COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

EFSA consultation on draft guidance document on uncertainty in scientific assessment

Introduction

1. The European Food Safety Authority (EFSA) has issued a public consultation on a Draft Guidance document on Uncertainty in Scientific Assessment.

2. The Committee is invited to respond to the EFSA consultation in order to help EFSA improve its guidance. In addition, the Committee is invited to consider whether it wishes to adopt any of the approaches described in the draft EFSA guidance.

3. The EFSA consultation closes on 10 September, therefore Members were invited to send comments in advance of preparation for the COT meeting on 8 September, in order to allow rapid finalisation of the response. However few Members have so far responded.

Previous COT discussions on uncertainty

4. The Committee has had a number of discussions on uncertainty over the past decade. The first of these was the COT Report on Variability and uncertainty in toxicology of chemicals in food, consumer products and the environment (2007).[1] One conclusion of this report was the research need for:

> *"Development of a framework for transparent expression of uncertainty in hazard characterisation, such as addressing and identifying critical data gaps"*.

5. In response to this recommendation the Food Standards Agency (FSA) commission a research project on "Development of a framework for evaluation and expression of uncertainties in hazard and risk assessment".[2]

6. In discussing the report of this project, Members recommended seeking input from the FSA Social Science Research Committee (SSRC). This led FSA to commission a further study on "Assessment of the COT

[1] http://cot.food.gov.uk/sites/default/files/cot/vutreportmarch2007.pdf
[2] http://www.food.gov.uk/science/research/foodcomponentsresearch/t01programme/t01projlist/t01056

uncertainty framework from a social science perspective: A theoretical evaluation" (Dr. Gene Rowe, 2010).[3] The SSRC discussed the report and issued advice on the results. (Making sense of risk and uncertainty: public engagement, communication and risk assessment policy, Jan 2012)[4]

7. The final COT conclusions on the topic were published in its 2012 Annual Report, noting:

> *"The COT agreed with the SSRC's advice that standardised terminology was unlikely to be helpful in communication of uncertainty, particularly to the general public. Rather, the wording needed to be tailored to the particular circumstances of each risk assessment. However, it was important to describe the major sources of uncertainty in the assessment, and the direction and potential magnitude of their impact. For estimates of quantitative parameters (e.g. dietary intake of a chemical), it was considered helpful to express uncertainty as a range of plausible numerical values. In contrast, qualitative questions (e.g. on whether or not a chemical was teratogenic), could be answered on the balance of available evidence, with an indication of how robust that evidence was (i.e. how likely it was that the conclusion might be overturned by future research). A checklist of sources of uncertainty, which had been proposed in the earlier report by Dr Andrew Hart, had been tried out by the Secretariat. So far it had not proved to be very helpful, but the COT agreed that it could be revisited at a later stage."*

The draft EFSA guidance

8. This draft EFSA guidance provides a "toolbox" of approaches to characterise, document and explain all types of uncertainty arising in EFSA's scientific assessments. The term "scientific assessment" is used because the remit of EFSA is not confined to risk assessment, for example including nutritional benefit and animal welfare. However the approaches described are of relevance to risk assessment and the work of the COT.

9. The draft guidance recommends a flexible, iterative approach, starting with simple approaches and then refining the analysis as far as is needed or possible within the time available. A wide range of approaches are described, building upon previously published approaches to uncertainty assessment. These include both qualitative and quantitative approaches, but the draft guidance stresses that overall uncertainty should be expressed in quantitative terms to the extent that is scientifically achievable, in order to avoid the ambiguity of qualitative expressions. Furthermore, the guidance states that when it is not possible to quantify uncertainty, assessors should avoid expressing their conclusions using words that could be interpreted as implying

[3] http://www.food.gov.uk/science/research/ssres/crosscutss/evaluncertframework

[4] http://ssrc.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/riskuncert.pdf

a probability statement (e.g. 'likely'). They should also avoid words with risk management connotations, such as 'negligible' or 'concern', unless scientific criteria have been agreed for their use.

10. In previous COT discussions on uncertainty, Members have expressed reservations about quantifying uncertainty in the absence of appropriate data. The EFSA guidance proposes a scheme for translating descriptions based on expert judgement into a subjective probability range, based on the approach of the Intergovernmental Panel on Climate Change (IPCC). This is shown in Table 7 on page 57 of the draft EFSA guidance and reproduced in Table 1 below.

Table 1: Scale proposed by the draft EFSA Guidance for harmonised use in EFSA to express the probability of uncertain outcomes.

Probability term	Subjective probability range
Extremely likely	99-100%
Very likely	90-99%
Likely	66-90%
As likely as not	33-66%
Unlikely	10-33%
Very unlikely	1-10%
Extremely unlikely	0-1%

Preliminary views of COT Members

11. Preliminary comments from Members are as follows:

- The EFSA draft document deals with the main issues helpfully and sensibly.
- It addresses the points previously raised by the COT, and there is agreement that a 'one size fits all' approach is not appropriate but that the process should be flexible and tailored to the particular requirements of each individual risk assessment.
- The need for absolute transparency is emphasised in that all uncertainties should be clearly identified and their respective contributions to the overall uncertainty discussed as far as this is possible. There is a useful discussion on qualitative and quantitative expressions of risk and uncertainty with the latter being desirable but not always possible.
- Perhaps it is a reflection of the work undertaken by EFSA, but the document seems to skip over the importance of problem formulation as a key determinant in the role of uncertainty analysis (not uncertainties in the problem formulation). The assessor does not always need to know how uncertain an estimate is, as long as there is confidence that

it is conservative, for example in cases of accidental contamination. Some of this is addressed in the document, but there is no guidance on the importance of knowing what is sufficient as opposed to what is comprehensive (see case study comment). The target quantity and required level of confidence may already have been established by precedent, so no additional such work would be required by the assessor.

- "Uncertainty is personal and temporal". This is true for some uncertainties but not for all. Some measurement uncertainties are not personal.
- Much of risk assessment depends on subjective, though expert, judgement. This utilises a weight of evidence approach. It is understandable that in the interests of transparency one would like to see the uncertainty in each line of evidence evaluated. There is likely to be considerable variability in how effectively different scientists can achieve this. More importantly, there is perhaps a concern that with the need to be explicit about all assumptions and their uncertainties, some experts will become more conservative. The expert judgement involved in synthesising the evidence may be too complex and deep to enable complete and explicit elaboration. There is a need to recognise this and develop improved means of expressing such uncertainty which will not put the quality of the assessment at risk.
- In the case study it might be helpful to provide some indication of how far it is necessary to go before being able to provide advice that is sufficiently uncertain to enable risk management decisions.
- Did the authors assess the time and resources necessary to undertake uncertainty analyses/sensitivity analyses of the different levels of complexity proposed. Will this be an output of the work of the panels in the pilot implementation phase of the guidance.
- Section 5 (Main steps of uncertainty analysis) was considered particularly helpful.
- The melamine case study was interesting and informative.
- The draft guidance is somewhat verbose and repetitive.
- Figure S1/Figure 1: it may be useful to have an additional step where EFSA's interpretation of a mandate is verified with the decision maker(s) before deciding how to proceed. The general layout of the figure could be improved to make it clearer.
- Table 7: the probability values are limited to 0-1% at the lower end. In patient information leaflets for medicines, probability for undesirable effects are listed as very common (≥1/l0), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥ 1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports, not known (cannot be estimated from the available data). The text does clarify that the table is not intended to be restrictive, but there is always a danger of anchoring.
- The following citations are not listed in the reference list:
    - Miles and Frewer (2003)
    - Johnson and Slovi (1995, 1998)

Questions on which the views of the Committee are sought

12. Members are invited to comment on the draft EFSA report and to consider the following questions:

i). Do Members have specific comments on the overall document, or its individual sections?

ii). Taking into account that the closing date for submission of responses is 10 September, do Members agree to the Secretariat compiling and submitting a COT response.

iii). Should the Committee review its approach to expression of uncertainty (perhaps after finalisation of the EFSA guidance)?

Secretariat
August 2015

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EFSA consultation on draft guidance document on uncertainty in scientific assessment

Public consultation on Draft Guidance document on Uncertainty in Scientific Assessment

Available at: http://www.efsa.europa.eu/en/consultations/call/150618

Note: For copyright reasons the document in this Annex is not included in the published version on the COT website.

Secretariat
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