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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used to Identify Substances with the Potential to Cause Acute Systemic Toxicity

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests data and information on approaches and/or technologies currently used to identify substances with the potential to cause acute systemic toxicity when swallowed, inhaled, or absorbed through the skin. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce acute systemic toxicity.

DATES:

Receipt of information: Deadline is **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

Data and information should be submitted electronically to [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: [warren.casey@nih.gov](mailto:warren.casey@nih.gov); telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

**Background:** Acute systemic toxicity tests are conducted to determine the potential for a single or short-term dose of a substance to cause illness or death when inhaled (inhalation toxicity testing), swallowed (oral toxicity testing), or absorbed through the skin (dermal toxicity testing). These tests are required by multiple regulatory agencies and can use large numbers of animals. NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, supports efforts to develop, validate, and implement alternative approaches for acute systemic toxicity testing that replace, reduce, or refine use of animals in testing.

**Request for Information:** NICEATM requests data and information on approaches and/or technologies currently used to identify substances with the potential to cause acute systemic toxicity. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo tests currently required by regulatory agencies that assess acute oral, dermal, or inhalation toxicity. Of specific interest are chemical-specific data from non-animal tests for acute systemic toxicity hazard, as well as available data on the same chemicals from in vivo acute systemic toxicity tests, such as ethical human or animal studies or accidental human exposures.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is

**[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Responses to this notice will be posted at <http://ntp.niehs.nih.gov/go/iv->

data. Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

**Background Information on NICEATM:** NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) provides authority for ICCVAM and NICEATM in the development of alternative test methods. Information about NICEATM and ICCVAM is found at <http://ntp.niehs.nih.gov/go/niceatm> and <http://ntp.niehs.nih.gov/go/iccvam>.

Dated: July 12, 2016.

John R. Bucher, Ph.D.

Associate Director, National Toxicology Program.

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