40 CFR Part 799

[OPTS-42006F; FRL 3668-2]

RIN 2070-AB94

Unsubstituted Phenylenediamines; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a final rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring manufacturers and processors of *ortho*-phenylenediamine (*o*-pda; CAS No. 95-54-5), *meta*-phenylenediamine (*m*-pda; CAS No. 108-45-2), *para*-phenylenediamine (*p*-pda; CAS No. 106-50-3) and the sulfate salts of *m*-pda (*m*-pda.H_2SO_4; CAS No. 54-17-08) and *p*-pda (*p*-pda.H_2SO_4; CAS No. 1624-57-75) to perform testing for neurotoxic effects, chemical fate, and aquatic toxicity. Manufacturers and processors of *m*-pda and the sulfate salt of *m*-pda are also required to perform testing for mutagenic effects in the sex-linked recessive lethal and bone marrow cytogenetics assays. The results of human health, chemical fate, and aquatic toxicity testing will determine additional testing for these effects.

DATES: This rule shall become effective on January 16, 1990. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern daylight time on December 26, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 544-0551.

SUPPLEMENTARY INFORMATION: This action is in response to the Interagency Testing Committee's (ITC) designation of the phenylenediamine (PDA) chemical category for health and

environmental effects testing (45 FR 35897, May 28, 1980).

I. Introduction

A. Test Rule Development Under TSCA

This final rule is part of the overall implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*) which contains authority for EPA to require the development of data relevant to assessing the risk to human health and the environment posed by exposure to particular chemical substances or mixtures (chemicals).

Under section 4(a) of TSCA, EPA must require testing of a chemical substance to develop health or environmental data if the Administrator makes certain findings as described in TSCA under section 4(a)(1)(A) or (B). Detailed discussions of the statutory section 4 findings are provided in EPA's first and second proposed test rules, which were published in the Federal Register of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

B. Regulatory History

The ITC designated the PDA category, consisting of 50 chemicals, for consideration for testing for health and environmental effects in its Sixth Report, published in the Federal Register of May 28, 1980 (45 FR 35897).

EPA issued an Advance Notice of Proposed Rulemaking (ANPR) for 13 of the high production PDA's, published in the Federal Register of January 8, 1982 (47 FR 973). Subsequently EPA issued a TSCA section 8(a) manufacturers' reporting rule on June 22, 1982 (47 FR 26992), and a section 8(d) health and safety data reporting rule published in the Federal Register of Sept. 2, 1982 (47 FR 38780), which included all of the PDA's recommended by the ITC.

After reviewing comments submitted in response to the ITC's recommendation, the ANPR, the section 8(a) and 8(d) rules, and data from the public record, EPA issued a notice, published in the Federal Register of January 30, 1985 (50 FR 472), stating that the PDA category had been subdivided into three subcategories: (1) Five unsubstituted PDA's (hereafter "pda's") (2) eight toluenediamines, and (3) 34 PDA's not subject to testing. EPA then issued a proposed test rule (NPRM) for the unsubstituted pda's under section 4(a) of TSCA published in the Federal Register of January 6, 1986 (51 FR 472). The NPRM proposed testing of *o*-, *m*-, and *p*-pda for aquatic oxidation rate and toxicity to aquatic organisms and testing of *m*-pda for mutagenicity in the *Drosophila* sex-linked recessive lethal (SLRL) test. EPA subsequently extended the comment period an additional 30 days (51 FR 7593, March 5, 1986). No new data have been received for the 34 subcategory 3 chemicals which would change EPA's decision not to require testing of these chemicals at this time. The toluenediamines are being considered for separate rulemaking. EPA concluded from its analysis of public comments that the NPRM should be modified, and therefore issued its proposed modifications for public comment published in the Federal Register of January 14, 1988 (53 FR 913). The modified NPRM proposed that acute neurotoxicity testing, namely the functional observation battery and the motor activity tests, be added for all three isomers. Positive results lasting more than 24 hours would trigger subchronic neurotoxicity testing and neuropathological examination. EPA also proposed that mutagenicity testing of *m*-pda be expanded to include, in addition to the previously proposed *Drosophila* sex-linked recessive lethal (SLRL) assay, the *in vivo* mammalian bone marrow cytogenetics test—chromosomal analysis (MBMC) in the mouse. Positive results from the SLRL could trigger the mouse specific locus test. A positive MBMC would trigger a dominant lethal test in the mouse, which if positive, would trigger a heritable translocation test in the same species. EPA further noted that positive Chinese hamster ovary test (CHO) data identified as a result of the public comments was sufficient to trigger an oncogenicity bioassay. The modified NPRM also retained the original proposal that chemical fate testing be conducted for all three isomers. It proposed that the acute aquatic toxicity testing of *o*- and *p*-pda with rainbow trout, *Daphnia* and *Gammarus* be condensed into one tier and that the number of acute-test species be reduced. The results of these acute aquatic tests would be used to determine whether chronic toxicity testing would be triggered and to identify the most sensitive vertebrate and/or invertebrate in which to conduct the chronic testing. The proposed chronic testing included the fish partial life-cycle flow-through test and the invertebrate life-cycle flow-through test in *Daphnia magna*. *m*-Pda would be retested with the aphnia life-cycle test.

As stated in the proposed rule, EPA expects the sulfate salts of *p*-pda and *m*-pda to produce substantially the same toxicological effects as their respective free bases. The salts that are known to have been produced and that were cited by the ITC include *p*-pda.H_2SO_4 (CAS No. 1624-57-75) and *m*-pda.H_2SO_4 (CAS No. 54-17-08). Accordingly, EPA is making the findings for the sulfate salts, as well as their respective free bases. Thus, the final rule requires manufacturers and processors of *m*-pda and the sulfate salt of *m*-pda to conduct all of the testing of *m*-pda or its salt as required by this rule, and manufacturers and processors of *p*-pda and the sulfate salt of *p*-pda to conduct all the testing of *p*-pda or its salt required by this rule. Hereafter, when this preamble refers to *m*-pda or *p*-pda, the salts of *m*-pda and *p*-pda are also meant to be included, except in Unit III.C when actual test substances are specified.

II. Public Comment

Comments in response to the modified NPRM for pda's were received from E. I. DuPont de Nemours, Inc. (DuPont) (Ref. 9) and the Neurobehavioral Toxicity Test Standard Committee (NTTSC), Psychopharmacology Division of the American Psychological Association (Ref. 19). These comments and EPA's responses to these comments are summarized below.

A. Exposure Potential Under TSCA Section 4(a)(1)(A)

Dupont argued that industry has supplied enough information to show that workplace exposure to the pda's is in the range of 0.01 to 0.03 mg/m^3, and that protective clothing and face masks are worn by people handling any of the isomers (Ref. 9). This level is below the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 0.1 mg/m^3 for *p*-pda. Consequently, there is no evidence of exposure under TSCA section 4.

EPA acknowledges that workplace levels of pda's may vary from 0.01 to 0.03 mg/m^3, and that workers involved with the manufacture of the pda's may wear or may not wear the protective clothing described by DuPont (Ref. 20). However, EPA notes that users of *m*- and *p*-pda reported exposure levels from "nil" to 1.5 mg/m^3 and that one user of *m*-pda provided an unsubstantiated estimate for shipping-handling exposure of 50 mg/m^3 (Ref. 20). The ACGIH TLV of 0.1 mg/m^3 to skin is "sufficiently low to minimize the number of persons who become sensitized (to *p*-pda) but it is recognized that the limit is not low enough to prevent exacerbation of asthma in those already sensitized to *p*-pda" (Ref. 21). The TLV does not address exposure to either *o*- or *m*-pda nor does a TLV based on sensitization data address EPA's concern for potential oncogenic effects from exposure to *m*-pda or potential

neurotoxic effects from exposure to *p*-, *o*-, or *m*-pda. Consequently, there is no way to ascertain the actual risk of exposure at these levels until testing is conducted.

In addition to the 817 people reported by DuPont to be potentially exposed to one or more of the three isomers during their uses (Ref. 20), the National Occupational Exposure Survey (Ref. 1) reports that as many as 59,483 workers in 6,187 plants may be exposed to at least one of the pda's. Hence, EPA believes that exposure to pda's may occur during processing and use, as well as at least occasionally during manufacture, and that this potential exposure is sufficient to support EPA's section 4 findings. Because EPA is concerned about oncogenic and neurotoxic effects, there is an adequate basis for the finding that manufacturing, processing and use of pda's may present an unreasonable risk of injury to human health.

B. Health Effects Hazards Potential

1. *Neurotoxicity*. The neurotoxicity testing proposal in the modified NPRM generated opposing responses from NTTSC and DuPont. NTTSC agreed with EPA's proposal for neurotoxicity testing, and recommended that motor activity data be collected as part of the functional observation battery (Ref. 19). NTTSC also suggested that an evaluation of schedule-controlled operant behavior, visual impairment, and kindling behavior (electrochemical measurement of seizure potential) would provide better baseline neurotoxicity data for the pda's. NTTSC volunteered to help EPA develop experimental procedures to measure these effects.

EPA agrees with NTTSC that both motor activity and functional observation battery should be included in the neurotoxicity testing program. EPA agrees that the testing program does not include measures of "higher cognitive functioning (e.g., schedule-controlled operant behaviors)." The effect of pda's on "cognitive functioning" has not been adequately characterized, yet concern for this effect still exists. Schedule-controlled operant behavior (SCOB) testing is not being required at this time. However, because of the concerns raised in the public comments, data received from the required testing will be reviewed for evidence of potential effects on cognitive functioning. A public program review will be initiated to determine whether to require SCOB testing according to the test standard in 40 CFR 798.6500.

The pda data provide some evidence that exposure to pda's may produce visual disturbances. It is not clear that these effects represent a direct effect on the eye. Von Oettingen (Ref. 2) concluded that edema around the head was more likely due to vascular changes than to a direct effect upon the nerve. Consequently, EPA does not believe sufficient justification exists to require visual impairment testing.

EPA agrees with NTTSC that the proposed testing does not adequately examine the potential alterations in seizure susceptibility nor does it assess the effects of pda's on kindling behavior. EPA also agrees that exposure to pda's may increase seizure potential. However, EPA is not requiring that these tests be conducted initially.

DuPont criticized the neurotoxic effects testing proposed in the modified NPRM as inappropriate, asserting that adequate, modern testing data do not support the central nervous system (CNS) effects observed in the turn-of-the-century, anecdotal reports cited in the modified NPRM, and that adequate consumer/worker controls are already in place (Ref. 9).

EPA agrees with DuPont that the evidence presented by NTTSC in its response to the NPRM (51 FR 472), and discussed in the modified NPRM (53 FR 913), did not definitely prove neurotoxic effects, nor did it demonstrate a lack of neurotoxic effects from exposure to pda's. Available literature shows a consistent pattern of neurobehavioral effects. While the nervous system cannot be determined with certainty to be the primary target for these effects, this possibility cannot be excluded. Convulsions after treatment with pda's have consistently been reported since the turn of the century in many animal species, and these data imply a direct neurological effect. Although convulsions were reported at lethal concentrations, there is concern that subconvulsive concentrations may pose a health risk. The repeated administration of convulsive agents at subconvulsive dose levels can result in the development of a permanent state of seizure susceptibility (Ref. 3). Further concern is indicated by studies which demonstrate that a single superconvulsant exposure in the developing organism can increase seizure susceptibility later in the adult (Ref. 4); the immature brain may be more vulnerable to seizures than the adult brain. Many neurobehavioral effects for such convulsants as picrotoxin, bicuculline, and carbolines have been reported at subconvulsant concentrations (Ref. 5). These data suggest that dermal exposure to pda's may cause seizures and neurological damage. EPA believes that the data leave sufficient uncertainty as to neurotoxic effects to justify neurotoxic effects testing for all three isomers.

When all of the required neurotoxicity testing data have been received by EPA, the data will be reviewed and a public program review will be initiated. If EPA determines, from its review of the data developed by this rule, that additional testing is warranted, EPA will issue a subsequent notice proposing testing for seizure potential or other effects.

2. *Mutagenicity*. DuPont argued that mutagenic effects of pda's are adequately characterized. Comments submitted in rulemakings for other section 4 chemicals state that EPA's proposed mouse specific locus testing and the heritable translocation testing cannot be done. DuPont pointed out that the notice failed to identify whether a visible or biochemical specific locus test would be used, that the micronucleus test is more economical than the bone marrow testing, and that the heritable translocation test and bone marrow testing could effectively be done in the same animals, if EPA continues to require these tests. DuPont questioned the applicability of the sex-linked recessive lethal test (SLRL) for predicting genetic effects in mammals.

EPA has proposed separately to amend the requirement for the mouse visible specific locus test (MVSL; 53 FR 51847, December 23, 1988), for proposed and final test rules promulgated under section 4(a) of TSCA. EPA is proposing to allow test sponsors for this test rule to choose either the MVSL or the mouse biochemical specific locus test (MBSL), proposed under 40 CFR 798.5195, to test for heritable mutations in mammals. EPA believes that the MBSL and MVSL are comparable tests and are acceptable for detecting this endpoint in mammals. EPA is proposing a reporting requirement of 51 months for the completion of testing for either the MVSL or MBSL once triggered. If the MVSL proposal becomes final, it will apply to all existing and prospective section 4 test rules, including this rule for pda's.

If the specific locus test is triggered, selection of route of exposure will be decided as part of the program review of the required mutagenicity testing.

EPA agrees with DuPont that the mouse micronucleus assay would provide useful information on the mutagenic potential of *m*-pda, and is therefore allowing this requested change. EPA is also requiring that *m*-pda be tested in the *in vivo* mammalian bone marrow cytogenetics test: Micronucleus assay (40 CFR 798.5395), rather than the

MBMC chromosomal analysis test in the modified pda's proposal.

The available data on mutagenic potential of the pda's indicate that these chemicals have potential effects on the gonadal tissue in mammals (Refs. 6 and 7). The SLRL assay cannot be extrapolated to man and the data from this assay are not intended to be used in this way. SLRL results will be taken as an indication of the ability of *m*-pda to interact with gonadal DNA to induce heritable mutations in non-mammalian species. These results will be incorporated into the body of mutagenicity data examined at the program review stage of testing, as described in the modified NPRM.

3. *Oncogenicity.* DuPont argued that sufficient information already exists to determine the potential cancer risk from exposure to *m*-pda and that further testing is unnecessary. DuPont also reported that correspondence with Dr. M. Matsuyama, director of the Japanese bioassay on *m*-pda, has revealed negative test results. Dr. Matsuyama has forwarded a copy of the published bioassay results to EPA (Ref. 8). EPA is reviewing the data included in the Japanese study and this information will be included in the total body of information reviewed by EPA when EPA decides whether oncogenicity testing is to be initiated.

In the proposed rule, EPA proposed that oncogenicity testing would be triggered from positive SLRL results (51 FR 472, 476 & 493). In the reopening of comments, EPA noted that oncogenicity testing has already been triggered from a positive CHO assay (53 FR 913, 914). Other language in the document suggested that other positive mutagenicity tests would trigger oncogenicity testing (53 FR 913, 921). EPA also noted that, although oncogenicity testing had been triggered and that oncogenic potential for *m*-pda was inadequately characterized, a review of all scientific evidence would be completed before oncogenicity testing would be initiated (53 FR 913, 914). DuPont questioned the applicability of the SLRL for predicting oncogenicity. EPA reiterates that the oncogenicity test has been triggered by existing mutagenicity data; therefore SLRL data are not needed for purposes of an oncogenicity trigger. However, all mutagenicity data will be part of the scientific evidence reviewed by EPA to determine whether oncogenicity testing shall be initiated.

Regrettably a typographical error was perpetuated in both the proposed rule and the reopening of comments. EPA intended to propose oncogenicity testing (40 CFR 798.3300) rather than combined chronic toxicity/oncogenicity testing (40 CFR 798.3320). However, in both documents, required oncogenicity testing is described as being conducted in accordance with 40 CFR 798.3320 (51 FR 472, 476; 53 FR 913, 921). These tests differ in numbers of required test species, duration of testing, and measured endpoints and 40 CFR 798.3320 does not adequately address the oncogenic potential of *m*-pda at this time. Therefore, although EPA did make the finding that oncogenicity testing is necessary (if indicated by the weight of evidence review after completion of the SLRL), EPA is not specifying the test standard in this rule. If oncogenicity testing is indicated, EPA will publish a **Federal Register** notice of the proposed oncogenicity test standard for comment.

C. Chemical Fate and Aquatic Toxicity

1. *Indirect photolysis.* DuPont argued that the chemical fate data collected were state-of-the-art, and any additional analytical exercise requiring identification of break-down products would be very costly exploratory research and consequently inappropriate for section 4 rulemaking. DuPont argued that EPA presented inadequate arguments for use of humic acids in the testing and that EPA's explanation for rejecting the Delaware River data was unsatisfactory.

EPA agrees with DuPont that the analysis of break-down products would be very costly; therefore, EPA is not requiring chemical analysis beyond that needed to document the concentrations of the pda's in the test solutions as required in the test guidelines.

EPA maintains that indirect photolysis testing is necessary and that including humic acids in the test system is necessary to adequately complete this testing. DuPont states that "DuPont, with EPA's approval and participation, designed studies in 1984 and 1985 to determine the oxidative half-lives of the pda's. These studies sought information both about environmental disappearance of pda's and the mechanisms of pda toxicity. DuPont completed these studies and performed additional work to provide the EPA with more information than it had originally requested..." (Ref. 9).

EPA notes that discussions with DuPont on the oxidation rate studies occurred in 1984, prior to the onset of the studies referenced by DuPont in their comments. Repeated efforts were made by EPA to include DuPont in the development of the Indirect Photolysis Guidelines, so that DuPont's planned studies would follow EPA's protocol for the pda's (Refs. 10 and 11). DuPont contacted the individuals involved in developing the guidelines (Ref. 12), but since the development of the indirect photolysis guidelines did not correspond with DuPont's testing schedule, the oxidation rate study was completed in accordance with DuPont's protocol (Ref. 12 and 13). Throughout these discussions, EPA reminded DuPont that the oxidation rate study must be environmentally relevant (Ref.10), and that EPA reserved the right to review both the protocol and the data generated for their relevance to EPA's needs (Refs. 10, 11, and 15). If the data met these needs, EPA could reconsider its proposed testing; if the data did not, EPA would proceed with the indirect photolysis requirement, including addition of humic acid to the testing solutions (Ref. 16). The modified NPRM presents EPA's rationale for requiring the indirect photolysis study and the reasons why the oxidation rate studies submitted by DuPont do not meet EPA's needs (53 FR 913, 916–917).

The additional work submitted by DuPont in response to the ANPR included a study measuring the disappearance rate of *p*-pda in Delaware River water. In addition to the concerns listed in the modified NPRM, the following conditions have been identified as unacceptable: (1) Although DuPont's report implied that molecular oxygen is intimately involved in the oxidation of *p*-pda, documentation of molecular oxygen depletion was not included in DuPont's report; (2) the study report did not document quality control; and (3) the composition of the test water was unknown. Because of these deficiencies, EPA has not modified its decision to require the indirect photolysis testing.

2. *Aquatic toxicity.* DuPont argued that the aquatic toxicity tests submitted to EPA were reliable because the data were collected according to EPA-approved protocols, that chemical detection levels were state-of-the-science, that flow-through testing would not improve data reliability, that EPA did not provide adequate arguments for the inadequacy of the chronic *Daphnia* test for *m*-pda, and that *Gammarus* is not a good test organism (Ref. 9).

EPA approved DuPont's protocols prior to the onset of the 1985 studies in *Daphnia*, fathead minnows, and algae with acceptance of study results being contingent upon EPA's review (Ref. 18). In the modified NPRM, EPA reported that these studies were flawed. EPA test guidelines require flow-through testing for chemicals that may hydrolyze, oxidize, volatilize, or biodegrade to maintain constant chemical concentrations throughout the duration

of the experiment. Pda's are expected to oxidize. EPA acknowledges that DuPont used state-of-the-science analytical techniques to determine pda concentrations in the test solutions; however, constant chemical concentrations were not maintained in the tests submitted by DuPont. EPA has chosen not to require the fathead minnow and daphnid acute toxicity tests to be repeated; these data will be used in combination with the acute flow-through rainbow trout and *Gammarus* studies to determine the most sensitive species for testing in the fish partial life-cycle test and to assess the acute hazard of pda's to aquatic organisms.

The chronic *Daphnia* test lacks adequate documentation for chemical concentration measurements. EPA acknowledges that DuPont used state-of-the-science analytical techniques to determine *m*-pda concentrations in the test solutions. However, this test is a static-renewal test. EPA guidelinesrecommend that test concentrations should be measured, at a minimum, in each chamber before the test and in each chamber on 7, 14, and 21 days of the test to determine actual chemical concentrations being tested. DuPont's study does not identify whether test chamber concentrations were measured before or after the daphnids were exposed to the chemical solution. The test concentrations also varied from 22.5 to 66.7 percent of the nominal concentrations, a variation EPA believes could have been reduced by conducting a flow-through assay. However, EPA has chosen not to require repetition of this study. The data will be combined with the fathead minnow and rainbow trout partial life-cycle test results to assess the long-term hazard of *m*-pda to aquatic organisms.

EPA disagrees with DuPont that *Gammarus* testing is not well documented. *Gammarus* is a good test organism because it provides data for response of amphipods to chemical toxins, has shown comparability with daphnids in response to toxic stresses, and sometimes is a more sensitive species than *Daphnia*.

EPA is, therefore, requiring aquatic toxicity testing according to the testing scheme presented in the modified NPRM. All three isomers shall be tested in the rainbow trout and *Gammarus* acute tests. Since the daphnid and fathead minnow LC_{50}s for *p*-pda are less than 1 mg/L and for *o*-pda the daphnid LC_{50} is less than 1 mg/L, testing for *p*- and *o*-pda will proceed to the daphnid life-cycle and the fish partial life-cycle test in the more sensitive species of rainbow trout or fathead minnow. For *m*-pda, a fish partial life-cycle test shall be conducted because of 1985 data showing the maximum acceptable toxicant concentration (MATC) to be less than 0.1 mg/L. The results of the rainbow trout acute testing will be compared to the fathead minnow acute toxicity data to determine the more sensitive species for testing *m*-pda. Chemical-specific sensitivity of fish to the pda isomers may provide results requiring testing of the three isomers in different fish species. Although the aquatic invertebrate acute testing will provide needed data measuring species sensitivity to pda's, EPA chronic invertebrate test guidelines are available only for daphnids. Consequently, all chronic aquatic invertebrate testing is being required in *Daphnia magna*.

3. *Reporting deadlines.* DuPont found the reporting deadlines unrealistic, stating they fail to allow adequate time for critical administrative paths involved in the proposed tiered testing. However, insufficient evidence was presented to show that pda's present unique qualities should cause EPA to alter the reporting requirements proposed in the NPRM and modified NPRM. Therefore, the required reporting deadlines will remain the same as required for other section 4 final rules.

4. *Cost of testing.* DuPont disagreed with EPA's estimated testing cost. DuPont argued that actual testing costs would total approximately $1 million more than EPA's estimate. EPA has evaluated DuPont's submission and finds it difficult to determine the differences in the costs since DuPont did not provide the rationale for its estimate. For all three isomers, DuPont estimated the partial life-cycle test in rainbow trout to be $30,000 and $120,000, oxidative half life and oxidative by-product assays $100,000 and $200,000, and chronic neurotoxicity test $540,000. EPA's estimated price range for the required rainbow trout partial life-cycle assays for all three isomers is $54,000 to 120,000 and for the subchronic neurotoxicity testing $285,000. EPA is not requiring chronic neurotoxicity testing at this time. The required indirect photolysis testing for all isomers is estimated to be $15,000 to $18,000. However, since publication of the modified NPRM, the estimated cost of the mouse biochemical specific locus test has been updated to between $350,000 and $600,000. EPA's total estimated cost for testing would therefore increase to $1.8 to $2.6 million, approaching DuPont's cost estimation. EPA believes that this cost does not impose an excessive economic burden upon the pda industry (see Unit IV of this preamble).

III. Final Health and Environmental Effects Test Rule for Unsubstituted Phenylenediamines

A. Findings

EPA is basing the final health and environmental effects testing requirements on the authority of section 4(a)(1)(A) of TSCA.

1. *Health effects testing.* EPA finds that the manufacture, processing, and use of *m*-pda and *m*-pda.H_2SO_4 may present an unreasonable risk of mutagenic and oncogenic effects, and that manufacture, processing, and use of *m*-, *o*-, *p*-pda, *m*-pda.H_2SO_4, and *p*-pda.H_2SO_4 may present an unreasonable risk of neurotoxic effects in humans because (1) as many as 59,483 workers in 6,187 plants may be exposed during manufacture, processing and use to at least one of the three isomers (Ref. 1); and (2) for *m*-pda, a potential genotoxic, oncogenic and neurotoxic hazard exists, and for *o*-pda and *p*-pda a potential neurotoxic hazard exists from this exposure. Under section 4(a)(1)(A)(ii), EPA also finds that there are insufficient data to reasonably predict such effects on human health from the manufacturing, processing, and use of these pda's. Under section 4(a)(1)(A)(iii), EPA finds that testing of these pda's is necessary to develop data for potential genotoxic, neurotoxic, and oncogenic hazards to determine whether manufacture, processing, or use of pda's does or does not present an unreasonable risk of injury to human health.

In this rule EPA finds that testing is necessary to determine the potential oncogenic hazard from exposure to *m*-pda. A determination of whether oncogenicity testing will be initiated and the required test standard for testing for oncogenic effects will be included in the weight-of-evidence review. If such testing is indicated, EPA will publish this determination and propose a test standard for comment in a separate Federal Register notice.

a. *Mutagenicity.* The finding that *m*-pda "may present an unreasonable risk" of mutagenic toxicity is based on its positive Ames assays and a comparative study which showed *m*-pda to be the most potent mutagen of 11 aromatic amines tested (51 FR 472, 474), positive results in the *in vivo* Chinese hamster ovary chromosomal aberration test, and inhibition by *m*-pda of mouse testicular cell DNA synthesis *in vitro* (53 FR 913, 914).

b. *Neurotoxicity.* The finding that these pda isomers "may present an unreasonable risk" of neurotoxicity is based on available literature reports of a consistent pattern of neurobehavioral effects resulting from exposure to pda's. These reports suggest that dermal exposure to pda's may cause seizures at very low levels, cause adverse physical and neurological effects and visual disturbances, and that subcutaneous injections cause clonic and tonic spasms indicating interference with brain metabolism. These data leave sufficient uncertainty and data gaps to justify neurotoxic effects testing for all three isomers (53 FR 913, 916).

c. *Oncogenicity.* The finding that *m*-pda may present an unreasonable risk of oncogenicity is based on a positive Chinese hamster ovary assay (53 FR 913, 914).

2. *Chemical fate and environmental effects testing.* EPA finds that pda's may present an unreasonable risk to the environment and that data are insufficient to determine aquatic toxicity of pda's. EPA finds that: (1) Concentrations of these pda's in the environment could reach levels which may be harmful to aquatic organisms and they may persist long enough that exposure to them may present an unreasonable risk of acute or chronic injury to aquatic organisms. In addition, the finding that these pda's "may present an unreasonable risk" to aquatic organisms is based upon the literature values for acute toxicity of these pda's to aquatic organisms, structure-activity relationships with toluenediamines (51 FR 472, 475), and aquatic toxicity data submitted by DuPont (53 FR 913, 916–918; Unit II.C of this preamble). (2) There are insufficient data to characterize potential environmental persistence and toxicity of these pda's. (3) Testing is necessary to characterize the environmental persistence and aquatic toxicity of *m*-, *o*-, and *p*-pda to help determine whether manufacturing, processing, or use of these pda's does or does not present an unreasonable risk of injury to the environment.

The reason chemical fate testing is being required is based upon the chemical properties of these pda's, biodegradation efficiency in activated sludge, structure-activity relationships with toluenediamines (51 FR 472, 475), and the uncertain environmental relevance of existing chemical fate data (53 FR 913, 916-917; Unit II.C).

B. Test Standards

1. *Health effects.* On the basis of the findings given above for health effects testing, EPA is requiring that *m*-pda be tested for mutagenic and oncogenic effects, and that *m*-, *o*-, and *p*-pda be tested for neurotoxic effects, chemical fate, and aquatic toxicity. These tests shall be conducted in accordance with specific test guidelines set forth in 40 CFR parts 795, 796, 797, and 798. The tests are to be conducted in accordance with EPA's TSCA Good Laboratory Practice (GLP) Standards in 40 CFR part 792. On the basis of the findings presented in Unit III.A.1 of this preamble for human health effects, EPA is requiring that *m*-pda be tested for mutagenicity, using *Drosophila* sex-linked recessive lethal and mouse bone marrow micronucleus assays, as stipulated in 40 CFR 798.5275 and 798.5395, respectively. A positive bone marrow assay would trigger a dominant lethal assay in mice using the procedure in 40 CFR 798.5450. A positive result in the dominant lethal assay may, after a public program review, trigger the heritable translocation assay using the procedure in 40 CFR 798.5460. If the dominant lethal assay is negative, no further chromosomal aberration testing will be required for *m*-pda.

If the sex-linked recessive lethal assay is positive, after a public program review, the MVSL (40 CFR 798.5200) will be triggered. If the proposed amendment for the requirement of the MVSL is promulgated prior to the onset of the MVSL testing, the test sponsor may choose to conduct either the MVSL or the MBSL and shall notify EPA in writing of its choice in its first interim report. If the sex-linked recessive lethal assay is negative, no further gene-mutation testing will be required.

A determination of whether oncogenicity testing shall be initiated will be made at the completion of the mutagenicity testing program, at which time EPA will make a weight-of-evidence determination and conduct a public program review as referenced in Unit II.B.3 of this preamble. If the test must be initiated, EPA will propose the oncogenicity test standard for comment.

On the basis of the findings presented in Unit III.A.1 of this preamble for human health effects, EPA is requiring that *m*-pda, *o*-pda, and *p*-pda be tested for neurotoxic effects (acute functional observational battery and motor activity test) using the test guidelines in 40 CFR 798.6050 and 798.6200. Results of the acute testing may trigger subchronic neurotoxicity testing and neuropathological examination, as specified in 40 CFR 798.6050, 798.6200, and 798.6400.

EPA will hold a public program review prior to requiring the initiation of the mouse specific locus assay, the heritable translocation assay, the chronic oncogenicity assay, or additional neurotoxicity testing. Public participation in this program review will be in the form of written comments or a public meeting. A request for public comments or notification of a public meeting will be published in the **Federal Register**. Should EPA determine, from the available weight of evidence, that proceeding to the mouse specific locus test, heritable translocation test, oncogenicity test, or neurotoxicity testing is no longer warranted, EPA would propose to repeal that test requirement(s) and, after public comment, issue a final amendment to rescind the requirement(s). If oncogenicity testing must be initiated, EPA will propose the standard for conducting such testing in a separate **Federal Register** notice.

2. *Chemical fate.* On the basis of the reasons presented in Unit III.A.2 for chemical fate testing, EPA is requiring that *m*-,*o*-, and *p*-pda be tested in the indirect photolysis screening test as specified in 40 CFR 795.70.

3. *Environmental effects.* On the basis of the justifications presented in Unit III.A.2 for environmental effects testing, EPA is requiring that acute toxicity testing of *m*-, *o*-, and *p*-pda be conducted on (1) rainbow trout (*Salmo gairdneri*) using the test guideline in 40 CFR 797.1400; and (2) in *Gammarus* sp. using the test guideline specified in 40 CFR 795.120. Since existing fathead minnow or daphnid acute toxicity test data or algal bioassay test data satisfy at least one of the decision criteria for each chemical, as defined in the NPRM and modified NPRM, fish partial life-cycle testing shall be conducted for *o*-,*p*-, and *m*-pda's as specified in 40 CFR 797.1600 in the more sensitive species of either rainbow trout (Salmo gairdneri) or fathead minnow (*Pimephales promelas*). The acute fish toxicity testing may provide data requiring the different isomers to be tested in different fish species in the fish partial life-cycle test. *Daphnia magna* life-cycle testing shall be conducted for *o*-and *p*-pda's as specified in 40 CFR 797.1330.

EPA is requiring that the TSCA health effects, chemical fate, and environmental effects test guidelines referenced in Unit III.B of this preamble, and subsequent revisions, shall be the test standards for the purposes of the required tests for pda's. The TSCA test standards for health effects, chemical fate, and aquatic toxicity specify generally accepted minimum conditions for determining health effects, chemical fate, and aquatic organism toxicities for substances such as pda's to which humans and the environment are expected to be exposed. EPA believes

that these test methods reflect the current state of the science for testing chemicals such as pda's for the specified endpoints.

C. Test Substance

EPA is requiring that *m*-, *o*-, and *p*-pda, each of at least 98 percent purity, shall be used as the test substances. EPA expects that the free bases may not be sufficiently stable to be used as test substances for repeated dose health effects testing. Thus, as stated in the proposed rule (51 FR 472, 478) either the hydrochloride or sulfate salt of *m*-pda is an acceptable test substitute for the oncogenicity test because it should be more stable. In addition for this final rule, either the hydrochloride or sulfate salt of *m*-pda, *p*-pda, or *o*-pda is an acceptable substitute for the subchronic neurotoxicity testing if any of the free bases prove to be unstable under the conditions of the study. Such salts must be of at least 98 percent purity.

D. Persons Required To Test

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

Because EPA has found that manufacturing, processing, and using *p*-pda, *o*-pda, *m*-pda, and the sulfate salts of *p*-pda and *m*-pda may result in an unreasonable risk to human health or the environment, EPA is requiring that persons who manufacture or process, or intend to manufacture or process, *p*-, *o*-, *m*-pda and the sulfate salts of *p*-pda and *m*-pda at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements for the particular substance as required by this rule. The end of the reimbursement period will be 5 years after the last final report is submitted, or an amount of time equal to that which was required to develop data if more than 5 years, after the submission of the 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 qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR part 790.

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

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

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for unsubstituted pda's. As noted in Unit III. C, EPA is interested in evaluating the effects attributable to unsubstituted pda's and has specified relatively pure substances for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR part 790 for single-phase rulemaking.

E. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with its TSCA GLP Standards which appear in 40 CFR part 792.

In accordance with 40 CFR part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans within 45 days before initiation of each study.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. EPA's reporting requirements for each of the test standards are specified in Tables 1 and 2. Except as noted, progress reports for all tests are required at 6-month intervals starting 6 months from the effective date of the final test rule.

EPA is requiring that manufacturers of *m*-pda and its sulfate salt shall report the study results and submit interim reports according to the schedule on the following Table 1.

Table 1—Required Testing, Test Standards, And Reporting Requirements For *meta*-Phenylenediamine

Test	Test standard (40 CFR section)	Reporting deadlines for final reports (months)[1]	Interim 6 month reports required
Health Effects Testing:			
1. *Drosophila* sex-linked recessive lethal (injection)	§ 798.5275	12	1
2. Mouse visible specific locus test (gavage)[2]	§ 798.5200	51	8
3. Mouse bone marrow micronucleus assay (oral)	§ 798.5395	12	1
4. Dominant lethal assay	§ 798.5450	24	1
5. Heritable translocation [2]	§ 798.5460	25	3
6. Oncogenicity [2]	[Reserved]	53	8
7. Acute functional observational battery (oral)	§ 798.6050	6	-
8. Acute motor activity test (oral)	§ 798.6200	6	-
9. Subchronic functional observational battery (oral)	§ 798.6050	18	2
10. Subchronic motor activity test (oral)	§ 798.6200	18	2

Table 1—Required Testing, Test Standards, And Reporting Requirements For *meta*-Phenylenediamine—Continued

Test	Test standard (40 CFR section)	Reporting deadlines for final reports (months)[1]	Interim 6 month reports required
11. Neuropathology	§ 798.6400	18	2
Chemical Fate Testing:			
12. Indirect photolysis	§ 795.70	8	-
Aquatic Toxicity Testing:			
13. Acute rainbow trout (flow-through)	§ 797.1400	9	-
14. Acute *Gammarus* test (flow-through)	§ 795.120	9	-
15. Fish partial life-cycle test [4] (flow-through)	§ 797.1600	18	2

[1] Calculated from the effective date of final rule, except as noted.
[3] Figure indicates the reporting deadline, in months, calculated from the date of notification of the test sponsor(s) by certified letter or FEDERAL REGISTER notice that, following public program review of all the then existing data for *m*-pda, EPA has determined that the testing must be performed.
[3] Testing standard will be proposed in a separate FEDERAL REGISTER notice if oncogenicity testing is to be initiated. Reporting deadline will be calculated from the date of promulgation of test standard
[4] Test species to be determined from results from acute toxicity testing with rainbow trout and fathead minnow.

EPA is requiring that manufacturers and processors responsible for the testing of *p*- and *o*-pda shall report the study results and submit interim reports according to the schedules in the following Table 2.

Table 2—Required Testing, Test Standards, And Reporting Requirements For *ortho*- And *para*-Phenylenediamine

Test	Test Standard (40 CFR)	Reporting deadlines for final reports (months)[1]	Interim 6 month reports required
Health Effects Testing:			
1. Acute functional observational battery (oral)	§ 798.6050	6	-
2. Acute motor activity test (oral)	§ 798.6200	6	-
3. Subchronic functional observational battery (oral)	§ 798.6050	18	2
4. Subchronic motor activity test (oral)	§ 798.6200	18	2
5. Neuropathology	§ 798.6400	18	2
Chemical Fate Testing:			
6. Indirect photolysis	§ 795.70	8	-
Aquatic Toxicity Testing:			
7. Acute rainbow trout (flow-through)	§ 797.1400	9	-
8. Acute *Gammarus* test (flow-through)	§ 795.120	9	-
9. Fish partial life-cycle test (flow-through) [2]	§ 797.1600	18	2
10. Daphnid life-cycle	§ 797.1330	12	1

[1] Number of months after effective date of the test rule.
[2] Test species to be determined from results from acute toxicity testing with rainbow trout and fathead minnow.

TSCA section 14(b) governs EPA disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, EPA will publish a notice of receipt in the **Federal Register** as required by section 4(d).

Persons who export a chemical which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR part 707. In brief, as of the effective date of this test rule, an exporter of *m*-pda, *o*-pda, *p*-pda, or the sulfate salts of *m*-pda and *p*-pda must report the first annual export or intended export of the unsubstituted pda to any one country. EPA will notify the foreign country of the test rule for the chemical.

F. Enforcement Provisions

EPA 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 TSCA or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce ***". EPA considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for unsubstituted pda's. 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, interpretations and evaluations, and to determine compliance with TSCA GLP Standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1)

of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. EPA maintains that laboratory inspections are necessary to provide this assurance.

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

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

Individuals as well as corporations could be subject to enforcement actions. Section 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.

IV. Economic Analysis of Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (see supporting documentation (2)(a) in Unit VI.A of this preamble) that evaluates the potential for significant economic impact 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 pda's: (1) Price sensitivity of demand, (2) market expectations, (3) industry cost characteristics, and (4) industry structure.

Total testing costs for the required testing for pda's are estimated to range from $1.8 to $2.6 million. To predict the financial decision-making practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period in order to finance the testing expenditure in the first year.

The annualized test costs (using a 7 percent cost of capital over a period of 15 years) range from $197,000 to $280,000. Based on 1984 production of 60 million pounds, the total unit test costs range from $0.0033 to $0.0047 per pound. These costs are equivalent to (percent of current price, current price in dollars per pound): *p*-pda: 0.08–0.12, $4.00; *m*-pda: 0.16–0.23, $2.07; *o*-pda: 0.1–0.14, $3.25.

EPA believes that the potential for adverse economic impact resulting from the costs of testing is low. This conclusion is based on the following observations:

1. The annualized cost of testing is very low, at approximately 0.12–0.23 percent of product price in the upper-bound case.

2. Demand for pda's does not appear to be sensitive to a price increase in this range.

Refer to the economic analysis contained in the public record for this rulemaking for a complete discussion of test cost estimation and potential for economic impact resulting from these costs (see supporting documentation (2)(a) in Unit VI.A of this preamble).

V. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the NTIS (PB 82–140773). On the basis of this study, EPA believes that there will be available test facilities and personnel to perform the testing in this proposed rule.

EPA has reviewed the availability of contract laboratory facilities to conduct the neurotoxicity testing requirements (Ref. 17) and believes that facilities will be made available for conducting these tests. The laboratory review indicates that few laboratories are currently conducting these tests according to TSCA test guidelines and TSCA GLP Standards. However, the barriers faced by testing laboratories to gear up for these tests are not formidable. Laboratories will need to invest in testing equipment and personnel training, but EPA believes that these investments will be recovered as the neurotoxicity testing program under TSCA section 4 continues. EPA's expectations of laboratory availability were borne out under the testing requirements of the C9 aromatic hydrocarbon fraction test rule at 40 CFR 799.2175. Pursuant to that rule, the manufacturers were able to contract with a laboratory to conduct the testing according to TSCA test guidelines and TSCA GLP Standards.

VI. Rulemaking Record

EPA has established a record for this rulemaking proceeding [docket number OPTS-42006F]. This record includes:

A. Supporting Documentation

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

(a) Notice of proposed rule on unsubstituted phenylenediamines (51 FR 472; January 6, 1986).

(b) Notice of reopening comment period for unsubstituted phenylenediamines (52 FR 913; January 14, 1988).

(c) Notice containing the ITC designation of the phenylenediamines category to the Priority List (45 FR 35697; May 28,1980).

(d) Notices relating to EPA's health effects test guidelines and TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).

(e) Notice of final rule on test rule development and exemption policy and procedures (49 FR 39772; October 10, 1984).

(f) Notice of interim final rule on test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(g) Notice of final rule on data reimbursement policy and procedures (48 FR 31786; July 11, 1983).

(h) Advance Notice of Proposed Rulemaking for the phenylenediamines (47 FR 973; January 8, 1982).

(i) Notice of Agency decision not to require testing of certain phenylenediamines (50 FR 4267; January 30, 1985).

(j) TSCA test guidelines final rule (40 CFR parts 796, 797, and 798: September 27, 1985).

and modifications (52 FR 19056; May 20, 1987).

(k) Notice of extended comment period for ANPR (51 FR 7583; March 5, 1986).

(l) Notice of final rule on 2-mercaptobenzothiazole (53 FR 34154; September 7,1988).

(m) Notice of final rule on C9 aromatic hydrocarbon fraction (40 CFR 799.2175).

(2) Support Documents: consisting of:

(a) Economic analysis document.

(b) Ethyltoluene and Trimethylbenzene technical support document.

(c) Cresols support document.

(3) Communications before proposal consisting of:

(a) Written public and intra-agency or interagency memoranda and comments.

(b) Records of telephone conversations.

(c) Records or minutes of informal meetings.

(d) Reports—published and unpublished factual materials.

B. References

(1) National Occupational Exposure Survey. Computer Print-out. U. S. Environmental Protection Agency, Washington, D. C. (October 3, 1988).

(2) Von Oettingen. US Public Health Service Bulletin 271 (1941).

(3) Cain, D.P. "Transfer of pentylenetetrazol sensitization to amygdaloid kindling." *Pharmacology, Biochemistry and Behavior*. 15:533-536 (1981).

(4) Gilbert, M.E. and D.P.Cain, "A single neonatal pentylenetetrazol or hyperthermia convulsion increases kindling susceptibility in the adult rat." *Developmental Brain Research*. 22:169–180 (1985).

(5) Sanger, D.J. "GABA and the behavioral effects of anxiolytic drugs." *Life Science*. 63:1503-1513 (1985).

(6) EPA. "Notice of proposed rule on unsubstituted Phenylenediamines." (51 FR 472; January 6, 1986).

(7) EPA. "Notice of reopening comment period for unsubstituted Phenylenediamines." (53 FR 913; January 14, 1988).

(8) Amo, H., M. Matsuyama, H. Amano, et al. "Carcinogenicity and toxicity study of *m*-phenylenediamine administered in the drinking-water to (C57BL/6 x C3H/He)F1 mice." *Federation of Chemical Toxicology*. 26(11/12): 893–897 (1988).

(9) DuPont. "DuPont comments: Unsubstituted Phenylenediamines: Proposed Rule (OPTS 42008D)." Washington, D.C.: Office of Toxic Substances. U.S. Environmental Protection Agency (February 26, 1988).

(10) DuPont. Phone Contact: T. Lewis to J. Helm (September 5, 1984).

(11) EPA. Phone contact: J. Helm to N. Krivanek (October 4, 1984).

(12) DuPont. Phone Contact: N. Krivanek to P. Kennedy (September 12, 1984).

(13) EPA. Phone Contact: J. Helm to K.D. Dastur (September 26, 1985).

(14) DuPont. Letter: K.D. Dastur to R. Northrop. "Phenylenediamines"(August 5,1985).

(15) EPA. Phone Contact: J. Helm to T. Lewis (November 14, 1984).

(16) EPA. Phone Contact: J. Helm to K.D. Dastur (August 28, 1985).

(17) EPA. Evaluation of TSCA test guidelines for neurotoxicity testing. Mathtech, Inc. Contract numbers 68–02–4235. Regulatory Impact Branch, Office of Toxic Substances, Washington, DC (April 4, 1987).

(18) EPA. Letter: EPA response to ecotoxicity protocols submitted by DuPont. From: Ralph Northrop, U. S. Environmental Protection Agency, to: K.D. Dastur, E.I. DuPont De Nemours & Company (November 14, 1984).

(19) NTTSC. "Comments on the proposed test rule for unsubstituted Phenylenediamines (FR 53: 913–922)." American Psychological Association, Psychopharmacology Division. Washington, DC, Office of Toxic Substances, US Environmental Protection Agency (February 25, 1988).

(20) E.I. DuPont de Nemours & Co., Inc. "Phenylenediamines: Response to Interagency Testing Committee (OPTS-42008)." Washington, DC, Office of Toxic Substances, U.S. Environmental Protection Agency (April 6, 1982).

(21) American Conference of Governmental Industrial Hygienists, Inc. "Documentation of the Threshold Limit Values Fourth Edition 1980: Supplemental Documentation 1982." page, 330 (1982).

Confidential Business Information (CBI), while part of the record, is not available for public view. A public version of the record, from which CBI has been deleted, is available for inspection in the TSCA Public Docket Office, Rm. NE–G004, 401 M St. SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VII. 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. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order; i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U. S. enterprises to compete with foreign enterprises.

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

B. Regulatory Flexibility Act

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

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to average 4,841 hours for *m*-pda, 3,227 hours for *p*-pda, and 6,454 hours for *o*-pda. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070–0033), Washington, DC 20503.

List Of Subjects In 40 CFR part 799

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

Dated: November 2, 1989.

Linda F. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR part 799 is amended as follows:

PART 799—[AMENDED]

a. The authority citation continues to read as follows:

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

b. Section 799.3300 is added to read as follows:

§ 799.3300 Unsubstituted phenylenediamines.

(a) *Identification of test substance.* (1) The unsubstituted phenylenediamines (pda's), *para*-phenylenediamine (*p*-pda, CAS No. 106–50–3), or its sulfate salt (*p*-pda.H_2SO_4, CAS No. 1624–57–75), *meta*-phenylenediamine (*m*-pda, CAS No. 108–45–2), or its sulfate salt (*m*-pda.H_2SO_4, CAS No. 54–17–06), and