ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS–42187L; FRL–5742–2]

RIN 2070–AC76

Amended Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).
ACTION: Amended proposed rule; extension of comment period.

SUMMARY: EPA is amending the proposed rule issued under section 4(a) of the Toxic Substances Control Act (TSCA) (61 FR 33178, June 26, 1996) that would require manufacturers and processors to test those hazardous air pollutants (HAPs) specified in the proposal for certain health effects. Under this amended HAPs test rule proposal (''amended HAPs proposal''), EPA would require that testing be conducted using eleven TSCA health effects test guidelines issued by EPA on August 15, 1997 (62 FR 43820), codified at 40 CFR part 799, subpart H, instead of the eleven OPPTS draft harmonized test guidelines cross-referenced in the June 26, 1996 proposed rule. The Agency is soliciting comments on the application of these part 799 test guidelines to the amended proposed HAPs test rule. In addition, the Agency is amending the proposed HAPs test rule by removing the testing requirements for phenol; specifying export notification requirements; reviewing the status of the proposals for enforceable consent agreements (ECAs) for pharmacokinetics (PK) studies submitted by industry; revising the economic assessment; including additional support documents in the rulemaking record; and describing other changes and clarifications to the proposed test rule. In addition, EPA is inviting ECA proposals for all of the HAPs chemicals for which PK proposals have not been received to provide for alternative testing to meet the requirements contained in the proposed HAPs test rule, as amended in this notice.

EPA is also extending the public comment period in order to provide interested individuals with sufficient time to consider the effects of the newly promulgated TSCA test guidelines referenced in enforceable test standards in this amended HAPs proposal, the economic assessment for this amendment, and other changes described in this action, and to comment accordingly.

DATES: Written comments on this proposed rule must be received by EPA on or before February 9, 1998. The public comment period on the June 26, 1996 proposed rule is being extended from January 9, 1998 to February 9, 1998.

ADDRESSES: Submit three copies of written comments on the proposed HAPs test rule, as amended, identified by document control number (OPPTS–42187A; FRL–4869–1) to: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (OPPT), Document Control Office (7407), Rm. G–099, 401 M St., SW., Washington, DC 20460. See Unit V. of this preamble for further instructions.

Comments and data may also be submitted electronically to oppt.ncic@epamail.epa.gov. Follow the instructions under Unit V. of this document. No confidential business information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: For general information: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. ET–543B, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 554–1404; TDD: (202) 554–0551; e–mail: TSCA–Hotline@epamail.epa.gov. For technical information contact: Richard W. Leukroth, Jr. , Project Manager, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC, 20460; telephone: (202) 260–0321; fax: (202) 260–8850; e-mail: leukroth.rich@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 1996 (61 FR 33178), EPA issued a proposed test rule for the following hazardous air pollutant chemicals that would require health effects testing to be conducted using eleven draft harmonized test guidelines developed by EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS): 1,1'-biphenyl (CAS No. 92–52–4), carbonyl sulfide (CAS No. 463–58–1), chlorine (CAS No. 7782–50–5), chlorobenzene CAS No. 108–90–7), chloroprene (CAS No. 126–99–8), *ortho*-cresol (CAS No. 95–48–7), *meta*-cresol (CAS No. 108–39–4), *para*-cresol (CAS No. 106–44–5), diethanolamine (CAS No. 111–42–2), ethylbenzene (CAS No. 100–41–4), ethylene dichloride (CAS No. 107–06–2), ethylene glycol (CAS No. 107–21–1), hydrochloric acid (CAS No. 7647–01–0), hydrogen fluoride (CAS No. 7664–39–3), maleic anhydride (CAS No. 108–31–6), methyl isobutyl ketone (CAS No. 108–10–1), methyl methacrylate (CAS No. 80–62–6), naphthalene (CAS No. 91–20–3), phenol (CAS No. 108–95–2), phthalic anhydride (CAS No. 85–44–9), 1,2,4–trichlorobenzene (CAS No. 120–82–1), 1,1,2-trichloroethane (CAS No. 79–00–5), and vinylidene chloride (CAS No. 75–35–4).

The Agency also offered to consider the use of PK and other mechanistic data as a means to permit route-to-route extrapolation of data from the existing chemical data base as an alternative to conducting some or all of the testing that would be required under the proposed HAPs test rule. Since this original proposal, EPA has promulgated eleven new TSCA health effects test guidelines, received eight ECA proposals for PK studies and prepared preliminary technical analyses for each of these PK proposals, and updated the economic assessment in light of the changes to the guidelines that are explained in this amended HAPs test rule proposal. In addition, EPA has identified needed changes and clarifications to the proposed HAPs test rule. This action amends the original HAPs proposal to include these changes and clarifications.

For all aspects of the original HAPs test rule proposal that are not addressed by this amended proposal, the discussion in the preamble of the original HAPs test rule proposal continues to apply.

Table of Contents

I. Background

On June 26, 1996 (61 FR 33178), EPA proposed, under TSCA section 4(a), 15 U.S.C. 2603(a), the testing of 21 HAPs for certain health effects (the ''original HAPs test rule proposal''). The proposal also invited the submission of proposals for enforceable consent agreements (ECAs) for the HAPs chemicals which would include pharmacokinetics (PK) studies (61 FR 33178, 33189). On September 11, 1996 (61 FR 47853) (FRL–5395–9), EPA announced a public meeting on the proposed HAPs test rule. The public meeting was held on October 1, 1996; a transcript of the meeting is included in the record for this rulemaking. In response to requests from industry, on October 2, 1996, EPA held a meeting with potential submitters of alternative testing proposals that would include PK studies. At this meeting, EPA clarified the types of information the Agency was seeking in the PK ECA proposals. A copy of the meeting summary is included in the record for this rulemaking.

The deadline for written comments on the proposed HAPs test rule contained in the June 26, 1996 **Federal Register** proposal was December 23, 1996. EPA has successively extended the comment period on this proposed rule as follows: On October 18, 1996 (61 FR 54383) (FRL–5571–3), the comment period was extended from December 23, 1996 to January 31, 1997; on December 23, 1996 (61 FR 67516) (FRL–5580–6), it was extended from January 31, 1997 to March 31, 1997; on February 28, 1997 (62 FR 9142) (FRL–5592–1), it was extended from March 31, 1997 to April 30, 1997; on March 28, 1997 (62 FR 14850) (FRL–5598–4), it was extended from April 30, 1997 to June 30, 1997; on May 30, 1997 (62 FR 29318) (FRL–5831–6), it was extended from June 30, 1997 to August 15, 1997; on July 15, 1997 (62 FR 37833) (FRL–5732–2), it was extended from August 15, 1997 to September 30, 1997; on September 26, 1997 (62 FR 50546) (FRL–5748–8), it was extended from September 30, 1997 to December 1, 1997; and on November 28, 1997 (62 FR 63299) (FRL–5759–2), it was extended from December 1, 1997 to January 9, 1998. These extensions to the comment period were necessary to allow the Agency more time to finalize eleven TSCA health effects test guidelines to be cross-referenced in this amended HAPs test rule proposal, and to respond to the PK ECA proposals submitted by industry.

By this action, EPA is extending the public comment period of the original HAPs proposed rule from January 9, 1998 to February 9, 1998. This extension of the comment period is needed to provide commenters with sufficient time to consider the effects of the TSCA test guidelines, the economic assessment for the amended HAPs proposal and other changes described in this action, and to comment accordingly.

II. TSCA Test Guidelines for HAPs Chemicals

A. Background to Test Guidelines Used in this Amendment

The original proposed HAPs test rule cross-referenced eleven draft harmonized health effects test guidelines developed by the Office of Pollution Prevention and Toxic Substances (OPPTS) of the EPA. These draft OPPTS harmonized guidelines had previously been made available for public comment in the **Federal Register** of June 20, 1996 (61 FR 31522 (FRL–5367–7)). The draft harmonized guidelines were designated as the OPPTS draft Series 870 test guidelines in the June 20, 1996 **Federal Register** announcement. In the original HAPs proposal, EPA stated that it was considering one of three alternative approaches for referencing test guidelines in the test standards proposed for HAPs testing (61 FR 33178, 33187). Deficiencies with each of the three approaches led EPA to promulgate eleven TSCA health effect guidelines on August 15, 1997 (62 FR 43820), codified at 40 CFR part 799, subpart H. EPA is proposing to cross-reference these guidelines in the test standards proposed for HAPs testing, and intends to cross-reference them, as appropriate, in subsequent TSCA section 4(a) test rules. Until the establishment of the new TSCA test guidelines in subpart H, EPA had been cross-referencing in test rules an earlier set of TSCA test guidelines in 40 CFR parts 795 through 798, originally promulgated in 1985 (50 FR 39252, September 27, 1985).

The Agency, in developing the TSCA test guidelines established in part 799, subpart H, adopted seven of the OPPTS final harmonized test guidelines and four guidelines developed by the Organization for Economic Cooperation and Development (OECD). The only significant difference between the TSCA test guidelines and the OPPTS final harmonized test guidelines is that certain recommended procedures in the OPPTS final harmonized test guidelines are made mandatory to provide for enforceability. Table 1 in § 799.5053 of this amended proposal shows how the TSCA test guidelines would be referenced in enforceable test standards for the HAPs test rule.

An explanation of the process by which the TSCA test guidelines were developed from the OPPTS draft harmonized test guidelines, along with a discussion of the significant changes made to the draft harmonized guidelines in developing the TSCA guidelines, is described in the final rule adding the new TSCA test guidelines to 40 CFR part 799, subpart H (62 FR 43820, August 15, 1997) (FRL–5719–5). The official record for the rulemaking for the TSCA test guidelines has been established under document control number OPPTS–42193, and has been included in the record for this rulemaking. This record contains the basic information considered by EPA in developing the TSCA test guidelines. The record includes the OPPTS draft harmonized health effects test guidelines, references contained in the TSCA test guidelines, an explanation of the process of developing OECD test guidelines for genetic toxicity with EPA's role in this international process, and the final report of the Scientific Advisory Panel that provided peer review comments to EPA which were considered by the Agency in developing the OPPTS final harmonized guidelines.

B. Summary of Basic Testing Requirement Changes Proposed by this Amendment

The eleven TSCA test guidelines which are specified as basic testing requirements in Table 1 of § 799.5053 that EPA is proposing to use for testing the chemicals in the HAPs test rule are as follows:

1. TSCA acute inhalation toxicity with histopathology, 40 CFR 799.9135.
2. TSCA subchronic inhalation toxicity, 40 CFR 799.9346.
3. TSCA prenatal developmental toxicity, 40 CFR 799.9370.
4. TSCA reproduction and fertility effects, 40 CFR 799.9380.
5. TSCA carcinogenicity, 40 CFR 799.9420.
6. TSCA bacterial reverse mutation test, 40 CFR 799.9510.
7. TSCA *in vitro* mammalian cell gene mutation test, 40 CFR 799.9530.
8. TSCA mammalian bone marrow chromosomal aberration test, 40 CFR 799.9538.
9. TSCA mammalian erythrocyte micronucleus test, 40 CFR 799.9539.
10. TSCA neurotoxicity screening battery, 40 CFR 799.9620.

11. TSCA immunotoxicity, 40 CFR 799.9780.

EPA is proposing to use the TSCA test guideline § 799.9370 ''TSCA prenatal developmental toxicity'' as the basic testing requirement for developmental toxicity testing in this amended proposal. This guideline is based on the OPPTS final harmonized 870.3700 guideline entitled ''Prenatal Developmental Toxicity Study'' (to be published when all OPPTS harmonized health effects guidelines have been finalized). The original HAPs proposal cross-referenced OPPTS draft 870.3600 ''Inhalation Developmental Toxicity Study'' as the guideline for the developmental toxicity endpoint. The Agency prefers the approach taken by the OPPTS final harmonized 870.3700 guideline (the basis for the TSCA § 799.9370 guideline) over that taken by the OPPTS draft 870.3600 guideline because the OPPTS final harmonized 870.3700 guideline provides a broader testing approach. Furthermore, the OPPTS final harmonized 870.3700 guideline incorporates the testing specifications included in the OPPTS draft 870.3600 guideline.

The original HAPs proposal cross-referenced four OPPTS draft Series 870 harmonized genotoxicity test guidelines: 870.5385 ''*In vivo* Mammalian Cytogenetics Tests: Bone Marrow Chromosomal Analysis;'' 870. 5395 ''*In vivo* Mammalian Cytogenetics Tests: Erythrocyte Micronucleus Assay;'' 870.5100 ''*Escherichia coli* WP2 and WP2 uvrA Reverse Mutation Assays;'' and 870.5300 ''Detection of Gene Mutations in Somatic Cells in Culture.'' See Unit IV.C. ''Test Guidelines'' of the original HAPs test rule proposal and Table 1 in § 799.5053 of the original HAPs proposal (61 FR 33178, 33187, 33197–33199). OPPTS later determined that the above-referenced genotoxicity test guidelines would not provide a sufficient basis for developing OPPTS final harmonized test guidelines for genotoxicity and looked to international efforts begun in 1989 by the OECD to develop an internationally accepted set of genotoxicity test guidelines. By September 1996, four OECD genotoxicity test guidelines had undergone extensive peer review and revision that included participation by U.S. scientific experts in the area of genotoxicity. The four OECD final revision genotoxicity test guidelines were approved by the member countries of the OECD in September 1996. In February 1997, these four genotoxicity guidelines were read from the OECD homepage (http://www.oecd.org/ehs/test/testlist.htm). OPPTS reformatted these documents and designated them as OPPTS final Series 870 harmonized test guidelines, to be published when all OPPTS harmonized health effects guidelines have been finalized. These four Series 870 final OPPTS harmonized test guidelines were adopted and published as TSCA test guidelines at 40 CFR part 799, subpart H (62 FR 43820, August 15, 1997).

In summary, the genotoxicity test guidelines to be cross-referenced as basic testing requirements by this amended HAPs proposal were developed based on the following documents:

The OECD final revision test guideline 471/472 ''Bacterial reverse mutation assay'' was adopted as OPPTS final harmonized test guideline, 870.5100 ''Bacterial reverse mutation test,'' which in turn, provided the basis for TSCA test guideline § 799.9510 ''TSCA bacterial reverse mutation test.''

The OECD final revision test guideline 476 ''*In vitro* mammalian cell gene mutation test'' was adopted as OPPTS final harmonized test guideline, 870.5300 ''*In vitro* mammalian cell gene mutation test,'' which in turn, provided the basis for TSCA test guideline § 799.9530 ''TSCA *in vitro* mammalian cell gene mutation test.''

The OECD final revision guideline 475 ''Mammalian bone marrow chromosome aberration test'' was adopted as OPPTS final harmonized test guideline, 870.5385 ''Mammalian bone marrow chromosomal aberration test,'' which in turn, provided the basis for TSCA test guideline § 799.9538 ''TSCA mammalian bone marrow chromosomal aberration test.''

The OECD final revision test guideline 474 ''Mammalian erythrocyte micronucleus test'' was adopted as OPPTS final harmonized test guideline, 870.5395 ''Mammalian erythrocyte micronucleus test,'' which in turn, provided the basis for TSCA test guideline § 799.9539 ''TSCA mammalian erythrocyte micronucleus test.''

EPA has documented the Agency's participation in the OECD revision process for updating the genotoxicity test guidelines (U.S. EPA Memorandum, March 10, 1997 (a)), the relationship among the OPPTS draft Series 870 harmonized genotoxicity test guidelines cross-referenced in the original HAPs test rule proposal, the OECD test guidelines, and the OPPTS final Series 870 harmonized test guidelines (U.S. EPA Memoranda, February 27, 1997; and March 10, 1997(b)), and the relationship between the TSCA 40 CFR part 799 series test guidelines and the OECD test guidelines in the record for this rulemaking (see also 62 FR 43820, August 15, 1997). Copies of these documents are available as described in Unit V. of this preamble.

These changes are summarized in the following Table 1.

Table 1.—List of TSCA Test Guidelines Cross-referenced in the Proposed HAPs Test Rule, As Amended, and the Corresponding OPPTS Draft Harmonized Test Guidelines

TSCA test guidelines cross-referenced in the amended HAPs test rule proposal (40 CFR)	OPPTS draft harmonized test guidelines cross-referenced in the original HAPs test rule proposal
799.9135 TSCA acute inhalation toxicity with histopathology	870.1350 Acute Inhalation Toxicity with Histopathology
799.9346 TSCA subchronic inhalation toxicity	870.3465 Subchronic Inhalation Toxicity
799.9370 TSCA prenatal developmental toxicity (derived from 870.3700)[1]	870.3600 Inhalation Developmental Toxicity Study
799.9380 TSCA reproduction and fertility effects	870.3800 Reproduction and Fertility Effects
799.9420 TSCA carcinogenicity	870.4200 Carcinogenicity
799.9510 TSCA bacterial reverse mutation test (derived from OECD 471/472)[1]	870.5100 *Escherichia coli* WP2 and WP2uvrA Reverse Mutation Assays
799.9530 TSCA *in vitro* mammalian cell gene mutation test (derived from OECD 476)[1]	870.5300 Detection of Gene Mutations in Somatic Cells in Culture
799.9538 TSCA mammalian bone marrow chromosomal aberration test (derived from OECD 475)[1]	870.5385 *In vivo* Mammalian Cytogenetics Tests: Bone Marrow Chromosomal Analysis

Table 1.—List of TSCA Test Guidelines Cross-referenced in the Proposed HAPs Test Rule, As Amended, and the Corresponding OPPTS Draft Harmonized Test Guidelines—Continued

TSCA test guidelines cross-referenced in the amended HAPs test rule proposal (40 CFR)	OPPTS draft harmonized test guidelines cross-referenced in the original HAPs test rule proposal
799.9539 TSCA mammalian erythrocyte micronucleus test (derived from OECD 474)[1]	870.5395 *In vivo* Mammalian Cytogenetics Tests: Erythrocyte Micrnucleus Assay
799.9620 TSCA neurotoxicity screening battery	870.6200 Neurotoxicity Screening Battery
799.9780 TSCA immunotoxicity	870.7800 Immunotoxicity

[1] See explanation of derivation in Unit II.B. of this preamble.

A revised § 799.5053 ''Chemical testing requirements for hazardous air pollutants,'' based on the use of the TSCA test guidelines for HAPs chemical testing, is included as part of this amended proposal.

The eleven TSCA test guidelines described in Table 1 of this preamble are included in the record for this rulemaking. The **Federal Register** notice containing the TSCA test guidelines is available electronically from the EPA's World Wide Web site, http://www.epa.gov/fedrgstr/, under the heading: ''Rules and Regulations;'' by internet e-mail: guidelines@epamail.epa.gov; by mail; or, from the TSCA Non-Confidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

EPA is soliciting comments on the eleven TSCA test guidelines to be incorporated in enforceable test standards under this amended HAPs proposal. To be considered in this rulemaking, comments must be submitted in the manner specified in the ''ADDRESSES'' section at the beginning of this document.

III. Changes and Clarifications

In addition to cross-referencing the TSCA test guidelines, this amended HAPs proposal is making other changes and clarifications to the original HAPs proposal, which are set forth as follows:

A. Phenol—Removal of Testing Requirements

The original HAPs proposal included testing requirements for phenol (CAS No. 108–95–2). On January 17, 1997, EPA published a document (62 FR 2607) which announced a testing consent order (Order) under TSCA section 4 that incorporated an ECA concluded between EPA and fourteen specified companies. In the ECA, the companies agreed to perform certain health effects tests on phenol. In addition, the January 17 document included a direct final rule which added phenol to the list of chemical substances in 40 CFR 799.5000 that are subject to testing consent orders and hence subject to export notification requirements under TSCA section 12(b). EPA received adverse comment with respect to making entities that are not signatory to the ECA subject to export notification requirements for phenol. Because of those adverse comments, on May 23, 1997 (62 FR 28368), EPA removed the export notification rule. EPA did not withdraw the Order or the ECA, and signatories to the ECA remain subject to export notification requirements. EPA intends to propose a phenol export notification rule at a future time. Because EPA anticipates receiving the necessary test data on phenol pursuant to the ECA and Order, EPA is amending the proposed HAPs test rule to remove all phenol testing requirements.

The documents entitled: ''Economic Assessment for the Amended Proposed TSCA Section 4(a) Test Rule for 21 Hazardous Air Pollutants,'' discussed in Units VI.A. and VI.D. of this preamble, and ''Additional Information on Small Entity Impacts of the Amended Proposed TSCA Section 4(a) Test Rule for 21 Hazardous Air Pollutants,'' discussed in Unit VI.C. of this preamble, have not yet been modified to reflect the reductions in impact and burden associated with the deletion of phenol testing, but will be so modified by the time the final rule is promulgated.

Unit VI. of this preamble contains data from the above economic assessment with all references to phenol removed. Similarly, Table 1 in § 799.5053, which sets forth the testing required for the chemicals in the proposed HAPs test rule, as amended, does not include phenol.

B. Export Notification Requirements

In the original HAPs proposal, EPA did not state that export notification under TSCA section 12(b), 15 U.S.C. 2611(b), would be required for the HAPs chemicals in the final rule. Section 12(b) of TSCA requires all persons who export or intend to export a chemical substance or mixture for which the submission of data is required under TSCA section 4 to notify EPA of this export or intent to export. Regulations interpreting the requirements of TSCA section 12(b) appear at 40 CFR part 707, subpart D. In brief, as of the effective date of the HAPs test rule, an exporter of any subject HAP chemical would be required to report to EPA the first export or intended export of the chemical to each foreign country of export. EPA would then notify the foreign government about the HAPs test rule as it relates to that chemical.

Accordingly, EPA is amending the original proposed HAPs test rule to require export notification for all the chemicals for which testing would be required under the amended HAPs proposal, and has changed § 799.5053 accordingly.

C. Persons Required to Test

1. *General.* In the original HAPs proposal, EPA indicated that persons who manufacture HAP chemicals included in the proposed rule as byproducts, as defined in 40 CFR 791.3(c), would be subject to the requirements set forth in the proposed rule. In addition, EPA proposed to exempt those manufacturers and processors that produce the HAP chemicals included in the proposed rule only as an impurity, as defined in 40 CFR 790.3, because it would be difficult and prohibitively expensive for EPA, manufacturers, and processors to identify with complete assurance all chemical substances that contain the HAP chemicals included in the proposed rule solely as an impurity and EPA would find it difficult to apply both the exemption and reimbursement processes to those who manufacture and/or process these HAP chemicals solely as an impurity. Furthermore, the Agency indicated that EPA's data reimbursement regulations established under TSCA section 4(c) (40 CFR part 791) state that those persons who manufacture or process chemical substances as impurities are not subject to test requirements unless a particular test rule specifically states otherwise (40 CFR 791.48(b)) and that EPA found no basis to propose such a requirement for

the original HAPs proposal (61 FR 33178, 33189, 33190).

EPA has received inquiries from industry seeking clarification of the distinction between byproduct and impurity in a variety of contexts in the manufacture of products and in the course of chemical processing (see document numbers 3, 8, 9, 10, 11, 12, and 14 referenced in Unit V.I. of this preamble). EPA's review has revealed that certain HAP chemicals included in this amended HAPs proposal are manufactured or processed as byproducts or impurities in quantities large enough that they can be identified in databases available to the Agency (Chemical Update System (CUS), Toxic Release Inventory (TRI), Aerometric Information Retrieval System Facility Subsystem (AFS)). Certain owners and operators of facilities that have, during the latest year prior to the publication of the final HAPs rule in the **Federal Register**, manufactured (including imported) or processed HAP chemicals included in this amended proposal in amounts equal to or greater than 25,000 lb are required under section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA), 42 U.S.C. 11023, to report the TRI releases of these substances and, accordingly, know or should know whether they are manufacturing or processing these HAP chemicals. (EPCRA section 313 also requires reporting by facilities that use 10,000 lb or more of a listed toxic chemical during a calendar year). The toxic chemicals release reporting regulations promulgated pursuant to EPCRA section 313 additionally provide a de minimis exemption for chemicals otherwise subject to TRI requirements when the chemicals are present in mixtures in concentrations of less than one percent by weight (or 0.1% for carcinogens) (40 CFR 372.38(a)). Because chemical manufacturers and processors are among the persons required to report to TRI, manufacturers and processors generally should know the composition of chemicals that they manufacture or process at least at or above one percent by weight of composition.

By this amendment, EPA is proposing to modify criteria to determine when persons subject to the HAPs test rule must comply with the rule. The original HAPs proposal did not provide a volume cutoff beyond the provisions of 40 CFR 790.42(a) for manufacturers and processors as a means for determining when certain classes of persons would be required to comply with the rule. (The regulations cited above provide that, while legally subject to a test rule, processors, persons who manufacture less than 500 kg (1,100 lb) of the chemical annually, and persons who manufacture small quantities of the chemical solely for research and development, are not required to comply with the rule unless directed to do so by EPA in a subsequent notice if no manufacturer has submitted a notice of its intent to conduct testing.) Under the original HAPs proposal, all other manufacturers were required to comply with the rule when promulgated (''initially comply'').

The criteria proposed in this amended proposed rule provide an equitable means for determining which entities would be initially and secondarily responsible for testing HAPs chemicals: testing would be conducted primarily by persons owning facilities at which large volumes of HAPs chemicals are manufactured, while persons owning facilities at which smaller volumes of HAPs chemicals are manufactured would only be required to comply with the rule if no manufacturer submits a notice of its intent to conduct testing.

It is reasonable to expect that persons who manufacture or process chemicals containing HAPs should know the composition of the chemicals they manufacture or process at or above one percent by weight, and should know if they manufacture or process 25,000 lb or more of a chemical per year at any facility. Accordingly, EPA is amending the proposal to specify those who must initially comply with the HAPs rule: (1) any person who during the last complete corporate fiscal year prior to the publication of the final rule in the **Federal Register**, manufactured (including imported) at a particular facility any of the HAP chemicals included in this amended HAPs proposal in an amount equal to or in excess of 25,000 lb (regardless of the form of the HAP chemical, i.e., as a Class 1 substance, as a component of a mixture, as a byproduct, as an impurity, as a component of a Class 2 substance, or as an isolated intermediate), and (2) any person who during the last complete corporate fiscal year prior to the publication of the final rule, manufactured (including imported) at a particular facility any of the HAP chemicals as a component of a chemical substance or mixture that comprises one percent or more by weight of the chemical substance or mixture, as long as the amount of the HAP chemical is equal to or in excess of 25,000 lb. EPA is proposing to amend the ''Persons required to submit study plans, conduct tests and submit data'' text of § 799.5053 to reflect this change. (''Naturally occurring substances,'' as described at 40 CFR 710.4(b), and non-isolated intermediates, as defined at 40 CFR 704.3, are not to be considered in determining whether a person is responsible for HAP chemical testing.) If, during the last complete corporte fiscal year prior to the publication of the final rule in the **Federal Register**, a person manufactured 25,000 lb or more of a HAP chemical, as such, or in another substance or mixture at a concentration of one percent or more (as long as the amount of the HAP chemical is equal to or in excess of 25,000 lb), that person would be required to comply initially with the rule.

This approach is consistent with the policy of the United States, expressed by Congress in section 2(b)(1) of TSCA, 15 U.S.C. 2601(b)(1), that development of data regarding the effect of chemical substances and mixtures on human health and the environment should be the responsibility of those who manufacture and process such chemicals. The following examples are provided to guide companies in determining whether they are subject to the proposed HAPs test rule, as amended:

a. *Class 1 and Class 2 substances.* Under the amended HAPs proposal, testing would be required for HAP chemicals included in the proposed rule that are manufactured (including imported) or processed in the form of a Class 1 substance or as a component of a Class 2 substance. A Class 1 substance is a chemical substance with a composition that can be represented by a specific, complete chemical structure diagram. Examples of Class 1 substances are 1,1,2-trichloroethane, 1,1'-biphenyl and hydrochloric acid. A Class 2 substance is a complex combination of substances that cannot be represented by a specific, complete chemical structure diagram. Examples of Class 2 substances are light paraffinic distillates (petroleum), brominated soybean oil, and propoxylated tall oil. Class 1 and Class 2 substances that are in U.S. commerce are listed on the TSCA chemical substance inventory and have Chemical Abstracts Service (CAS) numbers. See 40 CFR 720.45(a)(1)(i) for the distinction between Class 1 substances and Class 2 substances.

Example 1: Producer—Class 2 Substance Containing a HAP Chemical

Company Z produces chemical substance E. Chemical substance E has a Chemical Abstract Service (CAS) number, includes several different chemical species, and cannot be represented by a specific, complete chemical structure diagram, i.e., it is a Class 2 substance. Chemical substance E appears on the TSCA Chemical Substance Inventory and was reported as a Class 2 substance. The composition of chemical substance E

includes chemical B (which is a HAP chemical that is included in the amended HAPs proposal) that was produced in the manufacture of chemical substance E. Chemical B is normally present in concentrations that range from 1 to 6 percent by weight of chemical substance E.

Company Status: EPA considers Company Z to be a producer of HAP chemical B. Irrespective of whether it intended HAP chemical B to be an integral part of chemical substance E, Company Z is a producer of HAP chemical B, if the amount of HAP chemical B produced at a concentration of one percent or greater at any facility during the company's last complete corporate fiscal year were more than 25,000 lb, Company Z would be required to comply initially with the rule.

Example 2: Processor—Class 2 Substance Containing a HAP Chemical

Company Z, which produces chemical substance E as discussed in Example 1, also applies chemical separation techniques on chemical substance E (a Class 2 substance that contains HAP chemical B) to produce chemical substances F and G. The separation proceeds without chemical reaction and no additional amount of HAP chemical B is produced. Chemical substance F, a Class 2 substance, contains some of the HAP chemical B that was a component of chemical substance E in concentrations that exceed one percent by weight. Chemical substance F has no separate commercial purpose and is disposed of as waste. Chemical substance G, a Class 1 substance, also contains some HAP chemical B in concentrations that exceed one percent by weight of G.

Company Status: Company Z is considered to be a processor of HAP chemical B with respect to the production of chemical substance F, a byproduct, and chemical substance G, a commercial product. However, Company Z remains responsible for producing HAP chemical B because of its original production of chemical substance E (see Example 1 above). Therefore, as a manufacturer and processor of HAP chemical B, Company Z would be required to comply initially with the amended HAPs test rule proposal if the total amount of the HAP chemical B component were 25,000 lb or more at any facility during the company's last complete corporate fiscal year after the publication of the rule. If another company had purchased chemical substance E from Company Z and had performed a similar separation process resulting in the production of chemical substances F and G, both of which contain HAP chemical B as an unintentionally present component, the purchaser would be considered only to be a processor of HAP chemical B as an impurity and, therefore, as a processor, must comply with the requirements of the rule only if directed to do so by EPA in a subsequent **Federal Register** notice because no manufacturer has submitted a notice of its intent to conduct testing. (Note that HAP chemical B was present in chemical substances F and G at greater than one percent concentration). Additional information regarding the status of processors is provided in this Unit of the preamble.

b. *HAPs present as part of mixtures.* Under the amended HAPs proposal, testing would be required for HAP chemicals included in the proposed rule that are manufactured (including imported) or processed as part of a mixture, as that term is defined by TSCA section 3(8). For example, a combination of substances that is manufactured as a result of a chemical reaction, but that could have been prepared without chemical reaction, is considered a mixture under TSCA section 3(8). If a HAP chemical is produced as a result of this chemical reaction, the person who manufactured the mixture has also manufactured the HAP chemical. A person who produced the same mixture but without chemical reaction would be considered to be a HAP processor.

Example 3: Manufacturers of Mixtures

Two companies, Company Y and Company Z, produce mixtures as commercial products that have the same composition and that contain HAP chemical B in concentrations that exceed one percent by weight of the mixture. Company Y purchases the components of the mixture and combines them without a chemical reaction occurring. Company Z creates the mixture by reacting chemicals. During the chemical reaction HAP chemical B is formed.

Company Status: Company Z has manufactured HAP chemical B and would be required to comply initially with the amended HAPs proposal if the total amount of chemical B manufactured is 25,000 lb or more at any facility during the company's last complete corporate fiscal year prior to the publication of the test rule. Company Y is a processor of HAP chemical B and, therefore, must comply with the requirements of the rule only if directed to do so by EPA in a subsequent **Federal Register** notice because no manufacturer has submitted a notice of its intent to conduct testing.

c. *Isolated intermediates.* Under the amended HAPs proposal, testing would be required for HAP chemicals included in the proposed rule that are manufactured (including imported) or processed in the form of isolated intermediates. HAP chemicals produced in the form of non-isolated intermediates (as defined at 40 CFR 704.3) are not subject to the amended HAPs proposal.

Example 4: Producer—Non-isolated and Isolated Intermediates

A company produces but does not isolate chemical substance H, a Class 2 substance that contains HAP chemical B in concentrations that exceed one percent by weight. Immediately following this production in a continuous flow process, chemical substance H is reacted with other chemicals to form chemical substance I, which the company isolates, packages and distributes in commerce. Chemical substance I does not contain any HAP chemical because chemical B in chemical substance H completely reacts in the formation of chemical substance I.

Company Status: Chemical substance H is a ''non-isolated intermediate,'' defined at 40 CFR 704.3. Although HAP chemical B is formed as part of chemical substance H, chemical B is reacted entirely in the continuous flow process. Therefore, the company would not be subject to the requirements of the amended HAPs proposal because the final product, chemical substance I, does not contain HAP chemical B.

If Class 2 chemical substance H had been removed from the reaction vessel, stored, and reacted later to form chemical substance I, chemical substance H would have been an isolated intermediate that contained HAP chemical B. In this case, the company would be required to comply initially with the amended HAPs proposal, if the amount of HAP chemical B that is manufactured during the company's last complete corporate fiscal year prior to the publication of the rule in the **Federal Register** were 25,000 lb or more at any facility, due to the company's production of a HAP chemical as part of an isolated intermediate.

2. *Processors.* The Agency has proposed findings under TSCA sections 4(a)(1)(A) and 4(a)(1)(B) for the manufacturing and processing of the chemicals contained in the proposed HAPs test rule. See Supporting Documentation 3(a), (b) and (c) and References 11, 12 and 16 as cited in Unit III.C. ''Review of Data and Selection of HAPs'' and Unit V. ''Findings'' of the original HAPs test rule proposal (61 FR 33178, 3384, 33185, 33190). The terms ''process'' and ''processor'' are defined at TSCA sections 3(10) and 3(11), respectively

Accordingly, in the preamble to the original HAPs proposal (61 FR 33178, 33189), EPA stated that persons who manufacture (including import) or process, or intend to manufacture or process, any of the HAPs chemicals would be subject to the testing requirements in the rule. The preamble also explained that manufacturers would be required to submit letters of intent to conduct testing or exemption applications under 40 CFR 790.45. However, under 40 CFR 790.42, processors, small-quantity manufacturers, and manufacturers of small quantities solely for research and development purposes would not be required to submit letters of intent or exemption applications unless directed to do so in a subsequent notice as described in 40 CFR 790.48(b).

The text of § 799.5053 in the original HAPs test rule proposal did not include

processors in the class of persons required to submit study plans, conduct tests, and submit data. The text of § 799.5053, however, did reference the fact that processors (and small-quantity manufacturers and manufacturers of small quantities solely for research and development purposes) would become subject to these requirements only after notification in the **Federal Register** that no manufacturer had notified EPA of its intent to conduct testing.

The text of § 799.5053 of this amended HAPs proposal makes it clear that while processors would be included in the class of persons subject to the rule, processors, small quantity manufacturers, manufacturers of small quantities of HAP chemicals solely for research and development purposes and persons who, at any facility, manufacture a HAP chemical subject to this rule in an amount less than 25,000 lb or as a component of a chemical substance or mixture and comprises less than one percent by weight of the chemical substance or mixture (as long as the amount of the HAP chemical is equal to or in excess of 25,000 lb) would need to comply with the requirements to submit study plans, conduct tests, and submit data only if no manufacturer submits a notice of its intent to conduct testing and if these persons are directed to do so in a subsequent notice published in the **Federal Register**.

3. *Carbonyl sulfide.* The original HAPs proposal identified carbonyl sulfide as the first chemical substance to be subject to a TSCA section 4 test rule that is produced almost exclusively as a byproduct (61 FR 33178, 33190). In the original HAPs proposal, EPA noted that persons who manufacture the subject HAPs chemicals, including carbonyl sulfide, as byproducts, as defined in 40 CFR 791.3(c), would be subject to the testing requirements set forth in the proposed rule. EPA also indicated that all persons reporting the release of carbonyl sulfide to the TRI pursuant to section 313 of EPCRA would be considered to be manufacturers of carbonyl sulfide and would be subject to the provisions of the HAPs test rule.

In preparing the economic analysis for carbonyl sulfide for the amended HAPs proposal, EPA utilized information from 1995 reports to both the TRI and AFS databases. For 1995, all those reporting release information to the TRI and AFS databases on carbonyl sulfide are manufacturers.

The Agency is hereby clarifying that all persons who manufacture carbonyl sulfide would be subject to the HAPs testing requirements, whether or not they report release information to the TRI, or in EPA's AIRS AFS database. As explained in Appendix A of EPA's economic assessment and the additional information document on small business impacts prepared for this assessment, EPA relied on information taken from the TRI and AFS databases to identify facilities releasing carbonyl sulfide (see Units VI.A., VI.C., and VI.D. of this preamble). EPA recognizes that these facilities may not represent the complete universe of facilities that produce carbonyl sulfide and that the information derived from these databases is not exhaustive. To the extent that there are additional manufacturers not identified in the Agency's economic assessment, the testing burden on any individual manufacturer may be reduced.

D. Testing Subject to GLP Requirements

In this amended HAPs proposal, EPA is clarifying the text of § 799.5053 to indicate that the required testing under the HAPs test rule shall be carried out following TSCA Good Laboratory Practice Standards (40 CFR part 792). The text of § 799.5053 in the original HAPs proposal stated that, among other things, testing should be conducted as specified in 40 CFR part 792 (see 61 FR 33178, 33197), but did not indicate that GLPs are codified at 40 CFR part 792. The text of § 799.5053 contained in this amended HAPs proposal clarifies this point.

E. Cresols—Clarification of Test Substances

EPA is clarifying that the provision of the HAPs test rule relating to cresols requires separate testing of each cresol isomer (i.e., *ortho*-isomer (CAS No. 95–48–7), *meta*-isomer (CAS No.108–39–4), and *para*-isomer (CAS No. 106–44–5)), as indicated in Table 1 in § 799.5053 in both the original HAPs proposal and this amended HAPs proposal. Therefore, each cresol isomer is subject to acute toxicity, subchronic toxicity, neurotoxicity, and immunotoxicity testing (61 FR 33178, 33198). Documentation supporting the findings for each cresol isomer, and all other subject HAPs chemicals, was previously described in Unit III. C. ''Review of Data and Selection of HAPs'' and Unit V. ''Findings'' of the original HAPs proposal (61 FR 33178, 33184, 33185, 33190). See Unit X. A. ''Supporting Documentation,'' Items (3)(a), (b), and (c) and Unit X. B. ''References,'' Items (11), (12), and (16) of the original HAPs proposal (see 61 FR 33178, 33195). Testing of cresols in particular is discussed at Unit III. D. ''Previous TSCA Testing Actions Affecting These Chemical Substances'' and Unit IV. B. ''Test Substance'' of the original HAPs proposal (61 FR 33178, 33185, 33186). See Unit X. A. ''Supporting Documentation'' of the original HAPs proposal, Items (1)(g) and (j) (61 FR 33178, 33194). It should be noted that the data for cresols summarized in the table entitled ''TSCA Section 4 (a) Statutory Findings'' (61 FR 33178, 33191) are based on the mixture of all three cresol isomers. As previously stated (61 FR 33178, 33186), EPA believes that it would be very burdensome to test every possible variation of the cresol mixture and is therefore proposing to test each isomer. This approach follows that taken in the final test rule for cresols (51 FR 15771, 15776, April 28, 1986).

Table 1 in § 799.5053, which sets forth the testing required for the chemicals in the proposed HAPs test rule, as amended, has been changed to clarify that testing is required for each cresol isomer.

F. Use of Acute and Non-Acute Data in Residual Risk Determinations

EPA is correcting an error in the preamble to the original HAPs proposal. In Unit II. ''Uses of Data'' (61 FR 33178, 33179 (third column)), the Agency indicated that non-acute data will be used by EPA to meet its statutory obligation under section 112(f) of the Clean Air Act (CAA), 42 U.S.C. 7412(f), to assess residual risk after the imposition of technology-based emission standards (maximum achievable control technology or MACT standards) required by CAA section 112(d), 42 U.S.C. 7412(d). However, as discussed at the public meeting held on the proposed HAPs test rule on October 1, 1996, the Agency intends that the residual risk determinations under the Clean Air Act be based on both acute and non-acute data. See pages 24 and 25 of the official transcript of the October 1, 1996 public meeting on the proposed test rule, included as part of this rulemaking record.

G. Submission of Equivalence Data

In Unit V. F. ''Persons Required To Test'' of the original HAPs proposal (61 FR 33178, 33189–33190), EPA did not indicate that those who file exemption applications would not be required to submit equivalence data, although this was indicated in Unit VII.B. of the original HAPs proposal. EPA is clarifying that the Agency is not proposing to require those who file exemption applications to submit equivalence data as a condition for exemption from the testing for the chemical substances subject to the HAPs test rule.

H. Other Changes to Regulatory Text

In addition to the changes made to the text and table in § 799.5053 ''Chemical testing requirements for hazardous air pollutants'' of the amended HAPs proposal that are set forth in previous sections of Unit III. of this preamble, the following changes have been made:

1. EPA has changed the titles of columns 2, 3, and 4 in Table 1 of § 799.5053 of the original HAPs proposal (61 FR 33178, 33197–33199) from: ''Chemical substance/required testing,'' ''OPPTS harmonized guidelines,'' and ''Specific requirements under this section'' to: ''Chemical name/types of testing,'' ''Basic testing requirements (test guideline),'' and ''Changes from guideline.'' The Agency believes that this change of nomenclature clarifies the meaning of Table 1. The corresponding description throughout the text of § 799.5053 has been revised to incorporate these changes.

2. In the original HAPs proposal at § 799.5053, EPA indicated that ''*E. coli* reverse mutation'' and ''gene mutation'' tests would be required for the HAP chemical carbonyl sulfide. The titles of these tests have been changed in § 799.5053 of the amended HAPs proposal to ''Bacterial reverse mutation'' and ''Mammalian gene mutation,'' respectively, to reflect corresponding changes in the titles of the referenced guidelines.

3. In the original HAPs proposal at § 799.5053, EPA designated paragraph (b)(1)(ii)(C) in Table 1 to indicate an oral route of exposure. No testing via an oral route of exposure was required in Table 1. Consequently, paragraph (b)(1)(ii)(C) has been changed. In the amended HAPs proposal, this paragraph now indicates a vapor-phase route of exposure specifically for *in vitro* cytogenetics testing.

4. In the original HAPs proposal, EPA did not indicate the route of exposure for the *in vitro* cytogenetics testing for the HAP chemical carbonyl sulfide (61 FR 33178, 33199). EPA is indicating in Table 1 of § 799.5053 that the route of exposure for the Bacterial reverse mutation and the Mammalian gene mutation testing would be vapor-phase as indicated in paragraph (b)(1)(ii)(C).

5. In the original HAPs proposal, EPA omitted additional testing requirements in the test standard for acute toxicity testing for chlorobenzene in Table 1 of § 799.5053 (61 FR 33178, 33198). Revised § 799.5053 corrects Table 1 to include the additional testing requirements specified in paragraph (b)(2) *''Modifications applicable to acute testing''* for chlorobenzene.

6. Paragraph (b)(5) *''Reproductive toxicity and fertility study test modifications''* of § 799.5053 in the original HAPs proposal has been deleted since it contains the same requirements as paragraphs (b)(1)(ii)(A) and (b)(1)(ii)(B), which specify that the route of exposure would be either vapor-phase inhalation or inhalation of aerosol.

7. In the original HAPs proposal, the guideline for developmental toxicity testing (OPPTS draft 870.3600) cited in Table 1 of § 799.5053 (61 FR 33178, 33197–33199) would have required developmental testing to be conducted using inhalation as the route of exposure. The TSCA prenatal developmental toxicity test guideline (40 CFR 799.9370) specified for developmental toxicity testing in this amended HAPs proposal does not indicate the route of exposure for testing. Table 1 of § 799.5053 has been changed to include specific references to the route of exposure for each HAP chemical substance for which developmental toxicity testing is proposed under this amended HAPs proposal.

8. In this amended HAPs proposal, EPA cites the TSCA immunotoxicity test guideline (40 CFR 799.9780) in Table 1 of § 799.5053 (61 FR 33178, 33197–33199). This test guideline contains four different test methods. EPA is proposing that immunotoxicity testing under the HAPs test rule include only the determination of antibody response to the administration of sheep red blood cell antigen. The Agency is further proposing that either the antibody plaque-forming cell assay (§ 799.9780(g)(1)(i)) or the ELISA immunoglobulin quantification assay (§ 799.9780(g)(1)(ii)) shall be used to meet the testing requirements. The natural killer cell assay (§ 799.9780(g)(1)(iii)) and the enumeration of splenic or peripheral blood cells (§ 799.9780(g)(2)) are not being proposed for HAPs testing. Accordingly, § 799.5053(b)(4) has been changed to clarify the immunotoxicity testing requirements and Table 1 of § 799.5053 includes notations to so indicate.

IV. Status of Proposals for Pharmacokinetics Studies and Other Proposals for Enforceable Consent Agreements and Orders

A. Proposals for PK Studies

1. EPA's Invitation for Proposals

In the original HAPs proposal, EPA invited proposals for pharmacokinetics studies and other mechanistic data to support route-to-route extrapolation of data from existing studies for the subject HAPs chemicals (61 FR 33178, 33188, 33189). The PK studies would be used to inform the Agency about route-to-route extrapolation of toxicity data from routes other than inhalation when it is scientifically defensible in order to empirically derive the inhalation risk. The PK proposals could form the basis for negotiation of enforceable consent agreements (ECAs) that would provide for testing in lieu of some or all of the tests proposed in the HAPs test rule, as amended.

The Agency has received alternative testing proposals for eight HAPs chemicals. These proposals are as follows:

(1) Diethanolamine (CAS No. 111–42–2), submitted by the Chemical Manufacturers Association, Alkanolamines Panel, and entitled ''Proposal for Pharmacokinetics Studies of Diethanolamine'' (November 25, 1996).

(2) Ethylene dichloride (CAS No. 107–06–2), submitted by the HAP Task Force, and entitled ''Proposal for Pharmacokinetics Study of Ethylene Dichloride'' (November 22, 1996).

(3) Ethylene glycol (CAS No. 107–21–1), submitted by the Chemical Manufacturers Association, Ethylene Glycol Panel, and entitled ''Proposal for Pharmacokinetic Studies of Ethylene Glycol'' (November 5, 1996).

(4) Hydrogen fluoride (CAS No. 7664–39–3), submitted by the Chemical Manufacturers Association, Hydrogen Fluoride Panel, and entitled ''Proposal for a Physiologically-Based Pharmacokinetic (PBPK) Model for Hydrogen Fluoride'' (November 22, 1996).

(5) Maleic anhydride (CAS No. 108–31–6), submitted by the Chemical Manufacturers Association, Maleic Anhydride Panel, and entitled ''Developing an Inhalation Testing Program for Maleic Anhydride'' (November 8, 1996).

(6) Phthalic anhydride (CAS No. 85–44–9), submitted by the Chemical Manufacturers Association, Phthalic Anhydride Producers Task Group, and entitled ''Testing Proposal of the Chemical Manufacturers Association, Phthalic Anhydride Producers Task Group in Response to EPA's Proposed Rule for Phthalic Anhydride'' (November 22, 1996).

(7) 1,2,4-Trichlorobenzene (CAS No. 120–82–1), submitted by the Chlorobenzene Producers Association (CPA), and entitled ''Proposal to Use the Pharmacokinetics, Physical, and Chemical Properties of 1,2,4-Trichlorobenzene to Fill Data Gaps'' (November 25, 1996).

(8) 1,1,2-Trichloroethane (CAS No. 79–00–5), submitted by the HAP Task Force, and entitled ''Proposal for Pharmacokinetics Study of 1,1,2-Trichloroethane'' (November 22, 1996).

Copies of the PK proposals and the Agency's preliminary technical analyses of these proposals have been placed in the public record for this action (OPPTS–42187B, FRL–4869–1).

2. The Agency's Evaluation of the Proposals

The following provides a background to EPA's method of evaluating the PK proposals. As the original HAPs proposal indicated (61 FR 33178, 33189), EPA used the Gerrity and Henry (1990) decision tree as an element in evaluating the PK proposals and also used mechanistic data in determining the appropriateness of route-to-route extrapolation from the existing data base as an alternative to conducting some or all of the testing required under the proposed HAPs test rule. Pharmacokinetics and mechanistic data may be used to inform the Agency about route-to-route extrapolation when EPA determines that extrapolation from existing studies may provide sufficient data to substitute for required testing under the proposed rule. Pharmacokinetics and mechanistic data alone may not be used to substitute for proposed required testing when studies by a route other than inhalation do not exist or are deemed by EPA to be inadequate. In such cases, however, pharmacokinetics and mechanistic data may be used to support a decision that required testing could be conducted using routes other than inhalation (see document referenced in Unit V.J.2. of this preamble).

In many cases, the proposals that EPA received went beyond PK by including alternate testing strategies to respond to the testing identified in the proposed HAPs test rule. EPA's evaluations of these proposals identify changes or additions that provide for testing of these HAP chemicals as an alternative to the testing contained in the proposed HAPs test rule. If this testing is incorporated into ECAs, and if the data resulting from testing under the ECAs are acceptable to the Agency, such testing will provide an alternative to some or all of the testing proposed for these substances in the HAPs test rule. If testing under these ECAs does not fulfill the Agency's needs, EPA reserves the right to meet these needs through rulemaking.

The Agency has prepared preliminary technical analyses of each PK proposal (ethylene dichloride, hydrogen fluoride, maleic anhydride, phthalic anhydride, 1,2,4-trichlorobenzene, ethylene glycol, diethanolamine and 1,1,2-trichloroethane) and sent each to the appropriate submitter. EPA notes that, as a result of unexpected complexities arising in the review of the PK proposals and contrary to the statement in the preamble to the proposed HAPs test rule, the Agency has not been able to conclude ECAs relating to PK studies within 12 months of the date of the HAPs test rule proposal. EPA expects to make further progress on these ECAs in the next few months.

In each preliminary technical response to a submitter of a PK proposal, EPA requested the submitter either to express a continued interest in pursuing the ECA process as an activity distinct from the test rule process, in light of the Agency's preliminary technical analysis, or to submit a revised proposal which takes into consideration the Agency's comments. Depending on each submitter's response, EPA will determine whether or not to proceed with the ECA process for that particular PK proposal.

B. Other Proposals for ECAs

EPA has received a proposal to develop a non-PK-related ECA for the HAP chemical methyl isobutyl ketone (CAS No. 108–10–1). This proposal was submitted to the Agency by the Chemical Manufacturers Association Ketones Panel on December 11, 1996, and is entitled ''Alternative Testing Proposal for Methyl Isobutyl Ketone.'' In addition, the EPA has received a proposal to develop an ECA for the HAP chemical 1,1'-biphenyl (CAS No. 92–52–4). This proposal submitted by the Biphenyl Workgroup on October 7, 1997, is entitled ''Developing a Test Plan for Assessing the Potential Risks of Inhaled Biphenyl.'' EPA has agreed to review the contents of these proposals and to provide comments on their technical merit and relevance to the proposed HAPs testing requirements.

EPA also received a proposal to enter into an ECA from the Chemical Manufacturers Association Cresols Panel to develop an alternative to the proposed HAPs testing for cresols. The proposal was dated April 9, 1997 and was accompanied by a document entitled ''Toxicological Profile for Cresols.'' The proposal focused on testing for only the *ortho*-cresol isomer. Subsequent telephone conversations between EPA and the Panel representative identified that the proposal was not fully developed (see documents referenced in Units V.G.3. and V.G.4. of this preamble). The proposal was later withdrawn by the CMA Cresols Panel.

EPA is hereby inviting the submission of proposals for ECAs on all the HAPs chemicals for which ECA proposals have not been received, but not for phenol (see Unit III.A. of this preamble). Such proposals must clearly describe the rationale for proposing an alternative testing program, detail the full extent of the testing to be performed under the proposal, and describe how the proposed testing would meet the testing requirements contained in the proposed HAPs test rule, as amended.

ECA proposals to provide testing alternative to that described in the proposed HAPs test rule, as amended, should be labeled: ''ECA Proposal for (HAP chemical name) to Provide Alternative Testing to Meet HAPs Rule Testing Requirements,'' identified by Document Control Number (OPPTS–42187B; FRL–5742–2), and sent to U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Document Control Office (7407), Room G–099, 401 M St., SW., Washington, DC 20460. Proposals for ECAs must be received no later than February 9, 1998. EPA will also seek to complete the development of any ECAs expeditiously, and, whenever possible, will work to complete such agreements within 12 months from the date of the Agency's acceptance of the proposal.

EPA will review the submissions and may select candidates for negotiation based on the ability of the proposal to fulfill the data requirements that are set forth in this amended HAPs proposal. If the Agency decides to proceed with the ECA process, it will publish a notice in the **Federal Register** soliciting persons interested in participating in or monitoring negotiations for the development of ECAs for PK studies to notify the Agency in writing.

C. The ECA Negotiation Process

Under its regulations, EPA is required to provide the public with an opportunity to comment on and participate in the development of ECAs. (The procedures for ECA negotiations are described at 40 CFR 790.22(b).) Under the ECA process, EPA will publish a notice in the **Federal Register** soliciting interested parties to participate in or monitor negotiations for ECAs on those HAPs chemicals for which the Agency has decided to proceed. The notice will also announce a date for one or more public meetings to negotiate the ECAs. At the meetings to negotiate the PK ECAs, EPA may raise issues, based on the Agency's further review of the PK proposals, that differ from those contained in the Agency's preliminary technical analyses. If ECAs are successfully concluded, they will be

incorporated into testing consent orders, by which means they become enforceable.

It is important that all submitters of ECA proposals—and potential submitters—recognize the significance of responding to the request for comments on the proposed HAPs test rule, as amended. The submission of a proposal to develop an ECA to conduct testing alternative to that contained in the HAPs test rule is no guarantee that the process will conclude with an agreement. Comments on the proposed HAPs test rule, as amended, should be submitted as an activity separate from the ECA process. To be considered in this rulemaking, comments must be submitted in the manner specified in the ''ADDRESSES'' section at the beginning of this document.

V. Public Record and Electronic Submissions

The official record for this rulemaking, including the public version, which does not include any information claimed as CBI, has been established for this rulemaking under document control number (OPPTS–42187A; FRL–4869–1). This docket also includes all material and submissions filed under docket number OPPTS–42193 (FRL–5719–5), the record for the rulemaking for the TSCA test guidelines, and all material and submissions filed under docket number OPPTS–42187B (FRL–4869–1), the record for the receipt of proposals for developing ECAs for alternative testing of HAPs chemicals. This record contains the basic information considered by EPA in developing this proposed rule, as amended, and appropriate **Federal Register** notices. The public version of this record, including printed, paper versions of electronic comments, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at:

oppt.ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by document control number (OPPTS–42187A; FRL–4869–1). Electronic comments on this proposed rule, as amended, may be filed online at many Federal Depository Libraries.

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this rulemaking. Persons submitting information any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will make the information available to the public without further notice to the submitter. No CBI should be submitted electronically.

Electronic Availability: *Internet:* Electronic copies of this document and various support documents are available from the EPA Home Page at the **Federal Register** - Environmental Documents entry for this document under ''Regulations'' (http://www.epa.gov/fedrgstr/EPA-TOX/1997/). *Fax-On-Demand:* Using a faxphone call 202–401–0527 and select item 4640 for an index of available material and corresponding item numbers related to this document.

In addition to the documents listed in Unit X. of the original HAPs proposal, the record includes the following documents that are referenced in this amended HAPs proposal. Note that certain documents are listed in both the original HAPs proposal and the amended HAPs proposal.

A. **Federal Register** notices pertaining to this amended HAPs proposal consisting of:

1. ''Toxic Substances Control Act Test Guidelines'' (50 FR 39252, September 27, 1985).
2. ''Cresols; Testing Requirements'' (51 FR 15771, April 28, 1986).
3. ''Small Business Size Standards'' (61 FR 3280, January 31, 1996).
4. ''Proposed Testing Guidelines; Notice of Availability and Request for Comments'' (61 FR 31522, June 20, 1996).
5. ''Proposed Test Rule for Hazardous Air Pollutants; Proposed Rule'' (61 FR 33178, June 26, 1996).
6. ''Proposed Test Rule for Hazardous Air Pollutants; Notice of Public Meeting'' (61 FR 47853, September 11, 1996).
7. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule and Extension of Period for Receipt of Proposals for Enforceable Consent Agreements for Pharmacokinetics Studies'' (61 FR 54383, October 18, 1996).
8. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule'' (61 FR 67516, December 23, 1996).
9. ''Testing Consent Order for Phenol'' (62 FR 2607, January 17, 1997).
10. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule'' (62 FR 9142, February 28, 1997).
11. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule'' (62 FR 14850, March 28, 1997).
12. ''Testing Consent Order for Phenol'' (62 FR 28368, May 23, 1997).
13. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule'' (62 FR 29318, May 30, 1997).
14. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule'' (62 FR 37833, July 15, 1997).
15. ''Toxic Substances Control Act Test Guidelines'' (62 FR 43820, August 15, 1997).
16. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule'' (62 FR 50546, September 26, 1997).
17. ''Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period on Proposed Rule'' (62 FR 63299, November 28, 1997).

B. TSCA Test guidelines referenced in this amended HAPs proposal consisting of:

1. 799.9135 TSCA acute inhalation toxicity with histopathology (62 FR 43820, 43824-43828, August 15, 1997).
2. 799.9346 TSCA subchronic inhalation toxicity (62 FR 43820, 43828-43832, August 15, 1997).
3. 799.9370 TSCA prenatal developmental toxicity (62 FR 43820, 43832-43834, August 15, 1997).
4. 799.9380 TSCA reproduction and fertility effects (62 FR 43820, 43834-43838, August 15, 1997).
5. 799.9420 TSCA carcinogenicity (62 FR 43820, 43838-43842, August 15, 1997).
6. 799.9510 TSCA bacterial reverse mutation test (62 FR 43820, 43842-43846, August 15, 1997).
7. 799.9530 TSCA *in vitro* mammalian cell gene mutation test (62 FR 43820, 43846-43850, August 15, 1997).
8. 799.9538 TSCA mammalian bone marrow chromosomal aberration test (62 FR 43820, 43850-43853, August 15, 1997).
9. 799.9539 TSCA mammalian erythrocyte micronucleus test (62 FR 43820, 43853-43857, August 15, 1997).

10. 799.9620 TSCA neurotoxicity screening battery (62 FR 43820, 43857-43860, August 15, 1997).

11. 799.9780 TSCA immunotoxicity (62 FR 43820, 43860-43864, August 15, 1997).

C. OPPTS draft harmonized test guidelines cross-referenced in the original HAPs proposal consisting of:

1. Acute Inhalation Toxicity with Histopathology, OPPTS 870.1350, EPA Pub. No. 712-C-96-291, June 1996.

2. Subchronic Inhalation Toxicity, OPPTS 870.3465, EPA Pub. No. 712-C-96-204, June 1996.

3. Inhalation Developmental Toxicity Study, OPPTS 870-3600, EPA Pub. No. 712-C-96-206, June 1996.

4. Reproduction and Fertility Effects, OPPTS 870.3800, EPA Pub. No. 712-C-96-208, February 1996.

5. Carcinogenicity, OPPTS 870.4200, EPA Pub. No. 712-C-96-211, June 1996.

6. *Escherichia coli* WP2 and WP2 uvrA Reverse Mutation Assays, OPPTS 870.5100, EPA Pub. No. 712-C-96-247, June 1996.

7. Detection of Gene Mutations in Somatic Cells in Culture, OPPTS 870.5300, EPA Pub. No. 712-C-96-221, June 1996.

8. *In Vivo* Mammalian Cytogenetics Tests: Bone Marrow Chromosomal Analysis, OPPTS 870.5385, EPA Pub. No. 712-C-96-225, June 1996.

9. *In Vivo* Mammalian Cytogenetics Tests: Erythrocyte Micronucleus Assay, OPPTS 870.5395, EPA Pub. No. 712-C-96-226, June 1996.

10. Neurotoxicity Screening Battery, OPPTS 870.6200, EPA Pub. No. 712-C-96-238, June 1996.

11. Immunotoxicity, OPPTS 870.7800, EPA Pub. No. 712-C-96-351, June 1996.

D. Other guidelines referenced in this proposal:

1. OECD final revision test guideline 471 / 472 ''Bacterial reverse mutation assay,'' as read from the OECD homepage: http://www.oecd.org/ehs/test/ testlist.htm (February 1997).

2. OECD final revision test guideline 476 ''*In vitro* mammalian cell gene mutation test,'' as read from the OECD homepage: http://www.oecd.org/ehs/test/ testlist.htm (February 1997).

3. OECD final revision guideline 475 ''Mammalian bone marrow chromosome aberration test,'' as read from the OECD homepage: http://www.oecd.org/ehs/test/ testlist.htm (February 1997).

4. OECD final revision test guideline 474 ''Mammalian erthyrocyte micronucleus test,'' as read from the OECD homepage: http://www.oecd.org/ehs/test/ testlist.htm (February 1997).

E. Test Guideline Support documents referenced in this proposal:

1. USEPA. Memorandum, Angela Auletta and Michael Cimino to Roger Nelson. HAPs Rule: OECD Process for Update of Genetic Toxicity Test Guidelines, March 10, 1997(a).

2. USEPA. Memorandum, Michael C. Cimino to Roger Nelson. Genotoxicity Test Guidelines for the HAPs Rule, February 27, 1997.

3. USEPA. Memorandum, Michael C. Cimino to Richard Leukroth. HAPs Rule: Adaptation of OECD Genotoxicity Test Guidelines, March 10, 1997(b).

4. Final report of the FIFRA Scientific Advisory Panel meeting, held October 29-30, 1996.

F. PK-related documents consisting of:

1. Chemical Manufacturers Association, Alkanolamines Panel, ''Proposal for Pharmacokinetics Studies of Diethanolamine'' (November 25, 1996).

2. U.S. EPA, ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Diethanolamine'' (November 21, 1997).

3. HAP Task Force, ''Proposal for Pharmacokinetics Study of Ethylene Dichloride'' (November 22, 1996).

4. U.S. EPA, ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Ethylene Dichloride,'' with cover letter (June 26, 1997).

5. Chemical Manufacturers Association, Ethylene Glycol Panel, ''Proposal for Pharmacokinetic Studies of Ethylene Glycol'' (November 5, 1996).

6. U.S. EPA, ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Ethylene Glycol, with cover letter (August 26, 1997).

7. Chemical Manufacturers Association, Hydrogen Fluoride (HF) Panel, ''Proposal for a Physiologically-Based Pharmacokinetic (PBPK) Model for Hydrogen Fluoride'' (November 22, 1996).

8. U.S. EPA, ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Hydrogen Fluoride'' (June 26, 1997).

9. Chemical Manufacturers Association, Maleic Anhydride Panel, ''Developing an Inhalation Testing Program for Maleic Anhydride'' (November 8, 1996).

10. U.S. EPA, ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Maleic Anhydride,'' with cover letter (July 10, 1997).

11. Chemical Manufacturers Association, Phthalic Anhydride Producers Task Group, ''Testing Proposal of the Chemical Manufacturers Association, Phthalic Anhydride Producers Task Group in Response to EPA's Proposed Rule for Phthalic Anhydride'' (November 22, 1996).

12. U.S. EPA. ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Phthalic Anhydride,'' with cover letter (July 10, 1997).

13. Chlorobenzene Producers Association, ''Proposal to Use the Pharmacokinetics, Physical, and Chemical Properties of 1,2,4-Trichlorobenzene to Fill Data Gaps'' (November 25, 1996).

14. U.S. EPA, ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for 1,2,4-Trichlorobenzene,'' with cover letter (July 15, 1997).

15. HAP Task Force, ''Proposal for Pharmacokinetics Study of 1,1,2-Trichloroethane'' (November 22, 1996).

16. U.S. EPA, ''Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for 1,1,2-Trichloroethane,'' with cover letter (June 26, 1997).

G. Other ECA proposals and related correspondence consisting of:

1. Chemical Manufacturers Association, Ketones Panel, ''Alternative Testing Proposal for Methyl Isobutyl Ketone,'' December 11, 1996 .

2. Letter from Charles M. Auer, EPA, to Barbara Francis, Chemical Manufacturers Association, March 3, 1997.

3. Letter from Carol R. Stack, Chemical Manufacturers Association, Cresols Panel to Charles M. Auer, EPA, April 9, 1997 (with attachment).

4. Contact report by Richard W. Leukroth, EPA, regarding discussion with Leah Porter and Elizabeth Watson, Chemical Manufacturers Association, Cresols Panel, May 19, 1997.

5. Biphenyl Work Group, ''Developing a Test Plan for Assessing the Potential Risk of Inhaled Biphenyl,'' with cover letter and attachment (October 7, 1997).

6. Letter from Charles Auer, EPA to John Murray, Biphenyl Work Group, November 4, 1997.

H. Technical support documents consisting of:

1. U.S. EPA, ''Economic Assessment for the Amended Proposed TSCA Section 4(a) Test Rule for 21 Hazardous Air Pollutants,'' OPPT/EETD/EPAB, November 14, 1997.

2. U.S. EPA, ''Section 4 Test Rule Support for 21 Hazardous Air Pollutants,'' OPPT/EETD/EPAB, April 4, 1995 (economic analysis for the original HAPs proposal).

3. U.S. EPA, ''Additional Information on Small Entity Impacts for the Amended Proposed TSCA Section 4(a) Test Rule for 21 Hazardous Air

Pollutants,'' OPPT/EETD/EPAB, November 14, 1997.

4. U.S. EPA, ''TSCA Test Guidelines: Cost Estimates for Health Effects Testing,'' OPPT/EETD/RIB, various dates.

5. U.S. EPA, ''EPA Interim Guidance for Implementing the Small Business Regulatory Enforcement Fairness Act,'' EPA SBREFA Task Force, February 5, 1997.

6. U.S. EPA, ''Draft Review of Economic Impact Methodology Applied to TSCA Section 4 Test Rules,'' OPPT/ETD/RIB, September 23, 1988.

7. U.S. EPA, ''Economic Analysis in Support of the Final Rule to Amend TSCA Section 12(b),'' OPPT/ETD/RIB, June 1992.

I. Letters, Facsimiles, electronic correspondence, and contact reports consisting of:

1. Letter from Gene P. Current, Weirton Steel Corp., to Gary Timm, EPA, August 26, 1996.

2. Letter from Marian K. Stanley, Chemical Manufacturers Association, to Gary Timm, EPA, August 28, 1996.

3. Electronic correspondence from Ed J. Dulac, Air Products and Chemicals, Inc., to Gary Timm, EPA, September 11, 1996.

4. Letter from Charles M. Auer, EPA, to Kathleen Roberts, Chemical Manufacturers Association, September 20, 1996.

5. Letter from Charles M. Auer, EPA, to Elizabeth Watson, Chemical Manufacturers Association, September 20, 1996.

6. Letter from Charles M. Auer, EPA, to Jack Murray, Synthetic Organic Chemical Manufacturers Association, September 20, 1996.

7. Letter from Charles M. Auer, EPA, to Caffey Norman, Halogenated Solvents Industry Alliance, September 20, 1996.

8. Fax transmittal from Rudolph J. Breglia, BP Oil, to Gary Timm, EPA, September 26, 1996.

9. Electronic correspondence from Steve Vasko, Eastalco Aluminum Company, to Gary Timm, EPA, October 1, 1996.

10. Electronic correspondence from Charlie Gjersvik, Goodwin & Broms, Inc., to Gary Timm, EPA, October 25, 1996.

11. Fax transmittal from Rudolph J. Breglia, BP Oil, to Dayton Eckerson, EPA, November 21, 1996.

12. Letter from Charles M. Auer, EPA, to Rudolph J. Breglia, BP Oil, July 29, 1997.

13. Note from Angela F. Hofmann, EPA, to Kevin Bromberg, Small Business Administration, September 9, 1997.

14. Contact report from Richard Leukroth and George Semeniuk, EPA, of phone call from Sharon Berryhill, Samendon Oil Corp., October 17, 1997.

15. Contact report from Richard Leukroth and Gary Timm, EPA, of phone call from Ray Scholten, Union Camp, October 20, 1997.

16. Letter from Charles M. Auer, EPA, to Gene P. Current, Weirton Steel Corp., November 21, 1997.

17. Letter from Charles M. Auer, EPA, to Ed J. Dulac, Air Products and Chemicals, Inc., November 21, 1997.

18. Letter from Charles M. Auer, EPA, to Steve Vasko, Eastalco Aluminum Company, November 21, 1997.

19. Letter from Charles M. Auer, EPA, to Charlie Gjersvik, Goodwin & Broms, Inc., November 21, 1997.

20. Letter from Charles M. Auer, EPA, to Rudolph J. Breglia, BP Oil, November 21, 1997.

21. Letter from Charles M. Auer, EPA, to Sharon Berryhill, Samendon Oil Corp., November 21, 1997.

22. Letter from Charles M. Auer, EPA, to Roy Scholten, Union Camp, November 21, 1997.

J. Meeting summaries consisting of:

1. Transcript of Public Meeting. October 1, 1996. ''Proposed Test Rule for Hazardous Air Pollutants 40 CFR Part 799.'' Prepared by: Carol J. Thomas Stenotype Reporting Services, Inc., 3162 Musket Court, Fairfax, VA 22030

2. Meeting Notes for the Pharmacokinetics Enforceable Consent Agreement Meeting. October 2, 1996. Prepared by: Leah Freeman and Michael Neal, Environmental Science Center, Syracuse Research Corporation, Syracuse, NY 13210.

3. Notes of EPA meeting with the Hydrogen Fluoride Panel, November 4, 1996.

4. Summary of meeting with Halogenated Solvents Industry Alliance HAP Task Force on 1,1,2-Trichloroethane and Ethylene Dichloride, November 5, 1996.

5. Summary of meeting with Small Business Administration on definition of ''small business'' to be proposed in the amended HAPs test rule, October 1, 1997.

VI. Regulatory Assessment Requirements

A. Economic Assessment

EPA has prepared a revised economic assessment entitled ''Economic Assessment for the Amended Proposed TSCA Section 4(a) Test Rule for 21 Hazardous Air Pollutants.'' This report evaluates the potential for significant economic impacts as a result of the testing required by this amended HAPs proposal. The costs estimated in the economic assessment are based on the use of the 11 TSCA test guidelines cross-referenced in this amended proposal. The total cost of providing test data on the HAPs chemicals under this amended proposal is estimated to range from $22.6 million to $39.3 million. These costs do not include data for phenol, which, as explained in Unit III.A. of this preamble, has been removed from the amended HAPs proposal. By comparison, the costs of providing test data on the HAPs chemicals under the original proposal were estimated to range from $25.2 million to $41.4 million (as indicated in the economic analysis for the original proposal). The costs developed in the economic assessment are based on test cost estimates that have been placed in the record for this rulemaking.

According to 40 CFR 790.42(a)(2), while legally subject to the HAPs test rule, processors of a HAP chemical would be required to comply with the requirements of the rule only if they are directed to do so in a subsequent notice as set forth in 40 CFR 790.48(b). EPA would only issue such a notice if no manufacturer or importer submits a notice of its intent to conduct testing. The Agency has never in fact notified processors of their obligation to test under such a notice, or applied the reimbursement procedures of 40 CFR part 791 to processors or even to manufacturers. Since EPA has identified at least one manufacturer or importer for each HAP chemical, the Agency presumes that at least one such manufacturer or importer would submit a notice of intent to conduct testing for each chemical and would actually conduct such testing, and thus that processors would not, at least initially, be burdened with the need to comply with the rule. Thus, in the economic assessment processors of the subject chemicals are not included.

To evaluate the potential economic effect of testing on HAP manufacturers and importers, EPA estimated the impact of the testing requirements as a percentage of chemical sales price. This measure compares annual revenues from the sale of a chemical to the annualized testing costs for that chemical. Annualized testing costs divide testing expenditures in the first year into an equivalent, constant yearly expenditure over a longer period of time. To calculate the percent price impact, testing costs (which include both laboratory and administrative expenditures) are annualized over 15 years using a 7 percent discount rate. Annualized testing costs are then divided by the total supply of the HAP chemical to derive the annualized unit test costs. The percent price impact is

calculated by dividing the annualized unit test costs by the sales price and multiplying by 100.

The upper-bound estimated total costs of testing (including both laboratory costs and administrative costs), annualized tests costs, price impact, and public reporting burden hours for the HAP chemicals in this amended HAPs test rule proposal are presented in the following Table 2. This table shows the maximum test costs, maximum price impacts (see Table 26 of the economic assessment) and public reporting burden hours (see Table C–3 of the economic assessment) estimated by EPA, which are presented in greater detail in the revised economic assessment document included in the public record for this action.

Table 2.—Summary of Economic Analysis for the Amended HAPs Test Rule Proposal

Chemical substances[1]	Maximum test costs		Maximum price impact (%)	Public reporting burden hours
	Total ($)	Annualized ($)		
1,1'-Biphenyl	2,518,183	276,483	0.7292	20,540
Carbonyl Sulfide	3,873,496	425,289	0.0424	35,560
Chlorine	105,186	11,549	0.0005	1,102
Chlorobenzene	1,218,931	133,832	0.1315	9,625
Chloroprene	1,592,388	174,836	0.0601	12,705
Cresol (3 isomers)	3,656,794	401,496	0.6069	28,875
Diethanolamine	2,518,183	276,483	0.2451	20,540
Ethylbenzene	1,934,638	212,413	0.0111	16,200
Ethylene Dichloride	2,397,668	263,251	0.0076	19,816
Ethylene Glycol	1,218,931	133,832	0.0068	9,625
Hydrochloric Acid	105,186	11,549	0.0048	1,102
Hydrogen Fluoride	2,518,183	276,483	0.1108	20,540
Maleic Anhydride	2,220,874	243,840	0.1258	22,755
Methyl Isobutyl Ketone	1,182,703	129,854	0.1384	9,247
Methyl Methacrylate	1,934,638	212,413	0.0200	16,200
Naphthalene	1,182,703	129,854	0.2081	9,247
Phthalic Anhydride	3,761,420	412,984	0.1174	34,513
1,2,4-Trichlorobenzene	977,636	107,339	0.8587	8,780
1,1,2-Trichloroethane	3,839,620	421,570	0.4138	35,275
Vinylidene Chloride	514,871	56,530	0.0853	4,561
Total	39,272,229	4,311,879		336,808

[1] The requirement for phenol testing has been removed from the amended HAPs proposal (see Unit III.A. of this preamble).

EPA believes, on the basis of these calculations, that the proposed testing of the HAPs chemicals does not impose any significant economic impact. Because these chemical substances have relatively large production volumes, the annualized costs of testing, expressed as a percentage of annual revenue, are very small—ranging from 0.0005 to 0.86 percent. Costs of testing are therefore found to be insignificant relative to revenues for companies producing these chemical substances. In addition, the TSCA section 12(b) export notification requirements that would be triggered by the final rule are expected to have a negligible impact on exporters—that of less than 1 percent of sales revenue. As discussed in more detail in the economic assessment, the Agency expects that the impact of the final HAPs rule will be less than that estimated in the original proposal. Although not considered in the economic assessment, EPA also anticipates further reductions in the estimated cost of the final rule attributable to the conclusion of any ECAs between EPA and industry.

While the rule imposes costs, it also has significant benefits which were not evaluated in the Agency's economic assessment. The data obtained from the HAPs test rule will assist the Agency in making regulatory decisions concerning the protection of human health from respiratory diseases such as asthma, emphysema and respiratory cancer; neurotoxicity; birth defects; and reproductive malfunction that are believed to be related to exposure to the hazardous air pollutant chemicals included in this rule. Specifically, data from this test rule will be used for the determination of significant residual risk after the imposition of MACT efforts to reduce human exposure to these chemicals. The data will also assist other agenices (e.g., Agency for Toxic Substances and Disease Registry, National Institute for Occupational Safety and Health, Occupational Safety and Health Administration, Consumer Product Safety Commission) in assessing chemical risks and in taking appropriate action within their programs.

EPA is seeking comment on the revised economic assessment. To be considered in this rulemaking, comments must be submitted in the manner specified in the ''ADDRESSES'' section at the beginning of his document.

B. Executive Order 12866 and Executive Order 12898; Unfunded Mandates Reform Act

Because the overall costs associated with testing under the amended HAPs proposal are expected to decrease relative to the original proposal, the amended proposal does not contain any provisions that would require additional consideration by the Office of Management and Budget (OMB) under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993) or Executive Order 12898, entitled Federal Actions to Address Environmental Justice in

Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). Similarly, the amended proposal does not require any actions under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). The Agency's activities related to these regulatory assessment requirements are discussed in the original proposed rule.

C. Regulatory Flexibility Act

For the original proposed HAPs test rule, EPA determined under section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, that the HAPs test rule, if finalized as proposed, would not result in a significant economic impact on small businesses. See Unit XI.B. of the preamble to the original HAPs proposal (61 FR 33178, 33196). In conjunction with this amended proposal, EPA has prepared and placed in the record for this action, a document that gives additional information on small entity impacts. As presented in this additional analysis, the new TSCA test guidelines cross-referenced in the amended HAPs proposal do not affect the Agency's previous determination with regard to small entity impacts. Since processors would not, at least initially, be burdened with the need to comply with the rule, processors are not included in the small entity analysis (see explanation regarding processors in the discussion of the economic assessment in Unit VI.A. of this preamble).

EPA does not believe that the impacts described in the analysis constitute a significant economic impact on a substantial number of small entities. The analysis states that the worst-case estimate shows that, on a HAP chemical by HAP chemical basis, a total of 8 manufacturers/importers (out of 365 manufacturers/importers initially burdened) may be affected by the rule. No manufacturers/importers for whom revenue data were available would be impacted by test costs that exceed 1 percent of their sales. For 8 manufacturers/importers whose revenues could not be determined, the size of the testing burden could not be determined and, therefore, the potential for impacts at greater than 1 percent of sales could not be ruled out. Nevertheless, in this context the rule would be unlikely to have a significant economic impact on a substantial number of small entities because the impacts of 1 percent or greater would be on fewer than 100 affected small entities.

Therefore, the Agency certifies that the HAPs test rule, if finalized according to this amended proposal, will not have a significant economic impact on a substantial number of small entities.

In the small entity analysis, the Agency has used the definition of a ''small business'' that is codified at 40 CFR 704.3 as ''small manufacturer or importer,'' which has been used for the general reporting and record keeping provisions for TSCA section 8(a) information gathering rules. According to section 601(3) of the RFA, agencies must use the definition of ''small business'' that is provided under the Small Business Act, 15 U.S.C. 631 *et seq.*, unless it establishes an alternative definition. The Agency may use the alternative definition for RFA purposes only after it has consulted with the Office of Advocacy of the Small Business Administration (SBA) and provided an opportunity for public comment.

Under the TSCA-related definition used by EPA, a manufacturer or importer is considered to be a ''small business'' if it meets either of the following criteria: (1) total annual sales of the company, combined with those of any parent company, are below $40 million and annual production volume or importation volume at the facility is less than or equal to 100,000 pounds; or (2) total annual sales of the company, combined with those of any parent company, are below $4 million (40 CFR 704.3). This definition also includes a provision that allows EPA to adjust the total annual sales values for inflation whenever the Agency deems it necessary to do so. EPA believes that specified levels of total annual sales, in conjunction with those for annual production or import volume, indicate the ability of a company to support chemical testing without significant costs or burden.

The small business size standards promulgated by the SBA (61 FR 3280, 3289–3291, January 31, 1996) for chemical manufacturers are based solely on the number of employees. For chemical manufacturing, however, the number of employees may not be closely related to the total annual sales of a company. Since chemical testing primarily requires a financial outlay, EPA believes that the number of employees is a less reliable measure of a company's ability to support testing than is a company's total annual sales. Therefore, in this rulemaking, the Agency is proposing to use the definition that appears at 40 CFR 704.3. This definition is discussed in the document entitled, ''Additional Information on Small Entity Impacts of the Amended Proposed TSCA section 4(a) Test Rule for 21 Hazardous Air Pollutants'' (see Unit V.H.3. of this document).

EPA is seeking comment on the use of the Agency's definition of ''small business,'' the ''Additional Information on Small Entity Impacts of the Amended Proposed TSCA Section 4(a) Test Rule for 21 Hazardous Air Pollutants'' document, as well as the small entity impacts analysis in the original proposal (61 FR 33178, 33196). EPA has consulted with the Office of Advocacy of the SBA concerning the Agency's use of the EPA definition. A summary of the meeting is in the record for this rulemaking (see document referenced in Unit V.J.5. of this preamble).

Any comments regarding the impacts that this action may impose on small entities should be submitted to the Agency in the manner specified under ''ADDRESSES'' at the beginning of this document.

D. Paperwork Reduction Act

The information collection requirements associated with test rules under TSCA section 4(a) in general, have been approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (PRA) under OMB control number 2070–0033 (EPA ICR No. 1139). The information collection requirements contained in this amended proposed rule, however, are not effective until the final rule, at which point the total estimated burden hours will be added to the total burden approved by OMB under control number 2070–0033. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information subject to OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the preamble of the final rules, are listed in 40 CFR part 9.

The list of public reporting burdens for the collection of information for chemical substances under the proposed HAPs test rule, as amended, as well as the numbers for the total public reporting burden and the overall average per chemical have changed from the numbers used in Unit XI.C. of the preamble to the original HAPs proposal (see: ''Paperwork Reduction Act'' (61 FR 33178, 33196)). As described in Unit VI.A. of this preamble, EPA has prepared an economic assessment which identifies the costs and burdens associated with the testing of the HAPs chemicals under the 11 TSCA test guidelines referenced in this amended

proposal. Table 3 compares the estimated public reporting burden hours for each of the HAPs chemicals in the amended proposal with the burden hours for each HAP chemical in the original proposal.

Table 3.—Comparison of Estimated Public Reporting Burden for the Original and Amended HAPs Test Rule Proposals

HAPs chemical	Estimated public reporting burden	
	Original HAPs test rule proposal	Amended HAPs test rule proposal
1,1'-Biphenyl	20,620	20,540
Carbonyl sulfide	47,644	35.560
Chlorine	693	1,102
Chlorobenzene	7,707	9,625
Chloroprene	13,039	12,705
ortho-Cresol	6,048	9,625
meta-Cresol	6,048	9,625
para-Cresol	6,048	9,625
Diethanolamine	21,826	20,540
Ethylbenzene	14,400	16,200
Ethylene dichloride	16,707	19,816
Ethylene glycol	7,816	9,625
Hydrochloric acid	693	1,102
Hydrogen fluoride	18,068	20,540
Maleic anhydride	35,849	22,755
Methyl isobutyl ketone	10,471	9,247
Methyl methacrylate	14,400	16,200
Naphthalene	10,580	9,247
Phenol[1]	693	
Phthalic anhydride	51,032	34,513
1,2,4-Trichlorobenzene	8,091	8,780
1,1,2-Trichloroethane	33,133	35,275
Vinylidene chloride	5,439	4,561
Av. Per HAPs response:	15,524	15,309
Total (all HAPs):	357,045	336,808

[1] The requirement for phenol testing has been removed from the amended HAPs proposal (see Unit III.A. of this preamble).

The total public reporting is now estimated to be 336,808 burden hours for all responses, as compared to the 357,045 burden hours indicated in the original proposal. The overall average public reporting burden for each HAP chemical is 15,309 burden hours, as compared to the 15,524 burden hours estimated in the original proposal. The overall average burden for each HAP chemical that is presented in the table in Unit XI.C. of the original HAPs proposal was calculated based on a total HAPs chemical count of 23 chemicals (each cresol isomer was considered to be a separate chemical moiety) (61 FR 33178, 33196). This method was also used to calculate the overall average public reporting burden for each HAP chemical for the amended HAPs proposal after the removal of data for phenol (a count of 22 chemicals).

As defined by the PRA and 5 CFR 1320.3, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. The burden hours contained in the original economic analysis and the table in Unit XI.C. of the original HAPs proposal (61 FR 33178, 33196), however, were based only on burdens associated with the cost of laboratory testing and not the other activities described in the PRA.

In addition, the total burden hours for cresols that were presented in the ''Paperwork Reduction Act'' section of the original HAPs proposal were not reported correctly in the chemical-by-chemical table at 61 FR 33196. The reported 6,048 hours was the estimate calculated for each cresol isomer, not all three isomers as indicated in the table. Nevertheless, the total burden of 357,045 hours for all responses that was indicated in the original HAPs proposal did include the burdens for all three cresol isomers.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments to EPA as part of your overall comments on this proposed action in the manner specified in the ''ADDRESSES'' section at the beginning of this document, or to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M Street, SW., Washington, DC 20460, with a copy to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Please remember to include the OMB control number in any correspondence. In developing the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposal.

E. Executive Order 13045

Neither the original HAPs proposal nor this amended proposal requires special consideration by OMB pursuant

to the terms of Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because the Executive Order does not apply to rulemakings initiated prior to the issuance of the Order, in this instance, June 26, 1996, or actions expected to have an economic impact of less than $100 million.

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements, Incorporation by reference.

Dated: December 15, 1997.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 would continue to read as follows:

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

2. Section 799.5053 as proposed to be added at 61 FR 33197, June 26, 1996, is revised to read as follows:

§ 799.5053 Chemical testing requirements for hazardous air pollutants.

(a) *General testing provisions*—(1) *Identification of test substance.* Table 1 in paragraph (a)(6) of this section identifies those chemical substances that shall be tested in accordance with this section. The purity of each test substance shall be 97 percent or greater unless otherwise specified.

(2) *Persons required to submit study plans, conduct tests, and submit data.* (i) For purposes of this section, the term ''facility'' is defined as ''all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or is under common control with such person). A facility may contain more than one establishment.'' The facility for a person who imports a chemical substance is the facility of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the United States.

(ii) All persons who, during the last complete corporate fiscal year prior to the effective date specified in Table 1 in paragraph (a)(6) of this section, manufacture (including import, manufacture as a byproduct as defined in 40 CFR 791.3(c), and manufacture, including import, as an impurity as defined in 40 CFR 790.3) or process any chemical substance specified in Table 1 in the form of a Class 1 substance (as described in 40 CFR 720.45(a)(1)(i)), or a component of a Class 2 substance (as described in 40 CFR 720.45(a)(1)(i)) or mixture (as defined in TSCA section 3(8)), but not as a component of a naturally-occurring substance (as defined in 40 CFR 710.4(b)) or a non-isolated intermediate (as defined in 40 CFR 704.3), at a facility shall: submit letters of intent to conduct testing, submit study plans, conduct testing under TSCA Good Laboratory Practice Standards, and submit data, as specified in this section and part 792 of this chapter, or submit exemption applications, as specified in part 790 of this chapter.

(iii) As explained in part 790 of this chapter, processors, small-quantity manufacturers, and manufacturers of small quantities of the chemical substances specified in Table 1 solely for research and development purposes must comply with the requirements of the rule only if directed to do so by EPA in a subsequent notice because no manufacturer has submitted a notice of its intent to conduct testing.

(iv) Manufacturers of a chemical substance specified in Table 1 who, during the last complete corporate fiscal year prior to the effective date specified in Table 1, at no facility, manufacture such substance in an amount equal to or in excess of 25,000 lb must comply with the requirements of the rule only if directed to do so by EPA in a subsequent notice because no manufacturer has submitted a notice of its intent to conduct testing.

(v) Manufacturers of a chemical substance specified in Table 1 who, during the last complete corporate fiscal year prior to the effective date specified in Table 1, at no facility, manufacture such substance in an amount equal to or in excess of 25,000 lb as a component of another chemical substance or mixture in which the proportion of the substance specified in Table 1 is equal to or in excess of one percent by weight must comply with the requirements of the rule only if directed to do so by EPA in a subsequent notice because no manufacturer has submitted a notice of its intent to conduct testing.

(3) *Export notification.* All persons who export or intend to export a chemical substance listed in Table 1 in paragraph (a)(6) of this section are subject to part 707, subpart D, of this chapter.

(4) *Applicability of test guidelines.* The guidelines and test standards cited in Table 1 in paragraph (a)(6) of this section are referenced here as they exist on the effective date listed in Table 1 for that specific test. Testing shall be conducted in accordance with test standards specified in Table 1, which references TSCA health effects test guidelines codified at subpart H of this part.

(5) *Testing requirements.* The chemical substances identified by Chemical Abstracts Service (CAS) number and chemical name in Table 1 in paragraph (a)(6) of this section shall be tested in accordance with the test standards set forth in Table 1. The column labeled ''Basic testing requirements (test guideline)'' references the applicable TSCA test guideline on which the test standard is based, and the column entitled ''Changes from guideline'' lists the ways in which the specific test standard differs from the basic testing requirement (test guideline), as specified in paragraph (b) of this section.

(6) *Reporting requirements.* Interim progress reports for each test shall be submitted every 6 months, beginning 6 months after the effective date of any specific test listed in the following Table 1. Final reports for any specific test shall be submitted by the deadlines indicated as the number of months after the effective date shown in the following Table 1.

TABLE 1

CAS No.	Chemical name/types of testing	Test standard		Final report	Effective date
		Basic testing requirements (test guideline)	Changes from guideline		
75–35–4	Vinylidene chloride:				

TABLE 1—Continued

CAS No.	Chemical name/types of testing	Test standard		Final report	Effective date
		Basic testing requirements (test guideline)	Changes from guideline		
	Acute	799.9135	(b)(2)	21 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
79–00–5	1,1,2-Trichloroethane:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Developmental	799.9370	(b)(1)(ii)(A)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Carcinogenicity	799.9420	(b)(1)(i)(D), (b)(1)(ii)(A)	60 mo	
	In vivo cytogenetics	799.9538 or 799.9539	(b)(1)(ii)(A)	14 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	
80–62–6	Methyl methacrylate:				
	Acute	799.9135	(b)(2)	21 mo	
	Developmental	799.9370	(b)(1)(i)(A), (b)(1)(ii)(A)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	21 mo	
85–44–9	Phthalic anhydride:				
	Acute	799.9350	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(1)(ii)(B), (b)(3)	18 mo	
	Developmental	799.9370	(b)(1)(ii)(B)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(B)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(B), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Carcinogenicity	799.9420	(b)(1)(ii)(B)	60 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(B), (b)(4)	18 mo	
91–20–3	Naphthalene:				
	Acute	799.9135	(b)(2)	21 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	21 mo	
92–52–4	1,1'-Biphenyl:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(1)(ii)(B), (b)(3)	18 mo	
	Developmental	799.9370	(b)(1)(i)(A), (b)(1)(ii)(B)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(B)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(B), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(B), (b)(4)	18 mo	
95–48–7	*ortho*-Cresol:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	
108–39–4	*meta*-Cresol:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	
106–44–5	*para*-Cresol:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	

TABLE 1—Continued

CAS No.	Chemical name/types of testing	Test standard		Final report	Effective date
		Basic testing requirements (test guideline)	Changes from guideline		
100–41–4	Ethylbenzene:				
	Acute	799.9135	(b)(2)	21 mo	
	Developmental	799.9360	(b)(1)(i)(A), (b)(1)(ii)(A)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	21 mo	
107–06–2	Ethylene dichloride:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Developmental	799.9370	(b)(1)(i)(C), (b)(1)(ii)(A)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
107–21–1	Ethylene glycol:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	
108–10–1	Methyl isobutyl ketone:				
	Acute	799.9135	(b)(2)	21 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	29 mo	
108–31–6	Maleic anhydride:				
	Acute	799.9135	(b)(2)	21 mo	
	Developmental	799.9370	(b)(1)(i)(A), (b)(1)(ii)(A)	12 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Carcinogenicity	799.9420	(b)(1)(ii)(A)	60 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	21 mo	
108–90–7	Chlorobenzene:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	
111–42–2	Diethanolamine:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(1)(ii)(B), (b)(3)	18 mo	
	Developmental	799.9370	(b)(1)(ii)(B)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(B)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(B), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(B), (b)(4)	18 mo	
120–82–1	1,2,4-Trichlorobenzene:				
	Acute	799.9135	(b)(2)	21 mo	
	Developmental	799.9370	(b)(1)(ii)(A)	12 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	21 mo	
126–99–8	Chloroprene:				
	Acute	799.9135	(b)(2)	21 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	

TABLE 1—Continued

CAS No.	Chemical name/types of testing	Test standard		Final report	Effective date
		Basic testing requirements (test guideline)	Changes from guideline		
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	21 mo	
463–58–1	Carbonyl sulfide:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Developmental	799.9370	(b)(1)(ii)(A)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Carcinogenicity	799.9420	(b)(1)(ii)(A)	60 mo	
	Bacterial reverse mutation	799.9510	(b)(1)(ii)(C)	6 mo	
	Mammalian gene mutation	799.9530	(b)(1)(ii)(C)	6 mo	
	In vivo cytogenetics	799.9538 or 799.9539	(b)(1)(ii)(A)	14 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	
7647–01–0	Hydrochloric acid:				
	Acute	799.9135	(b)(2)	21 mo	
7664–39–3	Hydrogen fluoride:				
	Acute	799.9135	(b)(2)	21 mo	
	Subchronic	799.9346	(b)(3)	18 mo	
	Developmental	799.9370	(b)(1)(ii)(A)	12 mo	
	Reproductive	799.9380	(b)(1)(ii)(A)	29 mo	
	Neurotoxicity	799.9620	(b)(1)(ii)(A), (b)(1)(iii)(A), (b)(1)(iii)(B)	21 mo	
	Immunotoxicity	799.9780	(b)(1)(ii)(A), (b)(4)	18 mo	
7782–50–5	Chlorine:				
	Acute	799.9135	(b)(2)	21 mo	

(b) *Changes from TSCA test guidelines.* The provisions in paragraphs (b)(1) through (b)(4) of this section when referenced in Table 1 in paragraph (a)(6) of this section under the column ''Changes from guideline,'' specify the manner in which the specific test standard differs from the TSCA test guideline upon which it is based.

(1) *Modifications applicable to all testing.* Only those provisions specifically referenced in Table 1 in paragraph (a)(6) of this section apply.

(i) *Test species.* The test animal shall be:

(A) A mammalian species other than the rat.

(B) A mammalian species other than the mouse.

(C) A mammalian species other than the rabbit.

(D) The male rat and the female mouse.

(ii) *Route of exposure.* Animals shall be exposed:

(A) Via vapor-phase inhalation.

(B) Via inhalation of aerosol.

(C) Via vapor-phase.

(iii) *Duration and frequency of exposure.* The test animal shall be:

(A) Exposed for a 4-hour period in an acute study.

(B) Exposed for 6 hours per day, 5 days per week for a 90-day period in a subchronic study.

(2) *Modifications applicable to acute testing.* When referenced in Table 1 in paragraph (a)(6) of this section, all provisions in this paragraph apply.

(i) The appraisal of pulmonary irritation shall be evaluated during exposure to the substance by the use of the mouse respiratory sensory irritation assay method as outlined in ASTM E–981–84 (see paragraph (b)(2)(iii)(C) of this section). This method assesses the breathing patterns of test animals. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is incorporated as it exists on the date of approval and notice of any change in this material will be published in the **Federal Register**. Copies of the incorporated material may be examined at the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC, 20460 or by contacting the American Society for Testing and Materials (ASTM), 100 Bar Harbor Drive, Conshohoken, PA 19428–2959. Copies may be inspected at the above address or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. For information on this test guideline, the references in paragraph (b)(2)(iii) of this section should be consulted.

(ii) *Results of respiratory sensory irritation assay.* Results shall be reported as follows:

(A) Data shall be included in the final report and tabulated to show:

(*1*) The magnitude of change in respiratory rate with exposure concentration and with time for each animal.

(*2*) A response concentration, which indicates the concentration at which the respiration rate is decreased by 50% (RD_{50}), will be calculated, along with the 95% confidence limits.

(B) Time-effect curves shall be included in the final report to evaluate the onset and shape of the response.

(iii) *References.*

(A) Alarie, Y., and Luo, J.E. ''Sensory Irritation by Airborne Chemicals: A basis to establish acceptable levels of exposure.'' *Toxicology of the Nasal Passages.* Hemisphere Publishing Corporation: New York pp. 91–100 (1986).

(B) Alarie, Y., and Stokinger, H.E. ''Sensory Irritation by Airborne Chemicals.'' *CRC Critical Reviews in Toxicology.* pp. 299–363 (1973).

(C) ASTM. ''Standard Test Method for Estimating Sensory Irritancy of Airborne Chemicals.'' In: *1984 Annual Book of ASTM Standards. Water and Environmental Technology.* Section 11. Volume 11.04 Designation E 981–84 pp. 572–584 (1984).

(3) *Modifications applicable to subchronic testing.* When referenced in Table 1 of this section, all provisions in this paragraph apply.

(i) *Respiratory tract pathology.* Respiratory tract pathology shall be performed as follows:

(A) Care shall be taken that the method used to kill the animal does not result in damage to the tissues of the upper or lower respiratory tract. The heart-lung, including the trachea, shall be removed in bloc.

(B) Representative sections of the lungs shall be examined histologically. This shall include trachea, major conducting airways, alveolar region, terminal and respiratory bronchioles, alveolar ducts and sacs, and interstitial tissues.

(C) The nasopharyngeal tissue shall be examined for histopathologic lesions. This shall include sections through the nasal cavity, and examination of the squamous, transitional, respiratory, and olfactory epithelia.

(D) The larynx mucosa shall be examined for histopathologic changes. Sections of the larynx to be examined include the epithelium covering the base of the epiglottis, the ventral pouch, and the medial surfaces of the vocal processes of the arytenoid cartilages.

(ii) *Bronchoalveolar lavage.* Bronchoalveolor lavage shall be performed as follows:

(A) The lungs shall be lavaged *in situ* or after sacrifice. If the study will not be compromised, one lobe of the lungs may be used for lung lavage while the other is fixed for histologic evaluation. The lungs shall be lavaged using physiological saline after cannulation of the trachea. The lavages shall consist of two washes each of which consists of approximately 80 percent (e.g., 5 ml in rats and 1 ml in mice) of total lung volume. Additional washes merely tend to reduce the concentrations of the material collected. The lung lavage fluid shall be stored on ice at approximately 5 deg. C until assayed.

(B) The following parameters shall be determined in the lavage fluid as indicators of cellular damage in the lungs: total protein, cell count and percent leukocytes. In addition, a phagocytosis assay using the procedure of Burleson or Gilmour and Selgrade (Burleson et al., 1987; Gilmour and Selgrade, 1993) shall be performed to determine macrophage activity. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is incorporated as it exists on the date of approval and notice of any change in this material will be published in the **Federal Register**. Copies of the incorporated material may be obtained from the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC, 20460, for the Burleson citation by contacting the Society for Experimental Biology and Medicine, at Blackwell Science Ltd., 238 Main Street, Cambridge, MA 02142, and for the Gilmour and Selgrade citation by contacting Academic Press, Inc., Toxicology and Applied Pharmacology, 62777 Sea Harbor Drive, Orlando, FL 32887. Copies may be inspected at the above address or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. The following references may be consulted:

(*1*) Burleson, G.R. et al. ''Poly (I): poly (C)-enhanced alveolar peritoneal macrophage phagocytosis: Quantification by a new method utilizing fluorescent beads.'' *Proceedings of the Society for Experimental Biology and Medicine.* 184:468–476 (1987).

(*2*) Gilmour, G.I., and Selgrade, M.K. ''A Comparison of the Pulmonary Defenses against Streptococcal Infection in Rats and Mice Following O_3 Exposure: Differences in Disease Susceptibility and Neutrophil Recruitment.'' *Toxicology and Applied Pharmacology.* 123:211–218 (1993).

(4) *Modifications applicable to immunotoxicity testing.* The natural killer cell assay and enumeration of splenic or peripheral blood cells in § 799.9789 (g)(1)(iii) and (g)(2) are not required.

[FR Doc. 97–33451 Filed 12–23–97; 8:45 am]

BILLING CODE 6560–50–F