



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

## CHARTER

### NATIONAL TOXICOLOGY PROGRAM SPECIAL EMPHASIS PANEL

#### PURPOSE

In accordance with a determination by the Secretary of Health and Human Services, the National Toxicology Program (NTP) was established on November 15, 1978. The purpose of the NTP was to strengthen the Department's activities in the testing of chemicals of public health concern and in the development and validation of new toxicology test methods and to provide information about potentially harmful chemicals to health regulatory and research agencies, the scientific and medical communities, and the public.

The NTP has assumed an important role in providing scientific data and interpretations to regulatory and other health research agencies, the medical and scientific communities, and the public. The NTP relies upon the opinion and recommendations from ad hoc scientific experts for evaluating important issues of public concern. Such issues include the strength of the scientific evidence of the potential for harm from specific environmental or occupational exposures, the identification of toxicology knowledge gaps and data needs, and the evaluation of new/revised alternative toxicological methods of multi-agency interest that might improve or reduce, refine or replace the use of animals. The NTP has established specialized centers to coordinate many of these independent peer review activities and, in addition, sponsors special one-time reviews through its Liaison and Scientific Review Office.

NTP Special Emphasis Panels (SEP Panels) are technical, scientific advisory bodies established on an "as needed" basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening.

#### AUTHORITY

42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The Panel is governed by 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

The Panels shall advise the National Toxicology Program and its specialized centers on agents of public health concern, new/revised toxicological test methods, or other issues. The Panels shall provide independent scientific review and conduct objective and scientifically rigorous evaluations. They shall provide opinions and recommendations that include, but are not limited to, the strength of the scientific evidence that exposure to an agent is a hazard for human health,

the adequacy of new/revised toxicological test methods relative to current toxicological tests for assessing specific toxicities, or the validation status of test methods.

The Panel shall advise on the quality, reproducibility, and limitations of scientific findings; identify critical knowledge gaps and data needs; identify areas where improved or new test methods are needed; or advise on the design, conduct, and adequacy of validation studies for new/revised test methods.

As necessary and with the approval of the Scientific Review Official (SRO) or other designated Government official, the Panel may call upon special consultants, assemble working groups, and convene conferences and workshops.

### **STRUCTURE**

Members and Chairs shall be selected on an "as needed" basis in response to specific issues or areas to be considered. Members shall be selected from outstanding authorities knowledgeable in the various scientific disciplines pertinent to the specific issues or areas being considered.

Members of Department of Health and Human Services (DHHS) advisory committees may serve on a Panel if their expertise is required.

The Director, NTP, will assign full-time or permanent part-time NTP employees to serve as the Designated Federal Official (DFO), SRO, or designated Government official for the committee or to conduct individual meetings. Management and support services shall be provided by the Office of the Director of the Environmental Toxicology Program or the specific NTP Center.

### **MEETINGS**

Meetings of the Panel will be held as necessary, as determined by the DFO or other designated Government official, who shall also approve the agenda. A SRO or other designated Government official shall be present at all meetings of the Panel.

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 title 5, United States Code. 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 \$250 per day, plus per diem and travel expenses in accordance with Standard Government Travel Regulations. Members who are officers or employees of the United States Federal Government shall not receive compensation for service on the Panel.

**ANNUAL COST ESTIMATE**

The estimated annual cost for operating the Panel, including compensation and travel expenses for members but excluding staff support is \$181,417. The estimate of annual person-years of staff support required is 1.4, at an estimated annual cost of \$210,256.

**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 Panel's functions, dates, places of meetings, and a summary of the Panel's 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 National Toxicology Program Special Emphasis Panel will expire on January 7, 2011.

**APPROVED**

DEC 16 2008

Date

  
Redacted

Secretary



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**NOTICE OF RENEWAL  
NATIONAL TOXICOLOGY PROGRAM  
SPECIAL EMPHASIS PANEL**

I determine that renewal of the National Toxicology Program Special Emphasis Panel beyond January 7, 2009, is in the public interest in connection with the performance of duties imposed on the Department by law, and that these duties can best be performed through the advice and counsel of such a group. The Panel is continued until January 7, 2011.

I further deem that it is not feasible for the Department or any of its existing committees to perform these duties, and that a satisfactory plan for appropriate balance of Panel Membership has been submitted.

DEC 16 2008

Date

Redacted

Secretary