



Brussels, 17 October 2003
EFSA/SC/16 Final

**MINUTES OF THE 3RD PLENARY MEETING
OF THE EFSA SCIENTIFIC COMMITTEE
HELD ON 17 AND 18 SEPTEMBER 2003**

(ADOPTED BY WRITTEN PROCEDURE ON 17 OCTOBER 2003)

Participants

Scientific Committee (SC):

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

European Food Safety Authority (EFSA)

Geoffrey Podger (Executive Director)¹, Djien Liem (scientific co-ordination SC), Marie-Noëlle Costa (administration SC), Pilar Rodriguez-Iglesias (scientific co-ordination NDA Panel), Helen Kinghan (Communications division)²

European Commission (EC)

Michael Walsh (DG SANCO/Unit D5 - Relations with the EFSA)

1. Welcome, apologies for absence

The chair opened the meeting and welcomed the participants. Apologies for absence were received from Dr. Ada Knaap.

2. Adoption of the agenda

The Committee agreed with the proposal of the Secretariat to reserve some time in the morning of the 18th of September allowing Task Forces and Working Groups of the Committee to have a short

¹ Present on 17 September

² Present on 18 September

meeting to discuss further steps in relation to their activities. It also agreed to insert an agenda item 6* to agree on items for discussion at the next plenary meeting of the Committee. The agenda was adopted with these changes.

3. Declaration of interests

There were no interests declared.

4. Adoption of minutes of the previous meeting

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

5. Matters arising since the previous meeting

5.1 Feedback from Scientific Panels³

The chair invited the chairs of the panels to give feedback on matters arising in the panels that they wished to raise in the Scientific Committee.

- The chair of the AFC panel informed the Committee about the large number of substances to be evaluated by the panel and mentioned two new draft proposals for legislation carrying additional implications for the panel. The proposal on additives would require the re-evaluation of all currently authorised additives, and the other would require the evaluation of all enzymes used in human food. In the area of chemically defined flavouring substances, preparatory work is carried out by an external expert group. It is foreseen that it will now be necessary to use external experts and institutes for the preparatory work on other parts of the work programme of the panel.
- EFSA organised a meeting of an Ad-hoc Expert Group of the AFC panel in July to consider the possible occurrence of semicarbazide (SEM) in packaged foods. The Expert Group noted uncertainties in both the analytical and toxicological aspects and was therefore not in the position to give scientifically based risk assessment advice on the possible occurrence of semicarbazide in foods in contact with food packaging gaskets⁴.

Industry will be considering further studies to confirm or otherwise the presence of SEM and to determine the scope for minimising the potential risk. EFSA itself has initiated short

³ **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;

⁴ See: http://www.efsa.eu.int/pdf/p_afc_doc_01.pdf

term genotoxicity studies as, in the view of the ad-hoc group⁵, there are currently insufficient data to draw a conclusion.

- The chair of the FEEDAP panel informed the Committee on the extensive work programme of this panel. The chair was advised to investigate the possibility to subcontract parts of the work.
- The FEEDAP panel received requests to evaluate enzymes in animal context. The chair suggested it would be sensible to discuss the approach used by the FEEDAP panel with the AFC panel, since many of the enzymes in food and feed were the same.
- The chair of the PPR panel informed the Committee about the work programme and its working procedures. It was noted that many requests to the Panel originate from the ongoing peer review of active substance dossiers carried out elsewhere. However these requests are currently slow in coming through to the Panel's work programme.
- The chair of the PPR panel requested some guidance on the handling of new information submitted by the company during the final stages of the preparation of an opinion. In cases involving existing authorisations, the PPR panel was advised to keep the original timetable and to accurately describe which documentation was used as a basis for the opinion. New information could always constitute the basis for a further request to the EFSA to consider whether this information would lead to a change of its opinion. In cases involving new substances not yet authorised, it might be appropriate to defer the opinion until the new data were considered.
- The chair of the GMO panel indicated that an extensive number of GMO dossiers is in the pipeline; 8 dossiers should be dealt with in the coming 6 months. The preparation of an opinion on guidance notes for contained use of genetically modified micro-organisms is in progress and a Working Group on the use of antibiotic marker genes has initiated its activities. The chairman expressed concerns that other important own initiatives may become second priorities. The panel has developed a new working procedure and is considering the priorities for the different tasks to be fulfilled by the panel.
- The chair of the BIOHAZ panel explained that the panel has been given a very broad mandate and may therefore expect requests of varying nature. The Executive Director offered to investigate the situation together with the chair of the BIOHAZ panel and the Commission.
- The chair of the CONTAM panel asked whether it would be possible to start the activities of the Working Group (WG) on Exposure Assessment of the Scientific Committee as soon as possible. In the framework of an ongoing evaluation of organotin compounds, the panel identified a need to agree on a consistent approach of available data on the occurrence of substances in food and on the consumption of (categories of, items of) food in different geographical regions in Europe.

The Committee noted the importance to have a platform to agree on a consistent approach of the scientific information that is used for an exposure assessment by the EFSA panels

⁵ See: http://www.efsa.eu.int/pdf/pressrel20030728_en.pdf

and it therefore agreed to start the activities of the Exposure Assessment WG as soon as possible.

The Committee accepted Professor Bo Jansson's offer to become chair of the Exposure Assessment WG. Professor Jansson will prepare a draft mandate for further discussion at the plenary meeting in December and requested the chairs of the panels to propose experts with practical experience in exposure assessment to join the WG.

- The chair of the CONTAM panel requested the Scientific Committee also to increase its priority for probabilistic (exposure and effect) modelling in the risk assessment process (a subject assigned as an issue for future consideration by the Committee – *cf.* Minutes of the 2nd plenary meeting).

The Committee noted that certainties and uncertainties in probabilistic modelling will also be taken on board by its Working Group on a Uniform Approach for Genotoxic and Carcinogenic Substances (GENTOX) and that it may be better to wait until this working group could agree on a future approach for the EFSA. Until that time, panels are advised to use innovative approaches wherever this is appropriate and properly justified in the report.

- The chair of the CONTAM panel requested the members of the Committee to propose ad-hoc experts with a background in veterinary toxicology who could contribute to the work of the Contaminants Panel's Working Group on Undesirable Substances in Feed.
- The chair of the AHAW panel informed the Committee about the high workload on this panel. The panel considers the possibility to get support from national agencies.

5.2 Feedback from Task Forces/Working Groups

Task Force on 'Non-nutritional components' in the European diet

The Task Force had a meeting in the morning of September 18th. The chair of the Task Force informed the Committee about the wide-ranging discussions during that meeting. The Task Force agreed to use the existing draft (not yet circulated) as a starting point for the preparation of a background document for further discussion at the plenary meeting in November. After a discussion of the background document in the plenary, the Committee may wish to decide whether or not the issue is sufficiently defined to prepare scientific advice.

Working Group on Emerging Risks (EMRISK)

The Working Group had a meeting in the morning and the afternoon of September 18th. The chair of the Working Group informed the Committee that a first important step might be to identify the experts/research groups/networks that could assist EFSA in building its capacity in the identification and evaluation of emerging risks. The WG discussed different ways (e.g. contracting a consultant, organising a workshop) to achieve this and plan to agree on an appropriate strategy at an extended meeting after the plenary meeting of the Committee. The intention is to assist EFSA in the preparation of a tender to be launched in October and to prepare a background document for further discussion at the plenary meeting in November.

Working Group on a Uniform Approach for Genotoxic and Carcinogenic Substances (GENTOX)

In the absence of the chair of this Working Group, the feedback was given by Josef Schlatter. The composition of this working group is not yet established and the chairs of the panels that did not reply so far were reminded to nominate experts from their panels to join this working group. The chair of the Working Group is also seeking participation from external experts.

The intention is to prepare a background document with a draft terms of reference for further discussion at the plenary meeting in November. Documents that were considered by a working group of the former SCF in 2002 could serve as a starting point for the preparation of the background document.

Working Group on EFSA's Crisis Management Plan

The chair of the Working Group introduced a preliminary draft of a background document dealing with the possible ways that the EFSA Scientific Committee/Panels could be of help in a crisis situation. During the discussions, the following remarks were made:

- The EFSA Executive Director expressed his gratitude to the Working Group that prepared this document, because it will help the development of crisis management plans of EFSA and the Commission.
- The ability to detect weak signals occurring before the development of the crisis and rapid response were considered to be essential.
- The Executive Director intends to create a *permanent emergency response unit* in EFSA to be reinforced in the case of a crisis. The filtering of alerts and rapid responses could form a regular task of this unit.
- EFSA should be able to handle a crisis since its start and would probably need to develop a mechanism to reach at very short notice all necessary experts. .
- In the case of a food/feed crisis, EFSA may be requested to provide a very quick risk assessment, to give advice on analytical methodologies to be applied during the crisis or to evaluate risks associated to different management options. Under such conditions, it should be possible to abandon the usual panel-opinion-adoption-system and to invite an ad-hoc expert group to provide the required scientific advice.
- The *risk communication* role of the EFSA will be carried out according to a pre-defined and tested procedure that takes into account typical features of crisis situations.
- In order to develop adequate contingency planning procedures it might be valuable to verify historical cases for existing experience in crisis management.

The Working Group on EFSA's Crisis Management Plan was requested to revise the working document on the basis of the outcome of the discussions. The EFSA's Executive Director noted that the working group may expand its mandate to "what should EFSA do in case of a food or feed crisis". The Committee agreed to discuss a revised working document at the plenary meeting in November.

5.3 General information from EFSA

EFSA's Work Programme

The Committee discussed the Draft Work Programme of the Scientific Committee and the Panels that was prepared for the Management Board (MB) meeting of 16 September 2003 (version MB 16.09.2003 – 7 ANNEX II). Several members expressed the wish to check the way the current information is presented with respect to the names of the substances to be evaluated, the description of requests and the way the year of demand and expected date of completion have been specified.

The Secretariat proposed that the chairs and the scientific co-ordinators of the panels will check the contents of the work programmes for each of the panels individually. At a later stage, EFSA will try to produce a document containing the work programmes of all Scientific Panels and Committee.

Feedback from the Management Board meeting of 16 September 2003

The EFSA Executive Director presented the outcomes of the Management Board meeting of 16 September focusing on issues that could be relevant for the Scientific Committee and the Panels.

- The EFSA is preparing media handling guidelines to provide agreed guiding principles between EFSA and the Scientific Committee and Panels. They reflect the general commitment to openness, to the clear communication of scientific findings and to providing a proper level of support to the independent members of the Scientific Committee and Panels. The document in preparation will be submitted for discussion at the plenary meeting in November.
- The chairs of the Scientific Panels were requested to indicate to EFSA if the panels would need additional expertise in a specific area. EFSA intends to launch a call for additional experts in case the chairs would identify such a need. In case an additional call for experts will be launched, it will provide an opportunity to address the geographical and gender balance issues that were raised in the meeting of the Management Board of 29 April 2003.
- The Management Board discussed developments in the area of staffing. Since the beginning of 2003, the staff of EFSA has more than doubled in size to around 50 people. The planned size in 2004 will be around 140 and a further growth until 200-300 is foreseen by the end of 2005. This estimate is based on the requirements in the present Regulation and takes no account of further work which may be allocated to EFSA.

Minutes of Scientific Committee and Panels

The Committee agreed with a request of the Executive Director to get agreed minutes of plenary meetings on EFSA's website within a month of the meeting. The Committee proposed the following procedure for the Scientific Committee:

1. Secretariat to distribute a first draft of the minutes within one week of the meeting,
2. Members to comment within two weeks after the day of distribution, and
3. Members to comment on a revised draft within one week of its distribution.
4. EFSA to publish the final version on its website.

EFSA Colloque

The chair invited Helen Kinghan to explain the objectives and the programme of the first EFSA Colloque with its stakeholders that will take place in the Andromeda Hotel in Ostend from 23-25 October 2003. The programme aims to draw out some EFSA's actions expected from the consumers and industry and possible inputs and interactions with different stakeholders. The invited people include consumer and industry representatives, the chairs of the Scientific Committee and Panels, Commission representatives and EFSA staff.

5.4 Action list of the Scientific Committee

The Committee discussed an updated the action list distributed by the Secretariat. The following agreements were made:

- *Requests for EFSA scientific opinions by the European Parliament and EU Member States.* The Task Force on Guidelines for the preparation of requests for EFSA opinions has completed its work related to the draft guidelines of the Commission. The Committee agreed on a final text of the letter to the Executive Director with comments of the Committee on the draft guidelines. The Secretariat will send the letter to the Executive Director for further consideration.

As a follow-up, the EFSA requested the Committee, with the help of the Task Force, to assist in the preparation of guidelines for the preparation of requests for scientific opinions of the EFSA for the European Parliament and EU Member States.

- *Qualified Presumption of Safety.* Dr. Chesson offered to prepare a background document for the November plenary of the Scientific Committee, based on the discussions during the August meeting of the Committee.
- *Liability.* As declared by the legal officer of EFSA at the previous meeting, the listing of names of members or experts in opinions will cause no problems of individual liability. The members requested EFSA to send to all members and experts of the Scientific Panels and Committee a letter in which the liability issue is clearly explained.

6. Interface between Risk Assessment and Risk Management – Feedback from a European workshop held in The Netherlands from 3-5 September 2003

The Scientific Co-ordinator informed the Committee about the European Workshop on the Interface between Risk Assessment (RA) and Risk Management (RM) that was held in Noordwijkerhout from 3-5 September 2003.

The main objectives of this EC funded workshop were to identify obstacles to the appropriate interfacing of RA and RM in decision-making and to recommend ways of improving the interface between RA and RM, including novel scientific approaches and the research required to develop them. The workshop was primarily focused on risk assessment issues relevant to the EFSA but the

findings may also be applicable to other areas of decision-making, including all types of health and environmental risks.

The workshop was attended by 95 participants from various European countries, from the United States EPA and FDA, and from ILSI, WHO, the Commission and the EFSA. Participants included scientists, and decision-makers experienced in working at the interface of science and policy on the national and international level. The workshop was attended by members of EFSA's Management Board, the Scientific Committee and the Panels, and the scientific co-ordinators of EFSA.

It is the organiser's intention to publish the outcomes of the workshop in a scientific journal. This will comprise a range of issues considered during the workshop such as general principles and approaches for appropriate interaction between RA and RM, potential difficulties to implementation of the proposed approaches, and future research priorities.

The Committee noted that the outcomes of the workshop could be relevant for the establishment of general working procedures of the EFSA. It therefore agreed on the following actions:

- To invite Dr. Andy Hart, organiser of the workshop, for the plenary meeting of the Scientific Committee in November to give a presentation of the main outcomes of the RA-RM workshop;
- To circulate the draft report of the workshop once it will become available;
- To prepare a reflection document about the possible relevance of issues raised during the workshop for the EFSA. Dr. Anthony Hardy and Dr. Pierre Le Neindre offered to take the responsibility to prepare such a reflection document for the December plenary of the Committee.

6* Agenda items for the next plenary meeting

Based on the plenary discussions, the Secretariat identified the following agenda items for a future plenary meeting of the Scientific Committee: (aside from regular agenda items)

- Working Group on Exposure Assessment - Discussion of a background document with a draft mandate for the WG (December)
- Working Group on a Uniform Approach for Genotoxic and Carcinogenic Substances (GENTOX) - Discussion of a preliminary outline and a proposal of experts to be invited to join this WG (October/November)
- Working Group on Emerging Risks (EMRISK) – Discussion of a background document with a draft mandate for the WG (November)
- Working Group on EFSA's Crisis Management Plan – Discussion of a revised working document (November)
- Task Force on Guidelines for the preparation of requests for scientific advice from EFSA – Discussion on general guidelines (timing to be discussed)
- Task Force on 'Non-nutritional components' in the European diet – Discussion of a background document prepared by the Task Force (November)

- EFSA's Work Programme – Feedback from the Scientific Panels on the harmonisation of the presentation of items in the work programme of the Scientific Panels (November/December)
- European Workshop on the Interface between Risk Assessment and Risk Management – Main outcomes and relevance for EFSA (November/December)
- Qualified presumption of safety – Discussion of a background document (November)
- Media Handling Guidelines for the members of the Scientific Panels and Committee (November)

As there were no background documents becoming available for the plenary meeting of October, the Committee decided to cancel the plenary meeting of 15-16 October and defer all agenda items to the plenary meeting of 19-20 November. In view of the number of agenda items the Secretariat proposed to extend this plenary meeting to a full 2-day meeting.

7. Any other business

The Secretariat was informed that there are problems to properly access certain pages on the science domain on EFSA's website and was asked to check whether this could be solved. The Secretariat explained that EFSA is working on a new website that will be launched in the autumn of this year.