



Brussels, 23 September 2003

EFSA/SC/12 Final

**MINUTES OF THE 2ND PLENARY MEETING
OF THE SCIENTIFIC COMMITTEE OF THE EFSA
HELD ON 27 AND 28 AUGUST 2003**

(ADOPTED ON 17 SEPTEMBER 2003)

Participants

Scientific Committee (SC):

Andrew Chesson, John D. Collins, Tito H. Fernandes, Albert Flynn, Fergal O’Gara, Werner Grunow, Anthony R. Hardy, Bo O. Jansson, Ada G.A.C. Knaap (Vice-Chair), Pierre F.G. Le Neindre (Vice-Chair), Josef R. Schlatter, Vittorio Silano (Chair) and Philippe Vannier

European Food Safety Authority (EFSA)

Djien Liem (scientific co-ordination SC), Marie-Noëlle Costa (administration SC), Antoine Cuvillier (legal advice), Bart Goossens (scientific co-ordination BIOHAZ Panel), Suzy Renckens (scientific co-ordination GMO Panel), Pilar Rodriguez-Iglesias (scientific co-ordination Nutrition Panel)

European Commission (EC)

Taina Säteri (DG SANCO/Unit D5 - Relations with the EFSA), Elke Anklam¹ and Ole Peter Ostermann¹ (DG Joint Research Centre)

1. Welcome, apologies for absence

The chair opened the meeting and welcomed the participants. Apologies for absence were received from Susan Barlow, Harry Kuiper and Josep Vives-Rego (Scientific Committee members), Geoffrey Podger (Executive Director of EFSA) and Paul Vossen (EC/DG Research). Dr. Werner Grunow and Prof. Fergal O’Gara were present on behalf of the AFC and GMO Panel, respectively.

¹ Present on 27 August.

2. Adoption of the agenda

The scientific co-ordinator distributed a revised agenda during the meeting. An additional item was inserted as agenda item 9 "On a generic approach to the safety assessment of micro-organisms used in feed/food and food/feed production – Discussion of further steps in relation to a working document produced by a Joint SCAN/SCF/SCP Working Group and the comments on it received by the Commission". The proposed agenda was adopted with these changes.

The chair noted that the revised draft agenda was lacking a separate agenda item allowing the chairs of the Scientific Panels to provide feedback on matters relevant for the Scientific Committee. The Committee agreed with the chair's proposal to include this as a regular agenda item from the next plenary meeting onwards.

The Committee requested the Secretariat to send the documents not only by email but also as paper copy by registered mail. In view of the work associated with distributing paper documents by registered mail, the Committee agreed that the documents prepared by rapporteurs and experts shall become available for the Secretariat two weeks before the meeting ².

3. Declaration of interests

There were no specific interests declared.

4. Adoption of minutes of the previous meeting

The minutes of the first plenary meeting were adopted subject to incorporation of the changes proposed by the Committee.

5. General information from EFSA

EFSA's work programme

The Secretariat informed the Committee that it is preparing a document that will provide an overview of the requests for scientific advice by the Scientific Panels and Committee of the EFSA. The intention is to make this document available in the public domain on EFSA's website and to have it regularly updated.

² See also Art. 9 of Management Board Decision MB 17.10.2002 – 3 adopted (see: http://www.efsa.eu.int/pdf/decision_panels_mb_04_en.pdf): "Wherever possible, documents including reports and draft opinions prepared by a Rapporteur or external expert shall be available to the Members and external experts one week before the meeting."

Forthcoming events

The Committee was informed about the Colloque EFSA is organising in Ostend, Belgium, from 23-25 October. The main objective of this Colloque is to start a dialogue with its stakeholders. The chairs of the Scientific Panels and Committee have been invited to take part in this important event.

Media training

The Committee was also informed that EFSA is organising a media training for the chairs of the Scientific Panels and Committee. The first training (one day) is planned to take place on 30 or 31 October. A second training is foreseen in the spring of 2004.

6. Discussion of draft Commission guidelines for the preparation of requests for scientific opinions of the EFSA

The chair of the *Task Force on the draft Commission guidelines for the preparation of requests for EFSA scientific opinions* introduced a working document with a proposal of comments on the draft Commission guidelines for the preparation of requests for scientific opinions by the EFSA. The working document is meant to assist EFSA in the preparation of the Authority's comments on the draft guidelines to the Commission.

The Committee could agree with the document in general and proposed a few modifications in the working document.

The following general remarks were made:

- A European Workshop on the Interface between Risk Assessment and Risk Management will take place in Noordwijkerhout, The Netherlands, from 3 to 5 September (for details, see www.RA-RM.com). The Committee noted that the outcomes of this workshop could be relevant for a further consideration of the guidelines.
- The Committee noted that EFSA may need a similar guideline for the European Parliament, the Member States and for self-tasking. EFSA may wish to establish internal procedures for the way it will deal with these requests.
- The Committee expressed its willingness to give advice on how these procedures could be established and on appropriate criteria for prioritisation of the requests received by EFSA.

The Secretariat was asked to finalise the working document based on the modifications proposed by the Committee, to send it to the Executive Director of the EFSA on its behalf and to check EFSA's orientation on the issue indicated in the above reported second bullet point.

7. Discussion of a general format for scientific opinions of the EFSA

The Committee discussed a proposal of the EFSA Secretariat for a general format of scientific opinions of the Authority. During the discussions, the Committee reached general agreement on the following issues.

Comments on the proposed structure

The Committee had only minor comments on the structure of the opinion as proposed by the EFSA Secretariat. A scientific opinion of the EFSA must at least include the background and terms of reference of the request to the EFSA as provided by the client, it must include an assessment chapter (possible subheadings to be discussed by the Committee in a later stage) addressing the questions posed to the EFSA, how the information was evaluated and which issues were considered of key-relevance for the opinion. Furthermore, the opinion should include a section with the conclusions and, if any, the recommendations, and it should list the references and documentation made available to the EFSA on which the opinion was based.

Summary

The Committee agreed to include a summary that summarises which questions were addressed, which information was evaluated, the key issues that resulted to the opinion, and the conclusions and, if any, recommendations based on the assessment. The services of the Communications division will be available on a consultative basis to assist the Panels or Committee with the formulation of a summary that is informative for both the technical and non-technical reader. The Committee also agreed with the proposed approach that with the adoption of the opinion, the Panel or Committee would also automatically adopt the contents of the summary. The text of the English summary has to be considered as the definitive text; the French and German translations thereof should include a declaration that the English summary is the definitive text.

Listing of names of Members of the Scientific Panel/Committee

The Committee agreed that the opinion should contain a list of the members of the Scientific Panel/Committee. The opinion is considered to be a collective opinion of the Scientific Panel/Committee, but, for transparency reasons, the Committee agreed to include a list of the members in the opinion.

- The Committee concluded that it is unnecessary to precede the list of members by 'approved by'.
- Members that have a declaration of interest regarding this particular request, which excludes them from the adoption of an opinion, will be 'marked' with an asterisk. Information on the declarations of interest will be found in the minutes of the meeting, together with the names of any members that declared a possible interest but were considered able to participate in the discussions and adoption of the opinion. The Committee was informed that EFSA is preparing a code of conduct to provide guidance on how to declare an interest.
- The Committee discussed the situation when a certain member of the Scientific Panel/Committee would be unable to attend the meeting where the opinion will be adopted.

The Committee felt that it is unnecessary to draw a rule for this situation as the opinion of this particular member can always be expressed before the plenary meeting will take place.

- In case of a minority opinion, the Scientific Committee referred to the common rules of procedure (see also Article 19 of Decision MB 17.10.2002 – 3. adopted³): “The opinions of the Scientific Committee and Panels within the meaning of Article 29 of the Regulation, shall include any minority opinions. Minority opinions shall be attributed to their authors and shall include supporting argumentation.”
- The legal officer of EFSA declared that listing names of members or experts will cause no problems of individual liability as the legal responsibility will remain with EFSA provided that it concerns the work done by the members on EFSA's behalf.

Acknowledgement of preparatory work of ad-hoc experts

In case a Scientific Panel or Committee wished to acknowledge the preparatory work of ad-hoc experts, the Committee agreed to include a separate section (acknowledgement) with a list of names of ad-hoc experts that contributed to the preparation of the draft opinion. The Committee advised to include this section immediately after the list of names of the members. It was felt unnecessary to repeat names of Scientific Panel or Committee members in case they were also member of the expert group that prepared the draft opinion.

Publication of reports

The Committee noted that reports of working groups can also be published. The proposal was however only dealing with a general format of scientific opinions and not with a general format of reports.

Follow-up

As to the general format of opinions, the Committee agreed on the following steps:

- Secretariat to revise the proposed format on the basis of the modifications proposed by the Committee.
- To send this revised document as an advice of the Scientific Committee to the Executive Director of the EFSA for comments. In case the Executive Director could not agree with the proposed format it wished to re-discuss the general format in the presence of the Executive Director at its next plenary meeting.
- To distribute the updated version to all Panels and the Committee as a starting point for the preparation of their opinions.

Reconsideration of the format for opinions

The Committee noted that it could not spend any time on a further harmonisation of the contents of the assessment chapter at this stage. It wished to come back to these details of the general format of opinions at a later stage.

³ See: http://www.efsa.eu.int/pdf/decision_panels_mb_04_en.pdf

The Committee requested to be informed as soon as possible when a new EFSA opinion will be published on the internet. The Secretariats of the Scientific Panels will be asked to inform the Committee members via the Secretariat in case a new opinion has been released.

8. Discussion on ‘non-nutritional components’ of European diets

The Chair of the Task Force informed the Committee that a working document is being prepared about ‘non-nutritional components’ in the diet. These ‘non-nutritional components’ are consumed by a large portion of the European population and there is no legislation established yet. The working document was not yet ready for distribution because the Task Force wished to have more time for discussion.

The Commission services explained the legal framework for this category of products. The experts requested the Commission to prepare a written document explaining the legislative framework to allow the experts to continue with the preparation of a background document. This background document could then be considered by the Committee at a future plenary meeting taking into account:

- a specification of the products concerned
- an overview of the legislation in this area
- the current situation
- whether or not there is reason for concern, taking into account information provided by the national food authorities and information provided by the Commission
- possible options for how the Committee could proceed its considerations.

The Committee was informed that ILSI Europe had organised a Workshop on Principles for the Safety Assessment of Botanicals and Botanical Preparations in Food and Food Supplements in Marseille from 13-15 May 2002⁴. The Secretariat was requested to contact ILSI to have access to the documents resulting from this workshop.

9. On a generic approach to the safety assessment of micro-organisms used in feed/food and food/feed production – Discussion of further steps in relation to a working document produced by a Joint SCAN/SCF/SCP Working Group and the comments on it received by the Commission

The Committee considered a working document produced by a Joint Working Group of the former Commission’s SCAN, SCF and SCP proposing a new approach for the safety assessment of micro-organisms in food/feed and food/feed production (referred to as ‘Qualified Presumption of Safety’ or QPS⁵). This working document was put on the websites of the former SCAN, SCF and SCP with

⁴ See <http://www.ilsa.org/file/ILSIEurope-Newsletter47.pdf>

⁵ See http://europa.eu.int/comm/food/fs/sc/scf/out178_en.pdf

a request for comment by June 30, 2003. The Secretariat distributed a compilation of the comments as received by DG SANCO until the end of June as a separate document.

The working document was explained by Dr. Chesson who chaired the former Joint SCAN/SCF/SCP working group. Based on the discussions of the possible ways this issue could be taken up by the Committee, the Committee requested Dr. Chesson and the Secretariat to prepare a note for the Scientific Committee to explain the situation and the potential of the proposal, including a clear outline of possible consequences for the existing legislation. Scientific Committee will then decide if it wishes to send a proposal for inclusion in EFSA's work programme to the EFSA Executive Director. Once the EFSA Executive Director could approve its inclusion on EFSA's work programme, the Secretariat will prepare a mandate for the Scientific Committee for further consideration of the QPS document.

10. Matters arising since the previous meeting

The Committee was informed about the following matters arising since the first plenary meeting:

- *EFSA's responsibility with respect to 'water'.* At the first plenary meeting it was requested to clarify EFSA's responsibilities with respect to water. According to Regulation 178/2002⁶, food has been defined to include drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. The Commission services informed the Committee that DG Environment is responsible for the Community legislation with respect to drinking water. The Standards set in Directive 98/83/EC on the quality of water intended for human consumption are generally based on WHO guidelines and opinions of the Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment. Whenever it is concerning Community legislation in the area of natural mineral water, however, it is DG SANCO having the legal responsibility. In case scientific advice is needed in the area of natural mineral water, DG SANCO would pose its requests for scientific advice to the EFSA.
- *Advice from the Scientific Committee on EFSA's crisis management plan.* The Secretariat requested the Committee to advise on draft documents produced by DG SANCO and by EFSA in the area of crisis management. The Committee agreed to create a Task Force to prepare a working document with advice from the Scientific Committee on EFSA's crisis management plan for discussion at the next plenary meeting of the Scientific Committee (see agenda item 11.3).
- *Exchange of views on risk communication with the new Head of Communication.* The Secretariat informed the Committee that Anne-Laure Gassin has been appointed as the new Director of Communication at the EFSA and that she will take up her position in October.

⁶ REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

The Committee agreed with the proposal of the Secretariat to arrange a meeting with Ms. Gassin in the beginning of 2004.

- *How to handle BSE issues in the EFSA.* Bart Goossens, scientific co-ordinator of the Scientific Panel on Biological Hazards (BIOHAZ), explained the history and recent decisions on the handling of BSE issues in the EFSA. It is EFSA's intention to create a separate unit in EFSA and a working group of experts that will deal with the Geographical BSE Risk assessment (GBR). It is not foreseen to involve the Scientific Panels or Committee with activities in this area.

11. Work programme of the Scientific Committee

11.1 Feedback from Scientific Panels

The chairs of the Scientific Panels were requested to inform the Committee on activities in their panels and the working groups created under these panels. The Committee recognised that the same information will also be made available via the minutes of the plenary meetings of the respective panels. However, in case the panel identified a matter of more generic nature and wished to have this issue discussed with the members of the Scientific Committee, the panel chairs were invited to express this under this specific agenda item.

The following comments were made:

- The Secretariat was requested to provide an overview of risk assessment procedures in accession countries. The Secretariat will transfer this request to the Advisory Forum.
- There was a general need for (more) information on the priorities of the European Commission related to its requests for scientific advice.
- Different panels discussed the list of possible issues for further consideration by the Scientific Committee. The AFC and CONTAM panel also discussed the priorities of the various items. The consideration of genotoxic and carcinogenic substances was attributed a high priority.
- Various panels expressed the wish to have a discussion on procedures for the handling and prioritisation of 'own-initiative' requests ('self-tasking') (see also agenda item 11.2).

11.2 Discussion of possible issues for further consideration by the Scientific Committee

Draft procedure for 'own-initiative' requests ('self-tasking')

The procedures the Committee proposed for the consideration of a general guideline for the preparation of requests for scientific opinions of the EFSA (agenda item 6), the 'non-nutritional components' in the European diet (agenda item 8) and the consideration of the QPS document (agenda item 9) formed the basis of the Committee's request to EFSA to develop a standard procedure the Authority will apply for the handling of 'own-initiative' requests ('self-tasking', as laid down in Article 29(1)(b) of Regulation 178/2002 and Article 1(2) of Commission Regulation

1304/2003). The Secretariat proposed the following procedure for the preparation of 'own-initiative' requests (will be further explained at the 3rd plenary meeting of the Committee):

- For each plan to issue an 'own-initiative' opinion, a background document should be prepared containing a clear scientific argumentation, a draft mandate and an indicative time-frame (well justified in case of urgency). The background must include all relevant information which should allow EFSA to understand why the question has been raised. It must explain the scientific issue to be addressed and Community interest of the question.⁷
- The background document shall then be send to the EFSA Executive Director who will assess this task on the basis of the relevance, the resource impact and adequation with work priorities as set out in the work programme adopted by EFSA's Management Board. Where the request would significantly affect the work programme, prior consent from the Board would be required.
- Once approved by the EFSA Executive Director, the Secretariat will formally submit a request with a mandate to the appropriate Scientific Panel or Committee for further consideration.

In line with Article 1(2) of Commission Regulation 1304/2003, all own initiative opinions should be processed as any request for opinion (recorded in the register of requested and own initiative opinions, possibility to combine requests, deadline setting, level or urgency as appropriate) and others laid down in Article 29 of Regulation 178, which itself cross refers to the Board decision concerning the establishment and operations of the SC and panels (publication of the web, minority opinions, possibility for public consultation on preliminary opinions, technical hearings etc.; see Art. 17 and 18).

Selection of items to be included in the work programme of the EFSA Scientific Committee

The Committee was informed that EFSA is preparing an overview of the requests on which the various EFSA Panels are currently working. This will become a reference document for the different components of the EFSA (e.g. Management Board, Advisory Forum, Scientific Panels and Committee, EFSA staff) and will be publicly available on EFSA's website.

As to the work of the Scientific Committee, the work programme has not been established yet. For these reasons, the Committee agreed to select issues it wished to see on the current work programme of EFSA's Scientific Committee.

The Committee agreed that the following items can be considered as items on the work programme of EFSA Scientific Committee:

- Advice of the SC on a general format of opinions of the EFSA.
- Comments of SC on guidelines for preparation of requests for scientific opinions of the EFSA.
- Non-nutritional components of the EU diet.

⁷ This background document must meet essentially the same requirements as requests for EFSA scientific opinions prepared by the European Commission, the European Parliament or the Member States.

- Qualified presumption of safety.
- Consideration of genotoxic and carcinogenic substances.
- Emerging risks.
- Crisis management.

The other issues on the list were considered as possible issues for future consideration by the Scientific Committee.

11.3 Establishment of working groups

The Committee agreed to create a Working Group on Emerging Risks (EMRISK) to assist EFSA to build up a capacity to identify and evaluate emerging risks. The intention is to invite a consortium of experts to report to EFSA on a regular basis on possible emerging risks as a result of process changes (e.g. environmental, food and feed processing, consumer behaviour) that might affect the safety of the food chain. The Working Group will assist EFSA in preparing a tender for to be launched in October 2003 and to prepare procedures for EFSA for the evaluation of emerging risks. Committee members Professor Bo Jansson (chair), Dr. Pierre Le Neindre, Dr. Philippe Vannier, Professor John Daniel Collins and Professor Albert Flynn accepted the invitation from the Secretariat to join this Working Group.

The Committee also agreed to create a Working Group on a Uniform Approach for Genotoxic and Carcinogenic substances (GENTOX). Committee members Dr. Ada Knaap (chair) and Dr. Josef Schlatter agreed to become members of this working group. The chair of the GENTOX working group proposed to prepare a preliminary framework with a proposal of experts to be invited for further discussion at the 4th plenary meeting of the SC and asked the chairs of the Scientific Panels to verify a possible representation from their Panels in this working group. The task should not be done in isolation. It is therefore foreseen to invite experts from SANCO's Scientific Committees dealing with non-food issues and to create a link with similar platforms of other international organisations (e.g. WHO/FAO, ILSI, United States EPA and FDA). The Committee is aware that due to the complexity of the issue this working group may need at least a year to complete its work.

Finally, the Committee agreed to create a Working Group on EFSA's crisis management plan. Committee members Dr. Pierre Le Neindre and Professor Tito Fernandes accepted the task to join this Working Group. The Working Group proposed to prepare comments on a draft crisis management plan of the Commission and a first response of the EFSA for further discussion at the 4th plenary meeting of the Committee.

12. **Any other business**

Some members seem to receive all kinds of questions from the press, the industry and other organisations related to the work of the EFSA. The Committee agreed with the proposal of the Secretariat that these questions should be addressed to the Communications division (questions from the press or other organisations) or to the Secretariat (questions from industry) of the respective Scientific Panel or Committee of the EFSA.