

Committee functions to provide advice on the activities and priorities of the National Toxicological Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (Center) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and to provide advice on ways to foster partnership activities and productive interactions among all stakeholders. The Advisory Committee is composed of knowledgeable representatives drawn from academia, industry, public interest organizations, other state and Federal agencies, and the international community.

The NTP established the Center and ICCVAM to fulfill specific mandates provides to the National Institutes of Environmental Health Sciences (NIEHS) by Public Law 103-43, Section 1301. The NIEHS was directed to (1) develop and validate toxicological testing methods including alternative methods that can reduce or eliminate the use of animals in acute or chronic toxicity testing, (2) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (3) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use. Criteria and processes for validation and regulatory acceptance were developed in conjunction with 14 other Federal agencies and programs with broad input from the public. These are described in the document Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods NIH Publication No. 97-3981, March 1997, that is available on the internet at <http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/iccvam.html> or by request to the Center at the address provided below.

As a standing committee, ICCVAM was subsequently established as a collaborative effort by the NIEHS and 13 Federal regulatory and research agencies and programs. The ICCVAM provides cross-agency coordination and communications on issues relating to validation, acceptance, and national/international harmonization of toxicological test methods. The ICCVAM works with the Center to carry out the scientific review of proposed methods of multi-agency interest and provides recommendations regarding their usefulness to appropriate agencies. The ICCVAM also provides a mechanism for interagency communication with stakeholders throughout the process of test method development and validation. The

following Federal regulatory and research agencies and organizations are participating in this effort:

Consumer Product Safety Commission  
Department of Defense  
Department of Energy  
Department of Health and Human Services  
Agency for Toxic Substances and Disease Registry  
Food and Drug Administration  
National Institute for Occupational Safety and Health/Centers for Disease Control and Prevention  
National Institutes of Health  
National Cancer Institute  
National Institute of Environmental Health Sciences  
National Library of Medicine  
Department of the Interior  
Department of Labor  
Occupational Safety and Health Administration  
Department of Transportation  
Research and Special Programs Administration  
Environmental Protection Agency

The Center was established to provide operational support for the ICCVAM and to assist Federal agencies by coordinating and facilitating (1) the interagency review and adoption of toxicological test methods of multi-agency interest and (2) the participation and communication with other stakeholders throughout the process of test method development and validation. The Center organizes, in collaboration with ICCVAM, independent scientific peer reviews and workshops for test methods of interest to Federal agencies. Peer review panels are convened to develop scientific consensus on the usefulness of test methods and to generate information for specific human health and/or ecological risk assessment purposes. Expert workshops and panel meetings are convened to evaluate the adequacy of current test methods for assessing specific toxicities, to identify areas in need of improved or new methods, to evaluate proposed validation studies, to evaluate the status of methods at various stages of validation, and to develop recommendations and priorities for related test method research, development, and validation. The Center provides an opportunity for partnerships with other agencies and organizations to facilitate the development, validation, and review of alternative testing methods. The Center and ICCVAM seek to promote the scientific validation and regulatory acceptance of toxicological test methods that will enhance agencies' ability to assist risks and make decisions and that

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### National Toxicology Program; Meeting of the Advisory Committee on Alternative Toxicological Methods

Pursuant to Section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Toxicological Program (NTP) Advisory Committee on Alternative Toxicological Methods, U.S. Public Health Service. The meeting will be held from 1:00 p.m. to 5:00 p.m. on March 7, 2000 and from 8:45 a.m. to 4:15 p.m. on March 8, 2000 in the Conference Center, Building 101, South Campus, NIEHS, 111 Alexander Drive, Research Triangle Park, North Carolina, 27709. The entire meeting is open to the public and time is planned for persons who would like to make public comments. Preregistration is not required and attendance is limited only by the space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations are asked to notify the contact person listed below in advance of the meeting.

#### Background

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services has established an Advisory Committee on Alternative Toxicological Methods. The

will refine, reduce, and replace animal use whenever possible. The Center's office is located at the NIEHS and can be contacted by telephone: 919-541-3398, FAX: 919-541-0947, or email: [iccvam@niehs.nih.gov](mailto:iccvam@niehs.nih.gov).

#### Agenda

The agenda for the March 7th session will consist of presentations and discussions about new emerging technologies that are being developed and their potential usefulness in toxicological assessments. The Committee will also discuss issues and recommendations relevant to the validation of new and revised test methods that may incorporate these technologies. On March 8, the Committee will hear presentations and discuss issues relating to processes, priorities, and recent and proposed activities of the NTP Center and ICCVAM. The revised publication, *Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM* (revised October 20, 1999), is available on the internet at <http://iccvam.niehs.nih.gov/doc1.htm>.

#### Tentative Agenda

##### National Toxicology Program Advisory Committee on Alternative Toxicological Methods

Conference Center, Building 101, South Campus, NIEHS, 111 Alexander Drive, Research Triangle Park, North Carolina, 27709

*Tuesday, March 7*

1:00 p.m. Call to Order and Introductions  
1:05 p.m. Welcome

*Application of Emerging Technologies to Toxicology Testing: Gene Expression Assays*

1:10 p.m. Introduction and Overview of Gene Expression Assays and Microarray Technology; Application of Gene Expression Patterns to *In Vitro* and *In Vivo* Toxicological Assessments

- Discussion (15')

2:05 p.m. Application of Gene Expression Technology to Drug Development

- Discussion (10')

2:45 p.m. Break

3:00 p.m. Real Time and Quantitative PCR

- Discussion (10')

3:30 Proteomics

- Discussion (10')

4:00 p.m. Bioinformatics

- Discussion (10')

4:30 p.m. Committee Discussion: Validation Issues for New Technologies

5:00 p.m. Public Comments

*Wednesday March 8, 2000*

8:45 a.m. Call to Order and Introductions

8:55 a.m. Welcome from the NTP

9:05 a.m. Update on NTP Center and ICCVAM Activities

- Discussion (25')

10:00 a.m. Break

10:15 a.m. Regulatory Acceptance Status of ICCVAM Recommended Methods:

- EPA
- FDA
- OSHA
- CPSC

11:00 a.m. Summary of Revisions to ICCVAM Test Methods Submission Guidelines

11:30 a.m. Committee Discussion/Recommendations on Submission Guidelines

12:00 p.m. Public Comments

12:15 p.m. Lunch Break

*Development and Validation of New Test Methods*

1:15 p.m. Introduction to Session

1:25 p.m. Current ICCVAM/NICEATM Role in Test Method Development and Validation

- Discussion (15')

1:55 p.m. Current NIEHS External Activities for Support of Test Method/Model Development and Validation

2:40 p.m. Break

3:00 p.m. Open Discussion: Future Directions

4:00 p.m. Public Comments

4:15 p.m. Adjourn

A detail agenda with meeting schedule and the Committee roster will be available prior to the meeting on the NTP web site (<http://ntp-server.niehs.nih.gov>) and by contacting the NTP Executive Secretary, Environmental Toxicology Program, P.O. Box 12233, A3-07, NIEHS, Research Triangle Park, North Carolina 27709, telephone: 919-541-3971 and FAX: 919-541-0295. Summary minutes will also be available subsequent to the meeting by contacting the address above.

#### Solicitation of Public Comment

The Advisory Committee on Alternative Toxicological Methods meeting is open to the public, and time is reserved on both days for any interested member of the public to give oral comments on the activities, directions, or priorities of the Center and/or on any of the agenda items

discussed at the meeting. In order to facilitate planning for the meeting, persons wishing to make an oral presentation are asked to notify the Executive Secretary prior to the meeting at the address given above; however, registration for public comments will also be available on-site at the meeting. A person registering to make comments will be asked to provide his/her name, affiliation, mailing address, phone, fax, e-mail and supporting organization (if any).

Written comments can accompany or be provided in lieu of making oral comments. All comments must include name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any) and should be sent to the Executive Secretary at the address given above.

Dated: February 7, 2000.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

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