Report on the EPAA Workshop

“Knowledge sharing to facilitate regulatory decision making”

22 September 2014, CEFIC offices, Brussels

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Toxicological Testing and Alternative Methods

Animal testing is often performed to evaluate the toxicity of substances used as consumer products, chemicals, food additives, fragrances, pesticides, animal and human pharmaceuticals and cosmetics.

Regulations (and/or guidelines) often prescribe a specific regime of predefined test methods to be used to determine the hazard of substance and possible risks to human health and/or the environment.
The concept of the three R’s was defined in the “Principles of Humane Experimental Technique” by William M. S. Russell and Rex L. Burch (1959).
Needs and Requirements...

- Predictivity
- Reliability
- Animal Welfare
- Time
- Costs
- Test substance use
- Regulatory Acceptance
- REACH
  - Producer’s Responsibility
  - Cosmetics Regulation
- other Regulations
Aims

- To bring together the different stakeholders within EPAA to share knowledge and experience on the use of alternative methods in different decision making scenarios.
- To define how further progress could be made, by identifying barriers and developing recommendations to promote adoption of alternative methods across all sectors.
- To draw a list of recommendations to overcome potential challenges/barriers that could delay the adoption and use of alternative methods in the regulatory framework.
Workshop attendance & structure

- Attended by **fifty invited participants** from the European Commission, national and EU authorities, different industry sectors, and animal protection organizations

- **Four case studies** were presented:
  - The waiving of 2-year rodent carcinogenicity studies in the pharmaceutical sector
  - The application of alternative methods for skin sensitization in the chemicals sector
  - The replacement of animal testing in the cosmetics sector exemplified with genotoxicity assessment
  - The use of Thresholds of Toxicological Concern (TTC) for non-animal safety assessment of fragrances

- Break out groups to **brainstorm in general recommendations**
Recommendations I

Encourage **close collaboration** and a dialogue

Promote **international harmonization** of regulatory requirements

Involve all **relevant regulatory authorities** from the **early stages** of the planning of research projects on

Define **clear criteria** (e.g. via ‘harmonized templates) to **assess** the **relevance** of a new method
Recommendations II

Bear more in mind **reduction** and **refinement** measures

Decide on a case-by-case basis, **whether full validation** of a test method is **required**

Encourage **data sharing** between companies (also cross-sector wise) and between regulatory authorities as crucial in promoting regulatory acceptance

Students’ **education** and the continuing education and training of scientists and regulators
Knowledge about and support of 3Rs methods and 21st century toxicological paradigm

Networking and communication between scientists 
(1) developing, 
(2) validating and 
(3) using 3Rs 
methods and 
(4) authorities

- Incentives promoting the application of newly accepted test methods
- Students education and continuing education of scientists and regulators
- Cross-sector collaboration
- Involvement of regulatory agencies during all stages of test method development
- Determination of criteria promoting the acceptance of test methods
- Data sharing and resolution of intellectual property issues
- Establishment of certainty on prerequisites for test method and data acceptance
- International collaboration & harmonization
- Consideration of replacement, reduction, and refinement methods

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Concluding remarks

• Despite the diversity of affiliations and backgrounds, the discussions had revealed many topics of convergence and agreement.

• Activities such as the organized workshop serve to build the trust and confidence that both the companies and the regulators require for a better understanding on how to further promote the acceptance and use of alternative methods into the regulatory context.