

## ▪ **LEARNING FROM TEN YEARS OF WORK IN THE EFSA SCIENTIFIC COMMITTEE**

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## **Scientific advice is an essential tool for safety managers of the food/feed chain**

- **The need for effective, timely and qualified scientific and technical advice mechanisms to support the work of Community managers in charge for ensuring food/feed safety has been recognized at an European level since long time as it is shown by the initial establishment of the Scientific Committee for Food in 1974 ( Commission Decision n. 234 of 18 April 1974).**
- **Moreover, several other Committees were also established with competences on different segments of the food/feed chain (e.g. animal health, animal nutrition, plant health).**

## The development of scientific advice at the Community level

- Therefore, the establishment of EFSA through Reg. EC 178/2002 represents the most recent step in a long process characterized by several structural and regulatory developments to find an optimal solution to the provision of scientific advice to food/feed safety managers at an European level.
- Probably, the most important step in such a development was the important reform undertaken in 1997 (Commission Decision 97/579/EC) when the BSE crisis was very high on the European agenda.

## Eight Scientific Committees were established in 1997 (Commission Decision 97/579/EC)

- Scientific Committee on Food,
- Scientific Committee on Animal Nutrition,
- Scientific Committee on Animal Health and Animal Welfare,
- Scientific Committee on Veterinary Measures relating to Public Health,
- Scientific Committee on Plants,
- Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers,
- Scientific Committee on Medicinal Products and Medical Devices,
- Scientific Committee on Toxicity, Ecotoxicity and the Environment.

## New procedures and expert selection mechanisms

- In order to ensure an effective coordination of the 8 Scientific Committees they were all transferred to the responsibility of the General Directorate of the European Commission for Consumer Protection and the so called “Scientific Steering Committee”, was established consisting of all the chairmen of the different Scientific Committees and of a small number of external experts.
- The secretariats of the Scientific Committees and of the working groups were, at the time, provided by the EC .
- Members were appointed in each Scientific Committees, for a term of three years, following a complex selection based on a specific call for manifestation of interests, and they were not allowed to remain in office for more than two consecutive terms.

## New procedures and selection mechanisms

- Independence from all external influences had to be granted;
- Yearly and case by case declarations of any interests which might have been considered prejudicial to their independence;
- Each working party had to be chaired by a member of the Committee;
- The agendas, minutes and opinions of the Scientific Committees were made publicly available ;
- Minority opinions were always included in the minutes and attributed to members at their request.
- The members and external experts were obliged not to divulge information acquired as a result of the work

## The last step in the development of the mechanism for scientific advice provision to food/feed safety managers

- The establishment of EFSA as an independent European Agency with its Management Board, Advisory Forum, ten Panels ( AHAW ; ANS; BIOHAZ; CEF; CONTAM; FEEDAP; GMO; NDA; PLH and PPR) and the Scientific Committee and with a clear mandate in risk assessment and communication for the all food/feed chain, clearly represent the distillation of the many lessons learnt from the previous experiences ;
- It is evident by the analysis of Regulation 178/2002 and EFSA's internal regulation and practice that all the approaches previously positively tested have been saved when establishing EFSA .

## Effective innovation was also pursued in establishing EFSA

However, important innovations were also adopted especially to ensure:

- (i) a high degree of independence of EFSA and its accountability to the European Institutions (i.e. Commission, Parliament and Member States);
- (ii) an adequate budget to support a intensive workplan to be carried out by the EFSA's staff and external experts

## Main EFSA's achievements in risk assessment

- Between 2003 and 2012, more than 3000 scientific outputs have been published in the EFSA Journal. As many as 2200 of these outputs are scientific opinions adopted, since EFSA's inception, by its Scientific Committee and ten scientific Panels in their respective areas of competence, whereas the remaining ones are mainly technical reports and documents on related issues.
- To carry out risk assessment throughout the whole food/feed chain, EFSA's Scientific Committee and Panels have adopted as many as about 100 innovative/harmonized methodologies in about 10 years and have applied them to thousands cases.
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## The role of the Scientific Committee

The role of the Scientific Committee (SC) during its first ten years of its life can be summarized in terms of “providing guidance” on :

- HOW TO ENSURE TRANSPARENCY AND QUALITY OF THE EFSA SCIENTIFIC OPINION ; and
- INNOVATIVE AND HARMONIZED METHODOLOGIES FOR RISK ASSESSMENT.

**MOREOVER, THE SCIENTIFIC COMMITTEE HAS CARRIED OUT SPECIFIC RISK ASSESSMENTS ON SOME TRULY MULTISECTORAL ISSUES.**

## Ensuring transparency, quality and coherence of EFSA's scientific opinions

Throughout its mandate, the SC focussed on producing guidance documents on optimal approaches to deal (during risk assessment) with issues crossing the competences of most EFSA Panels (and obviously also of more general interest) such as :

- Exposure assessment (EFSA, 2005) and relative uncertainties (EFSA, 2006):
- Urgent questions to EFSA and how to carry out Internal and External (INEX) review of EFSA's scientific work to give a continuing feedback about the quality of the work (EFSA, 2007).
- Transparency of the process and of science in risk assessment , respectively in 2006 (EFSA, 2006) and 2009 (EFSA, 2009).
- Statistical approaches (EFSA, 2011);
- Default assumptions (EFSA, 2012) ;
- Terminology in risk assessment (EFSA, 2012) .

## EFSA internal units or task forces

The SC has also supported the establishment and work of several EFSA's internal units and task forces to deal with specific cross-cutting issues in risk assessment. This has made possible to empower EFSA's staff and to improve and harmonize specific components of the risk assessment process in EFSA . Most successful examples are: (i) the EFSA Food Consumption Database that plays a key role in making possible the evaluation of exposure to hazards; (ii) the harmonisation of the monitoring and reporting of zoonoses, foodborne outbreaks and antimicrobial resistance throughout EU Member States; and (iii) the approach to identify emerging risks.

Other examples of active task forces are those on :

- (i) Endocrine active substances (EFSA, 2010);
- (ii) Environmental (ecological) risk assessment (EFSA, 2011).

## Innovative and harmonized methodologies for risk assessment by the SC

- Risk assessment of genotoxic and carcinogenic substances (EFSA 2005 and 2012);
- Identification of emerging risks (EFSA 2007 and 2012);
- Qualified presumption of safety of microorganisms (EFSA 2007);
- Benchmark Dose (BMD) approach in risk assessment (EFSA 2009);
- Risk/benefit assessment of food (EFSA 2010 );
- 90-Day toxicity test on whole food and feed (EFSA 2011 );
- Harmonization of genotoxicity testing strategies ( EFSA 2011);
- Safety evaluation of traditional botanical food supplements and the Compendium (EFSA 2004, 2009c, 2009d, 2010b and 2012e);
- Threshold of Toxicological Concern as a risk assessment tool (EFSA 2012c).

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## SPECIFIC RISK ASSESSMENTS ON TRULY MULTI-SECTORAL ISSUES : Animal cloning (EFSA, 2008, EFSA, 2009e, EFSA, 2010a and EFSA, 2012b)

- Death and disease rates of cattle and pigs clones are significantly higher than those observed in conventionally reproduced animals. However, Somatic Cell Nucleus Transfer (the most common technique used to clone animals) has also resulted in the production of healthy cattle and pig clones, and healthy offspring that are similar to their conventional counterparts based on parameters such as physiological characteristics, behaviour and clinical status.
- There is no indication that differences exist in terms of food safety for meat and milk from clones and their progeny compared with those from conventionally bred animals, assuming that meat and milk are derived from healthy animals, which are subject to relevant food safety regulations and controls.

## **SPECIFIC RISK ASSESSMENTS ON TRULY MULTI- SECTORAL ISSUES; Nanomaterials and nanotechnologies (EFSA, 2009a, EFSA, 2011a)**

- The risk assessment paradigm (hazard identification, hazard characterization, exposure assessment and risk characterization) was considered applicable for engineered nanomaterials (ENMs) (EFSA, 2009a). It became evident that the majority of the available information on toxicity of ENMs is from *in vitro* studies or *in vivo* studies using routes of exposure other than food.
- In 2011, a practical approach for assessing potential risks arising from applications of nanoscience and nanotechnologies in the food and feed chain was produced by the SC (EFSA, 2011).

## **The main general future challenges of the SC**

They will be related to implementation of the recently adopted EFSA Science Strategy for 2012-2016 by including the:

- (i) implementation of the Integrated Quality Management System;
- (ii) organisation of a multi-annual data collection work program;
- (iii) systematic identification of main research priorities;
- (iv) further development of the EU Menu to evaluate food consumption in different countries;
- (v) further work on scientific transparency in risk assessment (RA) especially when dealing with uncertainties and with RA terminology; and
- (vi) development of a harmonised risk assessment approach applicable, although with some specificities, throughout the all food/feed sector.



## Specific priority issues identified by EFSA's Scientific Committee in 2012 for future work

### They will include:

- Identification of emerging risks by a standing *ad hoc* Working Group, under the umbrella of the SC, composed of representatives of the SC and Panels.
- Hazard characterisation of botanicals and botanical preparations to work out the third version of the Compendium and developing a safety assessment approach through a QPS methodology.
- Consideration of overall exposure estimates (including non-food sources) for the safety assessment of carcinogenic, genotoxic and other highly-toxic substances in food/feed

## Specific priority issues identified by EFSA's Scientific Committee in 2012 for future work (continued)

- Risk assessment of chemical mixtures in the area of plant protection products and the possible extension of this approach to other sectors.
- Developing a project to ensure a systematic and early identification of data that would require an updating of opinions already adopted by EFSA.
- Harmonising environmental risk assessment methodologies and developing test methodologies in the area of ecotoxicology

## Specific priority issues identified by EFSA's Scientific Committee in 2012 for future work (continued)

- Updating SC's guidance document on the risk assessment of engineered nanomaterials released in 2011 taking into account developments occurring at international (i.e. Organisation for Economic Co-operation and Development (OECD)) and third country (i.e. U.S. Food and Drug Administration (FDA)) level and by specifically considering the issues related to the definition of nanomaterials being worked out at European level.
- Collaboration with the World Health Organization (WHO) and other risk assessment bodies in the development of international consensus on a harmonised approach for the application of the concept of TTC in the area of food and feed safety.

## CONCLUSIONS

- In the last ten years the SC has addressed many challenging areas of an increasingly complex science and has made an important contribution to EFSA's recognized success in ensuring the safety of food and feed across the EU and preventing major food/feed crisis.
- The work of the SC has been often at the forefront of scientific thinking and at times controversial. Therefore, the SC has been fully engaged in public consultations on its work. The results consist of opinions generally supported by a wide consensus.
- A further important achievement of the SC has been its ability to provide an effective platform that has allowed open and systematic internal consultation on most of the different issues addressed by EFSA. Through this, the SC has proven to be able to initiate and achieve highly effective consensus building procedures.

## The EFSA's external evaluation on the 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.....

- Many thanks for your kind attention !