European Food Safety Authority

Parma, 6 October 2006
EFSA/SC/295

MINUTES OF THE 20TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 14-15 SEPTEMBER 2006 IN PARMA

(adopted by written procedure on 23 October 2006)

PARTICIPANTS

Scientific Committee (SC):
Sue Barlow, Andrew Chesson, Dan Collins, Erik Dybing, Albert Flynn, Claudia Fruijtier-Pölloth, Tony Hardy, Ada Knaap, Harry Kuiper[1], Pierre Le Neindre, Jan Schans, Josef Schlatter, Vittorio Silano, Staffan Skerfving, Philippe Vannier.

European Food Safety Authority (EFSA):
For item 1 and 6: Catherine Geslain-Lanéelle (Executive Director) and Herman Koëter (Deputy Executive Director, Director of Science)
For item 1 and 3: Dirk Detken (Deputy Director, Legal Affairs)
For item 7: Anne Theobald (Scientific Officer Food Contact Materials, AFC Team)
For item 9: Thierry Beniflah (Director of Information Technology - IT), Marzia Bocchia (IT Project Manager – Science), Marco Spizzi (Infrastructure Team Leader, IT Department)

Secretariat of the Scientific Committee [2]: Djien Liem (Scientific Coordinator, Head of Team), Silvia Bellocchio (Secretary), Bernard Bottex (Scientific Officer), Mark Egsmose (Senior Scientific Officer), Juliane Kleiner (Scientific Coordinator, Deputy Head of Team), Marina Paluzzi (Secretary), Chris Totté (Administrative Assistant).

European Commission (EC):
Michael Walsh (DG SANCO/Unit 03 – Science and Stakeholder relations)

[1] Present on 14 September 2006
[2] EFSA Science - Team on Horizontal Scientific Issues

1. GENERAL INTRODUCTION BY EFSA

Djien Liem welcomed the participants to the inaugural meeting under the second mandate of the Scientific Committee, which will last three years and presented a general introduction on the mission of EFSA. Djien Liem chaired the meeting until the election of the Chair of the Scientific Committee.

1.1 Introduction by the Executive Director and Deputy Executive Director

Catherine Geslain-Lanéelle welcomed the participants, congratulating the Chairs of the Panels on their recent election, and thanking all participants for accepting the invitation to work for the EFSA Scientific Committee in the coming three years. She stressed the importance of the Scientific Committee, not only for the provision of scientific advice on multi-sectorial issues, but also for providing a platform for scientific exchange between the Chairs of the Panels, and for being a link between the Science and other EFSA Departments.

Catherine Geslain-Lanéelle furthermore highlighted two priorities she has been working on since her appointment as Executive Director, i.e. 1/ to develop scientific cooperation and networking with Member States in close collaboration with the Advisory Forum, which will result in an increased awareness and credibility of EFSA among Member States, and 2/ to improve EFSA's reactivity in the event of a crisis by developing adequate procedures for producing prompt statements. The role of the Scientific Committee and the importance of developing networks were reiterated in this context.

Herman Koëter welcomed the "new" members of the Scientific Committee, and expressed his pleasure that most of the former members had reapplied. He pointed out that the Scientific Committee had developed considerably during the last 3 years, gaining more visibility and recognition for the harmonisation of risk assessment procedures, its work on multi-sectorial issues, and for the direct advice it had given to the EFSA. Herman Koëter also expressed his appreciation to Michael Walsh for representing the Directorate General for Health and Consumer Protection of the European Commission during meetings of the Scientific Committee and its working groups, and therefore facilitating the link between risk assessment and risk management.

Catherine Geslain-Lanéelle announced that in autumn 2007 several events will be organized to celebrate EFSA's 5 years existence, on which occasion different parts and bodies of EFSA will hold meetings both in Brussels and in Parma. She invited the Scientific Committee to provide suggestions on how to organise these events and which scientific questions could be addressed on these occasions.

1.2 EFSA's Scientific Work Programme

Djien Liem presented the mission and tasks of EFSA, with a special focus on the terms of reference for the Scientific Panels and Scientific Committee, its working themes and the role of EFSA's Science department.

1.3 Declaration of interests, independence and confidentiality

Dirk Detken introduced EFSA's rules related to the declaration of interests, independence and confidentiality. The members of the Scientific Committee were asked to submit their declarations in accordance with the rules of EFSA. The signed declarations of interests will be published on the EFSA website.

1.4 Expert compensation guide

Djien Liem introduced the rules governing the compensation which the experts are entitled to, and the administrative aspects associated to it. Participants proposed several suggestions in order to improve the flexibility of the system. The Scientific Committee agreed to prepare a letter compiling proposals and arguments for reviewing the expert compensation guide and associated allowances, which would be co-signed by the ten Chairs and addressed to EFSA Management Board.

2. ADOPTION OF THE AGENDA

The question whether economical aspects should be considered in the risk assessments done by some EFSA Panels was added to the agenda The draft agenda was adopted, taking into account the above-mentioned request.

3. ELECTION OF CHAIR AND VICE-CHAIRS

The Scientific Committee members[3] and Commission representative were invited to introduce themselves.

Djien Liem explained the procedure for the election of the Chair and two Vice-Chairs. The Committee members were given the opportunity to propose candidates for the positions of Chair and Vice-Chairs of the Scientific Committee and to provide information in support of their proposal. Participants unanimously decided to elect the Chairman and Vice-Chairs using an open procedure.

Prof. Vittorio Silano was elected as Chair. Dr. Ada Knaap and Dr. Pierre Le Neindre were elected as Vice-Chairs of the Scientific Committee.

Vittorio Silano chaired the rest of the meeting.

[3] http://www.efsa.europa.eu/en/science/sc_commitee/sc_member.html

4. MEETING DATES 2006 AND 2007

The 21st SC Plenary meeting will be held on 6 and 7 November 2006; the 22nd SC Plenary meeting will be held on 14 and 15 December 2006. Meeting dates for 2007 will be set via email exchange.

5. FOR DISCUSSION: MANDATE FOR THE SCIENTIFIC COMMITTEE IN 2006 AND BEYOND

Djien Liem introduced an updated version of the mandate for the Scientific Committee for the end of 2006 and beyond. Particular attention was directed to the role of the Committee regarding:

- The provision of advice on scientific collaboration and networking with scientific experts and research organisations at national and international level
- The provision of advice on request of EFSA on appropriate steps to build up EFSA's capability to systematically collect and analyse information on emerging risks and other matters relevant for EFSA's work
- To prepare scientific or technical advice on request of EFSA on matters relevant to the management and organisation of the Authority

Participants underlined the fact that the Scientific Committee does not have the expertise to be involved in the building-up of opinions that are in the remit of several panels, but can help by developing procedures to improve the handling of such cases, e.g. by providing guidance on 1/ how to allocate a question to the most relevant panel, 2/ how to address the question (e.g. by creating a working group composed of experts from different panels), and 3/ how to co-adopt the opinion (i.e. adoption of the whole document vs. specific sections).

The staff of EFSA's Team on Horizontal Scientific Issues, comprising the Secretariat of the Scientific Committee, were invited to introduce themselves.

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

Management Board meeting of 20 June 2006

The EFSA Management Board adopted during its 20 June 2006 meeting six recommendations for action arising from the independent EFSA evaluation report:

- Develop active networking and stronger cooperation with Member States
- Strengthen EFSA's relationships with its institutional partners and stakeholders
- Enhance EFSA's organisation
- Enhance the impact and effectiveness of EFSA communications
- Develop EFSA's role in nutrition
- Define EFSA's medium and long-term vision.

The Management Board will review twice a year the implementation of these recommendations.

The Management Board also discussed during this meeting the plan of action regarding the functioning of the EFSA Scientific Committee and Panels. The adoption of the document was postponed to a future meeting, in order to allow EFSA Staff and the Scientific Committee to make proposals of actions in line with the recommendations of the evaluation report.

EFSA's strategy related to GMO RA
The Scientific Committee was informed about EFSA's on-going and future plans for co-operation with Member States in GMO risk assessment.

Scientific cooperation and networking with Member States
A working group composed of members of the Advisory Forum and scientific experts (incl. representatives of the Scientific Committee) will be set up to prepare draft strategy for scientific cooperation with Member States. It is intended to present the strategy to the Advisory Forum and the Management Board by the end of 2006. The Scientific Committee agreed to create an ad-hoc Working Group that will look at the documents already available and prepare a list of suggestions, in collaboration with all Panel Chairs.

Report of the AF WG on the input of national authorities
A working group of the Advisory Forum looked at the input of national authorities in EFSA's work and prepared some recommendations to enhance the exchange of scientific information amongst the Advisory Forum members and EFSA. The members of the Scientific Committee welcomed this initiative and recognizing that it illustrates the will of the Member States to collaborate and share data with EFSA, now look forward to its concrete implementation.

EFSA Symposium on Nutrition and Health Claims, Bologna, 8-10 November 2006
A symposium on nutrition and health claims will be organized in Bologna from 8 to 10 November 2006. The main objectives are to explain EFSA's role within the context of the new EU legislation, and to provide stakeholders with the opportunity to exchange views on possible approaches to addressing nutritional profiles and substantiate health claims.

7. WORK PROGRAMME OF THE SCIENTIFIC COMMITTEE

7.1 Ongoing scientific work

Participants were provided with a state-of-play of the ongoing work of the Scientific Committee projects.

- Benchmark dose (BMD) approach

The objective of this activity is to look at the advantages and limitations of the BMD approach, as an alternative to the traditionally used no-observed adverse effects levels (NOAEL) approach and to prepare an opinion on the preferred approach to be used for risk assessments conducted by EFSA's Panels and Expert Groups. It is planned to provide the Scientific Committee with a draft opinion for discussion by the end of 2007.

- Safety assessment of botanicals and botanical preparations

The Scientific Committee members were provided with a work plan describing the activities of the working group for the coming months; three subgroups will be created in order to:

- look at the possible use of the Qualified Presumption of Safety (QPS) approach for a simplified safety assessment of botanicals and botanical preparations for which there is an established body of knowledge
- finalise two lists of botanicals, *viz.* those with toxic properties and those with medicinal properties, and propose some prioritisation criteria for safety assessment.
- develop further a tiered approach currently proposed for a more extensive safety assessment of botanicals and botanical products that are not granted QPS

The participants suggested giving the priority to the two first subgroups.

Following the recommendation of the Advisory Forum, contacts will be established with national authorities that have an interest in this subject in order to exchange information and discuss possibilities for further collaboration. Participants were informed that the European Commission has been asked to look at food supplements other than vitamins and minerals; regular feedback on the activities of the working group will therefore be maintained with DG SANCO.

- Emerging Risks

Following the scientific opinion related to the early identification of emerging risks adopted in June 2006, the Scientific Committee will now consider the recommendations of the working group to establish an applicable system within EFSA. In the short term, contacts will be established with other bodies to learn from their experience regarding recognition/detection classification assessment and filing of emerging hazards/risks. Important elements for a functioning system are the use of the EFSA's Panel members' expertise and the scientific cooperation with Member States. An action plan will be discussed by the working group in order to define priorities and assign a new mandate to the Scientific Committee.

It was brought to the attention of the participants that food imported from third countries into the European Union should be considered as a potential source of emerging risks; the occurrence of blue-tongue disease as a result of the introduction of exotic serotypes in Europe was given as an example.

- Exposure assessment

The draft opinion on uncertainty in dietary exposure assessment is undergoing a final revision and will be submitted to the Scientific Committee for possible adoption in December 2006.

The validation of EFSA's concise European food consumption database including data from five countries is finished. The database will now be completed with the inclusion of consumption data from all remaining European countries. To facilitate this exercise, a European network of food consumption database managers has been created with the help of the Advisory Forum. This network will have its first meeting before the end of the year.

The members of the Advisory Forum have also been asked to provide EFSA with names of experts in exposure assessment from their respective countries. The objective is to increase EFSA's capacity in the area of exposure assessment and to bring new views and ideas for the improvement and harmonisation of exposure assessment methods. A database will be created identifying the expertise for each of the experts.

- Qualified Presumption of Safety (QPS)

Following the publication of the opinion related to a generic approach to the safety assessment of microorganisms in food and feed which was adopted by the Scientific Committee in April 2005, the working group has started looking at the applicability of the QPS approach for different groups of micro-organisms (filamentous fungi, *Bacillus*, Gram+ non-spore forming bacteria (GPNS), and yeasts). Experts are considering whether QPS should be granted at the *genus* or species level, and if there are some micro-organisms for which the QPS approach cannot be used. The outcome of this work will be collated into a draft opinion and released on the EFSA website for public consultation.

- Transparency in risk assessment – Scientific Aspects

A first guidance document on procedural aspects for transparency in risk assessment was endorsed by the Scientific Committee in April 2006. A new working group composed of members of the Scientific Committee and Scientific Panels will now address the science related issues, e.g. sufficiently detailed description of the strengths, robustness and limitations of the data used for the risk assessment.

- Welfare of experimental animals

This new working group of the Scientific Committee will develop a comprehensive overview of all current EU legislative and guidance documents that address experimental animals and their welfare, determine which guidance documents and procedures are currently applied by the EFSA Panels, and propose a process to harmonise the application of guidance and legislative elements across EFSA Panels. The working group will have its first meeting before the end of the year.

7.2 Expression of interest to chair/participate in particular SC Working Groups

Participants were invited to participate in those activities of the Scientific Committee they are interested in, and to identify colleagues / external experts who could actively contribute to the projects.

7.3 Possible issues for future consideration by EFSA's Scientific Committee

- Preliminary Work Programme 2007

Participants were provided with the preliminary work programme for 2007 and asked for input, especially for the section "investing in food safety science". The Work Programme will be adopted by the Management Board in January 2007.

- Post Marketing Surveillance

The issue of post marketing surveillance is of relevance to the work of several Panels and a draft mandate is currently being developed.

- Qualitative progress indicators

The Scientific Committee proposed to provide assistance to EFSA in the development of qualitative progress indicators to assess the quality and impact of the Panels' work. The progress indicators currently used by the Management Board to assess progress do not reflect the reality and are prone to be misunderstood by others.

- Risk-benefit assessment of food

A draft mandate has been prepared following the EFSA colloquium held in July 2006. The participants of this colloquium underlined that risk-benefit assessments should be made on a case-by-case basis when there is a need to compare the risk with the potential benefit. It was considered it was now premature to develop a prescriptive framework for risk-benefit assessment, but it was suggested to consider the development of a guidance document with respect to methodologies, approaches, tools and possible limitations.

The members of the Scientific Committee recommended to examine possible overlap with already ongoing research activities in order to avoid duplication of the work. They acknowledged the importance and urgency of the question but underlined also its complexity.

The mandate for this new activity of the Scientific Committee will be updated for adoption at the next plenary meeting.

- Methodology for Quantitative Risk Assessment of pathogenic micro-organisms

Aspects of Quantitative Microbiological Risk Assessment (QMRA) are currently being considered by a working group of the BIOHAZ Panel in the context of a mandate from the European Commission. QMRA approaches are also the subject of wider consideration by that Panel.

- Activities in the field of nanotechnology

Anne Theobald presented an overview of the ongoing activities in the field of nanotechnology and underlined the uncertainties on how to address this topic, the definition of nanotechnology, and the question of safety for consumers and users. Most of the data are related to inhalatory exposure and there are no data available on oral exposure. Moreover, materials have been tested in animal experiments only. It can therefore not be assessed yet whether results from animal experiments can be extrapolated to humans in the case of nanoparticles. The EFSA secretariat was requested to keep the Scientific Committee informed about ongoing developments in the area of nanotechnology. It wished to come back to this subject as soon as more information has become available to define the questions that might be addressed.

- Development of a mid to long term work plan for EFSA.

Members of the Scientific Committee were invited to provide EFSA with subjects to be addressed in the future and their degree of priority. Proposals will be reviewed during the next plenary meeting.

8. REPORT BACK FROM THE FIRST PLENARY MEETING OF THE NEW SCIENTIFIC PANELS

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

AFC

The opinion on Bisphenol A was on the agenda of the 1st and 2nd meetings of the renewed Panel. Draft opinion will be submitted to the Panel for possible adoption at its November meeting.

AHAW

This Panel received a mandate to look at dairy cow's welfare that will lead to two years of work. The European Commission has been asked for clarification of the mandate.

During its last plenary meeting, the Panel had a four hours exchange of views with a representative from DG SANCO to get feedback on the value of previously published opinions. This exercise was considered as very useful and it was decided to have this exchange on a yearly basis.

Following the recent blue-tongue outbreak, the Panel identified the need for EFSA to develop procedures which enables a quick response in case of an emerging issue.

BIOHAZ

The Panel met on three occasions. Ongoing work includes Quantitative Risk Assessment of the BSE risk in sheep, QMRA issues and reviewing possible modes of transmission of Avian Influenza including the contamination of water supplies with this virus.

CONTAM

The new Panel is composed of 11 new members who showed immediately strong commitment.

The Panel received a question on marine biotoxins which included 9 biotoxins. Each of these biotoxins covers a whole class of compounds and this may therefore result into a complex evaluation.

The NDA Panel has been contacted for assistance with regard to the question on the risk assessment of nitrates in vegetables, which should also include considerations on the beneficial effects of vegetable consumption.

FEEDAP

The Chair indicated that this Panel is virtually at its saturation point regarding the workload which can be managed. However the burden will even increase when all the existing substances have to be re-evaluated and some solutions have to be found.

GMO

Following the inadvertent contamination of Rice by LL601, the European Commission asked EFSA to give a scientific advice on the possible consequences. As the dataset is very limited the evaluation cannot be considered as a safety assessment.

The Panel prepared a report, as a self-task, on the use of animal feeding trials for the safety evaluation of whole GM food / feed. A public consultation with experts in the field is planned before the document is finalised. As the testing of whole foods is of interest to all panels the draft document will be also circulated to other Panels before its adoption.

NDA

The Panel had its first meeting in July 2006 and welcomed 6 new members.

A new working group on nutrition and health claims has been set-up and EFSA will hold a three-day conference in November 2006 to explain EFSA's scientific role within the context of the new EU legislation on nutrition and health claims.

PLH

The Panel hold its first plenary meeting in June 2006 and has already received four questions. Any risk assessment for plant health has to consider the probability for a new pest to enter Europe and the consequences if the hazard enters. In the context of international standards recognized by WTO-SPS, it is difficult to ignore completely any economical considerations. It should be therefore explored to which extent economic impact assessment is to be included in the scope of EFSA.

The first task of the Panel will consist in peer-reviewing the existing pest risk analyses as conducted by the EPPO, individual Member States and APHIS (USA).

PPR

The Panel welcomed 10 new members and has a broad expertise to cover both toxicology and environment aspects. The panel was asked to look at the safety of Maximum Residue Limits (MRLs) when addressing uncertainties in the different areas and will also work on cumulative risk assessment under the MRL regulation. A colloquium will be organised by EFSA on this issue next 28 and 29 November 2006 and the outcome of the discussion will be considered when preparing the opinion. The panel will be also responsible for updating / creating the guidance documents for the risk assessment of pesticides. The Scientific Committee was informed that such an exercise implies risk management decisions regarding the degree of protection to be provided to the European consumers and the environment. Member States have been contacted via the Standing Committee of Food Chain (DG SANCO) for views on priorities for the list of guidance documents to be updated / created. A working group composed of PPR Panel experts, representatives from the Member States and industry through trade associations (ECPA) is now set up to revise the Guidance Document on Risk Assessment for Birds and Mammals.

9. EFSA EXTRANET – PRESENTATION BY THE IT DEPARTMENT

Thierry Beniflah and Marzia Bocchia gave a presentation on content management at EFSA and more specifically on a new extranet system that will be implemented by the end of the year to exchange information and documents between the EFSA Secretariat and experts of the Scientific Committee. This secure workspace will offer different functionalities such as a forum for discussion, a list of tasks to be done, a calendar to set meeting dates, and the possibility to upload / download documents for comments. The new Extranet, once tested, will be implemented step by step, first at the Scientific Committee level, and later at the working groups' level. The participants welcomed this new tool as a significant step forward to facilitate the work of the experts. They stressed the importance of the IT Department being available to provide assistance to the experts while they are becoming familiarised with this tool.

10. ANY OTHER BUSINESS

The Scientific Committee was informed about the death last 29 June 2006 of Prof. Marco Maroni, Director of the International Centre for Pesticides Safety. Prof. Maroni was a member of the former EFSA PPR Panel and his contributions were very much appreciated. The Scientific Committee is sadly joining in the expression of condolences to his family and colleagues.

11. CLOSURE OF THE MEETING

The Chair of the Scientific Committee thanked all participants for their respective contributions.