



EU Science: Global Challenges & Global Cooperation

4-8th March, 2013

European Parliament, Brussels



7th March: New Regulatory Science in System Toxicology: Is an Update Needed, What Would Be the Critical Elements and by When?

Regulatory toxicology is used to control about \$10 trillion (£6.2 trillion) worth of worldwide trade in chemicals, drugs, pesticides, food and consumer products. While Europe has been pursuing change under the label of alternative methods and the 3Rs (reduce, replace, refine) for more than two decades, it was only a 2007 National Research Council report on the subject that prompted serious efforts to change the US system. The 3Rs approach had suggested either optimising animal tests (fewer animals or less pain and distress) or replacing traditional tests with in vitro or in silico models for harmonization.

The answer emerging in Europe is to combine various information sources in integrated (or intelligent) testing strategies (ITS).

Despite the enormous possible impact this could have with EU legislations like REACH or the testing ban for cosmetic ingredients, efforts are still limited. The answer emerging in the US is to adopt a new, molecular description of toxic action based on pathways of toxicity (PoT)—the biomolecular pathways that lead to a cell being harmed. This approach represents a paradigm shift in toxicity testing—identifying a substance's effect on harmful cellular pathways, rather than interpreting effects on cell lines or entire organisms.

Synergies exist between these two approaches and two economic partners.

Worldwide Implementation of the 3Rs in Regulatory Toxicology: What are the Leadership Challenges and Opportunities?

The EU member states have a long tradition of incorporating the 3Rs (replacement, reduction and refinement) into laws and policies. The tradition has extended to the organic documents that underlie the European Union (i.e., Article 13 of the Lisbon Treaty on the Functioning of the European Union). For example, EU's chemical regulation (REACH), the Directive on the Protection of Animals Used for Scientific Purposes (2010/63/EU), and Cosmetics Regulation incorporate animal welfare into their basic policy schemes.

As in vitro, computational and other non-animal based approaches in toxicology have evolved, more and more nations have begun to incorporate 3Rs principles into their national laws and regulatory schemes.

This workshop will examine the state of the implementation of the 3Rs worldwide, with a focus on EU leadership and how the EU can continue its forward-looking approach to the 3Rs. The workshop will also assist in identifying ways to ensure high quality science and global consistency through opportunities for harmonization.

Details and Registration:

<http://www.globalsciencecollaboration.org>

March 7th: Welcome and Introduction: MEP PRODI

1st PART - Panel discussion: **UPDATE ON THE KNOWLEDGE or PARADIGM SHIFT?**

Panel Discussion and Audience Questions

- Thomas Hartung- Director, Center for Alternatives to Animal Testing (CAAT)
- Emily McIvor- HSI
- Donald Prater- FDA
- Adrianno Henney- VIRTUAL LIVER
- Rex Fitzgerald- SCAHT
- Robert Barouki - INSERM
- Francois Busquet- CAAT EUROPE- as MODERATOR

2nd PART - Panel discussion: **BENEFITS FOR COMMON REGULATORY SAFETY APPROACHES**

Panel Discussion and Audience Questions

- Richard Sigman - OECD
- Thomas Hartung- CAAT
- Cliff Elcombe (TBC) - CXR BIOSCIENCES
- Adrianno Henney- VIRTUAL LIVER
- Bas Blaauboer- UTRECHT UNIVERSITY
- Gernot Klotz- CEFIC
- Ulrich Deschl (TBC)- BOEHRINGER-INGELHEIM
- David Demortain- INRA - as MODERATOR

Welcome and Introduction: MEP (TBA)

Panel Discussion and Presentations

3Rs Implementation in North America

- Paul Locke- Policy Program Director, Center for Alternatives to Animal Testing (CAAT)

3Rs Implementation in Latin America

- Octavio Presgrave- BraCVAM

3Rs Implementation in the EU

- Björn Hansen- EC

3Rs Implementation in Japan, India, China, and Korea (Pacific Basin)

- Richard Fosse- GSK

3Rs Implementation in Australia

- Brett Lidbury- Australian National University

Final Presentation: 3Rs Wrap-up and Summary
What We Have Learned Today on the State of the Implementation of the 3Rs

- Joyce Tischler- Animal Legal Defense Fund