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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Environmental Health Sciences: Validation and Acceptance of Alternative Testing Methods: Request for Comments

Introduction

Section 1301 of the National Institutes of Health Revitalization Act of 1993 (Public Law No. 103-43) directed the National Institute of Environmental Health Sciences (NIEHS) to establish an Applied Toxicological Research and Testing Program to conduct applied research and testing regarding toxicology. The Act specified that the toxicology-related activities to be carried out by the program would include: (i) Establishing criteria for the validation and regulatory acceptance of alternative testing methods; and (ii) recommending a process through which scientifically validated alternative methods can be accepted for regulatory use. The purpose of this announcement is to invite interested parties to provide information for consideration in the formulation of these criteria and processes.

Background

In response to the directives in Public Law No. 103-43, the NIEHS has established the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to develop recommendations relating to the validation and acceptance of new and revised testing methods that would be useful to Federal agencies. Many new and revised

test methods represent alternative methods, models, and approaches in that they: (a) Result in the reduction of the total number of animals required in a test; (b) incorporate refinements of procedures to lessen or eliminate pain or distress to animals; or (c) provide for the partial or total replacement of animals with non-animal systems, or the replacement of one animal species with another (e.g., a mammalian species replaced by a nonmammalian or invertebrate species).

The Committee's goals include recommending criteria and processes that will: (1) Encourage the development of new methods and improvement of existing test methods to generate data useful for risk assessment; (2) lead to the scientific validation of new and improved test methods; (3) increase the likelihood of regulatory acceptance of scientifically valid new test methods; and (4) encourage the refinement and reduction of animal use in testing, and the replacement of animals with nonanimal methods and/or phylogenetically lower species, when scientifically feasible.

Action

Comments and information are invited from interested parties regarding criteria for the validation and acceptance of alternative testing methods, and processes for the regulatory acceptance of scientifically validated alternative methods. Information is sought regarding the following broad topics:

Types of information necessary to evaluate the practical utility of a test method;

Essential components and processes applicable to the validation

of test methods;

Principles and criteria for assessing the validity of a test method; i.e., do considerations vary depending upon whether the test is: (a) in vivo vs. in vitro; (b) a screen or a replacement; or (c) mechanistically-based or not;

Factors relevant to the acceptance of validated test methods by regulatory and scientific agencies.

The Committee will consider such comments and information prior to the preparation of a draft document. Opportunity for comment on the Committee's draft document will be announced at a later date, and a public meeting will also be announced.

Comments and information should be sent within 60 days of the publication of this announcement to Dr. William Stokes, NIEHS, MD-A2-05, P.O. Box 12233, Research Triangle Park, North Carolina 27709. For further information regarding this request, please contact Dr. Stokes by mail at the above address, by FAX at 919/541-0719, by telephone at 919/541-7997, or by Internet e-mail at Stokes@NIEHS.NIH.GOV.

Dated: November 29, 1994.

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Deputy Director, NIEHS.

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