European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

MINUTES OF THE 35TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 7-8 APRIL 2009 IN PARMA

[adopted on 25 May 2009]

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, John D. Collins, Anthony Hardy, Klaus-Dieter Jany, Sirpa Kärenlampi[1], Ada Knaap, Pierre Le Neindre, Jan Schans, Josef Schlatter, Vittorio Silano (Chair), Philippe Vannier.

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle (Executive Director), Bernhard Berger[2], Hubert Deluyker, Lucia de Luca[3], Anne-Laure Gassin[4], Miriam Jacobs[5], Riitta Maijala, Ilias Papatryfon[6], Carola Sondermann[7], Didier Verloo[8].

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

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

[1] Replacing Harry Kuiper
[2] Present for item 7 and 8
[3] Present for item 13
[4] Present for item 6
[5] Present for item 7
[6] Present for item 8
[7] Present for item 7
[8] Present for item 7 and 15

1. OPENING AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. Apologies where received from Andrew Chesson (Chair of the FEEDAP Panel), Albert Flynn (Chair of the NDA Panel), John Christian Larsen (Chair of the ANS Panel), David Lovell, Staffan Skerfving and Harry Kuiper (Chair of the GMO Panel) who was replaced by Vice-Chair Sirpa Kärenlampi.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

Anthony Hardy declared an interest in agenda item 10 "Harmonisation of Terminology in Risk Assessment" as his institute (UK Central Science Laboratory) was contracted in 2007 by DG Health and Consumers to prepare a report on terminology and expressions used by the former and current non-food Scientific Committees (published in November 2007). The EFSA Secretariat did not consider that his past involvement in this DG Health and Consumers project constituted a conflict of interest with the discussions planned under agenda item 10.

There were no other additional declarations of interest other than those already reported in the Annual Declarations of Interest.

4. ADOPTION OF THE MINUTES OF THE 34TH SC PLENARY

The minutes of the 34th Scientific Committee plenary were adopted and will be published shortly after the meeting.

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

Advisory Forum, 18-19 February 2009

The participants were updated on the issues discussed at the 30th EFSA's Advisory Forum (AF) meeting in Ljubljana (Slovenia).

During the AF meeting, it was proposed to invite regularly EFSA's Heads of Units to present updates on the work programme in each of the respective scientific areas and to explore with the members of the AF possible ways for strengthening scientific cooperation. The mandate with the specific terms of reference of the proposed network will be presented for discussion at the next AF meeting.

The AF agreed to start an ESCO project on isoflavones (see also agenda item 8). A draft mandate was approved and a working group will be established subject to the agreement of the SC (later point on the agenda).

Visit of the EFSA Delegation to US Federal Institutions, 9-13 March 2009

An EFSA delegation composed of the EFSA Executive Director Catherine Geslain-Lanéelle, Hubert Deluyker (Director of the Scientific Cooperation and Assistance Directorate), Vittorio Silano (chair of the EFSA Scientific Committee) and Vittoria Villamar (assistant to the Executive Director) visited the Centre for Disease Prevention and Control (CDC) in Atlanta, the Centre of Epidemiology on Animal health (USDA-CEAH) in Fort Collins, the Animal and Plant Health Service (USDA-APHIS), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) in

Washington DC. The EFSA delegation was accompanied during the first two days by Pia Makela (Head of the Zoonosis Unit), Didier Verloo (Head of the Assessment Methodology Unit) and Marta Hugas (Head of the Biohaz Unit). Anthony Hardy (Chair of the PPR Panel), John Christian Larsen (chair ANS Panel), Josef Schlatter (chair of the Contam Panel) and Phillipe Vannier (chair of the AHAW Panel) also supported the EFSA delegation. Delegates received a general introduction to the activities conducted by the Federal Institutions relevant to EFSA. The US Federal Institutions showed a deep interest in EFSA's mission, legal status, working procedures, as well as a good awareness of EFSA main activities. Key areas to foster future collaboration have been identified and key contacts with responsible officials in the different US Agencies visited were established. The US visit was considered as very relevant and fruitful for EFSA.
The Executive Director thanked the chairs of the Panels who participated in this important visit.

Management Board, 31 March 2009

The Management Board approved the nomination of 174 independent experts to renew the EFSA Scientific Committee and eight Scientific Panels for the next term of three years.
The draft Management Plan and draft budget for 2010 was presented and discussed. Five additional posts have been forecasted and an increase of 1.9% of the budget. 2010 will be the end of the rapid growth of EFSA, as planned in the establishment plan. EFSA will now work on further strengthening its internal organisation to keep improving the efficiency and the support to the Scientific Committee and Panels.

Renewal of the Scientific Committee and Panels

EFSA received 848 applications, out of which 732 were eligible. The number of eligible candidates per post increased by 7% compared to the 2006 call. The applicants were from 42 different nationalities. The selected experts will be contacted and will be asked to confirm their willingness to be appointed. A reserve list will also be established. The final list of the nominated experts will be published early June 2009.

6. DRAFT OPINION ON TRANSPARENCY IN RISK ASSESSMENT – SCIENTIFIC ASPECTS

A draft opinion "Transparency in risk assessment – scientific aspects", updated after reviewing the comments received during the public consultation, was presented for adoption to the Scientific Committee. In addition, a report on the outcome of the public consultation on the draft opinion was presented. Most of the comments received were in support of the general principles presented in the opinion. The Scientific Committee adopted the opinion, subject to incorporation of the comments made during the meeting.
The final opinion, a compilation of the comments received and a report summarising the outcomes of the public consultation is available on EFSA's website[9].

7. REPORT BACK FROM SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

Harmonisation of Risk Assessment Approaches between EFSA and the Member States

[9] Available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902513151.htm

The Head of the Scientific and Cooperation Directorate presented a draft list of possible topics for harmonisation of risk assessment approaches between EFSA and the Member States that will be discussed at the Advisory Forum meeting in April. The Scientific Committee expressed an interest in a number of topics proposed and requested to continue the discussions at its next plenary to set priorities, taking into account the comments that will be given by the Member States.

Raising EFSA's scientific visibility – update on the project

The objective is to develop the current EFSA Journal into an online journal, with the aim to publish one volume per month and have the journal indexed in bibliographic databases. A dedicated web area, as well as adjusted layout templates for EFSA's scientific outputs are currently under development. The launch of the EFSA Journal's web area is foreseen for October 2009. The Scientific Committee once again underlined that, for legal reasons, no external peer review can occur after the opinion has been adopted by a Scientific Committee or Panel.

An overview of EFSA's practical experiences with Guidance Documents

The Scientific Committee discussed the practical experiences with producing, using and implementing Guidance Documents. It may be worthwhile to evaluate the potential advantages and disadvantages of transforming Guidance Documents into guidelines for EU legislation purposes. Another objective, following the ESCO report on harmonisation in risk assessment, could be to explore future perspectives for the harmonisation of the presentation of Guidance Documents. The Scientific Committee recommended to ensure a good dialogue with the Commission services on this important issue.

8. ESCO REPORTS

ESCO report on Folic Acid

The report prepared by the EFSA Scientific Cooperation (ESCO) working group on analysis of risks and benefits of fortification of food with folic acid was presented. The report provides a review of current practice in Member States regarding the level of voluntary fortification of foods and categories of foods to which the addition of folic acid is allowed. Moreover, it considers new evidence regarding the risk of high intakes of folic acid and the need for a review of current guidance on safe upper levels of folic acid for all population groups. The Scientific Committee appreciated the work done by the working group and made some comments that will be incorporated in the report. The report will be presented at the Advisory Forum meeting in April 2009 and the final report will then be submitted to the EFSA Executive Director for further consideration.

ESCO Working Group on Botanicals and Botanical Preparations

The ESCO Working Group on Botanicals and Botanical Preparations will finalise its activity at the end of April 2009. The report, composed of the advice on the EFSA guidance document for the safety assessment of botanicals and botanical preparations intended for use as food supplements, and of the Compendium of botanicals reported to contain toxic, addictive, psychotropic, or other substances of concern, will be submitted to the EFSA Executive Director for further consideration. The final outcome will be presented to the Steering Group on Cooperation and the Scientific Committee in May

2009, and to the Advisory Forum in June 2009. A workshop to present the work done by the EFSA Scientific Committee and the ESCO Working Group on this issue will be considered for the second half of 2009.

ESCO Working Group on isoflavones

The German Federal Institute for Risk Assessment (BfR) has formally requested to EFSA to deliver a scientific opinion on the use of isolated isoflavones in food supplements. Preparatory work is needed before this task is assigned to the competent EFSA Panel. An ESCO working group on isoflavones will be created to collect all the relevant scientific information. The ESCO working group will undertake a review of the literature and of the data through a structured search strategy. It is intended to finalise the ESCO report by the end of the year. The SC endorsed the creation of this ESCO WG.

9. PRIORITIES OF THE SC FOR 2009-2013. CONTINUATION OF DISCUSSION FROM THE 34TH SC PLENARY

Follow up of the SC opinion on nanotechnology

The Scientific Committee agreed to create a working group on nanotechnology that would be composed of external scientific experts with thorough and excellent knowledge of the area. A draft mandate for this working group was discussed, the main task being to follow developments in the nanotechnology area. The Scientific Committee made several comments that will be considered and a revised mandate will be presented at the next Scientific Committee plenary.

On 26th March, a conference call with the US Food and Drug Administration (FDA) was held where the EFSA opinion on nanotechnology was presented and to exchange views. Positive feedback was given by FDA on the EFSA opinion.

EFSA presented its nanotechnology opinion at a recent meeting held by the EU Commission with Member State experts with a view to receive input in support of the next EU Commission Action Plan on nanotechnology.

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

The document was briefly presented and some questions were raised by the Scientific Committee. Due to the absence of David Lovell, who prepared the draft document, it was decided to postpone the discussion until the next Scientific Committee plenary.

Harmonisation of genotoxicity testing across the EFSA Panels

It is recognised that there are some differences between the genotoxicity testing requirements of the different EFSA Panels. Refining optimal strategies for genotoxicity testing is an area where there is currently considerable national and international activity. However the Scientific Committee recognises that complete harmonisation across the Panels might not be feasible due to differences in legal requirements. It was proposed to develop a commentary on genotoxicity testing strategies which would examine the current state of the science, especially with respect to new developments that may

have a future impact on options for basic testing batteries and strategies for follow-up of positive findings from the basic *in vitro* testing batteries. The Scientific Committee agreed with this proposal.

10. HARMONISATION OF TERMINOLOGY IN RISK ASSESSMENT

Anthony Hardy gave a short presentation about risk assessment terminology. The Scientific Committee would like to work further in this area, as such activity would be of particular importance for expressing outcomes of EFSA risk assessments and associated uncertainties in a harmonized way across Scientific Panels. A draft paper, as well as possible templates will be presented for further discussion at the next Scientific Committee plenary in May 2009.

11. REPORT BACK FROM WORKING GROUPS

SC Working Group on Risk-Benefit Assessment

The working group is developing a step wise approach for risk-benefit assessment which would imply an iterative exchange between risk managers and risk assessors. The draft opinion will be presented to the Scientific Committee in autumn 2009. A public consultation will be organised before finalisation and adoption of the opinion early 2010. In the framework of the DG Research funded BRAFO project, a workshop on risk-benefit assessment will be held end of October 2009. The Experts of the working group will be invited to participate at the BRAFO workshop.

SC Working Group on Threshold of Toxicological Concern

Work is in progress. There is an exponential increase in interest in the use of the TTC approach. The working group is following closely the work done by other organizations and by the Commission to keep track and avoid duplication of efforts.

SC Working Group on Benchmark Dose

The draft opinion on the use of the benchmark dose approach in risk assessment has been presented to the EFSA panels. Comments received will be considered by the working group for the finalisation of the draft opinion. It will then be presented for adoption at the next SC plenary meeting.

Follow-up on EFSA's opinion on animal cloning

The Commission requested EFSA to provide further advice on the implications of animal cloning. In particular, the Commission requested to provide an update on the recommendations included in the SC opinion published in July 2008. The scientific advice should focus in particular on the health and welfare of animal clones. In addition, the request is to extend the advice to cover current knowledge on cloning of sheep, goat and chicken, as only cattle and pigs were covered by the previous EFSA opinion. EFSA is requested to deliver its advice in June 2009.

12. IMPLEMENTATION OF A SYSTEM FOR THE REVIEW OF THE SCIENTIFIC QUALITY OF EFSA'S SCIENTIFIC OUTPUTS (INEX)

The self and internal review systems became operational in April 2008 as a first step of the implementation of the internal and external review procedure (INEX). For the self review, all scientific outputs adopted as of April 2008 were requested to be accompanied by a self review report. 194 self review reports covering 295 scientific outputs were submitted to the Director of the Risk Assessment Directorate.

The internal review process was based on a random selection of the scientific outputs to be reviewed. Anonymous and independent internal reviewers were selected. The comments of the internal reviewers were positive and the outputs were seen to be up-to-date, concise and well focused. The outcome of the self and internal review process will be discussed with the different EFSA panels to improve, where possible, the INEX process. An open call for the selection of experts for the external review process will be launched by the end of April 2009. A report on the external review process is targeted for the end of 2009.

13. DRAFT OPINION "EXISTING ALTERNATIVE APPROACHES INCORPORATING REPLACEMENT, REDUCTION AND REFINEMENT OF ANIMAL TESTING: APPLICABILITY IN FOOD AND FEED RISK ASSESSMENT"

A draft opinion was presented for adoption. The Scientific Committee adopted the opinion subject to incorporation of changes proposed by the members of the Committee. The Scientific Committee recommended that EFSA would follow-up the opinion with a review of progress in the field of alternative testing methods within three years time.

14. REPORT BACK FROM SCIENTIFIC PANELS

The Scientific Committee was updated on the outcome of the plenary meetings of the Scientific Panels since the last plenary meeting (for more details, please see the WebPages 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)

The Panel is currently working on a number of opinions on fish welfare, including stunning and killing fish. Five opinions were adopted at the last plenary and five more will be presented for adoption at the next plenary. New mandates were received from the Commission: African Swine Fever (ASF), genetic parameters on the welfare and the resistance to stress of commercial broilers and Epizootic Hemorrhagic Diseases (EHD). To deliver the opinion on EHD, the panel will examine and make use of the data from the scientific report of the art. 36 project on EHD due in October 2009. A self-tasking mandate was proposed for discussion on ticks as vector of animal diseases. This mandate is important in particular for the mandate on African Swine Fever.

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

The Chair of the ANS panel sent his apologies. A summary of the activities of the Panel was provided in writing. The opinion on the second Ramazzini study on Aspartame was adopted at the panel plenary in January 2009. A revision was considered in the view of new information provided by the Ramazzini Institute and re-adopted by the Panel at the last plenary. The approach for estimating exposure to food colors was discussed and will be included in the upcoming draft opinion on azo-dyes. The opinions on

selenius acid and on calcium phosphinate added for nutritional purpose to food supplements were adopted.

Panel on biological hazards (BIOHAZ)

A request for a self-taking mandate was agreed by EFSA to carry out the annual update of the Qualified Presumption of Safety list of microorganisms. Four opinions were adopted at the last plenary: TSE resistance in goats, meticillin resistant S*taphylococcus aureus*, the use of antibiotic resistance genes as marker genes in GM plants (prepared in cooperation with the GMO Panel), and an opinion setting a new target for the reduction of S*almonella* in breeding hens.

A combined food safety chapter addressing AHAW opinions on the welfare of the dairy cow is being prepared and will be present at the next plenary in April 2009.

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

Seven opinions on flavourings have been adopted. Guidance opinions are being developed for smoke flavouring and enzymes, especially regarding toxicological testing methods that should be used. The guidance for the evaluation of food enzymes has been published for public consultation. The opinion on dietary exposure assessment methods for smoke flavourings has been adopted at the last plenary. The guidance for the evaluation of food enzyme is in preparation. A stakeholder meeting will be held in May to discus the content of the guidance. A mandate on methylbenzophenone was discussed at the plenary meeting.

Panel on contaminants in the food chain (CONTAM)

Two opinions have been adopted at the last plenary: uranium in foodstuff and the opinion on nitrite as non desirable substances in animal feed. The statement about the processing on shellfish toxins has been adopted.

Panel of Genetically Modified Organisms (GMO)

The guidelines for the risk assessment of GM plants and derived food and feed, drafted in collaboration with the European Commission will be published soon. There was a good consultation procedure between the Commission and EFSA and the relevant issues are covered in the document. The guidance for the risk assessment of GM plants used for non-food and non-feed purposes is expected to be adopted at the next plenary meeting. A task on genetically modified animals is progressing. Further guidance is needed for GM microorganisms and there is a clear need to update existing guidelines. A collaboration agreement has been signed with the Joint Research Centre and EFSA, which is helpful also for GMO Panel. An opinion on the use of antibiotic resistance genes as marker genes in GM plants has been prepared in cooperation with the BIOHAZ Panel.

Panel on Plant health (PLH)

At the last plenary meeting, the discussion focused on the outcome of the public consultation of the guidance document on evaluation of pest risk assessments and on the draft opinion on the risk assessment made by UK on the oak processionary moth *Thaumetopoea Processionea.* A collaboration is ongoing with the Joint Research Centre to produce climate modelling

studies. The Panel received a new mandate to evaluate a new treatment of wood shavings proposed by the USA as an alternative pest risk management option for the EU territory.

Panel on plant protection products and their residues (PPR)

The main activity covers at present the development of 9 guidance documents; in particular, the revision of the aquatic and terrestrial ecotoxicology guidance documents were published for public consultation and the feedback of the consultation will be presented at the next plenary in April. The guidance document on the cumulative exposure of triazoles will likely be finalised in June during the last plenary of the current Panel. The Panel is considering the development of a guidance document on endocrine disruptors, involving also DG Environment on this important issue. A close collaboration with the GMO Panel is currently ongoing regarding the interplay between the Pesticide and the GM directives for the environmental impact. Data will be collected through the collaboration agreement with the Joint Research Centre on both climate data and information on protected crop systems.

15. EFSA EXPERTS' SURVEY

The expert survey, launched in 2008, was completed by 733 experts. There is a high satisfaction for the overall support related to administrative issues, in the scientific support and in the communication support. Areas were identified where further increase in satisfaction could be reached, but in general no areas of major concerns were found. EFSA will continue increasing the provision of scientific support to the experts and in providing better support and/or training on administrative procedures. EFSA is planning to repeat such an expert survey on a regular basis.

16. ANY OTHER BUSINESS

The Report on the project "Status of Health in the European Union (EUGLOREH)**"** project, initiated in 2005, was presented. The report assesses the status of health in EU through selected indicators and their trends mainly over the last 10 years. Moreover, it provides data and information to facilitate the identification of priority issues for future investigations or actions and when possible, of valuable relevant practicable approaches. The report does not identify priorities in public health but provides a reliable and scientifically-based picture of the health status in Europe, the nature of health determinants and relevant data gaps.