

**Endocrine Disruptors Methods Validation Advisory Committee (EDMVAC)**

**Meeting by Conference Call: 15-Day Intact Adult Male Rat Assay**

**August 2, 2005**

**12:00 PM - 2:00 PM (EDT)**

*DRAFT Agenda*

*Members of the public may join this conference call in person at the conference room in the RESOLVE offices at 1255 23<sup>rd</sup> St. NW, Suite 275, Washington, DC. To register to participate by phone, please contact Jane Smith, designated federal official for the EDMVAC, at [smith.jane-scott@epa.gov](mailto:smith.jane-scott@epa.gov) or 202/564-8476.*

***Meeting Objectives:***

- Review the EPA's interest and role in validating the Adult Male Assay,
- Review results from previous studies done by industry, and industry and EPA contracted laboratories,
- Present study design for interlaboratory validation,
- Justify selection of key aspects of the study design,
- Solicit commentary and advice from EDMVAC members regarding previous studies and proposed inter-laboratory validation study.

**12:00-12:05 Phoning In**

**12:05-12:10 Welcome, Introductions, Agenda Review, and Ground Rules**

**Objective:** Review objectives of conference call, agenda, and logistics.

**Format:** Presentation from Jane Smith, Designated Federal Official, EPA Endocrine Disruptors Program, Dr. Gerald LeBlanc, EDMVAC Chair, and Dr. Juliana Birkhoff, RESOLVE, Facilitator.

**12:10-12:15 EPA's Role in the Adult Male Assay**

**Objective:** Learn about the EPA's role in validating the Adult Male Assay and associated timeline.

**Format:** Mr. Gary Timm and Dr. Don Bergfelt, Endocrine Disruptors Program, EPA presentation, facilitated questions and answers from EDMVAC members.

**12:15-12:25 Industry's Role in the Adult Male Assay**

**Objective:** Learn about industry's role in validating the Adult Male Assay.

**Format:** Dr. Rick Becker, American Chemistry Council, presentation.

**12:25-1:00 Industry's Overview of the Adult Male Assay**

**Objective:** Learn about highlights from previous studies and the basis for the study design for inter-laboratory validation.

**Format:** Mr. John O'Connor, DuPont, presentation.

**1:00-1:40 Questions and Discussions**

**Objective:** Provide commentary and advice on all aspects of the assay and the design for interlaboratory validation. Specifically:

1. **Protocol optimization and transferability:** Considering the number of chemicals and latest efforts that have been run in the various industrial and contract laboratories in which expected results have been documented, does the EDMVAC agree that the protocol is ready for inter-laboratory validation? If not, what additional information would be necessary to proceed?
2. **Chemical selection:** Considering the number and types of chemicals that have been selected to challenge the assay over several modes of action and compare with previous results, does the EDMVAC agree with the selection of the number of laboratories and chemicals for inter-laboratory validation? If not, what should be considered?

**Format:** Facilitated discussion among EDMVAC members, presenters and EPA.

**1:40-1:55**      **Public Comment**

**1:55-2:00**      **Next Steps**

**2:00**            **Adjourn**