



The European Partnership
for Alternative Approaches to Animal Testing

EPAA Conference 2010

“Challenges and Opportunities”

Emily McIvor, Humane Society International/EU

EPAA Mirror Group Member

(Personal perspective: not the view of the group)

**‘Reduction and Refinement: Combining Excellence in Science and Animal Welfare’
30th November 2010, Brussels.**



EPAA

Mirror Group

Members

Members: Prof. Hermann Autrup - University of Aarhus

Prof. Jim Bridges - University of Surrey

Prof. Coenraad Hendriksen - Utrecht University

Prof. Peter Maier - University of Zürich

Emily McIvor - The Humane Society International-EU

Prof. Horst Spielmann - Freie Universität Berlin

Prof. Vera Rogiers - Vrije Universiteit Brussels

Barry Phillips – Eurogroup for Animals

Graham Moore – FELASA (Federation of Laboratory
Animal Science Associations)



EPAA

Mirror Group

Mirror Group Function and Responsibilities

- Provides independent advice
- Diverse backgrounds and interests
- Balances and comments on activities of industry and the Commission

Scrutiny of

- Work Programme
- Ongoing projects
- Output

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Challenges and Opportunities

REACH: Review / Reporting / TMR and data

Cosmetics/PPPs/Biocides

International Activity: test methods / bilateral agreements

21st Century Toxicology

Directive 2010/63

ECVAM and MS contributions . . . And more!

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REACH Review

- Commission evaluation of the REACH regulation in 2012, including the amount and distribution of funding made available by the Commission for the development and evaluation of alternative test methods (art 117.4 of REACH).
- Review of the European Chemicals Agency (art 75.2 of REACH)

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REACH Reporting (Article 117)

Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation.

The first report shall be submitted by 1 June 2011.

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REACH : Test Methods/data requirements/ comment period

- The TMR has been updated, a process created and further updates are expected shortly.
- The Extended One Generation Test for Reproductive Toxicity has been adopted by the OECD JM, but how and when will it be used in the EU?
- First registration deadline today – how will comments submitted under the 45 day rule be treated?

EPAA: 30th November 2010, Brussels.



And it's not just **REACH!**

- Cosmetics – Scientific Evaluation / Impact Assessment/
2013 Deadline
- Biocides – Conclusion of negotiation / data
requirements
- Plant Protection Products – data requirements under
review
- Animal Welfare Action Plan . . . And more!

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International Challenges and Opportunities

Bilateral Trade Agreement Objectives:

Promoting harmonization of 3Rs best practices (data requirements & acceptance of alternative non-animal testing strategies) across regulated product sectors/
Ensuring that animal-based contract testing/research in third countries meets EU standards as minimum /Trade in wild-caught animals for scientific purposes . . . ?

Example:

EU-Korea FTA, Annex 2-E(Chemicals)

- promoting alternative methods for assessment of hazards of substances and reducing animal testing;

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21st Century Toxicology

- Toxicology in the 21st Century: A Vision and A Strategy (NRC 2007)
- New Perspectives: EPAA initiative (2008)
- AXLR8: FP7 Funded Coordination Action
- Further international cooperation and coordination
- Multisectoral, multistakeholder – as appropriate for the scale of the challenge!



Directive 2010/63

- Increased emphasis on 3Rs (throughout)
- Requirement to use alternatives whenever possible (Article 4)
- Requirements for Member States to contribute to validation of alternative methods (Art 47/48)
- Requirement to establish the Union Reference Laboratory (ECVAM) (functions Annex VII)

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Conclusions

The next five years

- All 3Rs activity is important
- Ongoing projects will produce near term gains
- Longer term, the 'paradigm shift' is coming: increased awareness in all sectors and within all sectors is needed
- Constant horizon scanning – identification of short and long term goals

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