# Briefing from Day 1 – ECHA-MSCA interaction

Experts Workshop on Read-across Assessment

3 October 2012, ECHA, Helsinki, Finland

**Wim De Coen**
**Head of Unit, Evaluation I**
**ECHA**

# Main objectives of the workshop: day 1

- Discuss the generic approach of the Read Across Assessment Framework
- Discuss the basic concepts of Tier I & II
- Take on board MSCA suggestions or alternative proposals

- Agree on a way forward:
  - Communication to registrants
  - Sharing further practices amongst experts
  - Further refinement – Work in Progress
  - Identify points for further consideration

# Why an assessment framework and an expert group for evaluation of read-across cases?

The assessment of read-across is characterized by:

- Expert assessment
- The fact that read-across is a case-by-case prediction
- The freedom of the registrant to come with any theory and any data to build and support his case

Conclusion: the assessment has to rely strongly on the personal judgement of the expert.

***How to streamline the process by making it more consistent, transparent and structured?***

***use of an Assessment Framework (RAAF) and a Read Across Expert Group (RAEG)***

# RAAF & RAEG implementation and current practice in ECHA for evaluation of read-across cases

The RAAF will assist Evaluators to assess read-across Cases = ECHA working rationale and not a tool (!)

- Scientific Dossier Manager to apply Tier I of RAAF
- RAEG to evaluate only cases reaching Tier II of RAAF
- Consistent and traceable recommendation for Management
- Consistent, legally and scientifically sound conclusions for Draft Decision (outcome of REACH Evaluation)

# Possible assessment of read-across cases according to the RAAF

Assessment by ECHA could be done at two levels:

**Tier I** → A screening level, aimed at weeding out and addressing the obvious cases by assessing mostly their compliance with the legal text and the guidance.

**Tier II** → An expert-judgement level, addressing the well built cases that are not solved during Tier I.

# Main conclusions break out discussions

- The RAAF as currently developed is helpful for the assessment of Read across cases ➔ General structure / approach is supported
- The key aspects in general are fine, but have to be further improved by:
- Adding more key apsects
- Clarifying wordings and assumptions
- Preparing approach for highly complex cases
- Work in progress – exchange of expert views with MSCAs

# General feedback – 1

- RA is – as a default – endpoint specific
  - Can be expanded across endpoints but on a case-by-case basis
- Chemical categories are defined by Boundary description **and** identification of category members
- Positive vs negative RA:
  - Negative RA acceptance requires higher quality/more data than for a positive RA
  - Need for higher "level of comfort" in taking decisions for negative RA (especially for higher tier – more complex endpoints)

# General feedback - 2

- When making a hypothesis for a RA, supporting data are needed:
  - E.g. when based on metabolism, toxicokinetic information is key(case-dependent)

- Way forward:
  - RAAF approach = work in progress
  - Expert discussion with MSCAs will continue
  - In parallel, the idea circulated to generate relevant feedback & supporting industry based on ongoing RAAF developments

# Potential communication to registrants

- Opinion to work on "illustrative examples" based on good and bad cases that ECHA has evaluated so far?
- No ambition to develop the "gold standard" cases!
  - Case-specific issues
  - Use RAAF concepts as a basis for these examples (see background paper)
- How to reach to right audience?

# Main message

- ECHA supports Read Across approaches – good cases have been accepted already
- RA cases need to have a transparent hypothesis and corresponding robust documentation/argumentation
- Relying on RA requires significant effort = diligence when submitting cases ➔ Registrants should convince ECHA/MS of their case

# Thank you

wimdecoen@echa.europa.eu