European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

Parma, 22 October 2007
EFSA/SC/560

MINUTES OF THE 26TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 17-18 SEPTEMBER 2007 IN PARMA

(Adopted by written procedure on 29 October 2007)

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, Andrew Chesson[1], John D. Collins, Erik Dybing, Albert Flynn, Claudia Fruijtier-Pölloth, Tony Hardy, Ada Knaap, Sirpa Karenlampi , Pierre Le Neindre, Gabor Lovei, Josef Schlatter, Vittorio Silano (Chair), Staffan Skerfving, Philippe Vannier

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle (Executive Director), Herman Koëter (Deputy Executive Director, Director of Science), Dirk Detken[2] (Acting Head, Human Resources), Hubert Deluyker[3] (Head of SCA Department), Luisa Venier[4] (Legal Affairs), Simone Gabbi (Legal Affairs) [4]

Secretariat of the Scientific Committee:
Djien Liem (Scientific Coordinator, Head of Unit), Bernard Bottex (Scientific Officer), David Carlander (Scientific Officer), Juliane Kleiner (Team Leader, Scientific Committee), Daniela Maurici (Scientific Officer)

European Commission (EC):
Michael Walsh (DG SANCO/Unit 03 – Science and Stakeholder relations), Marina Marini (DG SANCO/Unit C7 – Risk Assessment)

[1] Present on the 17th September
[2] Present on the 17th September for agenda item 5
[3] Present on the 17th September for agenda item 4 and 7
[4] Present on the 17th September for agenda item 4

1. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. Jan Schans was replaced by Gabor Lovei (vice chair of PLH Panel) and Harry Kuiper was replaced by Sirpa Karenlampi (vice chair of GMO Panel.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

There were no specific expressions of declarations of interest.

4. FEEDBACK FROM EFSA ON ISSUES RELEVANT TO THE SCIENTIFIC COMMITTEE

- **MANAGEMENT BOARD MEETING, 11 SEPTEMBER 2007, BUCHAREST**

On 11 September 2007 the Management Board adopted a revised decision concerning the establishment and operations of the Scientific Committee and Panels. The amendments take into account the possibility to invite external experts to contribute to the work of the Scientific Committee and Panels, the new rules on the declarations of interest, a more detailed accelerated procedure to deal with different levels of emergencies and new rules for expert compensations. All experts will be informed of the new procedures in a letter.

The proposed new procedure for declaration of interest was discussed. Related documents will be revised after having received comments from the Scientific Committee (see below) and the policy on declarations of interest will possibly be adopted through a written procedure.

The Management Board agreed with the EFSA proposal to split the AFC Panel into two new Panels. One Panel dealing with food additives and nutrient sources, and the other with food contact materials, flavourings and processing aids, including enzymes. EFSA will send a proposal to the European Commission for an official decision. The intent is to have the new Panels operational by spring 2008.

The presentation of the work of the GMO Panel by the chair of the Panel, Harry Kuiper, was very much appreciated by the Management Board.

- **UPDATE ON STATUS OF ARTICLE 36 CALLS**

The Head of the Scientific Cooperation and Assistance Department, supported by Legal Affairs, gave a presentation on the status of the Article 36 calls. For 2007 there are in total 14 calls, 10 which are already under evaluation and the last 4 to be launched by October 15. An update of the Article 36 list of participating institutions will take place by the end of the year with addition of institutions from Romania and Bulgaria. A full revision of the Article 36 list is foreseen in 2008.

- **RECRUITMENT WITHIN EFSA**

The Scientific Committee was informed that there are currently 277 temporary agents in EFSA, with the expectation to be 300 by the end of the year.

- **MEETING ON "ENVIRONMENTAL IMPACT OF CULTIVATION AND MANAGEMENT OF GM CROPS"**

A meeting will be organised on the 2nd of October, to develop an EFSA strategy on the environmental impact of GM crops and how this relates to plant and pesticide risk assessment. The objective is to reach consensus on an approach which is applicable to the GMO, PPR and PLH Panels. As a follow-up a meeting will be organised with DG ENV and DG SANCO to explain EFSA's position and confirm that the approach is in line with the Regulation. The legal basis is set out in Directive No 2001/18/EC. The meeting will be held with environmental experts from the three Panels and EFSA staff.

- **SPECIAL ADVISORY FORUM MEETING ON GMO RISK ASSESSMENT, 13 NOVEMBER 2007**

A meeting with experts from Member States in GMO risk assessment will be held on November 13th, in Brussels, to compare EFSA's risk assessment approach for GMOs with those applied at national levels. Member States have been asked to nominate experts for this meeting and a questionnaire was sent to the Member States to collect information on current GMO risk assessment practices at national level.

- **EFSA'S 5TH ANNIVERSARY**

The Executive Director informed the Scientific Committee that joint events have and will take place in Member States. A whole week of events will be organised in Parma from 1-7 October, 2007 to make EFSA better known to the citizens of Parma and in Brussels from 19-22 November to present EFSA's work to decision makers, stakeholders and the general public. Members of the Scientific Committee have been invited to attend these events.

5. NEW PROCEDURE FOR DECLARATIONS OF INTEREST

The new procedure for Declarations of Interest (DoI) was presented and discussed. The Scientific Committee noted the detailed guidance provided, and stressed that EFSA should develop clear and transparent means to communicate the outcome and consequences of the evaluations of the DoIs. A wish was expressed to facilitate and simplify the procedure for the evaluation of the DoIs. Clarity, openness and transparency aspects are crucial.

6. EFSA DRAFT MANAGEMENT PLAN 2008 – ADVICE FROM THE SCIENTIFIC COMMITTEE ON PRIORITIES FOR 2008 AND BEYOND

In 2008 the Scientific Committee will look at the broader applicability of the threshold of toxicological concern approach in risk assessment carried out by EFSA. It was mentioned that more and more Panels are asked to do environmental assessments and that harmonisation of such procedures could be of value to ensure consistency. Other possible topics include an evaluation of the implementation of the Scientific Committee opinions within EFSA Panels, further work on the application of the margin of exposure approach for substances that are both genotoxic and carcinogenic and risk-benefit assessment of organic food. The Scientific Committee members are invited to provide further comments by end October and priority topics for 2008 will be agreed on at the next meeting. It is planned that the Management Board will adopt the Management Plan of EFSA for 2008 at its December meeting.

In order to address the increasing workload, the Scientific Committee agreed to involve two more external experts in their work. Based on the reserve list of the 2006 call for Scientific Panel and Committee members a short-list of possible experts will be prepared, discussed with the chair and vice-chairs of the Scientific Committee and suggestions for appropriate experts will be presented to the Scientific Committee at the next meeting

7. ACTIVITIES OF EFSA'S SCIENTIFIC COOPERATION AND ASSISTANCE DEPARTMENT

An appreciated presentation on the activities of the Scientific Cooperation and Assistance (SCA) Department was made by the head of the SCA department. The modus operandi for SCA is largely through networks with Member States. There are networks focusing on data collection and analysis of pesticide residue evaluation (PRAPER unit), zoonoses data (Zoonoses unit), food consumption data, chemical occurrence data, food composition data (Datex unit), emerging risks (Emerging Risks unit) and other ad hoc networks (Scientific cooperation unit). The Assessment and methodology unit is supports the Panels in various areas with specific needs.

8. REPORT BACK FROM THE SCIENTIFIC PANELS

The Executive Director informed the Scientific Committee that ways to handle the increased workload for the Panels are being discussed, including added resources to Panels that deal with application dossiers. The information from the Panel Chairs focused on the work plan for 2008. In particular, the following issues were brought to the attention of the Scientific Committee:

AFC

The evaluation of synthetic and natural colorants started in 2007 will be ongoing in 2008. Evaluation of the UK study on food additives and hyperactivity in children will also be a priority for completion in early 2008. Depending on data availability the new study on aspartame from the Ramazzini Institute will be reviewed. For nutrient sources considered under the PARNUTS Directive, 18 opinions are expected to be adopted by the end of 2007 and 14 in 2008. For food supplements, there are over 200 dossiers and many will be considered during 2008. For enzymes a draft guidance document is under preparation for public consultation early 2008. An updating of the opinions on food irradiation of the former Scientific Committee on Food is planned for 2008. For chemically defined flavourings the evaluations could not be completed to the original deadline and this work is now expected to be completed by summer 2008, as is the work on smoke flavourings. In the area of food contact materials, guidance documents on recycled material and on active and intelligent packaging are planned for 2008.

AHAW

More questions are received in the area of animal welfare than in the area of animal health. For 2008, animal health questions relate to infectious agents of fish, crustaceans and molluscs, as well as to emerging animal diseases. For animal welfare, several questions concern the welfare of fish, stunning of seals and welfare of cows which has a deadline in 2009. The self task activity on the preparation of guidance on the risk assessment of animal welfare is expected to be finalised in 2008 and will include proposals for welfare indicators.

BIOHAZ

Mandates for QMRA (Quantitative Microbial Risk Assessment) opinions on Salmonella in pigs and for campylobacter are expected. Concerning BSE, interaction with the European Commission is foreseen with regard to testing and management approaches. An opinion on the disposal of animal by-products in an environmental friendly way is scheduled. There is also an opinion planned on the efficacy for decontamination of food of animal origin. A self tasking activity on the transmission of antimicrobial resistance through food will be undertaken in cooperation with other Panels.

CONTAM

No major changes are foreseen in the type of work for 2008. The work in the area of undesirable substances in animal feed, specifically on botanical impurities, will continue in 2008. For coccidiostats as undesirable substances in animal feed, opinions on 3 compounds out of the 11 that are requested will likely be adopted soon and work on the others will continue in 2008. There are several newly received mandates for opinions. The terms of reference obtained from the Commission on the human health risks of cadmium and lead need some discussion with the Commission with respect to the exposure routes and risk groups to be covered.

FEEDAP

The basic regulation on feed additives (EC No 1831/2003) foresees a review of all feed additives within 7 years, e.g. by 2010 and for this the European Commission is still working on the Guidelines for applicants. By end of 2009 about 3000 dossiers could be expected. The need for an additional EFSA guidance document will depend on the content of the guidelines from the European Commission.

GMO

For 2008 it is estimated that 30 applications will arrive in addition to the 20 applications for renewal of existing products recently received. The collaboration with the FEEDAP Panel is working well and this cooperation is also foreseen for bioproteins. Recently an opinion, based on a self tasking activity, was adopted on the use of animal testing in GMO risk assessment. Several other self task activities such as for allergenicity, statistics and GM plants for non-food and feed purposes will continue in 2008.

NDA

The upcoming evaluations of Article 14 claims (disease risk reduction claims and claims for development and health in children) are expected to bring a large workload for the panel. The EFSA guidance document for these dossiers was published in June 2007. For Article 13 claims (general claims on food products), lists compiled by Member States are expected to arrive in early 2008. For Article 18 claims there is pressure on the European Commission to accept additional claims. The panel is currently working on nutrient profiles as well as population reference intakes, food allergens and novel foods.

PLH

Some of the 30 opinions in response to a request from the Commission on pest risk analyses made by France on "Organisms which are considered by France as harmful in French overseas departments" have been adopted and the work is expected to be finalised in the first half of 2008. The Panel is also expecting to start a few self tasking activities. Later in 2007, a colloquium on pest risk assessment will be held on invasion of species and their risk assessment.

PPR

The "Guidance document on risk assessment of pesticides for birds and mammals" will go to public consultation after the December plenary and is expected to be published in the spring. An Art. 36 call has been tendered to assist the preparation of guidance on operator protection. The Member States have been consulted on the next Guidance Document to be produced on the persistence of pesticides in soil.

9. UPDATE ON EFSA SCIENTIFIC COOPERATION (ESCO) WORKING GROUPS

The Director of Science explained the working procedure for reporting within the framework of EFSA scientific cooperation projects. The outcome of an ESCO WG is in principle a scientific cooperation report to the Executive Director. Once the report has been received, EFSA's Executive Director will decide on appropriate follow-up measures to take in relation to the report. The report could be seen as an end result, but may also be forwarded to an appropriate Scientific Panel or Committee as a basis for a future opinion. Both the Advisory Forum and the Scientific Committee will be kept informed about the progress of the scientific cooperation projects.

For the ESCO WG on Emerging Risks, the Scientific Committee agreed that an expert from each panel would be appointed to follow the ongoing work, to exchange view points and discuss possible indicators.

10. REQUEST FOR A SCIENTIFIC OPINION ON THE RISKS ARISING FROM NANOSCIENCE AND NANOTECHNOLOGIES ON FOOD AND FEED SAFETY AND THE ENVIRONMENT - DISCUSSION OF THE TERMS OF REFERENCE

The terms of reference received from the European Commission were re-discussed. The request to assess the need for specific risk assessment approaches of applications of nanotechnologies in the food and feed area was welcomed. However, the Scientific Committee was of the opinion that it would not be possible to conduct a generic hazard characterisation and risk assessment related to materials and processes based on nanoscience and nanotechnologies (points 1 and 3 of the original request) as these depend, *inter alia,* on the physical and chemical properties and the toxicokinetics of the nanoparticle in question. EFSA will send a proposal for a revised mandate to the European Commission based on the discussions in the Scientific Committee.

11. QUALIFIED PRESUMPTION OF SAFETY (QPS) – DRAFT OPINION – FOR DISCUSSION

The draft opinion was presented and the major aspects were discussed including whether the QPS approach is suitable for EFSA's need for a simplified safety assessment tool for microorganisms added to food and feed, and the need for EFSA to build and maintain lists of microorganisms that are granted QPS status was discussed.

Participants were informed that a meeting with the European Commission is scheduled before the draft opinion will be considered for adoption to discuss possible implications for risk managers of implementation of the QPS approach by EFSA.

The opinion will be amended taking into consideration the points raised during the discussion, as well as with the outcomes of the meeting with DG SANCO. It will then be presented for possible adoption at the next Scientific Committee plenary meeting.

12. BENCHMARK DOSE APPROACH – 1ST PART OF THE OPINION ON THE USE OF THE BMD APPROACH IN RISK ASSESSMENT – FOR DISCUSSION

A presentation was given on the first part of the opinion. It was felt that the BMD approach has some clear advantages over the currently used no-observed-adverse-effects-level (NOAEL) approach for dose-response analysis and the setting of health-based guidance values. With the BMD approach the uncertainties in the dose-response information can be evaluated and quantified. However there needs to be further discussion on how the BMD approach can be more widely implemented.

The BMD Working Group will continue its discussions and is aiming at presenting a draft opinion for endorsement for a public consultation at the plenary meeting of the Scientific Committee in February 2008.

13. DRAFT OPINION ON THE IMPLICATIONS OF ANIMAL CLONING ON FOOD SAFETY, ANIMAL HEALTH AND WELFARE, AND THE ENVIRONMENT – FOR DISCUSSION

The Scientific Committee commented on a preliminary draft of the opinion. The points raised by the Scientific Committee will be reflected by the Working Group. It is planned to present a draft opinion at the next Scientific Committee plenary meeting in November for endorsement for a public consultation. The opinion is foreseen to be adopted in February 2008.

14. DRAFT GUIDANCE DOCUMENTS ON THE SAFETY ASSESSMENT OF BOTANICALS AND BOTANICAL PREPARATIONS – FOR ADOPTION

Members of the Scientific Committee were presented with a proposal for a guidance document on the safety assessment of botanicals and botanical preparations for possible adoption. The participants welcomed the approach but raised some concerns that the document might be perceived as too prescriptive. It is indeed the intention of the guidance document to propose a framework for assessing the safety of botanicals and botanicals preparations used as food supplements and list what could be relevant data to consider when assessing safety. The draft guidance document will be modified to reflect the outcome of the discussion.

Members of the Scientific Committee were also presented with two compendia listing alphabetically botanicals reported to contain toxic, psychotropic or addictive substances, or reported to have also a medicinal use. It was made clear that these compendia are not finalised yet, without any judgement whether these botanicals are safe or unsafe for food supplement use, and that they should be considered as working tools to identify, for a given botanical, the active compound(s) that may deserve consideration when looking at safety aspects.

The updated guidance document will be presented again for possible adoption at the next Scientific Committee plenary meeting in November. The compendia are not subject to the adoption procedure but will be published together with the guidance document, once adopted, as associated working tools.

15. REPORT BACK FROM OTHER WORKING GROUPS

Welfare of Experimental Animals

All Panels that are involved with animals have been consulted. A draft document will be presented to the Scientific Committee early next year.

Transparency in Risk Assessment

Good progress is being made and a document will be presented to the Scientific Committee in February 2008 for possible endorsement for public consultation

Risk-Benefit Assessment

The working group is making progress and the next meeting is scheduled in October.

16. EU-EUROFIR AND NORDIC COUNCIL OF MINISTERS DATABASES ON BIOACTIVE COMPOUNDS – RELEVANCE FOR EFSA'S WORK

The EuroFIR database (supported by DG research) deals with bioactive constituents of major European plants with anticipated health beneficial effects and the NORTOX database deals with bioactive constituents of plants with potential toxic effects. The two databases have been developed under earlier DG Research-funded projects. The Scientific Committee was asked to provide advice on the usefulness of these databases for EFSA's work and to consider if and how EFSA could maintain these databases after the current funding has come to an end. The Scientific Committee felt that the databases would be of value for EFSA's work and that the completion and maintenance of these databases should be further explored by EFSA.

17. ANY OTHER BUSINESS

There was no other business.