(Amendment) (Final Rule); in 40 CFR part 1042, subparts C, D, G and H; was approved 07/08/2009; OMB Number 2060–0287; expires 07/31/2012.

EPA ICR Number 1745.06; Criteria for Classification of Solid Waste Disposal Facilities and Practices (Renewal); in 40 CFR part 257, subpart B; was approved 07/10/2009; OMB Number 2050–0154; expires 07/31/2012.

EPA ICR Number 2027.04; NESHAP for Flexible Polyurethane Foam Fabrication (Renewal); in 40 CFR part 63, subpart MMMMM; was approved 07/10/2009; OMB Number 2060–0516; expires 07/31/2012.

EPA ICR Number 2056.03; NESHAP for Miscellaneous Metal Parts and Products (Renewal); in 40 CFR part 63, subpart MMMM; was approved 07/10/2009; OMB Number 2060–0486; expires 07/31/2012.

EPA ICR Number 1656.13; Risk Management Program Requirements and Petitions to Modify the List of Regulated Substances under Section 112(r) of the Clean Air Act (Renewal); in 40 CFR part 68; was approved 07/10/2009; OMB Number 2050–0144; expires 07/31/2012.

EPA ICR Number 2317.01; Generator Standards Applicable to Laboratories Owned by Eligible Academic Entities (Final Rule); in 40 CFR part 262, subpart K; was approved 07/10/2009; OMB Number 2050–0204; expires 07/31/2012.

OMB Comments Filed

EPA ICR Number 2355.01; Restructuring of Stationary Source Audit Program (Proposed Rule); OMB filed comment on 06/30/2009.

EPA ICR Number 1975.06; NESHAP for Stationary Reciprocating Internal Combustion Engines (40 CFR part 63, subpart ZZZZ) (Proposed Rule); OMB filed comment on 07/04/2009.

EPA ICR Number 2348.01; NESHAP for Paints and Allied Products Manufacturing (40 CFR part 63, subpart CCCCCCC) (Proposed Rule); OMB filed comment on 07/07/2009.

EPA ICR Number 2332.01; NESHAP for Aluminum, Copper, and Other Nonferrous Foundries (Proposed Rule); OMB filed comment on 07/10/2009.

Dated: July 16, 2009.

John Moses,

Director, Collection Strategies Division.

[FR Doc. E9–17397 Filed 7–21–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2003–0010; FRL–8426–6]

1,2-Ethylene Dichloride; Completion of EPA Program Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA issued a testing consent order that incorporated an enforceable consent agreement (ECA) for 1,2-Ethylene Dichloride (EDC) in June 2003, using authorities under section 4 of the Toxic Substances Control Act (TSCA). The companies subject to the ECA agreed to conduct toxicity testing in a tiered testing program that included development of pharmacokinetics and mechanistic data and a computational dosimetry model for route-to-route extrapolations. The testing program was designed to satisfy the toxicological data needs for EDC identified in a TSCA section 4 proposed test rule for a number of hazardous air pollutant chemicals. The modeling is intended to allow toxicological studies conducted using oral exposures to be interpreted so that they could also be used to predict the effects of inhalation exposures. This notice announces the completion of the program review component of the ECA for EDC. This notice also states EPA's findings and conclusion regarding the adequacy of the derived models to perform satisfactory route-to-route extrapolations, responds to comments on the Tier I Program Review Testing, and establishes revised deadlines for completion of Tier II testing and computational route-to-route dosimetry modeling for extrapolations listed under Tier II of the ECA for EDC.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, 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: John Schaeffer, Chemical Control Division (7405M), Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8173; e-mail address: *schaeffer.john@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 and Other Related Information?

1. *Docket*. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2003–0010. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

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*.

II. Background

A. What is the EPA Program Review for EDC?

In the **Federal Register** of September 5, 2006 (71 FR 52329) (FRL–8088–3), EPA announced that it was conducting the program review component of the ECA for the EDC alternative testing program, and solicited public comment on data received under the Tier I Program Review testing segment of the ECA for EDC (CAS No. 107–06–2). 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 could proceed for the Tier II endpoints listed in the ECA for EDC. Details of the testing program for EDC are available in the ECA and in the **Federal Register** of June 3, 2003 (68 FR 33125) (FRL–7300–6), in which EPA announced it had entered into an ECA and issued a testing consent order for EDC. The ECA for EDC was developed in response to EPA's request for ECA proposal for health effects testing of a number of hazardous air pollutants (HAPs or HAP chemicals), including EDC (see the proposed test rule in the **Federal Register** of June 26, 1996 (61 FR 33177) (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 the extrapolation of testing administered by other exposure routes, such as the oral route, to predict for inhalation exposures. On November 22, 1996, Dow Chemical Company, Vulcan Materials Company (no longer in existence), Occidental Chemical Corporation, Oxy Vinyls, LP, Georgia Gulf Corporation, Westlake Chemical Corporation, PPG Industries, Inc., and Formosa Plastics Corporation, U.S.A. (the ''Companies''), under the auspices of the HAP Task Force, submitted a proposal for alternative testing of EDC that included physiologically based pharmacokinetics (PBPK) and model development to support route-to-route extrapolation of testing to be conducted under the ECA by the oral route. EPA considered this proposal sufficient to enter into ECA negotiations with the Companies and other interested parties (62 FR 66626; December 19, 1997) (FRL–5763–1). The ECA for EDC that resulted was announced in the **Federal Register** of June 3, 2003 (68 FR 33125). Since the route-to-route extrapolation of test results was 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 toxicity, with bronchoalveolar lavage (BAL) and histopathology, and acute neurotoxicity. The Tier I Program Review Testing consisted of studies to develop PK/MECH data, analyze glutathione metabolism, and perform model simulation. These studies were conducted to extend the computational dosimetry model of D'Souza et al. (1987, 1988; Refs. 1 and 2) to improve the model's application to the specific health effects endpoints for EDC listed in the ECA. The studies also enabled EPA to validate the model and verify the model's ability to adequately perform quantitative route-to-route extrapolations of dose response. Further description of the Tier I HAPs Testing and the Tier I Program Review Testing is provided in the **Federal Register** of September 5, 2006 (71 FR 52329). That notice, as well as the final study reports, can be accessed in the docket (EPA–HQ–OPPT–2003–0010) as explained in Unit I.B.

As specified in the ECA, the EPA program review is required before the Tier II Testing segment is undertaken. In the **Federal Register** of September 5, 2006 (71 FR 52329), EPA announced that it was conducting the program review component of the ECA for EDC, and solicited public comment on data received under the Tier I Program Review Testing segment of the ECA. Comments were to inform EPA's decision on whether or not additional data and/or model development were 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 EDC.

B. What were the Public Comments on the Tier I Program Review Testing for EDC?

EPA received two public comments in response to its solicitation for comments on the Tier I Program Review Testing. Comments from People for the Ethical Treatment of Animals (PETA) were on behalf of themselves and the following organizations: The Physicians' Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. PETA expressed support for the use of PBPK modeling to limit additional animal testing through the use of route-to-route extrapolation to existing studies. However, PETA also stated that they disagreed that additional Tier II tests (i.e., for reproductive effect or subchronic neurotoxicity) are needed; contending that existing studies for these effects are adequate. EPA disagrees, and its basis for requiring this additional testing is discussed in previous **Federal Register** documents, cited in Unit II.A. A second comment, from a private citizen, was focused on opposition to the manufacture of chlorine compounds in general, including EDC, and not the testing program.

C. What are the Conclusions of the EPA Tier I Program Review Testing for EDC?

The companies have completed the Tier I and Tier I Program Review testing segments of the ECA for EDC. The companies have also examined additional PBPK models and other available information in order to more fully update the model developed by D'Souza et al., 1987, 1988; as specified in the ECA agreement. The results of this work, the updated model, and model simulations have been discussed with EPA (Refs. 3 through 6) and have also been recently published as a peer-reviewed article in the scientific literature (Ref. 7). It is EPA's conclusion that the PBPK model developed by the test sponsors under the EDC ECA is acceptable for route-to-route extrapolations and that Tier II testing and extrapolation reporting can proceed as per the schedule set forth below (Ref. 8). Specifically, EPA concludes that:

1. The PK/MECH data report and Tier I toxicity studies 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 EDC PBPK model is appropriately chemical-specific, and suitably based on the current understanding of the kinetics of EDC.

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, along with additional data, show that periodicity was demonstrated and that the various data sets bearing on the issue of periodicity can be properly

interpreted and managed in the studies that support the model.

6. Refinements of the model related to absorption, tissue distribution, and metabolism were accomplished, or suitably explained, including the role of extrahepatic metabolism as it impacts the model dose metrics and route-to-route extrapolation; appreciably improving prior PBPK models of EDC.

It is EPA's decision that the HAP Task Force can proceed with the Tier II Testing under the schedule set forth in Table 1. of this **Federal Register** document.

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

Testing segment	Required testing	Test standard	Deadline for final report[1] (months)
.			
Tier II testing and/or extrapolation reporting	Subchronic toxicity route-to-route extrapolation of dose-response (oral Tier II testing to inhalation) of a study reported by Daniel, et al., (1994)	ECA appendix C.2 and C.6	12
.	Subchronic neurotoxicity (oral)	40 CFR 799.9620 (as annotated in ECA appendix D.2)	18
.	Subchronic neurotoxicity route-to-route extrapolation of dose-response (oral Tier II testing to inhalation)	ECA appendix C.3 and C.6	21
.	Reproductive toxicity (oral)	40 CFR 799.9380 (as annotated in ECA appendix D.3)	25
.	Reproductive toxicity route-to-route extrapolation of dose-response (oral data to inhalation, including Tier II testing and extant studies reported by Alumot, et al., (1976), Rao, et al., (1980), and Lane, et al., (1982))	ECA appendix C.4 and C.6	28

[1]Number of months after the date of publication of this **Federal Register** document, 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 this ECA must be submitted by the Companies to EPA.

III. References

1. D'Souza, R.W., Francis, W.R., Bruce R.D., and Andersen, M.E. Physiologically based pharmacokinetic model for ethylene dichloride and its application in risk assessment. P. 286–301, In: Pharmacokinetics in Risk Assessment. National Academy Press. Washington, D.C. (1987).

2. D'Souza, R.W., Francis, W.R., and Andersen, M.E. Physiological model for tissue glutathione depletion and increased resynthesis after ethylene dichloride exposure. Journal of Pharmacology and Experimental Therapeutics. 245(2):563–568. (1988).

3. EPA, Office of Prevention, Pesticides and Toxic Substances, Chemical Control Division. Letter from Jim Willis, Director, CCD to Dr. Peter Voytek, HAP Task Force. RE: EPA Tier I Program Review for EDC. January 10, 2007.

4. EPA and HAP Task Force. Technical Consultation Meeting on 1, 2-Ethylene Dichloride Program Review. February 12, 2007.

5. HAP Task Force. Letter from Peter E. Voytek, Manager, HAP Task Force to Jim Willis, Director, Chemical Control Division, Office of Pollution Prevention and Toxics, with Enclosure: Response to Issues Raised in EPA's Tier 1 Data Evaluation Meeting. May 23, 2007.

6. Sweeny, L. M. and Gargas, M.I. Physiologically based pharmacokinetic model development and simulations for ethylene dichloride (1,2-dichlorethane) in rats. Prepared by the Sapphire Group, Dayton Ohio for the HAP Task Force, Millwood, Virginia. Revised Draft Report. March 11, 2009.

7. Sweeny, L. M., Saghir, S. A., and Gargas, M.I. Physiologically based pharmacokinetic model development and simulations for ethylene dichloride (1,2-dichlorethane) in rats. Regulatory Toxicology and Pharmacology. 51:311–323. (2008).

8. EPA. Email from Rob Dewoskin, PhD, DABT, US EPA/NCEA (National Center for Environmental Assessment) to John Schaeffer. Review of Final report - EDC ECA Program Review Completion. April 22, 2009.

List of Subjects

Environmental protection, 1,2-Ethylene Dichloride, EDC, Hazardous chemicals.

Dated: July 10, 2009.

Jim Willis,

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

[FR Doc. E9–17170 Filed 7–21–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD; FRL–8930–3]

Flexible Approaches to Environmental Measurement—The Evolution of the Performance Approach

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Assuring the quality of environmental measurements is essential to the implementation of the Environmental Protection Agency's (EPA's or the Agency's) environmental programs, both regulatory and voluntary. In an October 6, 1997, Notice of Intent (FRL–5903–2), the Agency outlined a ''Performance Based Measurement System (PBMS)'' concept