

OPP-2003-0258. 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 Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

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.

II. Contractor Requirements

Under contract number 68-W-03-039, the contractor will perform the following:

The purpose of this contract is to support EPA and Agency position documents, reviews, and scientific technical assessments of potential hazards and risks of pesticides to human health and the environment. The contractor shall create Data Evaluation Reports which involve converting the studies supplied into a format specified by the program office and shall include secondary and Quality Assurance contractor reviews as specified:

- Review and evaluation of biopesticide, mammalian, non-target organisms toxicity, environmental fate, and product chemistry data.
- Review of confidential statement of formulations, manufacturing process, and labels
- Statements for compliance with United States Department of Agriculture National Organic Program Standards.

- Preliminary risk assessment for biopesticides.

- General assistance-biopesticide registration package review.

This contract involves no subcontractors.

EPA has determined that the contract described in this document involve work that is being conducted in connection with FIFRA, in that pesticide chemicals will be the subject of certain evaluations to be made under this contract. These evaluations may be used in subsequent regulatory decisions under FIFRA.

Some of this information may be entitled to confidential treatment. The information has been submitted to EPA under sections 3, 4, 6, and 7 of FIFRA and under sections 408 and 409 of FFCA.

In accordance with the requirements of 40 CFR 2.307(h)(3), the contracts with Tetrahedron, Inc., prohibits use of the information for any purpose not specified in these contracts; prohibits disclosure of the information to a third party without prior written approval from the Agency; and requires that each official and employee of the contractor sign an agreement to protect the information from unauthorized release and to handle it in accordance with the FIFRA Information Security Manual. In addition, Tetrahedron, Inc. is required to submit for EPA approval a security plan under which any CBI will be secured and protected against unauthorized release or compromise. No information will be provided to Tetrahedron, Inc. until the requirements in this document have been fully satisfied. Records of information provided to Tetrahedron, Inc. will be maintained by EPA Project Officers for these contracts. All information supplied to Tetrahedron, Inc. by EPA for use in connection with these contracts will be returned to EPA when Tetrahedron, Inc. has completed its work.

List of Subjects

Environmental protection, Business and industry, Government contracts, Government property, Security measures.

Dated: July 21, 2003.

Arnold E. Layne,

Director, Information Resources and Services Division, Office of Pesticide Programs.

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[BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2003-0027; FRL-7320-3]

Endocrine Disruptor Methods Validation Subcommittee under the National Advisory Council for Environmental Policy and Technology; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: There will be a meeting of the Endocrine Disruptor Methods Validation Subcommittee (EDMVS), a Subcommittee under the National Advisory Council for Environmental Policy and Technology (NACEPT), on August 18-20, 2003. This meeting, as with all EDMVS meetings, is open to the public. Seating is on a first-come basis.

DATES: The meeting will be held on Monday, August 18, 2003, from 1:30 p.m. to 5:45 p.m.; Tuesday, August 19, 2003, from 7:45 a.m. to 2:30 p.m.; and Wednesday, August 20, 2003, from 8 a.m. to 2:45 p.m. mountain daylight time.

Individuals requiring special accommodations at the meeting, including wheelchair access, should contact Jane Smith at the address listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the meeting, so appropriate arrangements can be made.

ADDRESSES: The meeting will be held at The Table Mountain Inn, 1310 Washington, Ave., Golden, CO 80401.

Requests and comments may be submitted electronically, by telephone, fax, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Jane Smith, Designated Federal Official for the EDMVS, Exposure Assessment Coordination and Policy Division (7203M), Office of Science Coordination and Policy, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8476; fax number: (202) 564-8483; or e-mail address: smith.jane-scott@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Notice Apply to Me?

This action is directed to the public in general. This action may, however, be of interest if you produce, manufacture, use, consume, work with or import pesticide chemicals and other

substances. To determine whether you or your business may have an interest in this notice you should carefully examine section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 (Public Law 104-170), 21 U.S.C. 346a(p) and amendments to the Safe Drinking Water Act (SDWA) (Public Law 104-182), 42 U.S.C. 300j-17. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding this action, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including 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-2003-0027. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other related information. 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 are available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566-0282.

2. *Electronic access.* A meeting agenda, a list of EDMVS members and information from previous meetings are available electronically, from the EPA Internet Home Page at <http://www.epa.gov/scipoly/oscpendo/edmvs.htm>. You may also go directly to the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket> to 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. Once in the system, select "search," then key in docket ID number OPPT-2003-0027.

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.I.

C. How Can I Request to Participate in the Meeting?

You may submit a request to participate in the meeting through electronic mail, telephone, fax, or in person. EPA would normally accept requests by mail, but in this time of delays in delivery of government mail due to health and security concerns, EPA cannot assure your request would arrive in a timely manner. Do not submit any information in your request that is considered CBI. Your request must be received by EPA on or before August 12, 2003. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPPT-2003-0027 in the subject line on the first page of your request.

1. *Electronically.* You may submit your request to participate electronically. Do not submit any information electronically that you consider to be CBI. Use WordPerfect 6.1/8.0 or ASCII file format and avoid the use of special characters and any form of encryption.

i. *EPA Docket.* You may use EPA's electronic public docket to submit a request to participate in this meeting. Go to EPA Dockets at <http://epa.gov/edocket>, and follow the online instructions for submitting materials. Once in the system, select "search," and then key in docket ID number OPPT-2003-0027.

ii. *E-mail.* Request to participate may be sent by e-mail to the person listed in **FOR FURTHER INFORMATION CONTACT**, or directly to the docket at oppt.ncic@epa.gov, Attention: Docket ID Number OPPT-2003-0027.

2. *Telephone or fax.* Send your request to participate to the individual identified in **FOR FURTHER INFORMATION CONTACT**.

D. How and to Whom Do I Submit Comments?

In accordance with the Federal Advisory Committee Act (FACA), the public is encouraged to submit written comments on the topic of this meeting. The EDMVS will have a brief period available during the meeting for public comment. It is the policy of the EDMVS to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EDMVS expects that public statements presented at its meeting will be on the meeting topic and not be

repetitive of previously submitted oral or written statements.

You may submit comments electronically 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. 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.E. 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-2003-0027. 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, Attention: Docket ID Number OPPT-2003-0027. 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 by courier or package service, such as Federal Express to the address identified in Unit I.D.2. 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 hand delivery or courier.* Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT-2003-0027. 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.

E. 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 technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

In 1996, through enactment of the Food Quality Protection Act, which amended the Federal Food, Drug, and Cosmetic Act, Congress directed EPA to develop a screening program, using appropriate validated test systems and other scientifically relevant information,

to determine whether certain substances may have hormonal effects in humans. In 1996, EPA chartered a scientific advisory committee, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), under the authority of the Federal Advisory Committee Act (FACA) to advise it on establishing a program to carry out Congress' directive. EDSTAC recommended a multi-step approach including a series of screens (Tier I screens) and tests (Tier II tests) for determining whether a chemical substance may have an effect in humans similar to that produced by naturally occurring hormones. EPA adopted almost all of EDSTAC's recommendations in the program that it developed, the Endocrine Disruptor Screening Program (EDSP), to carry out Congress' directive.

EDSTAC also recognized that there currently are no validated test systems for determining whether a chemical may have an effect in humans that is similar to an effect produced by naturally occurring hormones. Consequently, EPA is in the process of developing and validating the screens and tests that EDSTAC recommended for inclusion in the EDSP. In carrying out this validation exercise, EPA is working closely with, and adhering to the principles of the Interagency Coordinating Committee for the Validation of Alternate Methods (ICCVAM). EPA also is working closely with the Organization for Economic Cooperation and Development's (OECD) Endocrine Testing and Assessment Task Force to validate and harmonize endocrine screening tests of international interest.

Finally, to ensure that EPA has the best and most up-to-date advice available regarding the validation of the screens and tests in the EDSP, EPA formed the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) of the National Advisory Council for Environmental Policy and Technology (NACEPT). EDMVS provides independent advice and counsel to the Agency through NACEPT, on scientific and technical issues related to validation of the EDSP Tier I screens and Tier II tests, including advice on methods for reducing animal use, refining procedures involving animals to make them less stressful, and replacing animals where scientifically appropriate.

The EDMVS has held seven meetings since its establishment in September 2001. The objectives of the first meeting, which was held in October 2001, (docket control number OPPT-42212D) were for EPA to provide:

1. An overview of EPA's Endocrine Disruptor Program.
2. Background information on test protocol validation and approaches.
3. For the EDMVS to develop a clear understanding of their scope, purpose, and operating procedures.
4. The EDMVS and the EDSP to determine the next steps.

The objectives of the December 2001 meeting (docket control number OPPT-42212E) were for the EDMVS to provide input and advice on:

1. EDMVS's mission statement and work plan.
2. The *in utero* through lactation assay detailed review paper.
3. The pubertal assay study design for the multi-dose and chemical array protocols.
4. The mammalian one-generation study design.

The objectives of the March 2002 meeting (docket control number 42212F) were for the EDMVS to provide input and advice on:

1. EPA's implementation process and practical aspects of validation.
2. The *in utero* through lactation assay protocol.
3. The fish reproduction assay detailed review paper.
4. Special studies, the fathead minnow assays, vitellogenin assay, and avian dosing protocol.
5. The steroidogenesis detailed review paper.
6. The aromatase detailed review paper.
7. A proposed standard suite of chemicals for testing in the Tier I screening assays.

8. The current efforts related to evaluating the relevance of animal data to human health.

9. EPA's approach to addressing low dose issues.

The objective of the June 2002 teleconference meeting (docket ID number OPPT-2002-0020) was for the EDMVS to provide input and advice on the steroidogenesis detailed review paper.

The objectives of the July 2002 meeting (docket ID number OPPT-2002-0029) were:

1. To review the screening criteria, recommended by EDSTAC and adopted by EDSP for screens.
2. To receive an update of the National Interagency Center for the Evaluation of Alternate Toxicological Methods (NICEATM) estrogen and androgen receptor binding efforts.
3. To discuss and provide advice on general dose setting issues; and to provide comments and advice on:
 - A pubertal--special study--restricted feeding.

- A mammalian 2-generation draft propylthiouracil (PTU) special study.
- An amphibian metamorphosis detailed review paper.
- An invertebrate detailed review paper.

The objective of the December 2002 teleconference meeting (docket ID number OPPT-2002-0059) was for the EDMVS to provide input and advice on the Tier II fish life cycle assay detailed review paper.

The objectives of the June 5-6, 2003 (docket ID number OPPT-2003-0016) were for EDMVS to provide input and advice on:

1. The Tier II mammalian 2-generation special study on the one-generation extension results.
2. The Tier I steroidogenesis (sliced testes) study results.
3. The Tier I pre-optimization, substrate characterization for aromatase placental tissue study.

III. Objectives of the August 18-20, 2003 Meeting

The objectives of the August 18-20 meeting (docket ID number OPPT-2003-0027) are to:

1. Review and discuss the status/results of the prevalidation work on:
 - The fish screening assay, specifically: The survey of vitellogenin methods in fathead minnow, zebrafish and medaka; the comparative evaluation of the fathead minnow assays; and the fish screen (non-spawning) assay.
 - The steroidogenesis assay optimized protocol.
2. Provide input and advice on the:
 - EDSP's validation plans for the fish screening assay and steroidogenesis assay.
 - Strain/species white paper.
 - Chemicals used in EDSP's prevalidation and validation.
 - Avian detailed review paper.
 - Issues related to the pubertal assays.
3. Receive an update on the amphibian workshop conducted recently.

A list of the EDMVS members and meeting materials are available on our web site (<http://www.epa.gov/scipoly/oscpendo/edmvs.htm>) and in the public docket.

List of Subjects

Environmental protection, Endocrine system, Endocrine disruptors, Endocrine disruptor screening program.

Dated: July 23, 2003.

Kathryn R. Mahaffey,

Acting Director, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances.

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BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7536-5]

Science Advisory Board Staff Office; Advisory Council on Clean Air Compliance Analysis Health Effects Subcommittee; Notification of Upcoming Public Teleconference and Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board Staff Office is announcing a public teleconference and a public meeting of the Advisory Council on Clean Air Compliance Analysis (Council) Health Effects Subcommittee (HES).

DATES:

August 8, 2003. A public teleconference call meeting for the HES will be held from 11 a.m. to 12:30 p.m. (eastern time).

August 27-29, 2003. A public meeting for the HES will be held from 9 a.m. on August 27, 2003 to 2:30 p.m on August 29, 2003 (eastern time).

ADDRESSES: Participation in the teleconference meeting will be by teleconference only. The meeting location for the August 27-29, 2003, meeting of the HES will be in Washington, DC. The meeting location will be announced on the SAB Web site, <http://www.epa/sab> two weeks before the meeting.

FOR FURTHER INFORMATION CONTACT:

Members of the public who wish to obtain the call-in number and access code to participate in the teleconference meeting may contact Ms. Sandra Friedman, EPA Science Advisory Board Staff, at telephone/voice mail: (202) 564-2526; or via e-mail at friedman.sandra@epa.gov, or Ms. Delores Darden, EPA Science Advisory Board Staff at telephone/voice mail: (202) 564-2282; or via e-mail at darden.delores@epa.gov. Any member of the public wishing further information regarding the Council or the HES may contact Dr. Angela Nugent, Designated Federal Officer (DFO), U.S. EPA Science Advisory Board (1400A), 1200 Pennsylvania Avenue, NW.,

Washington, DC 20460; by telephone/voice mail at (202) 564-4562; or via e-mail at nugent.angela@epa.gov. General information about the SAB can be found in the SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION:

Background. Pursuant to the Federal Advisory Committee Act, Public Law 92-463, Notice is given that the HES will hold a public teleconference, as described above, to prepare for the public meeting, also described above. The purpose of the public meeting is to advise the Agency on its plan to develop a health effects assessment for the third in a series of statutorily mandated comprehensive analyses of the total costs and benefits of programs implemented pursuant to the Clean Air Act.

Background on the Council, the HES, and on the advisory project was provided in a **Federal Register** notice published on February 14, 2003 (68 FR 7531-7534).

The HES will be providing advice, through the Council, on the review document, "Benefits and Costs of the Clean Air Act 1990-2020; Revised Analytical Plan for EPA's Second Prospective Analysis" currently found at the following Web site, maintained by EPA's Office of Air and Radiation at: <http://www.epa.gov/oar/sect812/> under the link "Study Blueprint and Charge Questions Electronic Copy." This link provides electronic access to the Revised Analytical Plan, the "change pages" given to the Council and HES in July 2003, and the detailed review charge questions.

Procedures for Providing Public Comment. It is the policy of the EPA Science Advisory Board (SAB) Staff Office to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA SAB Staff Office expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes (unless otherwise indicated). For conference call meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Interested parties should contact the Designated Federal Official (DFO) at least one week prior to the meeting in order to be placed on the public speaker list for the meeting. Speakers should bring at least 35 copies of their comments and presentation