



Transparency in Risk Assessment

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To provide guidance to ensure confidence in the process and output of EFSA's scientific work

➤ Process related transparency issues

http://www.efsa.europa.eu/en/science/sc_committee/sc_documents/1494.html

➤ Science related transparency issues

- ✓ **Handling by EFSA of requests for scientific opinions (e.g. analysis/clarification of the question, refusal/modification)**
- ✓ **Selection of qualified independent scientists responsible for the assessment**
- ✓ **Facilitating adequate exchange of information and views (RA/RM interface)**
- ✓ **Involvement of stakeholders prior and during the RA**
- ✓ **Procedure for adoption of opinions**
- ✓ **Dissemination of opinions**
- ✓ **Confidentiality and access to documents**
- ✓ **Procedure for revising/updating scientific opinions**

1. General introduction
2. General principles for transparency in risk assessment
 - Data sources, availability and quality
 - Criteria for inclusion/exclusion of data
 - Assumptions
 - Variabilities
 - Complexity
 - Interpretation issues
3. Specific issues in various areas of assessment
 - Background highlighting specifics in the risk assessment methodology
 - structure according to chapter 2
4. Opinions issued by bodies other than EFSA

- Human chemical risk assessment
- Human biological risk assessment
- Animal chemical and biological risk assessment
- Animal welfare
- Human nutritional assessment
- Plant health risk assessment
- Environmental risk assessment

Example: Nutrition

- Data sources/quality:

e.g. Quality of individual studies

Inclusion/exclusion criteria

e.g. representativeness

- Assumptions:

e.g. Derivation of PRI: Average requirement + 2SD to meet needs of 97.5% of a population group

However if distribution is skewed this PRI may only meet 75% of a specific population group

- Variability:

e.g. Day-to-day variation in intakes of food

- Uncertainties:

e.g. Estimates of dietary intake

- Complexity:

e.g. Diet-related chronic diseases involving interactions of diet, lifestyle, environment, genetic factors

Impossible to identify all uncertainties but nomination of types of uncertainties considered with their weights (where possible also values) and its contribution to the final judgement is essential

- Guidance document will only highlight transparency issues but will not be a general guidance document on best risk assessment practices
- Focus will be on how to make risk assessment more transparent

- 9 chairs or representative of Scientific Panel
- 5 members of Scientific Committee
- 1 representative of DG SANCO Non-Food Committee
- 2 members of Scientific Panels with specific expertise, e.g. environmental risk assessment of GMO
- Commission representative

- November 2006: 1st WG meeting to agree on scope of activity
- January – December 2007: 5 working group meetings (Jan, April, July, Oct, Dec) to prepare draft guidance document
- February 2008: Possible adoption by scientific committee
- Public consultation prior to its publication may be considered

In- and external review of process and output of EFSA's scientific work (INEX)

Scientific Committee has been asked to develop a proposal for a review system to assess the quality of EFSA's scientific work. The approach should include both internal and external review and be based on best scientific practice

Proposed strategy

- Self-review by Scientific Panels and Committee taking into account a template for self review
- Internal Scientific review by EFSA senior staff members (10% of opinions published per year)
- External scientific review by top scientists independent of EFSA
- appreciation by intended users

Thank you!




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EFSA was set up by European authorities as part of a commitment to ensuring a high level of food and feed safety and consumer protection. EFSA is the keystone of the EU system of risk assessment for food and feed safety, and our scientific advice underpins the decisions of policy-makers and risk managers in the European Institutions and Europe's Member States.



Food is essential to life. We are committed to ensuring that Europe's food is safe.

