ACM/1065

ACMSF APPROACHES TO MICROBIOLOGICAL RISK ASSESSMENT:

DISCUSSION PAPER

RISK ASSESSMENT OUTPUTS

Introduction

1. At the last ACMSF meeting the committee were supportive of the proposed approach to risk assessment and the framework set out in ACM/1049a. There was recognition that different approaches may be needed for different areas of the Committee's work such as in developing or considering ACMSF risk assessments or reviewing those produced by the FSA or other bodies. ACM/1049a also highlighted the importance of interaction between risk assessors and risk managers in formulation of the risk assessment question. However, it did not address the format or articulate the language for risk assessment outputs and the secretariat was asked to provide a paper on this topic for discussion by the Committee. Most of the Committee's risk assessment outputs tend to be qualitative rather than quantitative and the paper provides some examples of possible approaches given the wide ranging nature of the questions which the Committee deals with. Risk assessments and risk outputs should take into account the impact of uncertainty and variability and it is suggested that the committee considers this to help improve transparency of the risk assessment process.

Qualitative risk estimates

2. Many organisations undertake risk assessment and the outputs may be qualitative, semi-quantitative or quantitative. Bodies such as Codex, WHO and FAO have highlighted the importance of quantitative risk assessments and examples at the international level include the FAO/WHO series undertaken by the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/. However, it is not always possible or necessary to undertake a quantitative risk assessment and the outputs from many expert groups and committees at national and international level have tended to be qualitative in nature. The widespread use of qualitative risk assessment has led to a wide range of terms and descriptors being used to characterise the level of risk and in some (fewer) cases the uncertainty associated with a risk assessment (see Annex A & B). If the basis for such descriptors are not clearly articulated then there is potential for ambiguity in interpretation of the risk assessment output. This is particularly so for stakeholders which are outside of the risk manager-assessor interface when developing and understanding the risk assessment question and the anticipated format of the output. There is also the question of consistency of approach. Whilst following a structured risk assessment framework should ensure that the key steps (hazards identification, exposure assessment, hazard characterisation, risk characterisation) are addressed, there is perhaps greater potential for the outputs of qualitative assessment to lack consistency between assessments if agreed descriptors are not followed.

3. There appears to have been little if any standardisation or harmonisation of such terms in an attempt to achieve consistency of approach across different disciplines which could be seen as a key element of good risk assessment practice. Flari and Wilkinson (2011) assessed the terminology in risk assessments used by the various scientific panels and the scientific committee of EFSA. Most assessments were qualitative although it was acknowledged that some of these contained quantitative components. However, it was noticeable that a wide range of descriptors (e.g. “Very low”; “Low”; “High”; “Safe”; “Unlikely to have any adverse effects”; “Negligible”; “As safe as”) were used in the description of risk. Flari and Wilkinson (2011) also noted that that very few of the papers appeared to clearly address the issue of uncertainty in relation to risk assessment.

4. Annex A provides examples of different approaches to describe the outputs of risk assessment in terms of descriptive estimates of risk. These are taken from different areas and are based on somewhat different approaches. In all cases the challenge is in selecting appropriate terminology from a risk assessment which will include gaps and data with various degrees of quality, completeness and representativeness. It is important to recognise that when such descriptors are used they need to be presented in the context of the issue under consideration.

Variability and uncertainty

5. Variability and uncertainty are two important parameters which influence the interpretation of the risk assessment and its outputs. Variability can relate to biological or other difference such as between consumers, strains of bacteria, processing plants etc. Uncertainty in the context of the risk assessment can relate to assumed scenarios, lack of knowledge concerning one or more parameters at steps in the risk assessment and the structure, detail and resolution of any model that is constructed for the assessment (Bogden and Spear 1987; Morgan & Henrion 1990; Wooldridge 2008; WHO/FAO 2009). Whilst uncertainty for a given parameter can be reduced by collecting more data, variability is an inherent characteristic which cannot be reduced, at least within the scope of the question being considered. This highlights an important aspect in developing the scope of the risk assessment question between the risk manager and the risk assessor. In the case of quantitative risk assessments the output can provide the statistical uncertainty associated with the risk estimate but in a qualitative assessment descriptors are usually used. In a semi-quantitative risk assessment the output may be in the form of a ranking (WHO/FAO 2009). Examples of different approaches to capturing uncertainty at different points in the risk assessment are presented in Annex B. These vary from examining uncertainty associated with individual parameters in a risk assessment to uncertainty associated with the risk estimate. How these are used in practice is important a particular challenge being how to capture risk estimate and uncertainty descriptors in text describing the context of the issue being considered.

6. Wooldridge (2008) has highlighted the importance of taking variability and uncertainty into account in a qualitative risk assessments. Whilst quantitative parameters can be included at the appropriate points in a risk assessment, unlike quantitative risk assessments the uncertainty and variability associated with such parameters is not easily reflected in the final risk estimate. Therefore in a qualitative assessment the variability and uncertainty need to be captured in descriptive terms (e.g. low, medium high, -, +, ++, +++, etc). Hart *et al.* (2010) have proposed schemes for systematically capturing and presenting uncertainty in the risk assessment process. The examples relate to chemical hazards but could be applied in a similar way in risk assessments for biological hazards. An example of this type of approach to examining sources of uncertainty in dietary exposure assessment has been published by EFSA (2007). Flari and Wilkinson (2011) in looking at the outputs from EFSA panels and the scientific committee suggested that uncertainties should be acknowledged explicitly even if they cannot be quantified.

7. GOS (2011) and Spiegelhalter & Riesch (2011) have recognised the potential of adapting approaches such as GRADE (Grading of Recommendations Assessment, Development and Evaluation) for the purposes of qualitatively judging reliability/uncertainty in risk assessment (see Annex B Table 4). GRADE is widely used in systematic reviews of medical interventions as part of the Cochrane collaboration http://www.cochrane.org/) and may offer an approach to examining quality of evidence in risk assessments with appropriate consideration of how such assessments are presented.

Other considerations

Risk assessor- manager interaction

8. Whilst there should be a functional separation between risk assessment and risk management, risk managers will have to use the outputs of a risk assessment and there should be a clear understanding at the outset about the potential output formats. At the stage of formulating the risk question it may not be possible to identify whether the output will be quantitative or qualitative. However, the potential outputs can be considered taking into account the urgency of the issue under consideration and resources available to undertake the assessment. The extent to which the format of a risk assessment output is agreed between the risk manager and risk assessor can have important implications for risk communication and follow-up work such as examining risk management options and their impact on the risk estimate or trying to reduce uncertainty by conducting further studies.

Communication issues for ACMSF

9. Qualitative risk assessment outputs need to reflect the consensus view of the Committee and address the questions posed by risk managers to the extent possible. The outputs of risk assessment are used by risk managers to inform decision making which may impact to a greater or lesser extent on different groups of stakeholders for example regulators, industry and consumers. Whilst the risk manager may have a clear understanding of what the output of the risk

assessment means, it may be more difficult for others to appreciate and understand the context and interpretation of the risk output unless this is communicated clearly (Hallman 2008; Spiegelhalter & Riesch 2011).

10. Clarity concerning the meaning of the output and associated uncertainty will be important in informing decision making. In many situations the risk estimate will need to be communicated to consumers. In most instances they will be unsighted on the formulation and framing of the risk assessment question but will be affected to a greater or lesser extent through their perception of the risk and how it has been communicated. In this respect there is a degree of uncertainty associated with perception of the risk output that is distinct from that associated with the risk assessment itself. Whilst qualitative descriptors for risk estimate and uncertainty might meet the output needs of the risk assessor and risk manager, for the purposes of wider communication these descriptors need to be set in context with text to provide further explanation with the aim of ensuring clarity about the issue as well as the outcome.

Proposed way forward

11. The Committee is invited to consider the options in three areas in relation to risk assessment outputs. These relate specifically to qualitative assessments but may also have a relevance to semi-quantitative and quantitative assessments where outputs will need to be articulated into a descriptive format for the purposes of wider communication. The Committee is invited to consider the following questions regarding the outputs from risk assessment.

    a) Whether the Committee wishes to use standardised descriptors to convey risk estimates in its work and if so what would the Committee wish to use? Options could include following an existing framework of descriptors or developing one specifically for the Committee's work.

    b) Should the degree of uncertainty associated with the risk assessment be expressed as standard descriptors as part of the output and if so what would the Committee wish to use? Options could include following an existing framework of descriptors or developing one specifically for the Committee's work.

    c) When carrying out a risk assessment using the tabular format (ACM/1049a) would the committee like to see the inclusion of a qualitative assessment of the uncertainty impacting on key parameters and if so what would the Committee wish to use? Options could include following an existing framework of descriptors or developing one specifically for the Committee's work.

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Annex A. Examples of schemes used to describe the outputs of risk assessment in terms of the risk estimate.

1.) Illustrative Risk Characterization Scoring

In a qualitative risk assessment, the risk estimate may be integrated into the qualitative (descriptive) considerations of "Negligible," "Low," "Medium," "High," and "Very High" from the outputs of the Exposure Assessment and Hazard Characterization steps. An example of integration is presented in the table below.

Table 2. Integration of the Outputs of Hazard Characterization and Exposure Assessment into the Qualitative Risk Characterization

Exposure Assessment Probability of Exposure	Hazard Characterization Severity of Adverse Health Effect	Qualitative Risk Characterization
Negligible	Negligible	Negligible
Low (Unlikely)	Negligible	Negligible
Medium (Possible)	Negligible	Low
High (Almost Certain)	Negligible	Low
Negligible	Low (Mild)	Low
Low (Unlikely)	Low (Mild)	Low
Medium (Possible)	Low (Mild)	Medium
High (Almost Certain)	Low (Mild)	Medium
Negligible	Medium (Moderate)	Low
Low (Unlikely)	Medium (Moderate)	Low
Medium (Possible)	Medium (Moderate)	High/Medium
High (Almost Certain)	Medium (Moderate)	High
Negligible	High (Severe)	Low
Low (Unlikely)	High (Severe)	Medium
Medium (Possible)	High (Severe)	High
High (Almost Certain)	High (Severe)	Very High
Negligible	Very High (Fatal)	Medium/Low
Low (Unlikely)	Very High (Fatal)	High
Medium (Possible)	Very High (Fatal)	Very High
High (Almost Certain)	Very High (Fatal)	Very High

Modified after National Cancer Institute, 2006. Common Terminology Criteria for Adverse Events v3.0. http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf.

Table from CAC (2011)

2.) Operational guidance on rapid risk assessment methodology

Risk matrix probability x impact = risk

		Probability			
		Very low	Low	Moderate	High
Impact	Very low	Very low risk	Low risk	Low risk	Moderate risk
	Low	Low risk	Low risk	Moderate risk	Moderate risk
	Moderate	Low risk	Moderate risk	Moderate risk	High risk
	High	Moderate risk	Moderate risk	High risk	High risk
	Very high	Moderate risk	High risk	High risk	Very high risk

Table from ECDC (2011)

3.) Risk level classification

Probability category	Interpretation
Negligible	**So rare that it does not merit to be considered**
Very low	**Very rare but cannot be excluded**
Low	**Rare, but does occur**
Medium	**Occurs regularly**
High	**Occurs very often**
Very high	**Events occur almost certainly**

Table from EFSA (2006) modified from OIE (2004)

Annex B. Examples of schemes used to assess or describe uncertainty in risk assessment.

1) Scoring of specific parameters in the risk assessment

Table 12 Qualitative assessment of the importance of various factors to the uncertainty in the calculated risk (the more stars the more important)

Factor	Importance
Differences in the qualitative analysis[5]	**
Factors relating to frequency assessment:	
Frequency assessments of pipeline failures	***
Frequency assessments of loading arm failures	****
Frequency assessments of pressurised tank failures	****
Frequency assessments of cryogenic tank failures	***
Factors relating to consequence assessment:	
Definition of the scenario	*****
Modelling of release rate from long pipeline	***
Modelling of release rate from short pipeline	*
Release time (i.e. operator or shut-down system reaction time)	***
Choice of light, neutral or heavy gas model for dispersion	****
Differences in dispersion calculation codes	***
"Analyst conservatism" or judgement	***

Table from Lauridsen *et al*.(2002)

2). Qualitative categories for expressing uncertainty in relation to qualitative risk estimates

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions
Medium	There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another
High	There are scarce or no data available; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them

Table from EFSA (2006)

3) Systematic approach to evaluating uncertainty

Table 1. Tabular format proposed for evaluating uncertainties in assessments of categorical questions involving two categories. The arrows in the right hand column express the influence of each line evidence on the overall conclusion, taking account of their strengths and weaknesses (uncertainties). Symbols and terms used must be defined in the table legend, or in accompanying text or tables (e.g. Table 2).

Overall question: insert question text here	**Influence on conclusion**
Study/line of evidence 1 – insert text description of the line of evidence including the direction of its influence on the conclusion (e.g. 'Four of five studies in animals showed a clear dose-response')	↑↑
• *Strength: text describing strength 1*	
• *Weakness: text describing weakness 1*	
Study/line of evidence 2 - insert text description including the direction of its influence on the conclusion	↓
Add more rows as needed	
Overall conclusion: **Insert verbal description of likelihood of 'true' answer being yes (or no)**	**Optional expression of likelihood as a probability, range of probabilities, or standard phrase**

Table 2. Table of standard terms established by the Intergovernmental Panel on Climate Change for expressing different degrees of likelihood (IPCC 2005), which could be adapted for expressing uncertainty in the assessment of qualitative questions. Care should be taken to ensure that the spacing of intervals and the terms used to express them are appropriate for the content and context of each assessment, while also avoiding using the same term with different meanings in different assessments.

Virtually certain	*> 99% probability*
Very likely	*90-99% probability*
Likely	*66-90% probability*
About as likely as not	*33 to 66% probability*
Unlikely	*10-33% probability*
Very unlikely	*1-10% probability*
Exceptionally unlikely	*< 1% probability*

After IPCC (2005)

↑↑↑ or ↓↓↓: line of evidence could be sufficient on its own to be confident of yes or no

↑↑ or ↓↓: contributes importantly towards yes or no

↑ or ↓: minor contribution towards yes or no

• : negligible influence on outcome in either direction.

From Hart *et al.* (2010) see also IPCC (2010) regarding Table 2

4) GRADE scale for quality of evidence (slightly modified)

High quality	Further research is very unlikely to change our confidence in the assessed risk
Moderate quality	Further research is likely to have an important impact on our confidence in the assessed risk and may change the estimate
Low quality	Further research is very likely to have an important impact on our confidence in the assessed risk and is likely to change the estimate
Very low quality	Assessed risk is very uncertain

Table from Guyatt *et al.* (2008) and modified for risk analysis according to Spiegelhalter & Riesch (2011)