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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Interagency Coordinating Committee on the Validation of Alternative Methods**

# Biennial Progress Report: 2016-2017; Availability of Report

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Biennial Progress Report: 2016-2017. This report, prepared in accordance with requirements of the ICCVAM Authorization Act of 2000, describes activities and accomplishments from January 2016 through December 2017.

**ADDRESSES:** The report is available at http://ntp.niehs.nih.gov/iccvamreport/2017/index.html.

**FOR FURTHER INFORMATION CONTACT:** Dr. Warren Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (984) 287-3118.

**SUPPLEMENTARY INFORMATION:**

**Background:** The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences (NIEHS) under NICEATM. ICCVAM's mission is to facilitate development, validation, and regulatory acceptance of new and revised regulatory test methods that reduce, refine, or replace the use of animals in testing while maintaining and promoting

scientific quality and the protection of human health, animal health, and the environment.

A provision of the ICCVAM Authorization Act states that ICCVAM shall prepare "reports to be made available to the public on its progress under this Act." The eighth ICCVAM biennial progress report describing ICCVAM activities and accomplishments from January 2016 through December 2017 is now available.

**Summary of Report Contents:** Key ICCVAM, ICCVAM agency, and NICEATM accomplishments summarized in the report include:

- Development of a strategic roadmap for incorporating new approaches into safety testing of chemicals and medical products in the United States.
- Publication of two guidance documents by the U.S. Environmental Protection Agency (EPA) in 2016. One included a policy statement to waive all acute dermal lethality studies for pesticide formulations. The other described a transparent, stepwise process for evaluating and implementing alternative methods for six-pack studies, which test for acute systemic toxicity by the oral, dermal, and inhalation routes; skin and eye irritation; and skin sensitization.
- Publication of notices permitting removal of back-titration hamsters for potency testing of vaccines containing Leptospira pomona and Leptospira grippotyphosa by the U.S. Department of Agriculture, further reducing the number of hamsters required for leptospirosis vaccine potency testing.
- Publication by the U.S. Food and Drug Administration of the Predictive Toxicology Roadmap for integrating predictive toxicology methods into safety and risk assessments.
- Development by NICEATM and EPA scientists of a defined approach that

combines data from 11 high-throughput screening assays with a computational model to identify chemicals with the potential to interact with the androgen receptor pathway.

- Development by NICEATM and ICCVAM scientists of a defined approach that uses non-animal approaches to predict murine local lymph node assay outcomes and human skin sensitization hazard and potency.
- Submission of a proposal to develop a performance-based test guideline for defined approaches to skin sensitization testing and assessment to the Organisation for Economic Co-operation and Development (OECD) by partners in the International Cooperation on Alternative Test Methods in 2016. The proposal was approved as part of the OECD workplan in 2017.
- Launch of the Integrated Chemical Environment, a publicly accessible online resource developed to provide high-quality curated data and computational workflows to facilitate chemical safety assessment, by NICEATM.

**Availability of Report:** The report is available at http://ntp.niehs.nih.gov/iccvamreport/2017/index.html. Links to this report and all past ICCVAM annual and biennial reports are available at http://ntp.niehs.nih.gov/go/iccvam-bien.

**Background Information on ICCVAM and NICEATM**: ICCVAM is an interagency committee composed of representatives from 16 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 and integrated testing strategies with regulatory applicability. ICCVAM also

promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at http://ntp.niehs.nih.gov/go/iccvam.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at http://ntp.niehs.nih.gov/go/niceatm.

Dated: July 24, 2018.

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