European Food Safety Authority

Brussels, 13 June 2005
EFSA/SC/156 Final

MINUTES OF THE 12TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 14-15 APRIL 2005

(adopted by written procedure on 13 June 2005)

PARTICIPANTS[1]

Scientific Committee (SC):
Andrew Chesson, John D. Collins, Tito H. Fernandes, Anthony R. Hardy, Bo O. Jansson, Ada G.A.C. Knaap (Vice-Chair)[2], Pierre F.G. Le Neindre (Vice-Chair), Josef Schlatter, Vittorio Silano (Chair)[3], Philippe Vannier and Josep Vives-Rego

European Food Safety Authority (EFSA):
Marie-Noëlle Costa (Administrative Secretary of the SC), Anne-Laure Gassin (Director of Communications)[4], Juliane Kleiner (Scientific Expert Services), Herman Koëter (Deputy Executive Director and Director of Science)[4], Djien Liem (Scientific Co-ordinator of the SC), Geoffrey Podger (Executive Director)[4], Suzy Renckens (Scientific Co-ordinator of the GMO Panel)[5], Pilar Rodriguez-Iglesias (Scientific Co-ordinator of the NDA Panel)[5], Valérie Rolland (Assistant Scientific Co-ordinator of the SC)[4], Laura Soriano (Administrative Secretary of the SC)

European Commission (EC):
Laurent Bochereau (DG Research/Unit E3 - Safety of food production systems), Marina Marini (DG Health and Consumer Protection/Unit C7 - Risk Assessment), Michael Walsh (DG Health and Consumer Protection /Unit D5 - Relations with the EFSA),

[1] Abbreviations: AFC: Panel on food additives, flavourings, processing aids and materials in contact with food; FEEDAP: Panel on additives and products or substances used in animal feed; GMO: Panel on genetically modified organisms; NDA: Panel on dietetic products, nutrition and allergies; BIOHAZ: Panel on biological hazards; CONTAM: Panel on contaminants in the food chain; PPR: Panel on plant health, plant protection products and their residues; AHAW: Panel on animal health and welfare; AF: Advisory Forum; MB: Management Board
[2] Chair on 14 April (morning)
[3] Present on 14 April (afternoon) and 15 April
[4] Present on 14 April
[5] Present on 15 April

1 OPENING, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies were received from Susan Barlow (AFC), Albert Flynn (NDA) and Harry Kuiper (GMO).

Vittorio Silano announced to arrive in the afternoon of 14th April. Vice-Chair Ada Knaap chaired the morning session on the 14th of April.

2 ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3 DECLARATIONS OF INTEREST

No declarations of interest were made beyond those already made in the annual declarations of interest.

4 DISCUSSION AND POSSIBLE ADOPTION OF THE DRFAT MINUTES OF THE PREVIOUS PLENARY MEETING OF THE SC

The minutes were approved with some corrections. The final minutes can be found at http://www.efsa.eu.int/science/sc_commitee/sc_meetings/810/scm_11th_plenmeet_minutes1.pdf.

5 DISCUSSION AND POSSIBLE ADOPTION OF A DRAFT OPINION ON A GENERIC APPROACH FOR THE SAFETY ASSESSMENT OF MICRO-ORGANISMS USED IN FOOD AND FEED AND THE PRODUCTION OF FOOD/FEED ADDITIVES

The draft opinion as prepared by the Working Group on Qualified Presumption of Safety (QPS) of the Scientific Committee was introduced and discussed. The QPS working group revisited the working document as prepared by a joint working group of the former Scientific Committee on Animal Nutrition (SCAN), the Scientific Committee on Food (SCF) and the Scientific Committee on Plants (SCP) of the European Commission's Health and Consumer Protection Directorate General. The QPS working group took into account the comments received on the working document of the SCAN/SCF/SCP working group during a consultation period in the spring of 2003 and the suggestions made by the participants of the EFSA scientific colloquium that took place in December 2004. The Scientific Committee adopted the opinion as prepared by the QPS working group subject to incorporation of the modifications as suggested by the Committee. The full opinion can be found at http://www.efsa.eu.int/science/sc_commitee/sc_opinions/972_en.html.

6 GENERAL FEEDBACK FROM GEOFFREY PODGER, EFSA EXECUTIVE DIRECTOR

Geoffrey Podger informed the Scientific Committee about the outcomes of the Management Board (MB) meetings of 10 March 2005 and the meeting of the Advisory Forum (AF) of 8 April 2005. In addition, an update was given on other developments including the move to Parma[6]. In the following three sections, only those issues are summarised that led to some discussions during the 12th plenary meeting of the Scientific Committee.

6.1 Management Board (meeting of 10 March 2005)

Workplan 2006. The Management Board discussed the draft workplan for 2006 providing a general overview of the expected activities and highlights on new issues to be dealt with in 2006. The Scientific Committee was requested to provide advice on priorities in EFSA's work programme for 2006 before September 2005.

GMO. The MB discussed developments in the area of GMOs. The Scientific Committee took note of these discussions and continued to express its confidence in the GMO Panel.

Stakeholder Consultative Committee. The MB discussed the draft terms of reference for a Stakeholders Consultative Committee[7]. The discussions in the MB have not been finalised yet. The Chair requested Geoffrey Podger to keep the Committee informed about the Stakeholder Consultative Committee.

Renewal of the Scientific Committee and Scientific Panels in 2006. The Management Board discussed an EFSA document proposing procedures for the renewal of the Scientific Committee and Scientific Expert Panels in 2006[8]. From these discussions it became clear that the main objective remains to have the best available experts on the Scientific Panels and Committee and that all efforts should be made to achieve geographical balanced membership from all Member States, proportionate to the countries' size in terms of population.

6.2 Advisory Forum (meeting of 8 April 2005)

New Ad-hoc AF Working Group on the input of National Authorities. Herman Koëter requested the Scientific Committee members if they, or someone of their Panels, would be interested in joining a new ad-hoc Advisory Forum Working Group on the input of national authorities into the work of the Scientific Committee, Scientific Panels and other scientific expert working groups of EFSA. The task of this ad-hoc AF working group would be to consider the manner in which exchanges on scientific issues, information and data can be facilitated. The Ad-hoc working group is requested to report back to the Advisory Forum within 12 months. The first meeting is planned to take place on the 27th of

[6] For more specific information on the issues discussed at these meetings, see the specific pages of the Management Board and the Advisory Forum on EFSA's website.
[7] See http://www.efsa.eu.int/mboard/mb_meetings/832/5_tor_stakeholder_consultative_cte1.pdf
[8] See http://www.efsa.eu.int/mboard/mb_meetings/832/6_scientificexpertpanels1.pdf

May. Dr. Philippe Vannier, Professor Bo Jansson and Professor Tito Fernandes expressed their willingness to join this Working Group.

6.3 Other developments

Inauguration of the EFSA in Parma. Geoffrey Podger invited the members of the Scientific Committee to participate in this special event. The Chair expressed his gratitude on behalf of the Committee for Mr. Podger's invitation and subsequently proposed to reschedule the next plenary meeting from 16-17 June in Brussels to 21-22 June.

Article 36. The Chair asked for an update on progress made in relation to the designation of competent organisations by the Member States for a scientific network according to Article 36 paragraph 3 of Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002. Herman Koëter explained that a letter to the Permanent Representations, explaining the criteria required for institutions to be eligible, is almost ready. The letter will be accompanied by a questionnaire to assist Member States with the selection of appropriate candidates and to facilitate EFSA's processing of the information to be used in the preparation for the list of competent organisations. Member States will be requested to complete the questionnaire for all nominated competent organisations and return it to EFSA through their Permanent Representations to the EU.

Public relations. The Scientific Committee was informed that EFSA had refused that a TV-journalist would make recordings during a meeting of the GMO Panel. Instead recordings were made prior to the meeting of the Panel in front of the EFSA building. Anne-Laure Gassin asked the Scientific Committee whether it would be a good idea to have some information material available in order to meet these kind of requests. The Committee will discuss her request at a future meeting.

7 PROGRESS REPORTS ON SPECIFIC SUBJECTS

7.1 Safety assessment of botanicals and botanical preparations – Discussion and possible adoption of a draft mandate for the Scientific Committee

The Scientific Committee discussed a draft mandate on botanicals and botanical preparations. The draft mandate was based on the discussion paper of the SC released in June 2004 and the responses to a questionnaire distributed by the EFSA Secretariat to the members of the Advisory Forum in October 2004. The draft mandate was adopted subject to incorporation of the modifications proposed by the Committee.

7.2 Welfare of experimental animals relating to EFSA's activities – Discussion and possible adoption of a draft mandate for the Scientific Committee

A draft mandate on the welfare of experimental animals relating to EFSA's activities was introduced and discussed. The draft mandate was adopted subject to incorporation of changes suggested by the Scientific Committee.

After incorporation of the modifications proposed, the draft mandates on botanicals and botanical preparations, as well as on animal welfare, will be sent to the Executive Director with a request to consider inclusion of the proposed activities in the work programme of the Scientific Committee. Once the final mandates have been received, these will be published on the webpages of the SC on EFSA's website.

7.3 Preparation of a guidance document on the interface between Risk Assessment (RA) and Risk Management (RM)

The Secretariat informed the Scientific Committee about the planning of activities for the preparation of a guidance document of the Scientific Committee on the interface between RA and RM. A draft guidance document will be prepared by an external expert. This draft will serve as starting point by an ad-hoc working group composed of members of the Scientific Committee and Panels, external experts and staff of EFSA. Commission representatives will be involved as observers.

8 DEVELOPMENTS IN RELATION TO THE 7TH FRAMEWORK PROGRAMME – FEEDBACK FROM DG RESEARCH

Laurent Bochereau, Head of Unit 'Safety of Food Production Systems' of DG Research, gave an overview of the projects launched in the 6th Framework Programme and an update of developments in relation to the 7th Framework Programme. The Scientific Committee was invited to provide recommendations to help implementing the various priorities defined for the 7th Framework Programme. Laurent Bochereau agreed to keep the Scientific Committee informed in order to ensure that there will be a timely submission of input from the Committee into further developments of the 7th Framework Programme. Tito Fernandes, Pierre Le Neindre and Djien Liem offered to be the contact points for DG Research on behalf of the Scientific Committee.

9 REPORT BACK FROM SCIENTIFIC PANELS AND SCIENTIFIC WORKING GROUPS

9.1 Report back from Scientific Panels

The Chairs of the Scientific Panels informed the Committee about opinions recently adopted as well as opinions in the process of adoption by written procedure[9]. In addition, the Chairs wished to bring the following specific issues to the attention of the Scientific Committee:

[9] For more specific information, see the specific pages of the respective Scientific Panels providing the minutes of the plenary meetings and the opinions adopted at these meetings on EFSA's website.

AHAW

- In line with expectations expressed at the previous plenary meeting, the AHAW Panel received a request for the evaluation of diagnostic tests for detection of brucellosis. The Panel received also two new mandates in the area of animal welfare.
- The Panel started a discussion about the role of a risk assessor in a Panel.
- In order to create more capacity the Panel recommends to increase the resources in the Secretariat and the SES to help the Panels in a proper implementation of appropriate risk assessment methodologies within the area of the Panel. A similar need was also expressed by the Chair of the BIOHAZ Panel. It was further suggested to consider the opportunity to make better use of the expertise available in the other Panels.

  The Committee agreed with the Chair of the Scientific Committee to have a structured discussion on the issue of needs for additional in-house support as well as outsourcing at a future plenary meeting. Dan Collins and Philippe Vannier offered to prepare a reflection paper for discussion at a future plenary meeting.

BIOHAZ

- The BIOHAZ Panel received a follow up on a previous mandate from the Commission related to the UK application on moderate risk in terms of BSE. This current mandate included updated results of surveillance data as compiled by the UK, supporting their earlier application for moderate risk status in terms of BSE. The data were distributed to the members of the WG that dealt with this question initially and their comments were presented at the BIOHAZ plenary. The experts considered the comments and the data as provided and concluded that these data confirm the conclusions of the EFSA opinion of April 2004.
- The Panel adopted three opinions at its March plenary and is preparing opinions divided over seven working groups, three of the four of which are TSE related.

CONTAM

- The Chair of the CONTAM Panel updated the Scientific Committee about opinions prepared in the area of undesirable substances in feed (e.g. POP's, mycotoxins) and on fluorine and boron in mineral water. The Panel is also preparing a statement on acrylamide in relation to the recent JECFA evaluation of February 2005.
- New requests were received with respect to Ochratoxin A and the impact of hormones and their risks for consumers.
- A CONTAM Working Group is preparing an opinion on the safety of consumption of wild and farmed fish; the discussion of the draft opinion is planned for June. An extensive draft opinion on non-dioxin-like PCBs is also planned to be discussed at the June plenary of the CONTAM Panel.

FEEDAP

- The Panel anticipates on receiving a request from the Commission to write guidelines for the safety assessment of herbal products used in animal feed. EFSA will launch a restricted call for tender for collection of additional data on the use and kind of botanicals and botanical preparations currently used in feed.

- The Panel is preparing annexes describing the approaches that will be applied in the safety assessments in the framework of the new feed regulation.
- The Chair of the FEEDAP Panel reported on experiences in relation to meetings in Parma. Several Panel members foresee a substantial increase in time commitment because of the move of the EFSA to Parma, which may cause problems in the future with respect to availability. Another problem raised was that the per diem which is substantially lower than for traveling to Brussels.

  EFSA has been made aware of this issue and Geoffrey Podger offered to inform all Panel and Committee members for further explanation of the implications.

GMO

Suzy Renckens informed the Scientific Committee about the following issues:

- The GMO Panel is dealing with self-taskings on animal feeding trials, on allergenicity assessment of GM foods and on post market environmental monitoring, the latter of which will be based on three stakeholder consultations with a final meeting end of May.
- The Chair of the GMO Panel reported on the launch of the EFSANET in the presence of member state representatives on the 16th of March and informed the Committee about an interview with the Panel Chair and shots taken of the Panel by the German ARD.
- The GMO Panel also contributed to an EFSA statement on the contamination of Bt11 with Bt10.

NDA

Pilar Rodriguez-Iglesias informed the Committee that the NDA panel will have its next plenary meeting next week. The following issues are on the agenda:

- Three draft opinions on upper levels of vitamins and minerals (sodium, chloride and phosphorus), draft opinions on phytosterols and lycopene.
- Two new request from the Commission. The first relates to the revision of the population reference intakes which were derived by the former SCF in 1993 and the second is dealing with low protein infant formulae and follow-on formulae based on whey protein partial hydrolysates.

PPR

- The PPR had a plenary meeting on the 6th of April. The follow-up of the opinion on variability of residues, which was adopted at the 16 February 2005 plenary meeting, was discussed. In addition, the Panel considered the progress on a number of other subjects the Panel is dealing with as well as questions it will possibly receive from the Commission and EFSA's PRAPeR unit.
- The Panel received questions from EFSA's PRAPER unit on a question concerning the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil, and on the full aquatic risk assessment, especially the use of the microcosm study for cyprodinil.
- A general discussion of the Panel raised the issue of increasing the publicity and scientific impact of the principles within adopted opinions, particularly the generic ones. In addition to the EFSA website, public and MS competent authorities should be better informed.
- The Panel considered the GENTOX opinion and agreed to provide comments during the consultation process.

- The Chair encouraged the Secretariat to collect information on Parma that could be valuable for the experts having more travellings to Parma in the near future.

9.2 Feedback from SC Working Groups

Working Group on the Benchmark Dose Approach (BMD)
It is planned to have a first meeting of the working group before summer. The Panel Chairs were reminded to indicate to the Secretariat if a member of their Panel would be willing to join the BMD Working Group.

Working Group on Emerging Risks (EMRISK)
The WG Chair introduced a status report. The EMRISK WG is mainly working as a "reference group" for the consortium (under co-ordination by the Dutch Food and Non-Food Consumer Products Authority) which has been contracted by EFSA to help building up a capability to identify and evaluate emerging risks. The WG will follow the EMRISK project carefully, and use the potential emerging risks identified by the Scientific Panels to test the system suggested by the contractor. The final report of the contractor is expected in February 2006. Once received, the WG will prepare a draft opinion for the Scientific Committee.

Working Group on Exposure Assessment (EXPOSURE)
The WG is revising the draft opinion for possible adoption at the next plenary meeting of the Scientific Committee.

Working Group on a harmonised approach for the consideration of substances that are both genotoxic and carcinogenic (GENTOX)
The Chair of the GENTOX WG updated the Committee about the progress made. The draft opinion has been made ready for public consultation on the web.
The Chair of the GENTOX WG received some comments from Panels on the process followed. She reminded the Panel Chairs that the process for the preparation of the draft opinion was as agreed at the October plenary meeting of the SC.
Finally, the WG Chair informed the Committee that EFSA is organising an international conference to introduce the new approach from 16-18 November 2005 in Brussels, if possible, in collaboration with other international organisations. The conference should attract an audience of experts in risk assessment, risk management and risk communication.

Working Group on Transparency in Risk Assessment (TRANSPARENCY)
Juliane Kleiner informed the Committee about the outcomes of the first meeting of the Transparency Working Group which was held on 16 March 2005. The TRANSPARENCY WG, which is composed of members of the Scientific Committee and EFSA staff, agreed on a provisional outline of a guidance document to promote integration of transparency in risk assessments carried out by the EFSA Scientific Panels and Scientific Committee. The next meeting of the WG will be on the 1st of July.

10 ANY OTHER BUSINESS

The Secretariat updated the Scientific Committee about developments in relation to EFSA's Review. The Secretariat offered assistance to the Evaluation Team to plan interviews with members of the Scientific Committee and Panels if requested.

The Scientific Committee was informed about a meeting on new diagnostic technology, Applications in animal health and biologics control, which will take place from 3-5 October 2005 in France.

The Chair closed the meeting and thanked the participants for the fruitful and active discussions during the meeting.