Risk Assessment Terminology, Expression of Nature and level of Risk and Uncertainties

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Comparative Review of Risk Terminology of EU Non-Food Scientific Committees

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- Background
- Comparative review of risk terminology
- Report Conclusions
- European discussions on harmonisation
- Concluding remarks

- Report available at
Background

- Risk analysis paradigm – risk assessment, risk management and risk communication
- Key principles – clear, easily understood, transparent, unambiguous
- Harmonised terminology to describe similar risks
- EU Scientific Steering Committee
  - 2000 2003
- International Programme on Chemical Safety (IPCS)
  - 2004
- European Food Safety Authority (EFSA)
  - Transparency GD procedural aspects (2006)
  - Transparency RA (December 2008)
- Chairs of the Community Scientific Committees and Panels responsible for risk assessment (2005)
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)
CSL report on terminology for DG SANCO

Objective

- Comparative review of terms and expressions used by the EU non-food scientific committees 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 expressions of risk

Common form: expression + qualifier  (e.g. low risk)

Seven main types of expression:
- “risk” + qualifier
- “margin of safety” + qualifier
- “concern” + qualifier
- “safe” + qualifier
- expression of evidence
- expression of effects
- expression of exposure

Types of qualifier:
- no.none
- low
- possible
- some
- high
- more
- less
- no change
Qualitative expressions of risk

- Huge variety of types and qualifiers
- Provide only a relative indication of level of risk
- Liable to variable interpretation
- Often do not distinguish between degree of effect and its probability
- Tendency to imply or infer risk management meaning re. acceptability of risk or need for action e.g. concern, safe, sufficient evidence
Quantitative expressions of risk

- Rare, especially in concluding sections of opinions

- Ratios of effect level to exposure (6 opinions)
  - E.g. margin of safety

- Ratios of exposure to effect level (13 opinions)
  - E.g. PEC/PNEC

- Percent of population affected
- Percent of occasions or events affected
- No. occurrences per unit time  
  5 opinions
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
Qualitative expression of uncertainty

- Wide variety of forms of expression, may not all be recognised as uncertainty
  - Use “uncertainty” as standard term and/or section heading?

- Communicate that true outcome or risk may be different from estimate, but not by how much or with what likelihood
  - Consider using ranges or bounds, scenario/sensitivity analysis, “what if” statements, subjective probabilities
Harmonisation of verbal risk expressions?

- Attractive in theory, but...
- Definitions must be quantitative to avoid variable interpretation
- May not improve risk communication
  - Multiple lists of terms may be required for different types and dimensions of risk, e.g. RR, cancer risk, MoS, PEC/PNEC ratios
  - Loss of information when expressing quantitative risk estimates
  - May be interpreted as implying risk management judgements
- More effective to communicate using the quantitative definition than the verbal term?
Alternatives to harmonised verbal terms?

- When quantitative estimates are available, include them in concluding sections
  - Express uncertainty to avoid false precision
  - Present together with other relevant evidence
  - Communicate with care (may require training/research)
Alternatives to harmonised verbal terms?

- Try to make subjective quantitative estimates
  - range or worst-case estimate
  - subjective probability of alternative conclusions

- If the science will not support a quantitative estimate, does it really support a qualitative one?
  - consider how it will be interpreted
  - make sure the uncertainty is clearly expressed
Expressing uncertainty

- “work towards a systematic approach” (Robert Madelin)

Tiered treatment of uncertainties:
- initially evaluate all uncertainties qualitatively
- if necessary, analyse most important uncertainties deterministically (e.g. what if / sensitivity analysis) or probabilistically
- …or, obtain more data to reduce key uncertainties
### EFSA approach adopted by REACH

<table>
<thead>
<tr>
<th>Sources of Uncertainty</th>
<th>Variability or Uncertainty</th>
<th>Direction &amp; Magnitude</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HAZARD ASSESSMENT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model</td>
<td>Source 1</td>
<td>VAR</td>
</tr>
<tr>
<td>Input parameters</td>
<td>Source 2</td>
<td>UNC</td>
</tr>
<tr>
<td>Source n</td>
<td>UNC</td>
<td>++/-</td>
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<tr>
<td><strong>EXPOSURE ASSESSMENT</strong></td>
<td></td>
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<tr>
<td>Scenario</td>
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</tr>
<tr>
<td>Source 3</td>
<td>UNC</td>
<td>+/-</td>
</tr>
<tr>
<td>Input parameters</td>
<td>Source 4</td>
<td>UNC</td>
</tr>
<tr>
<td>Source M</td>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

**Overall effect on hazard estimate**
E.g.: Mainly affected by overestimation from Source 2, which is uncertainty that may be reduced by...

**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…
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?
Evaluating uncertainty

- **Director General of SANCO, (Robert Madelin)2004:**
  “I would urge you to take account of the risk manager’s need to understand the level of uncertainty in your advice and to work towards a systematic approach to this problem”

- **Codex Working Principles:**
  “Uncertainties should be…
  …explicitly considered at each step
  …documented in a transparent manner
  …quantified to the extent that is scientifically achievable”

Systematic and transparent
Chairs of the Community Scientific Committees and Panels responsible for risk assessment

- EFSA (11)
- DG SANCO (3)
- DG EMPL (1)
- EMEA (5)
- ECDC (1)
- EEA (1)
- ECHA (1)

- European Food Safety Authority
- Health & Consumer Protection DG
- Employment, Soc Affairs & EO DG
- European Medicine Agency
- European Disease Control Centre
- European Environment Agency
- European Chemical Agency

Initiative Robert Madelin
(Brussels 2005, 2006)
(Stockholm Nov 2007)
(Parma Nov 2008)
EEA Workshop on Evaluating Evidence*

- Reviewed causes of divergent scientific committee opinions
  - Institutional differences
  - Differences in types of evidence admitted
  - Differences in rules for evaluating evidence
  - Terminology for expressing conclusions

- EEA proposal for strength of evidence terminology

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Causally linked to</td>
<td>Very Strong (&gt;95%)</td>
</tr>
<tr>
<td>Strongly associated with</td>
<td>Strong (65-95%)</td>
</tr>
<tr>
<td>Associated with</td>
<td>Moderate (35-65%)</td>
</tr>
<tr>
<td>Little evidence that</td>
<td>Weak (10-35%)</td>
</tr>
<tr>
<td>Unlikely to be</td>
<td>Very Weak (&lt;10%)</td>
</tr>
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*Copenhagen, 28-29 May 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?
Thank you for your attention

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