European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

Parma, 24 July 2007

EFSA/SC/519

MINUTES OF THE 25TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 9-10 JULY 2007 IN PARMA

(adopted by written procedure on 7 August 2007)

PARTICIPANTS

Scientific Committee (SC):
Dan Collins, Albert Flynn, Tony Hardy, Ada Knaap, Harry Kuiper, Pierre Le Neindre, Jan Schans, Vittorio Silano, Staffan Skerfving, Josef Schlatter, Joerg Hartung, Erik Dybing

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle (Executive Director), Herman Koëter (Deputy Executive Director, Director of Science), Dirk Detken[1] (Acting Head, Human Resources), Anne Theobald[2] (Scientific Officer, AFC panel), Torben Hallas-Moller[3] (Head of the AFC panel)

Secretariat of the Scientific Committee:
Djien Liem (Scientific Coordinator, Head of Unit), Silvia Bellocchio (Secretary), Bernard Bottex (Scientific Officer), David Carlander (Scientific Officer), Juliane Kleiner (Team Leader, Scientific Committee), Daniela Maurici (Scientific Officer),

European Commission (EC):
Michael Walsh (DG SANCO/Unit 03 – Science and Stakeholder relations)
Marina Marini (DG SANCO/Unit C7 – Risk Assessment)

[1] Present on the 9th July for agenda item 7
[2] Present on the 10th July for agenda item 10
[3] Present on the 9th July for agenda item 9

1. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. Apologies were received from Sue Barlow, Andrew Chesson, Claudia Fruijtier-Pölloth and Philipe Vannier. The AHAW Panel was represented by Joerg Hartung, Vice-Chair of the Panel.

2. ADOPTION OF THE AGENDA

The agenda was adopted after addition of an item on the possible extension of the Scientific Committee with Standing Scientific Advisors

3. DECLARATIONS OF INTEREST

There were no expressions of declarations of interest.

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

- **EFSA STEERING GROUP ON COOPERATION (SGC) MEETING , 15TH MAY 2007**

The Steering Group on Cooperation had its second meeting on the 15th May in Brussels, where several proposals for projects for scientific cooperation between Member States and EFSA were discussed and agreed on. These proposals including background and the terms of reference were forwarded to EFSA's Advisory Forum for agreement at its recent meeting in June 2007 and to the Scientific Committee for possible agreement at this meeting (see agenda item 5). The outcome of these EFSA scientific cooperation projects (ESCO projects) would be a scientific report or technical advice to the Executive Director and if appropriate could be provided by the Executive Director to the appropriate Scientific Panel(s) or Committee as preparatory work for their activities.

- **MANAGEMENT BOARD MEETING, 19TH JUNE 2007, PARMA**

The Executive Director summarized the presentation given at the Management Board meeting on "Further improvements to the efficiency of EFSA scientific activities". EFSA identified three main areas, i.e. workload, work condition and recognition for further action and a review for each Panel is foreseen. For the planning and delivering of support to the Panels, multi-annual programmes will be prepared to better predict the workload. An annual review of the programmes and workload with the Commission is foreseen.

A proposal is in preparation to divide the AFC panel into two panels. This proposal will be submitted for possible adoption to the Management Board in September 2007.

For the Scientific Committee, it is envisaged to appoint two Standing Scientific Advisors to assist with the increased workload.

A new Commission rule for daily allowances of experts will soon be approved and then implemented for the EFSA experts. It was reiterated that flexibility is given by EFSA to organize meetings in locations that best suit the experts.

In the context of achieving better recognition for the experts' work, the development of a scientific journal was proposed. The journal would be under the leadership of the Scientific Cooperation and Assistance department and could start in early 2008.

Participants were informed that the heads of Scientific Panel/Committee support units are currently identifying priorities so as to provide support to their experts and implementation of actions. The resulting document summarising the priorities and actions to be implemented will be shared with the Scientific Committee.

- **ADVISORY FORUM, 28-29 JUNE 2007, BRATISLAVA**

The Advisory Forum meeting in Bratislava (28th-29th June) was organized in conjunction with a joint event with the Slovakian authorities. The minutes can be found at :
http://www.efsa.europa.eu/en/advisory_forum/adv_meetings/af_22nd_meeting.html

The mandates for scientific cooperation projects related to emerging risks, and fostering harmonised risk assessment approaches in Member States were approved (see also below, agenda point 5). Members of the Advisory Forum asked for a presentation during their next meeting in September 2007 of the current activity of the Scientific Committee regarding the safety assessment of botanicals and botanical preparations before the terms of reference are approved. The next step is for EFSA to organize the new EFSA Scientific Cooperation (ESCO) working groups to address these projects.

A meeting with Member States GMO risk assessment experts in Member States will be organised in the fall of 2007 to compare EFSA's risk assessment approach for GMOs with those applied at national levels.

EFSA has sent a letter to the Environment Council related to the EFSA risk assessment of GMOs as well as the EFSA statement on MON 863.

- **EFSA'S 5TH ANNIVERSARY**

The Executive Director expressed his gratitude to Vittorio Silano for the organization of the successful Scientific Conference "EFSA and Food Safety in the EU: achievements and challenges" which was organised on behalf of the Italian Ministry of Health on 7 June 2007. The scientific meeting was an excellent opportunity to celebrate EFSA's 5th Anniversary.

5. MANDATES FOR EFSA SCIENTIFIC COOPERATION (ESCO) WORKING GROUP – FOR DISCUSSION AND POSSIBLE APPROVAL

- **Fostering harmonized risk assessment approaches in Member States**

The draft mandate was discussed and approved subject to minor modifications. Members were informed that Austria had volunteered to take the lead for this project in cooperation with France and Germany. A report summarising the existing guidelines, guidance and quality management documents in EFSA and in the Member States which have been developed for risk assessments in the fields of EFSA's remit and providing advice on specific methodologies which require further harmonisation at EU level will be prepared by December 2008

- **Emerging Risks**

The draft mandate was discussed and approved taking into account minor amendments suggested by the Advisory Forum. The present working group of the Scientific Committee on emerging risk will be asked to join the new ESCO working group together with additional experts suggested by the Advisory Forum and EFSA's Scientific Panels. From the Advisory Forum, France, Portugal, Ireland, UK Austria and Belgium have already expressed their willingness to be part of the working group. The chair of the present Scientific Committee's working group, will continue to chair the ESCO working group. The present working group will submit a report summarising the achievements made so far and which will suggest the way forward to the new ESCO working group. The first ESCO working group meeting is foreseen for September 2007. Members of the Scientific Committee advised that collaboration with the European Centre for Disease Control (ECDC) should be strengthened. In autumn, the new Unit on Emerging Risks of the Scientific Cooperation and Assistance Department is expected to be in place which will provide the support to the work of the ESCO working group.

- **Mandate for an ESCO working group on Botanicals and Botanical Preparations**

Members of the Scientific Committee were informed that the guidance document on the safety assessment of botanicals and botanical preparations used in food as supplements (see point 13) is close to finalisation and should be proposed for adoption by the end of the year. The experts of the current working group of the Scientific Committee identified as a follow-up the need to test the proposed guidance with a certain number of case studies, as well as to work further on at the completion and prioritisation of the compendia of botanicals. It was proposed to assign this task to an ESCO Working Group, thereby involving further the European Member States in this activity. The draft mandate for this ESCO Working Group was discussed and approved by the Scientific Committee.

6. DRAFT DEFINITION ON EMERGING RISKS

A draft EFSA working definition of an emerging risk, which was prepared by the Scientific Committee's emerging risks working group, was presented and discussed. The definition was adopted, subject to minor amendments and will be published on the EFSA web site.

7. DECLARATIONS OF INTEREST

EFSA presented the new procedure for the Declaration of Interest (DoI). A new annual DoI form has been developed, which is now required to be filled in by all Scientific Panels/Committee members and members of working groups. The (revised) forms and procedure will be also presented to the Management Board at its September meeting.

8. REPORT BACK FROM ACTIVITIES OF EFSA'S SCIENTIFIC COOPERATION AND ASSISTANCE DEPARTMENT

The Department of Scientific Cooperation and Assistance (SCA) will from now on be invited to report to the Scientific Committee on the progress made.

- *Assessment Methodology unit*

The Assessment Methodology unit contributes to the application and harmonisation of qualitative and quantitative scientific methods and to the development of new approaches. The unit has given statistical support to the GMO unit when preparing its statement regarding the safety of the genetically modified maize MON 863. It will also be involved in risk assessment harmonization.

- *Data Collection and Exposure Unit*

The Data Collection and Exposure Unit deals with the collection, collation and analysis of food consumption and chemical occurrence data in food and feed for exposure assessment in support of EFSA's Scientific Panels and Committee, and contributes to the scientific development and application of new exposure assessment methodologies. The project on the concise food consumption database, which has been initiated under the auspices of the Scientific Committee, has been handed over to this unit. A data warehouse for food occurrence data is currently being developed.

- *Zoonoses Unit*

The Community summary report on "Trends and sources of zoonoses, zoonotic agents, anitimicrobial resistance and foodborne outbreaks in the European Union in 2005" has been published. The data for the year 2006 have now been collected and the analysis has started.

9. REPORT BACK FROM THE SCIENTIFIC PANELS

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

AFC Panel

The 23rd plenary meeting of the Panel was devoted to flavourings; the Panel adopted a statement on the use and misuse of a scientific article on the genotoxic potential of estragole alone and in the matrix of tarragon. The Panel strongly advised against using the results of such experiments as those described in the article to extrapolate to other naturally occurring toxic substances which may act through a completely different mechanism.

In its 24th meeting the Panel adopted among others, an opinion on the colour Red 2G (E 128): this was the first opinion in a series of re-evaluation of all permitted food colours. The Panel withdrew the existing ADI of this substance.

AHAW

A guidance document for animal welfare risk assessment is in preparation. The document has been sent to Panel members for comments.

Three working groups dealing with the welfare of pigs have been established: fattening pigs, sows and boars, and tail biting. The respective reports have been discussed and will be adopted by written procedures. The working groups on the welfare of trout species, sea bass and other fish are in progress and opinions may be ready for possible adoption in October.

The work on the welfare of dairy cows is in progress. A report is expected for beginning of 2009.

A new working group to prepare an opinion on animal welfare aspect of killing and skinning seals has been set up.

BIOHAZ

Two opinions which related to protocols for evaluation of new rapid tests to detect BSE/TSE have been adopted at the last plenary meeting. With reference to the latest EFSA zoonoses report it was emphasised that agreement on definitions is very important. The Panel has recently received a new mandate on the microbiological safety of reptile meat.

CONTAM

The Panel adopted an opinion on hormones residues in bovine meat and meat products. The Panel is still busy with the evaluation of the 11 coccidiostats for non-target animals but cannot use dossier-related data submitted to the FEEDAP Panel. The Scientific Committee pointed out that it would be useful to continue discussion on how data can be shared.

GMO

A scientific colloquium on the impact of genetically modified plants on the environment was held in Tabiano (Parma), from the 21-22 June 2007. The draft conclusions of the colloquium were supportive of the case-by-case approach, as required by the Regulation and outlined in the EFSA guidance document. There was also a broad consensus among the participants on the current approach to environmental risk assessment. A summary report will be prepared and published on the web site.

The Chair of the Panel reported the good assistance provided from the Scientific Cooperation and Assistance Department for the opinion on the maize MON863. The Executive Director thanked the Panel for their strong commitment on this issue. It was highlighted again that the Panel is faced with answering many questions coming from stakeholders in addition to the already heavy workload with respect to the evaluation of applications and provision of guidance documents.

NDA

Some 300 comments were received via the public consultation on the draft guidance to applicants on the submission of health claims for authorisation. In addition a technical meeting with experts of the EFSA Stakeholder Consultative Platform was held in June 2007. The guidance document has now been finalised, taking into account the comments received, and adopted.

PLH

The Panel is currently working on 30 opinions in response to a request from the Commission on pest risk analyses made by France on "Organisms which are considered by France as harmful in French overseas departments". However the information provided in these assessments is not always sufficient for an appropriate review of the concerned plant health risks

The Panel is also working on its own procedures for the evaluation of plant health risk analyses. Two opinions have been published.

PPR

The Panel adopted an opinion on the risk assessment of pesticides in air. At the request of the European Commission, this discusses the "FOCUS air report" published in summer 2006.

The Panel is revising the existing "Guidance document on risk assessment of pesticides for birds and mammals". A workshop was held in Valencia (Spain) in May 2007 where Member States and Industry were invited to discuss how to the development of the Guidance Document. The opportunity for exchange was highly appreciated. The document will most probably be finalized by the end of the year and is part of around 25 available guidance documents that the panel is requested to revise. The panel is exploring solutions to meet this workload , since it may not always be appropriate to use the article 36 procedures to outsource the task, or to work on more than 2-3 guidance documents at the same time, since it involves always the same group of experts. The proposed timeframe of 12 months to complete the revision of a guidance document, including a public consultation, is considered generally unrealistic.

10. MANDATE ON RISK ARISING FROM NANOSCIENCE AND NANOTECHNOLOGIES ON FOOD AND FEED SAFETY

A question has been received from the European Commission (DG SANCO) for an initial opinion on the risks arising from nanoscience and nanotechnologies on food and feed safety and the environment. EFSA has already being monitoring the development in nanotechnology, with a focus on information collection on possible applications in the food area and information exchange with Member States. The risk assessment of nanoparticles and nanomaterial was also discussed at EFSA's Advisory Forum meeting in April 2007 and Member States appreciated the initiative taken to work together and initiate a plan to establish a harmonised EU approach for the risk assessment of nanoparticles and nanomaterials in the food and feed area. Members were informed that EFSA recently set up an internal working group, composed of scientists from various scientific units to review the available information on risk assessment in areas within EFSA's remit. A compilation of the relevant data will be made available in September 2007.

The mandate received by the Commission was considered very broad and a dialogue was recommended so as to tailor the question. EFSA needs to be given a better overview of projects initiated by DG SANCO in this respect.

The European Commission representative informed the meeting that an initial review of regulatory texts indicated that particle size is systematically taken into account in the relevant areas. A more detailed review is ongoing to verify to what extent the aspect of the size of the particle is covered.

Finally it was mentioned that the recent opinion by the EC's non-food Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterial published in March 2007 provides already an excellent review on the appropriateness of methods for risk assessment and there is now no need for EFSA to repeat this.

It was concluded that EFSA should have a close dialogue with the European Commission on what the needs are: a proposal for revision of the mandate will be made thereafter.

11. PRIORITIES FOR THE SCIENTIFIC COMMITTEE. WORK PROGRAMME 2008.

Members were reminded that the EFSA 2008 Management Plan is planned to be adopted by the Management Board in December 2007. They were invited to provide suggestions and priorities for the EFSA workplan by end August 2007. The workplan for 2008 will be discussed at the September 2007 plenary meeting of the Scientific Committee

12. PROPOSAL FOR A REVIEW SYSTEM FOR EFSA'S SCIENTIFIC ACTIVITIES

EFSA asked its Scientific Committee to develop a proposal for a review system to assess the quality of EFSA's scientific work. The proposal developed by the Scientific Committee is comprised of four components, i.e. a self review, an internal scientific review, an external scientific review and an appreciation of EFSA's scientific work by the intended user.

It was confirmed that such a review system is meant to be understood as an evaluation of the conformity of EFSA's scientific work with best risk assessment practices and should not result in a new evaluation of the data. The document was discussed and some amendments were proposed. At the end of July, a revised version will be sent to the Scientific Committee for adoption by written procedure.

13. BOTANICALS

The guidance document on the "Safety assessment of botanicals and botanical preparations used in food as supplements" was presented. The document does not cover novel food and GMO since they fall under specific regulations. The guidance document proposes a tiered approach to assess safety of Botanical Preparations. Two Compendia were also presented: Compendium 1 lists Botanicals and botanical preparations that have been considered for a food and/or food supplement use and that have been reported to contain toxic or addictive or psychotropic substances; Compendium 2 lists Botanicals and Botanicals Preparations that have been considered for food and/or food supplement use and have been reported to have also a medicinal use. The documents will be updated according to the comments made by the members; it is intended to submit the guidance and compendia for possible adoption at the September plenary meeting of the Scientific Committee.

14. DRAFT DOCUMENT ON WAYS TO ENHANCE EFSA'S RESPONSIVENESS TO URGENT QUESTION - FOR POSSIBLE ADOPTION

The document "Approaches to enhance EFSA's responsiveness to urgent questions (request No EFSA-Q-2007-127) was discussed and adopted, subject to minor modifications. EFSA will elaborate some guidance on the format of an EFSA statement, which will be discussed with the Scientific Committee.

15. RISK BENEFIT ASSESSMENT – OUTLINE OF THE DOCUMENT AND COMPOSITION OF THE WORKING GROUP

A draft outline of the document to be developed by the working group of the Scientific Committee was presented. There will be a chapter dealing with the definitions of health benefits.

16. ANIMAL CLONING

The composition of the working group, timeframe and outline of the document were presented.

17. REPORT BACK FROM THE WORKING GROUPS

- *Welfare of Experimental Animals*

The document "Animal testing in food and feed safety" has been sent to all the Panel coordinators for comments and additional inputs. The comments received will be discussed at the next working group meeting in July. The document will most probably be presented at the next Scientific Committee plenary meeting.

- *Qualified Presumption of Safety*

The technical reports looking at the QPS approach for different groups of micro-organisms have been updated according to the comments received during the public consultation. The working group will meet in early of July to prepare the opinion on whether the QPS approach is suitable for the EFSA Panels needs and, if so, on how the approach should be implemented. A meeting will be organised with the European Commission to discuss the QPS approach and possible implications for risk managers before it is proposed to the Scientific Committee for adoption.

- *Transparency*

It is planned to finalise a draft guidance document for public consultation by February 2008.

- *Benchmark Dose (BMD)*

The work is in progress and it is planned to present the first part of the document describing the BMD approach at the next SC plenary meeting in September.

18. DATES FOR PLENARY MEETINGS 2008

The dates for the 2008 Plenary Meetings have been proposed:

28th SC Plenary:	Thursday 14 February 9:00 h – Friday 15 February 2008 14:00 h (Parma)
29th SC Plenary:	Monday 21 April 13:00 h – Tuesday 22 April 2008 16:00 h (Parma)
30th SC Plenary:	Tuesday 15 July 9:00 h– Wednesday 16 July 2008 14:00 h (Parma)
31st SC Plenary:	Thursday 25 September 9:00 h – Friday 26 September 2008 14:00 h (Parma)
32nd SC Plenary:	Monday 1 December 13:00 h – Tuesday 2 December 2008 16:00 h (Parma)

If needed, an additional Plenary Meeting could be held on the 19th December 2007.

19. EU-EUROFIR AND NORDIC COUNCIL OF MINISTERS DATABASES ON BIOACTIVE COMPOUNDS

The EuroFIR database (supported by DG research) deals with bioactive constituents with anticipated health beneficial effects and the NORTOX database deals with bioactive constituents with potential toxic effects. The two databases are based on the outcome of earlier DG research projects. A workshop was organized on the 2nd and 3rd of May in Parma to discuss the usefulness of these databases for EFSA's work and to consider if and how EFSA could maintain these databases after the current funding has come to an end. Due to time constraint this agenda item was postponed to the next plenary meeting.