

Box 12233, Research Triangle Park, NC 27709; telephone: 919-541-5021; facsimile: 919-541-0295; or E-mail: thayer.niehs.nih.gov.

Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, are asked to notify the NTP Executive Secretary at least seven business days in advance of the meeting (see contact information above).

A preliminary agenda is provided below. A copy of the agenda, committee roster, and any additional information, when available, will be posted on the NTP Web site (<http://ntp-server.niehs.nih.gov>) under "What's New" or available upon request to the NTP Executive Secretary (contact information provided above). Additional information about SACATM is available through the NICEATM/ICCVAM Web site (<http://iccvam.niehs.nih.gov>) under "Advisory Committee". Following the meeting, summary minutes will be prepared and available at this Web site and upon request to the NTP Liaison and Scientific Review Office (contact information above). Information about NICEATM and ICCVAM activities can also be found at the NICEATM/ICCVAM Web site (<http://iccvam.niehs.nih.gov>) or by contacting the Director of NICEATM, Dr. William Stokes (919-541-2384, or e-mail: niceatm@niehs.nih.gov).

Preliminary Agenda

Scientific Advisory Committee on Alternative Toxicological Methods— March 10–11, 2004

Hyatt Regency Hotel, 301-657-1234 or 800-233-1234, One Bethesda Metro Center, Bethesda, MD 20814.

March 10, 2004

8:30 a.m.

1. Call to Order and Introductions
2. Welcome and Remarks from NIEHS/NTP
3. Welcome and Remarks from ICCVAM Chair
4. Update on Activities of the NTP Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
5. Update on Activities of the European Centre for the Validation of Alternative Methods (ECVAM)
6. Toxicology in the 21st Century: The Role of the National Toxicology Program
 - a. Public Comment
7. Update on Animal Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of a Meeting of the Scientific 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 Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on March 10–11, 2004, in the Hyatt Regency Hotel, One Bethesda Metro Center, Bethesda, MD (301-657-1234 or 800-233-1234). The meeting begins each day at 8:30 a.m. The SACATM provides advise on the statutorily mandated duties of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the activities of the NTP Center for the Evaluation of Alternative Toxicological Methods (NICEATM).

Agenda

The meeting is being held on March 10–11, 2004 from 8:30 a.m. until adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are asked to register with the NTP Executive Secretary (Dr. Kristina Thayer at the NTP Liaison and Scientific Review Office, NIEHS, P.O.

- 12 p.m.
Lunch Break (on your own)
- 1 p.m.
8. ICCVAM Strategic Planning Process
 - a. Public Comment
 9. ICCVAM Recommended Performance Standards for In Vitro Dermal Corrosivity Methods
 - a. Public Comment
 10. Evaluation of the Predictivity of In Vivo Dermal Corrosivity Test Methods
 - a. Public Comment
 11. Overview of ILSI/HESI Subcommittee's Activities on Identification of Biomarkers of Toxicity and Summary of First Meeting
 12. Validation of Genetically Modified Mouse Models
 - a. Public Comment
- 5 p.m.
Adjourn

March 11, 2004

- 8:30 a.m.
1. Introductions and Call to Order
 2. ICCVAM–NICEATM–ECVAM Workshop on Validation of Toxicogenomics-Based Test Systems
 - a. Public Comment
 3. In Progress Test Method Evaluation Nomination: In Vitro Test Methods for Identifying Substances Causing Irreversible Ocular Damage
 4. New Test Method Nominations: EPA Test Method Nomination for Test Methods to Identify Negative, Mild, and Moderate Ocular Irritants (*i.e.* Those With Reversible or No Effect)
 - a. Public Comment
- 11:30 p.m.
Lunch (on your own)
- 12:30 p.m.
New Test Method Nominations continued: In Vitro Vaccine Potency Tests for Veterinary Leptospira Vaccines
 - a. Public Comment
6. Report on the ECVAM Workshop on In Vitro Replacements for Acute Systemic Toxicity
 - a. Public Comment
- 2:45 p.m.
7. Other Issues
- 3:15 p.m.
Adjourn

Public Comment Welcome

Public input at this meeting is invited and time is set aside for the presentation of public comments on any agenda topic. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. In order to facilitate

planning for this meeting, persons wishing to make an oral presentation are asked to notify the NTP Executive Secretary (contact information above) by March 1, 2004, and to provide their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any). Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to provide a copy of their statement to the NTP Executive Secretary (contact information above) by March 1, 2004, to enable review by the SACATM and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the SACATM and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site (<http://ntp-server.niehs.nih.gov>) under "What's New".

Persons may also submit written comments in lieu of making oral comments. Written comments should be sent to the NTP Executive Secretary and should be received by March 1, 2004, to enable review by the SACATM and NIEHS/NIH prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document.

Background

The SACATM was established January 9, 2002 to fulfill section 3(d) of Public Law 106–545, the ICCVAM Authorization Act of 2000 [42 U.S.C. 2851–3(d)] and is composed of scientists from the public and private sectors (**Federal Register**: March 13, 2002: Vol. 67, No. 49, page 11358). The SACATM provides advice to the Director of the National Institute of Environmental Health Sciences (NIEHS), the Interagency Coordinating Committee on the Validation of Alternative Toxicological Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding statutorily mandated duties of the ICCVAM and activities of the NICEATM. The committee's charter is posted on the Web at <http://iccvam.niehs.nih.gov>

under "Advisory Committee" and is available in hard copy upon request from the NTP Executive Secretary (contact information above).

Dated: February 2, 2004.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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