European Food Safety Authority

Brussels, 14 April 2005
EFSA/SC/151 Final

MINUTES OF THE 11TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 28 FEBRUARY – 1 MARCH 2005

(adopted on 14 April 2005)

PARTICIPANTS[1]

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

Ad-hox expert
Robert Anton

European Food Safety Authority (EFSA):
Marie-Noëlle Costa (Administrative Secretary of the SC), Giovanni Fuga (Communications department)[2], Anne-Laure Gassin (Communications Director)[2], Juliane Kleiner (Scientific Expert Services), Herman Koëter (Deputy Executive Director and Director of Science), Djien Liem (Scientific Co-ordinator of the SC), Geoffrey Podger (Executive Director)[2], Valérie Rolland (Assistant Scientific Co-ordinator of the SC), Carola Sondermann (Communications department)[2], Laura Soriano (Administrative Secretary of the SC)

European Commission (EC):
Marina Marini (DG Health and Consumer Protection/Unit C7 - Risk Assessment), Arne Flåøyen (DG Research/Unit E3 – Safety of Food Production Systems), Michael Walsh (DG Health and Consumer Protection /Unit D5 - Relations with the EFSA), Basil Mathioudakis[2] (DG Health and Consumer

[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] Present on 28 February

Protection /Unit D4 - Food Law and biotechnology), Katharina Adler[2] (DG Health and Consumer Protection /Unit D4 - Food Law and biotechnology) and Fabio d'Atri[2] (DG Health and Consumer Protection /Unit D4 - Food Law and biotechnology)

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1 OPENING, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. There were no apologies for absence.

2 ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3 DECLARATIONS OF INTEREST

No declarations of interest were made for any agenda items beyond those already made in the annual declarations of interest.

4 GENERAL FEEDBACK FROM GEOFFREY PODGER, EFSA EXECUTIVE DIRECTOR

Geoffrey Podger informed the Scientific Committee about the outcomes of the Management Board meetings of 16 December 2004 and 18 January 2005 and the meeting of the Advisory Forum of 2-4 February 2005. In addition, an update was given on other developments including the move to Parma.

4.1 Management Board (meetings of 16 December 2004 and 18 January 2005)

On 26 November 2004, the Chair of the Management Board received a fax and accompanying report of Friends of the Earth (FoE) which was particularly critical regarding risk assessments carried out by the EFSA Scientific Panel on Genetically Modified Organisms (GMO). The report was circulated to the members of the Management Board and shared with and discussed in the GMO Panel. The Management Board supported the views of the Chair of the Management Board who considered the criticisms in the FoE report to be unjustified and gave a vote of confidence to the GMO Panel. EFSA's official response to the report from the FoE regarding risk assessments of EFSA's GMO Panel and a response of the Chair of the Management Board, which was endorsed by the Management Board has been published on EFSA's website[3].

The Management Board raised concerns about the severe restrictions of the European Parliament as to the grading of the staff to be recruited. The European Parliament had proposed to downgrade the

[3] See: http://www.efsa.eu.int/mboard/correspondence/786_en.html

grades available to the Authority for recruiting staff in order to promote the recruitment of more junior staff. The Chair of the Scientific Committee shared the concerns of the Management Board and hopes that it would remain possible to recruit highly qualified staff.

The Management Board also considered the procedures for the renewal of the Scientific Committee and Scientific Panels in 2006. Geoffrey Podger invited the SC members to have an exchange of views on this matter. The basic selection procedure is laid down in the Authority's Founding Regulation, but more work could be done on promoting and disseminating the kind of work that the Authority does, especially in the new Member States to attract more candidates. The Authority would consult and get advice from national authorities. The Chair of the Scientific Committee accepted Geoffrey Podger's request to write a letter to the academia and other scientific institutions for drawing their attention to the forthcoming renewal of the Scientific Committee and Scientific Panels.

During the Board's discussions of 18 January 2005, it was noted that the issue of nanotechnology and nano-science is not yet covered in EFSA's Management Plan 2005. It was agreed to consult the Scientific Committee on how and when it would be appropriate for the Authority to get involved in these activities. The Scientific Committee agreed to reconsider the issue of nanotechnology and nano-science at one of its future plenary meeting.

Geoffrey Podger informed the Scientific Committee that EFSA is intending to launch a project to assess the impact of EFSA's opinions.

4.2 Advisory Forum (meeting of 3-4 February 2005)

The Advisory Forum discussed a report on the crisis scenario exercise held with the Advisory Forum at its meeting on the 30th of September in Rome. The objective of the exercise was to work through a potential crisis situation to identify the level and nature of action required from the different institutions and agencies at national and European level. The exercise is seen as a preparation step for the joint EFSA/Commission crisis simulation exercise which will be held later on in 2005.

EFSA provided a statement on the possible risks associated with BSE in goats[4]. The Chair of the Scientific Committee expressed his appreciation for EFSA's action to clarify the possible risks involved with the finding of BSE in goats.

The Advisory Forum was updated about the progress of the project to establish a videoconferencing network between National Agencies, the EFSA and the Commission. The network is aimed to facilitate communication among senior staff, especially in situations of emerging risks.

The Advisory Forum agreed to set-up an ad-hoc Working Group of Member State representatives to develop procedures on how MS could become more involved (exchange of information etc.) in the work carried out by the Scientific Panels and Committee. The output of this activity is expected within one year.

[4] See: http://www.efsa.eu.int/advisory_forum/adv_meetings/791/af_doc4_feasibility_bse_goat1.pdf

4.3 Other developments, including the move to Parma

The move to Parma (e.g. move of staff, establishment of the Scuola per l'Europa, flight connections, meeting sites etc.) seems to go well. The aim to achieve that the whole staff will have moved in October 2005 is feasible[5]. This summer, a more long-term decision has to be taken on a final office building for EFSA.

Geoffrey Podger updated the Scientific Committee about EFSA's review. A contractor has been selected to conduct the review. On the 25th of February a kick-off meeting took place to agree on a work plan and a timetable for the EFSA review. A Steering and a Technical Committee have been created. The report of the contractor should be adopted at the December meeting of the Management Board.
The Scientific Committee expressed the wish to have a more structured discussion on relevant issues for the EFSA review at a future meeting. The Secretariat will prepare a draft agenda for a structured discussion at the next meeting and will circulate the list of questions to be answered by the reviewer.

5 RISK COMMUNICATION

5.1 Experiences in risk communication

Anne-Laure Gassin, Director of Communications, gave a presentation on the role and experience of the EFSA in the area of risk communication in Europe, comprising the approach taken, an overview of media results covering the period since the establishment of the Authority, the collaboration between EFSA and the Advisory Form and the involvement of the Scientific Committee and the Panels.

5.2 Discussion: how can we further improve the communication of EFSA's risk assessments

The SC underlined the importance of a link between EFSA and the scientific community and stakeholders. The issue of diversity of the Stakeholders and their various expectations was raised. Identification and EFSA's relationship with the stakeholders will be discussed at a future meeting in the presence of Christine Majewski and Victoria Villamar (Department of International & Institutional Affairs).

The role of the Commission and EFSA in communication should be distinct and complementary. In all cases the content and extent of the information communicated should be discussed between the risk assessors and the risk managers. The publication of press releases and particular information on a case-by-case basis require collaboration between the Panels/SC Chair, the Scientific Secretariat and

[5] See also agenda item 5 of the minutes of the Management Board meeting of 16 December 2004 (see http://www.efsa.eu.int/mboard/mb_meetings/740/minutes_16december_mb-1801051.pdf) .

the Communications Department. Chair of Panels/SC should also help in identifying potential sensitive issues in advance.

The issue of providing summaries understandable for the non-technical reader was addressed more extensively. Preparing summaries require major efforts when difficult technical issues have to be explained in lay-terms. It is also challenging to address underlying uncertainties in scientific opinions in a short summary. Summaries should be produced by the Panels supported by EFSA staff. In addition it was discussed whether two separate summaries could be prepared (an opinion scientific abstract and an explanatory summary for lay-readers), however it might be confusing to address two messages in different formats to various groups of readers. Therefore, it was concluded that only one summary should be prepared. Recruitment of in-house scientific editors would help in improving scientific summaries for the non-technical readers.

The Annual Reports produced by EFSA could also be used a good vehicle of information intended for wide target audience.

6 BOTANICALS AND BOTANICAL PREPARATIONS

6.1 Experiences of AFSSA and the Council of Europe in the evaluation of botanicals and botanical preparation - Presentation by Professor R. ANTON, Faculty of Pharmacy, University Louis Pasteur, Strasbourg (FR)

Robert Anton was invited to give a presentation on French and European experiences with regard to the use and safety of herbal ingredients in food supplements. In France there is no authorization regulation, however, a framework for the evaluation of the safety, the effect and the claims of foodstuff made from plants for the human diet has been developed based on a decision tree procedure. The *ad hoc* Group on Food Supplements of the Committee of experts on nutrition, food safety and consumer health in the Council of Europe is currently developing guidelines on the safety of plant-based food supplements and consumer interest in those supplements.

6.1.1 Overview of current initiatives and activities in EU Member States – State-of-play of an inventory among members of the Advisory Forum

Djien Liem informed the Committee on the results of a questionnaire which was distributed to the members of the EFSA Advisory Forum in order to assess the current situation in the EU countries. Twenty-five countries have responded to the questionnaire and they evaluated the issue as of moderate or of major concern. Access to data on main categories of botanicals available on the market and consumer exposure to them was indicated as difficult in most cases, even if data might be available. Some countries suggested that EFSA develops positive/negative list of botanicals, establishes safe limits of use, gathers existing information and develops guidance on toxicological and analytical documentation requirements for safety assessment. The Advisory Forum will be informed of the outcome of the survey and further steps by EFSA, as below, at their next meeting in April.

6.3 Discussion of further steps

The Commission will present a report on the use of substances others than vitamins and minerals as food supplements by July 2007. Current needs relate to the identification of categories of substances (including herbal extracts) to be listed in the Annex to the Regulation on food supplements, how the substances are regulated at national level and specifications requirements if substances are approved. A positive/negative list cannot be drawn as long a regulatory framework does not exist. The SC welcomed the offer of the Commission to work together with the SC Secretariat to discuss further valuable developments in this area. Arne Flåøyen (DG Research) will provide EFSA with information of ongoing projects funded by DG Research related to botanicals. After a discussion it was concluded that EFSA should develop a general framework focusing on the safety assessment of botanicals and botanical preparations taking into account experiences of some countries (*e.g.* France, Denmark) and European institutions (Council of Europe, EMEA). The SC Secretariat will prepare a draft mandate together with the Chairman of the SC that will be submitted to the committee at the next plenary meeting.

7 DISCUSSION AND POSSIBLE ADOPTION OF DRAFT OPINIONS

7.1 Draft opinion on exposure assessments at EFSA as prepared by the Working Group EXPOSURE

Bo Jansson presented the draft opinion on exposure assessments prepared by the Working Group EXPOSURE. It addressed guidance documents on human exposure assessment already available, advice to provide effective support to exposure assessments carried out by EFSA as well as advice on ways to access to relevant information on food consumption and on concentrations of substances/agents in food. Several actions to be taken by EFSA were recommended. The SC reviewed the document in detail. As a certain number of changes were suggested, especially on internal organization and share of responsibilities in this field, the draft opinion will be revised. Because of the involvement of the Working Group in the organization of a Colloquium on "European Food Consumption Database: Current and medium to long-term strategies"[6], 28-29 April 2005, in Brussels, a revised draft opinion is likely to be presented at the SC plenary meeting on 16-17 June but may be circulated earlier for written comments.

7.2 Draft opinion on a harmonised approach for the consideration of substances that are both genotoxic and carcinogenic as prepared by the Working Group GENTOX

Ada Knaap presented the draft opinion prepared by the Working Group GENTOX on a harmonized approach for risk assessment of compounds which are both carcinogenic and genotoxic. The draft opinion was presented for approval to be published on the EFSA website for public consultation. The SC congratulated the Working Group for the high quality and clarity of the document and agreed with

[6] http://www.efsa.eu.int/science/colloquium_series/col_efcd/catindex_en.html

the margin of exposure approach and use of Benchmark dose method proposed by the Working Group. The draft opinion was reviewed in detail. Several members of the SC asked for some rewording of the section on the interpretation of the margin of exposure to clarify and better distinguish the risk assessors and risks managers' duties. The chairman of the Working Group will revise the text together with the SC Secretariat. A revised draft opinion will then be circulated to the SC for approval by written procedure.

It was announced that a Workshop might be organized in collaboration with WHO and ILSI Europe to discuss present approaches of organizations (WHO IPCS, US FDA, ILSI Europe), critical aspects and applicability through examples. It would be expected that such an event would lead to the use of common approaches at global level.

8 FUTURE RESEARCH ISSUES

Tito Fernandes presented a working document on priorities in food research. This document aimed to contribute to the establishment of priority research areas by DG Research. The priorities identified are largely related to the need to cope with some European-wide trends characterizing the present decade. The document was adopted with some modifications and will be sent to DG RESEARCH. The SC will be informed when further advice, more focused and detailed priorities, would be needed.

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[7]. In addition, the Chairs of the Panels wished to bring the following specific issues to the attention of the Scientific Committee:

AFC

- The AFC Panel modified the tolerable daily intake (TDI) for some tin stabilisers as adopted previously in line with the opinion adopted by the CONTAM Panel.
- The TDI for certain phthalates used in food contact materials which were derived by the former SCF (Scientific Committee on Food) was reconsidered and lowered.
- It was noted that the AFC Panel and the European Commission's SCCP (Scientific Committee on Consumer Products) were requested to provide opinions on the same substances, although for different use. The SCCP opinion differed from the SCF and EFSA opinions because different data sets were assessed. A system to ensure good exchange of information between EFSA and the Commission has been discussed at Directors' level. The Commission is responsible for ensuring coordination of questions on similar issues submitted to scientific committees in various instances.

[7] 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.

BIOHAZ

- The Panel started a self task on microbiological criteria for food.
- Questions related to the evaluation of commercial processes were objected to.
- Collaboration with the AHAW Panel on several topics was underlined.
- Some work on the safety of by-products will be outsourced.
- The presence and infectivity of TSE in small ruminants were addressed.

NDA

- The Panel adopted the last opinions in relation to applications for temporary labelling exemption of ingredients/substances derived from allergenic foods. Twenty-nine applications have been received in total.
- The remaining four opinions on upper safe levels for essential nutrients are in preparation.

PPR

- The Panel adopted an opinion related to the variability of pesticide residues in food. It will form the basis of a Community position at the forthcoming meeting of the Codex Committee on Pesticides Residues in April 2005.
- The Panel started to work on two new self tasking issues originating from the peer-review of pesticides risk assessments.
- The Panel Chair raised the issue of assessing review conclusions from two different sources, i.e. Member States' Rapporteur conclusions and EFSA peer-review conclusions, without the original comprehensive dossier.
- The Panel will discuss possible relevant self tasking activities at their next plenary meeting.

GMO

- The Panel Chair indicated that the Panel is dealing with a large number of new applications for genetically modified products.
- The Panel adopted the first opinion for cultivation use of a GMO.
- The Panel is further dealing with self-tasking activities on the value and limitations of animal feeding trials and on the allergenicity of GM foods.
- Members of the Panel have been interviewed to explain how they deal with uncertainties when performing scientific evaluations in the context of a DG RESEARCH funded project relating to precautionary principles. The Panel was unhappy with the conclusions drawn in the draft report received. EFSA expressed and explained its strong reservations to the project coordinator and DG RESEARCH.

AHAW

- The Panel Chair expressed the need for additional EFSA staff support in particular for checking the data submitted to the Panel and the consistency of risk assessment approaches.
- Several new questions have been received recently.

CONTAM

- The Panel Chair reiterated that there are still vacancies in the Panel in the area of veterinary toxicology and in the area of general toxicology.
- The Panel is still working on a number of questions in the area of undesirable substances in animal feed. A new Working Group has been established which will focus on plant products and toxins in feed.
- A new question from the Parliament on the overall impact and risk assessment of the consumption of Baltic herring has been integrated into the current work of the Working Group on the Safety of Wild and Farmed Fish.

9.2 Progress report from SC Working Groups

Working Group on Emerging Risks (EMRISK)

The Chairman of the Working Group informed the members of the Committee that the work of the contractor (i.e. the Food and Consumer Product Safety Authority of The Netherlands) has started. The contractor will assist EFSA in building capability of identifying, evaluating and prioritising potential emerging issues in the food and feed area. The first milestone will consist in looking back to previous experiences and examples to identify which aspects were critical in the process. The outcome will help to identify key sources of information.

A comprehensive list of ongoing DG RESEARCH funded projects was provided by DG RESEARCH. Panels were asked to indicate whether they have contact with the projects coordinators and to evaluate if any information would be relevant to the contractor.

Working Group on Exposure Assessment (EXPOSURE)

In the last two months the Working Group focused its work on the preparation of the draft opinion discussed above and on advising on the Colloquium programme mentioned above.

Working Group on a harmonised approach for the consideration of substances that are both genotoxic and carcinogenic (GENTOX)

The Working Group will meet again to finalise the draft opinion discussed above when the comments to be received during public consultation are compiled.

Working Group on Benchmark Dose (BMD)

The first meeting of the Working Group is likely to take place before the Summer. Chairs of the Panels should indicate to the Secretariat if members of their Panels would be interested in joining the Working Group.

Working Group Interface Risk Assessment-Risk Management

The identification of Working Group members is ongoing.

Working Group on Qualified Presumption of Safety (QPS)
The Working Group was finalising a draft opinion on a harmonised approach for the safety assessment of microorganisms at EFSA. It will be presented for adoption at the next plenary meeting.

9.3 New SC Working Groups – State-of-Play

Transparency in risk assessment
The draft mandate on transparency in risk assessment has been adopted by the Scientific Committee by written procedure. A detailed outline and subsequent steps will be defined at the first working group meeting (March 2005).

Animal welfare
The first meeting of the Animal Welfare Working Group is planned in March and will aim at preparing a draft mandate to be discussed at the next SC plenary meeting. Chairs of the Panels should indicate to the Secretariat if members of their Panels would be interested in joining the Working Group, which will advise EFSA in developing and implementing a pro-active policy on the welfare of experimental animals.

Post marketing surveillance
The Chairs of the Panels GMO and BIOHAZ are preparing a working document to be discussed at a future SC plenary meeting.

9.4 Role of EFSA in the evaluation of diagnostic tests for animal diseases

Hubert Deluyker presented a working document on the role of EFSA in the evaluation of Diagnostic Tests for animal diseases. When EFSA was established, the Commission asked EFSA to take the responsibility for the scientific evaluation of rapid *ante mortem* and *post mortem* Bovine-/Transmissible Spongiform Encephalopathy (BSE/ TSE) tests. EFSA has not been involved in the evaluation of any other diagnostic tests. EFSA's contribution in the future could comprise the development of guidelines for diagnostics for a specific disease and would focus on performance criteria. This would facilitate subsequent evaluations of validation study results of proposed assay methods regardless of their origin. The SC supported EFSA's involvement in the evaluation of diagnostic tests for specific animal diseases other than BSE/TSE.

10 VENUE OF FUTURE PLENARY MEETINGS

Herman Koëter clarified that plenary meetings of Panels/SC would take place in Parma. A letter will be circulated to Panels explaining EFSA's policy regarding the location of the meetings. Meetings could take place elsewhere than in EFSA's premises, if important scientific conferences would take place at a same time period, or if there would be interest in visiting professional facilities at a particular place in connection to a plenary meeting. Travel time and costs should be lower than if organizing a meeting at EFSA's premises. The same policy should apply to the organization of

working group meetings. However, more flexibility would be given in the light of tight deadlines to achieve or in relation to the geographical composition of the Working Group.

It was indicated that the EFSA MB met in Parma and that the EFSA AF met upon MS invitation at national food authorities' premises.

The SC noted the invitation of the Parc Cientific de Barcelona to visit its facilities and meet the scientific research teams. It will be discussed at a future SC plenary meeting when a more detailed planning is available and taking into account the criteria indicated above.

11 ANY OTHER BUSINESS

As there was no other business, the Chairman of the SC closed the meeting and thanked the participants for the fruitful and active discussions during the meeting.