European Food Safety Authority

Parma, 7 March 2007
EFSA/SC/411

# MINUTES OF THE 23RD PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 15-16 FEBRUARY 2007 IN PARMA

(adopted by written procedure on 11 April 2007)

## PARTICIPANTS

*Scientific Committee (SC):*
Sue Barlow, Andrew Chesson, Dan Collins, Erik Dybing, Albert Flynn[1], 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), Jan Bloemendal (Secretariat of the Advisory Forum), Dirk Detken (Senior Officer, Legal Affairs Unit), Anne-Laure Gassin (Director of Communications).

*Secretariat of the Scientific Committee*:
Djien Liem (Scientific Coordinator, Head of Unit), Silvia Bellocchio (Secretary), Bernard Bottex (Scientific Officer), Giulia Fratti (Secretary), Juliane Kleiner (Senior Scientific Officer Risk Assessment), Daniela Maurici (Scientific Officer), Marina Paluzzi (Secretary), Chris Totté (Administrative Assistant).

*Management Board:*
Patrick Wall (Chair), Marianne Elvander, Bart Sangster.

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

[1] Present only for point 11 "Exchange of views with the Chair and some members of the EFSA Management Board"

## 1. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants.

## 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

- EFSA is updating in a more comprehensive way the procedure for the preparation of opinions by the Scientific Panels and Committee. The objective is to highlight the role and remit of the parties involved and at which stage these parties should provide their input so that Panels have access to all relevant information before finalising and adopting an opinion.

- The Scientific Committee was informed that, as a follow-up of the meeting of the Chairs of Commission and EU Agency Scientific Committees held in October 2006, DG SANCO has contracted the Central Science Laboratory to work on the harmonisation of the terminology used in the risk assessment methodologies of the three non-food committees.

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

- **MANAGEMENT BOARD MEEETING OF 23 JANUARY 2007**

At the Board meeting in January, both the work plan as well as the budget for 2007 were adopted.

Members of the Management Board intend to meet members of the Scientific Panels and Scientific Committee to discuss the workload and possible options for handling the scientific activities to be conducted by EFSA.

In the context of the public consultation launched by DG SANCO on the question whether it would be appropriate for EFSA to receive fees for evaluating certain dossiers, the Management Board decided to have an open meeting to discuss the issue.

- **ADVISORY FORUM MEETING OF 8-9 FEBRUARY 2007**

A very positive discussion on possibilities to enhance the cooperation between EFSA and the European Member States took place at the Advisory Forum's February meeting. Several overlapping projects, for which there is a need to work together, as well as other topics of common interest, were discussed. It was decided to establish a Steering Group composed of members of the Advisory Forum, the EFSA Secretariat and the EFSA Scientific Committee to look at projects of interest, at ways to prioritise them and at new working groups yet to be established. The Steering Group on Cooperation will have its first meeting on 21 March 2007.

- **UPDATE ON EFSA 5TH ANNIVERSARY**

The dates and topics that have been selected for the EFSA 5th anniversary will be announced during the next meeting of the Management Board, to be held in Berlin on 26 and 27 March 2007. A meeting will also be organised with the Portuguese Presidency to discuss the summit.

A Scientific Forum will be held on 21 and 22 November 2007 in Brussels. The Scientific Committee was informed about several options for the programme of this Scientific Forum. The Scientific Committee acknowledged that the 5th anniversary is a unique event not only to highlight EFSA's achievements to date but also to look to the future. The participants came with several proposals for possible topics.
Members of the Scientific Committee advised that a different format to the one used for the EFSA colloquia be followed.

A one-day scientific meeting will be also organised jointly with the University of Parma. Speakers from Italy but also from other European countries will be invited.

## 6. POSSIBLE PROJECTS FOR SCIENTIFIC COOPERATION BETWEEN EFSA AND MEMBER STATES

The cooperation between EFSA and the Advisory Forum on scientific projects is expected to start around summer time. The outcome of these collaborative efforts could be used as an input for the Scientific Committee or Panels.

There is however already a number of projects of common interest (e.g. safety assessment of botanicals and botanicals preparations, emerging risks, European food consumption database) for which a more extensive cooperation already exists, or can be further implemented. It was suggested to involve some representatives from the Member States in existing working groups to facilitate the exchange of scientific information between EFSA and the Member States, and to ensure that they can make use of the outcome of the activity.

The members of the Scientific Committee provided comments on a number of projects proposed for implementing the strategy for cooperation and networking and on the deadlines proposed by the Advisory Forum. Before creating new working groups, leading to new meetings for the experts, the

Scientific Committee advised that the Steering Group should carefully look at the work that has already been done or is already ongoing in the Member States or in international organisations (e.g. FAO or WHO). Existing knowledge and manpower available in the Member States could be useful for these projects, which are of common interest. It was noted as well that no reference is made to the DG Research 7th Framework Programme, while some of the issues listed will probably be addressed by DG RTD.

## 7. UPDATE ON DECLARATIONS OF INTEREST

EFSA is working at strengthening its procedures for reviewing the declarations of interests of its experts. The draft procedures will be discussed at a future plenary meeting of the Scientific Committee.

## 8. 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 particular, the following issues were brought to the attention of the Scientific Committee:

*AFC*

The opinion on Bisphenol A was published on 29 January 2007 and was subject to several reports in the media. National food safety agencies welcomed the opinion, some highlighting the clarity it set out on the issue.

The Panel was asked by the European Commission to review a large number of flavouring substances that were previously evaluated by JECFA (Joint FAO/WHO Expert Committee on Food Additives). In this context the AFC Panel will closely look at the available genotoxicity data.

*AHAW*

The Panel had a fruitful collaboration with EMEA for the opinion on the risk of rabies introduction into the UK, Ireland, Sweden and Malta, as a consequence of the possible abandon of the serological test measuring protective antibodies to rabies. For upcoming opinions (e.g. Newcastle disease, avian influenza), which will address as well vaccines, a representative of EMEA will be invited to the respective working groups.

The Panel received a mandate on ticks as vectors of animal diseases but there are barely any good data available.

The Panel received in January 2007 a mandate from the European Commission on Blue Tongue Disease. However the mandate did not include the issue of the origin of the disease, which was considered as a classical example of a signal of an emerging risk that should be addressed quickly. A self mandate will be prepared. This issue will be further discussed during the workshop on emerging risks detection organised by the UK Food Safety Authority and EFSA in London on 5 and 6 March 2007.

Discussion has been initiated with FAO concerning an early information system for veterinary data.

*BIOHAZ*

The Panel has been asked by the European Commission to comment on an opinion released by a Member State on Scrapie in sheep and its possible transfer to humans.

The Quantitative Microbiological Risk Assessment of Salmonella in pigs will be outsourced, using Article 36.

*CONTAM*

The opinion on aflatoxins was adopted at the Panel's last meeting in January. Benchmark doses were calculated both from animal and human data to derive a point of reference for comparison with human exposure scenarios.

The Panel received a question on *camelina sativa,* whose oil has a high potential as bio-fuel. The question relates to whether residues of the process can be used as feed. These residues contain glucosinolates and other undesirable substances for which there are no data and therefore the Panel is not in a position to produce an opinion on this issue.

*FEEDAP*

There was no cross cutting issue since December 2006 on which to report back.

*GMO*

The draft opinion on the use of animal feeding trials, which was released for public consultation will be finalised taking into account the comments received during the consultation period.

In 2004 the GMO Panel published an opinion on a GM potato with altered starch composition, and for which a marker gene for antibiotic resistance is used for the selection, i.e. neomycinphosphotranferse (*npt*II). Recently WHO has issued a report listing those antibiotics that are of relevance for veterinary and human use. The European Commission is now consulting EMEA on the use of antibiotics as markers. The GMO Panel Chair emphasized the readiness of the Panel to take into account any new available information, including the evaluation performed by EMEA.

*NDA*

No issue was reported due to the absence of the Panel Chair during the meeting.

*PLH*

The Panel is dealing with four mandates that will result into six opinions. Four working groups have been established and it needs to be ensured that a harmonised risk assessment approach is being applied to deal with these questions throughout the various working groups. It was suggested to involve ad-hoc experts from the Member States or other institutions.

*PPR*

- Two opinions on the revision of Annexes II and III of Directive 91/414/EEC concerning data requirements for fate and behaviour in the environment, as well as toxicological and metabolism studies, have been adopted. The third opinion still to be adopted deals with data required for ecotoxicological studies.
- The update of the guidance document on risk assessment of pesticides for birds and mammals is ongoing. An advanced draft will be presented for public consultation in September 2007.
- The Panel has received a request from the European Commission regarding acute dietary exposure to pesticides in fruit and vegetables, asking for advice on how conservative the International Estimates of Short-Term Intake (IESTI) equation is in order to protect the total European population. The opinion is expected to be adopted at the next plenary meeting.
- The Panel has received some feedback from the European Crop Protection Association (ECPA) on the opinion related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. ECPA is challenging the conclusions of the opinion in view of new data that have been forwarded to the Panel. A self-task activity has been initiated to review these data and decide whether an update of the opinion is needed.

## 9. PROPOSAL FOR GRANT ALLOCATION IN 2007 AND 2008 IN THE FRAMEWORK OF ARTICLE 36

The work programme for grants and the projects that are proposed to be funded under Article 36 in 2007 and 2008 were presented to the participants. Only the institutions that are on the list adopted by the EFSA Management Board on 20 December 2006 can apply for these grants. The calls for proposals for 2007 will be launched from the end of March 2007.

The Scientific Committee expressed its support for the projects proposed for 2007 and recommended defining clearly the criteria for prioritisation and selection of projects. The participants also suggested that the proposals for projects be discussed with the Steering Committee of the Advisory Forum, as Article 36 is also a tool for an enhanced cooperation with the Member States.

## 10. CONSIDERATIONS ON HUMAN AND ANIMAL HEALTH RISKS ASSOCIATED WITH THE CONSUMPTION OF FOOD PRODUCTS FROM CLONED ANIMALS OR THEIR PROGENY

The US Food and Drug Administration recently published for public comment a document on the safety of food products obtained from cloned animals and their progeny. EFSA expects to receive a question on this issue from the European Commission in the near future.

The participants were informed that AFSSA has already published a report, making some recommendations on what should be looked at if products from cloned animals come into the European market. It was proposed to bring this topic to the attention of the Advisory Forum in order to ensure good coordination between EFSA and the Member States.

## 11. EXCHANGE OF VIEWS WITH CHAIR AND SOME MEMBERS OF THE EFSA MANAGEMENT BOARD

The Chair of the Management Board underlined the quality of the work done by the EFSA experts and appreciated the enormous amount of time they dedicate to EFSA. The Authority is now faced with an enormous workload and it was the objective of this discussion with the members of the Scientific Committee to provide the representatives of the Management Board with a comprehensive overview of all issues to be addressed.

The Scientific Committee thanked the members of the Management Board for taking the time to discuss the difficulties faced by EFSA's experts. EFSA opinions are based on the contributions produced by outside experts on a voluntary basis, as opposed to paid employees. There is therefore a need to value the scientific expertise provided to EFSA, so that scientists can go back to their management bodies and justify the added value for the time they spend for EFSA rather than for their institute. EFSA should communicate further with the experts' institutes to inform them on what their experts are doing, on the knowledge they bring back home on current activities at the European and international levels, and to make the point to these management bodies that the risk assessments that are performed at EFSA's level will not have to be performed again at the national level in their country. In addition, the Scientific Committee underlined that serious considerations should be given to the adequate level of financial compensations of expenses.

The workload issue is the main point of concern. The development of the Scientific Cooperation and Assistance Department, as well as the greater involvement of EFSA's Staff in the preparation of opinions will contribute to a reduction of this workload. Further discussion with the European Commission is needed regarding the mandating process and prioritisation of requests posed to EFSA. The developed strategy for cooperation with Member States should ensure that the activities conducted in EFSA and the Member States are of a complementary nature and that duplication of workload can be avoided. It was remarked that alternative forms of working should be further explored but that there is a limit as these alternative arrangements cannot replace face-to-face meetings of large working groups or plenary meetings.

The Chair of the Management Board thanked the participants for their remarks and suggestions. This first fruitful exchange will allow the Management Board to work together with the Scientific Committee on a strategic planning to deal with the workload. Panels' Chairs will be invited one by one to attend forthcoming Management Board meetings and to discuss their Panel's major achievements, work plan, difficulties and specificities.

## 12. REPORT BACK FROM WORKING GROUPS

- Benchmark Dose

The use of human epidemiological data in the BMD approach will be discussed at the next meeting.

- Emerging Risks

It was urged that all Panels should give further consideration to the identification of indicators of possible emerging risks and to include emerging risks as a standing agenda item for plenary meetings.

The UK FSA / EFSA workshop on emerging risks, to be held in London on 5 and 6 March 2007, will provide the opportunity to meet face to face with people working in the area and identify the key agencies working on this topic. Contacts will be established to initiate cooperation on this issue.

- Botanicals

The working group had two meetings beginning of February to work further on the lists of plants containing active substances of toxicological or medicinal concern, and to discuss the suitability of the QPS approach currently developed for the safety assessment of micro-organisms added to food and feed for the safety assessment of botanicals. Wheat bran, marigold as a source of lutein, and fennel were considered as case-studies.

A meeting will be organised with the EMEA Committee on Herbal Medicinal Products on 14 March 2007 to discuss respective work and possible cooperation regarding the safety assessment of botanicals used as traditional medicinal products.

- Welfare of Experimental Animals

The next meeting will take place on 16 March 2007. The working group is currently updating a report that reviews existing regulations and available guidance documents. Once updated and discussed by the Scientific Committee, the report will be circulated to all Panels in order to get a picture of what is being done in EFSA's Panels and what are the areas of improvement.

- Qualified Presumption of Safety – part II

A list of micro-organisms that could be proposed as candidates for QPS status, as well as the technical reports presenting the evidence considered to reach these conclusions have been put on the EFSA website for public consultation until 5 March 2007. The comments received from the public will then be taken into account when updating the list and reports, and preparing the draft opinion.

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

A first draft of the guidance document is being reviewed. Contributions have been requested by April 2007 to update the document that will then be presented to the Scientific Committee.

- Risk-benefit assessment of foods

The participants discussed the draft composition of the working group. The group will comprise experts from the relevant Scientific Panels, as well as additional external experts from Member States.

- In- and External review of the quality of EFSA's scientific work

The participants adopted the draft mandate. The objective of this activity is to develop a proposal for a review system to assess the quality of EFSA's scientific work. Such a proposal should meet present day standards of audit and peer review and the necessity for openness and transparency. It should consider not only the processes that are followed during the development, completion and delivery of EFSA's scientific outputs, but also the appreciation of the output by the intended users and the wider scientific community. The approach should include both internal and external reviews and be based on principles of best scientific practice. It was suggested to include a person working in quality assurance systems or in an accreditation body in the working group.

- EFSA's responsiveness to urgent questions

A working group of the Scientific Committee is currently developing a proposal on ways to enhance EFSA's responsiveness to urgent questions. All Scientific Panels have been invited to propose their views on how to deal with urgent questions. The members of the Scientific Committee underlined the importance of defining what an urgent question is, as distinct from a crisis or an emerging risk. Close contacts should also be ensured with the Communication Department to develop an adequate communication strategy.

## 13. UPDATE ON DG RTD PROGRAMME

In order to prepare the annual meeting between EFSA and DG RTD to be held on 28 February 2007, the participants were given a presentation on the first calls of the 7$^{th}$ Framework Programme (FP7), highlighting the research topics of interest for EFSA. Discussion followed to identify the Panels' research needs not covered by the programme.

The Scientific Committee highlighted the need to get timely access to relevant information from the projects, especially in the case of signals related to emerging risks.

## 14. UPDATE ON THE EXTRANET

Participants were introduced to the use of the new SC extranet. This secure web-based platform is intended to replace e-mail exchanges between the EFSA SC Secretariat and the experts for every day work. It was agreed that all documents for the next plenary meeting will be uploaded in this new system.

## 15. ANY OTHER BUSINESS

- A meeting will be organised on 2 and 3 May 2007 in Parma regarding the Eurofir-Basis database of active substances in plants. The objective is to discuss the possibility for EFSA to host and maintain the database up-to-date.
- Participants were informed of the obituary for Prof. Bobby Kroes, published in Toxicology Letters 169 (2007) 1-2.