LOOKING BACK:10 YEARS OF RISK ASSESSMENT DEVELOPMENT IN EFSA

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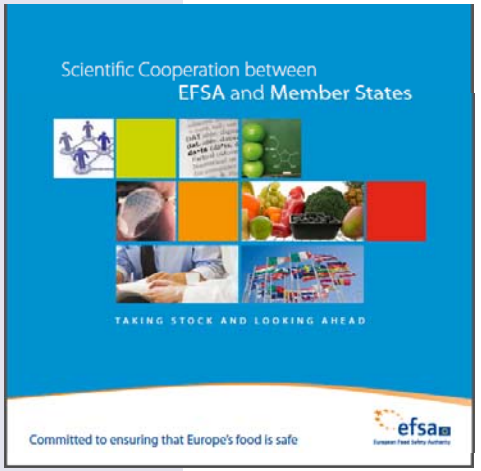
Where is EFSA today?

- Creation of scientific structure: **Scientific Committee and Scientific Panels**
- Development of **internal scientific support** structures
- Development of **guidance on methodologies for risk assessment and risk monitoring, procedures**
- Establishment of **cooperation activities throughout Europe** and with organisations in **third countries** and **international organisations**
- **Dialogue with its stakeholders and consults** on key scientific opinions

Working together, working for Europe

- Yearly analysis of EU-wide situation
  - Zoonoses
  - Antimicrobial resistance
  - Pesticide residues
- Food consumption data for exposure assessments
  - Increasingly sophisticated and harmonised data
- Cooperation in risk communication
  - Advisory Forum Working Group
  - Information exchange (e.g. STEC)
- Increasingly more structured cooperation
  - Medium-term planning with Advisory Forum,
  - Stakeholder Platform rolling work plan…



First 10 years of EFSA's: focus on risk assessment

- More than **3,000 scientific outputs** published in the EFSA Journal.
- As many as **2,200** of these outputs are **scientific opinions** adopted, by the **Scientific Committee** and **ten Scientific Panels**.
- The Scientific Committee and Panels adopted about **100 innovative/harmonized RA methodologies** and applied them to **thousands of cases**.
- This presentation deals with some distinctive features and results that has given a major contribution to **improve RA in the food/feed sector** at a European level and worldwide

Features of risk assessment in EFSA

The EFSA's work in risk assessment (RA) can be characterized by three important approaches:

(i)reviewing, updating and harmonizing existing RA methodologies and ***developing new*** RA methodologies, where needed;

(ii)undergoing a ***public consultation*** on each (draft) methodology developed, and adopting the resulting methodology based on a scientific opinion providing the background for the elements characterizing the guidance provided;

(iii)applying the methodologies developed to reply to the requests of opinions received by the European Commission, the European Parliament, Member States or identified by self-tasking and ***systematically assessing the quality*** of the work carried out.

The EFSA's SC Mission

According to EFSA's founding Regulation, the main tasks of the Scientific Committee consist of :

- The ***general coordination*** necessary to ensure the consistency of the procedure for formulating scientific opinions, in particular with regards to the adoption of working procedure and the harmonization of working methods; and

- The responsibility to provide ***opinions on multisectoral issues*** falling within the competence of more than one Scientific Panel and on issues which do not fall within the competence of any Scientific Panel.

The EFSA's SC Mission

A different, but also valid, way of spelling out the mission of EFSA's Scientific Committee, is as follows:

- ***Improvement*** of risk assessment and its reporting as well as the ***development of new*** risk assessment methodologies to better support decision-makers and protect the consumers; and

- ***Harmonisation*** of risk assessment approaches across EFSA's Panels and Working Groups (identifying commonalities and discrepancies) as well as across the EU and worldwide to avoid unnecessary repetition of animal testing and controversial results.

Highlights 2003-now

- *Chemical risk assessment*
- *Microbiological risk assessment*
- *Exposure assessment*
- *General RA methodologies incl. Ensuring transparency*
- *Multisectorial issues*

Highlights 2003-now

- **Chemical risk assessment**
  - MoE for substances that are both genotoxic and carcinogenic (2005 & 2012)
  - Alternative approaches for animal testing (2009)
  - Benchmark dose approach (2009)
  - Genotoxicity testing strategies (2011)
  - Threshold of toxicological concern (2012)

Highlights 2003-now

- **Microbiological risk assessment**
  - Qualified presumption of safety – opinion on the generic approach (2005)
  - Qualified presumption of safety – introduction of the approach for selected microorganisms (2007)

  QPS Work is now conducted under the responsibility of the Biological Hazards Panel

Highlights 2003-now

- **Exposure assessment**
  - Guidance on harmonised methods for the various Panels and on a suitable strategy for data collection (2005)
  - Uncertainty in dietary exposure assessment – A tiered approach in analysing uncertainties (2006)

  Major steps have now been undertaken and various EA activities are currently conducted by the DCM (formerly DATEX) Unit, in support of the Panels or directly for the Commission

Highlights 2003-now

- **General risk assessment methodologies**
  - Identification of emerging risks (2006 & 2011)
    - **Definition**: “Emerging risks are due to new hazards, increased exposure or increased susceptibility to known hazards”.
    - **Next step**: SC to create a standing working group on emerging risks in 2012.
  - A stepwise approach for human health risk benefit assessment of foods (2010)

Highlights 2003-now

- **General risk assessment methodologies**
  - Guidance on statistical approaches – statistical significance and biological relevance (2011)
  - 90-day toxicity test for whole food/feed (2011)
  - Default assumptions (2012)
  - Terminology in RA (2012)

Highlights 2003-now

- **General risk assessment methodologies**
  - Internal and external (INEX) review of EFSA's scientific outputs (2006)
  - Handling of urgent questions (2006)
  - Transparency in RA – procedural aspects (2006)
  - Transparency in RA – scientific aspects (2009)

Highlights 2003-now

- **Opinions/Reports on multisectorial issues**
  - Safety evaluation of traditional botanical supplements and the Compendium (2004, 2009, 2009, 2010 and 2012)
  - Nanomaterials and nanotechnologies (2009 & 2011)
  - Animal cloning (2008, 2009, 2010 & 2012)
  - Report of TF on Endocrine active substances (2010)
  - Report of TF on antimicrobial Resistance (2011)
  - Report of TF on Environmental Risk Assessment (2011)

Examples of innovative risk assesment methodologies developed by EFSA Panels

- Safety evaluation of : (i) processes for producing recycled plastic for food contact materials; and (ii) substances that can be used to manufacture active or intelligence materials and articles
- Guidance documents on scientific requirements for substantion of health claims
- Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA
- Guidance document for probabilistic dietary exposure assessment to pesticides
- Risk assesment methodologies developed by the FEEDAP
- Risk assessment of food and feed from GM animals and GM animal health and welfare (2012)

EFSA's external evaluation on provision of scientific outputs and technical support

… The provision of outputs originated from external requests is effective as it meets EFSA main stakeholders' needs, in terms of high quality, accessibility and reliability of outputs - and provides added value, through the use of an integrated approach and the developments of tools and procedures to support risk managers.

Also in emergency situations, outputs are appreciated, specifically for their clarity and timeliness, even if produced as an answer to an external request for urgent advice …

Future challenges

i. an effective system to regularly refine, update and consolidate the guidance documents developed so far:

ii. a mechanism to build consensus on their implementation in EU Member States, thus reducing unnecessary methodological differences likely to result in potentially damaging controversies within the EU;

iii. a collaborative approach to exchange qualified information on these risk assessment methodologies with International organizations and Third countries aiming at promoting a more effective harmonization worlwide.

Additional Future Challenges

Additional future challenges will be related to implementation of the EFSA Science Strategy 2012-2016:

iv.implementation of the Integrated Quality Management System;

v.organisation of a multi-annual data collection work program;

vi.systematic identification of main research priorities;

vii.further development of the EU Menu to evaluate food consumption in different countries;

viii.further work on scientific transparency in risk assessment (RA) especially when dealing with uncertainties and with RA terminology; and

ix.development of a harmonised risk assessment approach applicable, although with some specificities, throughout the all food/feed sector.

EFSA Journal - Indexation databases

European Food Safety Authority

- Food Science and Technology Abstracts (FSTA)
- CAB Abstracts
- SciFinder
- Web of Knowledge
- DTU Libraries
- International Portal on Food Safety, Animal & Plant Health (IPFSAPH Portal)
- Google scholar
- Directory of open access journals (DOAJ)