

WG on Evaluating Uncertainty, Weighing Evidence, Using Appropriate Terminology in Risk Assessment

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Why this Activity?

- Transparency- not to promote harmonisation
- To improve the robustness and hopefully acceptability of RAs.
- Inspired by by SANCO on Uncertainty Terminology; EFSA on Uncertainty Management, ECDC on Clinical Guidelines i& Terminology, & EEA on Evaluating Evidence/Sources of Divergent Opinions & Terminology for Causation.

Different Conclusions: “Same Knowledge” Evaluated?

**Classification of TCE risk assessment reports in 1995/6
(from Rudig 2002)**

- - - negative	+ - - Positive animal	+ - + Positive animal, negative human, plausible risk	+ + + Positive animal & human, plausible risk
1996 ACGIH	1996 HSIA, Online, Industry	1996 OECD/EU UK, Int.Org.	1995 IARC Int. org
			1996 Deutsche Forschungsgemeinschaft, DFG, Germany
			1996 MAK Germany, Occ. Agency

Annex 3 covers:

- Finding, collecting, evaluating and weighing relevant evidence
- Treatment of different types of evidence (human, cellular etc) and of positive/non-positive, negative, & inconsistent evidence
- Rules for determining likelihoods, confidences, & strengths of evidence
- Argumentation & Reasonings
- Terminology used for Uncertainty & Causality

Some Strengths of Scientific Evidence

- Beyond all reasonable doubt (criminal laws; scientific “proof”)
- Reasonable certainty (IPCC, 2007)
- Balance of probabilities/evidence (IPCC, 2001)
- Strong possibility (IARC on ELF 2002)
- Scientific suspicion of risk (Swedish Chemicals Law: SCENHIR ?)
- “Pertinent information” (WTO SPS justifying MS actions to, temporarily, protect health)

WG Conclusions

- Ambitious: but needed and doable
- Keep the 3 issues (Evaluation, Uncertainty, Terminology) together
- Focus on current (not “best”) practices and on promoting common understandings
- Appreciate the many legal, cultural and scientific differences between agencies/committees
- Aim for closer agreements on Terminologies.
- Improve Annex 3; clarify to whom Q're will be sent; seek NA views.

Some issues that Arose

- Examine ways of how “low grade” evidence can be better used
- Benefit/risk analysis is an emerging issue
- EMEA work on Terminology and Transparency;
- EMEA/EFSA work on possible bias from “intellectual Interests”
- Depth of Uncertainty analysis needs to be case specific (See NAS on “Science & Decisions: Advancing Risk Assessment”,08)

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