Subject: [Iccvam-all] ICCVAM Recommends Alternative Method to Identify Chemicals and Products with Significant Potential to Cause Allergic Contact Dermatitis

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The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) recently evaluated the usefulness of the murine local lymph node assay, or LLNA, for categorizing the potency of chemicals causing allergic contact dermatitis in humans. As announced in today's Federal Register, ICCVAM recommended to Federal agencies that the LLNA may be used to categorize some substances as strong sensitizers. Strong sensitizers are those substances considered to have a significant potential for causing skin hypersensitivity resulting in allergic contact dermatitis.

According to the U.S. Bureau of Labor Statistics, occupational skin diseases are the most common type of occupational illness. Many of these cases arise from repeated exposures to skin-sensitizing substances, which can lead to allergic contact dermatitis or ACD, an immunologically mediated hypersensitivity reaction. Studies have shown that ACD has a significant adverse impact on quality of life in affected individuals.

ICCVAM concluded that the LLNA can correctly categorize some substances as strong sensitizers using a criterion published in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, nearly half of the known human strong sensitizers evaluated by ICCVAM were not identified using the GHS criterion. ICCVAM concluded that additional information would need to be considered to confirm whether substances that do not meet this criterion are or are not strong sensitizers.

Substances with the potential to cause ACD can also be categorized with the traditional test methods using guinea pigs. However, the LLNA uses fewer animals than guinea pig test methods, requires less time to perform, provides dose-response information, and, in most cases, eliminates the potential for pain and distress in the test animal. In accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the LLNA should be routinely considered when planning animal studies to evaluate whether chemicals and products are strong sensitizers in order to minimize animal use and to avoid pain and distress.

The ICCVAM evaluation is detailed in a report entitled "ICCVAM Test Method Evaluation Report: Usefulness and Limitations of the Murine Local Lymph Node Assay for Potency Categorization of Chemicals Causing Allergic Contact Dermatitis in Humans" (NIH Publication No. 11-7709). The ICCVAM report and recommendations have been transmitted to Federal agencies for their review and response to ICCVAM in accordance with the provisions of the ICCVAM Authorization Act of 2000, which requires agencies to review the recommendations and respond to ICCVAM within 180 days.

ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) are also currently evaluating several in vitro and in chemico methods for their potential to further reduce and eventually replace the need for animals for ACD safety testing.

The ICCVAM Test Method Evaluation Report is available on the NICEATM-ICCVAM Web site at:
http://iccvam.niehs.nih.gov/methods/immunotox/LLNA-pot/TMER.htm

The Federal Register notice announcing the ICCVAM recommendations to Federal agencies is available at:
http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/FR/FR-2011-18639.pdf

More information about the ICCVAM evaluation of the use of the LLNA for potency categorization can be found on the NICEATM-ICCVAM Web site at:
http://iccvam.niehs.nih.gov/methods/immunotox/LLNApotency.htm

About NICEATM and ICCVAM

ICCVAM is an interagency committee composed of representatives from 15 U.S. Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of safety testing methods that more accurately assess the safety and health hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM also conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies.

ICCVAM has contributed to the approval or endorsement of over 40 alternative safety-testing methods by Federal regulatory agencies and international organizations since its establishment in 1997. Appropriate use of these test methods can significantly reduce animal use and improve animal welfare. ICCVAM has also identified critical research, development, and validation efforts needed to further advance numerous other alternative methods.

NICEATM and ICCVAM welcome nominations and submissions of alternative safety testing methods for validation studies and/or technical evaluations. Nominations and submissions are welcome from any individual or organization. Please contact NICEATM at niceatm@niehs.nih.gov for more information or to discuss a possible nomination or submission.

Additional information about other NICEATM and ICCVAM activities can be found on the NICEATM-ICCVAM Web site at http://iccvam.niehs.nih.gov/. Thank you for your interest and your support of NICEATM and ICCVAM.

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