

meeting is now available. The report contains (1) the Panel's evaluation of the updated validation status of the methods and (2) the Panel's comments on the updated draft ICCVAM test method recommendations. NICEATM invites public comment on the Panel's report. The report is available on the NICEATM-ICCVAM Web site at [http://iccvam.niehs.nih.gov/docs/immunotox\\_docs/LLNAPRPrept2009.pdf](http://iccvam.niehs.nih.gov/docs/immunotox_docs/LLNAPRPrept2009.pdf) or by contacting NICEATM at the address given below.

**DATES:** Written comments on the Panel report should be received by July 15, 2009.

**ADDRESSES:** Comments should be submitted preferably electronically via the NICEATM-ICCVAM Web site at [http://iccvam.niehs.nih.gov/contact/FR\\_pubcomment.htm](http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm). Comments can also be submitted by e-mail to [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Written comments can be sent by mail or fax to Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC 27709; (fax) 919-541-0947. Courier address: NIEHS, NICEATM, 530 Davis Drive, Room 2035, Durham, NC 27713. **FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes (telephone) 919-541-2384, (fax) 919-541-0947 and (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

In January 2007, the Consumer Product Safety Commission submitted a nomination to NICEATM and ICCVAM to assess the validation status of (1) the use of the LLNA to determine potency for hazard classification purposes, (2) LLNA protocols using non-radioactive procedures, (3) the LLNA limit dose procedure, and (4) the use of the LLNA to test mixtures, aqueous solutions, and metals (*i.e.*, an updated assessment of the applicability domain of the LLNA). In June 2007, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) endorsed these activities as high priorities for ICCVAM. NICEATM, on behalf of ICCVAM, also sought input from the public on these activities and requested data from studies using the LLNA or modified versions of the LLNA (72 FR 27815). After considering all comments received, ICCVAM endorsed carrying out these activities as high priorities. ICCVAM also developed draft LLNA performance standards to facilitate evaluation of modified LLNA protocols that are functionally and mechanistically similar to the traditional LLNA. These draft LLNA performance standards were made

public and comments were requested in September 2007 (72 FR 52130).

ICCVAM and NICEATM prepared draft background review documents (BRDs) that provided comprehensive reviews of available data and relevant information for each of the modifications and new applications of the LLNA. ICCVAM also developed draft test method recommendations regarding the proposed usefulness and limitations, standardized protocols, and future studies. NICEATM announced availability of the draft BRDs and draft recommendations for public comment and the public peer review meeting in January 2008 (73 FR 1360).

The Panel met in public session on March 4-6, 2008, to review these topics, and their report was made available in May 2008 (73 FR 29136). The draft BRDs and draft test method recommendations, the draft ICCVAM LLNA test method performance standards, the Panel's report, and all public comments were made available to SACATM for comment at their meeting on June 18-19, 2008 (73 FR 25754).

As a result of additional data received by ICCVAM subsequent to the March 2008 Panel meeting, the draft BRDs for the following were updated:

- The validation status of three modified LLNA test method protocols that do not require the use of radioactive substances.
- The use of the LLNA for testing pesticide formulations, other products, and aqueous solutions.

**Second Meeting of the Peer Review Panel**

The Panel met again in public session on April 28-29, 2009 (74 FR 8974). The Panel reviewed the revised draft ICCVAM documents for completeness, errors, and omissions of any existing relevant data or information. The Panel evaluated the information in the revised draft documents to determine the extent to which each of the applicable criteria for validation and acceptance of toxicological test methods (ICCVAM, 2003) had been appropriately addressed. The Panel then considered the ICCVAM draft recommendations for test method uses and limitations, proposed standardized protocol, proposed plans for development of test method performance standards, and proposed additional studies, and commented on the extent that the recommendations were supported by the information provided in the draft BRDs.

**Availability of the Peer Panel Report**

The Panel's conclusions and recommendations are detailed in the

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Independent Scientific Peer Review Panel Report: Updated Validation Status of New Versions and Applications of the Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals and Products: Notice of Availability and Request for Public Comments**

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Request for comments.

**SUMMARY:** NICEATM, in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), convened an independent, international, scientific peer review panel (hereafter, Panel) on April 28-29, 2009, to evaluate three non-radioactive modified versions and new applications for the Murine Local Lymph Node Assay (LLNA). The LLNA is an alternative test method that can be used to determine the allergic contact dermatitis potential of chemicals and products. The Panel report from this

*Independent Scientific Peer Review Panel Report: Updated Validation Status of New Versions and Applications of the Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals and Products* (available at [http://iccvam.niehs.nih.gov/docs/immunotox\\_docs/LLNAPRPrept2009.pdf](http://iccvam.niehs.nih.gov/docs/immunotox_docs/LLNAPRPrept2009.pdf)). The revised draft documents reviewed by the Panel and the draft ICCVAM test method recommendations are available at [http://iccvam.niehs.nih.gov/methods/immunotox/llna\\_PeerPanel.htm](http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel.htm).

#### Request for Public Comments

NICEATM invites the submission of written comments on the Panel's report. When submitting written comments, please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). All comments received will be made publicly available via the NICEATM-ICCVAM Web site at [http://iccvam.niehs.nih.gov/methods/immunotox/llna\\_PeerPanel.htm](http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel.htm). In addition, there will be an opportunity for oral public comments on the Panel's report during an upcoming meeting of SACATM scheduled for June 25–26, 2009 (74 FR 19562). Information concerning the SACATM meeting is available at <http://ntp.niehs.nih.gov/go/7441>. ICCVAM will consider the Panel report along with SACATM and public comments when finalizing test method recommendations. An ICCVAM test method evaluation report, which will include the final ICCVAM recommendations, will be forwarded to relevant Federal agencies for their consideration. The evaluation report will also be available to the public on the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm> and by request from NICEATM (see **ADDRESSES** above).

#### Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with

regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on their Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (67 FR 11358). SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov>/ see "Advisory Board & Committees" (or directly at <http://ntp.niehs.nih.gov/go/167>).

#### Reference

ICCVAM. 2003. ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods. NIH Publication No. 03–4508. Research Triangle Park, NC: NIEHS. Available at: <http://iccvam.niehs.nih.gov>.

Dated: May 19, 2009.

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