

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.