The European Centre for the Validation of Alternative Methods (ECVAM): Recent Contributions to ICATM and REACH, and Future Plans

50th meeting of the American Society of Toxicology, Washington DC

Joachim Kreysa, ECVAM, European Commission

ECVAM: is part of the European Commission, which is responsible for proposing and implementing EU-policies

- **ECVAM's mission is**
- **to promote non-animal methods** *for regulatory and scientific purposes*
- **to validate that that those alternative methods are reliable and relevant,** *e.g. provide a solid basis for risk assessment & risk management*
- **to promote EU and international acceptance** *of alternative methods by industry & regulators for safety assessments, and by scientists as useful alternatives to animal experiments.*

Validation is the process of verifying that a product or process meets certain (pre-)defined quality standards.

This process is concluded by a confirmation of this capacity of the validated test – the formal "VALIDATION"

Validation is a **Win-Win** option~

- Validated test methods are guaranteed to produce defined, high quality data;
- they are reliable and relevant for their purpose:
  - Risk assessment >> risk management
  - Research
- Relevant high quality data can be trusted and will be used for their defined purpose
  - Data producers and data users only have to worry about the data, not how they have been generated

ICATM

Aims to promote international acceptance of validated alternative methods through early agreement between ICATM partners on

1. **WHAT to do?** = Priorities for validation
2. *How to do it?* = Validation project plans
3. **Results** = Peer review
4. *Recommendations* = Harmonised rec.

To support the agreement,
ECVAM
adapts its procedures to ease cooperation and to allow all ICATM partners to use the final outcome of ECVAM validation activities

What to do? - priorities

- ECVAM informs ICATM partners of promising test submissions
- Joint interest => joint validation
- Shared interest => higher priority

How to do it? - Validation methods

Throughout ICATM we have common validation standards, incl. independent Validation Management Teams

- ICATM observers in **ECVAM** VMTs
- Observers highlight issues important for mutual acceptance
- Validation reports address these issues

Results – peer review / quality check

- ECVAM's peer review body is ESAC, the ECVAM Scientific Advisory Committee
  - ICATM partners are represented as observers
- ESAC verifies validation reports via specialised peer-review working groups
  - ICATM partners may propose specialists

Results – peer review

- Based on the WG-peer review report, ESAC drafts its peer review opinion independent from ICATM (incl. ECVAM) influence
- ESAC's opinion
  - provides clear justification for the positions taken
  - include in annex the complete background documentation (incl. validation report and peer review report)
  - reflects the independent view of the independent scientists that are forming ESAC

Recommendations

- Are the final product of all ICATM partners. They address the capacities and limitations of a given test method and indicate its possible uses
- ECVAM's recommendations
  - are based on ESAC opinions but may take into account other information
  - are addressed to the services of the European Commission that are in charge of regulatory acceptance at EU and international level

Recommendations

- ICATM partners comment draft before this is made public for comments
- ECVAM finalises the recommendation addressing / taking account of all comments
- ICATM partners use the material to draft their own, harmonised recommendations

Recommendations

- ICATM partner comment draft before this is made public comments
- ECVAM finalises the recommendation addressing / taking account of all comments
- ICATM partners use criteria to adopt their own, harmonised recommendations

IACVAM Regulatory Acceptance Board

European Agencies

European Commission

KoCVAM: KFDA

ICCVAM: FDA, EPA, OSHA,...

OECD

Harmonised recommendations are more convincing

Conclusion

Submitting your test method to ECVAM or any other ICATM partner for validation and/or peer review

is the best you can do for international acceptance & a global market!

http://ecvam.jrc.ec.europa.eu/

or

http://iccvam.niehs.nih.gov/SuppDocs/submission.htm

or

http://jacvam.jp/en/index.html

ECVAM's contribution to REACH

1. REACH requires data files for all chemicals on the EU-market – **animal testing = last resort**!
   - ECVAM provides info on existing alternatives: DB-ALM, website
   - ECVAM/ICATM provides quality assured alternative methods
2. EU accepted alternative methods **must** be used
   - Validation is required for acceptance
   - ECVAM promotes regulatory acceptance through early cooperation with regulatory scientists, risk assessors, risk managers, and regulators
   - Cooperation with industry is of equal importance

ECVAM contribution to REACH

1. "Search guide" for finding relevant information on alternatives
   - a web-based version comes in 2011
2. ECVAM's database on alternative methods (DB-ALM): high quality information

– http://ecvam-dbalm.jrc.ec.europa.eu/

Note: also relevant for promotion of alternative methods in research

ECVAM Future Plans

1. Improve procedures and cooperation networks
2. Provide guidance & support for development and validation of non-animal methods for use in
   - toxicological testing
   - research
3. Focus on peer review and regulatory acceptance
4. Enhance information activities

Stay in tune with ICATM partners

DNT_3 flyers are available!

DNT3

Developmental Neurotoxicity

- **Third International Conference on Alternatives for Developmental Neurotoxicity (DNT) Testing, May 10-13, 2011**
- **"Advancing the science of developmental neurotoxicity testing**
- **for better safety evaluation"**
- **Venue**: Centro Congressi Ville Ponti, Varese, **Italy**
- **Website:** http://ihcp.jrc.ec.europa.eu/dnt3conference/index.htm