

SCIENTIFIC OPINION

Transparency in Risk Assessment – Scientific Aspects

Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles¹

(Question No EFSA-Q-2005-050Ba)

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SCIENTIFIC COMMITTEE

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SUMMARY

The EFSA Founding Regulation (EC No 178/2002) states that risk assessments should be undertaken in a transparent manner. The European Food Safety Authority requested that the Scientific Committee provides guidance on relevant information to be included in EFSA's opinions to ensure the transparency of the risk assessments carried out by EFSA.

In 2006 the Scientific Committee published a guidance document addressing the procedural issues that are considered beneficial to improve such transparency.

The current document focuses on transparency in the scientific outputs produced by EFSA. This document deals with general principles to be applied in the identification of data sources, criteria for inclusion/exclusion of data, confidentiality of data, assumptions and uncertainties.

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² The footnote 1 has been added.

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The Scientific Committee is of the opinion that the principles described in this document for risk assessment apply to all the EFSA's scientific outputs and they are intended to be implemented by the Scientific Committee, Panels and all the EFSA Directorates. In particular, the following conclusions and recommendations were agreed upon:

General

The scientific outputs must be transparent with regard to the data, methods of analysis and assumptions that are used in the risk assessment process;

- Transparency is needed in all parts of the risk assessment
- To be transparent, a risk assessment should be understandable and reproducible;
- Where possible, harmonised assessment terminology should be used, preferably based on internationally accepted terminology;
- The procedure by which a risk assessment is completed needs to be based on accepted standards of best practice;
- When circumstances require that a scientific assessment is provided within a limited time period (e.g. in a crisis situation), the effect of this on the uncertainty of the response should be explained, and options and timescales for reducing that uncertainty should be described.

Scope and objectives

- The scope and objectives of the risk assessment should be considered and documented, and if necessary, clarified with the originator of the request before the commencement of the risk assessment.

Data and data sources

- A risk assessment requires a comprehensive description of the data considered and the experimental and/or environmental conditions under which those data were generated;
- The sources of all data used for the assessment, including unpublished data and personal communications, must be referenced and the data evaluated to determine their quality and relevance to the assessment. These should be reflected in the relative weight given to them in the assessment and taken into account in the overall evaluation of uncertainty;
- If data bases, data banks and information systems are used, their identity should be documented along with the key search terms and strategies applied and time period covered.

Inclusion and exclusion of data

- All the data and information available for the assessment are evaluated but only those judged to be relevant should be used as the basis for risk assessment;

- The inclusion/exclusion criteria applied to the data should be explained and described within the risk assessment. If data are excluded, this should be stated along with the rationale for their exclusion.

Confidential data

- The requirements in the 2005 Decision of the EFSA's Management Board apply to transparency and confidentiality of data. The approach taken is that the maximum amount of information linked to EFSA's activities shall be disclosed or made accessible to the public, and that only the essential minimum should be kept confidential where this is justified; in particular, the information related to the industrial property which are included in the authorisation dossiers.

Assumptions

- All assumptions should be documented and explained. Where alternative assumptions could reasonably be made, the related uncertainties can be evaluated together with other uncertainties (see below).

Assessment

- In qualitative assessments, conclusions are expressed in a narrative. In quantitative assessments conclusions are based, at least partly, on calculations or mathematical models. In both cases, transparency requires that every element of the reasoning, calculation or mathematical modelling should be communicated and justified;
- Whenever mathematical models are used, it should be described whether, by what means and to what extent they have been validated or evaluated.

Variability and uncertainties

- There may be differences in risk due to variability among individuals, populations, species or ecosystems. It is important to identify and describe the most influential contributors to variability in risk, preferably by statistical analysis of the underlying data. Any statistical difference must be interpreted in the light of its biological relevance;
- Although it may be impossible to identify all the uncertainties, each scientific output should describe the types of uncertainties encountered and considered during the different risk assessment steps, and indicate their relative importance and influence on the assessment outcome;
- Expression of uncertainty and variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable;
- Where factors are used to account for uncertainty, an explanation of their basis and their appropriateness or a reference to documents where that information may be found should be included;

- Where point estimates are used for variable or uncertain quantities, justification for the values chosen and assessment of their influence on the assessment should be included.

Conclusions of a scientific opinion

- Conclusions should address the terms of reference, should reflect the scope and objectives of the risk assessment and provide characterisation of the risk under consideration. All key scientific information underpinning the assessment should be outlined including uncertainties and data gaps;
- Conclusions should be based only on data previously described;
- The reasoning leading to the conclusions should be described. Where applicable, the degree of consistency with risk assessments by other bodies should also be stated.

Opinions issued by bodies/committee other than EFSA

- Risk assessments may be performed on a particular compound, agent or topic by different risk assessment bodies at national, European or international level. Such opinions should be considered by EFSA. Their relevance to EFSA's own risk assessment should be evaluated provided that a comprehensive description of all data, processes and methods is available;
- The same data set may, however, not be appropriate in a different context. Therefore, the terms of references need to be checked carefully before considering whether an opinion expressed by another body/committee can be used by EFSA;
- In case of diverging opinions, the procedure foreseen in Article 30 of Regulation (EC) No 178/2002 should be followed closely to identify and possibly to resolve diverging scientific opinion.

Key words: transparency, risk assessment, data sources, exclusion of data, confidential data, assumptions, variability, uncertainty, diverging opinions.

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BACKGROUND

The need to increase consumer confidence in the assessment of risks and safety of food (hereafter referred to as risk assessment) and to ensure a clear separation between risk assessment and risk management in particular were two of the main reasons for establishing the European Food Safety Authority (EFSA). The EFSA Founding Regulation (EC 178/2002) states that risk assessments should be undertaken in an independent, objective and transparent manner on the basis of the available scientific information and data. As the advice provided by EFSA underpins the decision making in the food and feed sector, risk managers and consumers need to understand the procedure through which the risks have been assessed and the validity and limitations of the outcome and the associated implications.

A clear formulation of any scientific request to EFSA as detailed ‘terms of reference’ is an essential step that must be taken before a risk assessment can be carried out.

Comprehensive and reliable exposure-effect data are rarely available. Therefore, risk assessment is often confronted with incomplete data generated in experimental systems including laboratory animals, *in vitro* and *in silico* approaches and/or data from case reports and epidemiological studies in human beings and animals. The information generated in this manner has to be combined with available human or animal exposure data in order to estimate the risk. Inherent in such an assessment is the involvement of varying degrees of uncertainty, for example uncertainties related to extrapolation from test animals to human beings or from test on one species to another one, exposure duration, gaps and deficiencies in the database. Therefore, it is important that the strengths and limitations of the data used and of the conclusions reached are thoroughly explained. In addition, the risk assessment should describe the underlying assumptions and uncertainties explaining the inclusion criteria as well as exclusion-criteria for specific data sets.

TERMS OF REFERENCE

The Scientific Committee was requested by the European Food Safety Authority to provide guidance on relevant information to be included in EFSA’s opinions to ensure the transparency of the risk assessments carried out by EFSA’s Scientific Committee and Panels. Such guidance should result in:

- process-related considerations, e.g. appropriate stakeholder involvement prior to and during the risk assessment, handling, justification or explanation of minority opinion (already addressed in EFSA 2006b);
- consistent and harmonised documentation;
- 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 to provide the reasoning 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;
- structured and stepwise progression through 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).

ACKNOWLEDGEMENTS

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ASSESSMENT

1. Introduction

The EU general food law (EC 178/2002) establishes the rights of consumers to safe food and accurate and reliable information. The European Community has chosen a high level of health protection⁴. It is important to ensure that consumers, other stakeholders and trading partners have confidence in the decision making processes underpinning food law, its scientific basis and the structure and independence of the institutions protecting health and other interests. Regulation (EC) No 178/2002 of the European Parliament and Council established the European Food Safety Authority (EFSA) to be an independent source of scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety including human and animal nutrition, animal health and welfare, plant protection and plant health. Within its mandate, EFSA carries out a wide range of risk assessments, safety assessments, risk-benefit assessments and evaluation of risk assessment documents dealing with human and animal nutrition, animal health and welfare, plant health and the environment. Hereafter in this document, for convenience the term risk assessment is used to cover all these activities. The risk assessments carried out by EFSA should be undertaken in an independent, objective and transparent manner on the basis of the available scientific information, data and understanding. In addition, EFSA also has to ensure that the public and interested parties receive reliable, objective, clear and unambiguous information in the fields within its mission. While EFSA's role is to undertake scientific risk assessments and to communicate their outcome, it is the role of the European Commission and Member States to manage the risk, based on EFSA's assessment and other considerations, e.g. technical, social, ethical and economic considerations.

In general, risk assessment follows the accepted methodology consisting of: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation (FAO/WHO, 1995; FAO/WHO, 1997; Codex Alimentarius Commission, 2003; European Commission, Scientific Steering Committee, 2003). For human and animal nutrition, animal health and welfare, plant health and the environment, the assessment concepts are similar in principle but terminology and specific procedures may differ.

The Scientific Committee was requested by the European Food Safety Authority to provide guidance on relevant information to be included in EFSA's opinions to ensure the transparency of the risk assessments carried out by EFSA.

In 2006 the Scientific Committee published a guidance document addressing the procedural issues that are considered beneficial to improve such transparency (EFSA, 2006b). The current document focuses on the scientific issues related to transparency in the risk

⁴ http://ec.europa.eu/food/intro_en.htm

assessment carried out by EFSA. This document deals with general principles including data sources, criteria for inclusion/exclusion of data, confidentiality of data, assumptions, variability and uncertainties. The Scientific Committee is of the opinion that the principles described in this document for risk assessment apply to all the EFSA's scientific outputs and they are intended to be implemented by the Scientific Committee, Panels and all the EFSA Directorates.

The Scientific Committee notes that in this document only general principles of transparency are addressed. It is anticipated that, where necessary, specific transparency measures implemented in areas covered by individual Panels or Units will be addressed at a later stage.

2. Need for transparency

The EFSA scientific outputs must be transparent with regard to the data, methods and assumptions that are used in the risk assessment process. This is enshrined as a central pillar in EFSA's founding Regulation (EC No 178/2002).

Transparency is needed in all parts of risk assessments, including:

- 1) the objective and scope
- 2) the source, nature and quality of the data, detailed methods, explicit assumptions, variabilities, identified uncertainties and their significance for the outcome
- 3) the output and conclusions

A transparent risk assessment should be clear, understandable and reproducible. It may help the clarity of the text if particularly complex technical descriptions are annexed to the assessment. Where possible, harmonised assessment terminology should be used, preferably based on internationally accepted terminology, e.g. IPCS risk assessment terminology (WHO, 2004)⁵.

Transparency in risk assessment contributes to:

- meeting the legitimate needs of stakeholders to understand the basis for risk assessment;
- allowing an informed debate on scientific issues;
- providing a framework in which consumers can have confidence;

To achieve this, the risk assessment procedure by which an opinion is reached needs to be based on scientifically accepted best practice. It is therefore important that existing European/international guidance documents on how to conduct risk assessment, for example those of the WHO, OIE, IPPC, OECD and Codex Alimentarius are taken into account. EFSA

⁵ EFSA is contributing to ongoing international efforts to further establish harmonised terminology (<http://www.who.int/ipcs/en/>)

has also established guidance documents in various areas. Guidance and guidelines are available for applicants on the data requirements and on the contents of dossiers for assessments carried out by EFSA in the context of regulatory frameworks. A technical report summarising the current guidance documents, guidelines and working documents developed or in use by EFSA is available on the EFSA website⁶. In addition, there are a number of specific methodological guidelines available such as Good Laboratory Practice and toxicity testing methods, e.g. OECD/EU guidelines.

The Codex Working Principles for Risk Analysis state that “Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable” (Codex, 2008). The Scientific Committee endorses this principle.

3. General measures to provide transparency

3.1. Scope and objectives

The scope and objectives of the risk assessment should be carefully considered, and if necessary, clarified with the originator of the request before the commencement of the risk assessment. Any questions that arise in the course of the assessment regarding the objective and scope of the assessment or report require immediately to be addressed so as to ensure the relevance of the final document.

Every risk assessment report or opinion should communicate the following elements:

1. The context of the assessment, including the questions that need to be answered;
2. The scope and the objectives of the risk assessment including the agent or activity assessed, the hazard(s), population(s) and scenario(s) considered including exposure, and the rationale for any limitations in scope;
3. The identification of any established risk assessment guidelines, data quality criteria, default assumptions, decision criteria etc. that exist for the problem in hand, and documentation and justification of any deviations from such standards where they exist;
4. The methods used to identify relevant data and other information, including the scope and criteria of literature searches.
5. Any minority opinion within EFSA should be attributed to their authors with their supporting arguments (EFSA, 2006b).
6. The scientific outputs should contain a glossary of technical terms and abbreviations, or refer to an accessible existing glossary if needed.

⁶ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm

3.2. Data and data sources

A risk assessment requires a comprehensive description of the data considered and the experimental and/or environmental conditions under which the data were generated. The scientific findings and other data may come from different sources including:

- peer-reviewed scientific papers;
- documents such as reports of national monitoring programmes and surveys;
- data submitted by applicants supporting authorisation requests.

Personal communications are cited only in specific instances where the information provided is highly pertinent to the issue in question at the time and fulfils scientific criteria.

The sources of all data used for the assessment, including unpublished data and personal communications, must be referenced.

Limitations in the availability, relevance and quality of data used introduce uncertainties into the assessment and its outcome. Therefore data from all sources should be evaluated to determine their quality and relevance to the assessment. This should be reflected in the relative weight given to them in the assessment and taken into account in the overall evaluation of uncertainty.

Transparency requires also that the identity of the data bases, data banks and information systems used should be documented along with the key search terms and strategies applied and time period covered.

When circumstances require that a scientific assessment is provided within a limited time period (e.g. in a crisis situation), the effect of this on the uncertainty of the response should be explained, and options and timescales for reducing that uncertainty should be described. EFSA has developed guidelines to address this issue (EFSA 2007a; EFSA 2007c).

3.3. Inclusion and exclusion of data

All the data and information available for the assessment are evaluated but only those judged to be relevant should be used as the basis for risk assessment.

Data of low quality should not be disregarded completely, as they may contain information important for the assessment. Instead, their implications should be considered, while taking into account the increased uncertainty caused by their reduced quality.

The criteria for inclusion/exclusion of data should be explained and described within the risk assessment. If data are excluded, this should be stated in the opinion along with the rationale for their exclusion.

Main aspects to be considered in making decisions to include or exclude individual data sets:

- study design and power (e.g. robust statistical design, potential bias);
- data quality (e.g. studies conducting in compliance with internationally agreed guidelines);

- relevance of the study for answering the specific question (e.g. exposure assessment of (sub)populations, geographical regions, materials or test organisms used);
- adequacy of data sets (e.g. coverage of endpoints, sensitivity, specificity, appropriate statistical treatment of data, representativeness of data);
- data sources (e.g. peer reviewed scientific literature, scientific reports, data bases, meeting abstracts).

3.4. Confidential data

EFSA's Management Board has adopted a decision (EFSA MB 10.03.2005) concerning implementing measures of transparency and confidentiality requirements and they are applicable to all activities undertaken by EFSA. The confidentiality of data has been also addressed in the EFSA guidance on procedural aspects related to transparency in risk assessment (EFSA, 2006b).

The balance between transparency and confidentiality is determined by the principle that the maximum amount of information linked to EFSA's activities shall be disclosed or made accessible to the public, and that only the essential minimum should be kept confidential where this is justified. Several regulations give the European Commission the exclusive competence to accept/reject confidentiality claims of third parties. In these cases EFSA is bound by the outcome of such decisions by the European Commission.

When EFSA receives a request for access to documents, it should process that request in accordance with the procedures and the principles laid down in Regulation (EC) No 1049/2001 and in Article 41 of the Regulation (EC) No 178/2002.

3.5. Assumptions

Every risk assessment contains assumptions. Obvious examples of assumptions include default values (e.g. for body weight) or extrapolation factors (e.g. from animals to humans). Assumptions are also often implied when using data: e.g. it is frequently assumed that a sample of data (e.g. concentrations measured in a sample of food items) is representative of a larger population. When calculations or mathematical models are used, the form of those calculations or models implies assumptions about the way that different input parameters jointly relate to the output: for example, when using a particular dose-response model it is assumed that this expresses the relation between dose and response more appropriately than other dose-response models that could have been chosen.

Transparency requires that all assumptions should be documented and explained. Where alternative assumptions could reasonably have been made, this is a form of uncertainty and should be documented and evaluated together with other uncertainties (see below). This type of uncertainty can be evaluated by repeating the assessment with alternative assumptions and then examining their impact on the assessment outcome.

3.6. Assessment

Assessment is the process through which data and assumptions are used to reach conclusions.

In qualitative assessments, conclusions are expressed in a narrative. In quantitative assessments conclusions are based, at least partly, on calculations or mathematical models. In both cases, transparency requires that every element of the reasoning, calculation or mathematical modelling should be communicated and justified. In many cases, the assessment follows an established approach, in which case it may be sufficient to provide a brief description and a reference to other documents where details on the approach are available. In other cases, a detailed description should be given.

In qualitative risk assessments, long paragraphs can be difficult for readers to comprehend; it may be more effective to present successive steps in the argumentation as a series of bullet points. Alternatively, at the end of a long argument, it may be useful to summarise the main elements. At stages in the assessment where several alternative lines of reasoning could be considered, these should be stated and the relative weight given to each should be described and justified. Where there is uncertainty about which line of reasoning should be preferred, the assessors should present the outcome of each alternative and communicate this as part of the evaluation.

In quantitative assessments, the calculations or mathematical models should be explained. In addition, sufficient detailed information should be provided to enable the appropriateness of the calculations or models to be checked. Where alternative calculations or model structures could reasonably be considered, the impact of this on the outcome of the assessment should be explored as part of the evaluation of uncertainty in the assessment. Whenever mathematical models are used, it should be described whether, by what means and to what extent they have been validated or evaluated.

3.7. Variability

Whereas variability in experimental systems is generally small, natural variability in individuals, populations and systems is generally larger. Sources of natural variability include:

- physiological status (e.g. gender, age, pregnancy and nutritional status, physical activity);
- lifestyle (e.g. dietary habits, smoking, alcohol consumption);
- environmental conditions (e.g. occupational exposures, climatic and farming conditions);
- genetic factors (e.g. the wide genetic diversity in many of the enzymes involved in the metabolism of xenobiotics; genetic variability of repair systems; genetic variability in receptor levels and affinities; variability of development rate of insects in response to temperature; variability in virulence of pathogens);

- Diseases (e.g. obesity, diabetes mellitus, and liver- kidney or cardiovascular diseases).

Some of the sources of variability (e.g. genetic factors) will act throughout the lifespan of an individual, whereas others (e.g. nutrition, age, lifestyles, exposure and diseases) will vary during an individual's life. Hence, there may be differences in risk due to variability among individuals, populations, species or ecosystems. It is important to identify and describe the most influential contributors to variability in risk, preferably by statistical analysis of the underlying data. Any statistical difference must be interpreted in the light of its biological relevance.

If point estimates are used for variable quantities, justification for the values chosen and their influence on the assessment should be included.

3.8. Uncertainties

Uncertainties may arise from limitations in the database, e.g. limited exposure data, gaps in the effect database, the limitation of the test systems and endpoints selected, inadequacy of study designs and the uncertainties in extrapolating between species. Measurement uncertainties may also occur. Uncertainties may be reduced by undertaking additional studies. Although it may be impossible to identify all the uncertainties, the assessment should include a description of the types of uncertainties encountered and considered during the different risk assessment steps. Their relative importance and their influence on the assessment outcome should be described.

When uncertainty factors are used, an explanation of their basis and a justification of their appropriateness need to be provided, or a reference to documents where that information may be found should be included. Where point estimates are used for uncertain quantities, justification for the values chosen and assessment of their influence on the assessment should be included.

In 2006, the Scientific Committee has published guidance on a tiered approach for achieving this within the context of dietary exposure assessment (EFSA, 2006a). Initially all relevant uncertainties may be analysed qualitatively using a tabular approach and, in many cases, this may be sufficient (e.g. EFSA, 2006c). If needed, those uncertainties that appear to be critical to the outcome may then be analysed deterministically or probabilistically (EFSA, 2007b). This approach has been used by the PPR Panel (e.g. EFSA, 2006c), by the CONTAM Panel (e.g. EFSA, 2008c) and is equally applicable to toxicological assessments (e.g. EFSA, 2008a) and ecological risk assessments (e.g. EFSA, 2008b).

Probabilistic approaches may be useful to quantify some of the uncertainties. When such approaches are used, the outcome of the risk assessment should be characterized by reporting a distribution of the risk estimates. However, use of quantitative methods does not take away the need for a qualitative evaluation of the remaining uncertainties.

3.9. Conclusion of the assessment

The conclusion should address the terms of reference, should reflect the scope and objectives of the risk assessment and provide characterisation of the risk under consideration. It should be based only on data previously already described in the assessment. All key scientific information, including uncertainties and data gaps, underpinning the assessment should be outlined. The reasoning leading to the conclusions should be described. When applicable, the degree of consistency with risk assessments by other bodies should also be described (see chapter 4).

4. Opinions issued by bodies/committees other than EFSA

4.1. Opinions expressed by international bodies/committees

Risk assessments may be performed on a particular compound, agent or topic by different risk assessment bodies on an international level (e.g. JECFA and JMPR), or on an EU level (e.g. by sister committees of the DG Health and Consumers, EMEA, ECHA and DG Employment). Such opinions should be considered by EFSA and their relevance to EFSA's own risk assessment should be evaluated provided that a comprehensive description of all data, processes and methods is available.

The nature of the question answered by an opinion and the data base used to answer the question are crucial. An individual data set may be appropriate for performing a specific risk assessment to answer a particular question. The same data set may, however, not be appropriate in a different context. In the area of chemical risk assessment, the data on the toxic potential of a chemical compound in mammals (used for the hazard characterisation of that chemical) can be used for different risk assessments, while human exposure assessments may differ widely depending on the context. Examples are the exposure of the general population versus exposure to the same chemical compound from the workplace, or specific exposures scenarios within the EU population versus international exposure scenarios. Therefore, the terms of reference need to be checked before considering the relevance for EFSA of an opinion expressed by another international body.

The following important information needs to be evident in the opinion of the other bodies:

- clear statement on the nature of the question to be answered;
- comprehensive description of the data used;
- comprehensive description of the processes and methods used in the assessment;

Based on the evaluation of this information, a decision can be taken on whether an opinion of an international body can be used by EFSA. The relevance of the assessment in the light of more recent data needs to be considered.

4.2. Opinions expressed by national bodies/committee

In principle, the same criteria as outlined in Section 4.1, also apply to opinions expressed by authorities in Member States which are relevant to EFSA.

4.3. Diverging opinions

Diverging opinions on the same topic expressed by different risk assessment bodies are difficult for risk managers to interpret. In general, such diverging opinions should be avoided. In that respect, EFSA should respect the procedure foreseen in Article 30 of Regulation (EC) No 178/2002 precisely to identify and possibly to resolve diverging scientific opinions.

CONCLUSIONS AND RECOMMENDATIONS

The Scientific Committee considers the following general principles as essential for scientific transparency in every risk assessment and they should therefore be implemented by the Scientific Committee, Panels and all the EFSA Directorates.

General

- The scientific outputs must be transparent with regard to the data, methods of analysis and assumptions that are used in the risk assessment process;
- Transparency is needed in all parts of the risk assessment.
- A transparent risk assessment should be understandable and reproducible;
- Where possible, harmonised assessment terminology should be used, preferably based on internationally accepted terminology;
- The procedure by which a risk assessment is completed needs to be based on accepted standards of best practice;
- When circumstances require that a scientific assessment is provided within a limited time period (e.g. in a crisis situation), the effect of this on the uncertainty of the response should be explained, and options and timescales for reducing that uncertainty should be described.

Scope and objectives

- The scope and objectives of the risk assessment should be considered and documented, and if necessary, clarified with the originator of the request before the commencement of the risk assessment.

Data and data sources

- A risk assessment requires a comprehensive description of the data considered and the experimental and/or environmental conditions under which those data were generated;
- The sources of all data used for the assessment, including unpublished data and personal communications, must be referenced and the data critically evaluated to determine their quality and relevance to the assessment. This should be reflected in the relative weight given to them in the assessment and taken into account in the overall evaluation of uncertainty;
- If data bases, data banks and information systems are used, their identity should be documented along with the key search terms and strategies applied and time period covered.

Inclusion and exclusion of data

- All the data and information available for the assessment are evaluated but only those judged to be relevant should be used as the basis for risk assessment;
- The inclusion/exclusion criteria applied to the data should be explained and described within the risk assessment. If data are excluded, this should be stated along with the rationale for their exclusion.

Confidential data

- The requirements in the 2005 Decision of the EFSA's Management Board apply to transparency and confidentiality of data. The approach taken is that the maximum amount of information linked to EFSA's activities shall be disclosed or made accessible to the public, and that only the essential minimum should be kept confidential where this is justified; in particular, the information related to the industrial property which are included in the authorisation dossiers.

Assumptions

- All assumptions should be documented and explained. Where alternative assumptions could be expected, the related uncertainties should be evaluated together with other uncertainties (see below).

Assessment

- In qualitative assessments, conclusions are expressed in narrative argument. In quantitative assessments conclusions are based, at least partly, on calculations or mathematical models. In both cases, transparency requires that every element of the reasoning, calculation or mathematical modelling should be communicated and justified;
- Whenever mathematical models are used, it should be described whether, by what means and to what extent they have been validated or evaluated.

Variability and uncertainties

- There may be differences in risk due to variability among individuals, populations, species or ecosystems. It is important to identify and describe the most influential contributors to variability in risk, preferably by statistical analysis of the underlying data. Any statistical difference must be interpreted in the light of its biological relevance;
- Although it may be impossible to identify all the uncertainties, each scientific output should describe the types of uncertainties encountered and considered during the different risk assessment steps, and indicate their relative importance and their influence on the assessment outcome;

- Expression of uncertainty and variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable;
- Where factors are used to account for uncertainty, an explanation of their basis and their appropriateness or a reference to documents where that information may be found should be included;
- Where point estimates are used for uncertain quantities, justification for the values chosen and assessment of their influence on the assessment should be included.

Conclusions of a scientific opinion

- Conclusions should address the terms of references, should reflect the scope and objectives of the risk assessment and provide a clear characterisation of the risk under consideration, including the degree of scientific uncertainty. All key scientific information underpinning the assessment should be outlined including uncertainties and data gaps;
- Conclusions should be based only on data previously described;
- The reasoning leading to the conclusions should be described. Where applicable, the degree of consistency with risk assessments by other bodies should also be stated.

Opinions issued by bodies/committee other than EFSA

- Risk assessments may be performed on a particular compound, agent or topic by different risk assessment bodies at national, European or international level. Such opinions should be considered by EFSA. Their relevance to EFSA's own risk assessment should be evaluated provided that a comprehensive description of all data, processes and methods is available and therefore fulfils the same quality criteria as applied to opinions expressed by EFSA;
- The same data set may, however, not be appropriate in a different context. Therefore, the terms of references need to be checked carefully before considering whether an opinion expressed by another body/committee can be used by EFSA;
- In case of diverging opinions, the procedure foreseen in Article 30 of Regulation (EC) No 178/2002 should be followed closely to identify and possibly to resolve diverging scientific opinion.

REFERENCES

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GLOSSARY / ABBREVIATIONS

AHAW:	Scientific Panel on Animal Health and Animal Welfare
ANS:	Panel on Food Additives and Nutrient Sources added to food
Biohaz	Scientific Panel on Biological Hazards
CEF:	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CODEX:	Codex Alimentarius Commission
CONTAM:	Scientific Panel on Contaminants in the food chain
EC:	European Commission
ECHA:	European CHEmicals Agency
EFSA:	European Food Safety Authority
EMEA:	European Medicines Agency
EU:	European Union
FAO:	Food and Agricultural Organization of the United Nations
FEEDAP:	Scientific Panel on Additives and Products or Substances used in Animal Feed
GLP:	Good Laboratory Practice
GMO:	Scientific Panel on Genetically Modified Organisms
IPCS:	International Programme on Chemical Safety
IPPC:	International Plant Protection Convention
JECFA:	Joint FAO/WHO Committee on Food Additives
JMPR:	Joint FAO/WHO Meeting on Pesticide Residues
NDA:	Scientific Panel on Dietetic Products, Nutrition and Allergies
OECD:	Organisation for Economic Co-operation and Development
OIE:	World Organisation for Animal Health
PLH:	Scientific Panel on Plant Health
PPR:	Scientific Panel on Plant Protection Products and their Residues
PRAPeR:	Pesticides Risk Assessment Peer Review Unit
SCCP:	Scientific Committee on Consumer Products
SCF:	Scientific Committee on Food
SCHER:	Scientific Committee on Health and Environmental Risks
WHO:	World Health Organization