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

PAPER FOR INFORMATION

COT response to the EFSA Consultation on a Draft Guidance Document on Uncertainty in Scientific Assessment

Secretariat
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Response of the Committee on Toxicity to the EFSA Consultation on a Draft Guidance Document on Uncertainty in Scientific Assessment

General comments

The COT considered the draft guidance to be a very good document, dealing with the main issues helpfully and sensibly, and providing a balance of qualitative and quantitative approaches with the latter being desirable but not always possible. The document addresses the points previously raised by the COT in its discussions on uncertainty, 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. However, it is somewhat verbose and repetitive.

Introduction

The explanation for the need for uncertainty analysis does not sufficiently reflect that in chemical risk assessment the uncertainty is not symmetrical. Risk assessors aim to be conservative, therefore greater uncertainty does not necessarily lead to a higher risk of adverse outcome.

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. 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.

Chapter 3

The document seems to skip over the importance of problem formulation (not uncertainties in the problem formulation) as a key determinant in the role of uncertainty analysis

The use of terms such as "low concern" are well established in the scientific community and are appropriate if built into the risk assessment policy, such as in the Margin of Exposure approach for substances that are genotoxic and carcinogenic.

Chapter 4

There is not always a clear distinction between qualitative and quantitative approaches, with a combination of both sometimes being inherent. It was not entirely clear when the different approaches might be considered appropriate. Flexibility is desirable but likely to result in inconsistency in approaches. Some uncertainties are unquantifiable and trying to quantify them would be a waste of resources. Quantification can also give a spurious impression of accuracy.

The IARC classification system (probably/possibly/not classifiable) was cited as an example of a qualitative approach to uncertainty that is accepted globally. Is EFSA saying that this is not appropriate?

Did the working group 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?

Chapter 5. Main steps of uncertainty analysis

This section was considered particularly helpful.

Chapter 6.1

"Uncertainty is personal and temporal". This is true for some uncertainties but not for all. Some measurement uncertainties are not personal.

Chapter 6.5

Much of risk assessment depends on subjective, though expert, judgement. This utilises a weight of evidence approach. Experts have years of accumulated knowledge that cannot be easily explained and documented, even in expert elicitation. 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. The importance of expert judgement is not fully recognised, and there could be a perception that experts are not needed if these approaches are applied.

Chapter 8

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.

Chapter 10.3

Table 7: the probability values are limited to 0-1% at the lower end. This contrasts with, for example, patient information leaflets for medicines, in which 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). COT members recognised that the

numbers in the patient leaflets are based on actual data, rather than on expert judgement, but this comparison highlights the potential for misunderstanding by the public. The possibility that the numbers would be mis-used by non-regulators was also raised. Consultation on understanding of the outputs was recommended.

Chapter 12

Particular difficulty in communicating on the outcomes of complex statistical analyses

Allergy labelling was mentioned as an example in which expression of uncertainty (“may contain”) was counterproductive, leading to over-usage which is not helpful for consumers with food allergy.

Melamine case study

The melamine case study was interesting and informative. 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 certain to enable risk management decisions.

References

The following citations are not listed in the reference list:

- Miles and Frewer (2003)
- Johnson and Slovi (1995, 1998)