's rules for compliance with NEPA published in the *Federal Register* of November 6, 1979 (44 FR 64174).

VI. Public Meetings

If persons wish to present comments on this proposed rule to EPA officials who are directly responsible for

developing the rule and supporting analyses, EPA will hold a public meeting on August 8, 1983 in Washington, D.C. This meeting is scheduled after the deadline for submission of written comments, so that issues raised in the written comments can be discussed by EPA and the public commenters. Information on the exact time and place of the meeting will be available from the OTS Industry Assistance Office (IAO). Toll Free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the U.S.A. (Operator-202-554-1404).

Persons who wish to attend or present comments at the meeting should call the IAO by July 7, 1983. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the IAO before making travel plans because the meeting will not be held if members of the public do not wish to make oral presentations.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

VII. Public Record

EPA has established a public record for this rulemaking (docket number OPTS-42031) which is available for inspection in the OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, D.C., from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. This record includes basic information considered by the Agency in developing this proposal, and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received.

The Public Record shall include the following information:

(1) Federal Register notices pertaining to this rule consisting of:

(a) Notice of proposed rule on biphenyl.

(b) Notice containing the FIC designation of biphenyl to the Priority List.

(c) Notices relating to EPA's environmental effects and chemical fate test guidelines and GLP standards.

(d) Notice of proposed rule on exemption policy and procedures.

(e) Notice of proposed rulemaking on reimbursement policy and procedures.

(2) Support Documents: consisting of:

- (a) Biphenyl support document.
- (b) Biphenyl economic evaluation.
- (3) Minutes of informal meetings.
- (4) Communications before proposal consisting of:
 - (a) Written public and intra-agency or interagency memoranda and comments.
 - (b) Telephone conversations.
 - (c) Meetings.
 - (d) Reports—published and unpublished factual materials, including contractors' reports.

VIII. 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. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the estimated annualized cost of the testing proposed for biphenyl is less than \$24,000 over the testing and reimbursement period. Second, because the cost of the required testing will be distributed over a large production volume the rule will have only very minor effects on users' prices (less than 0.2 percent) for this chemical, even if all test costs were passed on. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic effects of any type as a result of this rule.

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

IX. Regulatory Flexibility Act

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

X. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) authorizes the Director of OMB to review certain information collection requests by Federal agencies. The test rule proposed

in this Notice, if promulgated, could result in the submission of several types of information related to the required testing, including study plans and final reports for each test required by persons sponsoring the tests. For the reasons set forth in the Federal Register of June 5, 1981 (46 FR 30300), EPA believes that the test rule contained in this Notice does not constitute an information collection request as defined in the Paperwork Reduction Act.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

Dated: May 10, 1983.

Lee L. Verstandig,
Acting Administrator.

PART 799—IDENTIFICATION OF SPECIFIC CHEMICAL SUBSTANCE TESTING REQUIREMENTS

Therefore, it is proposed that a new § 799.925 be added to the proposed Part 799 to read as follows:

Subpart A—[Reserved]

Subpart B—Specific Chemical Testing § 799.925. Biphenyl.

(a) *Identification of test substance.* (1) Biphenyl (CAS No. 92-52-4) shall be tested in accordance with this Part.

(2) Biphenyl of 99 percent purity shall be used as the test substance.

(b) *Persons required to test.* (1) All persons who manufacture, process or intend to manufacture or process biphenyl from the effective date of this rule June 22, 1983, to the end of the reimbursement period shall submit study plans, conduct tests and submit data as specified by this part.

(2) Any person subject to the requirements of this section may apply to EPA for an exemption from study plan submission, testing and data submission. No later than 30 days after the effective date of this rule, each manufacturer of biphenyl must notify EPA by letter, of its intent either to submit a proposed study or to be exempted from testing for each test required in this rule.

(3) If manufacturers submit study plans, conduct testing, and submit data in a satisfactory manner, processors will be given an automatic exemption by EPA. If manufacturers fail to submit satisfactory study plans or data, all persons who process or intend to process biphenyl from the effective date of this rule to the end of the reimbursement period shall be directed in a special Federal Register Notice to

submit study plans, and to conduct tests and submit data as specified by this Part or be in violation of this rule.

(c) *Study plans*—(1) *Testing.* Testing shall be performed using a study plan submitted and approved in accordance with 40 CFR Part 770. All raw data, documentation, records, protocols, specimens and reports generated as a result of a study shall be developed, reported and retained in accordance with the EPA Good Laboratory Practice (GLP) standards in 40 CFR Part 792. These data and other reports shall be made available during an inspection or submitted to EPA upon request by EPA or its authorized representative.

(2) *Submission.* (i) Manufacturers of biphenyl who indicate they will perform testing must submit proposed study plans on or before 90 days after the effective date of this rule. Only one set of study plans should be prepared and submitted by persons who are jointly sponsoring testing.

(ii) If, by the date specified in paragraph (b)(2) of this section, no manufacturer of biphenyl files a letter of intent to submit a proposed study plan for any test required by this rule, EPA will so notify the manufacturers of biphenyl. If no manufacturer promptly decides to submit a study plan and conduct testing, EPA will publish a Federal Register notice of this fact and then (A) no later than 30 days after publication of such a notice, each processor must notify EPA by letter of its intent either to submit a proposed study plan for each test that will not be covered by a manufacturer's study plans or to be exempted from testing and (B) processors who indicate they will perform testing must submit proposed study plans on or before 90 days after publication of such a notice.

(iii) Manufacturers who do not notify EPA of their intent, either to submit a proposed study plan or to be exempted from testing for each test or study for which testing is required in this rule, will be considered in violation of the rule beginning on the 31st day after the effective date of the rule. Manufacturers who indicate they will perform testing, and which do not submit proposed study plans on or before 90 days after the effective date of this rule will be considered in violation of the rule beginning on the 91st day after the effective date of this rule. Each processor who fails to submit a letter of intent to submit a study plan or to request an exemption when required will also be considered in violation of this rule beginning on the 31st day after publication of the notice described in paragraph (c)(2)(ii) of this section.

(iv) If no study plan for conducting tests and submitting data is proposed for each test or study required in this rule, every manufacturer and every processor of biphenyl will be in violation of this rule beginning on the 91st day after publication of the notice described in paragraph (c)(2)(ii) of this section, until such a study plan is submitted by an appropriate sponsor.

(3) *Content.* (i) All study plans are required to contain the following information:

(A) Identity of the test rule and the specific test requirements of that rule to be covered by the study plan.

(B) (1) The names and addresses of the test sponsors.

(2) The names and addresses of the responsible administrative officials and project manager(s) in the principal sponsor's organization.

(3) The name, address and telephone number of the appropriate individual for oral and written communications with EPA.

(4)(i) The name and address of the testing facility, including responsible administrative officials and project manager(s) responsible for this testing.

(ii) Brief summaries of the training and experience of each professional involved in the study including study director, toxicologist(s), chemist(s), microbiologist(s), and laboratory assistants.

(C) Identity and data on biphenyl, including appropriate physical constants, spectral data, chemical analysis and stability under test and storage conditions.

(D) Study protocols, including rationale for: species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; incubation temperature; a description of diet to be used and its source, including nutrients and contaminants and their concentrations; a description of culture medium and its source; and a summary of expected spontaneous chronic disease, genealogy, and life span.

(E) Schedule for initiation and completion of major phases of long-term tests; schedule for submission of interim progress and final reports to EPA.

(ii) Information given under paragraph (c)(3)(i)(B)(4) of this section is not required in proposed study plans if the information is not available at the time of submission; however, the information must be submitted before the initiation of testing.

(4) *Adoption.* Upon receipt of proposed study plans, EPA will publish a notice in the Federal Register requesting comments on the ability of the study plans to ensure that data from the tests are reliable and adequate. EPA

will provide a 45-day comment period, and will provide an opportunity for an oral presentation on the request of any person. EPA may extend the comment period if it appears from the nature of the issues raised by EPA's review or public comment that further comment is warranted. Following the close of the comment period, EPA will publish a final rule adopting the study plans as proposed or modified as test standards for the testing of biphenyl.

(5) *Modification of study plans during conduct of study—(i) Application.* Any test sponsor who wishes to modify the adopted study plan for any test required under this rule must submit an application in accordance with this section. Application for modification shall be made in writing or by phone to the Chief, Test Rules Development Branch, with written confirmation to follow as soon as feasible. Applications must explain why the modification is necessary.

(ii) *Adoption.* To the extent feasible, EPA will seek comment on all significant changes in study plans. EPA will issue a notice in the Federal Register requesting comments on requested modifications in accordance with section 4(b)(5) of TSCA. However, EPA will act on the requested modification without seeking public comment (A) if EPA believes that an immediate modification to a study plan is necessary in order to preserve the accuracy of an on-going study or (B) if EPA determines that a modification clearly does not pose any significant, substantive issues. EPA will notify the sponsor of the Agency's approval or disapproval. When the Agency approves a modification, it will publish a notice in the Federal Register indicating that the study plan has been modified.

(d) *Environmental effects testing—(1) Aquatic macrophyte acute toxicity testing—(i) Required testing.* Testing shall be conducted with *Lemna gibba* G3 to develop data on the acute toxicity of biphenyl to aquatic plants.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for *Lemna* acute toxicity testing (EG-23) available in the public record for this rulemaking, be consulted. Additional guidance may be obtained by consulting the Organization for Economic Cooperation and Development (OECD) test guideline for *Lemna* available in the public record for this rulemaking and the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908).

(2) *Fish early life stage toxicity testing—(i) Required testing.* Testing

using flow-through systems shall be conducted with rainbow trout to develop data on the chronic toxicity of biphenyl to aquatic vertebrates.

(ii) *Study plans.* For guidance in preparing study plans it is recommended that the TSCA Environmental Effects Test Guidelines for the Fish Early Life Stage Toxicity Test (EG-11) published by NTIS (PB 82-232992), be consulted. Additional guidance may be obtained by consulting the OECD test guidance for fish partial life cycle available in the public record for this rulemaking and the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908).

(3) *Daphnid chronic toxicity testing—(i) Required testing.* Testing using flow-through systems shall be conducted with daphnids to develop data on the chronic toxicity of biphenyl to aquatic invertebrates.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for the daphnid chronic toxicity test (EG-2) published by NTIS (PB 82-232992), be consulted. Additional guidance may be obtained by consulting the OECD test guidance for aquatic invertebrates partial life cycle available in the public record for this rulemaking, and the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908), and references cited in the support document for this test rule.

(4) *Oyster acute toxicity testing—(e) Required testing.* Testing using systems that control for biphenyl evaporation shall be conducted with oysters to develop data on the acute toxicity of sediment-associated biphenyl to benthic invertebrates.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test guidelines for the oyster acute toxicity test (EG-5) published by NTIS (PB 82-232992), be consulted. Additional guidance may be obtained by consulting the OECD guidelines for mollusk acute toxicity testing available in the public record for this rulemaking and the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908). Since the testing requires the use of sediment-associated biphenyl, the paper of Lynch and Johnson (1982), which is available in the public record for this rulemaking, should also be consulted.

(5) *Oyster bioconcentration testing—(i) Required testing.* Testing using systems that control for biphenyl

evaporation shall be conducted with oysters to develop data on the potential chronic toxicity and bioconcentration of sediment-associated biphenyl to and in benthic invertebrates.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Environmental Effects Test Guidelines for the oyster bioconcentration test (EC-6) published by NTIS (PB 82-232992), be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908) and references cited in the support document for this test rule. Since the testing requires the use of sediment-associated biphenyl, the paper of Lynch and Johnson (1982), which is available in the public record for this rulemaking, should also be consulted.

(e) *Chemical fate testing—(i) Aerobic biodegradation—(1) Required testing.* Testing using systems that control for biphenyl evaporation shall be conducted to develop data on the persistence of biphenyl in aerobic sediments.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Chemical Fate Test Guidelines for Aerobic Aquatic Biodegradation (CG-2000) published by NTIS (PB 82-233008), be consulted. Additional guidance may be obtained by consulting the OECD test guidelines for ready biodegradability (301 A, B, C, D, and E) available in the public record for this rulemaking and the FIFRA Guidelines for Chemistry Requirements: Environmental Fate (PB 83-153973).

(2) *Anaerobic biodegradation—(i)*

Required testing. Testing using systems that control for biphenyl evaporation shall be conducted with biphenyl to develop data on the persistence of biphenyl in anaerobic sediments.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the TSCA Chemical Fate Test guidelines for Anaerobic Biodegradation (CG 2050) published by NTIS (PB82-233000), be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Chemistry Requirements: Environmental Fate (PB 83-153973).

(Sec. 4(e) of TSCA, Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*)

(FR Doc. 83-13746 Filed 5-20-83; 8:45 am)
BILLING CODE 6550-50-M