2006 Current Fiscal Year Report: Endocrine Disruptor Methods Validation Advisory Committee

Report Run Date: 04/25/2024 05:49:43 AM

1. Department or Agency	2. Fiscal Year
Environmental Protection Agency	2006

3. Committee or Subcommittee	3b. GSA Committee No.
Endocrine Disruptor Methods Validation Advisory Committee	21496

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/06/2004	05/06/2006	05/06/2006

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes		05/06/2006

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	No	

11. Establishment Authority Agency Authority

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
Request for Approval	04/23/2004	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
2	0	0	0	2

Meetings and Dates

Purpose	Start	End

Review EDMVAC mission statement and operating procedures; Update on EDMVAC Workplan; Review and discuss the Males and Female Pubertal Rat Assay, The Avian Species Comparison Study, Optimization of Steroidogenesis using the H295R cell line, EDSP's applied approach to validation, Avian Dosing Study, Avian 2-Generation Tier II Assay, and the OECD Uterotrophic Peer Review Report.	11/30/2005 - 12/02/2005
Review EDMVAC mission statement and operating procedures; Update on EDMVAC work plan; Review and discuss the Aromatase Assay, Steroidogenesis Cell Base H295R Assay, Male and Female Pubertals Interlaboratory Study, Fish Screen Assay Validation Status, and EDSP's Applied Approach to Validation.	04/18/2006 - 04/20/2006

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$15,000.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$200,060.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$39,998.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$7,983.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$2,500.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$135,662.00	$0.00
18d. Total	$401,203.00	$0.00
19. Federal Staff Support Years (FTE)	1.50	0.00

20a. How does the Committee accomplish its purpose?

The EDMVAC met twice in 2006, in November/December and April. At those meetings the EDMVAC recommended that development work on the Steroidogenesis sliced testes assay be postponed. EDMVAC recommended EPA pursue the Steroidogenesis h295r cell line assay in lieu of the sliced testes version. The EPA has accepted this recommendation. The actual recommendation can be viewed on the EDMVAC website at www.epa.gov/scipoly/oscpendo.

20b. How does the Committee balance its membership?

Membership to EDMVAC are solicited through the Federal Register and special attention is placed on ensuring balanced membership in terms of expertise and stakeholder representation. Members were selected on the basis of their relevant scientific expertise (e.g. endocrinology, mammalian and eco-toxicology, in-vitro testing, biostatistics, wildlife biology, icthyology) and diversity of perspectives on endocrine disruptor screening and testing methods and procedures, and toxicity test methods standardization and validation. Members were selected with balanced representation from the following sectors: the agrichemical and commodity chemical industries; environmental/public interest groups; industry and trade associations; Federal, State, local and Tribal governments; public health organizations; academia; and the general public. Selected staff from the Office of Pesticide Programs, Office of Pollution Prevention and Toxics, and the EDSP evaluated the nominees and made recommendations of selection to OPPTS management. The final recommendations are then forwarded to OGC and Agency Management for

final review and approval.

20c. How frequent and relevant are the Committee Meetings?

Estimated number of meetings is 4 per year. Estimated Total Meetings - 8. The EDMVAC met twice in FY 2006 to discuss Uterotrophic Fish Screen Assay, Avian species,and the Adult Male Rat Assay.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The Agency’s Endocrine Disruptor Screening Program is the only mandated endocrine program in the world. The identification, development and validation of endocrine screening and testing assays are at the forefront of both science and policy. The EDMVAC reviews protocols and data associated with optimization studies, intra-laboratory demonstrations and inter-laboratory testing on each of the 14 assays under consideration by the Agency. There are no other Agency committees in existence which include the broad spectrum of stakeholders in combination with the scientific expertise required to evaluate and provide advice on such technical material in such a large volume. The EDMVAC provides the forum to engage the public, stakeholders, and other interested parties, which they demanded, at this uniquely technical level and communicates the level of importance endocrine issues have in the Agency. The EDMVS was originally established in response to multiple stakeholder concerns about the validation of these assays and the lack of a mechanism for ALL interested parties to provide advice, input and opinions. Validating the assays involves literature reviews, study plans, protocols and data associated with optimization studies,

intra-laboratory demonstrations and inter-laboratory testing on each of the 14 assays under consideration by the Agency. The transparency of the EDSP program and the science through the FACA process will facilitate the adoption of policy and regulatory decisions in the future by the Agency. There are no other existing public forums which focus on the time-sensitive and often controversial issues emanating from the Food Quality Protection Act, involving endocrine issues, specifically, the validation of assays for the endocrine disruptor screening program.

20e. Why is it necessary to close and/or partially closed committee meetings?

There were no closed meetings in FY 2006.

21. Remarks

This committee sunset on May 6, 2006

Designated Federal Officer

William E Wooge Biologist/Designated Federal official

Committee Members	Start	End	Occupation	Member Designation
Christian, Mildred	11/01/2004	05/06/2006	President, Argus International, Inc	Representative Member
Combes, Robert	11/01/2004	05/06/2006	Scientific Director, Fund for the Replacement of Animals in Medical Research (FRAME)	Representative Member
Curren, Rodger	11/01/2004	05/06/2006	President, Institute for In Vitro Sciences, Inc.	Representative Member
Fairbrother, Anne	11/01/2004	05/06/2006	US EPA	Regular Government Employee (RGE) Member
Foster, Paul	11/01/2004	05/06/2006	National Institute for Environmental Health	Regular Government Employee (RGE) Member

Hattan, David	11/01/2004	05/06/2006	FDA, Office of Food Additive Safety	Regular Government Employee (RGE) Member
Jobling, Susan	11/01/2004	05/06/2006	Senior Fellow/Consultant	Representative Member
Kelce, William	11/01/2004	05/06/2006	Senior Scientist/Director, Pozen Pharmaceutical	Representative Member
Kennedy, Sean	11/01/2004	05/06/2006	Research Scientist, National Wildlife Research Centre	Representative Member
Kim, Nancy	11/01/2004	05/06/2006	Director Division of Envorinmental Health Assessment, NY State	Representative Member
LeBlanc, Gerald	11/01/2004	05/06/2006	Professor of Toxicology, NC State	Representative Member
Levine, Steven	11/01/2004	05/06/2006	Associate Fellow-Ecotoxicology, Monsanto Company	Representative Member
Orlando, Edward	11/01/2004	05/06/2006	Assistant Professor of Biology, Florida Atlantic University	Representative Member
Osimitz, Thomas	11/01/2004	05/06/2006	President, Science Strategies, LLC	Representative Member
Owens, James	11/01/2004	05/06/2006	Principal Scientist , Procter & Gamble Company	Representative Member
Snyder, Shane	11/01/2004	05/06/2006	Research and Development Project Manager, Southern Nevade Water Authority	Representative Member
Stevens, James	11/01/2004	05/06/2006	Professor, Department of Physiology and Pharmacology, Wake Forest University	Representative Member
Stokes, William	11/01/2004	05/06/2006	Director, Interagency Center for the Evauation of Alternative Toxicological Methods, NIEHS	Regular Government Employee (RGE) Member
Van der Kraak, Glen	11/01/2004	05/06/2006	Associate Dean of Research, College of Biological Science, University of Guelph	Representative Member

deFur, Peter	11/01/2004	05/06/2006	Affiliate Associate Professor, Center for Environmental Studies, Virginia Commonwealth University	Representative Member

Number of Committee Members Listed: 20

Narrative Description

Over the last several years, concern has grown about exposure to endocrine-disrupting, or hormonally active, chemicals. Evidence suggests that exposure to chemicals that mimic hormones (endocrine disruptors) may cause adverse health effects in wildlife and may affect human health as well. EPA is working to reduce uncertainty in our knowledge of endocrine disruptors, determine chemicals' potential for endocrine disruption, and identify the nature of adverse effects. EPA's strategic plan (goal 4) involves healthy communities and ecosystems by enhancing science and research (obj. 4.4) by providing the best available science. The EDMVAC provides scientific and technical advice on the testing protocols being developed and validated that will be used to assess chemicals' and pesticides' potential for endocrine disruption.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

NA

What is the approximate Number of recommendations produced by this committee for the life of the committee?

1

Number of Recommendations Comments

The EDMVAC recommended that the Agency no longer pursue the validation of the Steroidogenesis Sliced Testes Assay.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

100%

% of Recommendations Fully Implemented Comments

The EDMVAC recommended that the Agency no longer pursue the validation of the Steroidogenesis Sliced Testes Assay.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

0%

% of Recommendations Partially Implemented Comments

NA

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

The Agency prepared a reponse to EDMVAC Members accepting the recommendation. The recommendation and Agency response are available on the agency website and docket.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

The EDMVAC provides a wide range of advice on the endocrine disruptors screening program protocols and assays, for example, the number of laboratories to use for testing, the chemicals to use for testing (positives and negatives), the number of chemicals, the type of water (distilled, RO, tap), the number of replicates for testing, and the statistical tools to employ for data analyses, to name a few. The Agency considers or accepts the advice or recommendations of the EDMVAC as the assays progress through the iterative stages of validation.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑

Online Committee Web Site	☐
Online GSA FACA Web Site	☑
Publications	☐
Other	☑

Access Comments

EPA's Electronic Docket.