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June 7, 2007

Dr William S Stokes
Director, NICEATM
National Institute of Environmental Health Sciences
PO Box 12233, MD EC-17
Research Triangle Park, NC 27709

Re: **72 FR 23832; May 1, 2007; Public Comments Concerning the Draft NICEATM-ICCVAM 5-Year Plan (2008-2012)**

Dear Dr Stokes:

People for the Ethical Treatment of Animals (PETA) is the world's largest animal rights organization, with 1.7 million members and supporters. We appreciate the continued opportunity to comment regarding during the formulation of the draft NICEATM-ICCVAM 5-Year Plan (hereinafter, "the draft Plan") by presenting oral comments at the Town Meeting June 11, 2007. .

Upon its inception in 1997, we had great hopes for ICCVAM, whose intended purpose was to develop and promote regulatory acceptance of alternative methods that would refine, reduce and replace animal use in regulatory testing. In fact, the U.S. animal protection community was a strong proponent in the creation of ICCVAM. However, in contrast to the intended purpose, ICCVAM has become, over the past decade, a major obstacle to the development and use of alternative, non-animal methods. In spite of progress in other countries, ICCVAM has repeatedly wasted its limited resources on duplicative studies that have hindered progress in the US.

For example, ICCVAM's few evaluations of the methods that have been validated in Europe by ECVAM and that have received endorsement by ICCVAM's European counterpart—the ECVAM Scientific Advisory Committee (ESAC), have resulted in either a restriction of use or a rejection of the method: In addition, there are over a dozen alternative methods that have received ESAC endorsement that have yet to even be considered by ICCVAM.

Due in part to this demonstrated failure on the part of the SACATM and ICCVAM, Congress required ICCVAM to draft a five-year plan. SACATM's interpretation of the Congressional request was that SACATM and ICCVAM should "in partnership with relevant federal agencies, develop a 5-year plan that addresses the following two objectives: 1) research, development a, translation and validation of new and revised non-animal and other alternative assays for integration into federal agency testing programs and 2) identification of areas of high priority for new and revised non-animal and alternative assays…" In this regard, the Draft Plan is disappointing in its lack of direction and apparent lack of commitment to a coherent process to achieve either of its own objectives.

In November 2006 ICCVAM invited public comments and received comments from groups as varied as the American Chemical Council, private companies developing *in vitro* methods, and animal welfare organizations. In spite of very different agendas, these comments contained several common suggestions for a productive way forward. However, the current Draft Plan fails to incorporate or consider any of these suggestions.

Specifically, Chapter 1 of the Draft Plan describes "Research, Development, Translation and Validation Activities for Priority Test Methods", and the Draft Plan states that the criteria used for setting priorities are: 1) Potential impact on reducing, refining, or replacing animals for testing, 2) Applicability to multiple agencies, and 3) Potential to provide improved prediction of adverse health or environmental effects. However, the Draft Plan provides no overview, description or analysis of priority setting for either methods under development or for planned activities. Instead, Chapter 1 contains virtually the same laundry list of methods under consideration that was presented at the SACATM meeting in November 2006, with no explanation regarding the basis upon which they were chosen, or how these methods relate to the stated priorities. For example, there is no mention in the Draft Plan of alternative approaches for reproductive or developmental toxicity testing, methods that consume far more animals than any other methods under consideration. This suggests that the first priority above listed above was not actually used as a criterion in creating the Draft Plan.

In the November solicitation of comments, NICEATM/ICCVAM specifically asked the following question: Do you have comments on the priority areas for the development and validation of alternative test methods listed above?[1] In our December 2006 comments, we provided several suggestions for setting criteria and identifying needs, not a single one of which has been incorporated into the draft Plan.[2]

The implicit purpose of the Appropriations Committees' request for a five-year plan was to allow NICETAM and ICCVAM to develop and articulate a new approach for the future. But Chapters 3 and 4 of the draft represent grievously abandoned opportunities. Chapter 3 provides an opportunity for NICEATM/ICCVAM to outline a specific plan for improving regulatory acceptance of validated alternative methods. Such a plan would involve agency input of regulatory endpoints requiring animal testing, specific descriptions of replacement methods, and delineation of an integrated validation/regulatory use process. The Draft Plan repeatedly contains references to "continued" activities to interact with regulatory agencies and other stakeholders, such as "by broadly communicating the outcomes of ICCVAM review activities and/or workshops via the Federal Register, at national or international scientific meetings, via publications, and at training courses." This approach has been demonstrably ineffective for the past decade, and there is no reason whatsoever to believe it will be more successful in the future.

Similarly, Chapter 4 provides an opportunity to articulate new approaches to achieving productive partnerships and stakeholder participation. Again, the draft Plan contains only descriptions of past approaches to developing partnerships and fostering interactions, with several promises to continue these same approaches, all of which have achieved very limited success over the past decade. The point of requesting a five-year plan is to *re-strategize*, to develop *new* approaches to *improve* and *strengthen*

[1] FR Doc. E6–19094 Filed 11–9–06; 8:45 am]
[2] http://iccvam.niehs.nih.gov/docs/StrPlnPubCmts.htm

interactions. Again, several suggestions were provided in the animal protection community's December 2006 comments, none of which have been incorporated into the draft Plan.

One can only conclude from this failure of the NICEATM and ICCVAM to take this opportunity to develop new approaches, and the fact that previous comments have largely been ignored, that ICCVAM has no intention of making any substantive changes to improve its thus far ineffective approach. Once again, this leads us to question ICCVAM's commitment to both the intent and the process of its stated purposes and goals. We urge SACATM to ensure that the NICETAM and ICCVAM to take this opportunity to articulate a detailed and coherent plan for achieving its stated objectives, starting with the incorporation of comments made by the animal protection community both on December 31, 2006[3] and on June 7, 2007.

Sincerely,

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[3] http://iccvam.niehs.nih.gov/docs/5YrResponses/ICCVAM5yrplanHSLF.pdf