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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences, National Toxicology Program, Request for Data and Suggested Expert Panelists for Evaluation of the Current Status of the Frog Embryo Teratogenesis Assay--Xenopus (FETAX)

Background

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), with participation by 14 Federal regulatory and research agencies and programs, was established in 1997 to facilitate cross-agency communication and coordination on issues relating to validation, acceptance, and national/international harmonization of toxicological test methods. The Committee seeks to promote the scientific validation and regulatory acceptance of toxicological test methods that will enhance agencies' ability to assess risks and make decisions, and that will refine, reduce, and replace animal use whenever possible. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), provides administrative and technical support for ICCVAM, and serves as a communication and information resource. NICEATM and ICCVAM collaborate to carry out related activities needed to develop, validate, and achieve regulatory acceptance of new and improved test methods applicable to Federal agencies. These activities may include:

Test Method Workshops, which are convened as needed to evaluate the adequacy of current methods for assessing specific toxicities, to identify areas in need of improved or new testing methods, and to identify research efforts that may be needed to develop a new test method.

Expert Panel Meetings, which are typically convened to evaluate the validation status of a method following the completion of initial development and pre-validation studies. An Expert Panel is asked to recommend additional validation studies that might be helpful in further characterizing the usefulness of a method, and to identify any additional research and development efforts that might enhance the effectiveness of a method.

Independent Peer Review Panel Meetings, which are typically convened following the completion of comprehensive validation studies on a test method. Peer review panels are asked to develop scientific consensus on the usefulness and limitations of test methods to generate information for specific human health and/or ecological risk assessment purposes. Following the independent peer review of a test method, ICCVAM forwards recommendations on their usefulness to agencies for their consideration. Federal agencies then determine the regulatory

acceptability of a method according to their mandates.

Evaluation of FETAX

ICCVAM and NICEATM are currently planning an Expert Panel Meeting to assess the current validation status of the Frog Embryo Teratogenesis Assay--Xenopus (FETAX), a method proposed for evaluating the developmental toxicity potential of chemicals (Bantle JA, 1995, FETAX--A Developmental Toxicity Assay Using Frog Embryos, Fundamentals of Aquatic Toxicology, 2nd ed., G.M. Rand, ed, Taylor and Francis, USA. pp. 207-230). Possible applications of FETAX to human health and environmental assessments may include screening and prioritizing compounds for further testing, evaluating complex mixtures and environmental samples, and as supplemental information in a weight-of-evidence evaluation of toxicity hazards. NICEATM is preparing a background document summarizing the initial studies and the performance characteristics of FETAX. The Expert Panel will evaluate the conclusions presented in the background document

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and address the potential uses of FETAX. The Expert Panel will address additional test method development and validation efforts that should be considered that might further enhance and characterize the usefulness of FETAX for various applications and other relevant aspects of the Xenopus model.

Request for Data and Expert Names

The Center would welcome receiving data and information from completed, ongoing, or planned studies using or evaluating FETAX. Information should address the criteria for validation and regulatory acceptance provided in NIH publication 97-3981, ``Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods'' (http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/iccvam.html). Where possible, data and information should adhere to the guidance provided in the document, ``Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM'' (http://iccvam.niehs.nih.gov/doc1.htm), which is available on request from the NTP Center at the address provided below. Information submitted in response to this request will be incorporated into the background material provided to the Expert Panel. Meeting information, including date, location, and availability of the background document, will be announced in a future notice.

The ICCVAM also welcomes suggestions of scientists with relevant knowledge and experience who might be considered for the Expert Panel. For each person suggested, their name, address, and a brief summary of relevant experience and qualifications should be provided. Where possible, telephone, fax number, and/or e-mail addresses should also be provided. Information should be sent by mail, fax, or e-mail to the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods by October 7, 1999. Correspondence should be directed to: Dr. William S. Stokes, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, Environmental Toxicology Program, NIEHS/NTP, MD EC-17, PO Box 12233, Research Triangle Park, NC 27709; 919-541-3398 (phone); 919-541-0947 (fax); iccvam@niehs.nih.gov (e-

mail).

Dated: August 27, 1999.
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Director, National Institute of Environmental Health Sciences.
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