European Food Safety Authority

Brussels, 9 December 2004
EFSA/SC/113 Final

MINUTES OF THE 9TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 13-14 OCTOBER 2004

(adopted by written procedure on 9 December 2004)

PARTICIPANTS[1]

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), Vittorio Silano (Chair), Philippe Vannier, Philippe Verger and Josep Vives-Rego

European Food Safety Authority (EFSA):
Marie-Noëlle Costa (Administrative Secretary of the SC), Dirk Detken (Legal Affairs), Anne-Laure Gassin (Communications Director), Juliane Kleiner (Scientific Expert Services), Herman Koëter (Deputy Executive Director and Director of Science), Djien Liem (Scientific Co-ordinator of the SC), Christine Majewski (Head of International & Institutional Affairs), Pilar Rodriguez Iglesias (Scientific Co-ordinator of the NDA Panel), Valérie Rolland (Assistant Scientific Co-ordinator of the SC)

European Commission (EC):
Louis Bouthors (DG Enterprise/Unit F4 - Food Industry), Antonio di Giulio (DG Research/Unit E2 – Food Quality), Marina Marini (DG Health and Consumer Protection/Unit C7 - Risk Assessment), Elena Sachez Cuadrado (DG Research/Unit E1 – Strategy and Policy), Paul Vossen (DG Research/Unit E2 – Food Quality), Michael Walsh (DG Health and Consumer Protection /Unit D5 - Relations with the EFSA)

[1] 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; AF: Advisory Forum; MB: Management Board

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies for absence were received from Josef Schlatter and Geoffrey Podger. Ada Knaap informed the Committee that she had been invited to participate in a discussion on substances that are genotoxic and carcinogenic at a meeting of the Chairs and Vice-Chairs of the three new Scientific Committees of DG SANCO and would therefore be partly absent in the morning of the 13th of October.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATIONS OF INTEREST

3.1 Declarations of interest

There were no interests declared in addition to those in the annual declarations.

3.2 Annual declarations of interest

The Committee members were requested to send their updated annual declarations of interest to the Secretariat.
Herman Koëter informed the Committee that EFSA has prepared a guidance document on declarations of interest based on the code of conduct which had been adopted late 2003 by the Management Board and comments on this document from the members of the Scientific Committee and Panels. Herman Koëter invited the Scientific Committee and the Scientific Panels to send written comments on the latest draft of the guidance document to the Secretariat. The final text will be sent to the EFSA Management Board for endorsement.

4 GENERAL FEEDBACK FROM EFSA

4.1 Feedback from meetings

4.1.1 Management Board meeting of 14 September 2004

Herman Koëter informed the Scientific Committee about issues discussed at the latest meeting of the Management Board (MB). The following main issues were discussed:

- *New Panel members*. The Management Board agreed with the appointment of John Heritage to become member of the GMO Panel. There was no approval yet for the

replacement of a member of the Contaminants Panel that had to resign in the spring of this year. The proposal will be re-discussed once the Board has found an agreement on criteria for replacing experts resigning before the end of the mandate of the respective Scientific Panel or Committee. The Authority is preparing a paper for discussion at the December meeting of the Management Board.

In view of the current and expected workload, the Scientific Committee expressed the view that the Authority should replace as soon as possible Panel or Committee members unable to continue contributing to the work.

- *Evaluation of the Authority.* The Management Board discussed a paper[2] proposing the terms of reference for the evaluation of the Authority, the obligation of which is enshrined in Article 61 paragraph 1 of its founding Regulation 178/2002[3]. The intention is to outsource the evaluation to an independent consultant. The terms of reference of this evaluation is currently prepared by the Authority and the Commission and is expected to be formally approved by the Management Board at its meeting in December (see also 4.3).

- *Performance indicators.* The Management Board discussed a paper on performance indicators[4] as a means of helping discharging the Board's role of supervising the performance of the Authority. The paper describes several quantitative indicators proposed to monitor EFSA's ongoing performance on a regular basis (such as 'number of questions received', 'number of opinions adopted', 'number of staff installed in Parma', etc.) The Board will discuss an updated version of the paper at the next Board meeting in December.

  Several Scientific Committee members advised to link the development of performance indicators with the preparation of the Authority's evaluation, although it was understood that the Authority's evaluation has a much broader scope and that the performance indicators proposed were not meant to evaluate the quality of the scientific opinions. A simultaneous development of performance indicators for the scientific quality and the impact of the opinions prepared by the Scientific Panels and Committee was strongly supported by some members. It was also proposed to design a general policy how to respond to criticism on opinions. The Chair requested the Secretariat to prepare a proposal for quality indicators for discussion at a future plenary meeting of the Committee.

[2] See http://www.efsa.eu.int/mboard/mb_meetings/606/mb16_doc05_evaluation_en1.pdf
[3] This article states: "Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level. The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation reports and the recommendations shall be forwarded to the Council and the European Parliament and shall be made public."
[4] See http://www.efsa.eu.int/mboard/mb_meetings/606/mb16_doc04_performance_en1.pdf

4.1.2 Advisory Forum meeting of 30 September -1 October 2004

Herman Koëter updated the Scientific Committee about issues discussed at the latest meeting of the Advisory Forum (AF). The Forum held a crisis scenario exercise on the afternoon of September the 30th, at which also the rapid alert system for food and feed (RASFF) was presented briefly by the Commission to the Members of the Advisory Forum. On the second day of the meeting, 1 October, the following main issues were discussed:

- *The Authority's move to Parma.* The move is likely to occur as scheduled. A small administrative team would move in October and the Secretariat of the PPR Panel in November. The others, including the Executive Director, would move unit-wise at different time-points in 2005.

- *Botanicals.* Djien Liem presented the discussion paper of the Scientific Committee on botanicals and botanical preparations widely used as food supplements and related products[5]. The discussion paper was accompanied by a cover note[6] to draw the attention of the Advisory Forum to the concerns raised by the Scientific Committee and to make clear that the Authority would like to take initiatives, with the involvement of the Advisory Forum, on safety aspects associated with these products. As a first step, the members of the Advisory Forum were asked to complete and return a questionnaire attached to the cover note. The Forum agreed to complete and return the questionnaire by 8 December 2004 to the Authority. A report will be drafted, analysing and summarising the replies to the questionnaire, to facilitate the discussion by the Scientific Committee.

- *Extranet and videoconferencing.* The Advisory Forum exchanged views on setting-up an extranet to facilitate, among others, the sharing of documents. In addition to the extranet, the Authority will establish a videoconferencing capability between the Authority, national agencies, and the Commission. The equipment and service agreement would be available by the end of the year. Videoconference meetings could be very useful in a crisis situation and for urgent exchanges.

- *Microbiological criteria.* Herman Koëter updated the Advisory Forum on current activities of the BIOHAZ Panel in this area. The Panel has engaged in this subject as a self-task activity and has recently discussed and adopted the definitions of Food Safety Objectives (FSO's) and Performance Criteria (PC) as agreed earlier by the Codex Alimentarius. These concepts were part of a new approach for microbiological risk assessments to cover the production process as opposed to microbiological criteria which only focus on the end product. However, as the Commission continues to develop a Regulation on microbiological criteria, these will have to be addressed as well. Some countries expressed their concerns that not all microbiological criteria are science-based. The Authority was asked to keep the Forum members informed.

[5] See http://www.efsa.eu.int/science/sc_commitee/sc_documents/616_en.html
[6] See http://www.efsa.eu.int/advisory_forum/adv_meetings/632/af10_doc3_botanicals_en1.pdf

4.1.3 AESGP Conference on "Changing the Rules for Food Supplements and Herbal Products in Europe", 28-29 September 2004, Brussels

Valérie Rolland informed the Committee about the conference organised by the Association of the European Self-Medication Industry on "food supplements and herbal products". The conference addressed current trends and developments in Europe with respect to legislation, safety assessment and classification in the area of food supplements and herbal products (see also the paragraph on botanicals under point 4.1.2). The opportunity and feasibility of establishing a link with the new Committee for Herbal Medicinal Products of the European Medicines Agency (EMEA) to co-ordinate activities in this area, will have to be evaluated.

4.1.4 Update from EFSA's Communications Department

Anne-Laure Gassin gave an update on recent communication initiatives[7]. She drew attention of the Committee members to the EFSA Newsletter which is issued on a monthly basis, to the annual report which has become available in various languages and to the activities of the Communications Working Group of the Advisory Forum.

4.2 Upcoming events

4.2.2 Meeting EFSA – EC/DG RTD/E on 26 October

The Secretariat informed the Committee about the second meeting of officers of EFSA and the European Commission's Biotechnology, Agriculture and Food Research Directorate of DG Research that will take place in Brussels on the 26th of October. The main objectives of the meeting are to receive updated information on each others work, to strengthen contacts between RTD and EFSA scientific officers and scientific secretariats, to identify activities of a common interest, to emphasise the need of an efficient EFSA/RTD interface function and to explore ways to further improve the exchange of information on new insights and research needs.

> This information was positively received by the Scientific Committee. The EFSA was advised to screen opinions for recommendations for research and to improve the exchange of information of common interest for mutual benefit: for RTD/E to receive inputs and ideas helpful for its future work and framework programmes; for EFSA to timely receive up-to-date research developments as inputs in its scientific opinions. Other issues the Authority may wish to consider include the substantial time consumption needed when experts become involved in the evaluation of research projects and the possible conflicts of interest for some experts already involved in research projects proposed to DG RTD.

[7] See also http://www.efsa.eu.int/press_room/press_release/catindex_en.html

4.2.2 Advisory Forum Event, Berlin, 8-9 November

Christine Majewski gave an update about the programme and arrangements for the Advisory Forum event in Berlin[8]. Several Committee members will contribute to the programme: Vittorio Silano will present EFSA's scientific work programme and Albert Flynn will give a lecture at the risk-benefit session that will be chaired by Ada Knaap. The National Food Authorities will have a stand during the Event.

4.2.3 Stakeholder Event, Berlin, 9-10 November

About 80 participants have been invited to attend the Stakeholder event. At this event participants will discuss as main theme how to involve stakeholders in future activities of the Authority.

4.3 Preparations for the Authority's evaluation

(see also section 4.1.1)

The Committee exchanged views on the proposed activities and time frame as described in MB document 14.09.2004-5 "Evaluation – Article 61 of Regulation 178/2002"[2]. The Committee noted that the evaluation of the Authority will take place at an early stage after its establishment in 2003. The Committee wished to invest more time with the help of the Panels to reflect on the various issues described in MB document 14.09.2004-5 with particular emphasis to chapter 2 concerning the activities to be evaluated and to chapter 4 concerning the evaluation questions.

After the discussion, the Committee agreed on the following steps:

- Committee members were requested to submit suggestions for amendments to MB document 14.09.2004-5, in particular the evaluation questions as specified in chapter 4 to the Secretariat. The suggestions will be forwarded to the Technical Committee of the Management Board which is preparing the Authority's evaluation.
- The Committee would like to re-discuss the issue "Evaluation of the Authority", with a focus on key points for the interviews at the next plenary meeting of the Committee of 15-16 December 2004.
- The Committee would like to continue its work on this issue at the plenary meeting in February 2005 in order to take into consideration feedback from the members of the Scientific Panels.
- Meanwhile, the Panel Chairs will involve Panel members in formulating their comments and advice in relation to the forthcoming evaluation process at a future plenary meeting of their Panels. In case time would not allow extensive Panel discussions, Panel Chairs were requested to focus in particular on the Panel's needs, and on identifying possible constraints and obstacles.

[8] See http://www.efsa.eu.int/advisory_forum/af_events/catindex_en.html

5 FEEDBACK FROM A MEETING BETWEEN THE CHAIR AND VICE-CHAIRS OF THE SC, AND THE EXECUTIVE DIRECTOR AND DEPUTY EXECUTIVE DIRECTOR OF EFSA ON THE 6TH OF SEPTEMBER 2004

The Chair informed the Committee about the meeting with EFSA's Executive Director and Deputy Executive Director on the 6th of September. The objective of the meeting was to review the first year of EFSA's operation with particular reference to the role of the Scientific Committee and Panels. A note on the discussions has been attached as Annex 1. The participants in the above mentioned meeting came to the following main consensus conclusions:

- Scientific issues of key importance need to be determined exclusively by the Scientific Committee and Panels. For minor issues where the Scientific Committee and Panels do not need to be consulted, they should at least be effectively informed.
- It was agreed that the planned expansion of EFSA's scientific staff, not least through the creation of the Scientific Expert Services, should enable EFSA to provide more internal support to the external experts.
- A careful judgment and the views of the Panel Chairs and the Scientific Committee would be welcome to address the question whether for any of the Panels there is a need for a splitting into two Panels or whether any further Panel needs to be established to cope with new tasks.
- There is an advantage in further contracting out of work related to questions posed to the Scientific Committee and Panels, including self-tasks, albeit on the basis that the Scientific Committee and Panels retain wholly the responsibility for agreeing every resulting conclusion.
- The Scientific Committee will consider undertaking an exercise with the Panel Chairs to indicate, if any, which issues they are currently dealing with could more effectively be handled by EFSA's own expert staff.
- It was felt important that the role and work of the Scientific Committee and the Panels on fundamental scientific issues should be properly understood. The SC participation in events such as the Advisory Forum and Stakeholder Events was welcomed.

In welcoming the above-mentioned conclusions, the Scientific Committee discussed various issues in relation to the establishment of the Scientific Expert Services (SES) in EFSA. The discussion showed that there is no unique solution or model that may apply to the needs of the Scientific Panels for handling the considerable current and expected workload in the coming period. Different Panels may have different levels of willingness and ability to delegate work outside the Panel.

Issues in the future are: how to maintain/increase trust in scientific advice produced by the Authority, how to keep the right balance between recruitment of staff for the scientific secretariats and for the SES, and how to make best use of information and expertise available outside the EFSA. To this end, it was decided that:

- Panel Chairs, assisted by the Panel Secretariats and in consultation with the Panel members, will identify the kind of additional help the Panels would like to have in order to effectively carry out the work programmes they are committed to.

- The Secretariat will, therefore, develop proposals on the options available for the provision of support to the Scientific Panels and Committee, including:

    i) recruitment of additional staff for the Scientific Secretariats and the Scientific Expert Services;
    ii) contracting out of some work;
    iii) involvement of national authorities, research institutes, industry, consumer organisations and other stakeholders in specific projects.

  In such proposals the various issues raised by the Committee (see 'Discussion' above) related to scientific quality, credibility, balance and trust, as well as legal and strategic implications will be taken into consideration.

- The Committee will re-discuss these issue at a future meeting based on a discussion paper prepared by the Secretariat with input from EFSA's Management and the Chairs of the Scientific Panels based on the proposals made.

6 INVESTMENT IN FOOD SCIENCE: PRIORITY PROJECTS AND COOPERATION WITH NATIONAL RESEARCH CENTERS

Herman Koëter gave a short overview of the main issues of document "Investment in Food Science" (document was already presented at the Committee's previous plenary meeting), and introduced document AF 01.10.2004-7 outlining the main themes and targets in the Authority's work programme for 2005.

As to the "Investment in Food Science" document, Herman Koëter emphasised that the Authority wishes to reserve capacity for *forefront science* and for *self-tasking*. It was also mentioned that of the 13 self-tasking projects proposed (*cf.* item 13 of the document), seven activities were already started or finalised, five of which were proposed by the Scientific Committee. With respect to priority setting (*cf.* item 15 of the document), Herman Koëter welcomed suggestions from the Committee on the appropriateness of the seven criteria indicated: anticipated health impact, legal obligations and deadlines, level of urgency as indicated by the originator of the question, connections between the project and other activities, level of public interest, economic importance of the subject/issue and balance of work.

The establishment of the work plan for 2005 already started in March 2004. In addition to the projects for 2004, EFSA would like to give priority to activities on transparency in risk assessment (*cf.* agenda item 11), an evaluation of the benchmark dose approach, the

organisation of four-five scientific colloquia, to more network building and to the creation of an expert database. An updated version of Document AF 01.10.2004-7 will be discussed at the December meeting of the Management Board. The final version will be sent to the Board meeting of January 2005. The Scientific Committee members were asked to take note of the processes and were invited to provide input to the establishment of the Authority's work programme for 2005.

During the discussions the Committee noted that:

- The 25 Member States have already received a request from DG Research to indicate priorities for research by the 15th of October. An attempt should be made to avoid overlap and to look for synergism. The upcoming meeting with DG RTD/E will contribute to a better co-ordination of the activities conducted by EFSA and co-ordinated by DG Research.
- The subject of cooperation with national research centers in the Investment in Food Science document may deserve more attention.
- It should be verified whether the database of experts evaluating project proposals for DG Research could be also useful for EFSA's expert database.
- A better interaction is needed (i.e. between experts as well as between the Secretariats) with the three new Scientific Committees of the Commission's DG Health and Consumer Protection (SANCO).

Herman Koëter invited the Scientific Committee and the Scientific Panels:

- To comment on the criteria for priority setting as proposed under item 15 of the *Investment in Food Science* document.
- To indicate which issues would deserve priority in 2005.
- To indicate which additional self-taskings should be included in the Work Programme for 2005.
- To discuss the work programme for 2005 at the next plenary meeting of the Scientific Panels.

7 ANIMAL WELFARE – DISCUSSION ON FURTHER STEPS TO DEVELOP AND IMPLEMENT A PRO-ACTIVE AND SCIENCE BASED ANIMAL WELFARE POLICY IN EFSA

Herman Koëter introduced EFSA document MB 22.06.2004-5 entitled "Food and feed safety and the use of animals" which was prepared for the Management Board meeting of 22 June 2004 and invited the Scientific Committee to contribute with a more detailed document on EFSA's animal welfare policy.

The following general remarks emerged during the discussions:

- It was suggested to distinguish between farm animals intended for human consumption and laboratory animals for toxicity testing.
- Some Committee members were of the opinion that it might not be realistic to ask all the Panels to become involved in the development and implementation of the proposed animal welfare approach.
- The Committee was more in favour of developing in-house expertise on alternative methods to animal testing. It was suggested to focus on existing and new methods as complementary to animal testing. The Scientific Expert Services could for instance be charged with the task to keep track of what is being taken care of elsewhere.
- Taking into consideration the amount of activities in the area of animal welfare, it was suggested to organise a scientific colloquium to discuss the outcomes of the various evaluations carried out so far. It may also be a good opportunity to present the outcomes of own initiatives as for instance carried out by the GMO Panel. Prior to such an event it may be helpful to have a consensus document identifying ways on how to proceed.

The Chair concluded that the animal welfare is an important subject for the Authority. The Committee agreed with the Chair's proposal to create a working group composed of EFSA staff and external experts:

- to identify examples where animal testing was replaced by alternative methods;
- to set-up a database on existing regulations and guidance documents addressing alternative non-animal testing methods;
- to prepare a consensus document for discussion at a future plenary of the Committee identifying ways on how to proceed; this document could be used as starting point for the organisation of a scientific colloquium;
- to review the projects in the 5th and 6th Framework Programme dealing with alternative non-animal testing and the outcome of a conference on Animal Welfare which will take place on the 27-28 October 2004.

8 DISCUSSION ON PRIORITY ISSUES FOR FUTURE CONSIDERATION BY THE SCIENTIFIC COMMITTEE

Djien Liem provided an updated list of possible priority issues for future consideration by the Scientific Committee. The Committee went through the list to consider which items have already been completed, which ones are still valid and which further steps could be taken..
The discussion led to the selection of the following subjects the Committee considered as priority issues: (not necessarily ranked according to priority)

- General format for EFSA opinions: a general structure was already agreed in August 2003; however, the Committee wishes to define the structure of the assessment chapter.
- Exposure assessment in EFSA: ongoing activity, a draft opinion will be discussed at the next SC plenary of 15-16 December 2004.

- The use of the Benchmark Dose Approach in Risk Assessment: ongoing activity.
- Guidance on presentation of uncertainties, extrapolations and other assumptions in risk assessments: it was noted that this is an essential subject (*cf.* agenda item 11).
- Procedures and mechanisms aiming at reducing divergence of scientific opinions between EFSA and Community, national and international scientific advisory bodies: not started yet.
- Strategies for identifying and collecting the data and information needed by the Scientific Panels and Committee: EFSA has created a working group involving colleagues from the legislative services in DG Health and Consumer Protection to harmonise methods for (and co-ordinate) the collection of relevant food and feed safety information.
- Contribution to building up EFSA's capability for identification and evaluation of emerging risks: ongoing activity (*cf.* agenda item 10).
- Annual seminars/workshops for Panel/Committee members: standing matter (*cf.* agenda item 14).
- Use of human data in safety assessments (new): the Committee agreed that this issue needs more discussion to define how the issue could be dealt with. The Commission services referred to a guidance document on the use of human data in the risk assessment of plant protection products. The Committee decided to define further steps at a future plenary meeting of the Committee.
- Use of experimental animals for safety testing: the Chair of the AHAW Panel offered to prepare a working document addressing this issue for the next plenary meeting of the Committee.
- Transparency in Risk Assessment: see agenda item 11.
- Introduction of probabilistic (effect and exposure) modelling in the risk assessment process: is already (or will be) addressed by the Scientific Committee's Exposure, Gentox and BMD working groups.
- A harmonised approach for the consideration of substances that are both genotoxic and carcinogenic: ongoing activity; a draft opinion will be discussed at the December plenary.
- Establishment of a framework for risk benefit evaluations: an opinion on the risks and nutritional aspects of fish consumption is currently being addressed by a Joint Working Group of the CONTAM, NDA and AHAW Panel; a risk-benefit session has been organised at the Advisory Forum Event (8-9 November 2004).
- Qualified Presumption of Safety: ongoing activity; WG created under the chairmanship of Andrew Chesson, QPS approach subject of scientific colloquium taking place on 13-14 December.
- Botanicals and botanical preparations: ongoing activity; issue addressed at AF meeting of 1 October 2004 (*cf.* agenda item 4.1.2).
- Post market surveillance: the Chairs of the GMO and BIOHAZ Panel will jointly prepare a working document for a future plenary meeting of the Committee.

Due to time limitations, the Committee postponed a discussion on the following subjects to the next plenary meeting:

- Evaluation of current procedures for testing of chemicals for evaluation of risks for target populations.
- Cumulative exposures to various toxicants.
- Synergistic and additive effects.

9 THE INTERFACE BETWEEN RISK ASSESSMENT AND RISK MANAGEMENT – PROGRESS OF DISCUSSIONS IN THE SCIENTIFIC PANELS

Djien Liem informed the Committee about the progress on the discussions in the Panels. In addition to the workshop report (see www.ra-rm.com), the Secretariat provided a cover note and a common template for submission of comments on the principles and approaches related to the interface between risk assessment and risk management as proposed by the workshop participants.

The discussions in the Scientific Panels have not been finalised yet. Once all comments have been received the Secretariat will prepare a working document compiling and summarising the comments from the Panels. This document will then be used as starting point for a concluding discussion at a future plenary meeting of the Scientific Committee.

10 REPORT BACK FROM SC WORKING GROUPS

Working Group on Emerging Risks (EMRISK)

The Chair of the EMRISK Working Group gave an update on the progress made. The contract with the contractor is expected to be signed soon. Once this has been accomplished, the WG plans to have a first meeting to discuss the work to be carried out. Valérie Rolland explained the remaining steps and timetable of the procurement process. In order to prepare the first meeting with the contractor, Panel Chairs were reminded to submit their top-5 of emerging issues to the Secretariat at their earliest convenience.

The Committee was asked whether it could approve the invitation of a member of the new Scientific Committee on Emerging and Newly Identified Risks (SCENIHR), recently established under the Commission's DG SANCO, to become an additional member of the EMRISK WG. The Committee approved to ensure a better co-ordination of the activities of the two Committees on this issue and to avoid unnecessary duplication of efforts.

The Scientific Secretariat of the SCENIHR confirmed the good collaboration with the Secretariat of the EFSA Scientific Committee. Similarly to involving a member of the SCENIHR in the SC Working Group, the SCENIHR Secretariat is planning to involve a member of the EMRISK WG in a Working Group of the SCENIHR once such a WG has been created.

Working Group on Exposure Assessment (EXPOSURE)

The Chair of the EXPOSURE WG gave an update on the progress made so far. The WG is preparing a draft opinion for discussion at the December plenary of the Committee.

The WG is also preparing a second draft opinion dealing with uncertainties in exposure assessment. It is aiming at submitting a draft for discussion at the plenary meeting in February or April 2005.

Valerie Rolland informed the Committee that the Exposure Working Group has developed a draft template for a table of national food consumption data and wishes to verify with the Scientific Panels and Committee if they could agree with the proposed approach. The template will be circulated to the Scientific Panels and Committee. After the consultation round, a call for tender will be launched aimed at extending the food consumption table with data from other Member States.

Working Group on a harmonised approach for the consideration of substances that are both genotoxic and carcinogenic (GENTOX)

The Chair of the GENTOX Working Group will have its next meeting on the 21st and 22nd of November.

At the meeting with the Chairs and Vice-Chairs of the new Scientific Committees of DG SANCO on the 13th of October, it was agreed to collaborate and to try to achieve a harmonised approach as much as possible. In order to create a link between the activities of the food and non-food committees, EFSA will start inviting experts working for the SANCO Committees as additional experts to the meeting of the GENTOX WG. The Chair and a few other members of the WG also participated in a meeting on dose response modelling organised by WHO/IPCS in September.

The Committee agreed on the following plan in relation to the adoption of the opinion:

- The GENTOX Working Group will submit a draft opinion for discussion at the next plenary meeting in December.
- Once the Committee agrees with the approach proposed by the Working Group, the draft opinion will be published on the web for public comment. A simultaneous consultation of the Scientific Panels, the Commission and other stakeholders will take place in order to avoid unnecessary delay in the finalisation of the opinion.
- After the consultation round, the WG will prepare a final draft for adoption at a future plenary meeting of the Scientific Committee.
- Once the opinion is adopted, a scientific colloquium will be organised by EFSA, possibly in collaboration with ILSI Europe and WHO/IPCS.

Working Group on the Qualified Presumption of Safety (QPS)

The QPS Working Group had its first meeting on the 6th of October. Three members of the QPS WG did also participate in the Joint Working Group of the former SCAN, SCF and SCP that prepared the working document published on SANCO's website in the spring of 2003.

It is intended to focus the working group's activities on the views of all stakeholders in the issue including the Commission, industry and consumer organisations. It was, therefore, decided to organise a Scientific Colloquium[9] to collect views on the QPS approach before the WG will start its evaluation. The Scientific Colloquium will take place on 13-14 December 2004 in Brussels.
The next meeting of the QPS WG will take place on 29 November.

Working Group on the Benchmark Dose Approach (BMD)
Further steps in relation to the BMD Working Group will be taken after the December plenary of the Scientific Committee.

11 FEEDBACK FROM AN EFSA MEETING ON TRANSPARENCY IN RISK ASSESSMENT HELD IN BRUSSELS ON 28 MAY 2004

The Chair explained the objectives and outcomes of an ad-hoc meeting on transparency in risk assessment held on the 28th of May. It was arranged to facilitate an exchange of views between Bart Sangster, member of EFSA's Management Board, the Chair and Vice-Chairs of the Scientific Committee and EFSA's scientific staff about:

- Possible ways to advance in the science of Risk Assessment (RA).
- Approaches to improve the transparency of the RA process.
- Possible additional steps to ensure the quality of the work of the Scientific Panels and Scientific Committee.

The participants expressed the need to establish criteria for inclusion or exclusion of scientific information, to address uncertainties in the RA, to develop approaches for quantitative RA to provide more information on the extent of anticipated risks and to improve transparency through involvement of the public, stakeholders and other scientists in appropriate stages of the RA process. The participants considered that it was inappropriate to have public involved during the evaluations, but that involvement of stakeholders's views could be valuable during the formulation of the mandate, or, on a case-by-case basis, during the final stages of the preparation of the opinion. It was proposed to create an EFSA working group to address the before mentioned issues aimed at improving the transparency of the RA process and to hold a scientific colloquium about criteria for exclusion/inclusion of scientific information.

The Committee discussed the outcomes of the meeting and came with the following comments:

- The Committee agreed that the preparation by a working group of a guidance document to explain the criteria for inclusion or exclusion of scientific information would be helpful.

[9] See http://www.efsa.eu.int/science/colloquium_series/no2_qps/610_en.html

- For the preparation of such a guidance document, it was advised to verify what has been produced elsewhere. Several reports have been prepared in the UK and the US that could be used as a starting point.
- Some Committee members expressed concerns about the potential additional workload that may be associated with a policy to improve the transparency of the RA process. It was emphasised that it would go too far if Panels have to justify in- or exclusion of papers for all literature related to a certain issue. However, it was agreed that opinions should include a justification when a particular key source was or was not considered and relevant assumptions have to be clearly defined.
- As to the issue of uncertainties, the Committee noted the work of the Exposure WG on uncertainties in exposure assessment. Uncertainties in hazard characterisation will to a certain extent be taken on board by the GENTOX and BMD Working Group. It was suggested to look also at the consequences of the extent of uncertainties in relation to the outcome of a certain opinion.

The Committee advised to proceed with activities aimed at improving the transparency of the risk assessment process. The following steps were agreed upon:

1. A document will be prepared to indicate what is currently considered as good practice and which guidance EFSA would like to give to the Scientific Panels and Committee.
2. The initiative for these activities will be taken by the EFSA with assistance from the Scientific Committee.
3. EFSA will create a steering group involving the Chair and Vice-Chairs of the Scientific Committee, external experts and EFSA staff.
4. EFSA will consider contracting out the work to compile what is already available.
5. A draft of the document will be discussed in the Scientific Committee before finalisation.

12 REPORT BACK FROM SCIENTIFIC PANELS

The Chairs of the Scientific Panels informed the Committee about opinions recently adopted as well as opinions in the process of adoption by written procedure[10]. In addition, the Chairs wished to bring the following specific issues to the attention of the Scientific Committee:

AFC

- The Chair of the AFC Panel reported that it had adopted 18 opinions at its last plenary meeting and that 3 additional opinions are expected to be adopted by written procedure.
- The AFC Panel has closely collaborated with the Communications department on a press release associated with the parabens opinion that was adopted by the Panel at its previous plenary. The press release has been prepared because of the withdrawal of the ADI for one

[10] For more specific information, see the specific pages of the respective Scientific Panels providing the minutes of the plenary meetings and the opinions adopted at these meetings on EFSA's website.

of the parabens. The Commission has already undertaken actions to prepare to remove it from the list of authorised substances.

- At the last plenary, the Panel adopted its first two opinions on chemically defined flavourings. The Panel had an extensive discussion on the approach to estimate the exposure to these flavouring substances and agreed to apply a modified TAMDI approach in addition to the MSDI approach[11]. The risk assessment for some flavouring substances could not be finalised after application of the modified TAMDI approach. The Panel requested better data on use levels for these substances to pursue the risk assessment.

AHAW

- The Chair of the AHAW Panel reported on fruitful meetings with DG Research and DG AIDCO. DG AIDCO has prepared a request for the AHAW Panel to evaluate measures to prevent introduction of foot and mouth disease in the European Union.
- The AHAW panel has adopted an opinion on the risk of transmission of mycobacterium avian tuberculosis via bovine semen. The risk assessment approach taken by the Panel in this opinion will serve as an example for its future work.

BIOHAZ

- The Chair of the BIOHAZ Panel reported on the good collaboration with the AHAW Panel on overlapping issues such as the stunning and laying hens opinion.
- The BIOHAZ Panel had a fruitful exchange of views with an officer of DG Research on future research topics at its last plenary meeting.
- The Panel will have its 10th plenary meeting on 20-21 October in Parma and will discuss 3-4 opinions for adoption at that meeting.

CONTAM

- The Panel adopted three opinions, at its last plenary meeting, i.e. on the risks associated with ochratoxin A and fluorine in animal feed, and on the health risks of dietary exposure to organotin compounds.
- The Vice-Chair of the CONTAM Panel requested the Scientific Committee's opinion on the use of the Provisional Tolerable Daily Intake, a term which is often used by e.g. the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in case more data is needed. Once the data has become available, it allows JECFA to set a Tolerable Daily Intake. EFSA has not yet formally agreed to use the PTDI and, in case it wishes to use it, it may also need to define what is meant with the term *provisional*.
- Another question of the Vice-Chair was related to the uncertainty factors used in the Panel's opinion on boron in mineral water. The Committee was asked to ensure a consistent use of the uncertainty factors across the different Panels.
- The Committee will come back to the two issues raised by the CONTAM Panel at its next plenary meeting.

[11] See http://www.efsa.eu.int/press_room/press_release/673_en.html

FEEDAP

- The Chair of the FEEDAP Panel reported that no issues of general interest had arisen since the last plenary.

GMO

- The last plenary meeting of the GMO Panel took place in September in Montpellier. During that meeting the Panel finalised the guidance document for GM plants and derived food and feed. A special Working Group is still working on the issue of post market environmental monitoring. Once this work has been finalised, it is intended to include relevant outcomes of this work in the guidance document.
- The Panel appointed John Heritage, who recently joined the GMO Panel, as chair of the newly established Working Group on genetically modified micro-organisms and derived substances.
- The Panel also submitted a proposal to EFSA to create a self tasking activity to evaluate the potentials, values and limitations of animal testing for whole foods. Committee members suggested to involve toxicologists with expertise in non-GM novel foods in this working group and referred to recent publications of ILSI on this matter.
- The credibility of the GMO Panel is regularly being challenged by certain stakeholders, and the Panel is of the opinion that this issue should be addressed by EFSA As the Panel is also confronted with different opinions expressed by national committees, it proposed EFSA to organise a scientific colloquium with risk assessors across Europe to explain the strategy in this particular area.
- The Panel is considering involvement of expertise present with stakeholders in the area of risk assessment, and will consult experts from stakeholders on a case-by-case basis, depending on the topic to be discussed

NDA

- The Panel received 25 requests for scientific opinion concerning the evaluation of applications for temporary labelling exemption of ingredients/substances derived from allergenic foods. The legal timeframe requires these dossiers to be evaluated before the end of December; this is unrealistic.
- The Panel had no plenary meeting since the last plenary of the Scientific Committee. It will have its 6th plenary on 18-19 October 2004.

PPR

- The PPR Panel adopted two opinions including one on FOCUS ground water models at its last plenary in Parma. The Panel is still working on an evaluation of the possible use of FOCUS surface water models, originally developed for spray applications, for non-spray applications.
- The Panel needs to adopt four opinions dealing with five questions before the end of 2004. The Panel Chair expressed concerns about the tremendous workload, in particular for the staff of the PPR Secretariat which will move to Parma early November 2004.

- The Panel Chair reported on organisational problems (e.g. transportation to and from Parma, print and copy facilities) during the Panel's plenary meeting in Parma. The next plenary of the PPR Panel will take place on October 28th.

13 PRESENTATION OF DG RESEARCH ON THE CURRENT STATE OF IDEAS ON THE 7TH FRAMEWORK PROGRAMME FOR RESEARCH

Paul Vossen of the Research Directorate General of the European Commission presented the current developments and outlook on European science discussion. The current EU Research Policy Objectives were summarised and the Committee was updated about the outcomes, ongoing activities and outlook of the Framework Programmes. He invited the Scientific Committee to provide ideas, suggestions to ensure a good interfacing between EFSA and the EC's Research Directorate General.

14 DISCUSSION ON POSSIBLE SUBJECTS FOR EFSA SCIENTIFIC COLLOQUIA

The Secretariat invited the Scientific Committee to propose possible subjects for future scientific colloquia. The following subjects were proposed:

- Harmonised approaches for the consideration of substances which are both genotoxic and carcinogenic.
- Transparency in Risk Assessment.
- Animal testing.
- Post market surveillance food, feed and environmental aspects.

15 ANY OTHER BUSINESS

15.1 Future research issues

The Chair proposed to develop ideas for future research that could be submitted to DG Research for possible inclusion in the Framework Programme. It was agreed that the Secretariat would prepare a working document for discussion at a future plenary meeting of the Committee that includes a compilation of recommendations for further research indicated in the opinions released so far and the emerging issues indicated by the Scientific Panels on request of the EMRISK Working Group.

15.2 Meeting dates in 2005

The Committee agreed on the following dates for plenary meetings in 2005:

- 17-18 February
- 14-15 April
- 16-17 June
- 15-16 September (1.5 day, starting at 9h00 on 15 September)
- 17-18 October (provisional)
- 15-16 November (provisional)
- 12-13 December (starting at 13h00 on 12 December)

The Chair closed the meeting and thanked all participants for their active contribution.

European Food Safety Authority

EXECUTIVE DIRECTOR

Brussels, 4 October 2004
EFSA/SC/117

EFSA ONE YEAR ON[12]

Herman and I were very grateful to you, Ada and Pierre for our discussion last week to review progress with EFSA after the first year of its operation with particular reference to the role of the Scientific Committee and Panels.

We are all agreed that issues of key importance requiring the application of a range of scientific judgments need to be determined exclusively by the Scientific Committee and Panels. In issues where the Scientific Committee and Panels do not have the lead, they should at least be closely informed and consulted. At the same time the Scientific Committee and Panels are faced with a very heavy workload from the questions asked by the European Commission and, of course, we also need to be able to respond to questions from the Parliament and the Member States the likely future level of which is currently difficult to predict.

Against that background we looked together at the possible means of tackling the demand for EFSA advice. First we are agreed that the planned expansion of EFSA's scientific staff, not least through the creation of the Scientific Expert Services, should enable us to provide more internal support to our external experts, not the least through providing (early) draft versions of opinions or scientific reports. In addition the question will inevitably be raised in the context of the 2005 Review of EFSA as to whether any of the Panels should be formally divided or indeed a further Panel or Panels be created to cope with new tasks. This requires a careful judgment and the views of Panel Chairmen individually and the Scientific Committee collectively will be very welcome. We are all agreed that it is important to ensure that a breadth as well as depth of expertise needs to be present on each Panel and also that the scope for such changes to the Panel structure may actually prove to be rather limited.

We all see advantage in further contracting out of work related to questions posed to the Scientific Committee and Panels, including self-tasks, albeit on the basis that the Scientific Committee and Panels retain wholly the responsibility for agreeing every resulting opinion. Similar advantages are recognized in contracting out work related to assessments of substances in the context of Regulations defining strict procedures and time constraints. We in particular would suggest this option in relation to self-tasks of the Scientific Committee, although we also hope to provide more support from EFSA's internal staff in due course. More generally we all perceive the need to look at the contrasting levels of detailed work undertaken by the different Panels, as this may identify where there is scope for more contracting out or indeed internal support work in EFSA. We are agreed that keeping the Scientific

[12] Note of a meeting between the Chair and Vice-Chairs of the Scientific Committee and the Executive Director and Deputy Executive Director of EFSA on the 6th of September (submitted by the Executive Director on September 16th, 2004)

Committee and Panels closely informed of all developments and options in this area is key to a mutual understanding and support.

Finally on this issue, as I mentioned in my recent European Food Law Conference speech, there is a need to examine whether the Panels are currently being asked to deal with straightforward issues which do not require the application of their level of expertise and judgment and which could more efficiently be handled by EFSA's own expert staff, to the benefit also of the questioner as a quicker response would be delivered and other work for the customer could be speeded up. It would be extremely helpful if the Scientific Committee could undertake an exercise with Panel Chairmen to indicate the kind of issues which in their view would fall into this category. We would of course then need also to consult with our customers. Assuming however that such a system can be brought into operation, it would have as an essential safeguard that Panel Chairmen would be kept informed of advice under preparation in this way so that, if they wished, they could indicate any issues which they wished to see taken up in panel discussion.

More generally we noted that it was important that the role and work of the Scientific Committee should be properly understood. In this context we welcomed both the Scientific Committee participation in the forthcoming Advisory Forum and Stakeholder events. We are all very much of the view that there is much to be gained through structured Scientific Committee interaction with both national food authorities and academic institutions. There are already opportunities for interaction with the Advisory Forum and in particular over how national authorities can input to the work of the Scientific Committee and Panels without compromising their independence. We will also certainly support a public event with national academic institutions once nominated in the context of Article 36 of our founding Regulation and would welcome further discussion with the Scientific Committee on this.

In relation to the handling of in an emergency issues, we again all agree that time is unlikely to enable the preparation of formal opinions, at least immediately, but that we will continue to involve Panel Chairmen in these issues when they arise and seek to mutually agree a handling strategy.

As to the pivotal role of the Scientific Committee, we agreed that its guidance to the work of the Panels on fundamental scientific issues is indispensable. It was also recognised that its many tasks include taking initiatives to ensure that Panels are familiar with and apply the most advanced assessments tools and approaches being available, thus safeguarding EFSA's frontline position in food and feed science.

Finally we agreed that, in addition to the current attendance of Herman and/or myself at formal Scientific Committee meetings, there would also be mutual benefit in continuing these very useful more informal discussions. We look forward to doing this and I hope you will allow me to close this letter by thanking you personally, all the Members of the Scientific Committee and Scientific Panels for making such a major contribution to a successful first year for EFSA.

Geoffrey Podger
Executive Director