
SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

**MINUTES OF THE 39TH PLENARY MEETING OF THE EFSA SCIENTIFIC
COMMITTEE HELD ON 17 NOVEMBER 2009 IN BRUSSELS**

[adopted on 11 December 2009]

PARTICIPANTS

Scientific Committee (SC):

Susan Barlow, Andrew Chesson, John D. Collins, Corrado L. Galli, Anthony Hardy, Michael Jeger, Klaus-Dieter Jany, Ada Knaap, Harry Kuiper, John-Christian Larsen, David Lovell, Josef Schlatter, Vittorio Silano, Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):

Catherine Geslain-Lanéelle, Hubert Deluyker, Dirk Detken, Alexandre Feigenbaum¹, Anne-Laure Gassin, Riitta Maijala, Carola Sondermann² and Victoria Villamar.

Secretariat of the Scientific Committee:

Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici, Torben Nilsson and Francesca Piombini.

European Commission (EC):

Michael Walsh (DG Health and Consumers/Unit 03 – Science and Stakeholder relations)
Maive Rute³, Valerie Rolland⁴, Daniele Tissot⁵ and Antonio Di Giulio⁶ (DG Research – Directorate E – Biotechnologies, Agriculture, Food)

¹ Present only in the afternoon

² Present only in the morning

³ Present for agenda item 4

⁴ Present for agenda item 4 and 5

⁵ Present for agenda item 4 and 5

⁶ Present for agenda item 4

1. OPENING

The Chair opened the meeting and welcomed the participants. Apologies were received from Albert Flynn.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the invited experts. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

John-Christian Larsen declared an interest for agenda point 16 as his institute has been involved in the development of the database eBASIS. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of interest.

4. STRATEGIC RESEARCH PRIORITIES AND COLLABORATION WITH EFSA

Dr Maive Rute, Director of Directorate E, Biotechnologies, Agriculture and Food, at DG Research, presented current and upcoming activities of Directorate E. A new framework for the knowledge-based bio-economy (KBBE) is under progress and an action plan is to be adopted by October 2010. A staff working paper indicating achievements so far will form a point of departure for the action plan. In 2010 two conferences are planned to provide additional input into the action plan. On the 2nd June 2010, the 20th Anniversary conference on the EC-US Task Force on Biotechnology Research will be held in Barcelona and on 14th September 2010 a KBBE conference will be held in Brussels in cooperation with the Belgian presidency. The Barcelona conference will have a scientific focus whereas the Brussels conference will have more a policy setting approach.

Directorate E has good working contacts with several directorates including DG Health and Consumer (DG SANCO). Increased communication with organisations outside the Commission are foreseen, e.g. with the World Bank. A global initiative, proposed from New Zealand in relation to climate change, will aim to mitigate green house gas emission from agriculture as a step to reduce the ecological footprint of farming. For this initiative, a global research alliance has been proposed, including USA, India and several EU Member States. It is planned that this alliance will be launched at the upcoming Copenhagen climate meeting in December 2009.

Directorate E of DG Research is currently preparing an overview on GMO safety research since the last 10 years and a new Eurobarometer survey will be launched in 2010 to get some updated information on consumers' perception regarding GMOs. A number of ongoing research areas are still considered of priority and will be maintained in the 2010 action plan;

these include the improvement of pesticides' detection, and the monitoring of transmissible and susceptible diseases for animal health reasons.

The research agenda for 2010 is already underway and the preparation for the 2011 agenda starts from five grand challenges identified to be:

1. Primary production mitigation and adapting to climate change
2. Building sustainable, eco-efficient and competitive bio-economy
3. Food security and safety for Europe and beyond
4. Social inclusive and healthy Europe
5. Oceans for the future

The presentation of Dr Rute was well received by the Scientific Committee which acknowledged the overarching research program which has a strong determination to find more practical approaches for the general benefit of the society. The overall strategy and future actions fit well with EFSA's activities. In the health area there is interest to bring various fields, such as the medical, veterinarian and animal health fields closer to support a common understanding of health. The Scientific Committee further raised that early access to data and information from research projects is crucial for risk assessors, also in the field of emerging risks. It would be useful to develop a report mechanism to access early data from research projects partly funded by public money. Currently the best way to get access to information is via the project coordinators which could be resource intensive.

5. UPDATE ON THE 7TH FRAMEWORK PROGRAMME OF DG RESEARCH

Valerie Rolland (DG Research, Unit E3) and Daniele Tissot (DG Research Unit E4) presented an overview of the activities in the area of biotechnologies, agriculture and food. The 7th Framework Programme for 2007-2013 has a total funding on € 53 billion and is to support the knowledge-based bio-economy. The KBBE objectives are to form a preparedness to respond to grand social challenges and support EU policies (such as the common agricultural policy, animal health, environment and others) as well as to provide means to respond quickly to emerging research needs and to support coordination of national research programmes.

The FP7 KBBE Activity 2.2 "Fork to Farm" focus on consumers, nutrition, processing and packaging, improved quality and safety and environmental impacts with a total food chain concept. Activity 1 "Sustainable production and management of biological resources from land forest and aquatic environments" covers technologies such as "omics", converging technologies and biodiversity, improved crops and production systems, animal welfare, breeding and production, aquaculture and infectious diseases in animals including zoonoses. The projects for the 2011 work program will take about 18 to 36 months to be completed so results can be expected in 2014-2015.

The Scientific Committee appreciated the comprehensive presentation of ongoing and planned research projects which can be of interest for EFSA. The Scientific Committee suggested that EFSA could initiate some reflections to identify mechanism to assess research projects of special relevance for EFSA, and explore mechanisms to collect, coordinate and communicate EFSA's input to DG RTD for the 2011 work programme.

6. ADOPTION OF THE MINUTES FROM THE 38TH PLENARY MEETING

The minutes were adopted as tabled.

7. FEEDBACK FROM EFSA ON ISSUES RELEVANT FOR THE SCIENTIFIC COMMITTEE

• EFSA Management Board, 8 October 2009

Andrew Chesson, Chair of the Panel on additives and products of substances used in animal feed (FEEDAP), made a much appreciated presentation on the activities of the Panel. The Management Board renewed EFSA's Stakeholder Consultative Platform, re-appointing 24 organisations as full members for one year and finalising the list of bodies of associated members of the Platform. The Management Board also agreed on the work program for Article 36 grants for 2010.

• Visit of EU Commissioner Vassiliou, 16 October 2009

Androulla Vassiliou, EU Commissioner for Health, paid her 2nd visit to EFSA on 16th October. Scientific aspects on new technologies such as animal cloning and nanotechnology were discussed as well as issues related to communication. The Commissioner is supportive of the work carried out by EFSA. The Commissioner also attended the brick laying ceremony for the new EFSA building which is planned to be ready by summer 2011.

• European Parliament hearing of the Executive Director, 5 October 2009

During the hearing, Catherine Geslain-Lanéelle explained EFSA's competence for environmental risk assessment, how uncertainties are handled and the role of EFSA as a risk assessment body. Members of the Parliament raised questions in relation to GMOs and post market monitoring, nanotechnology, nutritional profiles, food additives and supplements as well as to aspartame. The budget restriction has been lifted by the Budget committee.

• Scientific Committee Away Day, 1 October 2009

During the Away Day the Scientific Committee discussed in depth several aspects of the integrated approach for risk assessment. A report from the meeting is under preparation and a more extensive discussion is foreseen at a future plenary meeting.

• Technical meeting with Member States and European Commission on art 13.1 health claims, 6 October 2009

The aim of the meeting was to update Member States and the European Commission on the evaluation status of Article 13.1 health claims. A report of this meeting is under preparation and will soon be published on the EFSA website.

- **Steering Group on Cooperation, 16 October 2009**

At the 7th meeting of the EFSA Steering Group on Cooperation (SGC), with participation of eight Member States, an update from the ESCO working group on isoflavones was discussed. The SGC also discussed alignment of databases for data collection and food classification. An EFSA Scientific Colloquium on data collection is scheduled for 2010 which will provide useful input for this exercise. The meeting also discussed medium term planning to strengthen cooperation and share workload with the resources given. This discussion will continue at the next meeting of the Steering Group on Cooperation foreseen in spring 2010.

- **Special AF meeting on plant health, 20-21 October 2009**

The 2nd meeting of the Advisory Forum representatives on Plant Health was held in Parma. The focus of the meeting was to strengthening the cooperation with Member States in this area and steps were taken to enhance exchange of data. The EFSA activities and the opinions of the Plant Health Panel were presented.

- **National expert meeting on aspartame, 10-11 November 2009**

A group of national experts nominated by their Member States with relevant scientific knowledge in relation to aspartame is looking at the published literature and other data made available since the safety assessment carried out by the former Scientific Committee on Food in 2002. This work was initiated by EFSA together with its Advisory Forum and is aimed at addressing the continued public concern that remained despite the risk assessments that have been undertaken. Besides the published literature, the national experts are also considering additional information gathered through a call for data issued in 2008. The meeting of 10-11 November was the second meeting of the national experts on aspartame. It was concluded that more work is needed before a report can be finalised. It is intended to submit the final report to a future meeting of the Advisory Forum for consideration and possible follow-up. The Scientific Committee discussed the progress on this activity and advised to clarify the status of the output when it will be published.

8. THE EFSA JOURNAL: FEEDBACK FROM THE EDITORIAL BOARD MEETING AND UPDATE ON THE PROJECT

Carola Sondermann from the Scientific Cooperation Unit gave an update on the EFSA Journal project and provided feedback from the first Editorial Board meeting held on November 16th. The Editorial Board is composed of the six Scientific Committee members who are not chairing a Panel and the EFSA Directors of Risk Assessment and Scientific Cooperation and Assistance. The Editor in Chief is Vittorio Silano. The Editorial Board discussed future developments of the EFSA Journal, issues on how to raise the visibility of the journal and the development of an editorial policy. The new EFSA Journal is scheduled to be launched on 15th December 2009.

9. REQUESTS FOR OPINIONS

- **EC mandate for the development of a protocol for 90-day feeding trials with whole food/feed**

The Scientific Committee endorsed, with minor editorial comments, a mandate to develop a protocol for 90-day feeding trials with whole food/feed. A draft composition of the working group was also presented. The kick off meeting of the WG is foreseen in January 2010

- **EC Mandate on nanotechnologies**

The Scientific Committee endorsed a revised mandate from DG SANCO with a request to develop a guidance document for risk assessment concerning potential risks arising from applications on nanoscience and nanotechnologies to food, feed and pesticides. A draft composition of the working group was also presented. The Scientific Committee noted the short timeframe provided for this work which is related to the estimated entry into force of new novel food Regulation.

- **EC Mandate “Residues of packaging from the use of products from the agri-food industry...”**

The Scientific Committee gave its support to a draft reply letter where DG SANCO is asked to reconsider the relevance of the mandate against other priorities within the EFSA work programme.

Additional mandates discussed at previous plenary meetings will take place at the December plenary meeting.

10. DECISION CONCERNING THE ESTABLISHMENT AND OPERATION OF NETWORKS

A decision concerning the establishment and operation of networks was presented by the Director of Scientific Cooperation and Assistance. The Scientific Committee welcomed the draft decision and provided comments and feedback for consideration. The decision will be proposed for adoption to the Management Board at its meeting in December 2009.

EFSA has already two established networks on BSE/TSE and microbiological risk assessment. The draft mandate for a third network for risk assessment on GMOs was presented and discussed.

Two additional networks will be created to replace the former Special Advisory Forum meetings: one for risk assessment in plant health, the second for risk assessment in animal health and welfare.

11. UPDATE ON RULES OF PROCEDURES FOR THE ESTABLISHMENT AND OPERATIONS OF THE SC AND PANELS AND THEIR WORKING GROUPS

At the last plenary meeting the Scientific Committee provided comments that have been incorporated in a revised draft that was presented by the Director of Risk Assessment. The Scientific Committee welcomed the revised text and made a few editorial suggestions. The rules will be proposed for adoption to the Management Board at its meeting in December 2009.

12. DRAFT MANDATE FOR THE CREATION OF AN ESCO WG ON NON-PLASTICS FOOD CONTACT MATERIALS

Alexandre Feigenbaum, Head of Unit on food contact materials, enzymes, flavourings and processing aids (CEF Unit) presented a draft mandate to create an EFSA Scientific Cooperation (ESCO) working group whose aim would be to collect information available in Member States on the evaluation of non-plastic food contact materials and analyse the information collected. The ESCO working group would prepare a report and organise a workshop with stakeholders. The Scientific Committee welcomed this ESCO project and agreed that CEF panel members would be invited to participate in this ESCO working group.

13. WHO VISIT TO EFSA – 26 OCTOBER 2009

The WHO delegation included Jørgen Schlundt and Angelika Tritscher from the Department of Food Safety, Zoonoses and Foodborne Diseases, Hilde Kruse from the Regional Office for Europe and Chizuru Nishida from Department of Nutrition for Health and Development. The discussion focused on the work programmes of EFSA and WHO in the area of food safety. There were several breakout discussions on microbiological risk assessment, zoonoses, animal health and welfare, nutritional issues, food additives contaminants enzymes, flavourings and identification of emerging risks. The meeting was a good opportunity to discuss overlapping issues and explore possibilities for improving cooperation, harmonisation and work sharing and for capacity building.

14. REPORT BACK FROM SCIENTIFIC PANELS

The Scientific Committee found the overview document on adopted opinions prepared by the Secretariat as very useful.

Panel on animal health and animal welfare (AHAW)

At the last plenary no opinions were adopted. Self task activities related to tuberculosis in wildlife and African Horse Sickness and a statement on besnoitiosis was discussed. The Panel will also provide input to the GMO Panel guidance on GM animals risk assessment.

Panel on food additives and nutrient sources added to food (ANS)

The Panel had no plenary meeting since the last Scientific Committee plenary.

Panel on biological hazards (BIOHAZ)

The Panel has been involved in a joint scientific report addressing antimicrobial resistance in an interagency project together with the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the European Commission's Scientific Committee on Newly Identified Health Risks (SCENIHR). The Panel is also working on a guidance document together with the CEF Panel to evaluate substances for removal of microbial surface contamination. Work is in progress also on an opinion addressing the risk of transmission of TSE via semen and embryos in small ruminants.

Panel on genetically modified organisms (GMO)

On 2nd of October, members of the GMO Panel attended the meeting on GMO organised annually by EFSA with environmental NGOs (Greenpeace, Global 2000 and Friends of the Earth). The guidance documents on GM animals will be discussed at the December plenary and will be published for public consultation early 2010. The Panel has also initiated a self task mandate to develop a more standardised approach to choose suitable comparators for risk assessment.

GMO draft opinion on assessment of allergenicity of GM foods/feeds

The GMO Panel has prepared a draft opinion on the assessment of allergenicity of GM food/feeds. The Scientific Committee gave its support for the document and to the public consultation. The working group that has prepared the document will consider the comments coming from the public consultation and finalise the document for adoption by the GMO Panel.

Panel on contaminants in the food chain (CONTAM)

The Panel has had no meeting since the last Scientific Committee plenary. At the upcoming meeting, draft opinions on lead, marine biotoxins and previous cargoes (when shipping edible oils and fats) will be discussed.

Panel on additives and products of substances used in animal feed (FEEDAP)

A new Regulation, EC/767/2009 on the placing on the market and use of feed establishes a procedure to have specific claims on feed materials. A provision in Article 13 of the Regulation stipulates that if a Member State competent authority has concerns on the substantiation of a claim, the Commission may obtain an opinion from EFSA which may add to the future workload of the Panel. An opinion on the assessment of the use of cobalt compounds as additives in animal nutrition was discussed at the last plenary.

Panel on food contact materials, enzymes, flavourings and processing aids (CEF)

The Panel had no meeting since the last Scientific Committee plenary.

Panel on plant health (PLH)

The Panel had no meeting since the last Scientific Committee plenary.

Panel on plant protection products and their residues (PPR)

At its last plenary, the 9 different guidance documents currently under development in relation to the revision of Regulation (EC) 91/414 were discussed. The delivery of a guidance document on aquatic ecotoxicology will be delayed and be ready around the same time as the terrestrial guidance document. The guidance document for pesticide exposure assessment of workers, operators, bystanders and residents is likely to be adopted by the end of the year. The Panel is also discussing, together with DG Environment, the importance of endocrine disruptors, but a new activity in this area is unlikely to be initiated on a short term.

15. REPORT BACK FROM WORKING GROUPS

- ***WG Risk benefit***

Some members of the working group have attended two workshops related to the DG Research-funded projects QALIBRA (QuAlity of Life – Integrated Benefit and Risk Analysis) and BRAFO (Benefit Risk Assessment of Foods). Both projects are considering possible approaches to compare risks and benefits, by means e.g. of a common currency such as Disability Adjusted Life Years (DALYs). It appeared that the EFSA draft approach for the human health risk benefit assessment of foods is in line with these projects. The working group held its meeting beginning of November; a draft opinion will be presented for endorsement for public consultation at the Scientific Committee plenary meeting on 2-3 February 2010.

- ***Threshold of Toxicological Concern (TTC)***

The working group held a meeting beginning of October where they examined the robustness of the databases underpinning the TTC concept. The working group is progressing and a first initial draft will soon be prepared for discussion within the working group. A fruitful meeting with a representative from the US Food and Drug Administration (US FDA) has taken place with some members of the working group and EFSA staff to discuss the Threshold of Regulation approach used by US FDA.

16. ANY OTHER BUSINESS

- ***Workshop on systematic review***

An EFSA workshop on the application of systematic review methodology to food and feed safety assessment is to be held in February 2010 prepared by the Assessment and Methodology Unit. Several Scientific Committee members expressed their interest to attend this workshop. A guidance document for the application of systematic review is under finalisation and will be published by the end of the year and used as part of the workshop documentation.

- ***Ebasis database of bioactive compounds***

The EuroFIR Basis (eBasis) is an internet deployed database that is being developed to provide access to both compositional and biological activity data for bioactive substances with anticipated health benefits present in plant foods. eBasis will be available for EFSA and its experts until the end of 2010. Information on how to access the database can be obtained from the Emerging Risk Unit.

- ***Feedback received from the Commission on the use of EFSA's Scientific Output***

This discussion point was postponed until the next meeting due to time constraints.

- ***Experts travelling to meetings***

The Scientific Committee raised concerns on the implementation of rules for travelling of the new mission guide. EFSA promised to come back on this issue with some clarifications at the next plenary meeting of the Scientific Committee.

- ***Next Scientific Committee plenary***

The next plenary will be 11th December in Brussels. The plenary meeting on 2-3 February 2010 will be held in Paris.