Technical Meeting on GMOs: EFSA's risk assessment approaches

HERMAN B.W.M. KOËTER,
Acting Executive Director.

Purpose of the meeting:

Share views on scientific and procedural issues related to EFSA's Scientific Panel's opinions on GMO's and, in general, on EFSA's work in this area.

Greenpeace:

"Greenpeace is opposed to the release of any genetically engineered organism to the environment because they pose potentially far-reaching and irreversible threats to the environment, biodiversity and non-target species"

Risk assessment:

Hazard identification

Hazard characterisation

+ Exposure assessment = Risk characterization

Risk characterisation:

"The qualitative and, wherever possible, quantitative determination, including possible uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions"

[OECD, 2003, Doc.ENV/JM/MONO(2003)15]

Risk characterisation (2):

- There is no situation or condition in life that is totally without risk;
- The role of the risk assessor is to characterise the risk under defined conditions;
- The role of the risk manager is to select and implement appropriate regulatory responses to the risks identified, taking into account political, social, economic and technical factors.

Improving risk assessments by establishing EFSA:

- Risk assessment separated from risk management (remains for the Commission);
- High level of openness and transparency;
- Fully independent.

Process of development of Scientific Opinions in EFSA:

- Selection of European Experts as Panel members;
- Declarations of interest;
- Confidentiality of data versus transparency;
- Scientific approach.

Selection of European Experts as SC/Panel members

- Publishing a call for experts;
- First selection by HR/Legal: apply eligibility criteria (e.g., education, language skills, full rights as citizen);
- Second selection by EFSA experts: apply selection criteria (essential criteria and assets), focus on experience, knowledge and skills.

Selection of European Experts as SC/Panel members (2)

- Review of the preselection of candidates by a team of senior European scientists of outstanding reputation;
- Confirmation of the shortlist;
- Submission of shortlist to EFSA Advisory Forum for comments and suggestions.

Selection of European Experts as SC/Panel members (3)

- Submission of shortlist, amended as appropriate, to the EFSA Management Board together with proposed candidates;
- Selection and appointment of the proposed candidates on the list, amended as appropriate, by the MB;
- Invitation to selected candidates to become member of the respective Panels/SC.

Process of development of Scientific Opinions in EFSA:

- Selection of European Experts as Panel members;
- Declarations of interest;
- Confidentiality of data versus transparency;
- Scientific approach.

A declaration of interest is not synonymous to a conflict of interest

Declaration of Interest: what to declare?

- Direct financial interests in company operating in food/feed business;
- Work carried out in the last 5 years for a company operating in the food/feed busines;
- Other links with food/feed business in the last 5 years;
- Intellectual interests.

Declaration of Interest: who should declare?

- All A-Grade staff in EFSA' Science, Communications, Legal and I&I departments;
- All members of the Management Board and Advisory Forum;
- All members of the SC, Expert Panels, Standing Expert Committees and all ad hoc Working Groups.

Declaration of Interest: when to declare?

- Annually for EFSA' staff, the Management Board and Advisory Forum;
- Annually for the SC, Expert Panels and Standing Expert Committees;
- At the start of the activity for all ad hoc Working Groups;
- Or more frequent as appropriate.

Process of development of Scientific Opinions in EFSA:

- Selection of European Experts as Panel members;
- Declarations of interest;
- Confidentiality of data versus transparency;
- Scientific approach.

EFSA‘s committment to transparency and openness:

- MB meetings are public – (webstreaming & open to the public);
- Agendas, minutes and documents of the MB and AF published on the web (more than required by EFSA‘s founding Regulation);
- Agenda‘s and minutes of SC/Expert Panels are published on the web;
- EFSA‘s opinions and status of opinions published on the website – (Register of Projects);
- EFSA‘s Newsletters, fact sheets, annual reports.

Confidentiality of data versus transparency:

- EFSA policy is that all documents produced by EFSA are publicly available;
- Regulations allow claims for confidentiality of documents or part of documents for business protection purposes: obligatory processes must be followed and in almost all regulations the final decision rests with the Commission or the Member State.

EFSA‘s committment to transparency and openness

But most importantly:

EFSA is making an effort to be more transparent in its scientific risk assessments by expressing and describing uncertainties and indicating the added value of each study provided.

Process of development of Scientific Opinions in EFSA:

- Selection of European Experts as Panel members;
- Declarations of interest;
- Confidentiality of data versus transparency;
- Scientific approach.

Scientific risk assessment approach:

- Risk assessment methodologies applied by all Panels and the SC are based on internationally agreed approaches by FAO, OECD, OIE, WHO/IPCS and various national authorities (e.g., Canada, Japan, US);
- Underlying tests are based on internationally agreed testing guidelines (OECD) and are conducted fully in accordance with principles of GLP.

Scientific risk assessment approach (2):

- Self-tasking is an important tool for the SC and Expert Panels to invest in new approaches and remain on the forefront of the scientific state-of-the-art in risk assessment;
- Examples of self-tasks include: (i) improving the concept of the 90-day study and finding other ways to address hazards of repeated exposure and (ii) assessing strength and weaknesses of new models for the assessment of allergenicity.

Other scientific issues of importance:

- Data requirements: different for pharmaceuticals, pesticides, food additives, food ingredients/new foods, cosmetics, etcetera;
- Statistical significance versus biological relevance: a variety of statistical methods is available to reduce the gap between “significantly different responses” and “biological relevance”: important elements include: incidence of findings, dose response relationships, trends.

Other scientific issues of importance (2):

- Expert judgement and evidence: evidence is a less sensitive tool and is not always possible. Expert judgement is based on profound scientific knowledge, familiarity and experience, but need more detailed explanation;
- Assessing human health risks and environmental safety are rather different concepts: human health risk assessment is a well established scientific discipline. Environmental assessment is a much younger science, still very much in development.