European Food Safety Authority

Parma, 24 January 2007
EFSA/SC/350

MINUTES OF THE 22ND PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 14-15 DECEMBER 2006 IN PARMA

(adopted by written procedure on 7 February 2007)

PARTICIPANTS

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

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle (Executive Director), Herman Koëter (Deputy Executive Director, Director of Science), Jan Bloemendal (Secretariat of the Advisory Forum), Dirk Detken (Senior Legal officer, Legal Affairs Unit), Tobin Robinson (Scientific Officer, FEEDAP Panel), Karen Talbot (Communications Advisor, Communication Department), Victoria Villamar (Senior Policy Officer, External Relations and Management Board Unit)

Secretariat of the Scientific Committee:
Djien Liem (Scientific Coordinator, Head of Unit), Silvia Bellocchio (Secretary), Bernard Bottex (Scientific Officer), Juliane Kleiner (Senior Scientific Officer Risk Assessment), Marina Paluzzi (Secretary)

European Commission (EC):
Marina Marini (DG SANCO/Unit C7 – Risk Assessment)

Invitee:
Ortwin Renn for agenda item 7

1. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. Apologies for absence were received from Erik Dybing and Jan Schans.

2. ADOPTION OF THE AGENDA

The agenda was adopted as distributed.

3. DECLARATIONS OF INTEREST

There were no expressions of declarations of interest.

4. MATTERS ARISING FROM THE MINUTES OF THE PREVIOUS PLENARY

Catherine Geslain-Lanéelle presented to the participants a first series of measures to facilitate the participation of experts to EFSA's meetings. She emphasised that EFSA is aware of the high workload of the Panel members and that short- medium- and long-term options will be examined and proposed to ease the workload of its experts. To this end a working group will be set-up.

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

- **HANDLING OF DECLARATION OF INTEREST**

Members were informed that EFSA is currently working on a procedure for the handling of declarations of interest of the Scientific Committee, the Panels and other EFSA experts. The draft procedure will be presented for comments to the Scientific Committee in April 2007. A test phase will be run before its implementation.

- **ADVISORY FORUM OF 30 NOVEMBER 2006**

The EFSA strategy paper for cooperation and networking between the EU Member States and EFSA, which has been drafted by a working group of the Advisory Forum and which also takes into account the comments made by the Scientific Committee Bureau, has been forwarded to the EFSA Management Board for endorsement. It was highlighted that the Scientific Committee will be consulted in the definition and priority setting of possible projects for scientific cooperation between EFSA and the Member States. Some potential specific projects already identified by the Advisory Forum working group will be reviewed at the next meeting of the Scientific Committee.

The Scientific Committee members underlined the need for efficient national network systems.

- **ARTICLE 36**

A list of competent organisations designated by the Member States which may assist EFSA with its mission will be presented on 19 December 2006 to the EFSA Management Board for possible adoption. It was emphasised that this list can be extended at a later stage and that the absence of an institute on the list does not mean that this institute is not suitable for working with EFSA.

- **MANAGEMENT PLAN 2007**

The draft Management Plan of EFSA for 2007 was tabled for information. The document will be submitted to the Management Board for possible adoption.

6. UNCERTAINTY IN EXPOSURE ASSESSMENT

The Scientific Committee adopted a guidance document related to uncertainties in dietary exposure assessment. The Scientific Committee strongly encouraged the Panels to incorporate the systematic evaluation of uncertainties in their risk assessments and to communicate this clearly in their opinions.

7. DG RTD SAFEFOOD PROJECT

Prof. Ortwin Renn presented the results of Work Package n°5 of the EC-funded project SAFE FOODS. The overall objective of the project is to further develop the risk analysis process regarding risks and benefits of foods, including evaluation of quality of life parameters, social and economical considerations. In particular attention is focussed on stakeholders participation in the various steps of the risk analysis process.. Work Package n°5 investigates the institutional challenges and solutions to systematic risk management. In this context a second stakeholder meeting will be organised in March 2007 in Brussels and EFSA experts are invited to use the opportunity of this event to express their views on the proposed approach.

8. FEASIBILITY OF EFSA RECEIVING FEES FOR PROCESSING AUTHORISATIONS

The Scientific Committee was informed about a proposal from DG SANCO concerning the feasibility of EFSA receiving fees for processing authorisations. The proposal has been put on DG SANCO's website for public consultation. The EFSA Management Board will officially respond to this proposal.

9. REPORT BACK FROM WORKING GROUPS

- Emerging Risks

The working group is currently looking at appropriate means to gather information from all relevant sources. One source of information will come from members of the Scientific Committee and Panels who can bring in new knowledge from a wide environment. Recruitment for the new dedicated unit on emerging risks is ongoing and EFSA's IT Unit will actively cooperate with this unit.

- Botanicals

Following the endorsement of the work plan by the Scientific Committee in May/June 2006, the composition of the working group has been slightly modified in order to add relevant expertise. The next meeting of the working group will take place in February 2007. In addition, meetings will be organised at the beginning of 2007 with the European Commission and the Herbal and Medicinal Plant Committee of EMEA to ensure the best possible cooperation between European agencies on this issue.

The safety assessment of plants and plant preparations was also considered as a good project for the scientific cooperation with European Member States.

- Experimental animal welfare

The working group had its first meeting in November 2006 and as a first step the group will develop a comprehensive overview of all current EU legislative and guidance documents addressing experimental animal welfare. The overview will also include an inventory on how the various Panels take into account experimental animal welfare in their risk assessments. As a second step a proposal will be prepared to harmonise the application of guidance and legislative elements across EFSA panels.

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

The next working group meeting will take place in January 2007.

- Benchmark Dose

The next working group meeting will take place end December 2006.

- Risk-benefit assessment of food

The updated mandate for a guidance document on human health risk-benefit assessment of foods was adopted at the meeting. The new working group will be composed of members of the various EFSA Scientific Panels. Good information exchange will be ensured with related EC-funded projects (SAFEFOOD, QALIBRA, BRAFO, BENERIS).

10. REPORT BACK FROM THE 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 addition, the following issues were brought to the attention of the Scientific Committee:

AFC

The opinion on bisphenol A has been adopted end of November 2006. Once edited, it will be published, accompanied by a press release in January 2007.

A guidance document on active and intelligent packaging is currently being prepared and a draft will be put out for public consultation in due course.

The Panel has been asked to give opinions on a small number of flavouring substances which cannot be named in the eventual published opinions for reasons of confidentiality that has been granted by the Commission. In the future the European Commission will not accept applications for which confidentiality for the name of the flavouring is claimed.

AHAW

The Panel has received mandates regarding the welfare of fishes and dairy cows, as well as a mandate on blue tongue disease linked to the introduction of an exotic serotype in Europe.

BIOHAZ

The draft opinion on the revision of the Geographical BSE Risk assessment (GBR) methodology was put on the EFSA website for public consultation.

The draft opinion on BSE in small ruminants has been slightly delayed as the risk assessment based on animals intended for human consumption required additional calculations and the Panel also received a request for more clarification of some of the aspects from a Member State. The opinion is expected to be adopted in early 2007.

CONTAM

There are 15 opinions for possible adoption on the agenda for the next Plenary meetings in 2007. The chairman asked for some advice on how to handle such a workload at Plenary meetings.

EFSA has been requested to conduct a safety assessment of nitrates including a risk-benefit assessment of eating vegetables. Different views are known to exist in various Member States on this issue. The help of the NDA Panel has been requested for this task.

FEEDAP

Two opinions on environmental risk assessment of feed additives went out for public consultation. The comments received have been reviewed and the section on aquatic target animals has already been adopted. The second part (on terrestrial target animals) will be adopted in January 2007. The whole document will be published on the EFSA website and an EFSA guidance document will be developed based on this work.

The Panel is anticipating a requirement to evaluate some 600 on botanical extracts used as flavours and a further 1600 specific chemicals. The method used by the AFC Panel to assess sensory additives will serve as a basis.

The anticipated difficulties associated with holder-specific authorisations for the same active ingredient have now materialised. As it is not allowed to cross reference data for confidentiality reasons, slightly different risk assessment outcomes due to different data sets have arisen.

The 1st viral product (a bacteriophage) has been submitted for authorisations for use in the food chain. Safety assessment approaches need to be developed for viruses.

GMO

The Panel has just finalised its draft guidance document on the use of animal feeding trials for the safety evaluation of whole GM plant derived foods/feed. The document was put on the EFSA website, together with a press release, for public consultation until the end of January 2007. The Scientific Panels and Committee members were invited to review the document and to provide comments.

The authorisations for the first GMO products that were assessed by DG SANCO's former Scientific Committee on Plants will have to be renewed. A guidance document was designed by the GMO Panel and made available on the EFSA website to assist applicants in the preparation of applications for renewal of authorizations. The EFSA assessment of renewals will take into account any new information, experience and data that have been collected during the authorization period.

Comments have been received during the web consultation on the guidance note for applicants regarding the risk assessment of hybrids of plants containing GM events combined by crossing. These comments are being reviewed for inclusion in the final document.

NDA

The new regulation on nutrition and health claims will come into force in January 2007. The priority task is the development of guidance on the preparation and presentation of applications for authorisation of claims together with the European Commission. The first draft is expected early 2007. The Panel will be required to evaluate dossiers for health claims that are submitted for authorisation. The Panel will also review existing health claims. Member States will have one year to prepare their lists of claims and EFSA will then have two years to evaluate these claims. At this stage it is difficult to anticipate the workload which will arise from this regulation but it is likely to be substantial. The Executive Director of EFSA announced that the resources available to the panel in terms of staffing are being strengthened.

PLH

No issues were reported due to the absence of the Panel Chair during the meeting.

PPR

The opinion "FOCUS landscape and mitigation" to provide modelling advice on pesticide residues moving through the environment (surface water) was just adopted and will be put on the EFSA website in January 2007. The next opinions to be adopted are on the revision of Annexes II and III of Directive 91/414 and the data required for fate and behaviour, as well as toxicology and metabolism assessment.

Member States have been consulted and have listed their priorities in term of revision of the guidelines for risk assessment of pesticides. The objective is to complete the first revised guidance document on risk assessment of birds and mammals by autumn 2007 and to go to public consultation before final adoption.

11. QPS – PUBLIC CONSULTATION

The package on the Qualified Presumption of Safety approach for the safety assessment of microorganisms deliberately added to food and feed that will be put on the EFSA website for public consultation was presented to the participants. The Chair of the Working Group also acknowledged all the experts who contributed to this work.

The Scientific Committee agreed with the consultation paper and recommended to stress that the list of microorganisms that are proposed for QPS status is a living list, and that QPS is only proposed as a working tool for EFSA's Scientific Panels. Following the review of comments received via the public consultation an opinion will be prepared related to the implementation of the QPS approach within EFSA. The public consultation will run from 15 January to 5 March 2007.

12. WORKING PROCEDURE FOR EFSA'S FINALISATION OF SCIENTIFIC OPINIONS

Members proposed that EFSA's management should be alerted on time on possible sensitive issues, which may need particular attention or follow-up after the adoption of a scientific opinion. A procedure to allow EFSA's management to be aware of the content of draft opinions prior to their fianlisation was recommended to be developed. After the adoption of the opinion by the Scientific Committee or a Panel, the content of the opinion should not be changed except for editorial changes.

13. FOLLOW UP 2ND MEETING OF THE CHAIRS OF COMMISSION AND AGENCIES

A follow-up table prepared by DG SANCO resulting from the discussion at the second meeting of the Chairs of Commission and Agency Scientific Committee and Panels involved in Risk Assessment (held on 24 and 25 October 2006) was discussed. EFSA and its Scientific Committee is appreciative of these meetings but would like to suggest that such meetings would concentrate more on the sharing of information and best risk assessment practices rather than creating new joint projects.

14. UPDATE ON EXTRANET

Participants were updated on the development of the EFSA Extranet. The section dedicated to the Scientific Committee was presented and is now ready to be implemented. The EFSA IT Department is to grant access codes to all experts working with the Scientific Committee. A short training programme on how to use the Extranet will be organised during the next Plenary meeting.

15. ANY OTHER BUSINESS

Participants were informed that the composition of all Scientific Panels and Committee Working Groups will be made public.

The Commission Services informed EFSA that the DG SANCO Scientific Committee on Emerging and Newly-Identified Health Risks is to receive a mandate on biocides and antimicrobial resistance, which might be of interest for some of the EFSA Scientific Panels.