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Dated: July 21, 1998.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 98-20045 Filed 7-27-98; 8:45 am]

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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 Public Law 92-463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Advisory Committee on Alternative Toxicological Methods, U.S. Public Health Service. The meeting will be held from 8:45 a.m. to 4:00 p.m. on September 25, 1998 in the Conference Center, Building 101, South Campus, NIEHS, 111 Alexander Drive, Research Triangle Park, North Carolina, 27709. The meeting will be open to the public from 8:45 a.m. to adjournment with attendance limited only by space available.

#### 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 Committee functions to provide advice on the activities and priorities of the National Toxicology 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 National Toxicology Program established the Center and ICCVAM to fulfill specific mandates provided to the National Institute of Environmental Health Sciences by P.L. 103-43, Section 1301. The NIEHS was directed to (1) develop and validate toxicological testing methods, including alternative methods than 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 Intragovernmental Coordination Committee on the Validation of Alternative Methods" NIH publication 97-3981, March 1997, which is available on the internet at <http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/ICCVAM.htm>, or by request to the Center at the address provided below.

A standing Intragovernmental Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was subsequently established as a collaborative effort by NIEHS and 13 other Federal regulatory and research agencies and programs. The ICCVAM facilitates cross-agency communication and coordination 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/CDC  
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 methods 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 to generate information for specific human health and/or ecological risk assessment purposes. Expert workshops 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, and to evaluate the validation status of methods. 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 assess risks and make decisions, and that will refine, reduce, and replace animal use whenever possible. The Center Office is located at NIEHS and can be contacted by telephone at 919-541-3398, fax 919-541-0947, or e-mail, [iccvam@niehs.nih.gov](mailto:iccvam@niehs.nih.gov).

#### Agenda

The primary agenda topics are concerned with presentations and discussions relating to processes, priorities, and recent and proposed activities of the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the Validation of Alternative Methods.

The Executive Secretary, Dr. Larry Hart, Environmental Toxicology Program, P.O. Box 12233, NIEHS,

Research Triangle Park, North Carolina 27709, telephone (919) 541-3971, FAX (919) 541-0295, will have available an agenda with times and a roster of Committee members prior to the meeting and summary minutes subsequent to the meeting.

Dated: June 17, 1998.

**Samuel H. Wilson,**

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

[FR Doc. 98-20041 Filed 7-27-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### **National Institute of Environmental Health Sciences; National Toxicology Program; Request for Comments on Test Methods Undergoing Review by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the National Toxicology Program Interagency Center for the Evaluation of Alternative Methods**

#### **Background**

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), with participation by 14 Federal regulatory and research agencies and programs, was established in 1997 to facilitate cross-agency communication and coordination on issues relating to validation, acceptance, and national/international harmonization of toxicological test methods. The Committee seeks to promote the scientific validation and regulatory acceptance of toxicological test methods that will enhance agencies' ability to assess risks and make decision, and that will refine, reduce, and replace animal use whenever possible. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (Center), in collaboration with ICCVAM, carries out related activities such as independent 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 to generate information for specific human health and/or ecological risk assessment purposes. Expert workshops are convened as needed to evaluate the adequacy of current methods for assessing specific toxicities, to identify areas in need of improved or new methods, to evaluate proposed

validation studies, and to evaluate the validation status of methods. Following the peer review of proposed test methods, the ICCVAM forwards recommendations regarding their usefulness to appropriate agencies for their consideration. Federal agencies then determine the regulatory acceptability of a method according to their mandates.

Additional information on the activities and functions of the ICCVAM can be found in the publication: Validation on Regulatory Acceptance of Toxicological Test Methods, a Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (NIH Publication 97-3981, March 1997). This report was prepared in response to the National Institutes of Health (NIH) Revitalization Act of 1993 (Pub. L. 103-43), which required the NIEHS to develop criteria and recommended processes for the validation and regulatory acceptance of alternative toxicological test methods. The report is available on the internet at <http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/ICCVAM.html>, or may be requested from the NTP Center address listed below.

#### **Request for Comments**

Interested parties are encouraged to submit information and data that would be helpful in evaluating the usefulness of two test methods for which upcoming independent scientific peer review meetings are being planned. The methods are: (1) *Corrositex*<sup>®</sup>, an in vitro method proposed for assessing the dermal corrosivity potential of chemicals and products; and (2) the Frog Embryo Teratogenesis Assay in *Xenopus* (FETAX), a method for demonstrating developmental toxicity. Potential regulatory applications of FETAX to human health developmental toxicity assessments include screening and prioritizing compounds for further testing, evaluating complex mixtures in environmental samples, and as supplemental information in a weight-of-evidence evaluation of human developmental toxicity hazards.

The Center would welcome receiving information and data from completed, ongoing, or planned studies using or evaluating these test methods. Data and information submitted should address one or more of the criteria for validation and regulatory acceptance as provided in NIH publication 97-3981, "Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the AD Hoc Interagency Coordinating Committee on the Validation of Alternative Methods". Where possible, data and information should adhere to

the guidance provided in the document "Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM", which is available on request from the NTP Center at the address provided below. Relevant information submitted in response to this request will be used to prepare test methods background review documents for use by peer review and expert panels. Peer review meetings and/or workshops for these methods will be announced in future notices as they are scheduled.

Information on these test methods should sent by mail, fax, or e-mail to the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods within 45 days of the appearance of this notice. The NTP Center mailing address, phone, fax, and e-mail are as follows: MD EC-17, P.O. Box 12233, Research Triangle Park, NC 27709; 919-541-3398 (phone); 919-541-0947 (FAX); ICCVAM@niehs.nih.gov (e-mail). Additional information can be obtained from: Dr. William S. Stokes, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, Environmental Toxicology Program, NIEHS/NTP, P.O. Box 12233, Research Triangle Park, North Carolina 27709, telephone (919) 541-3398, FAX (919) 541-0947, [emailstokes@niehs.nih.gov](mailto:emailstokes@niehs.nih.gov).

Dated: July 17, 1998.

**Samuel H. Wilson,**

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

[FR Doc. 98-20040 Filed 7-27-98; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### **Information Collection Renewal To be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** The collection of information listed below has been submitted to the Office of Management and Budget (OMB) for renewal under the provisions of the Paperwork Reduction Act. Copies of the specific information collection requirements, related forms, and explanatory material may be obtained by contacting the Service Information Collection Clearance Officer at the address listed below.