[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information: The National Toxicology Program requests information on assays and approaches useful for screening compounds for potential neurotoxicity.

SUMMARY: The National Toxicology Program (NTP) requests information on medium- or high-throughput technologies/assay systems, which allow for the batch screening of compounds (e.g., 25-50) in biochemical- or cell-based assays or alternative (non-rodent) animal models, that might be used to prioritize compounds for in vivo neurotoxicity testing.

DATES: The deadline for receipt of information is [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Information may be submitted electronically or as printed copy.

Electronic submissions: Email to barbourp@niehs.nih.gov.

Print submissions: Send 4 copies to Patrick J. Barbour, Contract Specialist, National Institute of Environmental Health Sciences (NIEHS), P. O. Box 12233 (MD K1-05), Research Triangle Park, NC 27709. Courier address: 530 Davis Drive, Keystone Building, Room 1059, Morrisville, NC 27560.

FOR FURTHER INFORMATION CONTACT: Patrick J. Barbour, Contract Specialist, NIEHS, P. O. Box 12233 (MD K1-05), Research Triangle Park, NC 27709. Courier address: 530 Davis Drive, Keystone Building, Room 1059, Morrisville, NC 27560. Email: barbourp@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background: For the purposes of this request for information (RFI), neurotoxicity means adverse outcomes to the nervous system resulting from exposure during any life stage. Special emphasis is placed on identifying assay systems that interrogate cellular and molecular events that are critical to the development and/or function of the nervous system. The NTP is also interested in receiving recommendations on molecular targets within critical cellular toxicity pathways in biochemical- or cell-based assays or alternative animal models that assess the potential ability of compounds to act as toxicants to the developing or adult nervous systems.

Request for Information:

1. Information on technologies/assays currently available for screening critical pathways involved in neurotoxicity where the endpoint is associated with a phenotypic manifestation of toxicity <u>in vivo</u> (adverse outcome).

a. The referred technologies/assays should have the ability to batch screen sets of at least 20 compounds to produce a concentration response curve suitable for defining the potency and efficacy of a response and have been demonstrated to be both reliable and relevant.

b. Specific information requested for each assay includes the robustness of the assay, dose-response and time-course toxicity profiles, as well as to what extent the assay informs on specific neurotoxicity life-stage windows (i.e., developmental, juvenile, ageing).

2. Information on assays that can be used to measure the activity of a compound on a molecular initiating event or key event within a neurotoxicity adverse outcome pathway.

3. Information on the best molecular or cellular targets that accurately characterize the activity of a compound within a specific pathway resulting in an adverse neurotoxic outcome.

4. Information on assays, technologies, or methods that will aid in identifying neurotoxic compounds, which are activated or deactivated by metabolic activity.

Respondents to this RFI are asked to provide the following: the Data Universal Numbering System or DUNS® number, organization name, address, technical and administrative points of contact (including names, titles, addresses, telephone and fax numbers, and email address), the North American Industry Classification System (NAICS) code, and size and type of business (e.g., 8(a), HUBZone, WOSB, SDVOSB, etc.). Information packages should not exceed one (1) page in length, excluding standard brochures. Telephone and facsimile responses will not be accepted. Electronic information should be submitted in Microsoft Office (Word, PowerPoint, Excel), Adobe PDF, or compatible formats sufficient to clearly read the information provided. Please include a cover page identifying the technical and administrative points of contact for the organization, including names, titles, addresses, telephone and fax numbers, email addresses, and organization name. The deadline for receipt of the requested information

is [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Responses to this request are voluntary. This notice does not obligate the U.S. Government to award a contract or otherwise pay for the information provided in response to this request. The U.S. Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this request should ensure that its response is complete and sufficiently detailed. Respondents are advised that the U.S. Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential, or sensitive information should be included in your response.

Background Information on the NTP: The NTP is an interagency program established in 1978 (43 FR 53060) to coordinate toxicology research and testing across the Department of Health and Human Services. Other activities of the program focus on strengthening the science base in toxicology, developing and validating improved testing methods, and providing information about potentially toxic chemicals to health regulatory and research agencies, scientific and medical communities, and the public. Information about the NTP is found at http://ntp.niehs.nih.gov.

Dated: March 25, 2013

John R. Bucher, Ph.D.

Associate Director, National Toxicology Program

[FR Doc. 2013-07420 Filed 03/29/2013 at 8:45 am; Publication Date: 04/01/2013]