

B. PK proposal materials consisting of:

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

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

List of Subjects

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: January 5, 1998.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

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ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-42201B; FRL-5765-5]

Enforceable Consent Agreement Development for Hydrogen Fluoride; Solicitation of Interested Parties and Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is soliciting interested parties who want to monitor or participate in negotiations on an enforceable consent agreement (ECA) concerning the use of pharmacokinetics (PK) studies and mechanistic data to help meet testing requirements for hydrogen fluoride in the proposed hazardous air pollutants (HAPs) test rule. In addition, EPA invites all interested parties to attend a public meeting to initiate negotiations on the ECA for hydrogen fluoride.

DATES: EPA must receive written notification requesting designation as an interested party for hydrogen fluoride on or before January 30, 1998. Those persons who identify themselves as interested parties for hydrogen fluoride may submit written comments to EPA on the PK proposal for this chemical, on EPA's preliminary technical analysis, and on other materials in the docket for the proposed HAPs test rule, that relate to the ECA process for this chemical by January 30, 1998.

The public meeting is scheduled from 8:30 a.m. to 12:30 p.m. on February 5, 1998.

ADDRESSES: Each comment must bear the docket control number, OPPTS-42201B. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. G-099, East Tower, Washington, DC 20460.

EPA will address these comments at the public meeting.

Comments and data may also be submitted electronically to: oppt.ncic@epamail.epa.gov following the instructions under Unit VI. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

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 document. Persons submitting information on 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.

The public meeting will be held at EPA Headquarters, 401 M St., SW., Washington, DC in the EPA Conference Center, North Conference Area in Room 1.

FOR FURTHER INFORMATION CONTACT: *For additional information:* Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. E-543B, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 554-1404, TDD: (202) 554-0551; e-mail address: TSCA-Hotline@epamail.epa.gov.

For technical information: Richard W. Leukroth, Jr., Project Manager, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260-0321; fax: (202) 260-8850; e-mail address: leukroth.rich@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. 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 "Laws and Regulations" (<http://www.epa.gov/fedrgstr/EPA-TOX/1998/>).

II. Background

EPA proposed health effects testing under section 4(a) of the Toxic Substances Control Act (TSCA) on June 26, 1996, for a number of HAPs chemicals (61 FR 33178) (FRL-4869-1). As indicated in the proposed HAPs test rule, EPA would use the data obtained from testing to implement several provisions of section 112 of the Clean Air Act (CAA), including the determination of residual risk, the estimation of the risks associated with accidental releases of chemicals, and determinations whether substances should be removed from the CAA section 112(b)(1) list of hazardous air pollutants (delisting). The data also would be used by other Federal agencies (e.g., Agency for Toxic Substances and Disease Registry (ATSDR), National Institute of Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), and Consumer Product Safety Commission (CPSC)) in assessing chemical risks and in taking appropriate actions within their programs.

In the proposed HAPs test rule, EPA invited the submission of proposals for PK studies for the HAPs chemicals, which could provide the basis for negotiation of ECAs. These PK studies would be used to inform EPA about the use of route-to-route extrapolation of toxicity data from routes other than inhalation to predict the effects of inhalation exposure, as an alternative to testing proposed under the HAPs test rule. EPA received a PK proposal for hydrogen fluoride from the Chemical Manufacturers Association, Hydrogen Fluoride Panel (CMA HF Panel) on November 27, 1996. Based on the PK proposal received for hydrogen fluoride, the Agency developed a preliminary technical analysis. A copy of this preliminary technical analysis was sent to the CMA HF Panel on June 26, 1997. The CMA HF Panel reviewed EPA's analysis and notified EPA on September 10, 1997, that it has a continued interest in pursuing the ECA process. A copy of the PK proposal, the EPA preliminary technical analysis and related references, and correspondence is contained in the public record for this ECA process. These materials will be used during discussions at the negotiating meeting. EPA has decided to proceed with the ECA process for hydrogen fluoride and is providing public notice that the Agency is hereby initiating the procedures for ECA

negotiations for the HAP chemical, hydrogen fluoride. The procedures for ECA negotiations are described at 40 CFR 790.22(b). EPA intends to publish, as appropriate, additional **Federal Register** documents to solicit interested parties and announce public meetings for other HAPs chemicals for which PK proposals were submitted.

The proposed HAPs test rule, as amended on December 24, 1997 (62 FR 67466) (FRL-5742-2), and the ECA negotiations on chemicals included in the proposed rule are separate and parallel activities. While the Agency's objective of obtaining data could be accomplished by either activity, EPA recognizes that the final testing program performed by industry may differ depending on whether it is accomplished under the final HAPs test rule or via the ECA process. During the course of ECA negotiations, additional information may be brought forward that could cause the Agency to re-evaluate the nature of the testing requirements as stated in the proposed HAPs test rule, as amended. This could result in the development of an ECA that would fulfill the Agency's data needs in ways not stated in the proposed HAPs test rule, as amended. It is therefore essential for all interested parties to recognize these differences at the outset and respond accordingly within the framework of these two separate and parallel activities. Comments on the proposed HAPs test rule, as amended, must be submitted under docket control number, OPPTS-42187A, as described in the proposed HAPs test rule published on June 26, 1996, as amended on December 24, 1997, and will be addressed by EPA via the rulemaking process, which is separate and distinct from the ECA process. Participation in the ECA process is described in Units II. through IV. of this document.

Negotiations on developing an ECA for the HAP chemical, hydrogen fluoride, will focus on the use of PK studies and mechanistic data to help meet testing requirements for hydrogen fluoride. In addition, discussion will include the adequacy of the available data base to be used for extrapolation to obtain the data needs identified for hydrogen fluoride in the proposed HAPs test rule, as amended. The objective of the ECA process is to conclude an ECA that will set in place an industry-sponsored testing program that will adequately address EPA's data needs for hydrogen fluoride.

III. Identification of Interested Parties

EPA is soliciting interested parties to monitor or participate in testing

negotiations on an ECA for hydrogen fluoride. The CMA HF Panel, the submitter of the PK proposal for hydrogen fluoride, and the member companies of the CMA HF Panel are already considered interested parties and do not need to respond to this document. Additionally, any persons who respond to this document on or before January 30, 1998 will be given the status of interested parties. Interested parties must respond in writing to the address specified in "ADDRESSES" at the beginning of this document. These interested parties will not incur any obligations by being so designated. Negotiations will be conducted in one or more meetings open to the public. The negotiation time schedule for hydrogen fluoride will be established at the first negotiation meeting and will not exceed a period of 4 months from the initial meeting. If an ECA is not established in principle within this timeframe and EPA does not choose to extend the negotiation time period, negotiations will be terminated and testing will be required under the final HAPs test rule. If the testing from the ECA does not meet the Agency's needs, EPA reserves the right to enter into rulemaking.

IV. Public Participation in Negotiations

Under EPA regulations, the Agency is required to provide the public with an opportunity to comment on and participate in the development of ECAs. The procedural rule for ECAs (40 CFR part 790) contains provisions to ensure that the views of interested parties are taken into account during the ECA process.

Individuals and groups who respond to this document will have the status of interested parties. All negotiating meetings for the development of this ECA for hydrogen fluoride will be open to the public and minutes of each meeting will be prepared by EPA and placed in the public docket for this ECA process. The Agency will advise interested parties of meeting dates and make available meeting minutes, testing proposals, background documents, and other materials exchanged at or prepared for negotiating meetings. Where tentative agreement is reached on an acceptable testing program, a draft ECA will be made available for comment by interested parties and, if necessary, EPA will hold a public meeting to discuss any comments that have been received and determine whether revisions to the ECA are appropriate. EPA will not reimburse costs incurred by non-EPA participants in this ECA negotiation process.

ECAs will only be concluded where an agreement can be obtained which is satisfactory to the Agency, manufacturers or processors who are potential test sponsors, and other interested parties, concerning the need for and scope of testing. In the absence of an ECA, EPA reserves the right to proceed with rulemaking.

A. The Agency will not enter into an ECA if either:

1. EPA and affected manufacturers or processors cannot reach an agreement on the provisions of the ECA; or

2. The draft ECA is considered inadequate by other interested parties who have submitted timely written objections to the draft ECA.

B. EPA may reject these objections if the Agency concludes either that:

1. They are not made in good faith;

2. They are untimely;

3. They are not related to the adequacy of the proposed testing program or other features of the agreement that may affect EPA's ability to fulfill the goals and purposes of TSCA; or

4. They are not accompanied by a specific explanation of the grounds on which the draft agreement is considered objectionable.

EPA will prepare an explanation of the basis for each ECA. The explanatory document will summarize the agreement (including the required testing), explain the objectives of the testing, and outline the chemical's use and exposure characteristics. The document, which will also announce the availability of the ECA, will be published in the **Federal Register**.

V. Proposal of Export Notification Requirements for Hydrogen Fluoride

EPA intends to publish a proposed rule in an upcoming **Federal Register** document to require export notification by all persons who export or intend to export hydrogen fluoride under TSCA section 12(b) upon the successful conclusion of an ECA for hydrogen fluoride.

VI. Public Record and Electronic Submissions

As described above, hydrogen fluoride is listed as a chemical that would be subject to testing requirements under the proposed HAPs test rule, as amended. This ECA negotiation process and the proposed rule, as amended, are separate and parallel activities. The official record for this ECA action, including the public version, has been established under docket control number OPPTS-42201B (including comments and data submitted electronically as described below). The

official record for this document also includes all material and submissions filed under docket control number OPPTS-42187A, the record for the proposed HAPs test rule, as amended, and all materials and submissions filed under docket control number OPPTS-42187B, the record for the receipt of alternative testing proposals for developing ECAs for HAPs chemicals.

The official record for this document, including the public version, which does not include any information claimed as CBI, has been established for this document under docket control number OPPTS-42201B. The public version of this record 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 B-607, 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 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number, OPPTS-42201B. Electronic comments on this document may be filed online at many Federal Depository Libraries.

The record contains the following information:

A. **Federal Register** notices/EPA documents pertaining to this notice consisting of:

1. "Proposed Test Rule for Hazardous Air Pollutants; Proposed Rule" (61 FR 33178, June 26, 1996).
2. "Amended Proposed Test Rule for Hazardous Air Pollutants; Extension of Comment Period" (62 FR 67466, December 24, 1997).

B. PK proposal materials consisting of:

1. Chemical Manufacturers Association, Hydrogen Fluoride (HF) Panel, "Proposal for a Physiologically-Based Pharmacokinetic (PBPK) Model for Hydrogen Fluoride" (June 26, 1997).
2. U.S. EPA, "Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Hydrogen Fluoride" and cover letter (June 26, 1997).

List of Subjects

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: January 5, 1998.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

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ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-42200B; FRL-5765-3]

Enforceable Consent Agreement Development for Phthalic Anhydride; Solicitation of Interested Parties and Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is soliciting interested parties who want to monitor or participate in negotiations on an enforceable consent agreement (ECA) concerning the use of pharmacokinetics (PK) studies and mechanistic data to help meet testing requirements for phthalic anhydride in the proposed hazardous air pollutants (HAPs) test rule. In addition, EPA invites all interested parties to attend a public meeting to initiate negotiations on the ECA for phthalic anhydride.

DATES: EPA must receive written notification requesting designation as an interested party for phthalic anhydride on or before January 30, 1998. Those persons who identify themselves as interested parties for phthalic anhydride may submit written comments to EPA on the PK proposal for this chemical, on EPA's preliminary technical analysis, and on other materials in the docket for the proposed HAPs test rule, that relate to the ECA process for this chemical by January 30, 1998.

The public meeting is scheduled from 1 p.m. to 5 p.m. on February 5, 1998.

ADDRESSES: Each comment must bear the docket control number, OPPTS-42200B. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. G-099, East Tower, Washington, DC 20460.

EPA will address these comments at the public meeting.

Comments and data may also be submitted electronically to: oppt.ncic@epamail.epa.gov following the instructions under Unit VI. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

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The public meeting will be held at EPA Headquarters, 401 M St., SW., Washington, DC in the EPA Conference Center, North Conference Area in Room 1.

FOR FURTHER INFORMATION CONTACT: For additional information: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. E-543B, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 554-1404, TDD: (202) 554-0551; e-mail address: TSCA-Hotline@epamail.epa.gov.

For technical information: Richard W. Leukroth, Jr., Project Manager, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260-0321; fax: (202) 260-8850; e-mail address: leukroth.rich@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. 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 "Laws and Regulations" (<http://www.epa.gov/fedrgstr/EPA-TOX/1998/>).

II. Background

EPA proposed health effects testing under section 4(a) of the Toxic Substances Control Act (TSCA) on June 26, 1996, for a number of HAPs chemicals (61 FR 33178) (FRL-4869-1). As indicated in the proposed HAPs test rule, EPA would use the data obtained from testing to implement several provisions of section 112 of the Clean Air Act (CAA), including the determination of residual risk, the estimation of the risks associated with