The EU Policy and Regulatory Framework on the RRRs:

The REACH Case

5th Meeting of Chairs

19 November 2009

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Policy Framework

Balance of interests:

- Animal Welfare: RRRs and Procedures
- Environment and Health: High Level of Protection

- But also:
  - Costs
  - Speed

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Will show the result of this balance in the case of REACH

What's New (ITS and Alternatives)?

- Annex XI, *in particular*:
  - Extensive frame for Categories, Grouping, QSAR, Read across, Weight of Evidence, in vitro, omnics, Exposure Based Waiving
  - ITS (substance tailored information gap moulded approaches and end-point covering hazard assessment)
  - OECD QSAR Toolbox
  - Integrated Assessment

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But much science is still needed to fully exploit the legislative frame!

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- The Legislative "Approach"
  - OECD (or Test Method Regulation) defines "gold standard" for information requirement
  - E.g., criteria for CLaP can be directly applied to results of "gold standard" tests
  - An information "package" which in sum total equals the information content of the "gold standard" is acceptable for Annex XI application provided:
    - Adequate for Classification and Labelling
    - Adequate for Risk Assessment
    - Adequate and reliable documentation
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Who?

What's New (ITS and Alternatives)?

- Adequacy for Classification and Labelling and Risk Assessment is determined ultimately by the **Commission** and it's **Comitology Committee**
- Adequacy for Classification and Labelling and Risk Assessment is determined initially by the **Risk Assessment Committee**
- Ad interim, adequacy of arguments for derogating from the standard information requirements is determined by the **Member State Committee**
- Initially, adequacy of arguments for derogating from the standard information requirements is evaluated by the **ECHA Secretariat**
- To start with, **Industry** decides what they think will be acceptable as adequate

REACH: Registration

Aim:

- Close the knowledge gap
- Ensure industry adequately manages risks from substances

- **Registration**
  - Tonnage based
  - Applies to chemicals manufactured in the EU and/or their importation
  - 30,000 substances to register
  - Registration deadlines: 2010, 2013, 2018

Industry's responsibility

And in 10 years:

- Data is available on substances on the EU market in volumes above 1 tonne;
- Data submitted for substances above 100 tonnes forms the basis for categories/read across for substances below
- Industry have harmonised most classification and labelling
- Risks managed for substances above 10 tonnes using acceptable and practical methods

International:

- Many REACH substances have undergone OECD hazard assessments
- REACH registration dossiers for the basis for industry meeting regulatory requirements elsewhere in the world (assuming progress on technical issues at OECD continue)

REACH: Data sharing

- Data sharing mechanisms of REACH
  - avoid unnecessary testing, while generating necessary information to identify hazards and manage risks of substances
  - avoid animal testing, tests on vertebrate animals as a last resort only
  - reduce costs to industry
- Inquiry and Substance Information Exchange Forums (SIEFs)

And in 10 years:

• Efficient data sharing mechanism in place creating an EU “data market”;

• Systematic establishment of industry co-operation on categories of chemicals

International:

•REACH data is shared with non-EU industry in order for them to meet regulatory requirements elsewhere in the world (assuming data ownership rules as in REACH gain universal acceptance)

A Plea

- Robust Study Summaries: Research scientists should volunteer and funding agencies should encourage that scientific results relevant for regulatory hazard and risk assessment should be made publically available as Robust Study Summaries (in the OECD format!)

Conclusions

- Theory: REACH creates a legal frame for ITS and alternative methods
- Theory and past practice: The scientific basis has been developed in the RIPs – still a long way to go
- Theory and practice: Test Methods in Test Method Regulation set the 'information standard' for applying ITS and alternative methods
- New Practice: (EC and) ECHA (RAC, MSC and Secretariat) are the "judges"

Thank you!

http://europa.eu.int/comm/environment/chemicals/index.htm

http://echa.europa.eu/home_en.asp/

http://europa.eu.int/comm/enterprise/chemicals/index.htm

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