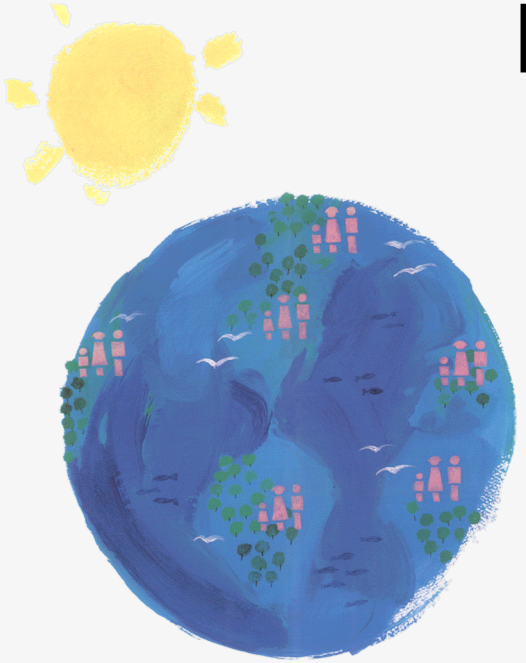
NICEATM

National Toxicology Program
Interagency Center for the Evaluation of Alternative Toxicological Methods

ICCVAM

Interagency Coordinating Committee on the Validation of Alternative Methods



NICEATM-ICCVAM Town Meeting Summary

Dr. Robert Scala, DABT, DATS

Town Meeting Moderator

SACATM Meeting
Bethesda, MD
June 12, 2007

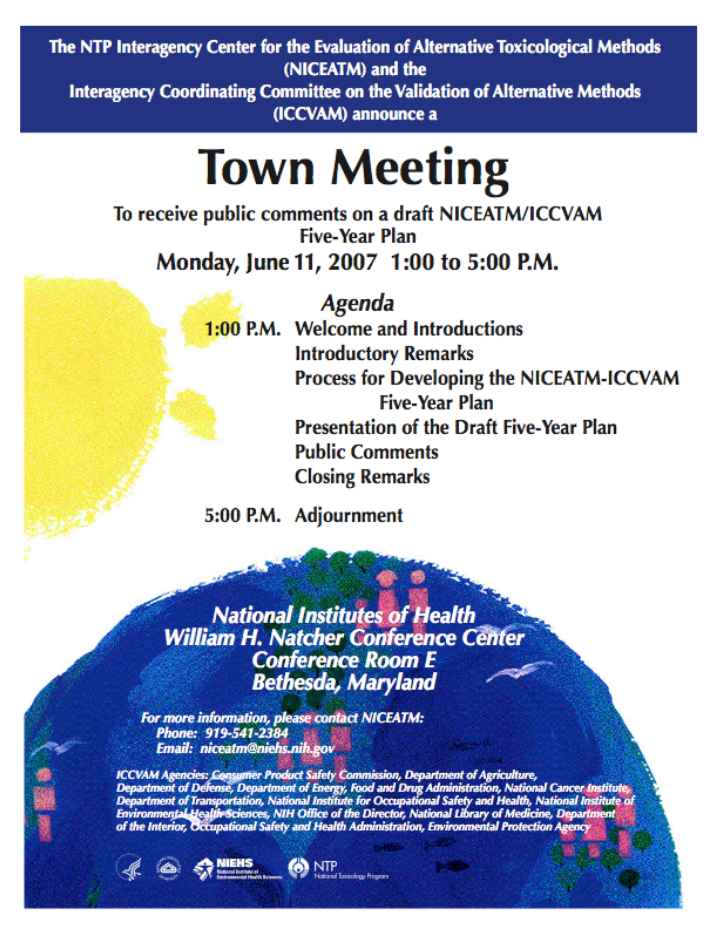
National Toxicology Program

NIEHS

National Institutes of Health

Department of Health & Human Services • USA

NICEATM-ICCVAM Town Meeting Summary



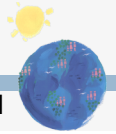
- Process for Developing the Plan - Dr. Stokes
- Presentation of the Plan - Dr. Wind
- Public Comments
  - Received Oral Comments from representatives of 4 organizations and 1 independent consultant
  - PETA, PCRM, IIVS, ARDF
- Closing Remarks Summarized Government's Appreciation for Public Interest in the Plan
- Total Attendance Over 90
  - Over 60 members of the public
  - 25 members of the ICCVAM and their respective Program Offices
  - 9 members of the SACATM
- We listened carefully and have grouped the comments according key challenges in the draft plan on which the public was asked to comment.

Summary of Public Comments - General Comments

- Support for the existing efforts by ICCVAM/NICEATM but that these efforts do not go far enough
- Need a plan that has deliverables with a timeline
- ICCVAM's focus should be on replacement alternatives and not so much on reduction and refinement
- ICCVAM and its peer review panels don't recognize the urgency for the need for alternatives
- The audience for whom the plan was requested would ordinarily be looking at high level issues, but the groups affected by the plan are more concerned with a detailed document that could be used as a blueprint for moving forward
- Encouraged ICCVAM to take leadership on development and validation of new alternative test methods in the U.S.
- Suggested that ICCVAM look at the outcomes (i.e., accepted/implemented alternative test methods) as a barometer for success
  - Presently not nearly high enough

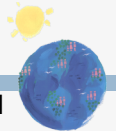
Comments on Challenge 1: Identifying Priority Areas and Activities

- No overview of priority setting
  - The current plan includes the same list of priorities previously provided.
- No description of the analysis that lead to priority setting
  - Priority setting should be more quantitative
- There were statements that the written comments offered previously on behalf of PETA, HSUS, PCRM, ARDF, AAVS (December 2006) were not considered in the current draft of the plan.



Comments on Challenge 2: Incorporating New Science and Technology

- Simply stating that a process is lengthy does not preclude ICCVAM from devising a plan for meeting this challenge.
  - Such a plan is noticeably absent from the current plan.



Comments on Challenge 3: Fostering Regulatory Acceptance and Use of Alternative Methods

- The Congressional request is an opportunity to outline a new plan for moving forward
  - However, the current plan is just a listing of continued activities that have already failed.
- In some cases, the public perception is that scientists don't completely understand the process, and/or that they are not interested in the goal of the process (i.e., moving alternative methods forward).
  - Perhaps the ICCVAM peer panels aren't properly informed of the peer review process.

Comments on Challenge 4: Developing Partnerships and Strengthening Interactions with ICCVAM Stakeholders (1)

- ICCVAM's limited resources are used on duplicative efforts (i.e., conducting peer reviews of ESAC-endorsed test methods)
- The current plan is just a description of past approaches that haven't been successful and therefore new approaches should be considered and described.
- Regarding the proposed collaborations with ECVAM and JaCVAM
  - ESAC endorsements do not lead to quicker ICCVAM approval ICCVAM continually fails to move forward ESAC-endorsed methods (or they place restrictions on their use)
  - Over 12 ESAC-endorsed methods have not been considered by ICCVAM
- NICEATM/ICCVAM should be more pro-active (and do more than just facilitate) by developing ways to help prioritize funding within agencies.

Comments on Challenge 4: Developing Partnerships and Strengthening Interactions with ICCVAM Stakeholders (2)

- The plan should revisit the evaluation process and determine if it in fact meets the needs of the stakeholders.
- A web-based scorecard could be used as an ongoing mechanism for tracking progress. This would allow:
  - Determining where activities are occurring
  - If they are the correct priorities
  - Defining areas where stakeholders might see an opportunity to “insert themselves”
- There is tremendous interest for funding of alternative methods - ARDF receives many more grant applications than they can fund.
  - ICCVAM should encourage/facilitate funding of alternatives research
- ICCVAM should become involved in the process of reviewing USDA draft notices for vaccine potency testing.
  - The perceived policy changes within the USDA have reportedly resulted in more animals being used as well as additional pain and distress.