

MISSION AND ACTIVITIES OF THE EFSA SCIENTIFIC COMMITTEE

Challenges for 2009 - 2012

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Role and objectives of the EFSA SC

Role of the Scientific Committee

- The EFSA SC has been, since its inception, fully aware of its special responsibility, as a part of EFSA, of contributing to the successful implementation of the many innovations brought by the current legislation in the interest of public health.
- Therefore, the SC activities, when compared to the Panels, have not been focussed on providing opinions in reply to external requests, but more on providing, through *self-tasking*, EFSA with all the scientific tools needed to fulfil its mission in an optimal and coherent manner.

Priority areas in the work of the SC

Main priority objectives of the SC:

- Increasing transparency and quality of the risk assessment carried out by EFSA (and other bodies)
- Harmonizing risk assessment, mainly at European level
- Developing new methodologies for risk assessment in specific sectors
- Developing a methodology for the identification of emerging risks

Priority areas in the work of the SC

Additional priority objectives:

- Assessing risks on specific subjects of a truly multidisciplinary nature
- Responding to particular needs identified by Member States
- Developing a methodology for the assessment of risks versus benefits
- Advising EFSA on the priority setting and planning of its activities

Highlights 2003-2009

Development and harmonisation of new methodologies for risk assessment in specific sectors

- **RA of Genotoxic and Carcinogenic Substances (2005)**

  The "margin of exposure" approach has been recommended as a methodology that enables a comparative assessment of risks posed by different genotoxic and carcinogenic substances.

- **Exposure Assessments in EFSA (2005)**

  Guidance has been provided on harmonised methods for exposure assessments to be carried out by EFSA's Panels and advice to EFSA on a suitable strategy for data collection (e.g. food consumption, occurrence data).

Highlights 2003-2009

Development and harmonisation of new methodologies for risk assessment in specific sectors

- **Uncertainty in Dietary Exposure Assessment (2006)**

  Dietary exposure assessments should start with a systematic examination of potential sources and types of uncertainty, to maximise the likelihood that important uncertainties are recognised. The use of tables was suggested to help with this task.

  A tiered approach to analysing uncertainties was also recommended. Each uncertainty in an assessment may be analysed at one of three tiers: qualitative, deterministic or probabilistic. Initially, all significant uncertainties may be analysed qualitatively. Those uncertainties that appear critical to the outcome may be analysed deterministically or probabilistically.

Highlights 2003-2009

Development and harmonisation of new methodologies for risk assessment in specific sectors

- **Qualified Presumption of Safety (2007)**

  A tool for setting priorities within the risk assessment of those microorganisms used in food/feed production.

- **Existing alternative approaches for animal testing (2009)**

  Summarizing possibilities for replacement, reduction and refinement (Three Rs) of toxicological animal testing within the different areas of EFSA's activities.

- **Application of the Benchmark Dose approach in RA (2009)**

  Evaluating the use of a new harmonised approach to improve the characterisation and quantification of the risks of specific substances at human exposure levels.

Highlights 2003-2009

Some additional issues addressed by the SC

- Process-related transparency issues in RA (2006)
- Science-related transparency issues in RA (2009)
- INternal and EXternal (INEX) review of EFSA's scientific work (2006)
- Handling of urgent questions (2006)
- Animal Cloning (2008/2009)
- Applications of Nanotechnology in food and feed (2009)
- Human Health Risk Benefit Assessment of foods (2010)

Highlights 2003-2009

Identification/Evaluation of Emerging Risks

- Identifying emerging risks is a fundamental task of EFSA
- EFSA SC opinion on identification of emerging risks (July 2006)
- An EC working group is established to promote collaboration among different European Agencies and Commission's Units (Nov 2006)
- Formal adoption of the *definition of emerging risks* (Aug 2007):

  Emerging risks are due to new hazards or to increased exposure or susceptibility to known hazards

- EFSA's Emerging Risks Unit established in 2008

Ongoing and planned 2009-2012

- ***Applicability of the Threshold of Toxicological Concern (self task)***

  To explore potential human health risks based on the TTC concept as priority setting tool and to provide more rapid advice on health risks.

- ***Nanomaterials and nanotechnologies (EC)***

  To update EFSA's guidance document on risk assessment to take into account potential risk arising from applications of nano-science and nano-technologies to food, feed and pesticides.

- ***90-day toxicity test on complex food and feed items (EC)***

  To produce a guidance document on how to carry out such a test and how to apply it to GMOs and to Novel Foods.

- ***Harmonisation of genotoxicity testing strategies (self task)***

  To provide a commentary and recommendations on strategies that can contribute to greater harmonisation between EFSA's Panels

Ongoing and planned 2009-2012

- ***Default assumptions (self task)***

  To develop a guidance on default assumptions used by Scientific Committee, Panels and Units in the absence of actual measured values

- ***Harmonization of terminology in risk assessment (self task)***

  To improve harmonisation and consistency of risk assessment terminology across Scientific Committee, Panels and Units

- ***Development of guidance on statistical approaches (self task)***

  To help Scientific Committee and Panels in the assessment biologically-relevant effects

- ***Discussion on endocrine active substances & environmental risk assessment (EFSA)***

  To develop a common strategy within EFSA on these relevant issues

Scientific cooperation between EFSA and the Member States

Examples of Fruitful Cooperation in the area of the SC:

- Safety assessment of *botanical and botanical preparations* intended as food ingredients and the associated Compendium
- Building EU's capability to identify and evaluate *emerging risks* in the area of food and feed
- Building *networks* in support of exposure assessments at EU level
- *Harmonisation* of risk assessment approaches across the EU (identifying commonalities and discrepancies)
- Regular *dialogue with Member States* through the AF on opinions developed by the Scientific Committee (e.g. transparency, animal cloning, nanotechnology, botanicals, emerging risks)

THANK YOU VERY MUCH

FOR YOUR KIND ATTENTION