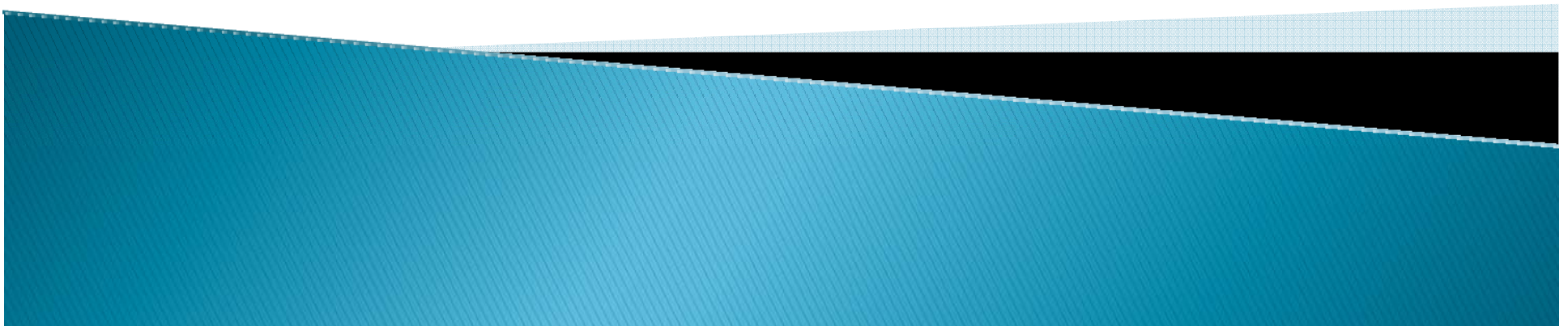


Workshop 4: Evaluation of Evidence

Leader: Jim Bridges

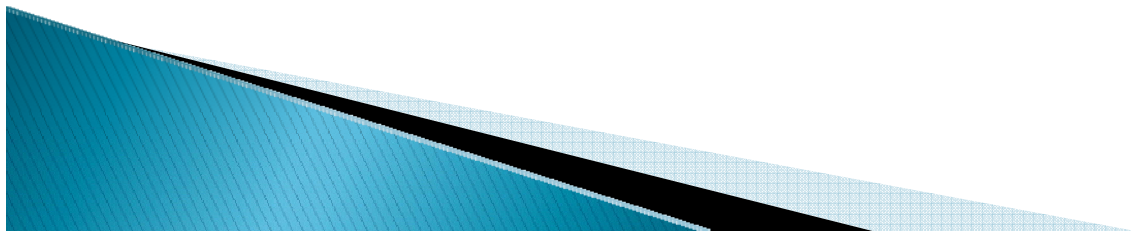
Rapporteur: Vicki Dellarco



WoE and Particular Challenges

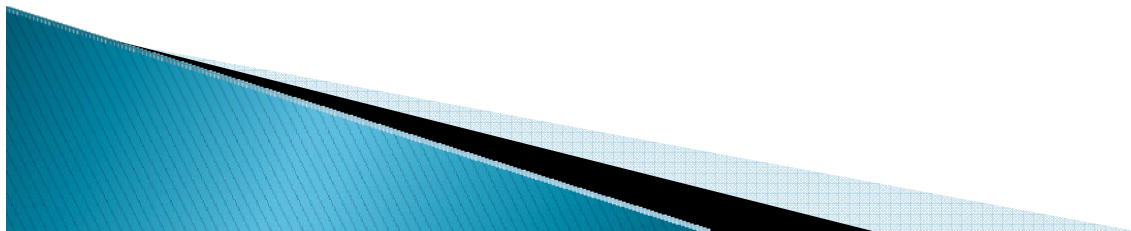
▶ Risk assessment

- 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



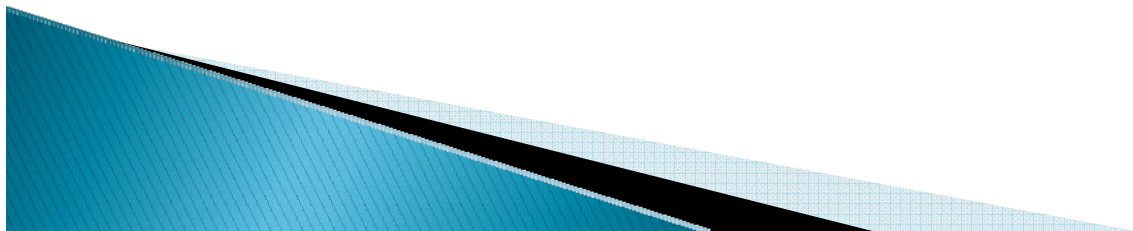
Workshop 4 – Aim

- ▶ 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



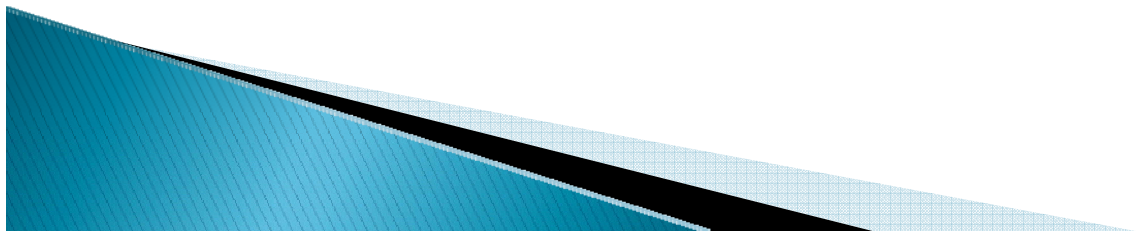
Workshop 4 – Evaluation of Evidence

- ▶ 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



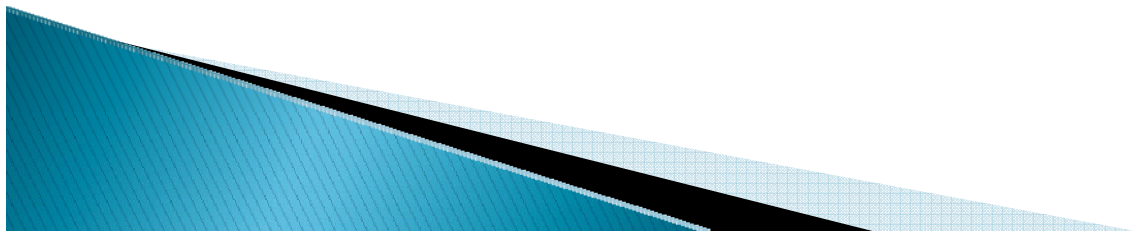
SCENIHR WoE Approach : Six Stage Process

- ▶ **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)



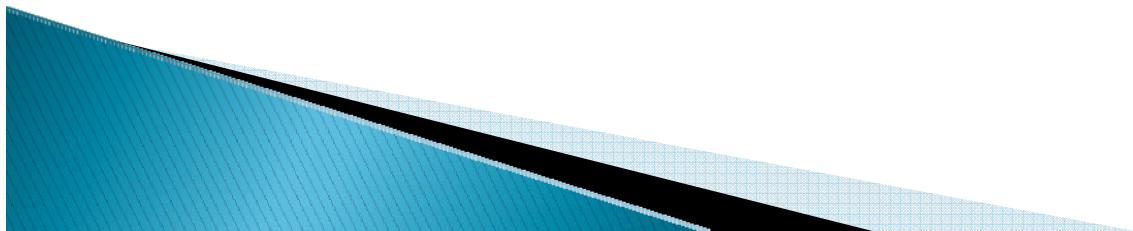
SCENIHR WoE Approach : Six Stage Process

- ▶ **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, low) and overall utility (high, moderate, low)
 - 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**



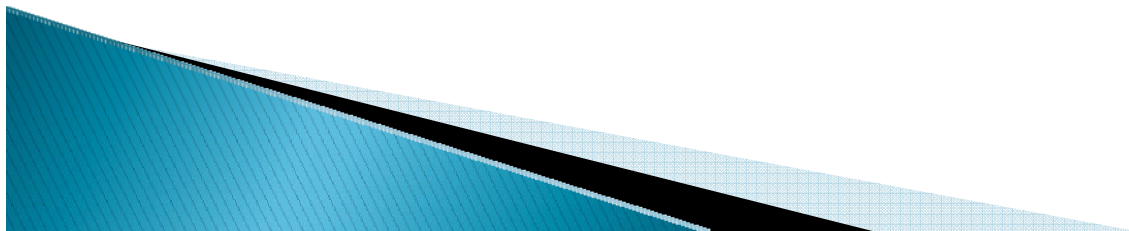
Workshop 4: Questions/Discussion Points

- ▶ 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?



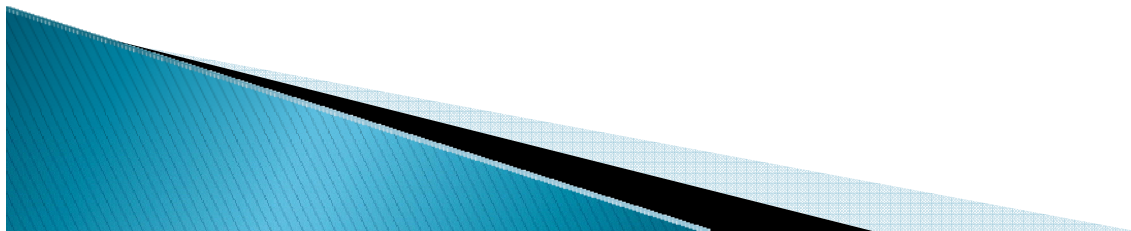
Workgroup 4: Discussion

- ▶ 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



This paper was produced for a meeting organized by Health & Consumers DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumers DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.