European Food Safety Authority

Brussels, 10 December 2003
EFSA/SC/30 FINAL

MINUTES OF THE 4TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 19 AND 20 NOVEMBER 2003

(adopted by written procedure on 10 December 2003)

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, Andrew Chesson, John D. Collins, Tito H. Fernandes[1], Albert Flynn, 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), Philippe Vannier and Josep Vives-Rego

Representatives:
Jeremy B. Sweet (GMO panel)

Experts:
Andy Hart (Central Science Laboratory, York)

European Food Safety Authority (EFSA):
Anne-Laure Gassin (Director of Communications), Herman Koëter (Director of Science), Geoffrey Podger (Executive Director), Marie-Noelle Costa (administration SC) and Djien Liem (scientific co-ordination SC)

European Commission (EC):
Achim Boenke[1] (DG Research/E2 – Food Quality), Louis Bouthors (DG Enterprise/Unit F4 – Food Industry), Patrick Deboyser[1] (DG Health and Consumer Protection/Unit D4 - Food Law and Biotechnology), Basil Mathioudakis[1] (DG Health and Consumer Protection/Unit D4 - Food Law and Biotechnology) and Michael Walsh (DG Health and Consumer Protection /Unit D5 - Relations with the EFSA)

[1] Present on 20 November

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies for absence were received from Harry Kuiper. Jeremy Sweet was present on behalf of the GMO panel.

2. INTRODUCTION OF HERMAN KOËTER, DIRECTOR OF SCIENCE AND DEPUTY EXECUTIVE DIRECTOR, AND ANNE-LAURE GASSIN, DIRECTOR OF COMMUNICATIONS

The Chair welcomed Herman Koëter and Anne-Laure Gassin and invited them to introduce themselves.

3. ADOPTION OF THE AGENDA

The Chair proposed to re-order the agenda items. The agenda was adopted with the proposed re-arrangement of items.

4. DECLARATIONS OF INTEREST

There were no interest declared.

5. FEEDBACK FROM SCIENTIFIC PANELS [2]

The Chair invited the Chairs of the panels to give feedback on matters arising in the Panels that they wish to raise in the Scientific Committee. The reports were as follows:

AFC

- The Chair of the AFC Panel gave an update on the semicarbazide issue. EFSA has been requested to provide a full risk assessment on semicarbazide from all sources.

AHAW

- The Chair of the AHAW Panel reported on the requests for scientific advice it had received from the Commission.
- The Chair and the scientific co-ordinator of the AHAW Panel will meet the Director of OIE (Office International des Épizooties) in December to exchange views on activities of common interest.

[2] 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

- For some of the questions, the AHAW Panel will collaborate with the BIOHAZ Panel. The Committee requested the EFSA Secretariat to provide proposals on general guidance for the handling of issues within the competence of more than one Scientific Panel.

BIOHAZ

- The Chair of the BIOHAZ Panel re-iterated previous statements that the BIOHAZ Panel deals with a wide range of questions, and expressed concerns about the growth of risk management issues to be handled by the Panel. These developments will be discussed at the next plenary meeting of the BIOHAZ Panel on 26-27 November.

CONTAM

- The Chair of the CONTAM Panel reported on a self-tasking issue the Panel wishes to take into consideration. The issue concerns the assessment of possible health risks of dietary exposure to perfluorinated octane sulphonates (PFOS). This issue may need collaboration with the AFC Panel. The Panel will prepare a draft mandate which will be sent to EFSA for further consideration.
- The Chair of the CONTAM Panel requested that the Secretariat pay attention to a careful preparation of the terms of reference of requests for scientific advice put to EFSA in order to prevent the Authority entering the area of risk management.

FEEDAP

- The Chair of the FEEDAP Panel addressed a few problems related to ongoing product-specific evaluations of coccidiostats. The Panel was confronted with dossiers from different companies with different information for similar properties. This has led to problems during the assessment. The EFSA secretariat requested the concerned companies whether they are willing to share the scientific data. The Secretariat is looking into the legal aspects of these problems in collaboration with the Commission services.

GMO

- The Vice-Chair of the GMO Panel addressed the problem of the imposed time-frames for the delivery of opinions. He reported that the GMO Panel will be dealing with a wide variety of questions, the scientific nature of which may pose a big challenge for the Panel in the forthcoming period.
- The Vice-Chair of the Panel reported also on 'self-tasking' issues that are currently considered by the Panel.
- The Committee was informed about the outcomes from the farm scale evaluations (FSE) of spring sown genetically modified crops to assess the potential implications of large scale growing of GMHT crops on farmland biodiversity. The findings of the FSE have been published in a special issue of *Philosophical Transactions of the Royal Society*.
- The Committee was informed that the general procedures for risk assessment, as described in some GMO related regulations, include a public consultation during the assessment period which is already subject to tight time constraints.

NDA

- The inclusion in new legislation of questions for EFSA, together with deadlines, could have a significant effect on the work programme of EFSA's Scientific Panels. EFSA needs to be aware of the inclusion of such questions when legislation is being adopted

PPR

- The Chair of the PPR Panel informed the Committee about recent opinions adopted by the Panel. In one case, a cascade of new information had been submitted by Industry during the final stages of the evaluation. EFSA had agreed that late submitted data would not be taken into consideration.
- The Chair expressed concerns about the very tight deadlines set in the framework of evaluations of existing and new pesticide formulations.

6. CO-ORDINATION WITH OTHER SCIENTIFIC COMMITTEES

Sue Barlow informed the Committee about her participation in an expert working group of the Commission's Health and Consumer Protection DG, which is charged with the preparation of a draft opinion for the SCTEE (Scientific Committee on Toxicity, Ecotoxicity and the Environment) on a BUAV-ECEAE [3] report entitled 'The way forward - Action to end animal toxicity testing'. A draft was discussed at the plenary meeting of the SCTEE on 12-13 November and adoption of the final opinion is expected before the end of 2003.

7. WORKING GROUP ON EXPOSURE ASSESSMENT – DISCUSSION OF A BACKGROUND DOCUMENT

The Committee discussed a draft mandate which was prepared by Bo Jansson and Philippe Verger. The Committee approved the proposed mandate subject to incorporation of a few changes proposed by the Committee. The proposed mandate will be sent to the Executive Director with a request to include the proposed activity in EFSA's work programme.

8. WORKING GROUP ON A HARMONISED APPROACH FOR GENOTOXIC AND CARCINOGENIC SUBSTANCES – DISCUSSION OF A BACKGROUND DOCUMENT

The Committee discussed and approved the draft mandate prepared by Ada Knaap and Josef Schlatter. The proposed mandate will be sent to the Executive Director with a request to include the proposed activity in EFSA's work programme.

[3] BUAV-ECEAE: British Union for the Abolition of Vivisection – European Coalition to End Animal Experiments

9. WORKING GROUP ON EMERGING RISKS - DISCUSSION OF A BACKGROUND DOCUMENT

The Committee discussed a background document prepared by the Working Group on Emerging Risks. The document proposes a number of actions that EFSA could consider in developing and implementing its strategy for the detection, identification and evaluation of emerging risks.

The Committee noted that EFSA's role in the area of emerging risks may require the Authority to commit substantial resources, including scientific staff, the national food authorities assembled in EFSA's Advisory Forum.and expertise from the Scientific Committee and Panels.

The Chair requested Bo Jansson to revise the document based on the suggestions provided by the Committee. The Committee agreed to discuss an updated background document at the next plenary meeting.

10. WORKING GROUP ON EFSA'S CRISIS MANAGEMENT PLAN – DISCUSSION OF A BACKGROUND DOCUMENT

Pierre Le Neindre and Tito Fernandes presented a draft document which described how the Authority might handle a food or feed crisis. In the document, it is proposed that EFSA should create a crisis unit to analyse signals, prepare emergency plans, evaluate experiences and liaise efficiently with experts of the Scientific Committee and Panels, national authorities and other relevant international organisations. The Committee noted that there is a clear link between the Authority's capability to prevent or handle a crisis and its capability to identify/evaluate emerging risks.

The Committee noted that crisis management is primarily the responsibility of the Commission, but that they should operate in close co-operation with the Authority and the Member States (*cf.* Articles 55 and 56 of EFSA's founding Regulation 178/2002). In Article 56 of EFSA's founding Regulation, it is stated that, should a crisis situation occur, the Commission shall set up a crisis unit in which the Authority shall participate.

The Committee was informed that a draft of the Commission's general plan for crisis management has been sent to the Member States. The Secretariat will distribute the document to the members of the Committee.

The EFSA Executive Director appreciated the document prepared by Pierre Le Neindre and Tito Fernandes and explained that their recommendations are in line with EFSA's plans. The Committee agreed with the Executive Director's proposal to bring the document to the attention of EFSA's Advisory Forum at its next meeting in December.

11. 'NON-NUTRITIONAL COMPONENTS' IN THE EUROPEAN DIET – DISCUSSION OF A BACKGROUND DOCUMENT

Introduction

The Committee discussed a draft background document prepared by Andrew Chesson and Vittorio Silano. The document describes the need for a better understanding of the nature of different categories of products presently marketed in the EU as food supplements and related products. This includes vitamins and minerals, as well as some other substances of natural or synthetic origin, such as herbal preparations with medicinal claims obtained from plants, or parts of plants, by various processes. Although several pieces of Community legislation have already been developed and implemented, concerns are raised in the document about the possible health risk of high intake of certain herbal products which may be contaminated with heavy metals, synthetic drugs and other undesirable substances or toxic substances naturally occurring in certain plants. As a first step, the authors suggested, among other things, the development of an inventory with the help of the competent authorities in Member States and the different stakeholders.

Discussion

The Committee discussed how EFSA could take up this issue. The Committee members agreed that there are potential health related problems in this area. It was also considered important to distinguish between the issues associated with improved controls and risk management and those related to risk assessment. The Committee was informed about the activities of a Council of Europe group on food supplement safety.

The Commission services provided an update of the latest developments in the legislative area, including recent discussions in the Standing Committee on the Food Chain and Animal Health, the fortification regulation and possible future changes in the food supplements Directive and the novel food Regulation.

The Commission services proposed that EFSA should consider the possibility of providing more guidance to petitioners with respect to the data required for safety assessment of such products. They also suggested looking at certain naturally occurring substances which are normally present only at low levels in the diet, but which pose a potential health hazard once they are extracted and marketed in concentrated forms.

The EFSA Executive Director proposed the following steps to the Committee: 1) to publicise this issue to inform consumers that there might be a problem; 2) to take this document to the Advisory Forum; 3) to further advise the Commission on possible implications of the legislative developments from a public health point of view; 4) to consult the Member States on whether it would be helpful for EFSA to develop generic guidelines on how to assess products in this category.

Follow-up

- The Committee requested that the authors update the background document, taking into account ongoing developments in the regulation on food fortification, including new steps in risk assessment, on-going amendments in the non-GM novel food regulation and properly take

into account associated issues being addressed by several EFSA Panels. The Chair invited all participants to provide additional input to this document.

- The Committee agreed to discuss an updated version of the background document at its next plenary meeting.
- Once the Committee has approved the document, it will constitute the basis of the Committee's scientific advice to EFSA, and it will then be brought to the attention of the Advisory Forum (AF).

12. QUALIFIED PRESUMPTION OF SAFETY – DISCUSSION OF A BACKGROUND DOCUMENT

The Committee considered an explanatory note to accompany the working document on the proposed qualified presumption of safety, which had been prepared by a joint working group of the former SCAN, SCF and SCP, and which had been published on SANCO's website for public consultation in June 2003.

The Committee agreed to request the above-mentioned mandate to continue with the consideration of the proposed qualified presumption of safety taking into account the comments received during the public consultation of the document. It also requested that the EFSA Secretariat and the Commission's Interface Unit ask for input from the Commission's competent services on the proposed safety assessment approach.

13. INTERFACE BETWEEN RISK ASSESSMENT AND RISK MANAGEMENT – FEEDBACK FROM A EUROPEAN WORKSHOP HELD IN THE NETHERLANDS, 3-5 SEPT 2003

13.1 Main outcomes of the workshop

The Scientific Committee invited Andy Hart of the Central Science Laboratory in York to present the preliminary outcomes of the European Workshop on the Interface between Risk Assessment and Risk Management that took place in Noordwijkerhout, The Netherlands, from 3-5 September 2003. In his presentation, the principles and approaches identified by the workshop participants to improve the interface between risk assessment and risk management were summarised. The results of the workshop will be published in a report which will be made available at www.ra-rm.com.

The Committee appreciated Andy Hart's presentation, which gave very helpful background information for both risk assessors and risk managers, and the Committee discussed the principles and approaches proposed. While the Committee had some reservations about the applicability of some of the principles in all circumstances, it was considered of utmost importance to reach agreement on a common language to be used by the risk assessor and the risk manager.

13.2 Possible issues for further consideration by the EFSA

Tony Hardy introduced a working document, which he had jointly prepared with Pierre Le Neindre, on the implications of the RA-RM Interface workshop for the EFSA. The Committee agreed that the paper could provide a basis for further in-depth consideration by the Scientific Committee and Panels.

The Committee agreed with the suggestion of the EFSA Director of Science that the EFSA Secretariat should prepare a proposal based on the workshop report for further consideration by the Scientific Panels and then by the Scientific Committee. The results of these individual discussions will be considered further by the Committee at a future meeting.

The Committee noted that some scientific advisory committees issued glossaries of terms to be used in the area of risk analysis. The EFSA Secretariat will circulate some of these documents at the next plenary meeting of the Scientific Committee.

14. GENERAL INFORMATION FROM EFSA

14.1 The EFSA Executive Director presented a set of draft guidelines which should be observed when talking to the media.. The Committee members proposed a few modifications to clarify the text. The final version of the 'Media Handling Guidelines for the Scientific Committee and Panels' will be published on EFSA's website.

14.2 The Committee was informed that a central EFSA telephone number had been published on the Authority's website. Members were advised that, when contacted by the media on matters relating to the work of EFSA, the contact person should be referred to the EFSA Communications Division.

15. ANY OTHER BUSINESS

Calendar 2003
The Committee agreed to cancel the December plenary because there are no issues expected to be ready for discussion at this meeting.

Calendar 2004
The Committee agreed with the Chair's proposal to hold bi-monthly plenary meetings, and to keep other dates reserved as *provisional* so that ad-hoc plenary meetings could be held when necessary.

- The bi-monthly meetings will take place on: 14/15 January, 17/18 March, 12/13 May, 27/28 July, 13/14 October and 15/16 December.
- Provisional dates include: 14/15 April, 16/17 June, 15/16 September and 17/18 November.