Attachment A

The Director of the Office of Science Coordination and Policy of EPA, Vanessa Vu, Ph.D., is Chairperson of the 26 member subcommittee. She was appointed to the position by the Administrator of EPA, Christine Todd Whitman, along with Deputy Chair, William Benson, Ph.D., Director of the Gulf Ecology Division in NHEERL, Office of Research and Development, EPA. Other members represent various industries and organizations including: agri-chemical and commodity chemical industries, environmental organizations, public health organizations, academia, animal welfare organizations, federal agencies, and state governments

Endocrine Disruptor Methods Validation Subcommittee Membership

Name and Title	Expertise
Vanessa Vu, Ph.D. Director, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, EPA **Chair**	Pharmacology
William Benson, **Ph.D.** Director, Gulf Ecology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, EPA **Deputy Chair**	Ecotoxicology
Mildred Christian, Ph.D. President and CEO, Argus International, Inc. Also, Executive Director of Research and Executive Director of Safety and Compliance for Argus Research - Charles River Laboratories	Reproductive and Developmental Toxicology
Theo Colborn, Ph.D Senior Scientist and Director, Wildlife and Contaminants Program, World Wildlife Fund	Ecotoxicology
Robert Combes, Ph.D. Scientific Director, Fund for the Replacement of Animals in Medical Experiments (FRAME)	Genetics, Biochemistry, Alternatives to In Vivo Testing
Rodger Curren, Ph.D. President, Institute for In Vitro Sciences, Inc.	Microbiology, Alternatives to In Vivo Testing
Peter deFur, PH.D. Associate Professor, Center for Environmental Studies, Virginia Commonwealth University	Aquatic Biology
Charles Eldridge, Ph.D. Professor of Physiology and Pharmacology, Wake Forest U. School of Medicine	Endocrinology

Endocrine Disruptor Methods Validation Subcommittee Membership

Name and Title	Expertise
Penelope Fenner-Crisp, Ph.D. Executive Director, Risk Science Institute, International Life Sciences Institute (ILSI)	Pharmacology
David Hattan, Ph.D. Director, Division of Health Effects Evaluation, Food and Drug Administration	Toxicology
Robert Kavlock, Ph.D. Director, Reproductive Toxicology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, EPA	Reproductive Toxicology; Endocrinology
William Kelce, Ph.D. Senior Scientist, Pharmacia Corp.	Reproductive/ Developmental Toxicology
Nancy Kim, **Ph.D.** Director, Division of Env'l Health Assessment NY State Dept. of Health	Chemistry, Health Risk Assessment
Timothy Kubiak, M.P.A. National Water Quality Coordinator, U.S. Fish and Wildlife Service, Dept. of Interior	Natural Resource Management
Gerald LeBlanc, Ph.D. Professor, Department of Toxicology, N.C. State	Biology/ Biochemistry
Ron Miller, Ph.D. Senior Toxicology Consultant The Dow Chemical Co.	Inhalation Toxicology
Susan Nagel, Ph.D. Research Associate Dept. of Pharmacology and Cancer Biology, Duke University Medical Center	Reproductive/ Environmental Endocrinology
"Willie" Owens, Ph.D. Principal Scientist, Environmental Science Dept. Procter and Gamble	Ecorisk Assessment and Life-cycle Assessment
Thomas Potter, Ph.D. Research Chemist, Southeast Watershed Research Service, USDA	Environmental Fate and Monitoring
Ted Schettler, M.D., M.P.H. Physician E. Boston Neighborhood Health Center	Medicine and Public Health
Shane Snyder, Ph.D. Project Manager R&D, Southern Nevada Water Authority	Environmental Toxicology and Zoology; Monitoring Using Cellular Assays

Endocrine Disruptor Methods Validation Subcommittee Membership

Name and Title	Expertise
James Stevens, Ph.D. Head of Global Human Risk Assessment, Syngenta Crop Protection, Inc.	Reproductive Toxicology
William Stokes, D.V.M. Director, National Toxicology Program, Interagency Center for the Evaluation of alternative Toxicological Methods (NICEATM), HHS Co-Chair of Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)	Laboratory Animal Science
Glen Van der Kraak, Ph.D. Professor and Chair, Dept. of Zoology University of Guelph	Fish and Wildlife Biology
Valerie Wilson, Ph.D. Deputy Director, Center for Bioenvironmental Research (CBR) of Tulane and Xavier Universities	Molecular Biology; Health Science Program Management
James Yager, Ph.D. Professor of Toxicology, Dept. of Health Sciences, Johns Hopkins University Bloomberg School of Public Health	Toxicology

Attachment B

National Advisory Council for Environmental Policy and Technology (NACEPT)
Endocrine Disruptor Methods Validation Subcommittee (EDMVS)
First Plenary Meeting
October 30-31, 2001

Washington Dulles Airport Hilton
Grand Ballroom III
13869 Park Center Road
Herndon, VA 20171
703-478-2900

DRAFT Agenda

Meeting Objectives:
- Present overview of the Environmental Protection Agency's (EPA) Endocrine Disruptor Program.
- Provide background information on test protocol validation and approaches.
- Develop clear understanding of the EDMVS scope, purpose, and operating procedures.
- Determine next steps.

Tuesday, October 30, 2001

9:00 – 9:15 Welcome and Opening Comments
Dr. Vanessa Vu, Chair, Director, Office of Science Coordination and Policy, (OSCP), EPA
Dr. William Benson, Vice-Chair, Director, Gulf Ecology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, (ORD), EPA

9:15 – 9:45 Introductions and Agenda Review
Paul De Morgan, Facilitator, RESOLVE

9:45 – 10:00 Orientation to the Federal Advisory Committee Act and Ethics
Peter Redmond, NACEPT Designated Federal Official (DFO), Office of Cooperative Environmental Management, (OCEM), EPA

10:00 – 10:15 Overview of NACEPT
Peter Redmond, NACEPT DFO, OCEM, EPA

10:15 – 10:30 Break

10:30 – 11:15 Overview of EPA's Regulatory Program for Endocrine Disruptors
Gary Timm, OSCP, EPA

11:15 – 12:00 Overview of EPA's Research Program for Endocrine Disruptors
Dr. Elaine Francis, ORD, EPA

12:00 – 1:00 Lunch

1:00 – 1:30 Overview of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Test Protocol Validation Process
Dr. Dave Hattan, Director, Division of Health, Food and Drug Administration

1:30 – 2:15 Endocrine Disruptor Screening Program's (EDSP) Approaches to Test Protocol Validation and Process: Relationships Between ICCVAM, Organization for Economic Co-operation and Development (OECD), EPA, and EDMVS
Gary Timm, OSCP, EPA

2:15 – 3:00 EDSP's Test Protocol Validation Program: Status and Timeline
Jim Kariya, OSCP, EPA

3:00 – 3:15 Break

3:15 – 4:30 Illustration of OECD Test Protocol Validation Process: the Uterotrophic Assay
Dr. James W. Owens, Procter and Gamble

4:30 – 5:15 Public Comment
Members of the public will be given an opportunity to comment on any aspect of the EDMVS work. The amount of time given to each individual will depend on the number of people wishing to provide comment.

5:15 – 5:30 Setting the Stage for Day Two

Wednesday, October 31, 2001

9:00 – 9:45 Overview of the Mission Statement
Jane Smith, EDMVS DFO, OSCP, EPA

9:45 – 10:45 EDMVS Operating Procedures
Paul De Morgan, Facilitator, RESOLVE

10:45 – 11:00 Break

11:00 – 12:15 Looking Forward and Planning Next Steps

- Discuss status and timeline.
- Identify information needs.
- Discuss agenda items and dates for next meeting(s).
- Review action items.

12:15 – 12:30 Summary of Meeting and Closing Comments

12:30 Adjourn

Attachment C

National Advisory Council for Environmental Policy and Technology (NACEPT)
Endocrine Disruptor Methods Validation Subcommittee (EDMVS)
Second Plenary Meeting
December 10-12, 2001
Agenda

RESOLVE
1255 23rd Street, N.W., Suite 275
Washington, D.C., 20037
(202) 944-2300

Meeting Objectives:
- **Reach agreement on the EDMVS mission statement and work plan;**
- **Offer input and advice on:**
- **The in utero through lactation assay Detailed Review Paper;**
- **The pubertal assay study designs for the multi-dose and chemical array studies; and**
- **The mammalian one-generation study design.**

<u>Monday, December 10, 2001</u>

1:00 – 1:10 **Welcome and Opening Comments**
Dr. Vanessa Vu, Chair, Office of Science Coordination and Policy, (OSCP), EPA
Dr. William Benson, Vice-Chair, Office of Research and Development, (ORD), EPA

1:10 – 1:30 **Introduction, Agenda Review, and Review of Previous Meeting Summary**
Paul De Morgan, Facilitator, RESOLVE

1:30 – 3:15 **Review Revised Mission Statement and Work Plan**
Jane Smith, EDMVS Designated Federal Official, OSCP, EPA

3:15 – 3:30 **Break**

3:30 – 5:30 **Presentation and Discussion of In Utero Through Lactation Detailed Review Paper**
Gary Timm, OSCP, EPA
Dr. Earl Gray, ORD, EPA

5:30 – 6:00 **Public Comment**

Members of the public will be given an opportunity to comment on any aspect of the EDMVS work. The amount of time given to each individual will depend on the number of people wishing to provide comment.

6:00 – 6:15 Setting the Stage for Day Two

6:15 Adjourn for the day

<u>Tuesday, December 11, 2001</u>

9:00 – 9:15 Settling In

9:15 – 9:45 Overview of Pubertal Studies
Jim Kariya, OSCP, EPA
Dr. Ralph Cooper, ORD, EPA

9:45 – 10:45 Presentation and Discussion of Pubertal-Single Dose Study
Dr. Ralph Cooper, ORD, EPA

10:45 – 11:00 Break

11:00 – 12:30 Presentation and Discussion of Pubertal-Multi Dose Study
Dr. Ralph Cooper, ORD, EPA

12:30 – 1:45 Lunch

1:45 – 3:15 Presentation and Discussion of Pubertal-Array Protocol
Dr. Ralph Cooper, ORD, EPA

3:15 – 3:30 Break

3:30 – 4:30 Other Items
- ***Update on Assessment and Implications of RTI Lab Fire***

4:30 – 5:00 Public Comment
Members of the public will be given an opportunity to comment on any aspect of the EDMVS work. The amount of time given to each individual will depend on the number of people wishing to provide comment.

5:00 – 5:30 Discussion of Information Needs and Approach to Distribution
Paul De Morgan, Facilitator, RESOLVE

5:30 – 5:45 Setting the Stage for Day Three

5:45 Adjourn for the day

Wednesday, December 12, 2001

9:00 – 9:15 Settling In

9:15 – 10:45 Presentation and Discussion of Mammalian One Generation Extension Study Associated with the Two Generation Study
Jim Kariya, OSCP, EPA
Dr. Paul Foster, CIIT Centers for Health Research

10:45 – 11:00 Break

11:00 – 11:30 Discussion of Outstanding Issues

11:30 – 12:00 Process Assessment
What is working? What can be improved?

12:00 – 12:30 Next Steps and Agenda for Third Meeting

12:30 Adjourn