European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

Parma, 8 July 2009

MINUTES OF THE 36TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 25-26 MAY 2009 IN PARMA

[adopted by written procedure on 8 July 2009]

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, John D. Collins, Albert Flynn[1], Anthony Hardy, Jörg Hartung, Klaus-Dieter Jany, Harry Kuiper[2], Ada Knaap, Pierre Le Neindre, David Lovell, Iona Pratt[3], Jan Schans, Josef Schlatter[4], Vittorio Silano (Chair), Staffan Skerfving and Piet Wester

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle, Hubert Deluyker, Anne-Laure Gassin, Gisele Gizzi[5], Ilias Papatryfon[6] and Olivier Ramsayer[7]

Secretariat of the Scientific Committee:
Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici and Ralf Reintjes

European Commission (EC):
Michael Walsh (DG Health and Consumers/Unit 03 – Science and Stakeholder relations)
Alejandro Herrero Molina (DG Joint Research Centre – Institute for Reference Materials and Measurements)

Hearing Expert
David Gee (European Environmental Agency[8])

[1] Left after lunch 26th of May
[2] Present on 25th May
[3] Left after lunch 26th of May
[4] Left after lunch 26th of May
[5] Present for agenda point 5
[6] Present for agenda point 12
[7] Present for agenda point 1
[8] Present 25th of May

1. OPENING AND APOLOGIES FOR ABSENCE

Apologies were received from Philippe Vannier, John-Christian Larsen and Andrew Chesson. The AHAW, ANS and FEEDAP Panel were represented by Vice-Chairs Jörg Hartung, Iona Pratt and Piet Wester, respectively. Oliver Ramsayer, new Director of EFSA's Administration Directorate was introduced to the members of the Scientific Committee.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted with a slight modification as the feedback from the European Commission on Opinions adopted by the SC in 2006-2009 foreseen under agenda point 5 became a separate agenda point, 5b.

3. DECLARATIONS OF INTEREST

Anthony Hardy declared an interest in agenda item 8 "Harmonisation of Terminology in Risk Assessment" as the Institute for which he was working (DEFRA – former UK Central Science Laboratory) was contracted in 2007 by DG Health and Consumers to prepare a report on terminology and expressions used by the non-food Scientific Committees (published in November 2007). The EFSA Secretariat did not consider that his past involvement in this project constituted a conflict of interest with the discussions planned under agenda item 8.

With regard to the Annual Declarations of Interest and the Specific Declarations of Interest for this meeting, there were no other interests declared than those already included in previous declarations and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof.

4. ADOPTION OF THE MINUTES OF THE 35TH SC PLENARY

The minutes of the 35th Scientific Committee plenary were adopted and will be published shortly.

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

Advisory Forum, 22-23 April 2009

The Scientific Committee members were updated on issues discussed at the 31st EFSA's Advisory Forum (AF) meeting in Bucharest (Romania). During the meeting, Belgium asked for an update on the assessment of health claims by the NDA Panel. France informed that AFSSA has issued an unfavourable opinion on *Stevia* as a sweetener. The AFSSA opinion will be brought to the attention of the ANS Panel who is also working on *Stevia.*

The workload of the EFSA Panels was discussed and the possibility for Member States to assist in specific scientific areas to share the workload was discussed. EFSA's cooperation with MS will be further discussed at the Management Board meeting in June.

The Head of the CEF Unit presented ongoing activities and identified areas where assistance from MS could be of help, e.g. for non-plastic packaging materials and enzymes. The participants proposed to have regular presentations at AF meetings of ongoing work by Panels' Chairs and Secretariats.

The participants were informed about the outcomes of a meeting with national experts on aspartame in April 2009. The participants looked at the published literature and other data that became available since the release of the opinion on aspartame of the (former) Scientific Committee on Food in 2002[9]. An organising team of experts nominated by Member States prepared for the meeting. A second national expert meeting is scheduled for November 2009.

The Advisory Forum also discussed the ESCO report on folic acid which will soon be published.

Steering Group on Cooperation (SGC), 18 May 2009

The SGC followed-up the discussion at the April Advisory Forum meeting on how Member States could contribute to the work of the CEF Panel especially in the area of non-plastic food contact material. The participants also discussed the outcomes of a survey among the Member States aimed at identifying subjects of priority in the area of harmonisation of risk assessment approaches across Europe. Once finalised, the outcomes of the survey will be brought to the attention of the Advisory Forum and Scientific Committee.

Visit to the European Chemicals Agency (ECHA), 20 May 2009

Delegations of EFSA and ECHA met at ECHA in Helsinki on May 20th to exchange views on possible cooperation in various areas of common interest, ranging from setting-up databases for the collection of data on chemicals and methodologies in the area of hazards and risk assessment to best practices in the area of risk communication. At the end of the visit, a memorandum of understanding between EFSA and ECHA was signed.

5B. REPORT BACK FROM EUROPEAN COMMISSION ON OPINIONS ADOPTED BY THE SCIENTIFIC COMMITTEE IN 2006-2009

The Commission services were requested to review the relevance for the European Commission of the output produced by the Scientific Committee. The Commission acknowledged the excellent work of the Scientific Committee and of the individual Panels. The Scientific Committee is a useful forum to discuss efforts to improve the general safety of the food chain.

[9] For further information about this activity, see http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178621457187.htm .

The Scientific Committee adopted two opinions during its current mandate (e.g. opinions on animal cloning and nanotechnology) for which the follow-up is still ongoing. The Commission representative explained that unlike the Scientific Panels, the work of the Scientific Committee relates mainly to EFSA's own initiative for scientific opinions as foreseen in Article 29 (b) of Regulation (EC) No 178/2002 (EFSA founding regulation). These include opinions, such as, transparency in risk assessment, uncertainties in dietary exposure assessment and qualified presumption of safety and relate to the role of general coordination to ensure the consistency of the scientific opinion procedure and harmonisation of working methods as provided for in Article 28 of the EFSA founding Regulation. Whilst the Commission recognises the importance of these opinions in discharging its responsibility, they do not have a direct legislative follow-up as is the case for most opinions requested by the Commission. However the Commission recognises the importance of the opinions of the Scientific Committee and intends continue and deepen its dialogue with EFSA to explore the longer term implications for risk management of such opinions.

With respect to systematic feedback to the Scientific Panels and the Scientific Committee, it was indicated that the current practice in each Panel of including an agenda item on feedback since the previous meeting should continue. In addition, a tabulated feedback would be provided twice annually by the Commission services.

The Scientific Committee welcomed the comments and feedback provided which was considered very important, especially for Panel members and secretariats, to understand the use made by the Commission of the EFSA opinions in the European regulatory framework. The feedback from the Commission is also very important for the Panel members to show the importance of the work to their home institutions.

Furthermore the need for reviewing the internal EFSA procedure of mandating (co)-opinions to the Scientific Panels was noticed.

6. DRAFT OPINION ON THE USE OF BENCHMARK DOSE APPROACH IN RISK ASSESSMENT

The Chair of the Benchmark Dose (BMD) working group introduced the draft opinion intended to evaluate the potentials and limitations of this new methodology and to advise whether such a new approach should be implemented across EFSA's Scientific Panels. The BMD approach is scientifically more advanced than the conventionally used No-Observed-Adverse-Effect Level (NOAEL) approach, as it also gives a quantitative measurement of the uncertainty of the outcome.

A Panel consultation, which was organised in the first few months of 2009, confirmed that the BMD approach has already been used by some Panels in several opinions. Once it is decided to use the BMD approach by the Panels, it is proposed that the implementation throughout the Panels will be done gradually in order to allow EFSA experts to get familiar with this new approach.

The Scientific Committee congratulated the working group for a well drafted opinion. During the discussion several comments were provided and after minor revision the opinion was adopted. The Scientific Committee took note of the appendix to the opinion which describes the use of available BMD software. The Secretariat will finalise the opinion for publication.

7. ESCO REPORT ON BOTANICALS

This agenda point was chaired by Vice-Chair Ada Knaap. The Chair of the ESCO working group presented the report prepared by the ESCO WG and the accompanying compendium.

The Scientific Committee took note of the documents which will also be presented to the Advisory Forum at the end of June 2009.

The Scientific Committee, on request of the EFSA Executive Director, will now consider the recommendations made in the ESCO report for updating its guidance document for the safety assessment of botanicals and botanical preparations intended for use as supplements. The updated guidance document will be proposed for discussion and possible adoption at the next plenary meeting in July 2009.

8. HARMONISATION OF TERMINOLOGY IN RISK ASSESSMENT

David Gee (European Environmental Agency) gave a presentation with the title "Evaluation and communication of Scientific Evidence on Environment and Health (ECSEEH)". In this presentation, a valuable overview of the context and rationale of the ECSEEH project was provided. In addition, examples of some divergent evaluations of evidence and reasons why evaluations may differ were given. The presentation also referred to the final report "Comparative review of risk terminology" of the Central Science Laboratory (UK) of a project which was commissioned by the European Commission.

Several organisations have developed systematic approaches for evaluation and expression of uncertainties in risk assessment, including EFSA and IPCS (International Program on Chemical Safety), as well as the GRADE (Grading of Recommendations Assessment Development and Evaluation) scheme, which is currently used in the medical field but may have suitable applications in other areas after adaptation.

During the discussions, the Scientific Committee acknowledged that many terms to communicate risks in various areas exist and that they should be interpreted in their correct context. It was commented that it may not be feasible or practical to harmonise terminology across all scientific fields but progress can be made, especially in the area of quantifying risk. This exercise is considered of importance to ensure openness and transparency.

The Scientific Committee suggested that the renewed Scientific Panels could initiate discussions on their use of risk assessment terminology and on the way different dimensions of risk and uncertainty are expressed. EFSA will prepare a document that should help and steer the Panels in their discussions.

9. THE JOINT RESEARCH CENTRE AND ITS ACTIVITIES IN SUPPORT TO EFSA

Alejandro Herrero, director of IRMM (Institute for Reference Materials and Measurements), presented the activities of DG Joint Research Centre (JRC).

The JRC consists of 7 different institutes, one being the IRMM, which are located in 5 Member States and are composed of about 3000 staff with a budget of about € 330 million. The JRC cooperates with more than 1000 public and private organisations, institutions and private networks and with more than 250 major networks. More information is found at www.jrc.ec.europa.eu.

A Collaboration Agreement was signed by EFSA and the DG-JRC in 2008. Examples of collaborations are: assessment of EU climatic suitability for the establishment of organisms harmful to plants and plant products, possible contribution of QSAR analysis to the evaluation of toxicological relevance of metabolites and degradation products of pesticides.

Examples of specific areas where the work of JRC is linked to EFSA are e.g. in providing studies related to genetically modified organisms by the Institute of Prospective Technical Studies (IPTS) in Seville which also hosts the secretariat of the European Co-existence Bureau and the co-ordination of the European Network of GMO Laboratories (ENGL) by JRC in Ispra. The JRC has also projects ongoing on nano-toxicology and nano-metrology and the IRMM produces nano reference materials. The JRC has also evaluated several BSE testing methods and has a database of testing methods for food contact materials.

The Scientific Committee expressed its appreciation for this presentation of the JRC and for the excellent cooperation between JRC and EFSA.

10. REPORT BACK FROM THE SCIENTIFIC PANELS

The Scientific Committee was updated on the outcome of the plenary meetings of the Scientific Panels since its last plenary meeting (for more details, see the web pages of the respective Panels on EFSA's website). In particular, the following issues were brought to the attention of the Scientific Committee:

Panel on animal health and welfare (AHAW)

At the April plenary, the AHAW Panel adopted opinions on the stunning and killing of turbot and farmed tuna. The Panel also discussed the four draft dairy cow opinions which are under preparation and a draft opinion on *Brucellosis*. A self-task mandate on ticks as vectors of

diseases has been initiated. The Panel has also received a new mandate to assess welfare of broilers.

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

The Panel Chair provided a written progress report on the outcome of the last two Panel plenary meetings in April and May where several opinions on nutrient sources (e.g. various yeast additives such as chromium yeast and vitamin D-enriched yeast) were adopted. The opinions on the Southampton colours have been postponed pending the obtaining of more refined exposure data. This may enable the Panel to come to a better conclusion regarding comparisons of the proposed ADIs with estimated intakes.

Panel on biological hazards (BIOHAZ)

At the April plenary, three opinions were adopted including an opinion on the use and mode of action of bacteriophages in food production. The Panel is also involved in the interagency/committee (EMEA, ECDC, and the non-food committee SCENHIR) work on the use of antibiotics and trends of antimicrobial resistance. The Panel also noted that there have been no recent indications of any food safety concerns from avian influenza.

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

At the May plenary, the Panel adopted around 20 opinions on flavourings, food contact materials and smoke flavourings. For flavouring opinions, the exposure assessments frequently present difficulties. The Panel also discussed a draft opinion on benzophenone which is scheduled for adoption at a next plenary.

Panel of Additives and products or substances used in animal feed (FEEDAP)

During the April plenary, the draft opinion on Ractopamine, a growth promoter which acts as a hormone receptor binder, was discussed. This substance is used in several countries outside the EU, including the USA, Mexico and Japan and has has reached an advanced stage in the approval in Codex based on a JECFA assessment, but is currently under discussion after this EFSA opinion .

Panel on Plant health (PLH)

At the May plenary, a guidance document on evaluation of pest risk assessments prepared by third parties was discussed as well as a draft opinion on processinary moth. The Panel also discussed a draft guidance document on a harmonised framework for pest risk assessment in the EU which is under preparation and which is scheduled for public consultation in the autumn.

Panel on plant protection products and their residues (PPR)

Work is in progress on several different guidance documents which are under preparation. On request of the European Commission, the Panel will review six earlier opinions on data requirements for active substances and formulations in the view of the revision of the

Directive EC 91/414. The outcome of this review will feed into the ongoing revision of the Directive which will probably be ready for implementation as new legislation in 2010.
The Panel also discussed activities on testing methods and requirements for endocrine disruptors for which DG ENV is currently preparing a work program to move ahead with this activity, especially to set up scientific criteria for the determination of endocrine disruptive properties and to ensure that there is a consistent approach in the legal requirements in REACH and the pesticide legislation. The draft opinion on the risk assessment of cumulative exposure of triazoles was also discussed. A workshop on "Improved realism in soil risk assessment" (IRIS) was held in May 2009 in Ispra (Varese, Italy) where PPR's guidance document on persistence in soil was presented.

11. REPORT BACK FROM WORKING GROUPS

SC Working Group on Risk-Benefit Assessment

There has been no meetings of this working group since the last plenary.

SC Working Group on Threshold of Toxicological Concern

The working group is making good progress. A draft compilation of existing databases have been put together which, once finalised, may be of wider interest to EFSA and its Panels.

Development of an EFSA statement on animal cloning

A draft statement prepared by the Scientific Committee and Advisory Forum Unit was presented to the Scientific Committee. The Scientific Committee appreciated the statement and agreed to provide additional comments on the draft in the following two weeks. The EFSA statement will be published in June.

12. REPORT BACK FROM SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

Article 36 work programme for 2010

A preliminary work program for 2010 on the Article 36 projects was presented. A total budget of € 7.44 million is reserved for these projects. The number of proposed calls is currently 47, which is likely to increase. The calls have been separated into four different categories; (1) support for the examination of authorisation dossiers, (2) preparatory work for risk assessment, (3) data collection and analysis supporting risk assessment and risk monitoring and (4) horizontal issues and scientific cooperation. The Scientific Committee was asked to provide additional comments to the work program by end of June and an updated work program will be presented again at the July plenary. It is planned to submit the final program to EFSA's Management Board for adoption at its meeting in October 2009.

13. PRIORITIES OF THE SC FOR 2009-2013. CONTINUATION OF DISCUSSION FROM THE 35TH SC PLENARY

Development of guidance on statistical approaches to assess adverse or biologically relevant effects

A background document has been prepared and the Scientific Committee is supportive of this timely self mandate. A draft mandate with the terms of reference will be prepared and presented for adoption at the July plenary.

Harmonisation of genotoxicity testing strategies

A background document has been prepared and the Scientific Committee is supportive of this self mandate. A draft mandate with the terms of reference will be prepared and presented for adoption at the July plenary

Draft self tasking mandate on nanotechnologies

A revised draft, based on the discussion held at the previous Scientific Committee plenary was presented. The Scientific Committee accepted the mandate and the process will be initiated at the July plenary meeting.

14. ANY OTHER BUSINESS

Feedback from the Assuring Safety without Animal Testing (ASAT) workshop "Reversal of the Toxicological Paradigm: Risk-based Assessment. 11-12 May 2009, The Hague

A report from this workshop was shared with the Scientific Committee and it was suggested that EFSA follows the developments in this area.

EMEA and EFSA cooperation

This agenda point has been postponed until the next plenary meeting.

CLOSURE OF THE PLENARY MEETING

As the Chair closed the last Scientific Committee plenary in this mandate (2006-2009) by extending his great appreciation to all members of the Scientific Committee for the work that has been carried out over the last three years. The Chair was thanked by the members and by the Executive Director for his excellent chairmanship.