Public Health Service

National Institute of Environmental Health Sciences; Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods, Now Available

The publication Validation and 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 is now available and may be obtained as described in this notice.

Background

The National Institutes of Health Revitalization Act of 1993 (Pub. L. 103–43, Section 1301) directed the National Institute of Environmental Health Sciences of the National Institutes of Health (NIEHS/NIH) to ''(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use'' (Appendix F).

In response to these mandates, NIEHS established an ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (the Committee) in 1994 to develop a report recommending criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to Federal agencies and the scientific community. The following Federal regulatory and research agencies and organizations participated in this effort:

Consumer Product Safety Commission
Department of Agriculture
  Agriculture Research Service
  Animal and Plant Health Inspection Service
Department of Defense
Department of Energy
Department of Health and Human Services
  Agency for Toxic Substances and Disease Registry
  Food and Drug Administration
  National Institute for Occupational Safety and Health/CDC
  National Institute of Health
  National Cancer Institute
  National Institute of Environmental Health Sciences
  National Library of Medicine
  Office of Laboratory Animal Research
Department of the Interior
Department of Labor
  Occupational Safety and Health Administration
Department of Transportation
  Research and Special Programs Administration
Environmental Protection Agency

The Committee met initially in September 1994, and then monthly or bimonthly until completion of the report in October 1996. The Committee interpreted its charge as the development of general criteria and processes for the validation and regulatory acceptance of new and revised toxicological test methods.

The specific goals of this Report are to:

- Communicate the criteria and procedures that Federal agencies should employ in considering new and revised test methods,
- Encourage the development of new and revised test methods that will provide for improved assessment of the potential toxicity of agents to human health and other organisms in the environment,
- Provide effective guidance for scientists for the validation and evaluation of new and revised test methods,
- Contribute to the increased likelihood of regulatory acceptance of scientifically valid new and revised test methods,
- Encourage the use of validated and accepted new and revised test methods,
- Encourage, when scientifically feasible, the reduction and refinement of animal use in testing and the replacement of animal methods with non-animal methods or of animal species with phylogenetically lower species.

In developing the initial draft report, the Committee considered information obtained from the following sources: (1) A questionnaire completed by each agency on their criteria and processes for test method validation and acceptance, (2) public comments submitted in response to a Federal Register notice published December 7,

1994, requesting interested individuals and organizations to provide information for consideration by the Committee (Appendix G), (3) presentations from various government scientists, (4) review of pertinent available literature, and (5) comments and suggestions from Federal agencies.

An NTP Workshop on Validation and Regulatory Acceptance of Alternative Test Methods was held on December 11–12, 1995, at the Crystal Gateway Mariott Hotel, Arlington, Virginia. The purpose of the workshop was to review the criteria and processes set forth in the draft report and accept comments and recommendations from workshop registrants and invited panelists, including representatives from industry, academe, public interest groups, and the international community. Written comments were also submitted in response to the Federal Register notice announcing availability of the draft report for public comment.

The draft report was also presented to participants at the Organization for Economic Cooperation and Development (OECD) Workshop on Harmonization of Validation Criteria for Alternative Test Methods held in Stockholm, Sweden, on January 22–24, 1996. Commends and recommendations generated by scientists from the 26 OECD member countries were considered by the Committee. The Committee prepared a revised draft report that was distributed to participating agencies for comment and concurrence prior to publication of the final Report.

Summary of the Report

The report totals 105 pages, and consists of four chapters. Chapter one is an introduction that provides a general overview of the need for toxicological test methods, how they are used, and the driving forces for the development and validation of new methods. Chapter two discusses the concept of validation and the criteria that should be met for a new or revised test method to be considered for regulatory risk assessment purposes. Chapter three discusses the criteria that should be used in considering the acceptability of a test method proposed for regulatory use. It also discusses the processes involved in achieving regulatory acceptance of a test method. A series of recommendations for developing a consistent and efficient process for evaluating new methods for regulatory acceptance is provided. Recommendations address development and validation, regulatory review of new methods, intra- and interagency coordination and harmonization, communication, and international harmonization. Chapter four discusses an implementation plan to facilitate the review and consideration of new test methods proposed for regulatory acceptance.

A standing interagency committee will be established to coordinate the development, validation, acceptance, and national/international harmonization of toxicological test methods. The committee will be designated as the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and will replace the ad hoc ICCVAM. The ICCVAM will seek to promote sound toxicological test methods that (1) enhance agencies' ability to assess risks and make decisions, and (2) reduce animal use, refine procedures involving animals to make them less stressful, and replace animals in toxicological tests, where scientifically feasible and practical. The Committee anticipates that this effort will help to better evaluate risks to human and animal health and the environment, reduce costs necessary to establish the safety of agents in commerce, and facilitate international trade.

Obtaining the Report

Retrieval instructions and the anticipated date for availability on the internet can be found at the NTP website: <http://ntp-server.niehs.nih.gov>. To receive a copy of the report, please contact the NTP Liaison and Scientific Review Office, NIEHS, PO Box 12233, MD A3–01, Research Triangle Park, NC 27709, or by FAX to: (919) 541–0295.

For further information about the Report, please contact one of the ICCVAM co-chairs—Dr. William Stokes at NIEHS, PO Box 12233, Research Triangle Park, NC 27709, telephone 919–541–7997, FAX (919) 541–0947, or internet email at stokes@niehs.nih.gov or Dr. Richard Hill at EPA, Mail Code 7101, 401 M Street, SW, Washington, DC 20460, telephone (202) 260–2897, FAX (202) 260–1847, or internet email at hill.richard@epamail.epa.gov.

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