40 CFR Part 799

[OPTS-42067A; (FRL-3070-6)]

Bisphenol A; 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 bisphenol A, hereinafter BPA, (4,4'-isopropylidenediphenol, CAS No. 80-05-7) to conduct a 90-day inhalation subchronic toxicity study with particular emphasis on pulmonary effects. EPA is also terminating the test rule process for acute and chronic aquatic toxicity testing of BPA. Both actions follow EPA's proposed rule on BPA published May 17, 1985 (50 FR 20691).

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ("daylight" or "standard", as appropriate) time on October 2, 1986. This rule shall become effective on November 3, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460. Toll free: (800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA to require health effects testing of BPA.

I. Introduction

A. Test Rule Development Under TSCA

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

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

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

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

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

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

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

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

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

B. Regulatory History

As published in the **Federal Register** of May 29, 1984 (49 FR 22389), the Interagency Testing Committee (ITC) designated BPA for priority testing consideration and recommended chemical fate testing, including octanol/water partition coefficient and persistence; health effects testing, including reproductive effects, chronic effects, and oncogenicity specifically as a result of inhalation exposures; ecological effects testing, including acute and chronic toxicity to fish, aquatic invertebrates, and algae; and bioconcentration. The Agency responded to the ITC's recommendations for BPA by issuing in the **Federal Register** of May 17, 1985 (50 FR 20691), a proposed test rule for aquatic acute and chronic toxicity testing and a 90-day inhalation subchronic toxicity study in the rat with a 21-35 day post-exposure recovery and observation period. The May 1985 document contains BPA's chemical profile, specifies who would be required to conduct the proposed testing, a description of the test substance to be used, and a discussion of EPA's TSCA section 4(a) findings.

On October 3, 1985, EPA held a public meeting to hear and discuss oral comments presented on various aspects of the proposed rule. The transcript for this meeting is contained in the record for this action. Most of the discussion at this meeting addressed the test data from studies the BPA manufacturers had initiated in the spring of 1985 in anticipation of EPA's proposed test rule. The test data and final reports for the industry studies are included in the record for this action.

II. Public Comment

Several comments were provided to the Agency by the manufacturers in response to the proposed rule for BPA. These comments were received in a letter dated July 16, 1985, from the Society of the Plastics Industry (SPI), a professional organization representing the BPA manufacturers (Ref. 1). Oral comments were also presented by the manufacturers in EPA's public meeting on October 3, 1985.

EPA believes several of the issues are no longer applicable to this rulemaking because of the testing the manufacturers have already undertaken and the subsequent termination of the process for portions of the proposed testing in light of these studies (see Unit III below). EPA responses to public comments on several issues still relevant to the final rulemaking are given below. These deal specifically with the question of which of the various aspects of the procedures specified in the TSCA Health Effects Test Guideline for Subchronic Inhalation Testing (40 CFR 798.2450) should be made mandatory, i.e., changing language in the guidelines by utilizing the word "shall" instead of "should".

SPI commented that further testing is not necessary because data from the BPA manufacturers'-sponsored acute and 2-week aerosol toxicity studies (see Unit IV.A. below) satisfy EPA's concern for the localized effects of BPA.

The Agency does not agree that these data are sufficient to reasonably predict localized effects from BPA exposure. In fact, EPA believes the test data heighten the concern and need for additional testing. An in-depth discussion of these data and EPA's concerns is provided in Unit IV.A. below.

SPI also commented that the requirement under § 798.2450(d)(8)(iv) for continuous monitoring of temperature and humidity and recording of these values at least every 30 minutes, is excessive. SPI believes records should only be required for the start and end of the exposure period and include one measurement approximately halfway through the exposure period.

EPA believes this requirement is not excessive. Equipment for continuous monitoring and chart recording of both parameters is readily available. EPA believes toxicity data may be

T-31

significantly influenced by abrupt changes in either condition and only through continuous monitoring, as prescribed in this standard, can their influence be determined and interpreted. EPA also believes that changes in temperature and humidity may affect the BPA dust levels in the exposure chamber and that every effort should be taken to minimize such changes.

SPI commented that hematologic and clinical chemistry requirements prescribed in the TSCA Guidelines are excessive for any rodent study. In particular, SPI stated that the requirements for pretest determinations defeat at least in part, one of the reasons for including a concurrent control group. Also, with the biological variability inherent in these parameters, SPI believed that comparisons between control and treated groups are far more meaningful than pretest versus test and post-test comparisons between small subgroups. SPI also raised questions as to which five rats should be used for blood collection: The same five throughout the study, five randomly selected at each time interval, or five drawn at random from test groups which have been increased in size to provide animals solely for one-time blood collection. SPI suggested that the hematology and clinical chemistry determinations are justified only at the conclusion of the study, i.e., at the time of sacrifice, and that they should be conducted on all animals.

EPA agrees with SPI's comments. EPA believes that unless a chemical is suspected of having specific properties which would mandate 30-day hematology and clinical biochemistry determinations in blood, it would appear adequate if these determinations were performed at the end of the test period. EPA believes that the data from the oncogenicity bioassay conducted by the National Toxicolgy Program (NTP) do not raise this concern since the blood effects found were not attributed by NTP to BPA exposure (50 FR 20696). It is always preferable to have baseline hematologic and clinical biochemistry values on the animals prior to their undergoing testing since there can be a wide margin of variability in the normal range values. However, if the testing laboratory provides historical control values for the species and strain of animals under test, it appears reasonable to accept such values in light of the fact that this same procedure is accepted by the Food and Drug Administration, the Organization for Economic Cooperation and Development (OECD), and EPA's Office of Pesticide Programs.

SPI also suggested that although the range of hematology and clinical chemistry determinations outlined in the guidelines may be appropriate under certain circumstances, a reasonable evaluation can be achieved with a clinical battery such as that used in the 2-week BPA dust inhalation study (Ref. 2).

EPA agrees with this comment and is recommending in this final rule that the hematological and clinical chemistry determinations be similar to those used in the 2-week aerosol toxicity study sponsored by SPI. EPA does not believe there is a necessity to conduct urinalyses because such data are available from toxicity testing done by NTP.

III. Decision To Terminate the Test Rule Process for Environmental Effects Testing of BPA

After proposing acute and chronic aquatic toxicity testing, the Agency received final study reports from SPI for the aquatic tests EPA had proposed. Because the testing proposed by EPA has been completed and the data, as described below, are adequate to reasonably predict the acute and chronic effects on fresh- and saltwater aquatic organisms, the Agency has decided to terminate that segment of the test rule process for environmental effects testing.

The results of freshwater acute tests using a measured test system showed that the 24-, and 48- through 96-hour LC_{50} values for the vertebrate (*Pimephales promelas* fathead minnow) were 4.7 and 4.8 ppm, respectively, and the 24- and 48-hour LC_{50} values for the invertebrate (*Daphnia magna*) were 15.5 and 10.2 ppm (Ref. 2). The 96-hour EC_{50} value for *Selenastrum capricornutum* was 2.73 mg BPA/ml by cell count and 3.10 mg/ml by total cell volume (Ref. 2).

EPA had also proposed that certain criteria be applied to the acute toxicity data for BPA to determine whether the chronic toxicity testing was necessary. EPA specified in the proposed rule that if the 96-hour LC_{50} value from any of the vertebrate and invertebrate acute test species was less than 1.0 ppm, or there were indications of chronicity (i.e., the ratio of the 48-hour to 96-hour LC_{50}'s is greater than 2), then chronic toxicity testing with the most sensitive test species should be performed. Therefore, because the 96-hour LC_{50} values submitted for BPA by SPI for the test species (vertebrate and invertebrate) were greater than 1 ppm, and the ratio of the 48-hour to 96-hour LC_{50} value is less than 2 in the fathead minnow (the ratio cannot be calculated for Daphnia because the study is not conducted over a 96-hour period), EPA believes further testing for chronic toxicity in the freshwater species is not warranted at this time.

Results submitted by SPI of saltwater acute tests using flow-through and measured test systems showed that the 24-, 48-, 72-, and 96-hour LC_{50} values for the vertebrate (*Menidia menidia* Atlantic silverside) were 12.0, 11.0, 9.3, and 9.3 ppm, respectively, and the invertebrate (*Mysidopsis bahia* Mysid shrimp) were 3.3, 1.5, 1.1, and 1.0 ppm, respectively (Ref. 3). The 96-hour EC_{50} values for *Skeletonema costatum* calculated by nonlinear interpolation were 1.0 mg/l (based on cell count) and 1.8 mg/l (based on chlorophyll a content). Again, applying EPA's proposed criteria for triggering chronic testing, the saltwater vertebrate and invertebrate 96-hour LC_{50} values were not less than 1.0 ppm, and the ratio of the 48-hour LC_{50} to the 96-hour LC_{50} values was less than 2. Therefore, EPA believes no further chronic testing for saltwater organisms is necessary at this time.

A separate and additional Ready Biodegradation Study was submitted by Shell Development Co. Greater than 90 percent BPA degradation was observed in all test waters within 4 days (Ref. 4). In this test, a spike of 3 mg/l BPA was added to four water samples: control, Houston ship channel water, Patricks Bayou water, and the chemical plant effluent. The study results eliminated the Agency's concern that BPA's environmental degradation might require years to achieve substantial BP reduction in natural waters (see 50 FR 20691; May 17, 1985).

EPA believes that because BPA is nonpersistent (90 percent degraded in 4 days), it can reasonably conclude that BPA will not have a high bioconcentration factor. In addition, the weight of evidence for BPA suggests its toxicity is in the 1 to 10 ppm range with little indication of chronicity. Based upon these factors, the Agency has concluded that there is no need to require further aquatic toxicity testing because the Agency is in a position to reasonably predict its toxicity at environmental levels.

IV. Final Health Effects Test Rule For BPA

A. Findings

EPA is basing the final subchronic toxicity testing requirements for BPA on the authority of section 4(a)(1)(A) of TSCA. EPA finds that the manufacture, processing, use, and disposal of BPA may present an unreasonable risk of

lung injury after chronic inhalation exposure. EPA also finds there are insufficient data to reasonably determine or predict such effects on human health, and testing is necessary to develop these data. The bases for these findings are given below.

Available literature shows that hundreds of millions of pounds of BPA are produced annually in the United States (Ref. 5). BPA is used in the manufacture of polycarbonate resins, epoxy resins, and polysulfone and phenoxy resins. The National Occupational Hazard Survey (NOHS) data base (Ref. 6) indicates as many as 33,000 people in the chemical industries may be exposed to BPA at 911 plants. The National Occupational Exposure Survey (NOES) data base (Ref. 7) indicates that 9,446 workers are exposed to BPA SPI places the number of exposed workers closer to 500 (Ref. 1). EPA believes that any of these figures, along with the exposure information provided in its proposed test rule for BPA, provides sufficient evidence of potential exposure to the chemical during manufacture, processing, disposal and use.

After proposing the health effects testing for inhalation subchronic toxicity testing of BPA dusts, the Agency received final study reports (Ref. 2) from SPI for an acute (6-hour, single exposure) aerosol toxicity study and a 2-week aerosol toxicity study. Both studies were conducted using the Fischer 344 rat.

In the acute aerosol study, groups of 10 male and female rats were exposed to 0 or 170 mg/m^3 of BPA for 6 hours. The mass median aerodynamic diameter (MMAD) and geometric standard deviation for the BPA aerosol was 3.9±3.5 microns. Body weights were obtained at selected intervals. Half the animals were necropsied the day after the exposure and the remaining animals were sacrificed 14 days later.

Histopathologic changes were observed in the most anterior regions of the nasal tissue. This consisted primarily of inflammation in the external nares and the anterior portion of the nasal turbinates. In addition, ulceration in the incisive ducts which communicate between the nasal and oral cavities was observed. However, under the conditions of the study, these microscopic changes appeared to be reversible within the 2-week recovery period. No evidence for systemic toxicity was observed.

In the 2-week aerosol study, 20 male and 20 female rats were exposed to 0, 10, 50 or 150 mg/m^3 of BPA for 6 hours per day for nine exposures in 2 weeks. The MMAD for the concentrations examined ranged from 2.6 to 6.2 microns. The geometric standard deviation varied from 3.2 to 3.6 microns. Animals were observed daily, and body weights were recorded periodically. Samples were collected for hematology, clinical chemistry, and urinalysis from those animals necropsied the day following the final exposure to BPA. Half of the male and female rats were necropsied on the day following the last exposure to BPA, and the remaining animals were sacrificed 29 days after the final BPA exposure.

Toxicologic effects related to BPA exposure were described in the report. These effects consisted of a slight decrease in body weight gain of male rats exposed to 150 mg/m^3 BPA and microscopic changes in the anterior portion of the nasal cavity of male rats exposed to 150 mg/m^3 and female rats exposed to 50 or 150 mg/m^3. These effects were not observed 29 days after the last exposure to BPA. No evidence of systemic toxicity was observed at any time throughout the study. No effects were observed in rats exposed to 10 mg/m^3.

Of particular interest to EPA were the microscopic changes in the anterior portion of the nasal cavity seen immediately after cessation of exposure. These were described as very slight to slight hyperplasia of the squamous epithelium at the mucocutaneous junction and were observed in 7 of 10 males at 150 mg/m^3. The same lesion was described for 9 of 10 females at 50 mg/m^3 and 10 of 10 females at 150 mg BPA/m^3. The hyperplasia of the squamous epithelium extended into the nasal cavity to involve the respiratory epithelium overlying the vomeronasal organ.

EPA believes that for the purpose of a general subchronic toxicity study, the information available in the National Toxicology Program's oral gavage bioassay as referred to in the proposed rule (50 FR 20696), and its preliminary studies should provide the data needed to evaluate the toxicity of this chemical. However, while general toxicity may not be expected to alter with different routes of administration for this chemical there may be a site specific effect seen with BPA because of the route of exposure to humans. The indications that a problem may be present have been discussed in the May 17, 1985 proposed rule, i.e., thickening of interalveolar partitions (Ref. 8), and are further supported by the findings of the studies recently conducted by the BPA manufacturers and submitted to EPA by the SPI.

The Agency believes further concerns for BPA's localized toxic effects are provided by the additional studies. The inflammation and bilateral focal hyperplasia of the mucocutaneous junction provide evidence that BPA causes respiratory effects. Although apparently reversible after 4 weeks of no further exposure, this does not alleviate the Agency's concern that a more prolonged exposure to BPA may cause irreversible damage. Characterization of the potential for irreversible respiratory damage as a result of continued exposure to BPA dust is inadequate, and test data beyond that currently available are necessary to determine such an effect.

EPA concludes that on the basis of the potential for long-term occupational exposure to BPA, the existence of evidence of respiratory effects related to BPA dust exposures, and the lack of sufficient data to reasonably determine or predict BPA's health risk to humans, a 90-day inhalation subchronic toxicity study with a 28-day minimum post-exposure recovery and observation period is necessary to characterize the effects of BPA dust on the pulmonary system.

B. Test Standards

On the basis of the findings given above for health effects testing, the Agency is requiring that a 90-day subchronic inhalation toxicity test with a post-exposure recovery and observation period of not less than 28 days, using a satellite test group, shall be conducted for BPA. The Agency is requiring that this testing be performed in accordance with the methodology cited in the TSCA Health Effects Test Guideline at 40 CFR 798.2450 and the TSCA Good Laboratory Practice Standards in 40 CFR Part 792.

The Agency is also requiring that the BPA dust administered in this study consist of BPA particles of respirable size, specifically in the range of 0.1 to 5.0 micrometers in diameter. EPA is requiring that a satellite group of 20 animals (10 animals per sex) be maintained in the inhalation study under the high BPA concentration level for 90 days and observed for reversibility, persistence, or delayed occurrence of toxic effects for a post-treatment period of not less than 28 days. EPA is also requiring that the following clinical hematological examinations shall be carried out at least two times during the test period (i.e., at terminal sacrifice at 90 days and at terminal sacrifice for the post-exposure recovery period): packed cell volume (PCV), hemoglobin (Hgb), erythrocyte count (RBC), total leukocyte

T-3

(WBC), red blood cell indices (MCV, MCH, MCHC), platelet count (PLAT), and differential leukocyte count (DLC). EPA is also requiring that the following clinical biochemical determinations shall be carried out at least four times during the test period (as stated above): blood urea nitrogen (BUN), glutamic pyruvic transaminase activity (SGPT) glutamic oxaloacetic transaminase activity (SGOT), alkaline phosphatase activity (AP), glucose (Glu), total protein (TP), albumin (Alb), globulins (Glob), and acid/base balance. The Agency is also requiring a limited gross pathology for all animals to include an examination of the external surfaces of the body all orifices, cranial, thoracic and abdominal cavities and their contents, and the esophagus, stomach, and upper small intestine. Finally, EPA is requiring an initial histopathological examination of only the respiratory tract and lungs of all test animals in the control, high dose, and satellite groups. Further examinations of other dose groups shall be contingent on the findings of the initial examination.

C. Test Substance

EPA is requiring that BPA of at least 99 percent purity shall be used as the test substance.

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(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 exposure giving rise to the potential risk occurs during use, distribution, or disposal.

Because EPA has found that insufficient data exist to reasonably determine the respiratory effects on human health from the manufacture, processing, use, and disposal of BPA, EPA is requiring that persons who manufacture (or import) and/or process BPA at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements contained in this rule. 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 last final report required under the test rule.

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

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

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

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for BPA. As noted in Unit IV.C above, EPA is interested in evaluating the effects attributable to BPA and has specified a relatively pure substance for testing.

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

E. Reporting Requirements

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

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans within 4 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. The Agency is requiring that manufacturers and processors responsible for the subchronic toxicity testing of BPA shall report the study results within 17 months from the effective date of this rule. Manufacturers and processors responsible for the subchronic effects testing of BPA shall submit progress reports to EPA 6 months and 12 months after the effective date of the final rule.

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

Persons who export a chemical substance or mixture which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707. In brief, as of the effective date of this test rule, an exporter of BPA must report to EPA the first annual export or intended export of BPA to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

F. Enforcement Provisions

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

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by TSCA section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substance or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce. . . ." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and

T-3

procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for BPA. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, and that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the rule.

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

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 of TSCA 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 that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions.

This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.48(b)). Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in TSCA section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

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

V. Economic Analysis of Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis 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 bisphenol A: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If there is no indication of adverse effect, no further economic analysis will be performed, however, if the first level of analysis indictes a potential for significant economic impact, a more comprehensive and detailed analysis is conducted which more precisely predicts the magnitude and distribution of the expected impact.

Total testing costs for the final rule for bisphenol A are estimated to range from $117,700 to $147,100. In order 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 cost of capital of 25 percent over a period of 15 years) range from $30,500 to $38,116. Based on the 1984 estimated production volume for bisphenol A of 762 million pounds, the unit test costs will be about 0.005 cents per pound. In relation to the selling price of 67 cents per pound for bisphenol A, these costs are equivalent to 0.007 percent of price.

Based on these costs and the uses of bisphenol A, the economic analysis indicates that the potential for significant adverse economic impact as a result of this testing rule is extremely low. This conclusion is based on the following observations:

1. The estimated unit test costs are very low, 0.007 percent of current price in the upper-bound case.

2. The overall demand for bisphenol A appears relatively inelastic due to its dominant usage as a captive intermediate and the highly dispersed uses of its end products.

3. The market expectations for bisphenol A are optimistic, with demand projected to grow by three to four percent annually through the balance of the 1980's.

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

VI. Availability of Test Facilities and Personnel

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

VII. Rulemaking Record

EPA has established a public record for this rulemaking proceeding [docket number OPTS-42067A]. This record includes:

A. Supporting Documentation

(1) **Federal Register** notice designating BPA to the priority list (49 FR 22389) and all comments received on BPA

(2) **Federal Register** notice of EPA's proposed test rule on BPA (50 FR 20691) and all comments received on the proposed testing.

(3) Economic impact analysis of final test rule for bisphenol A.

(4) Communications consisting of letters and meeting summaries.

B. References

(1) The Society of the Plastics Industry. Letter from Fran W. Lichtenberg to TSCA Public Information Office. July 16, 1985.

(2) The Dow Chemical Company. Letter from Leroy Hampton to the U.S Environmental Protection Agency. June 20, 1985.

(3) The Society of the Plastics Industry. Letter from Fran W. Lichtenberg to Philip Wirdzek September 25, 1985.

(4) The Society of the Plastics Industry Letter from Hugh Patrick Toner to Philip Wirdzek. February 27, 1986.

(5) U.S Environmental Protection Agency. Econosic Impact Analysis of Proposed Test Rule for Bisphenol A Washington, D.C., Office of Toxic Substances, EPA, 1984.

T-3

(6) National Institute for Occupational Safety and Health. Computer printout: National Occupational Hazard Survey. Cincinnati, OH. Retrieved March 17, 1984.

(7) National Institute for Occupational Safety and Health. Computer printout: National Occupational Exposure Survey. Cincinnati, OH. Retrieved May 5, 1984.

(8) Stasenkova, K.P., Shumskaya, N.I., Grinbert, A.E. "Certain laws governing the biological action of bisphenol A derivatives, depending on their chemical structure." Gig. Tr. Prof. Zabol. 6:30–33. (In Russian; English Translation.). 1973.

The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. G–0004, NE Mall, 401 M St., SW. Washington, DC 20460.

VIII. Other Regulatory Requirements

A. Classification of Rule

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

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

B. Regulatory Flexibility Act

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

List of Subjects in 40 CFR Part 799

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

Dated: September 11, 1986.

John 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. By adding § 799.940, to read as follows:

§ 799.940 Bisphenol A.

(a) *Identification of test substance.* (1) Bisphenol A (CAS Number 80–05–7) (hereinafter "BPA") shall be tested in accordance with this section.

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

(3) BPA shall be administered as a dust for inhalation and shall consist of particles ranging in size from 0.1 to 5 micrometers.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture or process BPA, other than as an inpurity, November 3, 1986 to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data or submit exemption applications as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Health effects testing*—(1) *Required inhalation toxicity testing.* Subchronic toxicity and recovery testing including the satellite test group, shall be conducted with BPA in accordance with the TSCA Health Effects Test Guideline for Inhalation Toxicity in § 798.2450 (a), (b), (c) and (e) of this chapter. The following additional testing requirements apply to bisphenol A:

(i) *Test procedures*—(A) *Animal selection*—(*1*) *Species and strain.* A mammalian species shall be used for testing. A variety of rodent species may be used although the rat is the preferred species. Commonly used laboratory strains shall be employed. If another mammalian species is used, the tester shall provide justification/reasoning for its selection.

(*2*) *Age.* Young adult animals shall be used. At the commencement of the study the weight variation of animals shall not exceed ±20 percent of the mean weight for each sex.

(*3*) *Sex.* (*i*) Equal numbers of animals of each sex shall be used at each dose level.

(*ii*) Females shall be nulliparous and nonpregnant.

(*4*) *Numbers.* (*i*) At least 20 animals (10 females and 10 males) shall be used for each test group.

(*ii*) If interim sacrifices are planned, the number of animals shall be increased by the number of animals scheduled to be sacrificed before the completion of the study.

(B) *Control groups.* A concurrent control group is required. This group shall be an untreated or sham-treated control group. Except for treatment with the test substance, animals in the control group shall be handled in a manner identical to the test group animals. Where a vehicle is used to help generate an appropriate concentration of the substance in the atmosphere, a vehicle control group shall be used. If the toxic properties of the vehicle are not known or cannot be made available, both untreated and vehicle control groups are required.

(C) *Satellite group.* A satellite group of 20 animals (10 animals per sex) shall be treated with the high concentration level for 90 days and observed for reversibility, persistence, or delayed occurrence of toxic effects for a posttreatment period of not less than 28 days.

(D) *Dose levels and dose selection.* (*1*) In subchronic toxicity tests, it is desirable to have a dose-response relationship as well as a no-observed-toxic-effect level. Therefore, at least three dose levels with a control and, where appropriate, a vehicle control (corresponding to the concentration of vehicle at the highest exposure level) shall be used. Doses should be spaced appropriately to produce test groups with a range of toxic effects. The data should be sufficient to produce a dose-response curve.

(*2*) The highest concentration should result in toxic effects but not produce an incidence of fatalities which would prevent a meaningful evaluation.

(*3*) The lowest concentration should not produce any evidence of toxicity. Where there is a usable estimation of human exposure, the lowest concentration should exceed this.

(*4*) Ideally, the intermediate dose level(s) should produce minimal observable toxic effects. If more than one intermediate dose level is used, the concentrations should be spaced to produce a gradation of toxic effects.

(5) In the low and intermediate groups and in the controls the incidence of fatalities should be low, to permit a meaningful evaluation of the results.

(6) In the case of potentially explosive test substances, care should be taken to avoid generating explosive concentrations.

(E) *Exposure conditions.* The animals should be exposed to the test substance ideally for 6 hours per day on a 7 day per week basis, for a period of 90 days. However, based primarily on practical considerations, exposure on a 5-day per week basis for 6 hours per day is the minimum acceptable exposure period.

(F) *Observation period.* (1) Duration of observation shall be for atleast 90 days.

(2) Animals in a satellite group scheduled for followup observations shall be kept for an additional minimum 28 days without treatment to detect recovery from, or persistence of, toxic effects.

(G) *Inhalation exposure.* (1) The animals shall be tested in inhalation equipment designed to sustain a dynamic air flow of 12 to 15 air changes per hour and ensure an adequate oxygen content of 19 percent and an evenly distributed exposure atmosphere. Where a chamber is used, its design should minimize crowding of the testing animals and maximize their exposure to the test substance. This is best accomplished by individual caging. To ensure stability of a chamber atmosphere, the total "volume" of the test animals shall not exceed 5 percent of the volume of the test chamber. Oronasal or head-only exposure may be used if it is desirable to avoid concurrent exposure by the dermal or oral routes.

(2) A dynamic inhalation system with a suitable analytical concentration control system shall be used. The rate of air flow shall be adjusted to ensure that conditions throughout the exposure chamber are essentially the same. Maintenance of slight negative pressure inside the chamber will prevent leakage of the test substance into the surrounding areas.

(3) The temperature at which the test is performed shall be maintained at 22° C (+2°). Ideally, the relative humidity shall be maintained between 40 to 60 percent.

(H) *Physical measurements.* Measurements or monitoring shall be made of the following:

(1) The rate of air flow should be monitored continuously but shall be recorded at least every 30 minutes.

(2) The actual concentrations of the test substance shall be measured in the breathing zone. During the exposure period the actual concentrations of the test substance should be held as constant as practicable and monitored continuously and shall be recorded at least at the beginning, at an intermediate time and at the end of the exposure period.

(3) During the development of the generating system, particle size analysis shall be performed to establish the stability of aerosol concentrations. During exposure, analysis shall be conducted as often as necessary to determine the consistency of particle size distribution.

(4) Temperature and humidity shall be monitored continuously and shall be recorded at least every 30 minutes.

(I) *Food and water during exposure period.* Food shall be withheld during exposure. Water may also be withheld if necessary.

(J) *Observation of animals.* (1) Each animal should be handled and its physical condition shall be appraised at least once each day.

(2) Additional observations should be made daily with appropriate actions taken to minimize loss of animals to the study (e.g. necropsy or refrigeration of those animals found dead and isolation or sacrifice of weak or moribund animals).

(3) Signs of toxicity shall be recorded as they are observed including the time of onset, the degree, and duration.

(4) Cage-sided observations should include but not be limited to changes in the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous sytems, somatomotor activity and behavior pattern.

(5) Animals shall be weighed weekly. Food consumption should also be determined weekly if abnormal body weight changes are observed.

(6) At the end of the study period all survivors in the nonsatellite treatment groups shall be sacrificed. Moribund animals shall be removed and sacrificed when noticed.

(K) *Clinical examinations.* (1) The following examinations shall be made on at least five animals of each sex in each group:

(i) Certain hematology determinations shall be carried out at least two times during the test period: at terminal sacrifice at the end of the 90-day test period and at completion of the post-exposure recovery period (satellite group). Hematology determinations which shall be appropriate to this study include: packed cell volume, hemoglobin, erythrocyte count, total leukocyte, red blood cell indices, platelet count, and differential leukocyte count.

(ii) Certain clinical biochemistry determinations on blood shall be carried out at least two times: at terminal sacrifice at the end of the 90-day test period and at completion of the post-exposure recovery period (satellite group). Clinical biochemistry test areas which shall be appropriate to this study include: blood urea nitrogen, glutamic pyruvic transaminase activity, glutamic oxaloacetic transaminase activity, alkaline phosphatase activity, glucose, total protein, albumin, globulins, and acid/base balance. Other determinations which may be necessary for an adequate toxicological evaluation include: analyses of lipids, hormones, Methemoglobin, and cholinesterase activity. Additional clinical biochemistry may be employed, where necessary, to extend the investigation of observed effects.

(2) The following examinations shall be made on at least five animals of each sex in each group:

(i) Ophthalmological examination, using an ophthalmoscope or equivalent suitable equipment, shall be made prior to exposure to the test substance and at the termination of the study. If changes in the eyes are detected, all animals should be examined.

(ii) Urinalysis is not recommended on a routine basis, but only when there is an indication based on expected or observed toxicity.

(L) *Gross pathology.* (1) All animals shall be subjected to a full gross necropsy which includes examination of the external surface of the body, all orifices and the cranial, thoracic and abdominal cavities and their contents, and the esophagus, stomach, and upper small intestine.

(2) At least the liver, kidneys, adrenals, brain, and gonads shall be weighed wet, as soon as possible after dissection to avoid drying.

(3) The following organs and tissues, or representative samples thereof, shall be preserved in a suitable medium for possible future histopathological examination: All gross lesions; lungs—which shall be removed intact, weighed, and treated with a suitable fixative to ensure that lung structure is maintained (perfusion with the fixative is considered to be an effective procedure); nasopharyngeal tissues; brain—including sections of medulla/pons cerebellar cortex and cerebral cortex; pituitary; thyroid/parathyroid; thymus; trachea; heart; sternum with bone marrow; salivary glands; liver; spleen; kidneys; adrenals; pancreas; gonads; uterus; accessory genital organs, epididymis, prostate, and, if present, seminal vesicles; aorta; skin; gall

T-37

bladder (if present); esophagus; stomach; duodenum; jejunum; ileum; cecum; colon; rectum; urinary bladder; representative lymph node; mammary gland; thigh musculature; peripheral nerve; eyes; femur—including articular surface; spinal cord at three levels—cervical, midthoracic, and lumbar; and exorbital lachrymal glands.

(M) *Histopathology.* The following histopathology shall be performed: (*1*) Full histopathology on the respiratory tract including nasal cavity, pharynx, larynx and paranasal sinuses of all animals in the control, high dose, and satellite groups.

(*2*) All gross lesions in all animals.

(*3*) Target organs in all animals.

(*4*) Lungs of animals in the low and intermediate dose groups shall also be subjected to histopathological examination contingent on the histopathological findings of the control, high dose, and satellite groups.

(*5*) When a satellite group is used, histopathology shall be performed on tissues and organs identified as showing effects in other treated groups.

(ii) [Reserved]

(2) *Reporting requirements.* (i) Subchronic toxicity testing, including the satellite test group, shall be completed and the final study report submitted to the Agency within 17 months from the effective date of this final rule.

(ii) Progress reports shall be suumitted at 6 month intervals, the first of which is due within 6 months of the effective date of this final rule.

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

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T-3