

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Public Health Service****National Toxicology Program; National Institute of Environmental Health Sciences (NIEHS); National Institute of Health (NIH) Notice of Meeting to Review the Corrositex® Assay as an Alternative Test Method for Assessing the Skin Corrosivity Potential of Chemicals; Request for Comments**

SUMMARY: Pursuant to Public Law 103-43, notice is hereby given of a public meeting sponsored by the NIEHS and the National Toxicology Program (NTP), and coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicology Methods (NICEATM). The agenda topic is the scientific peer review of the Corrositex® assay, which is proposed as an in vitro alternative toxicological test method for assessing the skin corrosivity potential of chemicals and products. The meeting will be held on January 21, 1999, at the Natcher Center, National Institute of Health, 45 Center Drive, Bethesda, MD, 20892. The meeting will take place from 8:30 a.m. to 5:30 p.m. and is open to the public.

Background

Public Law 103-43 directed the NIEHS to develop and validate alternative methods that can reduce or eliminate the use of animals in acute or chronic toxicity testing, establish criteria for the validation and regulatory acceptance of alternative testing methods, and 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 13 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 Interagency Coordinating 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>. Additional information on ICCVAM and NICEATM can be found through the ICCVAM/NICEATM web site <http://iccvam.niehs.nih.gov>.

An Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was

subsequently established in a collaborative effort by NIEHS and 13 other Federal regulatory and research agencies and programs. The Committee's functions include the coordination of interagency reviews of toxicological test methods and 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 Corrositex® assay was proposed to ICCVAM for consideration as a test to identify the potential of chemicals to cause skin corrosion. An ICCVAM Corrosivity Working Group composed of Federal employees determined that there was sufficient information available to merit an independent scientific peer review of the Corrositex® assay test method. Peer review has been determined to be an essential prerequisite for consideration of a method for regulatory acceptance. The peer review panel will be charged with developing a scientific consensus on the usefulness of the test method to generate information for human hazard identification purposes. Following evaluation at this peer review meeting, the proposed test method and results of the peer review will be forwarded by ICCVAM to Federal agencies for consideration. Federal agencies will determine the regulatory acceptability of a method according to their mandates.

Agenda

There will be a brief orientation on ICCVAM and the ICCVAM review process, followed by peer review of the proposed Corrositex® test method and supporting information. The peer

review panel will discuss the usefulness of the Corrositex® assay as an alternative to test methods currently accepted by government regulatory authorities for the assessment of skin corrosivity potential of chemicals and products. Copies of the Corrositex® Test Method Protocol and supporting documentation may be obtained from NICEATM, MD EC-17, P.O. Box 12233, Research Triangle Park, NC, 27709 (919-541-3398), FAX (919-541-0947), e-mail: ICCVAM@niehs.nih.gov. The Corrositex® test method documents and copies of written public comments can also be viewed at the Consumer Products Safety Commission, Reading Room, 4330 East West Highway, Bethesda, MD 20814 on Monday through Friday from 8 am. to 5 pm.

Public Comment

NICEATM invites the submission of written comments on the proposed Corrositex® test method, and other available information regarding the usefulness of the Corrositex® assay, including information about completed, ongoing, or planned studies. Written comments and additional information should be sent by mail, fax, or e-mail to NICEATM at the address listed above by December 10, 1998. Written comments will be made available to the peer review panel members, ICCVAM agency representatives and experts, and will be made available for attendees at the meeting. Members of the public who wish to present oral statements at the meeting should also contact NICEATM as soon as possible, but no later than January 10, 1999. Speakers will be assigned on a first-come, first-serve basis and will be limited to a maximum of five minutes in presentation length. Written comments accompanying the oral statement should be submitted in advance so that copies can be made and distributed to the peer panel members.

NICEATM will furnish an agenda and a roster of peer review panel members just prior to the meeting. Summary minutes and a final report of the Corrositex® assay peer review meeting will be available subsequent to the meeting upon request to the Center. Persons needing special assistance, such as sign language interpretation or other special accommodations should contact NICEATM as described above.

Dated: October 20, 1998.

Kenneth Olden,

Director, National Toxicology Program.

[FR Doc. 98-28713 Filed 10-26-98; 8:45 am]

BILLING CODE 4140-01-M