European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

Parma, 9 June 2008

MINUTES OF THE 30TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 21-22 APRIL 2008 IN PARMA

(Adopted by written procedure on 9 June 2008)

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, John D. Collins, Erik Dybing, Albert Flynn[1], Anthony Hardy, Ada Knaap, Harry Kuiper, Pierre Le Neindre, Jan Schans, Josef Schlatter, Vittorio Silano (Chair), Staffan Skerfving, Philippe Vannier

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle (Executive Director), Bernhard Berger[2] (Head of Scientific Cooperation Unit), Stef Bronzwaer[3] (Scientific Cooperation Unit), Hubert Deluyker (Head of Scientific Cooperation and Assistance Directorate), Riitta Maijala (Head of Risk Assessment Directorate), Carola Sondermann[4] (Scientific Cooperation Unit), Dirk Detken[5] (Head of Legal Affairs and Policy Unit), Ernesto Guisado Ferrer[6] (IT Project Manager), Claudia Heppner (Head of Contaminants Unit)

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

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

[1] Present on the 21st April
[2] Present for items 10 and 11
[3] Present for items 11 and 12
[4] Present for item 12
[5] Present for item 4
[6] Present for item 12

1. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. Apologies were received from Andrew Chesson and Claudia Fruijtier-Pölloth.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

There were no declarations of interest.

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

Report back from the Management Board, 27 March 2008

The Management Board adopted the annual activity report for 2007. The Board discussed the preliminary work plan and budget for 2009. The EFSA budget is expected to increase by € 7 million to € 73 million in 2009 and 355 temporary staff are foreseen by the end of 2009. The Board also discussed performance indicators, which will be reported on a quarterly basis. At the March meeting the Chair of the Plant Health Panel gave an appreciated presentation on the work of the PLH Panel. In the near future, the Scientific Committee will be consulted on the EFSA's Strategic Plan for 2009-2013.

Executive Director EP hearing, 2 April 2008

On 2 April 2008, the Executive Director addressed the European Parliament's Committee on the Environment, Public Health and Food Safety. The members of the European Parliament were updated on EFSA's activities and achievements and were asked to provide their views for the preparation of EFSA's Strategic Plan for 2009-2013. The members of the Parliament expressed concerns about the increasing workload for some of the EFSA Panels.

Memorandum of Understanding with ECDC, 3 April 2008

EFSA and the European Centre for Disease Prevention and Control (ECDC) have signed a Memorandum of Understanding to increase co-operation and exchange scientific information on topics of mutual interest including food safety, control of communicable diseases, infectious diseases prevention and emergency response. Similar Memoranda of Understanding are in preparation to strengthen the cooperation with European organisations such as the

European Medicines Agency, the European Chemicals Agency and the Joint Research Centre, as well as the Japanese Food Safety Commission and Food Safety Australia New Zealand (FSANZ). Visits to Japan and New Zealand are foreseen in September to further explore these initiatives.

Report back from the Advisory Forum meeting, 10-11 April 2008

At the 26th meeting of the AF, in Rome, extensive and constructive discussions on cooperation and networking took place. Denmark raised awareness on a recent publication from the HEATOX Project[7] investigating a possible association between dietary acrylamide intake and breast cancer. These outcomes will also be discussed at EFSA's 11th Scientific Colloquium "Acrylamide carcinogenicity – New evidence in relation to dietary exposure" to be held in Tabiano, Italy, from 22-23 May 2008.

Discussions were held on the combined toxicological effect of multiple chemical exposures raised by Norway and on the combined effects of endocrine disruptors raised by Denmark. These issues were also discussed at previous meetings of the Scientific Committee. The Chair of the PPR Panel informed that an opinion on accumulated exposures has been adopted by the Panel and will be published soon.

France gave a presentation on the incidence of BSE.

Riitta Maijala presented a discussion paper on the role of EFSA in contributing to the improvement of animal health in Europe.

Advisory Forum crisis exercise, 10 April 2008

At the AF meeting a crisis exercise was performed were a draft EFSA crisis manual was tested. The draft crisis manual was also used during an internal crisis exercise in January. The draft crisis manual will now be updated and shortened based on the comments raised during the exercises held internally and with the AF. The objective is to finalise the crisis manual by summer and the Scientific Committee is invited to provide further comments to the Secretariat on a shortened draft that will be shared at a later stage.

The Committee asked clarifications about some terms and definitions used in the draft crisis manual and the relation between this document and the recently adopted opinion of the SC on urgent questions.

EFSA is planning additional crisis exercises, involving sister agencies and the European Commission.

[7] This research project, funded by DG Research, was recently completed. The Final Leaflet and deliverables are available at http://www.heatox.org .

Visit of Members of the European Parliament, 14 April 2008

A delegation of the European Parliament's Committee on the Environment, Public Health and Food Safety has visited EFSA. The members of the Parliament were given an overview of EFSA and its activities including presentations from the Chair of the Scientific Committee. Participants agreed to have similar meetings on a regular basis, also in Brussels.

EFSA's role in animal health

The Scientific Committee members were updated on EFSA's role in animal health and presented with a draft report on EFSA's role in contributing to the improvement of animal health in Europe which is under preparation. EFSA has been very active in this area with 40 opinions adopted by the AHAW Panel, 15 opinions on zoonoses and 35 opinions on BSE and other TSEs by the BIOHAZ Panel. The Zoonoses Unit, in collaboration with EU and Member States, coordinates the annual reporting of zoonoses in the EU. EFSA also collaborates closely with the European Commission, European Parliament, Member States, other EU agencies such as ECDC and EMEA as well as with international organisation such as FAO, OIE and WHO.

The report outlines the main goals for EFSA's activities in the Animal Health area:

- Provide an integrated approach to deliver scientific advice
- Decrease the time to deliver opinions and improve data exchange
- Provide support for EU surveillance programmes
- Provide scientific support for EU crisis preparedness
- Avoid unnecessary divergence of scientific opinions
- Mobilise and coordinate scientific resources

The Scientific Committee commented that some of the goals are general in nature and there may be overlaps with other areas. The Committee also raised the general difficulty in getting access to research results that have not yet been published.

The report is scheduled for consultation before summer 2008 and EFSA has also scheduled a dedicated Advisory Forum meeting on Animal Health on 27-28 May 2008.

Update on the establishment of the ANS and CEF Panels

The call for experts for the Panel on food additives and nutrient sources added to food (ANS) and the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) was published on 15 January 2008 and the original deadline was extended to 17 March 2008. Eligible applications have been screened by EFSA staff and by external experts. A shortlist of suitable candidates has been provided to the Management Board for possible adoption at its meeting on 29th April 2008.

The current AFC Panel will continue its work until 8th and 9th July. On 10th July, the two new Panels will have their induction meeting. The Executive Director thanked the AFC Panel and its Chair Sue Barlow for all its excellent work.

INEX Implementation

The scientific advice adopted by the Scientific Committee on Internal and External Review system for EFSA's scientific work is being implemented within EFSA's Panels networks and Units. A guidance document including a checklist and a template is being prepared which will be followed during the preparation of all scientific opinions and reports for the self-review. In addition, an internal review of a sample of published opinions and reports will be started. Based on this, EFSA will produce an annual report to take stock of experience gained during this review process. In addition, an internal committee will be created to review and further develop the INEX process.

The Scientific Committee noted that the quality control of the review process is important, and that the Panels should be involved in the indicated process. The INEX process is not only to be applied for opinions but also for all other scientific outputs such as guidelines, reports, conclusions and statements.

The process will be presented to all Panels and at the Scientific Committee plenary meeting in July 2008.

5. DRAFT OPINION ON TRANSPARENCY IN RISK ASSESSMENT – SCIENTIFIC ASPECTS

A presentation of the draft opinion was provided by the chair of the working group. This draft is the second part of a self task initiated in 2005. The Scientific Committee adopted the first part of this self task "Transparency in risk assessment carried out by EFSA: Guidance Document on Procedural Aspects" in 2006.

It was felt that the work of EFSA in preparing opinions is already following the general principles proposed in the draft guidance. The Committee acknowledged the importance and high value of the document that is focussing on ensuring transparency in the scientific documents produced by EFSA.

The members of the Scientific Committee were asked whether it would be useful to provide an Annex to the opinion that would include default factors used by the Scientific Committee, Panels and other Expert Working Groups of EFSA. The Committee noted that such an overview might need significant additional work and it was therefore suggested to come back to this as a separate task to harmonise default factors used by the Scientific Panels, Scientific Committee and other expert working groups of EFSA.

The members were invited to provide additional comments in writing to the Secretariat. The draft will then be shared with the EFSA Scientific Panels for comments. The Transparency working group will then consider the comments received from the Panels and prepare an updated version of the draft opinion for discussion at the September plenary meeting.

6. UPDATED DRAFT OPINION ON ANIMAL CLONING

This item was chaired by the Scientific Committee vice chair Ada Knaap as Vittorio Silano is also the chair of the working group. The Committee discussed the draft opinion prepared by the working group on animal cloning. The working group was acknowledged and thanked for the huge efforts put in the preparation of the draft opinion.

The opinion had been published for public consultation and the working group has updated the opinion in light of the scientific comments received. The comments and a report on the outcome of the public consultation will be published together with the adopted opinion.

The Scientific Committee members provided several comments and suggestions on the draft opinion and it was decided that a small drafting group would be formed to address issues raised during the meeting. The drafting group would be composed of members of the Scientific Committee and some members of the former working group. An updated opinion will be presented for discussion and possible adoption at the next plenary.

7. REPORT BACK FROM THE WG ON NANOTECHNOLOGY

An outline of the draft opinion, indicating main issues, was presented by the chair of the working group. A working document produced after three working group meetings was also shared with the Committee members. The working group was acknowledged for its impressive work carried out within this short timeframe. Some concerns were raised that the timeframe provided for the opinion would be too short and that endorsement for publication for a public consultation at the next plenary meeting would be difficult to achieve. The working group will be requested to take into account the suggestions and comments made during the plenary and to assess the feasibility to prepare a draft opinion for endorsement for public consultation at the next plenary meeting.

8. SAFETY ASSESSMENT OF BOTANICALS AND BOTANICAL PREPARATIONS

This item was chaired by the Scientific Committee vice chair Ada Knaap as Vittorio Silano is also the chair of the working group. The members were informed about the outcomes of the public consultation organised on the draft guidance document on the safety assessment of botanicals and botanical preparations used as ingredients in food supplements. The members

discussed a report summarising how the comments made by the stakeholders were taken on board by the working group as well as the resulting updated guidance document.

The Scientific Committee members provided some comments, suggestions and editorial improvements for both documents. The participants agreed, subject to incorporation of the comments of the Scientific Committee, with the publication on the EFSA website of the comments received, the report summarising how comments were addressed by the working group, and the resulting updated guidance document.

9. IDENTIFICATION AND SELECTION OF EXPERTS

A draft decision of the Executive Director for the selection of experts was presented. The version presented during the meeting had already been updated with the comments provided earlier in writing by the Scientific Committee members. The final text of the decision concerning the selection of experts is expected to be published early June, with the launching of the European Database of Experts.

10. REPORT BACK FROM THE SCIENTIFIC PANELS AND THE SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

Scientific Panels

The Scientific Committee was updated on the outcome of the plenary meetings of the Scientific Panels 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
The Panel adopted and published on 14th March an opinion on the results of a study on the effect of some food colours and the preservative sodium benzoate on children's behaviour.

AHAW
The Panel is preparing an update of its opinions on Bluetongue and Avian Influenza taking into account new data that have become available since the adoption of these opinions.
The Panel adopted five opinions on the welfare of fish taking into account comments received from stakeholders. The Panel is also following the BIOHAZ self task activity on meticillin resistant *Staphylococcus aureus* (MRSA) and has asked to be associated to this work.

BIOHAZ
The Panel has endorsed a draft opinion on foodborne antimicrobial resistance as a biological hazard. The draft will be published on the website for public consultation. A call has been

launched under Article 36 on Quantitative Microbiological Risk Assessment (QMRA) in pigs in relation to Salmonella. The Panel has received a mandate to look into issues on Salmonella in poultry. In April a mandate was received requesting advice on the health risks of feeding non-ruminant Meat and Bone Meal (MBM) to non-ruminants in relation to the risk of TSE.

CONTAM

At its last two plenary meetings, the panel adopted the last set of opinions on the coccidiostat cross-contamination of animal feed. The Panel has also adopted an opinion on nitrate in food, an opinion on okadaic acid (marine biotoxins) and an opinion on perfluorinated substances (perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts). The Panel further adopted a statement to clarify findings on chloropanol esters as well as a minute statement regarding a risk assessment of non-dioxin like PCBs in France. The Panel Chair underlined that the CONTAM Panel is often faced with weak data sets to base its opinion upon which requires a thorough data search before it can start the actual evaluation. An emerging issue in the contaminants area is pharmacologically active substances not approved in the EU that might be detected, sometimes due to technology developments and improved detection methods. However, different methods used by different Member States will lead to different limits of detection. The need for some guidance on what to take as minimum required performance limits, and whether the TTC concept could be applied in such cases was underlined. The issue of the TTC concept and whether it could be applied more broadly in the food area was identified as a subject for a future activity of the Scientific Committee.

GMO

The Panel Chair informed that the EFSA guidance document for the risk assessment of GM plants and derived food and feed will be updated in the framework of the Action Plan of the European Commission regarding environmental and food/feed safety assessment of GMOs and derived food/feed. The Panel has been asked to give its opinion on a safeguard clause invoked by France concerning maize MON810 and is waiting for documentation to be provided. The Panel had a first experience with a GM plant proposed for cultivation under the EC Regulation 1829/2003, where the environmental risk assessment is done by a Member State. The Panel had a meeting in Parma with experts from this Member State that was invited to present its approach for the environmental assessment. The GMO Panel was pleased with this experience and is now progressing to conclude on the assessment of this application, taking into account the environmental assessment performed by the Member State.

PLH

At the last plenary 30 evaluations on plant pests risk assessments made by France for the French overseas department were adopted. The Chair of the Panel was invited to present these evaluations to the Standing Committee on Plant Health. The Panel received a new request concerning a different on Citrus imports between the European Union and South Africa. The Panel is specifically asked to assess the scientific background for the European Legislation. The Panel will initiate a self task activity to develop a guidance document for evaluation of pest risk assessments made by third parties.

PPR

At the last plenary the PPR Panel adopted an opinion on cumulative risk assessment of synergistic and additive effects of pesticides. A contract under Article 36 has been granted to test the proposed approach on a number of pesticides and to produce a report on the case study. A scientific opinion on the draft guidance document on risk assessment for mammals and birds, which was on public consultation, is expected to be adopted in June. After the adoption, the document will be discussed with risk assessors and risk managers to identify parts that will be used for the actual guidance document. One difficulty in applying this guidance is the risk manager's decision of protecting individuals or populations. It was underlined that the Panel is increasingly producing guidance documents which reflect the general mandates that have been received these last years. An Article 36 contract to produce a report on operator exposure is expected in December 2008 which will be used as an input for a guidance document. The Panel is revising a guidance document on persistence of pesticide in soil. The Panel has received a mandate to generate a new guidance document on protected crops in EU in relation to pesticide exposure and to evaluate releases to the environment due from crop systems under plastic or in greenhouses. This work is expected to be finalised by 2010.

Scientific Cooperation and Assistance Directorate

The PRAPeR Unit is expecting to come to conclusions on 59 substances in the peer review stages 3 and 4 in 2008. The peer review process is expected to be completed in July. A presentation was given on the Expert Database that EFSA intends to launch in June. A testing phase will take place in May, involving EFSA, the Advisory Forum, the Focal Points and the ESCO Working Group on the Expert Database. Several EFSA staff will attend a workshop on systematic literature review using the Cochrane method. The Scientific Committee will receive an update on the experience gained and consider at its July meeting whether it is useful for EFSA to organize a similar workshop for Panel members.

11. REPORT BACK FROM WORKING GROUPS

11.1 ESCO WG on Fostering Harmonised Risk Assessment Approaches across Europe

The ESCO working group intends to divide the work into two tasks, first to look at the procedural aspects and secondly to address the scientific aspects of harmonising risk assessment approaches across Europe. A questionnaire to provide input to the WG is under preparation and will be sent to the Members States. The Scientific Committee suggested that the transparency document under preparation (see agenda point 5) would provide a valuable starting point for this working group.

11.2 ESCO WG on Emerging Risks

The second meeting of this working group was held in April. The working group has established two subgroups, one which is addressing data collection and processing and the other subgroup is focusing on existing networks than can be applied and developed. Both subgroups held their first meeting in April. The secretariat of this working group has been transferred from the SCAF Unit to the Unit on Emerging Risks. The Emerging Risks WG now has a common approach in areas covered by other committees and agencies such as in SCENIHR, EMEA and ECDC.

11.3 ESCO WG on Botanicals

The first meeting of this ESCO working group took place in April. The draft guidance for the safety assessment of botanical ingredients was presented and the mandate of the working group was discussed. The ESCO working group will be divided into two subgroups; one will test the proposed framework for safety assessment with a number of real cases, and the other will further develop the information contained in the compendium. The ESCO Working Group has been given a one-year timeframe to complete these tasks and advise the Executive Director on the adequacy of the scientific framework developed so far by the Scientific Committee.

11.4 SC Working Group on Risk-Benefit Assessment

No meeting has taken place since the last plenary meeting. The working group will meet again at the end of May.

11.5 SC Working Group on Welfare of Experimental Animals

At its last meeting the working group discussed and approved an action plan including milestones. A scientific report is in preparation where similarities and discrepancies between the risk assessment approaches used by the different Panels will be evaluated, with particular emphasis on the possible improvement of the 3Rs approaches. Moreover, the draft report will provide an inventory of procedures currently applied in EFSA that have consequences for the 3Rs. A report is expected by the end of the year.

11.6 SC Working Group on Benchmark Dose Approach

There has been no meeting of the Working Group since the last plenary. In parallel to this activity, EFSA is following the work of the ILSI Europe Task Force on Margin of Exposure. Both groups are confronted with the question of the quality of the data, the value of the resulting modelling of the dose-response curve, and the relevance of the derived BMD/BMDL values. The working group will meet end of May to prepare a first draft of the opinion.

12. ANY OTHER BUSINESS

12.1 Steering Group on Cooperation, 26 May 2008, Copenhagen

The Scientific Committee members were invited to propose topics for the agenda of the meeting of the Steering Group on Cooperation. The Steering Group will discuss and evaluate the progress of the ongoing scientific cooperation activities carried out by EFSA and the Member States. It was agreed that it is desirable not to add new mandates until current ones have been completed.

12.2 DoI: presentation of IT tool

Riitta Maijala and Ernesto Guisado Ferrer presented a new IT application which has been developed to facilitate the regular update and handling of Declarations of Interest of the EFSA experts. The application will be launched in May 2008 and all EFSA experts will be duly notified.

12.3 Increasing awareness of EFSA's scientific work and recognition of the expert's work

An update on the work to increase awareness of EFSA's scientific work and the recognition of the expert's work was presented. The objective is to make the current EFSA Journal a journal that can be referenced in bibliographic databases. The Scientific Committee asked for a short document on this important issue to be addressed and discussed further at the next plenary meeting in July.

12.4 Proposal for dates of the Scientific Committee plenary meetings in 2008/2009

The Scientific Committee members were asked to take note of proposed meeting dates for 2009 and to inform the secretariat on any conflict. Plenary meetings will usually start in the morning of the first day and finish after lunch on the second day to allow the members to travel back on time.