

("CERCLA"), 42 U.S.C. 9601 *et seq.*, notice is hereby given that a proposed Agreement and Covenant Not to Sue associated with the San Fernando Valley Pollock Superfund was executed by EPA on April 7, 2000. The proposed Agreement and Covenant Not to Sue would resolve certain potential claims of the United States under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, against San Fernando Road Holdings, LLC. (the "Purchaser"). The Purchaser has acquired certain real property located at 3332-3340, 3360, 3368, 3370, 3380, 3424 and 3550 San Fernando Road in the City of Los Angeles, California ("the Property"). The Property consists of approximately 21.48 acres, which is improved with eight industrial warehouse buildings. The proposed settlement would require the Purchaser to pay EPA a one-time payment of \$ 200,000, and to conduct cleanup activities at the Property under the direction of the Regional Water Quality Control Board—Los Angeles Region.

For thirty (30) calendar days following the date of publication of this notice, EPA will receive written comments relating to the proposed settlement. EPA's response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105.

DATES: Comments must be submitted on or before July 17, 2000.

Availability

The proposed Agreement and Covenant Not to Sue and additional background documentation relating to the settlement are available for public inspection at the U.S. EPA, Region IX, 75 Hawthorne Street, San Francisco, CA, 94105. A copy of the proposed settlement may be obtained from Marie M. Rongone, Senior Counsel (ORC-3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA, 94105. Comments should reference "San Fernando Road Holdings, LLC Agreement and Covenant Not to Sue, San Fernando Valley Pollock Superfund Site," and "Docket No. 2000-04" and should be addressed to Ms. Rongone at the above address.

FOR FURTHER INFORMATION CONTACT: Marie M. Rongone, Senior Counsel (ORC-3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; E-mail: rongone.marie@epamail.epa.gov; Phone: (415) 744-1313; Facsimile (415) 744-1041.

Dated: May 9, 2000.

Keith Takata,

Director, Superfund Division, U.S. EPA,
Region IX.

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ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-42198C; FRL-6494-5]

1,1,2-Trichloroethane (TCE); Final Enforceable Consent Agreement and Testing Consent Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Under section 4 of the Toxic Substances Control Act (TSCA), EPA has issued a testing consent order (Order) that incorporates an enforceable consent agreement (ECA) with The Dow Chemical Company; Vulcan Materials Company; Occidental Chemical Corporation; Oxy Vinyls, LP; Georgia Gulf Corporation; Westlake Chemical Corporation; PPG Industries, Inc.; Borden Chemicals & Plastics Operating Limited Partnership; and Formosa Plastics Corporation, U.S.A. ("the Companies"). The Companies have agreed to perform toxicity testing and physiologically based pharmacokinetics (PBPK) and mechanistic (MECH) testing that is intended to satisfy the toxicological data needs identified in a proposed test rule for acute toxicity, subchronic toxicity, developmental toxicity, reproductive toxicity, neurotoxicity, carcinogenicity, *in vivo* cytogenetics, and immunotoxicity effects of 1,1,2-trichloroethane (TCE). This notice announces the ECA and Order for TCE and summarizes the terms of the ECA.

DATES: The effective date of the ECA and Order is June 15, 2000.

FOR FURTHER INFORMATION CONTACT: For general information contact: Barbara Cunningham, Director, Office of Program Management and Evaluation, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For specific information contact: John Schaeffer, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260-8130; fax: (202) 260-1096; e-mail address: ccd.citb@epa.gov.

SUPPLEMENTARY INFORMATION: This notice announces the ECA and Order for TCE and summarizes the terms of the ECA.

I. General Information

A. Does this Action Apply to Me?

The ECA and Order announced in this notice only affect those companies that signed the ECA for TCE: The Dow Chemical Company; Vulcan Materials Company; Occidental Chemical Corporation; Oxy Vinyls, LP; Georgia Gulf Corporation; Westlake Chemical Corporation; PPG Industries, Inc.; Borden Chemicals & Plastics Operating Limited Partnership; and Formosa Plastics Corporation, U.S.A. The Companies are members of the HAP Task Force, which is an association of manufacturers of TCE. However, as a result of the ECA and Order, EPA has initiated a rulemaking in the **Federal Register** of December 23, 1997 (62 FR 67036) (FRL-5762-9) under TSCA section 12(b)(1) which, when finalized, will require all persons who export or intend to export TCE to comply with the Agency's export notification regulations at 40 CFR part 707, subpart D.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS-42198C. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during

an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260-7099.

II. Background

A. What Is TCE?

TCE is used as a feedstock intermediate in the production of vinylidene chloride and some tetrachloroethanes (Ref. 1). It is used as a solvent where its high solvency for chlorinated rubbers and other substances is needed, and for pharmaceuticals and electronic components. An estimated 1,036 workers are exposed to TCE. The Chemical Abstract Service (CAS) Registry number for TCE is 79-00-5.

B. 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 "HAPs 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). In the HAPs proposal, the Agency made preliminary findings for TCE that:

1. TCE may present an unreasonable risk of injury to health.
2. TCE is or will be produced in substantial quantities, and there is or may be substantial human exposure to the chemical.
3. There are insufficient data to determine or predict the effects of activities on human health involving TCE.
4. Testing is necessary to develop health effects data for TCE.

See the **Federal Register** of June 26, 1996 (61 FR 33178, 33190, and 33193) (FRL-4869-1). See also Ref. 1.

The HAPs rule proposed testing of TCE for acute toxicity, subchronic toxicity, developmental toxicity, reproductive toxicity, neurotoxicity, carcinogenicity, *in vivo* cytogenetics, and immunotoxicity. See the **Federal Register** of June 26, 1996 (61 FR 33178 and 33197) (FRL-4869-1) and December 24, 1997 (62 FR 67466 and 67482) (FRL-5742-2).

III. ECA Development and Conclusion

A. How is EPA Going to Obtain Health Effects Testing on TCE?

In the proposed HAPs test rule, as amended, EPA invited the submission of proposals for pharmacokinetics (PK) studies for the HAPs chemicals, which could provide the scientific basis for alternative testing to the testing proposed and could provide the basis for negotiation of ECAs. See the **Federal Register** of June 26, 1996 (61 FR 33178 and 33189) (FRL-4869-1) and December 24, 1997 (62 FR 67466 and 67474) (FRL-5742-2). EPA uses ECAs to accomplish testing where a consensus is reached concerning the need for and scope of testing. The procedures for ECA negotiations and the criteria for determining whether a consensus exists are described at 40 CFR 790.22 and 40 CFR 790.24, respectively.

In response to EPA's request for proposals for ECAs, the HAP Task Force submitted a proposal for alternative testing involving PK studies for TCE on November 22, 1996 (Ref. 2). EPA responded to this proposal by letter on June 26, 1997 (Ref. 3), indicating that this approach could offer sufficient merit to proceed with ECA negotiations. As a result of the response of the HAP Task Force on December 12, 1997 (Ref. 4) to EPA's letter, EPA decided to proceed with ECA negotiations for TCE. Consequently, EPA published a document in the **Federal Register** of December 19, 1997 (62 FR 66628) (FRL-5763-2) soliciting interested parties to monitor or participate in these negotiations.

EPA held a public meeting to negotiate an ECA for TCE on January 12, 1998. The participants reached agreement on the general scope of the testing to be required under the ECA, and the HAP Task Force submitted a revised proposal for a testing program on February 27, 1998, which EPA responded to on September 24, 1998 (Refs. 5,6). A final version of the ECA was circulated to the HAP Task Force and returned to EPA for signature. On June 7, 2000, EPA signed the ECA and accompanying Order (Ref. 7).

B. What Testing Does the ECA for TCE Require?

As described in Table 1 of this unit, this ECA requires the following testing:

1. Tier I HAPs Testing (taken from the proposed HAPs test rule, as amended): Acute and subchronic toxicity by the inhalation route of exposure.
2. Tier I Program Review Testing: The development of PK/MECH data to inform route-to-route extrapolation of data from studies acceptable to EPA that

were performed by a route other than inhalation and, also, the development and application of PBPK model simulations. The PK/MECH data and PBPK modeling will be subject to program review by EPA to confirm the validity of the oral-to-inhalation extrapolations. This testing relates to the following endpoints: Neurotoxicity, developmental toxicity, and reproductive toxicity (in the rat); and developmental toxicity, immunotoxicity, and carcinogenicity (in the mouse).

3. Tier II Testing and/or Extrapolation Reporting:

- i. Acute neurotoxicity, subchronic neurotoxicity, developmental toxicity, and reproductive toxicity testing by the oral route of exposure.
- ii. Route-to-route extrapolation to the inhalation route for these acute neurotoxicity, subchronic neurotoxicity, developmental toxicity, and reproductive toxicity studies, as well as for the extant immunotoxicity and carcinogenicity studies which were also conducted by the oral route of administration (Refs. 8,9).

This testing will allow EPA to characterize certain potential health hazards resulting from inhalation exposure to TCE. Table 1 of this unit sets forth the required testing, test standards, and reporting requirements under the ECA for TCE.

In addition, EPA recognizes the concerns that have been expressed about animal testing. In this ECA, every effort is made to avoid unnecessary or duplicative testing. EPA supports the goals developed by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (<http://iccvam.niehs.nih.gov/home.htm>) to:

1. Encourage the reduction of the number of animals used in testing.
2. Seek opportunities to replace test methods requiring animals with alternative test methods when acceptable alternative methods are available.
3. Refine existing test methods to optimize animal use when there is no substitute for animal testing. EPA considers these goals to be important elements in developing health effects data for conducting scientifically sound chemical risk assessments. Thus, where testing must be conducted to develop adequate data, the Agency is committed to reducing the number of animals used for testing, including, whenever possible, by incorporating *in vitro* (non-animal) test methods or other alternative approaches that have been scientifically validated and have received regulatory acceptance. In addition, in this ECA,

which involves development of PBPK/MECH data, the subsequent route-to-

route extrapolations to existing data should result in the use of fewer test

animals as compared to developing all new data by the inhalation route.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR TCE

Testing segment	Required testing	Test standard	Deadline for final report ¹ (months)
Tier I HAPs Testing ...	Acute toxicity (inhalation)	40 CFR 799.9135 (as annotated in ECA Appendix D.1)	15
	Subchronic toxicity (inhalation)	40 CFR 799.9346 (as annotated in ECA Appendix D.2)	24
Tier I Program Review Testing.	PK/MECH data to support model validation and verification of oral-to-inhalation extrapolation for the following data needs in the F344 rat: a. Neurotoxicity b. Developmental toxicity c. Reproductive toxicity	ECA Appendix C (1–3)	15
	PK/MECH data to support model development, validation, and verification of oral-to-inhalation extrapolation for the following data needs in the mouse: a. Developmental toxicity b. Immunotoxicity c. Carcinogenicity	ECA Appendix C (1–3)	15
	PBPK model simulations	ECA Appendix C (1–5)	24
Tier II Testing and/or Extrapolation Reporting.	Acute neurotoxicity (oral)	40 CFR 799.9620 (as annotated in ECA Appendix D.3)	36
	Acute neurotoxicity extrapolation of oral data to inhalation.	ECA Appendix C	39
	Subchronic neurotoxicity (oral)	40 CFR 799.9620 (as annotated in ECA Appendix D.3)	42
	Subchronic neurotoxicity extrapolation of oral data to inhalation.	ECA Appendix C	45
	Developmental toxicity (oral)	40 CFR 799.9370 (as annotated in ECA Appendix D.4)	48
	Developmental toxicity extrapolation of oral data to inhalation.	ECA Appendix C	51
	Reproductive toxicity (oral)	40 CFR 799.9380 (as annotated in ECA Appendix D.5)	54
	Reproductive toxicity extrapolation of oral data to inhalation.	ECA Appendix C	57
	Immunotoxicity extrapolation of extant oral data in ECA Appendix E.2 to inhalation.	ECA Appendix C	33
	Carcinogenicity extrapolation of extant oral data in ECA Appendix E.3 to inhalation.	ECA Appendix C	30

¹Number of months after the effective date of the Order that incorporates this ECA 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 this ECA must be submitted by the Companies to EPA.

C. What are the Uses for the Test Data for TCE?

EPA will 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 will also be used by 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 in taking appropriate actions within their programs. See the proposed HAPs test rule published in the **Federal Register** of June 26, 1996 (61 FR 33178, 33179) (FRL-4869-1).

D. Does the ECA for TCE Meet all the Testing Requirements for TCE that were Contained in the Proposed HAPs Test Rule, as Amended?

In the proposed HAPs test rule, as amended, EPA required testing of TCE for acute toxicity, subchronic toxicity, developmental toxicity, reproductive toxicity, neurotoxicity, carcinogenicity, *in vivo* cytogenetics, and immunotoxicity by the inhalation route of exposure. The ECA for TCE requires testing for acute and subchronic toxicity

by inhalation, and developmental and reproductive toxicity, and neurotoxicity by oral exposure. This ECA does not require testing for carcinogenicity, immunotoxicity, or *in vivo* cytogenetics. Instead, this ECA is requiring that PK/MECH data and PBPK modeling be developed in order to extrapolate exposure by the oral route to the inhalation route. These extrapolations will be performed on extant data for carcinogenicity and immunotoxicity that have been determined to be acceptable to EPA, as well as data which will be developed under this ECA for developmental and reproductive toxicity and neurotoxicity.

The ECA does not require, and the final HAPs test rule will not require, *in vivo* cytogenetics testing because EPA

considers existing data to be sufficient to fill the testing need identified in the proposed HAPs test rule, as amended. These data include a study by Mazzulo, et al. (1986) demonstrating genotoxicity and a study by Doherty, et al. (1996) demonstrating cytogenicity, which are included as appendices to the ECA (Refs. 10,11). The Tier I HAPs Testing endpoints will not be included in the final HAPs test rule because such testing will be conducted under this ECA. Depending on the results of the EPA Program Review, the Agency anticipates that the balance of the testing for TCE that was identified in the proposed HAPs test rule, as amended, will also not be included in the final HAPs test rule because equivalent testing will be conducted as Tier II Testing and Extrapolation Reporting under this ECA.

The issuance of the ECA and Order constitutes final EPA action for purposes of 5 U.S.C. 704.

E. What if EPA Should Require Additional Testing on TCE?

If EPA decides in the future that it requires additional testing on TCE, the Agency will initiate a separate action.

IV. Other Impacts of the ECA for TCE

The issuance of the ECA and Order under TSCA section 4 subjects the Companies that signed the ECA to export notification requirements under TSCA section 12(b)(1), as set forth at 40 CFR part 707, subpart D, if they export or intend to export TCE.

In the **Federal Register** of December 23, 1997 (62 FR 67036) (FRL-5762-9), EPA proposed to amend 40 CFR 799.5000 by adding TCE to the list of chemicals subject to testing consent orders. The listing of a chemical substance at 40 CFR 799.5000 serves as notification to all persons who export or intend to export the chemical substance that:

1. The chemical substance is the subject of an ECA and Order.
2. EPA's export notification regulations at 40 CFR part 707, subpart D, apply to those exporters who have signed the ECA, as well as those exporters who have not signed the ECA (40 CFR 799.19).

When a final rule based on the proposed rule is published in the **Federal Register**, all persons who export or who intend to export TCE will be subject to export notification requirements.

V. Text of the Testing Consent Order

As indicated in the ECA for TCE, EPA is publishing the text of the Order in this notice. The Order is entitled: "United States Environmental

Protection Agency; Testing Consent Order for 1,1,2-Trichloroethane; Docket No. OPPTS-42198C," and reads as follows:

"Under the authority of section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603, the United States Environmental Protection Agency (EPA) issues this testing consent order (Order) to take effect on the date of publication of the notice in the **Federal Register** announcing the issuance of this Order. This Order incorporates the enforceable consent agreement (ECA) for 1,1,2-Trichloroethane (TCE)."

The Order was signed by Susan H. Wayland, Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances, on June 7, 2000.

VI. Paperwork Reduction Act

The ECA and Order announced in this notice do not contain any information collection requirements that require additional approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements related to test rules and ECAs issued under TSCA section 4 have already been approved by OMB under OMB control number 2070-0033 (EPA ICR No. 1139). The one-time public burden for this collection of information is estimated to be approximately 5,323 hours total. Under the PRA, "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. For this collection it includes the time needed to review instructions; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9.

VII. References

1. United States Environmental Protection Agency (USEPA), OPPT. TSCA Section 4 Findings for 21 Hazardous Air Pollutants: A Supporting Document for Proposed Hazardous Air Pollutants (HAPs) Test Rule. June 25, 1996.
2. The HAP Task Force. Letter from Peter E. Voytek to Charles M. Auer with attachment entitled: Proposal for Pharmacokinetics Study of 1,1,2-Trichloroethane, November 22, 1996. November 22, 1996.

3. USEPA. Letter from Charles M. Auer to Peter E. Voytek with attachment entitled: Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for 1,1,2-Trichloroethane, June, 1997. June 26, 1997.

4. The HAP Task Force. Letter from Peter E. Voytek to Charles M. Auer, USEPA. December 12, 1997.

5. The HAP Task Force. Letter from Peter E. Voytek to Charles M. Auer, USEPA, with enclosure entitled: Considerations for 1,1,2-TCE. February 27, 1998.

6. USEPA. Letter from Charles M. Auer to Peter E. Voytek, HAP Task Force, re: EPA final Position for ECA Development of 1,1,2-Trichloroethane (OPPTS-42198B), with attachment entitled: DRAFT-1,1,2-TCE ECA-9/23/98. September 24, 1998.

7. Final Enforceable Consent Agreement for 1,1,2-Trichloroethane and Accompanying Testing Consent Order, signed by EPA on June 7, 2000.

8. 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.

9. 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.

10. Mazzullo, M., Colaccai, 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.

11. 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.

List of Subjects

Environmental protection, Hazardous chemicals.

Dated: June 7, 2000.

Susan H. Wayland,
Acting Assistant Administrator for
Prevention, Pesticides and Toxic Substances.
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