Parma, 8 April 2009
EFSA/SC/831rev2

MINUTES OF THE 34TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 10-11 FEBRUARY 2009 IN PARMA

(Adopted on 7 April 2009)

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, John D. Collins, Albert Flynn, Klaus-Dieter Jany, Ada Knaap, Harry Kuiper, John Christian Larsen, David Lovell, Pierre Le Neindre, Jan Schans, Josef Schlatter, Vittorio Silano (Chair), Staffan Skerfving, Philippe Vannier.

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle (Executive Director), Andrea Altieri, Hubert Deluyker, Dirk Detken, Anne Laure Gassin, Gisèle Gizzi, Riitta Maijala, Ralf Reintjes, Elena Scaravelli, Karen Talbot, Luisa Venier, Didier Verloo.

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

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

Hearing expert:
Bart Sangster[1]

[1] Present for item 13

1. OPENING AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants. Apologies were received from Anthony Hardy, Chair of the PPR Panel.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

Sue Barlow declared that she took part in two ASAT (Assuring Safety without Animal Testing) workshops, and that she therefore has an intellectual interest in Agenda point 13 (trends and development in risk assessment).
Ada Knaap declared that she is part of the Steering Committee of the Dutch ASAT Programme and that she wrote a report on this issue. This interest is mentioned in her Annual Declaration of Interests.

John Christian Larsen declared that he is a member of the Institute of Food Research (IFR) who signed an article 36 contract for the delivery of a database on bioactive compounds (point 10 of the agenda).

EFSA considered that these intellectual interests were not leading to any conflict.

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

Report back from:

- **Management Board, 18 December 2008**

The Management Plan and the budget for 2009 were adopted. The EFSA budget will reach 73 million Euros in 2009.

- **Management Board, 29 January 2009**

The 2008 annual activity report was presented. The Management Board expressed its congratulations to the EFSA Staff and Experts for the quantity and quality of opinions adopted in 2008. This year was characterised by an increased collaboration with the European Member States by means of Article 36 and ESCO projects, a confirmed independence of EFSA with the implementation of the new policy on Declarations of Interests, a growing internal/external capacity with 96 % of the recruitment plan achieved, and the set-up of a network of 1200 European Experts who registered in the EFSA Expert Database. The budget execution in 2008 was 97 %.

Four members of the Advisory Forum were invited to the Management Board meeting to discuss the activities of the Advisory Forum. A presentation was given by the French member, discussing the role of EFSA and the national food safety agencies, highlighting the importance of a good collaboration between these bodies in order to avoid duplication of work. The members of the Scientific Committee expressed concerns about some of the views expressed in this presentation. The Advisory Forum will discuss the outcome of the discussions with the Management Board at its meeting on 18 and 19 February.

Members of the Management Board were informed about the implementation in 2009 of the quality system for EFSA opinions.

A strategic approach for the international activities of EFSA was adopted in January 2009; the main objectives are:

- to support the European Union in its international commitments;
- to ensure access to international scientific data and information in order to provide a strong basis for risk assessment and the identification of emerging risks;
- to increase EFSA participation to risk assessment at international level;
- to promote coherence in risk communication and build awareness of EFSA's activities at the international level.

An EFSA delegation comprising the Executive Director and some members of the Scientific Committee will visit the US FDA in March 2009 to strengthen this cooperation.

5. DRAFT OPINION ON THE APPLICATION OF NANOTECHNOLOGIES IN THE FOOD AND FEED AREA

The opinion on the potential risks arising from nanoscience and nanotechnologies on food and feed safety opinion, updated after reviewing the comments received during the public consultation, was proposed to the Scientific Committee for adoption. In addition a report on the outcome of the public consultation on the draft opinion was presented. Most of the comments received were in general agreement with the opinion.

The European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) recently adopted an updated opinion on risk assessment of products of nanotechnologies; the views expressed in this opinion are similar to the EFSA opinion. The SCENIHR opinion covers a wider area, including ecotoxicological aspects and is not specific for the food and feed area. As environmental aspects were beyond the scope of EFSA's mandate, it was decided to cross-reference the SCENIHR opinion.

The Scientific Committee adopted the opinion, subject to incorporation of the comments made during the meeting. The opinion will be published together with a compilation of the comments received and a report on the outcome of the public consultation.

Future EFSA activities in the food and feed area of nanoscience and nanotechnologies

EFSA has been invited to a meeting organised by DG Health and Consumers in March to discuss the future of the nanotechnologies-related activities in Europe. The main priority for EFSA will be allocated to research to generate data for safety assessment.

A task force will remain active within EFSA in order to be kept informed about developments in this area. Regular reports will be made to the Scientific Committee.

6. EXCHANGE OF VIEWS ON CRITERIA FOR PUBLIC CONSULTATION OF EFSA OUTPUTS

A document presenting the EFSA approach for public consultation will be discussed with the Stakeholders Platform end of March 2009. The document is part of the EFSA policy on openness and transparency, and clarifies which EFSA outputs should be subject to public consultation. A number of criteria have been proposed to decide in which situation draft outputs should be published for public consultation. The document describes also the fora to be consulted for the public consultation.

The Scientific Committee provided comments on the document. It was noted that most of the time, the interested audience for a public consultation would be composed of stakeholders with specific expertise in the field, rather than the general public.

7. 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 one on the stunning and killing of tuna fish. A number of different views were expressed on this issue during the plenary meeting, which led to a fruitful discussion on the content of the opinion.

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

Eight opinions were adopted on nutrient sources. The Panel is currently looking at the 2nd study on Aspartame from the Ramazzini Foundation.

Panel on biological hazards (BIOHAZ)

The Panel is currently working on a number of opinions on *Salmonella* in poultry. The Panel is also preparing an opinion on *Campylobacter*, as a follow-up of the EFSA colloquium "assessing health and benefits of controlling *Campylobacter* in the food chain" organised in December 2008.

A joint working group with the GMO Panel has been established to address the use of antibiotic resistance genes as marker genes in genetically modified plants.

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

The Panel adopted an opinion on the use of glass powder made from post consumer recycled glass, as well as an opinion on dimethyl ether as an extraction solvent to separate proteins from fat.

The guidelines for the evaluation of food enzymes are close to finalisation. These guidelines consider nanomaterials but do not propose specific requirements for enzymes derived from genetically modified microorganisms, since this falls under the competence of the GMO Panel. A stakeholder meeting will be organised to discuss the content of the guidelines.

Panel on contaminants in the food chain (CONTAM)

The Panel adopted an opinion on saponins as undesirable substance in animal feed, and a second opinion on cadmium in food. For the latter, the Assessment Methodology Unit of EFSA performed a meta-analysis of the available scientific data. The Panel will pay special attention to the clarity of the description of the approach used for the assessment and the rationale for the conclusions. A report with the technical details of the meta-analysis is planned to be published separately.

The Panel was asked by a Member State to prepare an opinion on uranium in foodstuffs, particularly in water. Uranium shows both chemotoxicity (kidney damage) and radiotoxicity. The Chair of the Panel informed the Scientific Committee that the Panel is able to perform the chemical assessment but does not have the expertise to do the assessment of the radioactive isotopes. This part of the question will be responded by an expert group of the Directorate General on Energy and Transport under article 31 of the Treaty establishing the European Atomic Energy Community.

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

EFSA published a press release on maximum vitamin A levels in feed for main food producing animals. The opinion comprises an evaluation of risk management options, as reducing the levels of vitamin A in feed may have a direct impact on animal development.

The Panel is looking at the organic forms of chromium; the experts started working on a generic assessment whether there is a requirement for chromium and if there is a possible toxicity. Once this generic assessment is available, the Panel will apply the assessment to specific products.

Panel on genetically modified organisms (GMO)

The guidance document for the risk assessment of GM plants and derived food and feed will form the basis for the guidelines in the regulation. The final document will contain general principles for risk assessment and a number of annexes where technical aspects are described.

The Panel has met with the Member States to discuss the safeguard clauses.

The Panel will start working on a guidance document for the risk assessment of GM animals. It is considered as an important topic for the future, especially for fish.

Panel on dietetic products, nutrition and allergies (NDA)

Panel's work on claims is ongoing, with around 40 article 14 dossiers evaluated and published so far. It was reiterated that when an opinion is published, interested parties have 30 days to comment to the European Commission. The first authorisation decisions should be taken by the European Commission in February 2009.

Over 4000 main entries for health claims have been submitted to the Panel under article 13 of Regulation (EC) 1924/2006. The full list has now been published on the EFSA website. For about half of these claims, there was not enough information, or the claims could not be evaluated by EFSA; they have therefore been sent back to the European Commission and Member States for clarifications.

The nutrient profile scheme and food consumption database are under development. An impact assessment is being discussed between the European Commission and the Member States on possible implications.

Panel on plant health (PLH)

The Panel is currently working on its guidance document on a harmonised framework for risk assessment in plant health. The Panel received also a request for expanding a pest risk assessment of the processionary moth as performed by UK to the European Union.

Panel on plant protection products and their residues (PPR)

No report back was made due to the absence of the Panel's Chair.

8. REPORT BACK FROM WORKING GROUPS

- **SC Working Group on Risk-Benefit Assessment**

Work is in progress; the working group is considering the suitability of various methodologies proposed by EU-funded research projects for EFSA's needs.

- **SC Working Group on Threshold of Toxicological Concern**

The first meeting of the working group was held in January 2009. Experts were informed about an opinion issued by the non-food Committees end of 2008. Participants had then a brainstorming session on the possible contents of the future EFSA opinion.

- **SC Working Group on Benchmark Dose**

An EFSA Panels' consultation on the draft opinion is currently ongoing. The document has been well received so far. It was suggested to describe further the possible use of the benchmark dose approach with human data. The Panel consultation ends mid-March 2009. It is foreseen to submit at the end of May an updated opinion to the Scientific Committee for adoption.

- **ESCO Working Group on Botanicals**

The ESCO working group is completing the Compendium on botanicals reported to contain toxic, addictive, psychotropic or other substances of concern. It is also testing the proposed approach for the safety assessment of botanicals and botanical preparations described in the guidance document of the Scientific Committee with a number of examples. The working group will deliver to the EFSA Executive Director by end of April 2009 an advice on the suitability of the approach for safety assessment, the reports on the tested examples and the compendium.

- **SC Working Group on Transparency**

The draft opinion was published on the EFSA website for public consultation; the deadline for comments is 15 February 2009. The comments will then be considered in an update of the opinion. It is intended to submit the draft opinion to the Scientific Committee for adoption in April 2009.

9. EXPERT SURVEY AND RENEWAL OF PANELS

- **Outcome of the Expert Survey**

The first results of the Expert Survey were presented to the Scientific Committee. The survey was completed by 733 experts; 87% of them indicated their satisfaction for the overall support provided by EFSA in relation to the work they have to perform for the Authority and 95 % mentioned an interest in continuing to participate in EFSA's work at least to some degree. An internal task force will now analyse in detail the results and propose some action points to the EFSA Management Team. EFSA has decided to have such a survey on a regular basis.

- **Update on the renewal of the SC/Panels**

EFSA received 848 applications, which represents a 7 % increase, as compared to 2006. It was clarified that an expert can be appointed for a maximum of three terms for the same Panel or the Scientific Committee. Having served three terms as a Chair of a Panel in the Scientific Committee does still allow the same expert to apply as member of the Scientific Committee for the next term.

10. REPORT BACK FROM SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

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

A consultation of the EFSA Panels has been organised regarding default assumptions used in risk assessments. The objective is to look at possible harmonisation across EFSA Panels, e.g. default body weight set at 60 or 70 kg.

A report on the consultation is being prepared and will be discussed at a future plenary meeting of the Scientific Committee.

- **Art 36 Contract on bioactive compounds**

An article 36 contract has been signed with the Institute of Food Research (IFR) to merge the EuroFIR-BASIS and the NORTOX-BASIS databases. The resulting database will be completed with the latest information on beneficial and toxicological effects of bioactive compounds. The effects on the measured biomarkers/indicators will be described. The final version of the database will be delivered in August 2009.

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

The draft opinion on existing alternative approaches to animal testing and their applicability in food and feed risk assessment was presented and discussed.

The Scientific Committee reviewed the draft opinion and made a number of comments and requests for clarifications. The document will be updated for adoption at the next plenary meeting.

12. PRIORITIES OF THE SC FOR 2009-2013. CONTINUATION OF DISCUSSION FROM THE 33RD SC PLENARY – EFSA/SC/833

The Scientific Committee discussed a number of areas of interest for future activities:

- **Use of statistical / novel approaches to assess adverse or biologically relevant effects**

  Issues of immediate relevance could be the definition of the relationship between statistical significance and biological importance, or better statistical characterisation of what is the level of equivalence in comparative approaches (e.g. GMO vs. conventional foods).

- **Methods for screening emerging risk information**

  It was reminded that there is a specific unit within EFSA in charge of setting up a system for the early identification of emerging risks; the question is therefore whether there is a way for the Scientific Committee to support further this Unit.

- **Supporting risk assessment of applications of nanoscience/nanotechnology**

  The Scientific Committee is invited to identify what could be possible follow-up and research needs in this area.

- **Endocrine disruptors**

  A considerable number of research projects are currently running in Europe and the rest of the world on this subject. It was advised to review existing activities before deciding issue(s) EFSA should tackle, in order to avoid duplication of work.

- **Harmonisation of environmental risk assessment approaches and need for scientific environmental impact analysis**

  This subject is of particular interest for the GMO and PPR Panels. A discussion paper will be developed on this issue.

- **Harmonisation of terminology in risk assessment**

  This topic was on the agenda of the 4th meeting of the Chairs and Secretariats of Commission and Agency Scientific Committees and Panels involved in Risk Assessment, during which the outcome of interagency discussions related to transparency and terminology was presented. The Scientific Committee should now consider to what extent it is feasible to harmonise food/feed risk assessment terminology across EFSA Panels.

It was decided to consolidate the ideas behind these various possible future activities and continue the discussions at the next plenary meeting.

13. TRENDS AND DEVELOPMENT IN RISK ASSESSMENT

Project "Assuring safety without animal testing" (ASAT)

Dr. Bart Sangster gave a presentation of the ASAT concept: assuring safety without animal testing. The concept considers that the human biology is responsible for the risk; the starting points will therefore be to identify the health risk that needs to be prevented, to identify the responsible human biology, and to identify the information needed to assess the risks. Experimental animal free technologies will be used to generate knowledge about the human biology, and *in silico*/*in vitro* experimental models will be developed to represent the human biology responsible for the health risk.

The Scientific Committee acknowledged the advantages of such approach for chemicals designed for human health but questioned its applicability for non-human targeted chemicals, e.g. environmental chemicals. This concept could provide valuable information in the risk assessment process but the level of acceptance of the outcome by the risk managers was questioned. The Scientific Committee expressed an interest to be kept informed about further developments of this concept.

14. ANY OTHER BUSINESS

The report on the 4th meeting of Chairs and Secretariats of Commission and Agency Scientific Committees and Panels involved in risk assessment is now published on the EFSA webpage.

As follow up of the 1st International Conference on Risk Assessment held in November 2008, DG Health and Consumers proposed some projects to be developed in the view of the 2nd International Conference on Risk Assessment that will be held in 2010. EFSA will identify the projects in which it would like to participate.