European Food Safety Authority

Brussels, 14 April 2004
EFSA/SC/58 Final

MINUTES OF THE 6TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 17 MARCH 2004

(adopted by written procedure on 14 April 2004)

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, Andrew Chesson, 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), Josef R. Schlatter, Vittorio Silano (Chair), Philippe Vannier and Josep Vives-Rego

European Food Safety Authority (EFSA):
Djien Liem (Scientific Co-ordinator of the SC), Anne-Laure Gassin (EFSA Communications Director), Herman Koëter (Deputy Executive Director and Director of Science), Christine Majewski (Head of International & Institutional Affairs), Silvie Mateljan (Administrative Secretary) and Pilar Rodriguez-Iglesias (Scientific Co-ordinator of the NDA Panel)

European Commission (EC):
Louis Bouthors (DG Enterprise/Unit F4 – Food Industry), Marina Marini and Valérie Rolland (DG Health and Consumer Protection /Unit C7 – Risk Assessment) Elena Sachez Cuadrado (DG Research/E1 – Strategy and Policy) and Michael Walsh (DG Health and Consumer Protection /Unit D5 - Relations with the EFSA)

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants, in particularly Ms. Valerie Rolland who will join the SC Secretariat on the 16th of April 2004.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

There were no interests declared.

4. MATTERS ARISING SINCE THE 5TH PLENARY MEETING OF 15 JANUARY 2004

4.1 General feedback from EFSA

Management Board meeting of 10 March 2004 in Dublin
Christine Majewski informed the Committee about the outcomes of the Management Board at its first open meeting in Dublin on the 10th of March. The Board considered EFSA's 2005 Management Plan and further development of its scientific activities. The Board also reviewed the Authority's 2003 activities and accounts.

EFSA Code of Conduct on Declarations of Interests
Antoine Cuvillier introduced the EFSA code of conduct on declarations of interests which was endorsed by the Management Board at its meeting of the 10th of March. The paper is intended to give guidance in relation to several points of critical importance relating to direct and indirect interests and the necessity to declare them in order to avoid potential conflicts of interest. The guidance will apply to all four main components of the EFSA, e.g. the Management Board, Advisory Forum, Scientific Committee and Panels and the management and staff of EFSA.
The members appreciated the availability of a code of conduct and provided comments on the document. The Secretariat will introduce the proposed changes in a new version of the document.

Information note concerning the Advisory Forum Event of 8-10 November 2004
Christine Majewski introduced an information note concerning an event that will take place in November 2004 at which the work of the Advisory Forum will be introduced. The Committee was requested to comment on themes and content for the event and to make suggestions on the basis of a proposal of a task force of Advisory Forum members.

Involvement of Stakeholders in Meetings of the Panels and Committee

Herman Koëter addressed the Authority's views in relation to the involvement of stakeholders in meetings of the Scientific Panels and Committee. EFSA considers it is appropriate to involve stakeholders in the case of information meetings, hearings and open dialogues on generic issues related to the work of the Panel or Committee. It is, however, considered not appropriate to involve stakeholders as observers during the discussions of a plenary meeting of the Panels or Committee. EFSA will prepare guidance for the Panels and Committee on the basis of experience gained. The Committee appreciated the proposal and agreed to have a continued discussion after a couple of meetings with the stakeholders.

EFSA to organise special meetings on specific scientific subjects

Herman Koëter also addressed EFSA plans to start the organisation of special meetings to discuss specific scientific issues with a broad platform including the members of the Panels and Committee, EFSA's stakeholders, external scientists and national authorities. The first event will focus on the issue of risk assessment of dioxins and related compounds. The Committee members were invited to provide other suggestions.

EFSA's new website

Anne-Laure Gassin informed the Committee about the features of the new website of the EFSA which became operational on the 1st of March. The Members were invited to provide suggestions for improvement of the new website in addition to those offered during the discussion.

4.2 Feedback from Scientific Panels

AFC

The Chair of the AFC Panel raised that the Panel is sometimes confronted with difficulties in providing advice on substances intended to be used in food packaging materials where the major burden of human exposure is estimated to come from its presence in the environment from other sources.

The Chair also noted that the Panel is dealing with safety assessments of nutrient sources for which there is an outside discussion on whether or not they should be considered as novel foods. The Chair would prefer that these kind of problems are solved before requests for safety evaluations are sent to the EFSA. It was also noted that efficacy aspects will probably not be in the mandate for the task on re-evaluation of existing additives, which seems to be in contrast with developments in the animal nutrition area.

Finally, the Committee was informed that the Panel and its Flavourings working group have extensively discussed the use of the *Maximised Survey Derived Intake* approach as followed in the evaluation programme of chemically defined flavouring substances. The Panel might wish to consult the Exposure Assessment WG of the Scientific Committee to advise on suitable approaches for exposure assessment of flavourings.

AHAW

The Chair of the AHAW panel focused his oral report on avian influenza. The Panel was wondering why there was no question from the Commission on avian influenza. The Commission was of the opinion that the human health aspects of avian influenza were outside the mandate of the EFSA. This opinion may change in the future, but until now the Commission saw no reason to send a request to EFSA.

BIOHAZ

The Chair of the BIOHAZ panel informed the Committee that the framing of some of the questions received by the Panel had led to difficulties regarding the formulation of an opinion. The Chair reiterated its previous request to improve the interaction with the Commission in advance of the formal request being sent to the EFSA.

The Chair asked EFSA when it will be possible to have a discussion of issues related to the interface between risk assessment and risk management. The report of the European Workshop held in the Netherlands in September 2003 is expected to be published on its website (i.e. www.ra-rm.com) before the end of March. The one-page note from EFSA on RA-RM issues will also become available before the end of March 2004. This note will be sent to the Panels. After the discussions in the Panels, this subject will be on the agenda of a future plenary meeting of the Committee.

CONTAM

The Chair of the CONTAM Panel informed the Committee about the resignation of one of the Panel members. The Chair is considering the replacement of this Panel member. One possibility could be to look for an expert in veterinary toxicology to address issues related to health effects in animals.

The Panel has adopted opinions on mercury and methylmercury in food, and on aflatoxin B1 as undesirable substance in animal feed at its plenary meeting in February. At the next plenary meeting, it expects to adopt opinions on cadmium and lead as undesirable substance in animal feed.

The Panel has prepared a terms of reference for a self-tasking on perfluorinated compounds (PFOS) and considerable progress was made in the preparation of an opinion on organotin compounds.

FEEDAP

The Chair of the FEEDAP Panel informed the Committee on problems with ongoing evaluations of brand-specific opinions and raised the issue of Commission expectations in relation to the work of the Panel, notable that the Commission appeared to see the Panel as its sole source of external scientific advice, transferring both the work of the Standing Committee and the former Scientific Committee to the Panel. This implied an extensive need for advice on product efficacy and control procedures. This is currently adding, and will continue to greatly add, to the workload of the Panel.

GMO

The Chair of the GMO Panel informed the Committee about the arrangement of a Public Consultation (stakeholder) meeting on the 25th of May to exchange views on the draft Guidance Document for GM Plants and derived food and feed to be notified under the new GM food and feed Regulation (EC) 1829/2003 or the Directive 2001/18/EC on the deliberate release into the

environment of GM organisms. The document will be available on the EFSA website from April 8 and is open for comments till April 30. In a later stage guidance documents will also be prepared for GM micro organisms and for food and feed additives derived from GM micro organisms. To this end the GMO Panel has set up working groups with also experts from the AFC and FEEDAP Panels.
Moreover, the Panel adopted an opinion on genetically modified (GM) herbicide-tolerant oilseed rape GT73 on the 1st of March. The setting of tolerance levels of herbicides/pesticides used on GM crops was identified as an issue of common interest of the GMO and PPR Panel. Furthermore the chair mentioned the finalisation of an opinion on GM maize MON863 and the hybrid MON863xMON810, and of a opinion on the safety assessment of antibiotic resistance marker genes used in genetic modification.

NDA
The Chair of the NDA Panel expects a significant workload in the framework of a new Directive amending Directive 2000/13/EC adopted on 22 September 2003 by the Council of the European Union. This new Directive establishes a notification procedure to the Commission on studies, currently being carried out by third parties, to determine which substances derived from allergenic ingredients are not likely to trigger allergic reactions. Third parties will have 9 months to notify and the Commission will have 3 additional months to adopt a list of those derived ingredients/substances which will be excluded from being mandatory mentioned in the label. To adopt that "negative list" the Commission will have to consult EFSA. This may imply that the NDA Panel will have less than three months for its evaluations after receipt of the dossiers.

PPR
The Chair of the PPR Panel explained that the Panel is now dealing with an increasing number of questions in toxicology on different active substances from the Peer review of the first stage under Directive 91/414/EEC under the responsibility of the Commission. In the sector of environment, next to questions from the Commission, the PPR Panel also prepared terms of reference for self-tasking on questions originated from the Peer review of the second stage. In addition there are a number of guidance documents and revisions of Annexes II and III of Directive 91/414/EEC which will come to the PPRE Panel for peer review in the next 12 months.

4.3 Feedback from Working Groups of the Scientific Committee

Working Group on a Harmonised Approach for Genotoxic and Carcinogenic Substances (GENTOX)
The Chair of the Working Group reported that the WG agreed on a possible outline of the draft opinion to be prepared. Several working papers will be prepared for the next meeting of the working group at the end of April. The Chair of the WG noted that it may come to identification of additional experts at its next meeting. The WG decided to await the installation of the new Scientific Committees in DG SANCO before it will also invite experts from the non-food risk assessment area.

Working Group on Emerging Risks (EMRISK WG)
The Working Group will have its next meeting on Thursday 18th of March. The Chair of the Working Group expressed a need for more co-ordination in this area with the Advisory Forum.

Working Group on Exposure Assessment(EXPOSURE WG)
The Chair of the Working Group reported on recent discussions in the Exposure Assessment Working Group on a possible organisation of exposure assessments in EFSA and on plans to create a common database in EFSA comprising food consumption and occurrence data.

5. DISCUSSION OF A DRAFT MANDATE FOR THE SC ON THE USE OF THE BENCHMARK DOSE APPROACH IN RISK ASSESSMENT

The draft mandate for the Scientific Committee on the use of the benchmark dose approach in EFSA's risk assessments of chemical substances was introduced and discussed. A revised version, incorporating changes suggested by the Committee will be sent to the EFSA Executive Director with a request to include it in the EFSA's work programme.

6. DISCUSSION OF FUTURE STEPS AND PLANNING WITH RESPECT TO SPECIFIC SUBJECTS

6.1 Qualified Presumption of Safety

The Committee discussed the way to proceed with the consideration of *Qualified Presumption of Safety*, a generic approach for the safety assessment of micro-organisms used in feed/food and feed/food production.

The Committee agreed to create a working group (QPS WG) composed of some members of the Joint Working Group of the former SCAN, SCF and SCP that prepared the Working Document in 2003, and members from the current Scientific Panels and Committee. The Chairs of the Panels were invited to inform the Secretariat about members from their Panels who are willing to become member of the QPS WG.

6.2 Non-nutritional components in the European diet

A revised background document on food supplements and related products widely present in European diets was introduced and discussed. The document will be updated by the Secretariat taking into account the suggestions for changes made by the members of the Committee and comments from the Commission on the legislative aspects and developments. This revised version will be submitted for a final discussion to the next plenary meeting of the Committee.

7. POSSIBLE ISSUES FOR FURTHER CONSIDERATION BY THE SCIENTIFIC COMMITTEE

The Committee acknowledged the ongoing work in the working groups of the Scientific Committee and discussed some other issues that could be considered by the Committee in the future.

The Committee expressed interest in contributing to the Authority's strategy and work in the area of risk communication. It agreed to have a more structured discussion on risk communication at a future meeting of the Committee on the basis of a working document prepared by EFSA's Communications Director.

The Committee also wished to devote a higher priority to seeking mechanisms to ensure whenever possible, that opinions produced by EFSA and other international bodies are consistent. Where differences do occur the reasons for this should be made clear (different time/data set etc).
A more detailed discussion and revision of the document on issues for further consideration will take place at the next Plenary.

8. ANY OTHER BUSINESS

8.1 The question was raised whether EFSA will be involved in the consideration of the 412 amendments on claims as discussed in the European Parliament (EU Food Law, No. 157, February 26, 2004).

8.2 As many consumers and other groups point out that many of the current terms on labels such as 'natural', 'traditional', 'fresh', 'artisan', and 'farmhouse' are confusing and may mislead consumers. The question was raised whether EFSA wishes to inform the consumer about the scientific background for these terms.

8.3 The Committee was informed about a leaflet about the main conclusions and recommendations from the European Network Safety Assessment of Genetically Modified Food Crops.