European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

Parma, 18 November 2009

MINUTES OF THE 38TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 29-30 SEPTEMBER 2009 IN PARMA

[adopted on 17 November 2009]

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, Andrew Chesson, John D. Collins, Albert Flynn, Corrado L. Galli[1], Anthony Hardy[2], Klaus-Dieter Jany, Ada Knaap, Harry Kuiper, John-Christian Larsen, David Lovell, Josef Schlatter, Vittorio Silano, Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle, Elisa Aiassa[3], Hubert Deluyker, Dirk Detken[4], Stefan Fabiansson[5], Pietro Ferrari[6], Anne-Laure Gassin[7], Riitta Maijala, Tobin Robinson[8], Elena Scaravelli[9], Didier Verloo[10].

Secretariat of the Scientific Committee:
Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici, Torben Nilsson, Francesca Piombini.

European Commission (EC):
Michael Walsh (DG Health and Consumers/Unit 03 – Science and Stakeholder relations)

[1] Present on 29 September
[2] Present on 30 September
[3] Present for agenda point 11 on 29 September
[4] Present for agenda point 12 and 13
[5] Present for agenda point 11 on 30 September
[6] Present for agenda point 11 on 30 September
[7] Present for agenda point 14
[8] Present for agenda point 11 on 30 September
[9] Present for agenda point 11 on 30 September
[10] Present for agenda point 11 on 29 September

1. OPENING

The Chair opened the meeting and welcomed the participants.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

There were no additional declarations of interest other than those already reported in the annual declarations of interest.

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

- **National Expert Meeting on dietary reference values**

EFSA organised a meeting on 7th-8th September 2009 in Barcelona with nutrition experts from Member States to exchange views on draft opinions published by the Nutrition (NDA) Panel in the area of Dietary Reference Values (DRVs) covering fats, carbohydrates, fibres and water as well as food-based dietary guidelines. The meeting was also an opportunity to brief the national experts about the comments received during the consultation period , to gain more comments and to clarify EFSA's scientific role in determining the DRVs.
The meeting was fruitful and opened the possibility for cooperation with Member States on dietary reference values for micronutrients.

- **Advisory Forum, 23rd-24th September 2009**

The participants were updated on the issues discussed at the 33rd Advisory Forum meeting in Stockholm. A fruitful discussion was held on various emerging issues raised by the Member States. EFSA presented a proposal to further strengthen the cooperation with the Member States through medium-term planning and the detailed discussions were referred to the Steering Group on Cooperation. The Chair of the NDA Panel presented the activities and cooperation with Member States in the NDA area.

5. UPDATE ON REQUESTS FOR OPINIONS

- **EC mandate for the development of a protocol for 90-day feeding trials with whole food/feed**

A first discussion on the mandate was held at the July plenary. The Scientific Committee is of the view that the mandate is too broad and could be more focused. The Committee agreed to initiate a dialogue with the Commission and that a revised mandate with a clarified Terms of Reference and a proposal for the composition of the working group will be presented at the November plenary.

- **EC mandate on nanotechnologies**

A dialogue with the Commission has been initiated to discuss the mandate, following recommendations given at the July plenary. A revised mandate will be presented at the next SC plenary in November together with a proposal for the composition of a working group.

- **Self task mandate for the development of guidance on statistical approaches to help to assess adverse or biologically relevant effects.**

The aim of this activity is to develop guidance on how to integrate statistical approaches and the results from toxicological and other studies presented in dossiers submitted to EFSA. The Panels have been consulted to identify areas where statistical approaches need to be addressed. The mandate will be amended following comments received and discussed at the November plenary.

- **Self-task mandate on genotoxicity testing strategies**

The preliminary list of experts to be invited for the EFSA working group on genotoxicity testing strategies as well as a tentative road map for the preparation of the opinion were presented. The process for the establishment of the working group has been initiated and the kick-off meeting will be probably held in January 2010.

6. POSSIBILE FUTURE ACTIVITIES FOR THE SC

- **Harmonisation risk assessment terminology**

EFSA has launched a negotiated procedure to produce a report where EFSA opinions published during the last 12 months will be screened to analyse how risks have been expressed by the various Panels and Scientific Committee. The outcome will be considered by a Scientific Committee working group with the objective to ensure further harmonisation of risk assessment terminology used in EFSA's scientific outputs.
The harmonisation of risk assessment terminology will be discussed at the 5th meeting of the Chairs and Secretariats of the EU Commission and Agency Scientific Committees and Panels involved in risk assessment that will be held in Brussels on 18th-19th November.

- **Building up expertise within EFSA on predictive toxicology software**

Several software have been developed worldwide to predict toxicity endpoints. EFSA Panels have sometimes used such tools for hazard characterisation of chemicals with limited toxicity data. It would be useful for EFSA to explore performance, reliability and utility of such *in silico* toxicity software systems and to build up expertise in predictive *in silico* toxicology to support Panels when using *in silico* prediction in their risk assessment.

The Scientific Committee proposed to consult Panels on their specific needs regarding predictive toxicology software and to explore the possibility to organise an EFSA colloquium/symposium in 2010.

Since other EU agencies are also confronted with the same needs, the topic on predictive toxicology tools will be proposed for further discussion at the 5th meeting of the Chairs and

Secretariats of the EU Commission and Agency Scientific Committees and Panels involved in risk assessment.

7. UPDATE ON NUTRITION (NDA) PANEL ACTIVITIES

The chair of the NDA Panel presented the ongoing work programme. Between July and December 2008 EFSA received from the European Commission a draft list with 4,185 main claims to be evaluated. This list was the result of a consolidation process carried out by the Commission, after examining over 44,000 claims supplied by the Member States. The Panel is proceeding with the adoption and publication of scientific opinions on the outstanding claims on the list. EFSA is liaising with the European Commission in order to define a more precise timetable for completion of the work taking into account possible additional claims to be evaluated.

The first batch of opinions related to general function health claims submitted under article 13.1 of Regulation (EC) 1924/2006 has been adopted and will be published on 1 October. The opinions provide scientific advice on 523 health claims relating to over 200 foods and food components. For approximately one third of the claims the outcomes of the evaluations were favourable as there was sufficient scientific evidence to support the claims. About 2000 claims have been sent back to the Commission and Member States for clarification.

EFSA convened a meeting with experts from Member States and the European Commission on 6th October 2009 in Brussels to discuss the evaluation of the 'general function' claims. Issues to be addressed include, among others, the outcome of claims evaluations completed, the procedural aspects e.g. accessibility of the documents, the timelines for EFSA's evaluation of claims received.

The European Commission requested EFSA to deliver scientific opinions on Dietary Reference Values for the European population. The mandate was allocated to the NDA Panel. Five opinions were published for public consultation in August 2009 and they are intended to be finalised by the end of 2009.

A national expert meeting on dietary reference values was held in Barcelona on 7th-8th September 2009. The meeting was the opportunity to exchange views between national experts and NDA Panel experts and staff on the draft opinions published for public consultation. Cooperation with Member States has been proposed on dietary reference values for micronutrients where the work is planned to start in 2010.

8. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

Three self-task mandates were discussed at the last plenary; development of animal welfare risk assessment guidelines, tick disease in wild life and good practise in conducting scientific assessment in animal health using modelling.

The work on the mandate on the impact of the genetic selection of broilers is ongoing and a public call for data was opened in July with deadline 15th October. A technical meeting on animal welfare aspects of genetic selection on broilers and broiler breeders has been held in September. During the meeting the background and the scope of the mandate, the purpose of the data collection and the methodological approach developed by the Panel was presented.

Panel on food additives and nutrient sources added to food (ANS)

The last plenary meeting was devoted to the evaluation of the six synthetic colours involved in the Southampton study. The opinions will be soon published.

Panel on biological hazards (BIOHAZ)

Two self-task mandates have been proposed and discussed at the last plenary in relation to viruses in food and in water. The opinion on BSE-related risk of bovine intestines has been adopted. A new Commission mandate has been received in relation to possible epidemiological or molecular association between TSE in animals and humans. The work to update the list of QPS organisms intentionally added to food and feed is ongoing.
The BIOHAZ Unit maintains two networks with Member States, one on microbiological risk assessment and one on TSE.

Panel on genetically modified organisms (GMO)

EFSA held a two-day conference on GMO risk assessment for human and animal health and the environment on 14th-15th September in Brussels. The conference was the opportunity for bringing together risk assessor from Member States, risk managers and representative from stakeholders including industry, consumers and environmental groups.
In line with EFSA's commitment to regular open dialogue with organisations with a legitimate interest in its work, EFSA invited NGOs to a meeting on 2nd October to discuss the latest scientific issues regarding GMOs.
The working group on assessment of allergenicity of genetically modified foods has finalised the draft report that was endorsed at the last plenary. The report has been now sent for Panel and Scientific Committee consultation and it is planned for adoption at the October plenary.

Panel on contaminants in the food chain (CONTAM)

The opinion on arsenic in food was discussed at the last plenary meeting and it will be adopted by written procedure and published in October. The Panel is currently working on opinions on lead in food, melamine in food and looking also at food contact materials as source of exposure. Work on marine biotoxins is still ongoing.

Panel on additives and products of substances used in animal feed (FEEDAP)

The Panel initiated a self task activity to evaluate the safety for the consumer and the user related to cobalt compounds used as feed additives. The potential impact on target animal health in view of the given genotoxic and carcinogenic properties of inorganic cobalt (II) compounds will be also evaluated. Three opinions were adopted at the last plenary meeting.

Panel on food contact materials, enzymes, flavourings and processing aids (CEF)

Seven opinions on flavourings have been adopted at the last plenary meeting. The guidance for the evaluation of food enzymes was published for public consultation and the comments have been considered where appropriate by the working group. The Guidance was adopted at the July plenary and published in August. Work is ongoing for the guidance opinions on submission of dossiers for smoke flavourings. A statement on the interpretation of the margin of safety for the smoke flavourings has been discussed by the Panel and is planned for adoption at the next plenary.

Panel on plant health (PLH)

The Panel discussed the possibility to embark on a self-task mandate on environmental risk assessment in plant health. General agreement was expressed by the Panel and the mandate will be sent for the Mandate Review Committee (MRC). A public consultation has been envisaged before adoption of the opinion. Three new mandates have been received from the Commission. The chair reported the active collaboration with the DG JRC with regard to modelling to produce estimate of pest distribution in EU. A special Advisory Forum meeting on Plant Health will be held on 20th-21st October in Parma.

Panel on plant protection products and their residues (PPR)

Six opinions updating data requirements for active substances in relation to the revision of annex II and III of Regulation (EC) 91/414 have been adopted. A joint working group composed by representatives of the Member States and the Commission will produce a document summarising the decision taken regarding the use of the EFSA guidance document on risk assessment for bird and mammals to derive EU guidance. This document will be presented to the Standing Committee before publication.

Note from the Secretariat

The Secretariat presented a proposal to facilitate the feedback on the state of play of the work conducted by the EFSA Panels. The Register of Questions could be used to produce a list of adopted opinions since last plenary meeting and this list could be sent to the Scientific Committee few days before the meeting with the possibility to indicate for each output whether there are any relevant issues to be considered by the Scientific Committee. The Scientific Committee welcomed the proposal of the Secretariat and suggested to include in the list also the self-task mandates endorsed by each Panel.

9. REPORT BACK FROM WORKING GROUPS

- ***Risk benefit***

The working group did not meet since the last plenary. The next working group meeting is planned for November. Bernard Bottex and Ada Knaap (Chair of the working group) attended the first QALIBRA (QuAlity of Life – Integrated Benefit and Risk Analysis) end-user EU workshop on Risk-Benefit Assessment for Foods held in Budapest 9-10 September 2009. The aims of the event were to communicate the key results of the QALIBRA project to food safety experts with a direct interest in risk-benefit analysis of food and give them a detailed introduction to the risk-benefit modelling approaches developed in the project. Further, the workshop included practical hands-on training with the risk-benefit software produced by QALIBRA, using case studies developed in the project, one on functional foods, the other on oily fish.

- ***Threshold of Toxicological Concern (TTC):***

An Article 36 has been launched for the preparation of a report on "Applicability of physicochemical data, QSAR and read-across in threshold of toxicological concern assessment". Deadline for the presentation of proposals is 1st October. The working group is making good progress and will meet twice before the end of 2009.

10. DISCUSSION ON RISK ASSESSMENT APPROACHES FOR:

- ***Food contact materials and flavourings (strategies for genotoxicity testing)***

The Head of the CEF Unit presented the state of the art of the different approaches for genotoxicity testing currently in use for food contact materials, flavourings and smoke flavourings and enzymes. The different approaches have triggered discussion on the need of harmonisation and consistency in the various areas. Possible harmonisation of test requirements will be addressed also by the newly established Scientific Committee working group on genotoxicity testing strategies, where representatives of the different Panels have been invited to participate. The CEF Panel will reconsider the requirements in the light of the work of the genotoxicity testing strategy SC working group.

- ***Smoke flavourings (use of margin of safety for the assessment)***

In 2009 the CEF Panel has issued 7 opinions on smoke flavouring primary products. For five of the products, the Panel concluded that the margins of safety are insufficient and that the use of these primary products at the proposed uses and use level is of safety concern. In July the Commission raised the question on "how high should the margin of safety be to ensure the safe use of the primary products". The CEF Panel has then proposed a self-task mandate to produce a statement on the interpretation of the margin of safety for smoke flavouring primary products. As the margin of safety is of general interest for EFSA's risk assessment practise, the Panel suggested to liaise with the Scientific Committee. The draft statement was presented and discussed. The statement is planned for adoption at the next plenary of the CEF Panel in November.

11. REPORT BACK FROM SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

- ***AMU workshop on systematic review and meta analysis: application in food and feed safety***

The Assessment Methodology Unit (AMU) presented the project on the application of systematic review methodology to food and feed safety assessment in support of decision making. A working group composed by EFSA staff and external experts from different areas has drafted a guidance document that will be published in December 2009. The guidance assesses the relevance of systematic review to risk assessment and examine how to integrate systematic review into food and feed safety assessments, considering the specific requirements of this field. An EFSA workshop will be organised in the beginning of 2010 to present the content of the guidance document and to discuss when and how systematic review could be implemented in EFSA. The Scientific Committee welcomed the proposal to organise a workshop on this subject. The dates proposed needs to consider availability of the Panels.

- ***Result of the Panel consultation on default assumptions used in risk assessment***

The DATEX Unit presented the draft technical report on default assumptions used in risk assessment by EFSA's Scientific Committee and Panels in the absence of actual measured data. In the absence of empirical data, default values are often used by the Panels to perform risk assessment in the different areas in the remit of EFSA activities. Panels and Units were consulted via a questionnaire and the information was collected in the technical report presented to the Scientific Committee. The Scientific Committee congratulated the DATEX Unit for the interesting report which provides an overview of the state of the art on default values presently in use by EFSA. This report is considered as a starting point for further efforts in harmonising the use of default assumptions across EFSA. The Scientific Committee proposed to draft a self-task mandate to follow up the project. The mandate will be presented and discussed at future plenary. The proposal to organise a workshop on this subject was also welcomed.

- ***Update of the DATEX working group on left censored data handling***

This working group concerns the handling of chemical contaminants data reported to be below the limit of detection. This data are typically left-censored and this presents difficulties in statistical analysis of the data. A working group was established coordinated by the DATEX Unit with the aim to explore in depth the robustness of the four different statistical approaches currently in use for handling left censored data. The performance of different approaches has been evaluated in a simulation study with parametric and non-parametric methods. Finalisation of the project is expected in November where also a report/guidance will be presented and recommendations on how to deal with occurrence data will be provided. The final report will be shared with the Scientific Committee.

- ***Update of the Emerging Risks (EMRISK) Unit and future activities***

The Head of Unit presented an overview of the recent and future activities on Emerging Risks. EFSA has started to execute its programme to develop an effective and transparent approach to identify emerging risks. This consists of an operational definition of emerging risks and an overall strategy for the collection, analysis and evaluation of the relevant data and

information. The strategy foresees four time scale: preparation of urgent issues, urgent questions (e.g. in a crisis situation), medium-term and long-term prediction of emerging risks. Current tools under development by EFSA/EMRISK are: Rapid Alerts (IT applications for data analysis of the Rapid Alert System for food and feed-RASFF); European Media Monitoring (EMM) system (assessment of information derived from the JRC media monitoring system); trade surveillance analysing data from Eurostat and UN Comtrade, a database for international trade. An evaluation process of these systems is ongoing for looking at their value for emerging risk identification, identified more components for further development, and established contacts with external information sources. The EMRISK Unit is at present focussing on the strategy for the medium-term identification of emerging risks.
The EMRISK Unit is also part of the exchange network information where representatives from Member States, European Commission and EU and International Agencies come together to agree on common strategies on emerging risks that may be of interest of more than one partner of the network.

The Scientific Committee acknowledge the good work of the EMRISK Unit and suggested the Advisory Forum as a useful forum for the identification of emerging risks, since a number of issues are already identified at Member State level.

The Scientific Committee asked clarifications about the procedures for handling crisis situations. The support on urgent issues involves the maintenance of the Emergency Manual the organisation of emergency or "crisis" training, and the technical and administrative support for answering urgent issues.

Emerging Risks will also be discussed at the 5th meeting of the Chairs and Secretariats of the EU Commission and Agency Scientific Committees and Panels involved in risk assessment that will be held in November in Brussels.

12. UPDATE ON RULES OF PROCEDURES FOR THE ESTABLISHMENT AND OPERATION OF THE SC AND PANELS AND THEIR WORKING GROUPS

The Head of the LPA Unit presented a draft proposal for amendments to the Management Board Decision concerning the establishment and operations of the Scientific Committee and Panels and of their working group. The original document, published in 2006, was amended in 2007 to incorporate the new rules on the Declaration of Interest for the Panel members and external experts participating at working group meetings. The purpose of the 2009 revision is mainly to reflect the creation of the CEF and ANS Panels; the possibility for the Executive Director to be assisted by the Mandate Review Committee in the assignment of tasks to EFSA's scientific bodies; the clear descriptions of the procedures to address minority opinions; the clear definition and separation of rules for working groups from those for EFSA Scientific Committee and Panels. The Scientific Committee made a number of comments that will be incorporated in a revised draft that will be presented at the next SC plenary. It is

intended to submit the final draft for possible adoption to the Management Board at its meeting in December 2009.

13. COOPERATION WITH EU BODIES FOR THE IDENTIFICATION AND MANAGEMENT OF POTENTIAL DIVERGENCES OVER SCIENTIFIC OPINIONS – DRAFT COMMON GUIDELINES

The Commission has prepared draft guidelines on cooperation between EU scientific bodies to prevent and manage possible divergences over scientific opinions. The Scientific Committee has been asked to comment on the draft proposal by middle of October. The final draft resulting from this consultation will be circulated at the 5th meeting of the Chairs and Secretariats of the EU Commission and Agency Scientific Committees and Panels involved in risk assessment.

14. ANY OTHER BUSINESS

- ***Interaction EFSA Panels/Committee with Communications Directorate***

EFSA is in the process to initiate the revision of its communication strategy and the role of the Scientific Committee and Panels in this revision is extremely important. The definition of priorities and of the issues to communicate is important for the effective communication to the media and to the public. EFSA will increase the multilingual outreach translating more documents in the four official languages of the Authority and some key documents in all the 23 official languages of the EU.

- ***Scientific Committee activity on Botanicals***

EFSA will organise a workshop with the participation of the Member States, the European Commission and stakeholders in Athens on 24th November 2009 to present the science-based approach developed by EFSA for the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. The workshop has been organised back to back with the AF meeting in Athens on 25th-26th November 2009 to facilitate the possible participation of AF members, taking note of the strong interest in the subject at the latest AF meeting.

- ***Extra SC plenary***

The extra SC plenary on 11th December in Brussels has been confirmed.

- ***Draft agenda SC away day***

The Scientific Committee will have an away day on 1st October in Salsomaggiore. The aim of the meeting is to have an in depth discussion on several aspects of common integrated approach interests of the Panel Chairs and of particular relevance for the Scientific Committee. The meeting will also help in prioritising which subjects should be dealt with and when, and how the newly developed approaches, once becoming available as SC opinion/guidance, can most effectively be implemented across EFSA's Panels.