European Food Safety Authority

Brussels, 11 February 2004
EFSA/SC/42 FINAL

MINUTES OF THE 5TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 15 JANUARY 2004

(adopted by written procedure on 10 February 2004)

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, John D. Collins, Tito H. Fernandes, Albert Flynn, Anthony R. Hardy, Ada G.A.C. Knaap (Vice-Chair), 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):
Anne-Laure Gassin (Director of Communications), Herman Koëter (Deputy Executive Director and Director of Science), Geoffrey Podger (Executive Director), Christine Majewski (International & Institutional Affairs), Marie-Noëlle Costa (Administrative Secretary of the SC) and Djien Liem (Scientific Co-ordinator of the SC)

European Commission (EC):
Elena Sachez Cuadrado (DG Research/E1 – Strategy and Policy), Antonio di Giulio (DG Research/E2 – Food Quality) and Michael Walsh (DG Health and Consumer Protection /Unit D5 - Relations with the EFSA)

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies for absence were received from Andrew Chesson and Bo Jansson.

2. ADOPTION OF THE AGENDA

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

3. DECLARATIONS OF INTEREST

There were no interests declared.

4 MATTERS ARISING SINCE THE LAST PLENARY MEETING OF 19-20 NOVEMBER 2003

4.1 General feedback in relation to EFSA's move to Parma and meetings of the Management Board and the Advisory Forum in December

EFSA's move to Parma

The Executive Director informed the Committee about the latest developments in relation to the Authority's move to Parma. A delegation of EFSA will meet with the Italian Authorities on 16 January to discuss plans with respect to office and meeting accommodation as well as possible provisions for EFSA staff in the region of Parma.

Management Board meeting of 3 December 2003

The Committee was informed about the discussions of EFSA's Draft Management Plan for 2004 during the meeting of the Management Board of 3 December. The Draft Management Plan provides an overview of objectives for the Authority for 2004 and includes a comprehensive part describing the scientific work to be carried out by the Scientific Panels and Committee with support of the Scientific Expert Services Department of the Authority. The Board considered the Management Plan as very comprehensive and ambitious, but expressed some concerns about the feasibility of the work programme proposed for 2004. In order to complete the anticipated workload, the Authority is planning to increase its staff members from 60 to around 150 in the course of 2004. A revised version of the document has been submitted to the next meeting of the Management Board of 20 January for final adoption.

Advisory Forum meeting of 11 December 2003

The Executive Director informed the Committee about the issues discussed at the December meeting of the Advisory Forum in The Hague. The Draft Management Plan 2004 which was

discussed at the Board meeting of 3 December, was also brought to the attention of the members of the Advisory Forum. The Forum also discussed a range of specific subjects on which the national food authorities and EFSA are collaborating.

4.2 New questions put to the Scientific Committee

The Secretariat informed the Committee that the mandates as proposed at its fourth plenary, on exposure assessment, a harmonised approach for genotoxic and carcinogenic substances, and the qualified presumption of safety, have been sent to the Executive Director for inclusion in EFSA's work programme (see minutes of the 4th Plenary Meeting of the Committee[1]). The Executive Director will send the terms of reference to the Chairman of the Scientific Committee.

4.3 Feedback from Scientific Panels [2]

The Chair invited the Chairs of the Panels to give feedback on matters arising in the Panels that they wished to bring to the attention of the Scientific Committee. The following issues were raised:

AFC

- As mentioned previously, EFSA has been requested to provide a full risk assessment on semicarbazide from all sources (e.g. through packaging, breakdown products from veterinary drugs, etc.). Completion of this task will depend on provision of further data on levels of semicarbazide in food in order to estimate exposure. The intention is to create a working group composed of experts from the AFC and CONTAM Panels. The Chair of the AFC Panel informed the Committee that additional toxicological information on semicarbazide and a progress report on the development of alternative seal technology by the industry were expected to be available for the next AFC Panel plenary meeting of 17-18 February.

AHAW

- The Chair of the AHAW Panel informed the Committee about a number of own initiatives for which draft mandates will be prepared for further consideration at its next plenary meeting of 29-30 January (see minutes of the plenary meeting of the AHAW Panel of 9 December[3]).

[1] See: http://www.efsa.eu.int/pdf/minutes_sci_04_adopted_en.pdf.

[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

[3] See: http://www.efsa.eu.int/pdf/minutes_ahaw_03_adopted_en.pdf

BIOHAZ

- The Chair of the BIOHAZ Panel informed the Committee about an issue which had arisen concerning the timing of risk management and risk assessment announcements. The issue will be discussed at the plenary meeting of the BIOHAZ Panel of 21-22 January.

CONTAM

- The Chair of the CONTAM Panel asked for advice from the Committee on the application of the benchmark dose approach. This approach has been used in specific studies considered in the ongoing risk assessment of non-dioxin-like PCBs and the risk assessment of methyl mercury. The Committee was requested whether it could agree on setting-up a working group under the responsibility of the Scientific Committee to prepare an opinion on the benchmark dose approach as a cross-cutting issue. The Chair of the CONTAM Panel accepted the invitation to prepare a draft mandate.

GMO

- The Chair of the GMO Panel informed the Committee about the opinion which was expressed by the Panel on the 25th of November related to the marketing of the GM herbicide tolerant maize NK603 and about the press conference which was held on December 11, 2003, in connection with the release of this opinion. Furthermore the Committee was informed about ongoing evaluations of two other GM crops.
- The Chair informed the Committee about the preparation of a Guidance Document for applications under the new GM food and feed Regulation (EC) 1829/2003. Priority will be given to the food and feed derived from GM plants, but in parallel, the Panel will also work on the development of guidance for food and feed produced from GM micro-organisms. The GMO Panel will publish a draft version of the Guidance Document on the Internet, will invite stakeholders for comments and will organise a stakeholder consultation before final adoption of the Guidance Document. Furthermore, the Committee was informed about self-tasking activities of the Panel, among them the formulation of an opinion on the use of antibiotic resistance marker genes. The Executive Director invited the chairs of the Scientific Panels and Committee to develop ideas on how they wish to organise stakeholder consultations based on their experience.

NDA

- The Chair of the NDA Panel asked whether there is a general EFSA procedure for reconsideration of opinions previously issued by other scientific advisory committees such as the (former) Scientific Committees of the Commission (e.g. SCAN, SCF, SCVMPH, SCP, etc.). The Chair of the Committee advised the Panels to take a pro-active approach in a consideration of the need to re-open discussions on previous opinions on the basis of new scientific information.

PPR

- The Chair of the PPR Panel informed the Committee about the opinions released in October/November and expected developments in 2004 based on discussions of its work programme at the Panel's last plenary (2 December). The PPR Panel expects an increasing

number of requests in 2004 comprising existing active substances of the first and second stages of the re-evaluation procedure under Directive 91/414/EEC and also new active substances. A special unit in EFSA has been established for the coordination of the Risk Assessment of the Peer Review (RAPeR) programme for the second list of 52 active substances and in the near future of the new active substances.

4.4 Feedback from Working Groups of the Scientific Committee

The Committee was informed about the outcomes of meetings of the Working Group on Exposure Assessment (EXPOSURE WG) which was held on 3 December and the Working Group on a Harmonised Approach for Genotoxic and Carcinogenic Substances (GENTOX WG) that took place on 4 December. Both Working Groups are under the responsibility of the Scientific Committee and have been composed of members of the Scientific Panels and Committee.

The EXPOSURE Working Group assisted the Secretariat to finalise the draft mandate that was prepared by the Scientific Committee at its plenary meeting in November. In addition, the Working Group discussed a possible organisation of exposure assessments to be carried out by the Authority in 2004. The WG proposes to focus its activities on *human exposure assessment* and that, where possible, it will try to avoid reinventing the wheel by using existing guidance documents (as produced by the former SSC, Codex, JECFA, IPCS, past/ongoing DG Research projects, etc.) for the exposure assessments to be carried out in the Scientific Panels and Committee. The WG will continue its discussions on the 27th of January.

The GENTOX WG met on 4 December to finalise the draft mandate as proposed by the Scientific Committee and to translate the proposed mandate into a possible work approach. The WG identified various useful documents which have been produced by different organisations and scientific advisory committees at national or international level (e.g. scientific committees of the Commission, ILSI, IPCS, FAO, OECD, WHO, national agencies, etc.). The WG members agreed to prepare working documents describing/evaluating the applicability of available concepts which are used by national and international organisations for the consideration of genotoxic and carcinogenic substances. The WG will continue its discussions on the 16th of February.

The Committee agreed to devote a more extensive discussion of the planned activities of the Working Groups on Exposure Assessment and on the Harmonisation of Genotoxic and Carcinogenic Substances once the Working Groups have defined a more detailed outline of their work programme.

5 BUILDING THE AUTHORITY'S CAPABILITY TO IDENTIFY AND EVALUATE EMERGING RISKS

5.1 Discussion of a draft mandate for the Scientific Committee

The Committee discussed a draft mandate on emerging risks as prepared by the Working Group on Emerging Risks during a meeting on the 18th of December. The proposed mandate was adopted subject to incorporation of changes proposed by the Committee. The proposed mandate will be sent to the Executive Director with the request to continue to work on the subject with the terms of reference as proposed.

5.2 Future steps

At its meeting in December, the Working Group on Emerging Risks also worked on the text of a Call for Tender with the objective to select a contractor who would identify key sources and procedures for transmission of information on emerging food-related risks in close collaboration with the Working Group and other relevant parties working in this area.

In addition, the Authority's Advisory Forum and its Scientific Panels will continue to be asked to give their input on emerging issues so as to give the Authority an early warning of matters of concern, and the Authority will continue to track emerging problems through its membership of the Rapid Alert System. These networks and other mechanisms will also enhance the Authority's capability to identify emerging matters. The Head of EFSA's International and Institutional Affairs informed the Committee about the latest developments.

6 ANY OTHER BUSINESS

6.1 The question was raised whether there was a need to harmonise assessments of environmental aspects in Scientific Panels of the EFSA. The Committee noted that most environmental aspects are dealt with by the non-food Scientific Committees of the Commission's Health and Consumer Protection Directorate-General but that some environmental issues are considered, for example, by the PPR and GMO Panels.

EFSA's Director of Science mentioned that the Authority will start to create scientific expert units in the Scientific Expert Services Department to provide in-house support on various issues to the Scientific Panels and Committee. The Committee was therefore of the opinion that there is at this moment no need to create a new specific working group under the responsibility of the Scientific Committee to look for possible harmonisation of environmental aspects.

6.2 Another question that was raised was whether there was a need to create a platform for evaluation of aspects related to (drinking, mineral, etc.) water. The Committee was informed that EFSA can be consulted on questions related to chemical substances or microbiological contamination in natural mineral water. For example, a question on levels of boron and fluoride in natural mineral

waters is currently being considered by the CONTAM Panel in close collaboration with experts from the NDA Panel. The Committee felt no need to create other platforms for evaluation of aspects related to water and confirmed that they were aware of the respective responsibilities of the Commission and EFSA in this area. The Committee agreed that close contact between EFSA and the Commission is essential.

6.3 The Committee was informed about an EU-US Food Safety Research Workshop jointly organised by the Commission's DG Research and the US Department of Agriculture from 15-17 December 2003 in Shepherdstown, West Virginia, USA. A full report is in preparation and will be distributed once it has become available.

6.4 The Secretariat was asked to alert members of the Scientific Committee and the Scientific Panels when new opinions will be published on EFSA's website. The Committee was informed that such an option will be integrated in the design of the new website of the Authority.