

*F. International Residue Limits*

No CODEX, Canadian or Mexican maximum residue levels have been established for zinc phosphide.

*G. Rotational Crop Restrictions*

Data for confined accumulation in rotational crops have been waived because the physical properties of zinc phosphide precludes transfer of residues to rotated crops (Zinc Phosphide RED, EPA 738-R-98-006, July 1998). Thus, rotational crop restrictions are not required.

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0056; FRL-7313-8]

### 1,1,2-Trichloroethane (TCE); EPA Program Review: Notice of Availability

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Under section 4 of the Toxic Substances Control Act (TSCA), EPA issued a testing consent order (Order) that incorporates an enforceable consent agreement (ECA) relating to 1,1,2-trichloroethane (TCE) (CAS No. 79-00-5). The companies subject to this ECA, the Dow Chemical company; Vulcan Materials Company; Occidental Chemical Corporation; Oxy Vinyls, LP; Georgia Gulf Corporation; Westlake Chemical Corporation; PPG Industries, Inc.; and Formosa Plastics Corporation, U.S.A., have agreed to conduct toxicity testing, develop a computational dosimetry model for route-to-route extrapolations of dose response, and develop pharmacokinetics and mechanistic (PK/MECH) data that are intended to satisfy the toxicological data needs for TCE identified in a TSCA section 4 proposed test rule for a number of hazardous air pollutant (HAP) chemicals. This notice announces the availability of a report describing the findings and conclusions for the program review component of the ECA for TCE, responds to comments on the Tier I Program Review Testing, identifies modifications to Tier II ECA activities, and establishes revised deadlines for completion of Tier II testing and computational route dosimetry modeling for extrapolations listed under Tier II of the ECA for TCE.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of

Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

*For technical information contact:* Richard W. Leukroth, Jr., or John E. Schaeffer, Jr., Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8157; e-mail address: ccd.citb@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Copies of this Document and Other Related Information?

1. *EPA Docket.* EPA has established an official public docket for this action under docket (ID) number OPPT-2002-0056. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA docket center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and telephone number for the OPPT Docket, which is located in EPA docket center, is (202) 566-0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgrstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

##### II. Background

###### A. What is the EPA Program Review for TCE?

In the **Federal Register** of October 16, 2002 (67 FR 63913) (FRL-7275-8) EPA announced that it was conducting the program review component of the enforceable consent agreement (ECA) for the 1,1,2-trichloroethane (TCE) alternative testing program, and solicited public comment on data received under the Tier I Program Review testing segment of the ECA for TCE (CAS No. 79-00-5). Comments were to inform EPA's decision on whether or not additional data and/or model development are needed before Tier II testing and computational route-to-route dosimetry modeling extrapolations can proceed for the Tier II endpoints listed in the ECA for TCE.

Details of the testing program for TCE are available in the ECA and in the **Federal Register** of June 15, 2000 (65 FR 37550)(FRL-6494-5), in which EPA announced it had entered into an ECA and issued a testing consent order for TCE. The ECA for TCE was developed in response to EPA's request for ECA proposals for health effects testing of a number of hazardous air pollutants (HAPs or HAP chemicals), including TCE (see the proposed test rule in the **Federal Register** of June 26, 1996 (61 FR 33178) (FRL-4869-1), and the proposed test rule, as amended, in the **Federal Register** of December 24, 1997 (62 FR 67466) (FRL-5742-2); February 5, 1998 (63 FR 5915) (FRL-5769-3); and April 21, 1998 (63 FR 19694) (FRL-5780-6). The HAPs rulemaking proposed testing for health effects by the inhalation route of exposure. In the proposed rule, EPA also invited the submission of proposals that included pharmacokinetics studies and model development that would permit route-to-route dosimetry extrapolation to predict for inhalation exposures. The ECA for TCE applies such an alternative approach to satisfy

data needs identified in the proposed HAPs rulemaking.

Under the TCE ECA testing program, the data needs for TCE are being addressed via an informed testing program that utilizes, wherever possible, extant data from acceptable studies performed by routes other than inhalation, testing by inhalation and the oral route, and development of pharmacokinetics and mechanistic (PK/MECH) data to support a computational dosimetry model to perform route-to-route extrapolations. Since this is a new approach, EPA and the companies included a program review step within the testing program. The testing program consists of Tier I HAPs Testing; Tier I Program Review Testing; EPA Program Review; and Tier II Testing.

Tier I HAPs Testing consisted of endpoint testing conducted by inhalation exposure for acute and subchronic toxicity. The Tier I Program Review Testing included: (1) Development of a computational dosimetry model specific for TCE in rats and mice; (2) simulation testing of the predictive capability of the model against an inhalation test data set; and (3) demonstration of the model's utility in supporting quantitative route-to-route dosimetry extrapolations. The test sponsors also developed PK/MECH data to support the application of the model to oral-to-inhalation extrapolations of dose-response for extant and Tier II Testing endpoint studies. Tier I HAPs Testing and Tier I Program Review Testing results are available in the legacy docket (OPPTS-42198C) and electronically in the e-Docket (OPPT-2002-0056).

The purpose of the program review was to determine:

1. Whether it is feasible and appropriate to apply Tier I Program Review testing data and data from other studies acceptable to EPA to support computational route-to-route extrapolations for endpoints listed in the Tier II testing segment of the ECA.

2. Whether the data from the Tier I Program Review testing segment provide a sufficient basis for conducting the endpoint testing and/or the computational route-to-route extrapolations specified in the Tier II testing segment.

3. The nature and scope of any additional work that may be required before Tier II testing and the application of the TCE model for route-to-route extrapolation reporting (e.g., development of additional PK/MECH data, modification to the TCE model).

#### *B. What were the Public Comments on the Tier I Program Review Testing?*

EPA received one public comment from the People for the Ethical Treatment of Animals (PETA). The comment was submitted by PETA and on behalf of themselves, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. PETA's comments were favorable on the use of the alternative approach to address data needs utilizing PBPK modeling which could result in a reduction in the number of animals used in toxicity testing to meet EPA's data needs. Although, PETA also stated their belief that the presently available data base for TCE is sufficiently extensive to characterize the toxicity of TCE, and that no additional testing is necessary, PETA did not include comments regarding the scientific merit of the PK/MECH data or PBPK model development for TCE.

EPA appreciates the expressed support for the application of alternative approaches that incorporate PBPK modeling as a means to address data needs for HAP chemicals. Although, computational approaches are an increasingly important tool for EPA to use in addressing data needs, they must be scientifically defensible and rely on the development of PK/MECH data relevant to the modeling approach. Computational dosimetry modeling approaches need critical empirical data from toxicity studies conducted in a scientifically adequate manner. EPA has concluded that the Tier II testing is necessary in this case. EPA's basis for this decision is presented in previous **Federal Register** notices, cited in Unit II.A.

#### *C. What are the Conclusions of the EPA Program Review?*

EPA has determined that the Tier I Program Review testing and data from other studies acceptable to EPA can support computational route-to-route dosimetry extrapolations for the endpoints listed in the Tier II testing segment of the ECA. More specifically, EPA has concluded that:

1. The PK/MECH data report and Tier I toxicity studies appear to have been conducted in accordance with the protocols and specifications as described in Appendix C of the ECA.

2. The available study records are sufficient to allow an evaluation of the quality of the studies performed.

3. The TCE PBPK model is appropriately chemical-specific, and suitably based on the current understanding of the kinetics of TCE.

4. The species, dose level, exposure regimens, and vehicles used are relevant for the toxicity data that are the object of the Tier II extrapolations.

5. The Tier I Program Review PK/MECH data demonstrated that periodicity was achieved in the studies that support the model.

EPA has also concluded, that the choice of dose metrics for Tier II computational route dosimetry extrapolations should be revised to correlate with Tier I study findings, and that selection of the dosing regimens for Tier II testing could benefit from predictions derived from the PBPK model for TCE. These changes to the original testing and extrapolation reporting are described in the revised Table 1 (Table 1. (amended)) of this **Federal Register** notice, and will be incorporated into protocol development under Tier II activities. EPA's program review activity, including the findings and conclusions, are described in a report titled: "Program Review Report on the Enforceable Consent Agreement for 1,1,2-Trichloroethane" (U.S. EPA, April 21, 2003). This report is available electronically from the e-Docket OPPT-2002-0056.

It is EPA's decision that the HAP Task Force can proceed with Tier II Testing under the schedule set forth in Table 1. of this **Federal Register** notice. The testing schedule corresponds to that originally set forth in the **Federal Register** notice announcing the ECA and Order for TCE, but is modified to include the additional time needed to complete the Program Review segment of the ECA for TCE, which was longer than originally anticipated, plus additional time for Tier II protocol development. Table 1. also identifies additional modifications to Tier II activities to correlate with Tier I study findings. EPA does not consider these modifications of the test schedules or Tier II activities to be significant.

#### *D. What are the Modifications to the ECA for TCE?*

This **Federal Register** notice incorporates modifications to the ECA for the TCE test schedule for Tier II ECA activities, clarifies protocol development for Tier II testing, expands consideration for dose metrics to be applied in the Tier II route dosimetry extrapolations and reporting, and identifies a change in signatory companies to the ECA. The testing schedule corresponds to that originally set forth in the **Federal Register** notice announcing the ECA and Order for TCE, but is modified to allow for the time needed to perform the EPA Program Review, which was longer than

anticipated. Additional time was also included in the schedule for Tier II testing protocol development. Footnotes in Table 1. have been revised to address refinements in Tier II protocol development and extrapolation reporting changes identified as modification to Appendix C.5 (General

Outline for Route-to-Route Extrapolation Reporting) to correlate with Tier I study findings. Finally, one of the signatory companies to the ECA, Borden Chemicals and Plastics Operating Limited Partnership, is no longer a participant in the ECA, due to bankruptcy. The remaining companies

that are signatories of the ECA for TCE have agreed to assume the responsibilities for this change in membership to the HAP Task Force. EPA does not consider these modifications to be significant.

TABLE 1. (AMENDED)—REQUIRED TESTING, TEST STANDARDS, REPORTING AND OTHER REQUIREMENTS FOR 1,1,2-TRICHLOROETHANE

Testing Segment	Required Testing	Test Standard	Deadline for Final Report <sup>1</sup> (Months)
Tier II Testing and/or Extrapolation Reporting	Acute neurotoxicity (drinking water)	§ 799.9620 (as annotated in ECA Appendix D.3)	12
	Acute neurotoxicity route-to-route extrapolation of Tier II drinking water acute neurotoxicity data to inhalation <sup>2</sup>	ECA Appendix C	14
	Subchronic neurotoxicity (drinking water)	§ 799.9620 (as annotated in ECA Appendix D.3)	18
	Subchronic neurotoxicity route-to-route extrapolation of Tier II drinking water subchronic neurotoxicity data to inhalation <sup>2</sup>	ECA Appendix C	21
	Developmental toxicity (drinking water)	§ 799.9370 (as annotated in ECA Appendix D.4)	24
	Developmental toxicity route-to-route extrapolation of Tier II drinking water developmental toxicity data to inhalation <sup>3</sup>	ECA Appendix C	27
	Reproductive toxicity (drinking water)	§ 799.9380 (as annotated in ECA Appendix D.5)	30
	Reproductive toxicity route-to-route extrapolation of Tier II drinking water reproductive toxicity data to inhalation <sup>4</sup>	ECA Appendix C	33
	Immunotoxicity (route-to-route extrapolation of extant oral data in ECA Appendix E.2 to inhalation) <sup>5</sup>	ECA Appendix C	9
	Carcinogenicity (route-to-route extrapolation of extant oral data in ECA Appendix E.3 to inhalation) <sup>6</sup>	ECA Appendix C	6

<sup>1</sup>Number of months after the effective date of this Federal Register Notice, which announces that EPA has concluded the EPA Program Review, when the final report is due. In addition, every 6 months from the effective date of the Order until the end of the ECA testing program, interim reports describing the status of all testing to be performed under the ECA for TCE must be submitted by the companies to EPA.

<sup>2</sup>Quantitative route-to-route extrapolations based on the Tier II acute and subchronic drinking water neurotoxicity study data, and developed for each of the following dose metrics: Parent compound in venous blood and brain, as maximum concentration (Cmax) and as the area under the time-concentration curve (AUC), and metabolite, as amount metabolized in the liver or brain per day normalized to organ weight.

<sup>3</sup>Quantitative route-to-route extrapolation based on the Tier II drinking water developmental toxicity study data, and developed for each of the following dose metrics: Parent compound in venous blood, as maximum concentration (Cmax) and as the area under the time-concentration curve (AUC), and metabolite, as amount metabolized in the liver per day normalized to liver weight.

<sup>4</sup>Quantitative route-to-route extrapolation based on the Tier II drinking water reproductive effects toxicity study data, and developed for each of the following dose metrics: Parent compound in venous blood, as maximum concentration (Cmax) and as the area under the time-concentration curve (AUC), and metabolite, as amount metabolized in the liver per day normalized to liver weight.

<sup>5</sup>Quantitative route-to-route extrapolation based on the PK/MECH data developed under this ECA and the data of Sanders et al. (1985), and developed for each of the following dose metrics: parent compound in venous blood and spleen, as maximum concentration (Cmax) and as the area under the time-concentration curve (AUC), and metabolite, as amount metabolized in the liver or spleen per day normalized to organ weight.

<sup>6</sup>Quantitative route-to-route extrapolation based on the PK/MECH data developed under this ECA and the data of NCI (1978), and developed for each of the following dose metrics: parent compound in venous blood and liver, as maximum concentration (Cmax) and as the area under the time-concentration curve (AUC), and metabolite, as amount metabolized in the liver per day normalized to liver weight.

**List of Subjects**

Environmental protection, Hazardous chemicals.

Dated: June 26, 2003.

**Philip S. Oshida,**

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

[FR Doc. 03-16927 Filed 7-8-03; 8:45 am]

**BILLING CODE 6560-50-S**

**FEDERAL COMMUNICATIONS COMMISSION****Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested**

June 27, 2003.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

**DATES:** Written comments should be submitted on or before September 8, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all Paperwork Reduction Act (PRA) comments to Judith B. Herman, Federal Communications Commission, Room 1-C804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov*.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection(s), contact Judith B. Herman at 202-418-0214 or via the Internet at *Judith-B.Herman@fcc.gov*.

**SUPPLEMENTARY INFORMATION:**

*OMB Control No.:* 3060-0800.

*Title:* FCC Wireless

Telecommunications Bureau  
Application for Assignment of  
Authorization and Transfers of Control.

*Form No.:* FCC Form 603.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Individuals or households, business or other for-profit, not-for-profit institutions, state, local or tribal government.

*Number of Respondents:* 32,151.

*Estimated Time Per Response:* 1.75 hours.

*Frequency of Response:* On occasion reporting requirement.

*Total Annual Burden:* 36,171 hours.

*Total Annual Cost:* \$7,073,000.

*Needs and Uses:* FCC Form 603 is a multi-purpose form used to apply for approval of assignment or transfer of control of licenses in the Wireless Radio Services. The data collected on this form is used by the FCC to determine whether the public interest would be served by approval of the requested assignment or transfer. This form is also used to notify the Commission of consummated assignments and transfers of wireless licenses that have previously been consented to by the Commission or for which notification but not prior consent is required. This form is used by applicants/licensees in the Public Mobile Services, Personal Communications Services, Private Land Mobile Radio Services, Broadcast Auxiliary Services, Fixed Microwave Services, Maritime Services (excluding ships) and Aviation Services (excluding aircraft).

The purpose of the form is to obtain information sufficient to identify the parties to the proposed assignment or transfer, establish the parties basic eligibility and qualifications, classify the filing, and determine the nature of the proposed service. Various technical schedules are required along with the main form applicable to Auctioned Services, Partitioning and Disaggregation, Undefined Geographical Area Partitioning, Notification of Consummation or Request for Extension of Time for Consummation.

The form is being revised to accommodate Promoting Efficient Use of Spectrum Through Elimination of Barriers to the Development of Secondary Markets; additional questions concerning the foreign

ownership; and clarifying existing instructions for the general public as noted in the Communications Act of 1934, Section 310(b)(4). There is no change to the estimated average burden or number of respondents.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

[FR Doc. 03-17337 Filed 7-8-03; 8:45 am]

**BILLING CODE 6712-01-P**

**FEDERAL COMMUNICATIONS COMMISSION**

[DA 03-1812]

**The International Bureau Revises and Reissues the Commission's List of Foreign Telecommunications Carriers That Are Presumed To Possess Market Power in Foreign Telecommunications Markets**

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice.

**SUMMARY:** In this document, the Commission revises and reissues its list of foreign telecommunications carriers that are presumed to possess market power in foreign telecommunications markets. Several Commission rules incorporate this list by reference. Recently the Commission updated these rules. In addition, carriers' names have changed as a result of a divestiture of national incumbent operators into regional operators. Thus, it was necessary for the Commission to revise and reissue the public notice.

**FOR FURTHER INFORMATION CONTACT:** Peggy Reitzel, Policy Division, International Bureau, (202) 418-1460.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Public Notice released June 5, 2003. By this Public Notice, the International Bureau revises and reissues the Commission's "List of Foreign Telecommunications Carriers that Are Presumed to Possess Market Power in Foreign Telecommunications Markets." The revised list of carriers reflects any corrections to carrier names that were incorrect or new names now used by the carriers since this public notice was initially released in 1999. This corrected list is identical to the list previously released, except for name changes that occurred as a result of a divestiture of national incumbent operators into regional operators. While the Commission's staff attempts to maintain current information as to the names of carriers on this list, we encourage interested parties to advise the