



THE HUMANE SOCIETY
OF THE UNITED STATES

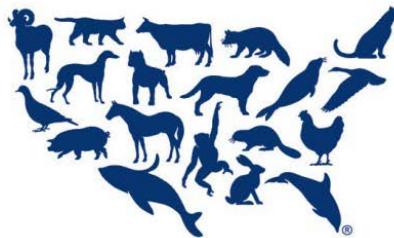
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Humane Society Family Comments on Draft of A New Vision and Direction for ICCVAM



HUMANE SOCIETY
INTERNATIONAL



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OF THE UNITED STATES



HUMANE SOCIETY
LEGISLATIVE FUND™

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ICCVAM's new vision:

- ✓ Better align ICCVAM and NICEATM with the vision laid out by the 2007 NRC Report on Toxicity Testing in the 21st Century
- ✓ Agencies will take a more active role in priority setting and operations
- ✓ Improved international coordination and involvement

A welcome revision that, if successful, will:

- bring ICCVAM in line with current scientific advances
- reinstate ICCVAM's role as a facilitator in the development and regulatory use of alternative methods
- Improve and expedite international implementation of alternative methods

Priority setting

The new plan:

- ✓ Strategic partnership with member agencies
- ✓ Alignment with regulatory needs

In addition:

- Partnership with the agencies for which the method is applicable throughout the validation process
 - in study designs
 - choice of standard and reference chemicals
- Validation Oversight Committee composed of members from each agency to which the method is applicable

Priority setting

Categorize projects:

1. Those in which ICCVAM will take the lead
 - a. Leptospira vaccine potency project (USDA)
 - b. Acute oral and dermal toxicity project (EPA)
2. Serve as an active partner
 - a. Sensitization (Cosmetics Europe, ECVAM)
 - b. Cytotoxicity to inform acute toxicity (ECVAM)
3. Function in a support role in collaborative projects
 - a. Various AOP development projects at OECD

With commensurate resources allocated to projects by category

Improving communications with stakeholders

- ✓ Agency-specific 3Rs content on website
 - Coordinating and facilitating role within and between related projects
 - Within and between agencies
 - ToxCast/Comptox and EDSP
 - Tox21 collaboration
 - Provide translational support/ logistical coordination
- ✓ ICCVAM-led workshops, webinars, etc.
 - more regular participation in other workshops and scientific meetings
 - priority topic workshops (EDSP)
 - ILSI-HESI projects

New paradigms for regulatory acceptance and utilization of alternative methods

- ✓ Improved international coordination
- ✓ Move toward integrated strategies
 - adopting and developing related pathway-based informational design
 - E.g. OECD's Adverse Outcome Pathway approach
- ✓ Consideration of statistical approaches to validation
 - Consideration of Bayesian network approaches*
 - *Jaworska, et al. 2013, J. App. Tox. May 14. doi: 10.1002/jat.2869
- ✓ Use of different evaluation processes for different applications (e.g. prioritization vs. hazard assessment)
 - tie assays/integrated strategies to pathway-based knowledge
 - coordination with international efforts in this area
 - OECD Test Guidelines Programme
 - AOP Wiki – JRC/EPA/OECD collaboration

Thank You

Looking forward to:

- Further details
- Working together to reduce reliance on animal testing

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