

## 40 CFR Part 799

(OPTS-42031A; FRL-2871-5)

**Toxic Substances; Biphenyl; Test Rule****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This rule promulgates EPA's decision to require manufacturers and processors to test biphenyl (CAS No: 92-52-4) for environmental effects and chemical fate under section 4(a) of the Toxic Substances Control Act (TSCA) according to protocols to be submitted to and approved by EPA. This regulation is in compliance with the Interagency Testing Committee's (ITC) designation of biphenyl for priority testing consideration.

**DATES:** In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1:00 p.m. eastern ["daylight" or "standard" as appropriate] time on September 26, 1985. This rule shall become effective on October 28, 1985.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office, Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460. Toll Free: (800-424-9065). In Washington, DC: (554-1404).

**SUPPLEMENTARY INFORMATION:** In the Federal Register of May 23, 1983 (48 FR 23080), EPA issued a proposed rule under section 4(a) of TSCA to require testing of biphenyl for environmental effects and chemical fate. The Agency is now promulgating a final rule.

**I. Introduction**

This notice is part of the overall implementation of section 4 of the Toxic Substances Control Act (TSCA; Pub. L. 94-469, 90 Stat. 2006 *et seq.*, 15 U.S.C. 2603 *et seq.*) which contains authority for EPA to require development of data relevant to assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

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

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

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

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

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

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

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

For a more complete understanding of the statutory section 4 findings, the reader is directed to the Agency's first proposed test rule package—chloromethane and chlorinated benzenes, published in the *Federal Register* of July 18, 1980 (45 FR 48524), and to the second package—dichloromethane, nitrobenzene, and 1,1,1-trichloroethane, published in the *Federal Register* of June 5, 1981 (46 FR 30300) for in-depth discussions of the general issues applicable to this action.

**II. Background****A. Profile**

Biphenyl (CAS No. 92-52-4) is a solid organic compound at ambient temperature and pressure (Ref. 1). Approximately 13 million pounds of biphenyl were domestically produced in 1984 (Ref. 2). Biphenyl is used primarily to produce dye carriers, heat-transfer fluids, and alkylated biphenyls (Ref. 3). As discussed in the proposed rule and its accompanying technical support document, 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. ITC Recommendations**

The Interagency Testing Committee (ITC) designated biphenyl for priority testing consideration in its Tenth Report, published in the *Federal Register* on May 25, 1982 (47 FR 22585). The ITC recommended that biphenyl be tested

for chronic toxicity to fish and invertebrates, toxicity to aquatic macrophytes, and chemical fate. The ITC based its designation of biphenyl of substantial production, on the reported use/disposal pattern of biphenyl and on the potential persistence of biphenyl and biphenyl byproducts in the aquatic environment.

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

The ITC was also concerned that mono- and dichlorobiphenyl might be produced by the chlorination of biphenyl at dye-carrier waste treatment facilities. EPA has concluded that release of mono- and dichlorobiphenyls resulting from chlorination of biphenyl at dye-carrier waste treatment facilities is likely to be insignificant because of low measured concentrations of biphenyl in dye-carrier waste treatment plant effluents and the extremely low estimated concentrations of mono- and dichlorobiphenyls that might be produced as a result of chlorination of such effluents.

**C. Proposed Rule**

EPA issued a proposed rule published in the *Federal Register* of May 23, 1983 (48 FR 23080) which would require that testing of biphenyl be performed for the environmental effects and chemical fate characteristics listed below:

1. Acute aquatic macrophyte toxicity
2. Chronic fish toxicity
3. Chronic daphnid toxicity
4. Acute oyster toxicity
5. Oyster bioconcentration and chronic oyster toxicity
6. Aerobic and anaerobic biodegradation

In the proposal, the EPA based its testing requirements on the authority of section 4(a)(1)(A) of TSCA. It found that: Environmental release of biphenyl from the chemical's use and disposal may present an unreasonable risk of effects to aquatic organisms because existing data suggest that biphenyl may have the potential to produce acute effects in aquatic plants, as well as chronic effects in aquatic vertebrates and invertebrates, and because of detected concentrations of biphenyl in the aquatic environment. In addition, EPA found that such releases of biphenyl may present an unreasonable risk of effects to sediment organisms because of the potential of

biphenyl to partition from water to sediments, to persist and possibly accumulate in aerobic and anaerobic sediments, to bioconcentrate or promote acute effects in benthic organisms, and because of detected levels of biphenyl in sediments. EPA found that there are insufficient data to reasonably determine or predict the environmental effects and chemical fate of biphenyl and that testing is necessary to develop such data.

### III. Public Comment

A public meeting on the proposed rule was held August 8, 1983.

Comments received by the Agency in response to the proposed rule for biphenyl were submitted by the industry Biphenyl Ad Hoc Group (BAHG), E.I. DuPont de Nemours and Company (Dupont), the American Textile Manufacturers Institute, Incorporated (ATMI) and the Natural Resources Defense Council, Incorporated (NRDC). Technical comments from the BAHG, which represents Chemol, Coastal States Marketing, Gulf, Koch Chemical, Monsanto Industrial Chemicals, Dow Chemical, and Sybron Chemical Company, and comments from the AMTI are addressed in Units III. A and B below. Legal comments received from the remaining commentors are addressed in Units III. C through F.

#### A. Environmental Effects Testing

The BAHG has commented that the release of biphenyl during its use and disposal is insignificant.

The Agency does agree that quantities of biphenyl being released to the environment result in relatively low reported concentrations (<1 to 15)g/l in water and 1 to 8)g/g in sediment (Refs. 4 through 12). However, based on these measured concentrations, and in conjunction with existing toxicity data, the Agency believes there is sufficient concern for further testing.

The BAHG has commented that biphenyl concentrations in water and sediment are not significant and biphenyl is not toxic or persistent in the aquatic and sediment environment. The BAHG further states that "... existing toxicity data conclusively demonstrates that biphenyl does not present an unreasonable risk to organisms in the aquatic or sediment environment".

The Agency believes that BAHG has not provided data to substantiate its position that biphenyl "... does not present an unreasonable risk to organisms in the aquatic or sediment environment ..." or that detected concentrations of biphenyl are insignificant.

Further, the Agency notes that the industry response that LC<sub>50</sub> values generally are 1 to 10 ppm, ignores the 24 hour LC<sub>50</sub> of 0.73 mg/l (ppm) and the no observed effect level (NOEL) of <0.25 mg/l (ppm) for *Daphnia magna* reported by Adams *et al.* (Ref. 13).

Acute toxicity data have been reported for fish (fathead minnows, rainbow trout, sheepshead minnows, blue gill, golden shiner, and catfish) with LC<sub>50</sub>'s ranging from 1.5 to <10 mg/l (Refs. 15 through 21). Reported acute toxicities for various invertebrates range from 1.9 to 4.7 mg/l. (Refs. 19, 21 and 22).

No data have been reported for chronic toxicity of biphenyl to fish or aquatic invertebrates. However, there are indications of chronic toxicity to aquatic invertebrates from the acute data reported by Heidolph *et al.* (Ref. 14) in which the concentration of biphenyl required to produce an LC<sub>50</sub> value in *D. Magna* is 5 times higher at 24 hours than at 48 hours. In addition, studies by the Analytical Biochemistry Laboratories, Inc. on the acute toxicity of Therminol™ to fathead minnows (Ref. 23) produced 24-hour and 96-hour LC<sub>50</sub>'s which indicate that biphenyl may produce chronic effects in freshwater fish. No data on acute or chronic toxicity to aquatic life exposed to biphenyl contaminated sediment have been reported.

Given the range of biphenyl concentrations producing acute effects in aquatic organisms, the indication of chronic effects observed from available acute toxicity test data, and the absence of chronic toxicity data on aquatic organisms exposed by ingestion of biphenyl contaminated sediments, the BAHG contention that biphenyl does not present an unreasonable risk to organisms in the aquatic or sediment environment cannot be substantiated.

The BAHG response does not consider another aspect of biphenyl toxicity which would be addressed by chronic testing, namely the toxicity to other life stages (eggs and larvae) which typically are more sensitive to toxicants than the life stages used in acute toxicity tests. The Agency believes that the use of acute toxicity test data alone is not adequate to evaluate the overall risk to aquatic organisms unless there is a large margin of safety relative to environmental concentrations and no evidence of chronic toxicity.

The BAHG comment that the log P for biphenyl is too small and not typical of the types of chemicals that are known to have high accumulative toxicity is not relevant to the concern for chronic toxicity of biphenyl to other life stages. The log P of biphenyl (4.02 measured; 3.95 to 17 estimated) (Refs. 24 and 25) is

large enough to expect that the chemical will sorb to sediments (concentrations up to 8 ppm have been reported in sediments) and also will be taken up by aquatic organisms. Given that the acute toxicity data for biphenyl show a range of LC<sub>50</sub>'s for aquatic organisms from 0.73 mg/l to <10.0 mg/l (Refs. 13 through 23) and that water (<1 to 5)g/l and sediment concentrations (1 to 8)g/g have been found (Refs. 4 through 12), the important question is whether the sediment-bound biphenyl is bioavailable. No test data are available to evaluate this concern. BAHG comments do not provide a basis for discounting the bioavailability of biphenyl associated with sediment.

The BAHG feels that existing data are adequate and no further testing is needed. The BAHG specifically responded to the proposed aquatic macrophyte testing and the acute, chronic and bioaccumulation testing with oysters. The BAHG feels that there is no justification to require testing with the aquatic macrophyte *Lemna gibba*. The following reasons were given: (1) There are no data which would indicate *Lemna* is more sensitive than algae, (2) surface water concentrations are too low to justify *Lemna* testing, and (3) *Lemna* is also not the prevalent species in the river systems where biphenyl manufacturing occurs or textile discharges are located.

The Agency agrees that there are no data which would indicate that *Lemna* is more sensitive to biphenyl than algae. Consequently, EPA is withdrawing the proposed rule requiring testing of *Lemna* for biphenyl. However, EPA believes that information for macrophytes is useful and has decided to develop data to determine a comparative toxicological profile between the aquatic macrophyte *Lemna gibba* and the aquatic algae *Selenastrum capricornutum*. This comparative study shall be undertaken by EPA.

In response to the requirement for acute, chronic and bioaccumulation tests with oysters the BAHG stated that, "there may be some justification for acute screening tests with benthic freshwater organisms such as midges or amphipod." The BAHG further states with reference to chronic and bioaccumulation studies, "... the studies not only go beyond what ITC recommended, they are not scientifically justified." The ITC did recommend chronic tests. Industry apparently feels that some acute toxicity tests with benthic organisms might be justified. The reason for testing with the oyster is that this organism is a filter feeder and can be used to test the toxicity of

biphenyl bound to sediments (suspended organic particles, clay, etc.). Based on the log P of biphenyl, some uptake of the chemical can be expected if the chemical is bioavailable. For purposes of hazard assessment, the Agency needs to know the uptake and depuration of biphenyl and the possible toxic effects, acute and chronic, of the chemical taken up from sediment as well as from the water column. The requirements for testing biphenyl in oysters is consistent with the Agency's mandate to require testing that will provide data to assess the chemical's risks.

The BAHG asserts that the tests which the Agency has proposed are "extensive" and "costly". BAHG did not, however, explain or substantiate what it means by "extensive" and "costly". The tests proposed by the agency constitute a minimal data set. The limited number of tests proposed are essential to performing an adequate environmental hazard and risk assessment for biphenyl. Based on the results of EPA's economic analysis, the economic impact of conducting the required tests is expected to be minimal (see Unit V).

#### *B. Chemical Fate*

Comments were not received with respect to the proposed chemical fate testing.

#### *C. Protocol Submission and the Phased Test Rule Process*

The Natural Resources Defense Council (NRDC) submitted comments concerning the need for requiring validated protocols and recommended modification of the Agency's two-phase test rule process. NRDC stated that the Agency should require test sponsors to use validated reference protocols or give adequate justification for any deviations from these protocols. NRDC cited the Agency's two-phase test rule process (as described at 47 FR 13012; March 26, 1982) as an apparent "reversal" of EPA's previous policy which has required that specific EPA, FIFRA or OECD testing protocols be followed by persons required to test under section 4(a) of TSCA. The proposed policy of demanding only that test sponsors select protocols listed in Agency guidelines, or develop protocols on their own, was cited as an approach "apparently developed in response to industry criticism that the requirements are too rigid and would inhibit innovation in testing methodologies." The commenter further characterized this decision as compromising the recognized need for reliable and adequate data.

The Agency disagrees with NRDC's view that the two-phase test rule process based on EPA's review and approval of chemical-specific study plans would compromise the ability of the test rule to generate reliable and adequate data. In general, EPA believes that issuance of generic test methodology guidelines, rather than generic test requirements, provides more flexibility for test facilities, test sponsors, and EPA itself in arriving at cost-effective, scientifically sound test methodologies, and facilitates the incorporation of scientific judgment where necessary on a chemical-specific basis. This approach also encourages scientific innovation and the development of more sophisticated and scientifically advanced testing methodologies. With either single-phase or two-phase rules a public comment period and an opportunity for a public meeting will allow interested parties to review and comment on the chemical-specific test standards. After this comment period, EPA will issue a final rule adopting chemical-specific test standards as required under section 4(b)(1)(B) of TSCA. A more detailed discussion of the Agency's views on these and other related issues may be found in the agency's Test Rule Development and Exemption Procedures final rule published in the *Federal Register* of October 10, 1984 (49 FR 39774).

NRDC also stated that the Agency should modify the timing of the two-phase test rule development process so that subsequent test rules, complete with specific protocols for testing, are published within one year of EPA's receipt of the ITC's recommendations. NRDC contended that application of the two-phase rulemaking process in the case of the biphenyl rule has resulted in the Agency's failure to meet the statutory deadlines for initiating rulemaking.

EPA does not agree that the Agency has not met its statutory responsibility for biphenyl. The Agency's statutory obligation under TSCA section 4(e)(1)(B) was fulfilled with the issuance of the proposed test rule for biphenyl. In so doing, EPA initiated rulemaking under section 4(a) to require testing appropriate to the actual exposures to biphenyl.

EPA shares NRDC's desire that test rules should be completed as rapidly as possible and the Agency is continuing to explore ways to better achieve that objective.

#### *D. Identification of Biphenyl Processing Activities*

Dupont commented that EPA should identify, to the extent practicable, those activities which the Agency considers to be biphenyl "processing" activities. Dupont believed that by identifying those activities which the Agency considers to be processing, persons who "process" biphenyl as opposed to those persons who "use" biphenyl would be put on notice that they are subject to the test rule.

The Agency considers that "processing" includes any preparation of biphenyl for distribution in commerce as part of a mixture, an article, or any product containing or composed of biphenyl. Processing also includes the use of biphenyl as a reactant or intermediate to produce another chemical substance for distribution in commerce. If a company only uses and discards biphenyl, the company is not a processor of biphenyl.

A processor is, among other things, one who prepares a chemical substance or mixture for distribution in commerce, after its manufacture, in the same or different form of physical state from that in which it was received by the processor (see TSCA section 3(10)). One who mixes, reacts, purifies, separates, repackages, or otherwise "prepares" a chemical substance or mixture for distribution in commerce is a processor. Thus, a person who reacts biphenyl to make another chemical substance for distribution in commerce is a processor subject to this section 4 test rule.

#### *E. Persons Subject to The Testing Requirements*

Because the Agency found in its proposal that the use and disposal of biphenyl may present an unreasonable risk to the environment, EPA proposed that persons who manufacture or process, or intend to manufacture or process, biphenyl would be subject to the testing requirements of a final rule. Citing legislative history to support its positions, Dupont commented that the Agency can require only those biphenyl manufacturers and processors to sponsor testing whose manufacturing and processing activities result in the use or disposal activities which the Agency identified in making its "may present an unreasonable risk" finding.

The Agency has reviewed the legislative history cited by Dupont and the plain language of section 4(b)(3)(B) and disagrees with Dupont's position as stated above. The legislative history which Dupont cites as supporting its position cannot be entitled too much

weight. The language in the House Report (Committee on Interstate and Foreign Commerce), which spoke of the need for a connection between the use identified under a section 4(a) finding and the person responsible for testing, accompanied language of a House bill which was never enacted (Ref. 26). Similarly, the language in the Senate bill to which Dupont refers was never enacted. Both the House and Senate language which tied testing responsibilities to specific uses of a chemical substance and those who manufactured and processed the chemical substance for such uses was eliminated in the Conference Committee. The version of section 4(b)(3)(B) that was finally enacted by Congress requires that all persons who manufacture or process a chemical substance be subject to the testing requirements if the insufficiency of data findings under section 4(a)(1)(A)(ii) or 4(a)(1)(B)(ii) are based on distribution in commerce, use, or disposal.

The plain language of TSCA section 4(b)(3)(B)(iii), unlike the House or Senate bills cited by Dupont, does not restrict testing responsibilities to only those who manufacture or process for certain uses. In the absence of a clear contrary indication in the Conference Report, the Agency must follow the statute's plain language and require that all persons who manufacture or process or intend to manufacture or process biphenyl be subject to the requirements of this final rule. (Unit IV.D.)

#### *F. Basis for the "May Present" Finding*

The Agency based its proposed finding under TSCA section 4(a)(1)(A) upon the position that the use and disposal of biphenyl-containing dye carriers and heat transfer fluids result in the environmental release of biphenyl that may present an unreasonable risk to aquatic organisms. Dupont commented that the Agency did not adequately support its position that the use of biphenyl may present an unreasonable environmental risk. Dupont contended that the use of biphenyl as a heat transfer fluid does not result in release of biphenyl to the environment. Thus, Dupont suggested that EPA must provide better support for its finding that the use of biphenyl may present an unreasonable environmental risk.

EPA has considered Dupont's comments and still believes that the environmental release of biphenyl can result in an unreasonable risk to the environment. While the Agency acknowledges that heat transfer fluid spills can be reprocessed, there is no absolute certainty that these spills will

be reprocessed. Therefore, if these occur there may be an environmental hazard.

With regard to biphenyl's use as a dye carrier, it has been reported that at least 95 percent of the biphenyl is released to wastewater treatment facilities and less than 5 percent is released as vapor. (Ref. 27). This small percentage released as vapor will have a short half-life and will most likely be oxidized by hydroxyl radicals through reactive oxidizable intermediates to nontoxic products such as carbon dioxide (Ref. 28).

However, approximately 17 million pounds of biphenyl that is used as a dye carrier is released for wastewater treatments. Although much of this disposed biphenyl is expected to be subsequently released to the atmosphere during aeration operations and oxidized, approximately 1-3 million pounds from these wastewater treatment plants is expected to partition into the plant sludge, and a certain portion (0.3-1.4 million pounds) may be contained in the wastewater effluent. (Refs. 29 and 30).

The Agency agrees with Dupont that use of biphenyl as a heat transfer fluid and dye carrier may not depending on the place and method of release immediately result in sufficient environmental release to pose a potential environmental risk. However, once biphenyl is disposed of into wastewater treatment plants after being used, a sufficient environmental release does occur to result in a potential risk to aquatic organisms. Biphenyl has been detected in water and sediment in a variety of locations in the United States. (Refs. 4 through 12). EPA believes that this environmental contamination has probably resulted from the use and disposal of biphenyl. Thus, the Agency is basing its section 4(a)(1)(A) finding for the final rule upon the environmental release of biphenyl resulting from its use and disposal.

### **IV. Final Test Rule for Biphenyl**

#### *A. Findings*

The EPA is basing its final testing requirements for biphenyl on the authority of section 4(a)(1)(A) of TSCA. EPA finds that environmental release of biphenyl from the chemical's use and disposal may present an unreasonable risk of adverse effects to aquatic organisms because of the existing data which suggest that biphenyl may have the potential to produce chronic effects in aquatic vertebrates and invertebrates and because of detected concentrations of biphenyl in the aquatic environment. In addition, EPA believes that such releases of biphenyl may present an unreasonable risk of adverse effects to

sediment organisms. This belief is based on detected levels of biphenyl in sediments and on the potential of biphenyl to partition from water into sediments, to persist and possibly accumulate in aerobic and anaerobic sediments, and to bioconcentrate and produce effects in benthic organisms. EPA believes that there are insufficient data to reasonably determine or predict the environmental effects and chemical fate of biphenyl and that testing is necessary to develop such data.

#### *B. Required Testing*

EPA is requiring that testing of biphenyl be performed for the environmental effects and chemical fate tests listed below:

1. Chronic fish toxicity
2. Chronic daphid toxicity
3. Acute oyster toxicity
4. Oyster bioconcentration and chronic oyster toxicity
5. Aerobic and anaerobic biodegradation

#### *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 Agency makes section 4(a) findings (manufacture, processing, distribution, use, and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the 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, 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 are subject to the rule. The end of the reimbursement period for the biphenyl test rule 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 IV. E.

#### E. Test Rule Development

Development of this test rule for biphenyl will be a two-phase process. In Phase I, this test rule is being promulgated for biphenyl specifying certain environmental effects and chemical fate characteristics for which test data are to be developed. In Phase II, following promulgation of the Phase I test rule, those persons subject to the rule will be required to develop study plans for the development of data pertaining to the effects and characteristics specified in the Phase I rule.

Within 30 days from the effective date of this final Phase I test rule for biphenyl, manufacturers must submit to EPA a letter stating their intention to sponsor testing or an application for exemption. Test sponsors must submit their study plans to EPA within 90 days from the effective date of this Phase I test rule. After an opportunity for public comment, EPA will promulgate a rule adopting the study plans, as proposed or modified, as the test standards and schedules for biphenyl for the tests required by the Phase I rule. Testing will also be subject to EPA's TSCA Good Laboratory Practices (GLP) standards. Persons who submit the study plans will be obligated to perform the tests in accordance with the test standards and schedules developed. Modifications to the adopted study plans can be made only with EPA approval.

Processors will not be required to submit letters of intent, exemption applications, and study plans, and to conduct testing, unless manufacturers fail to sponsor the required tests. The basis for this decision is that manufacturers are expected to indirectly pass the costs of testing on to processors through any increase in the price of biphenyl.

#### F. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with the TSCA Good Laboratory Practice (GLP) standards which appear in 40 CFR Part 792. These final GLP standards 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 second phase of this rulemaking in which study plans are approved. The procedures for the second phase rulemaking are described in 40 CFR Part 790.

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).

#### G. Enforcement Provisions

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

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce. . . ." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory audits and/or inspections will be conducted periodically in accordance with procedures outlined in TSCA section 11 by designated representatives of the EPA for the purpose of determining compliance with the 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 the TSCA GLP standards and the test standards established in the second phase of this rulemaking.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed

under test rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties calculated as if they have 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 per day for each violation. Intentional violations could lead to the imposition of criminal penalties of up to \$25,000 for each day of violation and imprisonment for up to 1 year. 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.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

#### V. Economic Analysis of Rule

To assess the economic impact of this rule, EPA has prepared an economic analysis that evaluates the potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of biphenyl: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations.

The total costs of conducting the required environmental effects tests are estimated to range from \$47,500 to \$116,100. Annualized costs range from \$12,303 to \$30,070. Based on these costs and the market characteristics of biphenyl, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is low. Although the market expectations for biphenyl in its major uses are not optimistic and the price sensitivity of demand appears

relatively elastic, this conclusion is supported by the following observations:

1. The annual unit cost of the testing required in this rule is very low. Based on an estimated 1984 production level of 13 million pounds and annual test costs ranging from \$12,303 to \$30,070, the unit costs of testing range from a low of 0.09 cents per pound to a maximum of 0.23 cents per pound. This represents approximately 0.13 to 0.33 percent of current price.

2. Biphenyl is produced as a secondary product to benzene by all but one producer. It is unlikely that the relatively small unit test costs would have a significant adverse effect on the overall profitability of these operations.

Refer to the Economic Analysis (Ref. 2) for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

#### VI. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," October, 1981, can be obtained through the National Technical Information Service (NTIS) Springfield, Virginia, (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 required in this test rule.

#### VII. Public Record

EPA has established a public record for this rulemaking (docket number OPTS-42031). This record includes basic information considered by the Agency in developing this rule and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received.

This record includes the following information:

##### A. Supporting Documentation

- (1) Federal Register notices pertaining to this rule, consisting of:
  - (a) Notice of final rule on biphenyl.
  - (b) Notice of proposed rule on biphenyl, May 23, 1983 (48 FR 23080).
  - (c) Notice containing the ITC designation of biphenyl to the Priority List, May 25, 1982 (47 FR 22585).

(d) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards, Nov. 29, 1983 (48 FR 53922).

(e) Notice of final rule on test rule development and exemption procedures, Oct. 10, 1984 (49 FR 39774).

(f) Notice of final rule concerning data reimbursement July 11, 1983 (48 FR 31785).

(2) Support documents, consisting of:
 

- (a) Biphenyl technical support document for proposed rule.

(b) Economic impact analysis of final test rule for biphenyl.

(3) Communications, consisting of:
 

- (a) Written public comments.

(b) Summaries of telephone conversations.

(c) Meeting summaries including transcript of public meeting held on proposed rule Aug. 8, 1983.

(d) Reports—published and unpublished factual materials, including contractors' reports.

##### B. References

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- (2) Mathtech Inc. *Economic Analysis for the Final Rule: Biphenyl*. Washington, D.C. Office of Toxic Substances, U.S. Environmental Protection Agency, Contract No. 68-01-6630 1985 (June).
- (3) Kirk-Othmer, Wannemacher, R., Demaria, A., "Dye carriers", in: *Kirk-Othmer Encyclopedia of Chemical Technology*, 3rd ed., Vol. 8, New York: Wiley-Interscience, pp. 151-158, 1979.
- (4) Elder, V.A., Proctor, B.L., Hites, R.A., "Organic compounds near dumpsites in Niagara Falls, New York", *Biomed. Mass. Spectr.* 8(9):409-415, 1981.
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- (9) Macleod et al., "Interlaboratory comparisons of selected trace hydrocarbons from marine sediments," *Anal. Chem.* 54(3): 386-392, 1982.
- (10) Tincher, W.C. 1973, "Effect of polyester fiber processing effluents on water quality," Report ERC-1873, Atlanta, Georgia: Georgia Institute of Technology, 51p.
- (11) Steinheimer, T.R., Pereira, W.E., and Johnson, S.M., "Application of capillary gas chromatography mass spectrometry computer techniques to synoptic survey of organic

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(13) Adams, W.J., et al., "Acute toxicity of biphenyl to *Daphnia magna*," Monsanto report ES-82-SS-64, St. Louis, MO: Monsanto Company, 1982.

(14) Heidolph, B., Gledhill, W.E., "Acute toxicity of biphenyl to *Daphnia magna*," Monsanto Report ES-83-SS-18, St. Louis, MO: Monsanto Company, 1983.

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(16) Dow Chemical Co. (May 1), Interagency Testing Committee Response: 1,1'-Biphenyl, Midland, MI, 1981.

(17) Haas, J.M., Earhart, H.W., Todd, A.S., "Environmental considerations concerning the selection of dye carrier solvents," *J. Am. Assoc. Text Chem. Color. Book of Papers*, (1974):442-447, 1974.

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Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Rm. E-107, 401 M St. SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

### VIII. Other Regulatory Requirements

#### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. 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 total cost of all the proposed testing for biphenyl is \$47,500 to \$116,100 over the market life of biphenyl. Second, the cost of the testing is not likely to result in a major increase in users' cost or prices. Finally, based on our present analysis, EPA does not believe that there will be a significant adverse effects 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. Any comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

#### B. Regulatory Flexibility Act

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

to be affected by reimbursement requirements.

#### C. Paperwork Reduction Act

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

#### List of Subjects in 40 CFR Part 799

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

Dated: September 3, 1985.

J.A. Moore.

Assistant Administrator for Pesticides and Toxic Substances.

#### PART 799—[AMENDED]

Therefore, 40 CFR Part 799 is amended as follows:

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

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

2. Part 799 is amended by adding § 799.925 in Subpart B to read as follows:

#### § 799.925 Biphenyl.

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

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

(b) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture or process Biphenyl from the effective date of this rule [October 28, 1985] to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests and submit data as specified in this section, Subpart A of this Part, and Part 790—Test Rule Development and Exemption Procedures of this Chapter.

(c) *Environmental effects testing—(1) 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 OTS 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 Pesticide Assessment Guidelines, Subdivision for Hazard Evaluation:

Wildlife and Aquatic Organisms published by NTIS (PB 83-153908).

(2) *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 OTS Environmental Effects Test Guidelines for the Daphnid Chronic Toxicity test (EG-2), published by NTIS (PB 82-232992), be consulted. Additional guidelines may be obtained by consulting Pesticide Assessment Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908), and references cited in the support document for the proposed test rule.

(3) *Oyster acute toxicity testing—(i) 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 OTS 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 Pesticide Assessment Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908). Because 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.

(4) *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 benthic invertebrates.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the OTS Environmental Effects Test Guidelines for the Oyster Bioconcentration Test (EG-6), published by NTIS (PB 82-232992), be consulted. Additional guidance may be obtained by consulting the Pesticide Assessment Guidelines for Hazard Evaluations: Wildlife and Aquatic Organisms (PB 83-153908) and references cited in the support document for the proposed test rule. Because 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 be consulted.

(d) *Chemical fate testing*—(1) *Aerobic biodegradation*—(i) *Required testing*.

Testing using systems that control for and quantify biphenyl evaporation that use a ratio of undisturbed sediment to water of 3:1—2:1 and that provide a mass balance of biphenyl distributed in water and sediment, volatilized or degraded to CO<sub>2</sub> or other products before and after biodegradation 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 OECD Test Guideline for inherent biodegradability in soil (304 A) published by OECD be consulted.

(2) *Anaerobic biodegradation*—(i) *Required testing*. Testing using systems that control for and quantify biphenyl evaporation that use a ratio of undisturbed sediment to water of 3:1—2:1 and that provide a mass balance of biphenyl distributed in water and sediment, volatilized or degraded to CO<sub>2</sub> or other products before and after biodegradation 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 OTS Chemical Fate Test Guidelines for Anaerobic Biodegradation (CG-2050), published by NTIS (PB 82-233008), be consulted.

(e) *Availability of test guidelines*. The OTS Environmental Effects Test Guidelines cited in this final rule are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (703-487-4650).

(Information collection requirements approved by the Office of Management and Budget under control number 2070-0033.)

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