

which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold, or used legally until they are exhausted, provided that such further sale and use comply with the EPA approved label and labeling of the affected product. Exception to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in a Special Review action, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

#### List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 30, 2002.

**Lind Vlier Moos,**

*Acting Director, Information Resources Services Division, Office of Pesticide Programs.*

[FR Doc. 02-26177 Filed 10-15-02; 8:45 am]

BILLING CODE 6560-50-S

### ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0056; FRL-7275-8]

#### 1,1,2-Trichloroethane Tier I Program Review Testing; Notice of Availability and Solicitation of Comment

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

**ACTION:** Notice.

**SUMMARY:** Under section 4 of the Toxic Substances Control Act (TSCA), EPA issued a testing consent order that incorporated an enforceable consent agreement (ECA) relating to 1,1,2-trichloroethane (TCE). The companies subject to this ECA agreed to conduct toxicity testing, develop a computational dosimetry model for route-to-route extrapolations, and develop pharmacokinetics and mechanistic testing 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 chemicals. This notice announces that EPA is starting the Program Review component of the TCE ECA alternative testing program, and solicits comment on data received under the Tier I Program Review testing segment of the TCE ECA. Comments are expected to inform EPA's decision on whether or

not additional data and/or model development are needed before Tier II testing and computational dosimetry modeling for route-to-route extrapolations proceed for the Tier II endpoints listed in the TCE ECA.

**DATES:** Comments, identified by docket ID number OPPT-2002-0056, must be received on or before November 15, 2002.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact:* Barbara Cunningham, Acting 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 about EPA's Program Review contact:* Richard Leukroth or John Schaeffer, 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 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 technical person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Copies of this Document or Other Related Documents?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT-2002-0056. OPPT-2002-0056 is the continuation docket for the TCE ECA which originated under OPPTS Docket Number 42198. 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 whose 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 Avenue, 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 the telephone number for the OPPT Docket, which is located in the 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/fedrgstr/>.

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.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. 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. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information for which disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

### C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA

will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPPT-2002-0056. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov), Attention: Docket ID Number OPPT-2002-0056. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. The disk or CD must be labeled: Attention: Docket ID Number OPPT-2002-0056. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Attention: Docket ID Number OPPT-2002-0056, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *By hand delivery or courier.* Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Building Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT-2002-0056. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the DCO is (202) 564-8930.

### D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

### E. What Should I Consider as I Prepare My Comments for EPA?

EPA invites interested parties to provide views on the Companies' Tier I Program Review testing reports titled: "Pharmacokinetics of 1,1,2-Trichloroethane in Rats and Mice" and "Physiologically Based Pharmacokinetic Model Development, Simulations, and Sensitivity Analysis for Repeated Exposure to 1,1,2-Trichloroethane." These reports describe a dosimetry model for route-to-route extrapolation and development of pharmacokinetics and mechanistic testing data (PK/MECH data) that will support the use of this model for quantitative route-to-route extrapolations specific to endpoints listed under Tier II of the TCE ECA. The model and PK/MECH data described in these reports, if deemed acceptable to EPA, will be applied to support the TCE ECA Tier II testing and computational dosimetry model extrapolation reporting called for under Tier II of the TCE ECA. EPA is interested in comments on the PK/MECH data, the TCE computational dosimetry model for route-to-route extrapolation, and the utility of resulting derived computational data from the TCE dosimetry model that will

be developed under Tier II of the TCE ECA. Additionally, EPA is interested in receipt of any data or information for the Agency to consider during development of EPA's Program Review of the TCE ECA alternative testing program with regard to approaches not considered as well as potential impacts of the various options (including possible unintended consequences).

You may find the following suggestions helpful in preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the science.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Background

### A. Why is EPA Requiring Health Effects Testing on TCE?

EPA proposed health effects testing under TSCA section 4(a) for a number of hazardous air pollutants ("HAPs" or "HAP chemicals"), including TCE in the **Federal Register** of June 26, 1996 (61 FR 33178) (FRL-4869-1), as amended in the **Federal Register** of December 24, 1997 (62 FR 67466) (FRL-5742-2), and April 21, 1998 (63 FR 19694) (FRL-5780-6). EPA's primary use of the data from this testing activity will be to implement several provisions of section 112 of the Clean Air Act (CAA), including determining residual risks (e.g., assessing risks remaining after imposition of technology-based emission standards (maximum achievable control technology or "MACT" standards)), estimating risks associated with accidental chemical releases, and determining whether or not subject chemicals should be removed ("delisted") from the CAA section 112(b) HAPs list. Other important uses of the data obtained via this testing activity will be to: (1) Help in better informing communities and citizens about chemical hazards in their own localities; (2) assist state and local

permitting authorities with establishing appropriate standards within their programs; and (3) help other EPA Program Offices and other Federal agencies (e.g., the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC)) in assessing chemical risks and taking appropriate action(s) within their own programs and under the Federal statutes that they administer.

### B. How is EPA Obtaining Health Effects Testing on TCE?

In the proposed HAPs test rule, as amended, EPA identified the following testing needs for TCE: Acute toxicity, subchronic toxicity, developmental toxicity, reproductive toxicity, neurotoxicity, carcinogenicity, *in vivo* cytogenetics, and immunotoxicity to be conducted by the inhalation route of exposure.

EPA also invited the submission of proposals regarding the performance of pharmacokinetics studies which would permit extrapolation from oral data to predict risk from inhalation exposure. Such proposals could provide the scientific basis for alternative testing to the testing proposed and form the basis for developing needed HAPs data via ECAs (61 FR 33178, June 26, 1996; 62 FR 67466, December 24, 1997). EPA uses ECAs to accomplish testing where a consensus is reached concerning the need for and scope of testing. The procedures for ECA negotiations are described at 40 CFR 790.22(b).

In response to EPA's request for ECA proposals, the Dow Chemical Company; Vulcan Materials Company; Occidental Chemical Corporation; Oxy Vinyls, LP; Georgia Gulf Corporation; Westlake Chemical Corporation; PPG Industries, Inc.; Borden Chemicals and Plastics Operating Limited Partnership; and Formosa Plastics Corporation, U.S.A. ("the Companies"), under the auspices of the HAP Task Force, submitted a proposal for alternative testing of TCE that included physiologically based pharmacokinetics (PBPK) and model development to support route-to-route extrapolation of extant studies acceptable to EPA and new testing to be conducted by the oral route (Ref. 1). On December 19, 1997, EPA announced the initiation of ECA discussions to develop an acceptable alternative testing program for TCE and solicited the involvement of interested parties (62 FR 66628) (FRL-5632-2). These discussions resulted in an ECA for TCE which was announced in the **Federal**

**Register** of June 15, 2000 (65 FR 37550) (FRL-6494-5). Under the TCE ECA alternative testing program (Ref. 2), these HAPs data needs 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 PK/MECH data to support a computational dosimetry model to perform route-to-route extrapolations. The official public docket for the development of the TCE ECA is established under docket control number OPPTS-42198B, while the official public docket for the receipt of data under the TCE ECA is established under docket ID number OPPT-2002-0056 (which is the continuation of OPPTS-42198B).

### C. What Testing Does the ECA for TCE Require?

The TCE ECA alternative testing program has four segments, as follows: Tier I HAPs testing; Tier I Program Review testing; EPA Program Review; and Tier II testing.

1. *Tier I HAPs testing.* This testing consisted of the following endpoint testing, conducted by inhalation exposure, that EPA deemed necessary to meet certain data needs identified in the proposed HAPs test rule: Acute and subchronic toxicity. In addition, EPA determined that existing cytogenicity studies conducted by Mazzulo *et al.* (1986) and Doherty *et al.* (1996) were adequate at this time to characterize the mutagenicity of TCE (Refs. 3 and 4).

2. *Tier I Program Review testing.* Under this segment of the TCE ECA alternative testing program, the test sponsor is to develop a computational dosimetry model, specific to TCE, for rats and mice, validate the model, and verify the model's ability to perform quantitative route-to-route extrapolations.

In addition, the test sponsor is to develop PK/MECH data to support the application of the model for the endpoints listed in Tier II of the TCE ECA. Model development and data from this testing are subject to the EPA Program Review. Specifically, the PK/MECH data will be applied to support: (1) Oral-to-inhalation extrapolation of existing immunotoxicity data in mice administered TCE via drinking water (Ref. 5); (2) oral-to-inhalation extrapolation of existing oral cancer bioassay data in mice administered TCE via corn oil gavage (Ref. 6); and (3) model simulations to demonstrate validation and verification of computational PBPK models for route-to-route extrapolation in order to

evaluate acceptability of oral drinking water exposure in rats for neurotoxicity testing, oral drinking water exposure in rats and mice for developmental toxicity testing, and oral drinking water exposure in rats for reproductive toxicity testing.

3. *EPA Program Review.* The use of PK/MECH data and computational dosimetry modeling to support route-to-route extrapolation is a new approach for EPA's Office of Pollution Prevention and Toxics under the TSCA section 4 chemical testing program. It is essential to the success of the TCE ECA alternative testing program for EPA to ensure that the model and the PK/MECH data used to support the route-to-route extrapolations are of the highest quality. For this reason, a Program Review requirement was incorporated into the TCE ECA.

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

4. *Tier II testing.* This segment of the TCE ECA alternative testing program consists of endpoint testing by oral exposure for neurotoxicity, developmental toxicity and reproductive toxicity. This segment also includes application of the TCE model for quantitative route-to-route extrapolation reporting (oral to inhalation) for Tier II endpoint testing (neurotoxicity, developmental toxicity, reproductive toxicity) and similar computational extrapolation reporting for certain extant studies for immunotoxicity (Ref. 5) and carcinogenicity (Ref. 6).

### III. Next Steps

#### *A. What is the Status of the Testing Program Developed in the ECA for TCE?*

Tier I HAPs testing for TCE is completed and reports for Tier I Program Review testing have been submitted by the Companies. Receipt of

these submissions was announced in **Federal Register** notices of April 10, 2002 (67 FR 17429) (FRL-6831-5); April 12, 2002 (67 FR 17996) (FRL-6831-4); and August 14, 2002 (67 FR 53001) (FRL-7193-1) and are available in the EPA Docket Center (OPPTS-2002-0056). As described in Unit II.C.3., and stated in Part VI. of the TCE ECA, the next step is for EPA to conduct a Program Review on the data collected from the Tier I Program Review testing segment of the TCE ECA alternative testing program. The outcome from this EPA review will determine whether or not additional PK/MECH data and/or model development are needed before Tier II testing and computational dosimetry model reporting for route-to-route extrapolations of Tier II endpoints can proceed as described in the TCE ECA.

#### *B. Is there an Opportunity for Public Participation in EPA's Program Review?*

This notice of availability and request for comments on the Companies' Tier I Program Review testing reports titled: "Pharmacokinetics of 1,1,2-Trichloroethane in Rats and Mice" and "Physiologically Based Pharmacokinetic Model Development, Simulations, and Sensitivity Analysis for Repeated Exposure to 1,1,2-Trichloroethane" provides an opportunity for public participation in the EPA Program Review of the TCE ECA. A description of EPA's objectives in conducting the Program Review for the TCE ECA alternative testing program is provided in Unit II.C.3.

#### *C. What Happens at the Conclusion of EPA's Program Review?*

A description of the possible outcomes of the EPA Program Review is provided in Part VII. of the TCE ECA document (Ref. 2). Following the EPA Program Review, EPA will place in the official public docket for this action (under docket ID number OPPTS-2002-0056) a copy of each comment received, and a copy of the letter informing the HAP Task Force of the outcome from EPA's Program Review.

### IV. References

The official public docket for this action contains the following information:

1. The HAP Task Force. Letter from Peter E. Voytek to Charles M. Auer with attachment titled: Proposal for Pharmacokinetics Study of 1,1,2-Trichloroethane, November 22, 1996. (Available from docket control number OPPTS-42187B.)
2. U.S. EPA, Enforceable Consent Agreement for 1,1,2-Trichloroethane.

September 30, 1999. (CAS No. 79-00-5) (Available from docket control number OPPTS-42198B.)

3. Mazzulo, M., Colacci, A., Grilli, S., Prodi, G., and Arfellini, G. 1,1,2-Trichloroethane: evidence of genotoxicity from short-term tests. *Japanese Journal of Cancer Research.* 77:532-539. 1986.

4. Doherty, A.T., Ellard, S., Parry, E.M., and Parry, J.M. An investigation into the activation and deactivation of chlorinated hydrocarbons to genotoxins in metabolically competent human cells. *Mutagenesis.* 11(3):247-274. 1996.

5. Sanders, V.M., White, Jr., K.L., Shopp, Jr., G.M., and Musson, A.E. Humoral and cell-mediated immune status of mice exposed to 1,1,2-trichloroethane. *Drug and Chemical Toxicology.* 8(5):357-372. 1985.

6. National Cancer Institute (NCI). Bioassay of 1,1,2-trichloroethane for possible carcinogenicity. Carcinogenesis: Technical Report Series No. 74. U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health. 1978.

### List of Subjects

Environmental protection, Hazardous chemicals.

Dated: October 8, 2002.

**Wardner G. Penberthy,**

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

[FR Doc. 02-26308 Filed 10-15-02; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0064; FRL-7277-8]

### Approval of Modifications to Test Marketing Exemption for a Certain Chemical

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

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's approval of modifications of the test marketing period for a test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA). EPA designated the original test marketing application as TME-02-0006. The test marketing conditions are described in this notice.

**DATES:** This notice is effective October 7, 2002.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact:* Barbara Cunningham, Acting Director,