

TECHNICAL REPORT OF EFSA

Outcome of Public Consultation on the EFSA Draft Opinion on “Transparency in risk assessment – scientific principles”¹

(Related to Question No EFSA-Q-2005- 050Bb)

Issued on 24 April 2009

BACKGROUND

On the 1 December 2008, the EFSA Scientific Committee endorsed a draft opinion of the Scientific Committee on “Transparency in Risk Assessment - scientific aspects”. The draft opinion had been prepared by an EFSA Scientific Committee working group composed of external experts and members of the Scientific Committee.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultations on key issues. The draft opinion was published for public consultation the 16 December 2008 until the 15 February 2009, 17:00 CET. EFSA has committed to publish the comments received as well as a short report on the outcome of the consultation (see annex 1).

COMMENTS RECEIVED

At the deadline EFSA had received 103 submissions (among which 19 repetitive comments are included), from 16 interested parties (non-governmental organisations, industry organisations and national assessment bodies). All comments received were scrutinized and subsequently tabulated with reference to the contributor and the section of the draft opinion to which the comment referred. There were 3 comments received outside the electronic form which thus did not fulfil the EFSA submission criteria (see annex 1). However, those comments were still considered and have been inserted in the table of comments. Duplicate comments received from the same contributor appear only once in the table. Comments submitted formally on behalf of an organization appear with the name of the organization. The table of all comments is published as a separate document on the EFSA website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902513151.htm.

SCREENING AND EVALUATION OF THE COMMENTS RECEIVED

General

The majority of the comments supported the general view of the opinion and of the various sections. Some comments congratulated EFSA for the good quality of the document.

General comments were related to the lack of detailed guidance about the documentation of the meetings or about how stakeholder involvement has taken place prior or during the risk assessment. Moreover, suggestions for rewording parts of the text were made.

It has been proposed to reconsider the format of the document since the summary has the same content as the chapter “Conclusions and Recommendations”.

¹ For citation purpose: Technical Report of EFSA on Outcome of Public Consultation on the EFSA Draft Opinion “Transparency in risk assessment – scientific aspects”. *EFSA Technical Report (2009) 263, 1-4*.

Specific comments

In several comments, a clarification was asked about the process of **inclusion and exclusion of data** in risk assessment. Consideration of literature not published in English was also suggested.

Some comments addressed the issue of **confidential data**. A clarification about the reasons for keeping confidentiality of data was suggested. The handling of other comments requested to clearly describe the **default assumptions** used during the risk assessment and to standardise as far as possible the risk assessment **terminology**.

About **uncertainties** in risk assessment, it was suggested to list them and to explicitly provide the source of uncertainty.

Finally, several comments addressed the issue of **opinions published by other bodies/committees** than EFSA where clarification in the text is required.

Incorporation of comments in the opinion

The comments were all discussed by the EFSA Scientific Committee working group on transparency in risk assessment. The consideration of the comments contributed, where appropriate, to a further enhancement of the opinion.

Acknowledgements

This report has been prepared by the Scientific Committee and Advisory Forum Unit.

ANNEX 1

The text below is from the EFSA website of the public consultation:

Public consultation on the Draft Opinion of the Scientific Committee on “Transparency in risk assessment - scientific aspects”

Deadline: 15 February 2009

EFSA's Scientific Committee has drawn up a draft opinion on ensuring transparency in scientific aspects of the risk assessment process. This is the second part of the Scientific Committee's recommendations on transparency, following its [guidance document on procedural aspects](#) of risk assessment published in May 2006.

This draft opinion focuses on general principles concerning scientific aspects of EFSA risk assessments, including identifying, documenting and explaining key factors underpinning the scientific process, their relative importance and their possible influence on the assessment outcome. These include:

- The rationale for any decision to include or exclude data and the strengths and limitations of the data set used.
- Key assumptions inherent in the risk assessment, for instance in relation to data extrapolation from test animals to human beings.
- Identification of limitations or uncertainties underlying the risk assessment, arising for example from limited exposure data.
- Variability factors for instance between different population groups or species that may affect the risk assessment.
- Different outcomes compared with other scientific assessments, including implications of potentially contradictory data and diverging views with other expert bodies.

This forms part of an overall framework of good risk assessment practices supported by the Scientific Committee's recommendations. These include EFSA's quality assurance process, based on the Scientific Committee's recommendations for an internal and external review, to continually review and strengthen the quality of EFSA's scientific work.

EFSA has also prepared a draft technical report summarising the guidance documents, guidelines and working documents developed or in use by EFSA and its Scientific Panels. This is to be read together with the draft opinion – it is not subject to the consultation. EFSA will review and update this document regularly.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft opinion. Interested parties are invited to submit written comments using the online form by 15 February 2009, 17:00 CET. Please note that comments submitted by e-mail or by post cannot be taken into account. It should be noted that a submission will not be considered if it:

- Is submitted after the deadline set out in the call
- Is presented in any form other than what is provided for in the instructions and template
- Is not related to the contents of the document
- Is related to individual cases
- Contains complaints against institutions, personal accusations, irrelevant or offensive statements or material
- Is related to aspects outside the scope of EFSA's activities

Comments complying with the criteria will be evaluated by EFSA's Scientific Committee and taken into consideration where these will enhance the scientific quality or understanding of the document. EFSA will publish the relevant comments received, as well as a short report on the outcome of the consultation.