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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Health Service**

**National Institute of Environmental Health Sciences; Notice of Establishment; Scientific Advisory Committee on Alternative Toxicological Methods**

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director of the National Institute of Environmental Health Sciences (NIEHS) announces the establishment of the Scientific Advisory Committee for Alternative Toxicological Methods (SACATM).

**SACATM**

The SACATM was chartered January 9, 2002, to fulfill section 3(d) of Pub. L. 106-545, the ICCVAM Authorization Act of 2000 (42 U.S.C. 285f-3(d)). The committee will function as an advisory committee in compliance with the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). The charter is posted on the web (<http://iccvam.niehs.nih.gov>) or is available in hard copy upon request from the National Toxicology Program (NTP) Liaison and Scientific Review Office, NIEHS, PO Box 12233, Research Triangle Park, NC 27709; telephone: 919-541-3971; facsimile: 919-541-0295 or [liason@starbase.niehs.nih.gov](mailto:liason@starbase.niehs.nih.gov).

The SACATM will provide advice to the Director of the NIEHS, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding statutorily mandated duties of ICCVAM. The duties of the ICCVAM include:

(1) Review and evaluate new or revised or alternative test methods, including batteries of tests and test screens, that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised or alternative test methods of interagency interest.

(2) Facilitate appropriate interagency and international harmonization of acute or chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods.

(3) Facilitate and provide guidance on the development of validation criteria, validation studies, and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders.

(4) Submit ICCVAM test recommendations for the test methods reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services (Secretary) (or the designee of the Secretary), to each appropriate Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for a test methods, including batteries of tests and test screens, for chemicals or class of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods.

(5) Consider for review and evaluation, petitions received from the public that—(A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and (B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method.

(6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the response from the agencies regarding these recommendations.

(7) Prepare reports to be made available to the public on its progress under the Act.

The SACATM will also provide advice to the Director of the NIEHS and the NICEATM on activities and directives relating to the NICEATM in three areas:

(1) Priorities and opportunities for alternative test methods that may provide improved prediction of adverse health effects compared to currently used methods or advantages in terms of reduced expense and time, reduced animal use, and reduced animal pain and distress;

(2) Development and implementation of more effective and efficient processes for determining the scientific validity and acceptability of proposed new test methods; and

(3) Ways to foster more effective and productive interactions between Federal

agencies and other involved stakeholders, including test method developers.

Future meetings of the SACATM will be posted on the NICEATM/ICCVAM web site (<http://iccvam.niehs.nih.gov>) and announced in the **Federal Register**. Additional information about the ICCVAM and the NICEATM is also available on the web.

Dated: March 1, 2002.

**Kenneth Olden,**

*Director, National Institute of Environmental Health Sciences.*

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