CHARTER

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

PURPOSE

The Director, National Institute of Environmental Health Sciences (NIEHS) established the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on January 9, 2002 to fulfill section 3(d) of Public Law 106-545, the ICCVAM Authorization Act of 2000 [42 U.S.C 285*l*-3(d)]. SACATM replaces the Advisory Committee on Alternative Toxicological Methods (ACATM). The purpose of SACATM is to advise the NIEHS, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding ICCVAM activities. SACATM also advises the NIEHS and the NICEATM on NICEATM activities. Outside advice by an officially chartered committee is key to the acceptance and the level of trust by the scientific and public sectors and to the broadening of partnerships beyond government.

The Department of Health and Human Services (HHS) has a vital role in safeguarding public health and developing strategies to accurately determine the safety or adverse health effects of chemicals and other substances to which the public is exposed. The Secretary of HHS established the NTP on November 15, 1978, to strengthen HHS's activities in the testing of chemicals of public health concern as well as in the development and validation of new and better-integrated test methods. The NTP is headquartered at the NIEHS and the Director of NIEHS serves also as Director of the NTP. Pursuant to section 463A of the Public Health Service Act, as amended (Act), 42 U.S.C. 285*l*-l, the NIEHS and the NTP established ICCVAM and NICEATM in 1998. Section 3(a) of the ICCVAM Authorization Act of 2000 [42 U.S.C. 285*l*-3(a)] designates ICCVAM as a permanent interagency coordinating committee of the NIEHS under the NICEATM.

The purposes of the ICCVAM as defined in the law are to increase the efficiency and effectiveness of Federal agency test method review; eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies; optimize utilization of scientific expertise outside the Federal government; ensure that new and revised test methods are validated to meet the needs of Federal agencies; and reduce, refine, or replace the use of animals in testing, where feasible.

NICEATM supports activities and collaborates with ICCVAM to facilitate the development, scientific review, validation, and interagency consideration of novel toxicological methods of multiagency interest that predict human health risks while reducing, refining, and/or replacing

animal tests. NICEATM promotes participation and communication with stakeholders throughout the process of test method development and validation.

AUTHORITY

As described in Section 3(d) of Public Law 106-545 [42 U.S.C. 285*l*-3(d)], SACATM is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the following statutorily mandated ICCVAM functions:

(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 HHS (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.

SACATM also provides advice to the Director of the NIEHS and NICEATM on activities and directives relating to 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 pain and distress, and the reduction, replacement, or refinement of animal use;
(2) The adequacy and effectiveness of processes used for determining the scientific validity and acceptability of proposed new or revised or alternative test methods; and
(3) Ways to foster more effective and productive interactions between Federal agencies and other involved stakeholders, including test method developers.

As necessary, and with the approval of the Executive Secretary, the Committee and its subcommittees may call upon special consultants, assemble ad hoc working groups, and convene conferences, workshops, or other activities.

STRUCTURE

The Committee shall consist of 15 members, including the Chair. Voting members shall be appointed by the Director, NIEHS, and include representatives from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories. Knowledgeable representatives from public health, environmental communities, or organizations using new or alternative test methodologies may be included as appropriate. There shall be at least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of the following categories: (1) personal care, pharmaceutical, industrial chemicals, or agricultural industry; (2) any other industry that is regulated by one of the Federal agencies on ICCVAM; and (3) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986.

The Director, NIEHS, shall select the Chair from among the appointed members of SACATM. None of these members serve as Representatives. A quorum for the conduct of business by the full SACATM shall consist of a majority of currently appointed members. A quorum for each subcommittee shall be three members.

Members and the Chair shall be invited to serve for overlapping terms of up to four-years; terms of more than two years are contingent upon renewal of the SACATM charter by appropriate action prior to its expiration. Members may serve after the expiration of their terms until a successor has been appointed.

The membership of SACATM shall include, as nonvoting ex officio members, the agency heads or their designees from the Federal agencies represented on ICCVAM. International regulatory and/or international research organizations may also be invited to designate a liaison member to SACATM. Liaison members shall not have voting privileges.

As necessary, subcommittees may be established by the Executive Secretary or other designated Government official within the Committee's jurisdiction. The advice/recommendations of a subcommittee must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. Ad hoc consultants do not count towards the quorum and may not vote. Subcommittee members who are not members of the parent committee may attend closed sessions of the parent committee meeting but they may not count towards the quorum of the parent committee and they cannot vote on committee actions. The Department Committee Management Officer shall be notified upon establishment of each standing subcommittee and shall be provided information on its name, membership, function, and estimated frequency of meetings.

The Director, NIEHS, will assign a full-time or permanent part-time NIEHS employee to serve as the Executive Secretary (also known as the Designated Federal Official or Government official) of the committee. Management and support services shall be provided by the NTP Office of Liaison, Policy, and Review, NIEHS and NICEATM.

MEETINGS

Meetings of the full Committee shall be held up to two times year, at the call of the Executive Secretary or other designated Government official. A Government official shall give advance approval of the agenda and be present at all meetings of the Committee and its subcommittees.

Meetings shall be open to the public except as determined otherwise by the Secretary of Health and Human Services in accordance with subsection (c) of section 552b of the Title 5, U.S.C. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept, as required by applicable laws and Departmental policies.

COMPENSATION

Members shall be paid at the rate of $200 per day, plus per diem and travel expenses, as authorized by section 5703, Title 5 U.S.C., as amended, for persons in the Government service employed intermittently. Members who are officers or employees of the United States Government shall not receive compensation for service on the Committee.

ANNUAL COST ESTIMATE

The estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is $65,627. The estimate of annual person-years of staff support required is 1.0, at an estimated annual cost of $92,570.

REPORTS

In the event a portion of a meeting is closed to the public, as determined by the Secretary of Health and Human Services, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)), and the Federal Advisory Committee Act, a report shall be prepared which shall contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of Committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Charter for the Scientific Advisory Committee on Alternative Toxicological Methods will expire on December 18, 2009.

APPROVED:

11-14-07
Date

David H. Wise
Acting Director, NIEHS and NTP

CHARTER FILING DATE 12/18/07