

Introduction to the workshop

Experts Workshop on Read-Across
Assessment, with the Active
Support of Cefic LRI

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Mike Rasenberg
Head of unit, C3 Computational
Assessment
ECHA

REACH and read across (RA)

- REACH
 - Registrant may adapt standard information requirements
 - Annex XI.1.5 “Grouping of substances and Read-across approach”
- Animal testing as last resort
 - “One-by-one” testing not necessary → grouping and RA
 - May have a significant impact on safety assessment if used incorrectly
- Responsibility of building the case with registrant
- Responsibility of evaluation of cases with ECHA and MS

Industry experience

- Experience in the application of read-across approaches within the context of the 2010 registrations
- Need to capture, evaluate and build upon this experience in anticipation of the expected greater number of “read-across approaches” for the 2013 registrations (>100 tonnes/annum).

Authority experience

- Many read-across cases to evaluate and (many) more to come;
- Guidance on how to build a read-across is not the same as Guidance on how to Evaluate a Read-Across
 - “building a strong hypothesis” versus “sufficiently addressed the uncertainty”
- Need to structure Read Across Evaluation in a framework: RAAF (Read Across Assessment Framework).

Workshop overall objective

The objective of the two-day workshop is to

- Exchange views on evaluation of read-across arguments in a dossier between ECHA, the Commission and MS (yesterday, feedback today)
- Expand the discussion to what constitutes a robust scientific justification for read-across (today).

Agenda items

- Present information on the read-across assessment framework (RAAF);
- Review case-studies of the application of read-across approaches;
- Identify the potential difficulties for the read-across acceptance;
- *Attempt* to reach common understanding of what scientifically valid read-across represents and how to characterise it.

Planned workshop outcomes I

- Presentation of the current thinking of ECHA on evaluation of read-across;
- Review of the current state of the science on the scope and applicability of read-across approaches from an industry perspective;
- Characterisation of the uncertainty associated with the use of read-across approaches and ways to address uncertainty;

Planned workshop outcomes II

- Better understanding of the barriers that can impede further adoption of read-across approaches as an integral component of chemical management under REACH;
- Recommending initiatives to overcome these barriers;
- Establishing a community of interest as appropriate, to further advance the debate.

Thank you

mike.rasenberg@echa.europa.eu