NICEATM/ICCVAM 5-Year Plan Information

The following information was submitted on 12/21/2006:

Name & Sponsoring Organization

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Are you submitting comments on behalf of a sponsoring organization? Yes
If yes, please enter the name of the organization: National Anti-Vivisection Society

Comments and Questions

1. Do you have comments on the priority areas for the development and validation of alternative test methods listed above?

   The establishment of the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM) as a permanent committee in 2000 was hailed with great enthusiasm by individuals and organizations promoting the replacement of animals with non-animal methodologies. The National Anti-Vivisection Society, an educational society promoting humane science, was especially pleased with this development because of the importance of both validating alternative testing and in requiring federal government agencies to use those tests in conducting their own research. We appreciate the opportunity to offer comments on the development of a National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)/ICCVAM five-year plan. One of the more obvious aspects of the work being conducted by NICEATM/ICCVAM is the painfully slow pace with which evaluation and validation of alternative test methods is taking place. Only a handful of tests methods have received approval in the six years since ICCVAM was made a standing committee. In the meanwhile, the European Centre for the Validation of Alternative Methods (ECVAM) is approving many more testing methods, many of which arent even being considered for review here in the U.S. In setting priorities for the next five years, it would seem sensible to set as a goal a review and approval of existing tests in use, both in the U.S. by private industry and by agencies throughout the world. If there is a test already in use there should be a system of fast-tracking implementation of that test method for review, including the use of data from reputable sources in industry and oversees. The universal acceptance of previously validated test methods would allow for faster implementation, and allow research on additional methods to move forward more rapidly while at the same time reaching the goal of replacement, reduction, and refinement of testing protocols for animals. In addition, The list of priorities given for the development and validation of alternative methods should also include the development of alternatives to the Mouse LD50 Assay for Botulinum Toxin Testing. While the U.S. Food and Drug Administration has itself stated that it no longer uses the LD50 test, its continued use in industry needs to be addressed and research into alternative viable methods should be made a priority. The replacement of all LD50 testing should be a priority in setting goals for NICEATM/ICCVAM in the next five years.

2. Considering available science and technology, what development, translation, and validation activities are most likely to have the greatest impacts within the next five years on refining, reducing, or replacing animal use?

   Not Provided.

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3. What research and development activities hold the greatest promise in the long-term for refining, reducing, or replacing animal use?

   In order to move forward with the development of alternatives, we strongly recommend that specific funding be earmarked for spending on research for the development of new alternatives, aside from any funding spent on the validation of tests already underway. The availability of government fundingthrough NIHspecifically for this purpose would encourage the submission of grants in an area that is currently under funded and therefore under represented at research institutions around the country. Additionally, while government agencies are under a directive to use alternative assays for research once they are validated, this has not been adopted or enforced in any substantive manner. In addition to requiring adherence to this directive, we would recommend that government agencies no longer accept data from animal tests in evaluating studies, where alternative methodologies are available. This could be phased in over a five year period in order to put industry, and government agencies, on notice and to develop their own plans for alternative non-animal testing plans.

4. What are appropriate measures for evaluating progress in enhancing the development and use of alternative test methods?

   We applaud the work of ICCVAM and hope that the next five years will see a jump forward in the development and implementation of non-animal methods by both the federal government and in private research in the U.S. A measure of success will be when federal agencies fully embrace the array of alternative tests available and when the initial plan for a research project is the alternative, not the use of millions of animals combined with justification for their use. Thank you for the opportunity to comment on this issue.