

Risk Assessment Terminology

Professor Tony Hardy
Science Director
Central Science Laboratory
Sand Hutton, York, UK



4th Chairs Parma
4-5th Nov 2008

a.hardy@csl.gov.uk



Non-food Scientific Committees

DG SANCO current (post-EFSA establishment)

- Scientific Committee on Consumer Products ([SCCP](#))
- Scientific Committee on Health and Environmental Risks ([SCHER](#))
- Scientific Committee on Emerging and Newly Identified Health Risks ([SCENIHR](#))

DG SANCO (pre - EFSA establishment, 2004)

- Scientific Committee on Cosmetic Products and Non-food products intended for Consumers ([SCCNFP](#))
- Scientific Committee on Medicinal Products and Medicinal Devices ([SCMPMD](#))
- Scientific Committee on Toxicity, Ecotoxicity and the Environment ([CSTEE](#))



Contract review study for DG SANCO

Objective

- Comparative review of terms and expressions used by **SCCP, SCHER, SCENIHR**, SCCNFP, SCMPMD and CSTEE

Purpose

- Assist current committees to identify best practice in the expression of complex ideas used in risk assessment

Scope

- Concluding sections of 100 example opinions (out of 632 opinions published 1998 – 2006)
- Specified types of terms and expressions



Main types of terms & expressions covered

- Nature of hazards identified
- Expression of risk
 - Qualitative expressions
 - Quantitative expressions
 - Expression of “*de minimis*” risk
- Expression of uncertainties
- Identification of missing information
- Overall conclusions
- Recommendations for action



Qualitative expression of uncertainty

ambivalent, appear, approximately, arbitrary, believe, borderline, cannot be assumed, cannot be excluded, considered, could, disagreement, estimated, expected, few/most, in general, incorrect, increasing evidence, indicate, likelihood, **may** (46), might, not detected/detectable, not established, open questions, outlier, perhaps, possible, potential, probably, prone to, reasonable, seem, should not, some, suggest, suspected, theoretically, **uncertain** (20) unclear, under- or overestimate, unexplained, unknown, variable



Main conclusions & recommendations

- Wide variety of verbal terms currently used
- Harmonisation unlikely to improve communication
- When quantitative estimates available, use them
- When the assessment depends on expert opinion, try expressing it quantitatively
- Adopt a systematic approach to uncertainty
- Avoid implying risk management judgements
- Explore new approaches with case studies?



EFSA approach adopted by REACH

	SOURCES OF UNCERTAINTY		VARIABILITY OR UNCERTAINTY	DIRECTION & MAGNITUDE
HAZARD ASSESSMENT	Model	Source 1	VAR	-
	Input parameters	Source 2	UNC	+++
		Source n	UNC	++/--
	Overall effect on hazard estimate E.g.: Mainly affected by overestimation from Source 2, which is uncertainty that may be reduced by...			
EXPOSURE ASSESSMENT	Scenario	Source 1	UNC	++
	Model	Source 2	VAR	+
		Source 3	UNC	+/-
	Input parameters	Source 4	UNC	-
		Source M		--
Overall effect on exposure estimate E.g.: Mainly affected by overestimation from Source 1 and Source 2. Source 1 can be reduced by means.... Data on variability of Source 2 out line that adopted conservative assumptions are plausible only if...				
RISK CHARACTERIZATION	Overall effect on risk estimate E.g.: The risk estimate appears to be overestimated mainly based on assumptions in exposure assessment, that may be revised on the basis of further investigation ...			

- REACH Chapter 19, Table R.19-3 Uncertainty analysis (ECHA, 2008)

Points for discussion

1. Is it useful to develop a set of harmonised terms for strength of evidence and other dimensions of risk?
2. What approaches could be considered for evaluating and expressing uncertainties, in addition to those mentioned above?
3. Is there a need to review the types of participation, the types of evidence admitted and approaches to the weighing of evidence by scientific committees?
4. What types of activity are required for progress on these issues in the short and medium term?
5. Would it help to develop case studies based on practical examples of risk problems?