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The weighing of scientific evidence: Approach of the SCENIHR

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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

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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.

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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.

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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

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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

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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

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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

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Evaluation of individual publications /data sets

	Good	Adequate/ Utilisable	Inadequate	Not assignable
Direct Relevance	X	X		
Indirect relevance	X	X		
Insufficient relevance				

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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

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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

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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

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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.

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Next steps

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