

415-1444. Revision of FR Notice
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Dated: November 18, 2003.

Joseph C. Montgomery,

*Director, NEPA Compliance Division, Office
of Federal Activities.*

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ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2003-0064; FRL-7334-5]

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.

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 December 10-12, 2003. The purpose of this meeting is to: Receive advice and input from the EDMVS on: The Pubertals assay and Aromatase assay prevalidation results; receive the introductory presentation on Adult Intact Male assay; and receive updates on: The Androgen Receptor Binding assay, efforts to finalize reference chemicals, and the Organization for Economic Cooperation and Development (OECD) Fish Drafting Group.

DATES: The meeting will be held on Wednesday, December 10, 2003, from 1 p.m. to 4:45 p.m.; Thursday, December 11, 2003, from 8:30 a.m. to 5 p.m.; and Friday, December 12, 2003, from 8:30 a.m. to Noon, eastern standard time.

Requests to participate in the meeting must be received by EPA on or before December 5, 2003. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPPT-2003-0064 in the subject line on the first page of your request.

Individuals requiring special accommodations at the meeting, including wheelchair access, should contact the technical person listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the meeting.

ADDRESSES: The meeting will be held at RESOLVE, 1255 23rd St., NW., Suite 275, Washington, DC.

Requests to participate in the meeting may be submitted by e-mail, telephone, fax, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

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

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: *TSCA-Hotline@epa.gov.*

For technical information contact: Jane Smith, Designated Federal Official (DFO), 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) 564-8482; e-mail address: *smith.jane-scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action 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 technical 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-2003-0064. 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.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. 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>.

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. Once in the system, select "search," then key in the appropriate docket ID number.

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

You may submit a request to participate in the meeting through e-mail, telephone, fax, or hand delivery/courier. We would normally accept requests by mail, but in this time of delays in delivery of government mail due to health and security concerns, we 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 December 5, 2003. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPPT-2003-0064 in the subject line on the first page of your request.

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.

1. *Electronically.* If you submit an electronic request to participate in the meeting or comments 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 request or 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 request or comment and allows EPA to contact you in case EPA cannot read your request or comment due to technical difficulties or needs further information on the substance of your request or comment. EPA's policy is that EPA will not edit your request or comment, and any identifying or contact information provided in the body of a request or comment will be included as part of the request or comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your request or comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your request or comment.

i. *EPA Docket.* You may use EPA's electronic public docket to submit a request to participate in the meeting or to submit comments. Go to EPA Dockets at <http://www.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-2003-0064. 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 request.

ii. *E-mail.* Requests to participate in the meeting or comments may be sent by e-mail to oppt.ncic@epa.gov, Attention: Docket ID Number OPPT-2003-0064. 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 request 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 request 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 hand delivery, courier, or package service, such as Federal Express, to the technical person listed under **FOR FURTHER INFORMATION CONTACT**. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption. Do not submit any disk or CD ROM through the mail. Disks and CD ROMs risk being destroyed when handled as Federal Government mail.

2. *Telephone or fax.* Telephone or fax your request to participate in the meeting to the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

3. *By hand delivery or courier.* Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Bldg., Rm. 6428, 1201 Constitution Ave., Washington, DC. Attention: Docket ID Number OPPT-2003-0064. 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.

II. Background

In 1996, through enactment of FQPA, which amended the FFDCA, 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 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 1 screens) and tests (Tier 2 tests) for determining whether a chemical substance may have an effect 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 OECD's 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 established the EDMVS under NACEPT. EDMVS provides independent advice and counsel to the Agency through NACEPT, on scientific and technical issues related to validation of the EDSP Tier 1 screens and Tier 2 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 eight meetings since its establishment in September 2001.

October 2001

The objectives of the first meeting, which was held in October 2001, (docket control number OPPTS-42212D) were for EPA to provide:

1. An overview of the 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.

December 2001

The objectives of the December 2001 meeting (docket control number OPPTS-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 1-generation study design.

March 2002

The objectives of the March 2002 meeting (docket control number OPPTS-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 1 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.

June 2002

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.

July 2002

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 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.

December 2002

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 2 Fish Life Cycle assay detailed review paper.

June 2003

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

1. The Tier II Mammalian 2-Generation Special Study and the 1-generation extension results.
2. The Tier I Steroidogenesis (Sliced Testes) Study results and validation plan.
3. The Tier I Pre-Optimization, substrate characterization for Aromatase Placental Microsomes Study results.

August 2003

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

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.

III. Meeting Objectives for the December 2003 Meeting

The objectives for the December 10-12, 2003 meeting (docket ID number OPPT-2003-0064) are for EDMVS to provide input and advice on:

1. Discuss the Pubertals assay and Aromatase assay prevalidation results and recommend next steps.

2. Receive introductory presentation on Adult Intact Male assay.

3. Receive updates on:

- Androgen Receptor Binding assay.
- Efforts to finalize reference chemicals.
- OECD Fish Drafting Group.
- Activities regarding *In Vitro* Fish assays.

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 disruptors, Hazardous substances, Health, Safety.

Dated: November 14, 2003.

Joseph J. Merenda, Jr.,

Director, Office of Science Coordination and Policy.

[FR Doc. 03-29186 Filed 11-20-03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0336; FRL-7333-7]

Dichlormid; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2003-0336, must be received on or before December 22, 2003.

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

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8033; e-mail address: campbell.princess@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of