European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

Parma, 30 January 2008
EFSA/SC/790

MINUTES OF THE 33RD PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 1-2 DECEMBER 2008 IN PARMA

(Adopted by written procedure on 30 January 2009)

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, Andrew Chesson[1], John D. Collins[2], Anthony Hardy, Jörg Hartung[3], Klaus-Dieter Jany, Ada Knaap, Harry Kuiper[4], John Christian Larsen, David Lovell, Pierre Le Neindre, Jan Schans, Josef Schlatter, Vittorio Silano (Chair), Staffan Skerfving.

European Commission (EC):
Michael Walsh

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle, Riitta Maijala, Hubert Deluyker, Anne-Laure Gassin[5], Andrea Altieri[6], Bernhard Berger[7], Ilias Papatryfon[8], Andras Szoradi[9], Davide Arcella[10], Ralf Reintjes[11], Elena Scaravelli[12], Gisèle Gizzi[13].

EFSA Secretariat of the Scientific Committee:
Djien Liem, Bernard Bottex, David Carlander, Daniela Maurici, Jeffrey Moon, Silvia Bellocchio, Sergio Beltra-Martinez

[1] Present on 2 December
[2] Present on 2 December
[3] Replacement of Philippe Vannier
[4] Present on 1 December
[5] Present for item 7
[6] Present for item 7
[7] Present for item 7
[8] Present for item 7
[9] Present for item 7
[10] Present for item 11
[11] Present for item 11
[12] Present for item 11
[13] Present for item 12

1. OPENING, INTRODUCTION OF NEW EXTERNAL EXPERT AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. He especially welcomed David Lovell as a new external expert of the Scientific Committee. Apologies for this meeting were received from Albert Flynn, Chair of the NDA Panel and Philippe Vannier, Chair of the AHAW Panel who was replaced by the Vice Chair Jörg Hartung.

2. ADOPTION OF THE DRAFT AGENDA

Agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

No additional declarations of interest than the ones listed in the annual declarations of interest were declared.

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

Management Board, 2 October 2008

This was the first meeting with the seven newly appointed members of the Management Board. Diána Bánáti was elected as Chair and Marianne Elvander and Bart Sangster as Vice Chairs. The Management Board discussed the draft Strategic Plan for 2009-2013 which was subject to a public consultation that ended 3 November 2009. The next Management Board meeting will be held on the 18th December where the Strategic Plan for 2009-2013 and the Management Plan for 2009 (including the budget) will be presented for adoption. The Management Board will also discuss the interim review of the Strategy for Cooperation and Networking with Member States as well as the programme and updated rules for Grants for 2009.

AF meeting on Plant Health, 8-9 October 2008

This was the 1st meeting of the Advisory Forum representatives on Plant Health. The Plant Health Panel outlined current issues and future challenges in plant pest risk assessment and presented the EFSA's activities in this area. The meeting addressed the issue of cooperation between EFSA, EPPO (European and Mediterranean Plant Protection Organization), national authorities and the European Commission, including DG Research in a constructive and open way. The intention is to have this meeting on a yearly basis.

Steering Group on Cooperation meeting, 23-24 October 2008

The meeting discussed and reviewed the progress of various scientific cooperation projects between the Member States and EFSA as well as the Strategy on Cooperation and Networking and the Work Plan for 2009. Several ESCO mandates will be reported to the Executive Director by the end of 2008,

and two mandates will continue in 2009. The participants discussed the lessons learned from these first ESCO working groups and highlighted the need for a clear mandate setting timelines. It was also suggested, when creating a new ESCO working group, to limit its size and apply the same procedure for selecting experts as applied for working groups of the Panels and Scientific Committee.

4th Chairs' meeting, 4-5 November 2008

EFSA hosted the fourth meeting of the Chairs and Secretariats of the Scientific Committees and Panels of the European Commission and EU Agencies involved in risk assessment. The participants discussed challenges in risk assessment, best risk assessment practices, data collection and emerging risks, as well as upcoming developments in risk assessment. A meeting report is in preparation and will be circulated to all members once it is finalised (early 2009).

1st International Risk Assessment Conference, 13-14 November 2008

This conference organised by DG Health and Consumers was attended by some Scientific Committee members and EFSA staff. The four main topics discussed at the conference were terminology, expressing and communicating uncertainties, emerging risk challenges and exposure assessment. The conference was valuable to promote international harmonisation on topics of common interest. The 2nd International Risk Assessment Conference is scheduled for 2010.

Advisory Forum meeting, 20-21 November 2008

At the 29th EFSA's Advisory Forum meeting in Copenhagen, items discussed included nanotechnology, transparency in risk assessment, interim review of the Strategy on Cooperation and Networking, the interim and final reports of the ESCO projects, the National Focal Points annual report and an update and exchange of views on matters raised by the Member States and EFSA. Presentations were given by the French and UK members on how quality of national risk assessments are handled in their countries. In addition, a recent AFSSA opinion on the presence of anisakidae in fishery products was presented.

Memorandum of Understanding with JRC

The Scientific Committee was informed about the collaboration agreement with the European Commission's Joint Research Centre which was signed in November 2008 to strengthen the EFSA and JRC cooperation in the field of food and feed safety, animal health and welfare, plant health, nutrition and emerging risks.

5. TRANSPARENCY IN RISK ASSESSMENT – SCIENTIFIC ASPECTS

The draft opinion prepared by the EFSA transparency working group on "Transparency in risk assessments carried out by EFSA – general principles" was discussed. The Scientific Committee Members acknowledged the working group for a well prepared draft opinion. The members provided comments and suggestions for clarifications and the draft opinion was endorsed for a public consultation, expected to be launched after editorial considerations before the end of the year. A separate document with a table of the various guidance and guideline documents used by EFSA's

Scientific Committee and Panels will be published in connection with the draft opinion. This document will be updated on a regular basis.

6. BENCHMARK DOSE

The draft opinion on the use of Benchmark Dose (BMD) in risk assessment as prepared by the Scientific Committee working group on BMD was presented. The Scientific Committee discussed the draft and provided comments. The Scientific Committee recognised the advantages of the BMD approach in comparison to the currently used NOAEL (No Observed Adverse Effect Level) in setting health-based guidance values, but also noted the limited experience and use of the BMD in the risk assessment. The Scientific Committee also noted the limited availability of suitable and validated software for the derivation of the BMD. It was agreed that the draft will be circulated to the EFSA Panels to receive their input on the applicability of the BMD in their respective areas. It is intended to finalise the opinion before the end of the current Scientific Committee mandate.

7. EFSA SCIENTIFIC COOPERATION (ESCO) REPORTS

Botanicals

An interim report on the ESCO working group on Botanicals was presented to the Scientific Committee. The draft guidance document[14] published on the EFSA website earlier this year proposes a two-level approach for the safety assessment of botanicals. An ESCO working group was created to test the proposed approach with a selected number of examples and to enlarge the information contained in the compendium of botanicals reported to contain toxic, addictive, psychotropic or other substances of concern. The ESCO working group is making good progress and is expected to deliver a final report to the EFSA Executive Director by May 2009. The Scientific Committee was also informed about a DG Research call on the risk-benefit assessment of plant-based food supplements (KBBE-2009-2-4-02 SICA).

Emerging Risks

A progress report was presented to the Scientific Committee of the ESCO working group on Emerging Risks. This ESCO working group has identified 11 indicators of possible emerging risks in the areas of chemical, microbial and nutritional hazards as well as identified key resources of information and best practices for data collection and exchange. The final report of this ESCO working group is expected to be sent to the EFSA Executive Director by the end of 2008. The Scientific Committee took note of the progress report.

Folic Acid

A draft interim report of the ESCO working group "Analysis of Risks and Benefits of Fortification of Food with Folic Acid" was presented to the Scientific Committee. The report presented a compilation of the situation regarding folic acid in different European countries, including information on various

[14] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178717026833.htm

topics in relation to folic acid, e.g. statistics on neural tube defects, data on food supplementation (voluntary or mandatory). The ESCO working group is preparing a scientific workshop which will take place in Uppsala, Sweden, on 21-22 January in 2009. The Scientific Committee took note of the progress report and provided its support for the workshop.

Harmonisation of Risk Assessment Approaches in Member States

The final report of the ESCO Working Group on Fostering Harmonised Risk Assessment Approaches in Member States was presented to the Scientific Committee. In line with the original intention of the SGC (Steering Group on Cooperation) the working group agreed to use existing guidance documents from EFSA as "reference documents" and ask Member States to describe possible discrepancies in their risk assessment approaches. A comprehensive questionnaire was therefore developed by the working group and responses have been compiled for all 27 EU Member States, Norway and Switzerland. One particular recommendation of the working group was to address further harmonisation of risk assessment approaches between Member States within the specific scientific areas. The Scientific Committee endorsed the report which will, as a next step, be sent to the EFSA Executive Director.

8. INTERIM REVIEW OF STRATEGY FOR COOPERATION AND NETWORKING

A draft of the interim review of the EFSA strategy for cooperation and networking was presented to the Scientific Committee. An internal working group carried out the review process and had sent a questionnaire to all Member States asking for feedback from the Scientific Committee and EFSA units. The review describes the main cooperation projects and activities undertaken to strengthen cooperation and networking and presents recommendations for improving existing co-operation activities. The Scientific Committee took note of the draft report and provided comments. The interim review will be submitted to the Management Board for discussion at its meeting on 18th December.

9. REPORT BACK FROM SCIENTIFIC PANELS

The Scientific Committee was updated on the outcome of the plenary meetings of the Scientific Panels since its last plenary meeting (for more details, please see the web pages of the respective Panels on EFSA's website). In particular, the following issues were brought to the attention of the Scientific Committee:

Panel on animal health and welfare (AHAW)

At its plenary meeting in October the Panel adopted fish welfare opinions on Sea Bass and Gilthead Sea Bream. The Panel is shortly to adopt a new opinion on the general approach to fish welfare. The Panel is of the view that intense fish farming is likely to gain in importance and has set up new working groups to deal with stunning and killing of eight species of farmed fish. The Panel is working on a mandate on welfare of dairy cows where four separate reports and risk assessments will be carried out on leg and locomotion problems, udder problems, reproductive and metabolic disorders

and behavioural problems. These assessments are scheduled to be adopted before the end of the term of the current Panel. An opinion was adopted on the risk of bluetongue transmission during transit into and out of restricted zones. A draft report on classical swine fever was discussed and the opinion will be presented for adoption at the next plenary. The Panel is also working on a self task on the development of risk assessment guidelines for animal welfare, which will partly be carried out through grants under Article 36. The issues to be considered have been divided in three main welfare categories: stunning and killing, transport and housing and management. The Panel is also preparing a new self task mandate on modelling.

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

The Panel held its 3rd plenary meeting in November. The Panel discussed and adopted several opinions on nutrient sources including calcium fluoride, aspartate sources, sodium monofluorophosphate, methionates and chromium polynicotinate. On silver hydrosol a statement was made as sufficient data to conclude an assessment was not available. In relation to food additives, the Panel discussed the second study from the Ramazzini Institute on aspartame where an opinion is being developed. An application on high viscosity white mineral oil was also discussed. New data from animal studies on taurine and glucurolactone, which are constituent in energy drinks have been provided and assessed. The studies did not raise any concerns.

Panel on biological hazards (BIOHAZ)

The Panel held its 43rd plenary in October when an opinion on the TSE (Transmissible Spongiform Encephalitis) infectivity in milk and milk products from small ruminants was adopted as well as a joint opinion with the AHAW Panel on food safety aspects of the welfare of fish. The Panel is working on 16 different mandates including 6 on *Salmonella*, three on TSE's and one on *Campylobacter*. A Scientific Colloquium on Campylobacter will be organised by EFSA in December 2008 in Rome. The Panel is also working on an opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants to be co-adopted with the GMO Panel.

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

The Panel held its 3rd plenary meeting in November where two guidelines where discussed. The finalisation of the guideline for active and intelligent packaging will have to await publication of the legislation to take into account possible last changes. The guideline for evaluation of enzymes is almost finalised but discussions are still ongoing on how to address allergenicity aspects. The guideline is expected to be adopted early in 2009. At the plenary, 19 opinions on flavourings were adopted. The Panel adopted also three opinions on food contact materials including an opinion approving a specific use of titanium nitride nanoparticles in PET to make plastic bottles. The opinion was based on the absence of migration of the substance into food.

Panel on contaminants in the food chain (CONTAM)

No plenary meeting has been held since the last Scientific Committee plenary. At the next plenary a draft opinion on marine biotoxins in shellfish (the yessotoxin group) and a draft opinion on gossypol as undesirable substances in animal feed will be presented for possible adoption.

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

On the 23rd October EFSA organised in Parma a meeting on feed additive applications under Regulation (EC) No 429/2008 where about 150 stakeholders participated. At the meeting EFSA presented issues that are relevant for all types of feed additives applications/dossiers and in parallel sessions specific issues related to three categories of feed additives (zootechnical, nutritional, technological) were discussed. Eleven opinions were adopted at the Panel plenary in November.

Panel on Plant health (PLH)

At its October plenary the Panel adopted an opinion on citrus black spot and its guidance document for evaluation of pest risk assessments prepared by third parties to justify phytosanitary measures under Council Directive 2000/29/EC. The Panel also discussed its self task activities and the formation of a working group to develop a guidance document on a harmonised framework for the assessment of risks of organisms harmful to plants and plant products. The Panel has recently received a request from the European Commission to address oak processionary moth.

Panel on plant protection products and their residues (PPR)

The Panel is currently working on the development of nine various Guidance Documents (GD): five of them have to be revised and four Guidance Documents will have to be newly developed. There is progress in setting up a joint working group, comprising representatives from the European Commission, nominated Member States and PPR Panel members to finalise the revised GD on risk assessment for birds and mammals on the basis of the comprehensive opinion on this GD, published in July 2008. Information will be provided at the next plenary on the revision on the Guidance Documents for aquatic and terrestrial ecotoxicology. It is expected that the revision of the aquatic GD will be completed within two years, and the terrestrial GD in three years.

10. REPORT BACK FROM WORKING GROUPS

SC Working Group on Risk-Benefit Assessment

The working group is progressing according to plan, and a public consultation on the draft guidance document for human health risk benefit assessment of foods is scheduled for summer 2009.

SC Working Group on Welfare of Experimental Animals

The Chair of the Working Group gave a presentation on the current status of the work of this Scientific Committee self tasking activity. A first part of the work was endorsed by the Scientific Committee in 2007. The second part which is under preparation is focusing on existing alternative approaches applicable in the food and feed sector. A draft report will be presented for discussion at the Scientific Committee plenary in February. The mandate of this working group is expected to be finalised under the term of the current Scientific Committee.

SC Working Group on Threshold of Toxicological Concern (TTC)

The Chair of the new Scientific Committee working group on TTC informed that the working group has been established and will be composed of 13 experts. The first meeting will be held in January

2009. Recently the non-food Scientific Committees of DG SANCO published a joint draft opinion on the use of the threshold of toxicological concern approach for the safety assessment of chemical substances for public consultation. This joint draft opinion provides a good review for the EFSA working group and an overlap of the opinions is not foreseen as the EFSA working group mandate is specific for the food and feed area. The Chair of the EFSA working group will submit comments on the joint draft opinion during the public consultation which ends on 2 January 2009.

SC Working Group on Nanotechnology

The public consultation of the draft opinion which was launched on 17th October closed on the 1st December and about 200 various comments were received. The Working Group will address relevant scientific comments at its next meeting with the aim to present a final opinion for adoption at the Scientific Committee plenary in February.

11. REPORT BACK FROM SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

Questionnaire on default assumptions in risk assessment used in the EFSA Panels

A questionnaire is under preparation to compile the various default assumptions used in risk assessments made by the EFSA Panels. There are seven general categories of assumption values used. The Scientific Committee provided feedback on the draft questionnaire which will be circulated within EFSA Panels and units. The results of the questionnaire will be presented and discussed at a future SC plenary and the work will be completed before the renewal of the Panels' mandates.

EFSA Food Safety Exigency Handling Manual

A presentation of the EFSA Food Safety Exigency[15] Handling Manual was given by the head of the Emerging Risk unit. The manual provides instructions how to handle a Food Safety Exigency within EFSA in cooperation with the Member States and the European Commission. EFSA is currently setting up a working group to plan simulation exercises to be carried out both internally and together with the Member States and the European Commission to test the response and preparedness to a hypothetical European wide food safety incident and to get input on the applicability of the manual. The Scientific Committee provided comments to the manual which is expected to be finalised by the end of February 2009.

12. EFSA'S USE OF SELF-TASKING

An overview of EFSA's use of self-tasking was presented. EFSA's use of self-tasking originates from Article 29 of EU Regulation (EC) 178/2002 which allows EFSA to issue scientific opinions on its own initiative on matters falling within its mission. From 2003 until October 2008 EFSA has carried out 95 self-tasks. The self-tasks correspond to 8 % of EFSA's outputs 30 % of which are still in progress. The average duration of a self-task is 9 months. In 2008 EFSA initiated 26 new self-task activities. Most of the self-task activities (80 %) are related to development of risk assessment methodologies, others

[15] "Exigency = a pressing or urgent situation"

concern development of guidance documents or data collection. The Scientific Committee expressed its support for self-tasking and considers self-tasking an important activity of EFSA.

13. TRENDS AND DEVELOPMENTS IN RISK ASSESSMENT

A short compilation of various issues raised at earlier Scientific Committee plenaries were presented and discussed. The Scientific Committee suggested that the secretariat in collaboration with selected Scientific Committee members should produce short background documents for additional consideration and priority discussion at the next Scientific Committee plenary in February.
The Chair of the BIOHAZ Panel presented a strategy paper developed by the Panel which identifies prospective challenges in the area of the BIOHAZ Panel. The document was a useful input in the development of the EFSA Strategic Plan 2009-2013. The Scientific Committee complimented the good quality of the document.

14. ANY OTHER BUSINESS

Renewal of the Scientific Committee/Panels

The Director of Risk Assessment Directorate presented information on the procedure and status of the renewal process of the Scientific Committee and Panels. The call for experts has been open since October 23 and will close on January 7, 2009. EFSA will evaluate the candidates and draw up a short list which will be communicated to the Advisory Forum before the Management Board makes the final decision about the candidates. The inauguration of the new Panels is planned in June-July 2009. The new Scientific Committee will have its first plenary meeting on 21-22 July 2009.

DG Health and Consumers Non-Food Scientific Committees – Public consultation of draft opinion: "Risk assessment methodologies and approaches for mutagenic and carcinogenic substances"

The DG Health and Consumers Non-Food Scientific Committees have published a draft opinion on "Risk assessment methodologies and approaches for mutagenic and carcinogenic substance" for public consultation. The SC Secretariat will submit comments on the draft opinion.