

Item 5.2: Overarching issues: Quality and relevance of information, uncertainty

Marja Ruohonen-Lehto

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Quality and relevance of information (1)

- Need to identify the information needed
- Need to understand how information will be used, how to interpret it
- Need to identify information gaps – more information needed?
- How to deal with scientific uncertainty – what level is acceptable

Quality and relevance of information (2)

Quality and relevance of information

- Relevant information from existing scientific literature
- From experience and previous risk assessments
- New experimental data (e.g. early tier toxicology testing)
- Confined field experiments
- Other scientific observations
- Relevance and level of detail – the nature of the modification, intended use, scale and duration



Quality and relevance of information (3)

- Scientifically sound methodologies – determined and documented -> to test risk scenarios

From the next topic, talk and slides by Helmut Gaugitsch

- Develop conceptual models, risk scenarios
- Establish risk hypotheses
- Develop an analysis plan & identify adequate methods

Uncertainty (4)

- Inherent and integral element of scientific analysis
- This is to be kept in mind through-out the risk assessment process
- Uncertainty may rise from
 - Lack of information – missing information, data that is imprecise or inaccurate (study designs, model systems, analytical methods)
 - Incomplete knowledge
 - Biological or experimental variability – heterogeneity in the population or variation in analytical assays
- Changes in the level of uncertainty during the risk assessment process -> need for iterations of parts or the entire process

Uncertainty (5)

- Uncertainty considered during the whole process
- Uncertainty considerations reported at the end of the process (in conclusions)
 - It is the responsibility of the decision-makers to decide how to use the information
 - Precautionary approach

Uncertainty (6)

Further considerations of uncertainty

- Differing interpretations of existing data
- Publication bias
- Lack of some relevant data
- May relate to qualitative and quantitative elements of the analysis
- The assessment shall include a description of the types of uncertainties
- Their relative importance and their influence on the outcome

Uncertainty (7)

- Distinctions between those that reflect natural variations in ecological and biological parameters (e.g. variations in susceptibility in populations or varieties) and possible differences in responses between species
- Experimental data shall be handled by proper statistical analysis
- Quantification of uncertainties in assumptions – e.g. extrapolation from environmental laboratory studies to complex ecosystems is more difficult