Therefore, EPA reserves the right to approved State or Tribal program.

2684(b)) makes it unlawful for any person to violate, or fail or refuse to comply with, any requirement of an approved State or Tribal program.

II. Federal Overfilling

III. Federal Overfilling

Section 404(b) of TSCA (15 U.S.C. 2684(b)) makes it unlawful for any person to violate, or fail or refuse to comply with, any requirement of an approved State or Tribal program. Therefore, EPA reserves the right to exercise its enforcement authority under TSCA against a violation of, or a failure or refusal to comply with, any requirement of an authorized State or Tribal program.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq. as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this document in the Federal Register. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

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


Laura Yoshii,
Acting Regional Administrator, Region IX.

ENVIRONMENTAL PROTECTION AGENCY


1,2-Ethylene Dichloride 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) for 1,2-ethylenedichloride (EDC). The companies subject to the 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 EDC 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 EDC ECA alternative testing program, and solicits comment on data received under the Tier I Program Review Testing segment of the EDC ECA. Comments are expected to inform EPA’s decision on whether data and computational dosimetry model development completed by the test sponsors are sufficient to proceed with the Tier II Testing and computational dosimetry modeling for route-to-route extrapolations listed in the EDC ECA.

DATES: Comments must be received on or before October 5, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2003–0010, by one of the following methods:


Hand Delivery: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2003–0010. 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) 586–8930. Such deliveries are only accepted during the DCO’s normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2003–0010. EPA’s policy is that all comments received will be included in the public docket without change and may be made available on-line at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your
name and other contact information in the body of your comment and with any disk or CD ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information for which 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 either electronically at http://www.regulations.gov, or in hard copy at the OPPT Docket, EPA Docket Center (EPA/DC), EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

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: 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 either technical person listed under FOR FURTHER INFORMATION CONTACT.

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

1. Technical and scientific considerations. EPA invites interested parties to provide views on the test sponsors’ Tier I Program Review Testing reports entitled: 1,2-Dichloroethane (EDC): Limited Pharmacokinetics and Metabolism Study in Fischer 344 Rats and Physiologically Based Pharmacokinetic Model Development and Simulations for Ethylene Dichloride (1,2-Dichloroethane) in Rats (Refs. 1 and 2). These reports describe a computational dosimetry model for route-to-route extrapolation and development of pharmacokinetics and mechanistic 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 EDC ECA. The computational dosimetry model and PK/MECH data described in these reports, if deemed acceptable to EPA, will be applied to support the EDC ECA Tier II Testing and computational dosimetry model extrapolation reporting called for under Tier II of the EDC ECA.

2. Submitting CBI. Do not submit CBI to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information contained in a disk or CD ROM that you mail to EPA, 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 claimed CBI. In addition to one complete version of the comment that includes 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.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

3. Tips for preparing your comments. When submitting comments, remember to:

i. Identify the document by docket ID number and further identifying information (subject heading, Federal Register date and page number).

ii. Follow directions. As discussed in Unit I.B.1., the Agency asks you to respond to specific questions regarding the EDC ECA program review.

iii. Explain why you agree or disagree with the materials under consideration for the EDC ECA program review; provide a convincing argument for your views or offer alternative ways to improve the science.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggested alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Testing is EPA Requiring for EDC?

EPA proposed health effects testing under TSCA section 4(a) for a number of hazardous air pollutants (HAPs or HAP chemicals), including EDC, in the Federal Register of June 26, 1996 (Ref. 3), as amended (Refs. 4 and 5). The testing needs for EDC identified in the HAPs proposed rule, as amended, are acute toxicity, subchronic toxicity, developmental toxicity, reproductive toxicity, and neurotoxicity (acute and subchronic), to be conducted by the inhalation route of exposure.

In that proposed TSCA section 4(a) rule, EPA also invited the submission of proposals that could use the performance of PK studies and computational dosimetry modeling to 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 under the rule and form the basis for developing needed HAPs data via ECAs (Refs. 3, 4, and 5).

On November 22, 1996, 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. (the Companies), under the auspices of the HAP Task Force (the principal testing sponsor), submitted a proposal for alternative testing of EDC that included physiologically based pharmacokinetics (PBPK) studies and computational dosimetry model development to support route-to-route...
extrapolation of testing to be conducted under the ECA by the oral route (Ref. 6). EPA considered this proposal sufficient (Ref. 7) to enter into ECA negotiations with the Companies and other interested parties (Ref. 8). The ECA for EDC was announced in the Federal Register of June 3, 2003 (Ref. 9). Under the EDC ECA (Ref. 10), the HAPs data needs for EDC are being addressed via an alternative testing program that utilizes testing by inhalation and the oral route, computational dosimetry model development, and development of PK/MECH data to support route-to-route extrapolation modeling for health effects endpoints identified in the ECA. EPA anticipates fulfilling all of the health effects testing requirements identified in the HAPs proposed rule, as amended, by implementation of the testing to be performed under the EDC ECA and Order.

B. How is EPA Implementing Testing for EDC Under the ECA?

The EDC 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 and/or Extrapolation Reporting.

1. Tier I HAPs Testing. The ECA testing and reporting requirements for Tier I HAPs Testing have been completed. Under this segment of the EDC ECA, the Companies performed endpoint testing for acute toxicity, with bronchoalveolar lavage (BAL) and histopathology, and acute neurotoxicity (Ref. 11). These studies were conducted under a combined protocol by inhalation exposure. The ECA acknowledged that macrophage function testing (a component of EPA’s acute toxicity test guideline 40 CFR 799.9135) is adequately fulfilled by existing data published by Sherwood et al. (1987; Ref. 12) and also acknowledged that the developmental studies reported by Rao et al. (1980; Ref. 13), in rabbits, and Payan et al. (1995; Ref. 14) in rats, adequately fulfill the HAPs rulemaking testing requirements for developmental toxicity testing for EDC.

2. Tier I Program Review Testing. The ECA testing and reporting requirements for Tier I Program Review Testing have been completed. Under this segment of the EDC ECA the Companies conducted studies to extend the computational dosimetry model of D’Souza et al. (1987, 1988; Refs. 15 and 16) in order to apply the model to the specific health effects endpoints for EDC listed in the ECA, validate the model, and verify the model’s ability to perform quantitative route-to-route extrapolations of dose response. The ECA provided for the development of PK/MECH data to support the application of the computational dosimetry model for the endpoints listed under Tier II of the EDC ECA. The Companies also provided model simulations with point and uncertainty estimates of internal dose metrics (parent chemical peak and area under the curve (AUC) concentrations in blood and brain, and 24-hour total glutathione (GSH)-dependent metabolism in lung and liver) in rats and humans to inform quantitative route-to-route extrapolations of the EDC dose response. Furthermore, based on an additional analysis of the D’Souza et al. model, the ECA was modified to include the kidney in the examination of GSH-dependent metabolism (Refs. 17, 18, and 19). Information derived from the GSH-metabolism, PK/MECH data, and model simulations will be used to evaluate the acceptability of performing:

i. Oral-to-inhalation extrapolation of subchronic toxicity data reported by Daniel, et al. (1994; Ref. 20) relevant to corn oil gavage.

ii. Oral-to-inhalation extrapolation of subchronic neurotoxicity data relevant to drinking water exposure of a study to be conducted under Tier II Testing.

iii. Oral-to-inhalation extrapolation of reproductive effects testing conducted under Tier II Testing and each dosing paradigm of studies reported by Alumot et al. (1976; Ref. 21), Rao et al. (1980, Ref. 13), and Lane et al. (1982; Ref. 22).

3. EPA Program Review. As indicated in Unit VI.C. of the EDC ECA and Unit II.B.3. of this notice, computational dosimetry model development and data from Tier I Program Review Testing are subject to an EPA Program Review. The EPA Program Review will determine whether the computational dosimetry model and the PK/MECH data used to support the route-to-route extrapolations of dose response are scientifically sound and provide the highest quality data. Specifically, as described in Unit VII. of the EDC ECA, the EPA Program Review will determine:

i. 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 of dose response for any or all of the endpoints listed in the Tier II Testing segment of the ECA, including data from studies conducted under the ECA; the ECA Program Review will determine:

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

iii. The nature and scope of any additional work (e.g., development of additional PK/MECH data, modification to the EDC computational dosimetry model) that may be required to support Tier II Testing and application of the EDC computational dosimetry model for route-to-route extrapolation of dose-response reporting for the testing endpoints listed under Tier II of the EDC ECA.

4. Tier II Testing and/or Extrapolation Reporting. This segment of the EDC ECA alternative testing program will consist of endpoint testing by drinking water exposure for subchronic neurotoxicity and reproductive toxicity. The reproductive effects toxicity testing is intended to confirm studies reported by Alumot et al. (1976; Ref. 21), Rao et al. (1980; Ref. 13), and Lane et al. (1982; Ref. 22), and provide data needed on fertility index, gestation index, gross necropsy, organ weight, histopathology, estrous cycle, sperm evaluation, vaginal opening, and preputial separation as described in the ECA. This segment will also include application of the EDC computational dosimetry model for quantitative route-to-route extrapolation reporting (oral to inhalation) for Tier II endpoint testing (subchronic neurotoxicity and reproductive toxicity) and similar computational extrapolation reporting for istance subchronic toxicity reported by Daniel et al. (1994; Ref. 20).

III. What Action is the Agency Taking?

A. What Opportunity is There for Public Involvement in EPA’s Program Review?

Tier I HAPs Testing for EDC is completed and reports for Tier I Program Review Testing have been submitted by the Companies. Copies of these submissions are available in the public docket (EPA–HQ–OPPT–2003–0010). As described in Unit II.B.3. and stated in Part VI. of the EDC 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 EDC ECA alternative testing program. As noted in Unit I.B., this notice of availability and request for written comments provides an opportunity for public comment on reports subject to this EPA Program Review.

B. What Happens at the Conclusion of EPA’s Program Review?

A description of the possible outcomes of the EPA Program Review is published in Part VII. of the EDC ECA. Following the EPA Program Review, EPA will place in the public docket for
this action (under docket ID number EPA–HQ–OPPT–2003–0010) 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. EPA will publish a Federal Register notice which announces the availability of a report describing the findings and conclusions of the Program Review, responds to comments on the Tier I Program Review Testing, identifies any modifications to Tier II ECA activities, and establishes revised deadlines as needed for completion of Tier II Testing and route-to-route computational dosimetry modeling for extrapolations listed under Tier II of the ECA for EDC.

IV. Materials in the Docket

The docket for this document has been established under docket ID number EPA–HQ–OPPT–2003–0010. The public docket is available for review as specified in ADDRESSES. The following is a listing of the documents referenced in this preamble that have been placed in the public docket for this document:


17. EPA. Letter dated March 24, 2004 from Wardner G. Penberthy to Peter E. Voytek with two attachments entitled: i. Addendum Modification to Enforceable Consent Agreement for 1,2-Ethylenedichloride (EDC).


22. Lane, R.W.; Riddle, B.L.; and Borzelleca, J.F. Effects of 1,2-dichloroethane and 1,1,1-trichloroethane in drinking water on reproduction and development in mice. Toxicology and Applied Pharmacology 63: 409–421 (1982).

List of Subjects

Environmental protection, 1,2-Ethylenedichloride, Hazardous chemicals.
FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 29, 2006.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Traders & Farmers Bancshares, Inc. Haleyville, Alabama; to become a bank holding company by acquiring 100 percent of the outstanding shares of Traders & Farmers Bank, Haleyville, Alabama.


Robert dev'Y. Frierson, Deputy Secretary of the Board.

[FR Doc. E6–14639 Filed 9–1–06; 8:45 am]
BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Populations.

Time and Date: September 18, 2006, 8:30 a.m.–5 p.m. September 19, 2006, 8:30 a.m.–5 p.m.


Status: Open.

Purpose: The purpose of the meeting is to identify data linkages for statistical purposes within and among Federal government agencies with a view to promoting best practices.

For Further Information Contact:

Substantive program information as well as summaries of meetings and a roster of Committee members may be obtained from Joan Turek, Ph.D., Staff to the Subcommittee on Populations, Office of the Assistant Secretary for Planning and Evaluation, Room 434E, 200 Independence Avenue, SW., Washington, DC 20201, telephone (202) 690–5945, e-mail joan.turek@hhs.gov; or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: http://www.ncvhs.hhs.gov/, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.


James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 06–7403 Filed 9–1–06; 8:45 am]
BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–06–05CL]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Formative Evaluation of Adults’ and Children’s Views Related to Promotion of Healthy Food Choices—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In FY 2004, Congress directed the Centers for Disease Control and Prevention (CDC) to conduct formative research on the attitudes of children and parents regarding nutrition behavior. Specifically, the conferees’ FY 2004 Appropriation Language instructs CDC to research parents’ and children’s viewpoints on “the characteristics of effective marketing of foods to children to promote healthy food choices.” Upon completion, a report detailing CDC’s