European Food Safety Authority

SCIENCE

MAKING RISK ASSESSMENT MORE TRANSPARENT: INFORMATION NOTE TO THE ADVISORY FORUM

1. Transparent, understandable and scientifically justifiable risk assessment approaches are critical to EFSA's success and harmonised transparent approaches and processes are a prerequisite when risks are assessed by the Scientific Committee, Scientific Panels and other Scientific Expert Groups of EFSA.

2. Under the auspices of the EFSA' Scientific Committee an activity has been set up to develop comprehensive guidance to promote that transparency becomes an integrated part of any risk assessment conducted by EFSA. The proposed background and terms of references (currently sent to the Scientific Committee for adoption by written procedure) are attached.

3. The activity was proposed by a Management Board member in 2003 and has been further developed by EFSA staff and the Scientific Committee. A working group consisting of members of the Scientific Committee, a few well recognized external experts and EFSA staff is currently being established and a first draft of the guidance document is expected by June 2005. Prior to its publication the guidance document will be discussed with relevant scientists and stakeholders at one of EFSA's Scientific Colloquia.

4. To assist the working group, Chairs of the Scientific Panels are currently invited to provide examples of how their Panels have successfully dealt with explaining underlying **uncertainties and assumptions** in already released opinions. The Chairs are also asked how they have dealt with selecting pivotal studies and, as appropriate, disregarded studies considered irrelevant, inappropriate or deficient. Following the provision of guidance on qualifiers of uncertainties and relevance of scientific studies, the project will address more fundamental concepts of risk assessment, including step-wise hazard and risk assessment frameworks as opposed to risk assessment following the completion of the full hazard characterisation based on given sets of data requirements (as discussed at the Advisory Forum Event in Berlin, 9th November 2004).

5. The general format of the EFSA' scientific opinions may be revisited including the drafting of summaries of opinions in order to make them better understandable for the non-technical reader.

6. The Scientific Committee also proposed to consider organising training courses in risk assessment once the guidance document(s) is/are finalised.

7. Complementary to the transparency project and in the context of Article 30 of EFSA's founding Regulation 178/2002 an activity is currently started by the Scientific Committee on procedures and mechanisms aiming at analysing and possibly solving divergence of scientific opinions between EFSA and community, national and international scientific advisory bodies. The part to be covered by the transparency working group would be the development of criteria to assess the strengths, weaknesses and flaws of opinions developed by third parties in order to decide whether these third party opinions could be adopted as EFSA's opinions, amended as appropriate.

Providing more Transparency in Risk Assessment: Development of comprehensive guidance

DRAFT MANDATE

Background

Consumer's lack of confidence in the earlier risk analysis process and in particular the lack of separation between risk assessment and risk management was one of the reasons for creating EFSA. EFSA's founding Regulation states that risk assessments should be undertaken in an independent, objective and transparent manner on the basis of the available scientific information and data (EC 178/2002). Since the advice given by EFSA provides a main basis for decisions on public safety, risk manager and consumer should be able to fully understand how risk is being assessed as well as the validity of the outcome.

Suitable and reliable human or animal dose-effect data covering all important life stages are rarely available. Consequently the risk assessment has to rely on data generated in experimental systems including experimental animals, *in vitro* and *in silico* assays and data from epidemiological studies in animals and humans. The generated information has to be integrated with available human or animal exposure data. Inherently such experimental systems involve varying degree of uncertainties, e.g. extrapolation from non-human species to humans, variability in the human population, exposure duration, gaps and deficiencies in the database. Therefore it is important that the description of the risk assessment is sufficiently detailed and explains the strengths and limitations of the data used, describes clearly the underlying assumptions and uncertainties and provides justification for decisions.

Making the inclusion- and exclusion-criteria for studies whose data have been used in a given risk assessment part of the final report (e.g. the use of human or animal data for the identification of the most sensitive endpoint as point of departure) is a prerequisite for understanding the level of uncertainty of the outcome.

A clear formulation of the question (i.e. "terms of reference") is another important step before carrying out any risk assessment. These "terms of reference" should include a clear definition of the concern and a plan for characterising and assessing the risk. Ideally formulation of the "terms of references" should be considered as an iterative process involving dialogue with stakeholders, where appropriate (FOSIE, 2002).

In conclusion, transparent and scientifically justifiable risk assessment approaches are critical to EFSA's success and harmonised transparent approaches are a prerequisite when risks are assessed by the Scientific Committee and Scientific Panels of EFSA. The proposed task is to provide guidance on relevant information to be made available to promote that transparency is an integrated part of any risk assessment.

Making RA more transparent; Information note

Terms of reference

EFSA is requested to prepare guidance to promote integration of transparency in risk assessments carried out by the EFSA Scientific Panels and Scientific Committee. Such guidance should result in:

- A sufficiently detailed description of the strengths, robustness and limitations of the data used for the risk assessment;
- A clear description of the underlying assumptions and uncertainties providing justification for decisions;
- A list of criteria for inclusion or exclusion of available scientific information for a given risk assessment, e.g. criteria for selection of pivotal studies and data, being part of the risk assessment;
- Process-related considerations, e.g. appropriate stakeholder involvement prior and during the risk assessment, handling of minority opinion;
- Consistent and harmonised documentation
- Structured and stepwise approaches in hazard and risk assessment, e.g. science-based decisions for the need of additional studies based on previous studies in a stepwise approach, resulting in an optimal set of toxicity tests (conceptual framework with decision points).

References

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