
DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****National Institute of Environmental Health Sciences; National Toxicology Program; Request for Comments on Test Methods Undergoing Review by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the National Toxicology Program Interagency Center for the Evaluation of Alternative Methods****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 decision, and that will refine, reduce, and replace animal use whenever possible. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (Center), in collaboration with ICCVAM, carries out related activities such as independent peer reviews and workshops for test methods of interest to Federal agencies. Peer review panels are convened to develop scientific consensus on the usefulness of test methods to generate information for specific human health and/or ecological risk assessment purposes. Expert workshops are convened as needed to evaluate the adequacy of current methods for assessing specific toxicities, to identify areas in need of improved or new methods, to evaluate proposed

validation studies, and to evaluate the validation status of methods. Following the peer review of proposed test methods, the ICCVAM forwards recommendations regarding their usefulness to appropriate agencies for their consideration. Federal agencies then determine the regulatory acceptability of a method according to their mandates.

Additional information on the activities and functions of the ICCVAM can be found in the publication: Validation on Regulatory Acceptance of Toxicological Test Methods, a Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (NIH Publication 97-3981, March 1997). This report was prepared in response to the National Institutes of Health (NIH) Revitalization Act of 1993 (Pub. L. 103-43), which required the NIEHS to develop criteria and recommended processes for the validation and regulatory acceptance of alternative toxicological test methods. The report is available on the internet at <http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/ICCVAM.html>, or may be requested from the NTP Center address listed below.

Request for Comments

Interested parties are encouraged to submit information and data that would be helpful in evaluating the usefulness of two test methods for which upcoming independent scientific peer review meetings are being planned. The methods are: (1) *Corrositex*[®], an in vitro method proposed for assessing the dermal corrosivity potential of chemicals and products; and (2) the Frog Embryo Teratogenesis Assay in *Xenopus* (FETAX), a method for demonstrating developmental toxicity. Potential regulatory applications of FETAX to human health developmental toxicity assessments include screening and prioritizing compounds for further testing, evaluating complex mixtures in environmental samples, and as supplemental information in a weight-of-evidence evaluation of human developmental toxicity hazards.

The Center would welcome receiving information and data from completed, ongoing, or planned studies using or evaluating these test methods. Data and information submitted should address one or more of the criteria for validation and regulatory acceptance as 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". 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", which is available on request from the NTP Center at the address provided below. Relevant information submitted in response to this request will be used to prepare test methods background review documents for use by peer review and expert panels. Peer review meetings and/or workshops for these methods will be announced in future notices as they are scheduled.

Information on these test methods should be sent by mail, fax, or e-mail to the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods within 45 days of the appearance of this notice. The NTP Center mailing address, phone, fax, and e-mail are as follows: MD EC-17, P.O. Box 12233, Research Triangle Park, NC 27709; 919-541-3398 (phone); 919-541-0947 (FAX); ICCVAM@niehs.nih.gov (e-mail). Additional information can be obtained from: Dr. William S. Stokes, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, Environmental Toxicology Program, NIEHS/NTP, P.O. Box 12233, Research Triangle Park, North Carolina 27709, telephone (919) 541-3398, FAX (919) 541-0947, emailstokes@niehs.nih.gov.

Dated: July 17, 1998.

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[FR Doc. 98-20040 Filed 7-27-98; 8:45 am]

BILLING CODE 4140-01-M
