



European Food Safety Authority

Brussels, 9 February 2005
EFSA/SC/124 Final

MINUTES OF THE 10TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 15-16 DECEMBER 2004

(adopted by written procedure on 4 February 2005)

PARTICIPANTS¹

Scientific Committee (SC):

Susan Barlow, Andrew Chesson², 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), Vittorio Silano (Chair), Philippe Vannier, Philippe Verger and Josep Vives-Rego

European Food Safety Authority (EFSA):

Marie-Noëlle Costa (Administrative Secretary of the SC), Juliane Kleiner (Scientific Expert Services), Herman Koëter (Deputy Executive Director and Director of Science), Djien Liem (Scientific Co-ordinator of the SC), Laura Soriano (Administrative Secretary of the SC)

European Commission (EC):

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 Present on 15 December

1 OPENING, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies for absence were received from Valérie Rolland.

2 ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3 DECLARATIONS OF INTEREST

There were no interests declared.

4 PROGRESS REPORT AND DISCUSSION ON SPECIFIC ISSUES

4.1 Food and feed safety and the use of animals: Progress report on initiatives to implement the EFSA policy

Herman Koëter introduced a progress report, which has been prepared for the Management Board meeting of 16 December 2004, on initiatives to implement EFSA's animal welfare policy (*cf.* EFSA document MB 16.12.2004-7³). Following the June Management Board meeting, the EFSA Secretariat prepared an overview of the current EU legislative and guidance documents that address experimental animals and animal welfare issues. This overview will be shared shortly with the Panels, the Scientific Committee and the working groups. The progress report also summarizes the outcome of the discussion of document MB 22.06.2004-5 on "Food and feed safety and the use of animals" at the 9th Plenary Meeting of the Scientific Committee and provides an outline of the activities schedule for the near future. The Committee was invited to provide comments on the progress report. These comments would be brought to the attention of the Management Board during the discussion of the document at its meeting on the 16th of December.

The Scientific Committee members expressed their appreciation for the progress report. The Committee agreed with the way EFSA wishes to implement its animal welfare policy. It noted that EFSA's policy is not only focused on the usefulness of alternative approaches in the area of food and feed safety, but also on alternative ways that may help improve the situation of animals in general.

The Scientific Committee agreed with EFSA's proposal to establish a working group of in-house and external experts which will prepare a consensus document for discussion at a future plenary meeting of the Committee. The consensus document would focus on identifying ways how to incorporate animal welfare approaches in EFSA's tasks and missions while maintaining the highest level of science in its activities related to food and feed safety. The Committee supported the proposal of the Chair of the

³ See http://www.efsa.eu.int/mboard/mb_meetings/740/7mbdecember2004animalwelfare1.pdf

AHAW Panel that experts of the Panel would join the new Working Group. The Committee also welcomed Dr Pierre Le Neindre's willingness to participate in this Working Group.

4.2 Evaluation of the EFSA

The Deputy Executive Director welcomed the comments from the Chair and Vice-Chairs of the Scientific Committee on the Draft Terms of Reference for the EFSA Evaluation (*cf.* MB Doc. 14.09.2004-5). He informed the Committee that since the last plenary meeting, the Terms of Reference has been revised in order to launch a call for tender for the selection of the evaluator which is incorporating elements raised by the Committee at its last plenary meeting and raised by the Chair and Vice-Chairs at their meeting on the 2nd of December. EFSA will seek opportunities for the Scientific Committee to meet the evaluator.

4.3 Botanicals and botanical preparations - Overview of current initiatives and activities in EU Member States

Djien Liem informed the Committee about the status of the replies to the questionnaire that was distributed to the members of the Advisory Forum at its meeting on the 1st of October. So far replies were received from thirteen countries. Without exception the issue was considered as *of moderate* or *of major concern*. The Secretariat is awaiting further replies and will then prepare a summary of the replies received and prepare a working document with a proposal on how to proceed.

Michael Walsh offered to update the Scientific Committee at its next plenary meeting on initiatives taken by the Commission on the issue of botanicals and botanical preparations.

Sue Barlow informed the Scientific Committee about guidelines for the safety assessment of botanicals recently published by the Council of Europe. The main author will be invited to attend the next plenary meeting of the Committee. She indicated that members of the AFC were willing to contribute to the future work on botanicals and botanical preparations.

4.4 Interface between Risk Assessment and Risk Management

A working document compiling the comments from the Scientific Panels and its members was introduced and discussed. The Committee agreed with the Chair's proposal to establish a small Working Group to prepare a position paper for a final discussion by the Scientific Committee at a future plenary meeting, taking into consideration the comments received from the Scientific Panels and its members. Josep Vives-Rego accepted the task to chair the proposed Working Group and offered to prepare a mandate for the Working Group. It was agreed that the task would include interface aspects related to the process of formulation and handling of requests for EFSA scientific opinions. The Committee agreed to adopt the final text of the proposed mandate by written procedure.

4.5 Transparency in Risk Assessment

Juliane Kleiner introduced a draft mandate for the preparation of a guidance document to improve transparency in risk assessment.

The Committee members supported the proposed activity as the outcome would provide a useful guidance for the current risk assessment work to be carried out by the Scientific Panels. Some explanation was asked about the objectives and the size of the activity. It was also suggested to screen opinions produced so far, to see how the panels have described uncertainties in the risk assessment and to revisit the general format for EFSA's scientific opinions. In addition, the Committee suggested that further efforts are made to prepare summaries of opinions which are more understandable for the non-technical reader. Furthermore it was proposed to consider organisation of training courses in the area of risk assessment.

The Scientific Committee agreed with the Chair's proposal that a revised mandate incorporating the suggestions made by the members will be circulated for final adoption by written procedure. The final proposal will then be sent to the Executive Director for consideration of inclusion in EFSA's work programme.

4.6 Quantitative risk assessment

The Scientific Committee discussed a working document on models used in risk assessment as prepared by Josep Vives-Rego. The working document was considered to be a good starting point for an exchange of views on how EFSA could proceed with regard to the use of models in quantitative risk assessment. The Committee noted that mathematical modeling is a rapid evolving science. There is a range of models available and the method to be selected may depend on the data available and the kind of risk assessment to be performed. Therefore the Scientific Committee wished to encourage EFSA to consider the creation of a network of experts in mathematical modeling to assist the Scientific Panels with their specific needs.

5 DRAFT OPINION ON EXPOSURE ASSESSMENTS AT EFSA

The Scientific Committee had a first discussion on a draft opinion on exposure assessment at EFSA as prepared by the EXPOSURE Working Group. The Committee agreed with the principle approach taken by the working group not to develop new guidelines and to rely on the number of guidelines which were already issued by other organisations. The Committee also agreed with the development of a concise database of food consumption data for the general European population in close collaboration with the Member States. Aside from food consumption data for adults it was also requested to execute a parallel exercise for the collection of food consumption data for children. In

relation to the collection of occurrence data in food and feed, the Committee considered the proposal to establish a data warehouse at EFSA to host the available European data.

The Chair of the EXPOSURE Working Group agreed to prepare a new version of the draft opinion incorporating the comments made by the members of the Committee for adoption at a future plenary meeting of the Scientific Committee.

The Chair of the Scientific Committee requested the Chair of the Exposure WG to convey the Scientific Committee's appreciation for the excellent work carried out by the Working Group.

6 EFSA'S WORK PROGRAMME IN 2005

6.1 Possible issues for future consideration by the Scientific Panels

The Scientific Committee discussed Chapter III "Scientific Activities" of the Draft Management Plan 2005 which has been submitted to the Management Board meeting of 16 December 2004 (EFSA Document MB 16.12.2004-5⁴). The Chairs of Scientific Panels made a number of suggestions for modification of the text. Their comments will be forwarded to the EFSA Secretariat for inclusion in the final version intended to be adopted at the Management Board meeting in January 2005.

6.2 Possible issues for future consideration by the Scientific Committee

The Committee revisited the list of issues included in item 8 of the minutes of the 9th Plenary Meeting and added comments to the following issues.

- Procedures and mechanisms aiming at analysing and possibly solving divergence of scientific opinions between EFSA and Community, national and international scientific advisory bodies.
Issue was considered a matter of high priority. The Secretariat offered to prepare a working paper for a future plenary meeting of the Scientific Committee.
- Use of human data in safety assessments: the Committee noted that relevant human data are already regularly included in the evaluations carried out by the different Panels but agreed that the consideration of ethical aspects of the use of human data are not within the remit of the Authority.
- Establishment of a framework for risk benefit evaluations: Ada Knaap distributed and shortly introduced the *Summary and Key messages* of a research project *Measuring Dutch meals - Healthy diet and safe food in the Netherlands* which was carried out by the National Institute of Public Health and the Environment in close collaboration with other institutes and organisations in the Netherlands. The Committee expressed its appreciation for the valuable work done in this research project. It was noted that to undertake a similar task at European level would require lots of resources (e.g. meetings, experts). The Committee agreed with the Chair's proposal to have a

⁴ See http://www.efsa.eu.int/mboard/mb_meetings/740/5mbworkprogram05finalmaster611annex1.pdf

discussion at a future meeting of the Committee which steps could be taken to have risk benefit evaluations also addressed by EFSA.

- Post market surveillance: the Chairs of the GMO and BIOHAZ Panel will jointly prepare a working document for the next plenary meeting of the Committee.
- Cumulative exposures to various toxicants and synergistic and additive effects: the Commission services indicated that this issue will be addressed in the new pesticide regulation (to be adopted around the end of the year). It was noted that additivity is already taken into account by the Panels in the setting of group Acceptable or Tolerable Daily Intakes for groups of structurally and toxicologically related substances. It was also noted that a special SOT workshop on response additivity would be organised on this issue in March 2005. The Committee therefore agreed to wait for the outcome of the special SOT workshop before any further steps would be taken.

The Scientific Committee also discussed the priority activities outlined in item 87 of the Draft Management Plan 2005. The following remarks were made:

- The Scientific Committee noted that the activity to establish a framework for risk-benefit evaluations was missing.
- The Committee questioned whether EFSA should play a practical role in the harmonisation of methodology for the detection of chemical and microbiological contaminants in food and feed, but would welcome EFSA's role in initiating and prioritising activities in this area.

The modifications proposed by the Scientific Committee will be forwarded to the EFSA Secretariat for inclusion in the final version of the Management Plan.

The Scientific Committee agreed with the Chair's proposal to prepare a note comprising the needs of the Scientific Panels and Committee as to the kind of additional expertise required to carry out the work programme in 2005. All Committee members were requested to submit their suggestions to the Secretariat. A working document comprising the suggestions will be discussed at the next plenary meeting of the Scientific Committee.

The Scientific Committee raised concerns about the proposed Establishment Plan for 2005 as included in the Draft Management Plan 2005. The Committee considered that the proposed plan may not fulfill the present needs of the Scientific Panels and the Scientific Committee for high level specialised scientific support.

6.3 Discussion on criteria for setting priorities

The Committee considered item 15 in EFSA Document AF 06.04.2004-8 describing the criteria for setting priorities and suggested a weighing of the proposed criteria.

7 FUTURE RESEARCH ISSUES

The Chair explained the reasons for making an inventory of future issues for the 7th Framework Programme of DG Research. Tito Fernandes accepted the Chair's request to prepare a working document with suggestions received from the Scientific Panels. All Panel Chair's have been requested to submit the requested information which will form the basis of a working document to be discussed at a future plenary meeting of the Committee.

8 REPORT BACK FROM SCIENTIFIC PANELS AND SC WORKING GROUPS

8.1 Feedback 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 procedure⁵. In addition, the Chairs wished to bring the following specific issues to the attention of the Scientific Committee:

AFC

- The AFC Panel adopted a statement on the use of boric acid and sodium borate as sources of boron. The opinion of the NDA Panel on the upper level for boron (sodium borate and boric acid) was considered as a starting point. A risk assessment on boron in mineral water is currently in preparation by the CONTAM Panel.
- The Chair of the AFC Panel noted that the CONTAM Panel has been asked to assess the presence of hydrocyanic acid in animal feed. An opinion on hydrocyanic acid in flavourings and other food ingredients with flavouring properties has been adopted by the AFC Panel on 7 October 2004.

AHAW

- The Panel received questions and comments from the Commission on certain information included in the animal transport opinion which was adopted on 30 March 2004.

BIOHAZ

- The Panel discussed the appropriateness of setting microbiological criteria at its last plenary meeting. Aspects of predictive microbiology as a tool in risk assessment are under review.
- The Chair of the BIOHAZ Panel reported on developments in the area of collecting information on the prevalence of foodborne pathogens other than the zoonotic ones and the activities related to the preparation of the annual community report on zoonoses for 2005.
- At its last plenary the Panel was also updated on the findings relating to a suspected case of BSE in a goat in France.

⁵ 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.

CONTAM

- The Chair of the CONTAM Panel informed the Committee about the problems arising when an important specific field of expertise is represented in the Panel by a single expert only, especially when this expert becomes ill.
- The Panel Chair informed the Committee about the preparation of a note by EFSA in relation to the outcome of the furan report which was recently adopted by the Panel by written procedure. This note will be published together with the report on the Internet.
- It is expected that two additional members will resign from the Panel, which implies that there will be three vacancies in the Panel. The Panel has requested EFSA to look for a replacement of the three members.

FEEDAP

- The Chair of the FEEDAP Panel raised concerns about charging Panels with questions on minor issues and requested the Secretariat to keep the Panels free from questions on issues for which there is obviously no safety concern. Similar *minor* questions were also received by the AFC Panel.

GMO

- The Panel Chair updated the Scientific Committee about the continuous opposition the GMO Panel is receiving. The Panel Chair was pleased with a document that has been prepared by EFSA in response to the publication of a report by Friends of the Earth. The EFSA document has been submitted for discussion at the Management Board meeting of 16 December 2004.
- The Panel is grateful to the GMO Secretariat which is increasingly capable of assisting in the handling of the large number of dossiers to be evaluated by the Panel.
- The Panel has proposed self-tasking activities on animal feeding trials and on allergenicity of GM foods.
- The Panel Chair informed the Scientific Committee that some Panel members were invited by FAO/WHO to participate in a CODEX discussion on GM issues.

NDA

- The Panel Chair gave a feedback on the issues discussed at the last plenary meeting of the Panel. The Panel is working hard on the evaluation of applications for temporary labelling exemption of ingredients/substances derived from allergenic foods and is also working on opinions in the area of novel foods and upper levels for vitamins and minerals.

PPR

- The Panel is addressing external questions on individual dossiers and internal questions arising from the scientific reviews of existing substances coordinated by EFSA. The Panel expects to review the revised Annexes II and III of Directive 91/414/EEC on pesticides and has worked on an extension of the Commission's guidance document on exposure assessment for birds and mammals. It has developed and published an own guidance document.

- The Panel is dealing with questions related to pesticide residues. The questions have been raised by the Commission in order to define the Community position at the next meeting of the Codex Committee on Pesticide Residues in April 2005.
- The first plant health question was received at the last plenary of the 14th of December. EFSA will prepare itself in the second half of 2005 to deal with scientific questions related to plant health.

The Chair of the Scientific Committee expressed his appreciation for the impressive production of scientific opinions by the Scientific Panels.

8.2 Feedback from SC Working Groups

Working Group on Emerging Risks (EMRISK)

The Working Group will have a first meeting on the 17th of December with the contractor that will assist EFSA in building the Authority's capability of identifying, prioritising and evaluating emerging issues.

Working Group on Exposure Assessment (EXPOSURE)

Besides the draft opinion discussed under agenda item 5, the WG is also preparing an opinion on uncertainties in exposure assessment. The intention is to submit a draft opinion to the Committee's next plenary meeting.

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

During a meeting of the Chair and Vice-Chairs of the Scientific Committee on the 2nd of December it was decided to defer the discussion of the draft opinion of the GENTOX WG until the plenary meeting of 28 February-1 March 2005. Members of the Working Group recognised that several points which are addressed in the opinion needed further clarification and justification, and wished to have an additional WG meeting in January 2005 to discuss these issues in more detail.

9 GENERAL FEEDBACK FROM EFSA

Djien Liem informed the Scientific Committee on the meeting of staff of EFSA and DG Research which took place on the 26th of October 2004. The outcome of this meeting will be used as a starting point for a strategic meeting between the Director of the Biotechnology, Agriculture and Food Research Directorate of DG Research and EFSA's Executive Director and Director of Science. The Committee will be kept informed about further developments.

Andrew Chesson gave feedback on the outcome of the Scientific Colloquium on the QPS approach for the safety assessment of micro-organisms used in food and feed, which took place on 13-14 December 2004 in Brussels. He referred to the presentation of Laura Tarantino of USFDA on the GRAS system that was developed following a long process in the US. There were four working groups addressing

different issues related to the QPS approach that have made very sensible suggestions and considerations that are to be taken up by the QPS Working Group on the needs for such an approach. There was also a need expressed to clarify the scope and objectives of the proposed approach.

The QPS Working Group will now start with a revision of the original document clarifying the approach on the basis of the suggestions and considerations expressed during this colloquium and the comments received by the Commission during the public consultation of the working document in 2003. The Working Group will also address how EFSA could implement the QPS approach in the future work of the Scientific Panels and Committee. The final version of the revised document and a proposal on how the approach could be implemented in EFSA will be brought to the attention of the Scientific Committee.

10 ANY OTHER BUSINESS

The Committee agreed to reschedule the February 2005 meeting until 28th of February (starting at 10:00) and the 1st of March. It will consider the draft opinion on GENTOX on the 1st of March.

EFSA was requested by various Panel Chairs to arrange assistance from the Communication Services during the preparation of summaries of future opinions with a potential high public interest. The Director of Communications, Anne-Laure Gassin, will be invited for the next plenary meeting of the Scientific Committee for an exchange of views on risk communication issues.

Seasons Greetings

Professor Silano thanked the members for their valuable contributions to the work of the Scientific Committee and Scientific Panels and wished them a Merry Christmas and a prosperous New Year.

Djien Liem thanked Professor Silano for his excellent chairmanship and expressed his appreciation on behalf of the Authority for all the work carried out by the members of the Scientific Committee in this first full year of operation.