# Workshop 4: Evaluation of Evidence

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### WoE and Particular Challenges

#### Risk assessment

- Multidisciplinary process (physics to epidemiology)
- Wide ranging (different risk management questions, different data situations)
- Can be controversial (judgements/opinions need to be transparent)
  - Which data have been used/not used and why, and how is it considered.
  - Ensure decision makers and stakeholders understand the basis for risk conclusions

#### Workshop 4 – Aim

- Discuss approaches for evaluating, incorporating & integrating evidence in risk assessment process focusing in particular on the following:
  - Identifying and selecting relevant publications for analysis
  - Weighing the data
  - Applying for risk assessment (RA)/risk management (RM) purposes

### Workshop 4 - Evaluation of Evidence

- Discussion framed by presentation of the draft weight of evidence framework/guidance document prepared by the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
  - ""Use of the scientific literature for risk assessment purposes – weight of evidence approach

## SCENIHR WoE Approach : Six Stage Process

- Step 1 Identification and collection of potentially relevant data in relation to the aim of RA/RM
  - How data was sought including limitations in process
- Step 2 Initial data screening to identify relevant data for purposes of answering questions
  - Criteria of acceptability
- Step 3 Evaluation of individual data sources
  - Criteria: relevance (direct, indirect, insufficient) and quality (good, adequate, inadequate, not assignable)

## SCENIHR WoE Approach : Six Stage Process

- Step 4- Weighing of individual lines of evidence and bringing together data sets
  - Indepth evaluation of lines of evidence (epidemiology, animal toxicology, Pk, MoA, SAR, exposure, etc)
  - Criteria; Consistency (High, medium, Iow) and overall utility (high, moderate, Iow)
  - Categorize papers examined

- Step 5 Weighing the totality of data (i.e., integrating step)
  - Contribution of the different lines to the opinion (strong, moderate, weak)
  - Short description of conclusion, including critical data gaps
- Step 6- Check that the process used and the rationale for the conclusions are clearly presented

### Workshop 4: Questions/Discussion Points

- What are the general characteristics of a WoE helpful to risk assessors and to risk managers?
- Are the criteria for acceptance and relevance of data sufficiently well defined at each stage?
- What are the next steps towards further refinement and harmonisation?

### Workgroup 4: Discussion

- Terminology
  - Weight of Evidence, relevance, consistency, etc.
  - Criteria for categorizing lines of evidence as "strong", "moderate", "weak"
- Publication bias
  - Difficult to address but need to be aware of bias toward positive findings
- Consideration of dose response relationships, outlier responses, surrogate data, etc
- Identification of critical data gaps that have impact on confidence

#### Workgroup 4 Discussion

- Scientific judgment at every step
- Purpose of WoE
  - provides an assessment for different risk management options (versus proving safety)
  - Framing the critical questions upfront (problem formulation) that will shape the assessment

### Characteristics of a WoE approach helpful to risk assessors & to risk managers

- Structured analysis to ensure a systematic and transparent approach
  - Consistency (between assessors from different scientific disciplines, among different risk assessments)
- Clear and explicit criteria for identifying, and evaluating relevant evidence
  - Clarity of data & model choices and the interpretative process
- Harmonisation of approach across different sectors/Countries
- Useful aid for risk assessors & risk managers

#### Next steps

- Initial and ongoing dialogue between risk managers and risk assessors
- Dialogue with research community (particularly on emerging in vitro/HTP technologies)
- Linkages among this Conference themes
  - In particular, need to merge WoE approach with approach to evaluating uncertainty and clarifying terminology
  - Pilot study for uncertainty project should consider WoE methodology

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