European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

Parma, 3 December 2007

MINUTES OF THE 27TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 19-20 NOVEMBER 2007 IN BRUSSELS

(adopted on 17 December 2007)

PARTICIPANTS

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

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle (Executive Director), Herman Koëter (Deputy Executive Director, Director of Science), Hubert Deluyker (Head of Scientific Cooperation and Assistance Department), Riitta Maijala (Head of Risk Assessment Department), Marta Hugas (Head of BIOHAZ Unit), Carola Sondermann (Senior Press Officer).

Secretariat of the Scientific Committee:
Djien Liem (Scientific Coordinator, Head of Unit), Silvia Bellocchio (Secretary), Bernard Bottex (Scientific Officer), David Carlander (Scientific Officer), Giulia Frattini (Secretary), 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. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. Apologies were received from Dan Collins (Chair of the BIOHAZ Panel).

2. ADOPTION OF THE AGENDA

The agenda was adopted as distributed.

3. DECLARATIONS OF INTEREST

The Declarations of Interests (DOIs) of the members of the Scientific Committee, using the new form developed by EFSA, have been published on the website. The publication of the DoIs of all Scientific Panels and its working group members will follow soon. EFSA will collect and review beginning of next year possible difficulties encountered by the experts when filling in their DOIs and when appropriate amend the guidance document.

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

- Special Advisory Forum meeting on GMO Risk Assessment – 13 November 2007

Over 60 experts participated in a very successful meeting allowing EFSA to gain a comprehensive overview of the GMO risk assessment approaches in the European Member States. Discussions focused on the approach designed and applied by the EFSA GMO Panel regarding the risk assessment of GMOs, and on a number of specific issues in this area, such as determining the biological relevance of statistically significant differences identified between GMOs and their conventional counterparts in compositional studies and/or animal feeding trials, conducting environmental risk assessments, and the use of animal feeding trials to test the safety and nutritional aspects of whole GM food/feed. A great majority of risk assessors from the Member States expressed their agreement with the case by case risk assessment approach for GMOs as designed by the GMO Panel. This implies that animal feeding trials with whole foods/feed should be considered based on scientific arguments, and not routinely. Furthermore the Member States risk assessors agreed with the initiatives taken by the GMO Panel regarding further development of risk assessment procedures.

In the area of environmental risk assessment, participants supported the development of more detailed guidance, such as generating specific data on potential adverse effects of GMOs on non-target organisms, field trial designs and parameters, and the way in which regional variations should be taken into account in environmental assessments. They also call for a better understanding of the effect of GM agriculture on the environment, as compared to other types of agriculture (conventional or organic) and discussed the possibility of a risk/benefit assessment approach, even if the assessment of environmental benefits is not explicitly required by the current legislation.

A report summarising the discussions and the outcome of the meeting will be distributed broadly as soon as available.

- EFSA's 5th Anniversary

The list of events planned for the EFSA 5th anniversary celebration in Brussels was presented. The Dutch Food Safety Authority will also celebrate its 5th anniversary, together with EFSA, on 6th December in The Hague.

- Splitting of the AFC Panel

EFSA will split its AFC Panel into two panels by spring 2008; one Panel will deal with food additives and nutrient sources added to food (incl. food supplements), and the other with food contact materials, enzymes, flavourings and processing aids. Both Panels will be supported by the same EFSA Unit. Current Panel members will be invited to indicate their willingness to participate in one or the other Panel. An open call will be launched by EFSA to select additional experts.

The European Commission was thanked for helping to make the interservice consultation as quickly as possible.

- Environmental impact of cultivation and management of GM crops

The 2001/18 Directive is asking for environment impact assessment of GMOs but the issue is also of relevance for other EFSA Panels such as the PPR and PLH Panel. Members of the respective Panels and EFSA staff have discussed the feasibility of environment impact assessment and possible consequences for the work of the various panels. A meeting will be organised with DG Environment to further discuss this topic.

5. PREPARATION OF THE MULTIANNUAL WORKPROGRAMME OF EFSA/SCIENTIFIC COMMITTEE

Next year the Scientific Committee will dedicate a half day meeting to review its mission and to discuss its working priorities for the coming years. This multi-annual work plan may be shared with other organisations to ensure complementary work.

6. DRAFT OPINION ON THE IMPLICATION OF ANIMAL CLONING ON FOOD SAFETY, ANIMAL HEALTH AND WELFARE, AND THE ENVIRONMENT

A first version of the draft opinion on food safety, animal health and welfare and environmental impact of animals derived from cloning and their offspring and products obtained from those animals was presented. Several comments were made by the participants on the different sections of the document. It was recommended that the uncertainties of the assessment should be clearly expressed.

The working group will be requested to update the document accordingly and to submit a final draft to the next plenary meeting of the Scientific Committee for endorsement for public consultation.

7. QUALIFIED PRESUMPTION OF SAFETY

The draft opinion introducing a Qualified Presumption of Safety (QPS) approach for the assessment of selected microorganisms referred to EFSA was adopted by the Scientific Committee. The document has been previously discussed with the European Commission who confirmed that the approach is compatible with existing legislation. The QPS approach remains an EFSA internal working tool for generic risk assessment and has no legal status; therefore the fact of using a strain of a microorganism granted QPS does not replace the obligation for pre-market authorisation process where legislation exists.

The opinion, which contains a first list of microorganisms with QPS status, as well as the technical reports that are presenting the evidence considered for granting / refusing QPS status will be published on the EFSA website. QPS will now be implemented across EFSA's Panels and a group of experts will be charged with the maintenance and regular review of the QPS list.

The QPS approach will be presented to the European Member States during the next meetings of the Standing Committee on Food Chain and Animal Health (Feed section on 17-18 December 2007 and Food section early 2008).

The Chair of the QPS Working Group thanked all colleagues who contributed to this activity. He acknowledged particularly the Chairs of the four subgroups who examined the applicability of the QPS approach for Bacillus, Gram-positive non-sporulating bacteria, yeasts and filamentous fungi, respectively.

8. GUIDANCE DOCUMENT ON THE SAFETY ASSESSMENT OF BOTANICALS AND BOTANICAL PREPARATONS

The Scientific Committee adopted for public consultation the guidance document on the safety assessment of botanicals and botanical preparations used in food as supplements. The guidance document, as well as the two compendia listing botanicals that have been considered for food use and that have been reported to contain toxic, addictive, psychotropic and/or medicinal substances, will be published on the EFSA website for a 6-week public consultation starting beginning of December 2007.

The EFSA Scientific Cooperation (ESCO) Working Group in charge of testing the proposed approach with real cases and develop further the compendia will start its activities in February 2008, once the guidance document has been updated with the comments received during the public consultation.

The participants were informed that EMEA provided some more comments lately. It was decided to address these comments together with the ones submitted by the stakeholders during the public consultation.

The Members of the Scientific Committee congratulated the Botanicals working group for the work done in producing the guidance document.

9. WELFARE OF EXPERIMENTAL ANIMALS: INTERIM REPORT GIVING AN OVERVIEW OF THE TEST REQUIREMENTS IN THE AREA OF FOOD AND FEED SAFETY

An interim report giving an overview of the test requirements in the area of food and feed safety was presented to the Scientific Committee as the first outcome of the Terms of Reference given to the Scientific Committee working group on this topic. The experts will now look at the existing guidelines used by the various EFSA Scientific Panels and to what level they can be compared and harmonised.

10. WORKING STRATEGY FOR NANOTECHNOLOGY

Participants were provided with a proposal for the composition of a working group, the revised Terms of Reference, and a tentative roadmap for the preparation of the opinion. The Scientific Committee suggested additional expertise on immunotoxicology for the working group, which brings the composition to 15 experts identified both by the members of the Advisory Forum and by EFSA.

11. FEEDBACK FROM THE 3RD CHAIRS MEETING OF COMMISSION/AGENCY SCIENTIFIC COMMITTEES/PANELS, HELD ON 6-7 NOV 2007

The Scientific Committee discussed a document summarising the points agreed by the participants of the 3rd Chairs meeting which was attended by Chairs (or Vice-Chairs) of all the Panels. The document provides a list of topics identified for further cooperation in the following areas:

- Emerging risks: the mandate of the interagency working group has been extended. A meeting will be organised beginning of 2008 with other organisations that have an emerging risks detection system already in place;
- Nanotechnology: the existing dialogue will be extended; a seminar will be organised next 2-3 October 2008 where the EFSA opinion will be presented;
- Internal cooperation: an international conference on risk assessment will be organised in Brussels on 13-14 November 2008;
- Harmonisation of terminology: a workshop will be organised in May 2008.

EFSA reiterated its need for appropriate feedback from the risk managers on how the scientific opinions are used.

The 2008 meeting of the Chairs of Commission and Agency Scientific Committees/Panels will be organised by EFSA in Parma.

12. REPORT BACK FROM THE SCIENTIFIC PANELS AND ACTIVITIES OF THE SCIENTIFIC COOPERATION AND ASSISTANCE DEPARTMENT

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

A working group has been established to review the Southampton study on food additives and hyperactivity in children; the panel expects to have the draft opinion for adoption by spring 2008.

The Panel has adopted the opinion on the artificial sweetener Neotame.

AHAW

The Panel has received a new mandate to look at the data on avian influenza obtained from the last years' events and interpret them in regard of the situation in the European Union.

The draft opinion on the animal welfare aspects of killing and skinning seals will be proposed for adoption beginning of December 2007. A meeting involving experts from different countries, including Canada was organised during the preparatory phase.

A discussion has been initiated with the European Commission on animal welfare indicators. This question of proposing welfare indicators is also addressed under the 7th Framework Programme of DG Research.

CONTAM

Two opinions on coccidiostats as well as the opinion on ethylcarbamate, were adopted and the opinion on the risk involved in the human consumption of reptile meat was coadopted. The workload of the panel remains high and the Chair informed the participants that the panel might not be able to adopt all the opinions on the agenda of the next plenary meeting due to the number of opinions to be adopted and the limited time available.

The Panel asked for further guidance on how to communicate uncertainties in exposure assessment, as an extensive description could send a wrong signal. The Working Group on Transparency of the Scientific Committee was asked to develop a common approach for the EFSA Scientific Panels.

FEEDAP

The Guidance for the assessment of compatibility for feed of zootechnical microbial additives with antimicrobial substances was published on the EFSA website for public consultation.

A Stakeholder meeting was organised in November 2007 where relationship between the notifiers, EFSA as assessor, and EFSA as advisor were discussed. It was made very clear that there will never be any contact between the Panel and the notifiers to ensure the independency of the work of the panel. Notifiers will be given the possibility to contact the EFSA Secretariat when looking for an advice on a specific point.

Participants were informed about possible confidentiality issues for data in the case of co-adopted opinions, as the regulations applicable to the EFSA Panels have different requirements in terms of data that can or cannot be disclosed.

The Panel will have to re-evaluate all the feed additives by 2010. Priorities will be set up by the European Commission and groups will be created so that additives can be assessed on a block basis. The Panel appreciated this good exchange with Risk Managers for planning and prioritising the panels' work.

GMO

The guidance report on the use of animal feeding trials for the safety and nutritional assessment of whole food/feed has been adopted after public consultation on the EFSA website. EFSA is now in the process of publishing the report in a peer reviewed scientific Journal. The report is available on request in the meantime.

The draft opinion on the risk assessment of GM plants used for non-food or non-feed purpose will be proposed for adoption at the plenary meeting of the GMO Panel in November 2007.

The Chair of the Panel asked for more EFSA guidance on the number of rounds of questions and answers that should be allowed for a dossier.

The Chair of the Panel was invited by the Japan Food Safety Authority to exchange information on risk assessment strategies for GMOs as developed by EFSA and on current activities of the Panel regarding further development of risk assessment strategies. EFSA is in the process of formalising its relationship with the Japan Food Safety Authority and will sign an agreement beginning of next year.

NDA

The Panel adopted the final group of opinions on allergens.

The Panel has been asked to provide an advice on nutrient profiles by January 2008 including a scheme. The EFSA Science Colloquium organised on this topic in October 2007 was providing useful input.

At present industry has only provided a limited number of application dossiers for claims due to a lack of definition. Three applications were received so far on children claims; they have been put on hold until the European Commission has clarified what is understood by children claims.

Member States are currently providing their lists of claims under article 13. The European Commission will compile these lists and provide EFSA with a single list early 2008. The size of the expected list is still unknown. The European Commission has decided that additions to this list would be possible from 2008 onwards and not 2010 as initially announced; this decision will add up to the panel's workload, and adequate staff support is therefore essential.

PLH

The panel is currently reviewing 30 pests risk assessments made by France for the "Départements d'Outre-Mer". The panel is requested to formulate an advice on the opinion itself and on the organism considered.

A guidance document for pest risk assessment is being developed and will be finalised by end of this year. A scientific colloquium is organised by EFSA on 6 and 7 December 2007 to discuss the scientific aspects of the approach.

An "article 36 call" has been launched for data collection in order to perform pests risk assessments in the European Union. The Panel was asked to liaise with DG Research, as the topic of the call is close to a project of the 7th Framework Programme. Members of the Advisory Forum will be invited to propose institutes with expertise in plant health to expand the article 36' list.

PPR

The draft guidance on risk assessment for birds and mammals has been published on the EFSA website for public consultation. Taking into account the comments received during the consultation period, an updated version will be proposed to the panel for adoption next year. The Panel proposed that means should be thought of on how this guidance can be reflected also in legislative texts.

The next guidance document to be developed by the panel will deal with the persistence of pesticides in soil.

Report back from the Scientific Cooperation and Assistance (SCA) Department

The Head of Department gave a presentation on ongoing activities. The participants highlighted the need for a more extensive discussion during the next plenary meeting on data collection, as well as what the priorities should be.

A framework contract has been launched for data management and statistical analysis; it will allow the Panels to contact very quickly pre-listed institutes when a need is identified.

The assistance provided by the SCA Department in analysing data is appreciated by the Panels, as it contributes to lowering the workload of the experts. Panels have different wishes for the tasks to be

performed by the SCA Department in 2008. These tasks will have to be prioritised to fit with the available resources.

The Scientific Committee expressed their wish to be consulted on setting priorities for topics for the EFSA Science Colloquia.

Contacts have been established with some Editors of peer-reviewed scientific journals to discuss the possibility of increasing the dissemination of EFSA opinions and scientific reports.

13. REPORT BACK FROM OTHER WORKING GROUPS

- Benchmark Dose Approach (BMD)

The comments made by the Scientific Committee during its last plenary have been taken into account, e.g. to ensure a better balance between the NOAEL and the BMD approach. The opinion will provide some guidance on the harmonised introduction of the BMD approach in risk assessment carried out by EFSA Panels and all Panel members will be consulted before adoption of the document

- Emerging Risks

The newly established ESCO Working Group is composed of 8 members of the previous working group of the Scientific Committee and 13 members nominated by the Member States. It will be subdivided into subgroups to ensure the most efficient completion of specific tasks.

Contacts have been established with the Joint Research Centre to explore the possibility of customizing their Europe Media Monitor system for EFSA needs

- Transparency in Risk Assessment (work plan phase II: scientific aspects)

A restructuring of the guidance document has been proposed at the last working group meeting and a small drafting group is currently revising the text to be discussed at the next working group meeting in December 2007. The document is still expected to be proposed for adoption for public consultation at the April 2008 plenary meeting. The public consultation step will include a dedicated stakeholder meeting.

- Risk-benefit assessment of foods

The work on risk benefit assessment of foods is in progress. The working group is following DG Research ongoing projects such as BRAFO, BENERIS and QALIBRA in order to ensure complementarity of work.

14. ANY OTHER BUSINESS

An additional meeting of the Scientific Committee will take place on 19 December 2007 in Brussels to review and possibly adopt for public consultation the draft opinion on animal cloning.