



# The weighing of scientific evidence: Approach of the SCENIHR

Prof Jim Bridges  
Chair of the EU Scientific Committee  
on Emerging and Newly Identified  
Health Risks



# Why do we need weight of evidence guidelines?

- Transparency of risk assessments for stakeholders
- Clarity of data, model choices and the interpretative process for decision makers
- Consistency between assessors, in particular from different scientific disciplines
- Harmonisation of approach across different sectors/ Countries
- An aid for risk assessors



# WoE and the particular challenges for SCENIHR

- SCENIHR is a very multidisciplinary committee (physics to epidemiology) and its task are very wide ranging.
- One of its main activities is to provide advice on emerging issues where available data base varies greatly from task to task
- Often it is involved in areas where lobbying is already active. Its opinions therefore need to be as transparent as far as it practicable.
- A need to differentiate between data that has been used/not used/ not seen and to indicate why.



# Considerations in developing the weight of evidence guidelines

- To examine approaches currently used by different bodies and their utility for SCENIHR purposes
- To identify a framework that is acceptable across the full range of scientific disciplines
- To produce flexible guidelines that can be used for the majority of tasks and facilitate the work.
- To help decision makers and stakeholders to understand better the basis for the RA conclusions.



# WoE: a six stage process

1. Identification and collection of potentially relevant data
2. Initial data screening to identify useful data for the task
3. Evaluation of individual publications etc
4. Weighing of individual lines of evidence
5. Weighing the totality of data
6. Checking that the process used and the rationale for the conclusions are clearly presented



# Stage 1: data sources

To set out clearly how the data was sought and any limitations in the process:

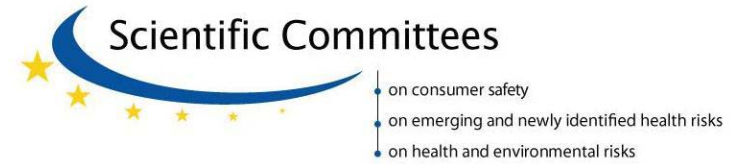
- i) accessibility within the time allotted
- ii) translation of language difficulties
- iii) any concerns with the trustworthiness of particular sources
- iv) to clarify rules on the use of confidential data in the light of the need for transparency



# Stage 2: initial screening of data

## ***Criteria***

- i) Suitability based on title alone or plus abstract
  
- ii) Readiness of accessibility of the data in a suitable form
  
- iii) Level of detail provided (eg abstract only or full paper)
  
- iv) Any evident quality indication



# Stage 3: Evaluation of individual publications etc

**Purpose-** to identify particular data that should be used for the RA

**Criteria-** Quality – good, adequate/ utilisable, inadequate, not assignable

Relevance- Direct, indirect, insufficient.

**Citation of data not used-** publications noted but not considered suitable for the purposes of developing the RA





# Evaluation of individual publications /data sets

|                           | Good | Adequate/<br>Utilisable | Inadequate | Not<br>assignable |
|---------------------------|------|-------------------------|------------|-------------------|
| Direct<br>Relevance       | X    | X                       |            |                   |
| Indirect<br>relevance     | X    | X                       |            |                   |
| Insufficient<br>relevance |      |                         |            |                   |



# Potential lines of evidence

- Physicochemical information
- Exposure measurements
- Toxicokinetics
- Computer modelling (exposure/SAR etc)
- Animal studies/environmentally relevant species/systems
- Mechanisms /mode of action
- Epidemiology
- Other human studies
- Other data



# Stage 4: Weighing individual lines of evidence

**Purpose** - to weigh the data for individual lines of evidence

**Criteria** - Consistency- high, medium, low

Overall Utility- high, moderate , low

**Citation of data** - publications that are relevant, of sufficient quality and important for the RA

- publications that are relevant, of sufficient quality but not necessary for the

RA



# Stage 5: Integration of all lines of evidence

**Purpose-** to identify the relative importance of the selected data on the relevant lines of evidence and the assessment of the strength of the overall evidence

## **Assessment-**

WoE exposure- strong, moderate, weak

WoE hazard- strong, moderate, weak

## **Notes on-**

\*The data available and its use

\*Uncertainty

\*Any other critical points

## **Overall-**

WoE risk - strong, moderate, weak



# Assessment of the total evidence

Line of evidence                  Strong          moderate          weak

**Exposure**

|               |  |   |   |
|---------------|--|---|---|
| -measurements |  |   | X |
| -modelling    |  | X |   |
| -overall      |  |   | X |

**Hazard**

|               |   |   |   |
|---------------|---|---|---|
| -epidemiology |   |   | X |
| -animal       | X |   |   |
| - in vitro    |   | X |   |
| - QSAR        |   |   | X |
| - overall     |   |   |   |

**Risk**

|          |  |  |   |
|----------|--|--|---|
| -overall |  |  | X |
|----------|--|--|---|



## Stage 6: clarity of process used and basis for the conclusions

- Checking the data sources and attributions
- Consistency in the weighing of different lines of data.
- Ensuring that the way the data has been weighed is as transparent and understandable by risk managers as is reasonably practicable.



# Next steps

- Additional discussions
- Final working version –mid April
- Sharing with other organisations
- Further trialling with particular risk assessments
- Publication

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