



This document is scheduled to be published in the Federal Register on 10/26/2016 and available online at <https://federalregister.gov/d/2016-25924>, and on [FDsys.gov](https://fdsys.gov)

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Short-term Alternative Animal Models or In Vitro Tests Used to Identify Substances with the Potential to Cause Excessive Inflammation or Exaggerated Immune Responses;

Request for Information

**SUMMARY:** The National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIEHS) requests available data and information on approaches and/or technologies currently used to identify substances with the potential to cause excessive inflammation or exaggerated immune responses leading to tissue injury 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 that could be used to evaluate the potential of chemicals to induce inflammation and immune-related conditions.

**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 at

<http://ntp.niehs.nih.gov/go/input>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Dori Germolec, Toxicology Branch, Division of NTP, NIEHS; email: [germolec@niehs.nih.gov](mailto:germolec@niehs.nih.gov); telephone: (919) 541-3230.

**SUPPLEMENTARY INFORMATION:**

**Background:** NTP has an interest in developing more efficient and scalable test platforms to provide the scientific basis for predictive models of chemical effects on

human disease. Short-term toxicity tests may be conducted to determine the potential for a single or short-term dose of a substance to cause inflammation-related responses or impact local and systemic immune function when inhaled (inhalation toxicity testing), swallowed (oral toxicity testing), or absorbed through the skin (dermal toxicity testing). A number of observations support a role for environmental influences on inflammatory and immune-related diseases such as diabetes. One specific use of information received in response to this request is to assist NTP in identifying in vitro or alternative animal model screens that might be used to assess the potential for chemicals to cause outcomes related to Type 1 diabetes. In addition, information received from this request will provide fundamental knowledge on the use of these in vitro platforms for identifying environmental triggers of excessive inflammation and exaggerated immune responses that could lead to tissue injury.

**Request for Information:** NTP requests available data and information on approaches and/or technologies currently used to identify substances with the potential to cause excessive inflammation or exaggerated immune responses leading to tissue injury.

Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo tests currently used in the assessment of immune toxicity and autoimmunity.

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 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 NTP:** NTP is an interagency program established in 1978 (43 FR 53060) to strengthen the Department's activities in toxicology research and testing and to develop and validate new and better testing methods. Other activities of the program focus on strengthening the science base in toxicology and providing information about potentially toxic chemicals to health-regulatory and research agencies, scientific and medical communities, and the public. NTP is located administratively at the NIEHS. Information about NIEHS and NTP is available at <http://www.niehs.nih.gov> and <http://ntp.niehs.nih.gov>, respectively.

Dated: October 20, 2016

John R. Bucher, Ph.D.

Associate Director, National Toxicology Program

[FR Doc. 2016-25924 Filed: 10/25/2016 8:45 am; Publication Date: 10/26/2016]