European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

MINUTES OF THE 43RD PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 29-30 JUNE 2010

Agreed on 13 September 2010

PARTICIPANTS

Scientific Committee (SC):
Albert Flynn[1], Corrado L. Galli, Anthony Hardy, Harry Kuiper[1], Klaus-Dieter Jany, Michael Jeger, Ada Knaap, John Christian Larsen, Josef Schlatter, Vittorio Silano, Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):
Andrea Altieri[2], Bernard Berger[3], Hubert Deluyker[4], Marta Hugas[5], Riitta Maijala, Ilias Papatryfon[6] and Carola Sonderman[7],

Secretariat of the Scientific Committee:
Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander[8], Daniela Maurici, Torben Nilsson[1], Tomas Öberg and Francesca Piombini.

European Commission (EC):
Michael Walsh

[1] Present on 29 June
[2] Present for agenda item 13
[3] Present for agenda items 11 and 12
[4] Present on 30 June
[5] Present for agenda item 8
[6] Present for agenda item 12
[7] Present for agenda item 11
[8] Present for agenda items 6 and 10

1. OPENING

The Chair welcomed the participants. Apologies were received from Sue Barlow, John Daniel Collins and Catherine Geslain-Lanéelle.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the invited experts. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

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

- **EFSA Advisory Forum, 19-20 May February 2010**

Vittorio Silano presented to the Advisory Forum the role and the work of the Scientific Committee, as well as various examples of possible improvements for a continued fruitful cooperation with Member States. Participants discussed medium-term planning for a better use of resources in EFSA, the European Commission and the Member States. It was proposed to involve Member States, in particular, at an early stage in the development of risk assessment methodologies; Member States confirmed their willingness, depending on their capacity, to become more involved in EFSA's work, both regarding methodologies and routine work.

The preliminary work programme on grants and procurement, as well as the preliminary Management Plan for 2011 were discussed with the Member States.

EFSA's Communication Strategy for 2010-2013 was discussed. The importance of cooperation between EFSA and European Member States in risk communication, as well as the need for tailoring messages depending on the target audience was underlined. The reviewed Communication Strategy will be submitted to the Management Board for adoption in October 2010.

- **Technical meeting with Stakeholders on health claims, 2 June 2010**

The purpose of the meeting was to share information on the current status of EFSA's scientific health claim evaluations and to exchange views with the 400 participants from the food and beverage industry, Member States, and the European Commission. Participants discussed various aspects of the process, such as how the NDA Panel assesses and documents

whether a claim is substantiated, what data requirements and relevant studies are considered pertinent, and what are considered beneficial physiological effects and risk factors for disease risk reduction claims.

EFSA will pursue its dialogue with stakeholders through on-line consultations and technical workshops to provide additional guidance to applicants in selected areas, such as gut and immune function, antioxidants, satiety, and mental function. EFSA will start with a workshop on gut and immune function claims, which will take place before the end of 2010. EFSA will also further update its briefing document on claims for applicants in light of the meeting discussions and taking into account all comments received. An updated briefing document will be published on EFSA's website in the coming months.

- **EFSA Visit to Shanghai Expo, 4-12 June 2010**

A delegation from EFSA visited China in the framework of the European Union's participation to the SHANGHAI EXPO 2010 "Better city, Better life". Members of the delegation attended and gave presentations in several events:

- Securing Food Safety for a Healthy Life Conference on 5 June 2010
- Seminar on Research for Healthy Life Conference on 6 June 2010
- Sino-European Food Safety Cooperation Forum from 6 to 11 June 2010 (BTSF: Better Training for Safer Food)
- Bilateral meeting EU (EFSA/SANCO/EC Delegation) - Chinese Authorities (Ministry of Agriculture) on GMOs on 9 June 2010
- Ad Hoc meeting EU (SANCO/EFSA/EC Delegation) - Chinese Authorities (AQSIQ) on Nicotine residues in mushrooms on 11 June 2010

The Chinese Authorities showed an in depth knowledge of EFSA's work; the visit to China provided a good platform to develop further cooperation on food safety.

- **EFSA Management Board, 17 June 2010**

The Management Board discussed the terms of reference and composition of the Stakeholder Consultative Platform, one objective being to ensure that membership reflects a wider spectrum of sectors in the food and feed chain. The Platform is composed of 24 members. In addition to these, it was decided that any stakeholder can ask to be observer.

The Management Board discussed the draft Commission report on the advisability and feasibility of establishing fees for EFSA. The importance of maintaining the independence of EFSA and its advice was underlined. The report should be issued in September and discussed by the Parliament and the Council in 2011.

- **EFSA Scientific Colloquium on food classification, 23-24 June 2010**

90 scientists and stakeholders from 33 countries, including the USA and Australia, attended the 14th EFSA Scientific Colloquium on Food Classification: unambiguous ambiguity – the challenge of describing food. The objective was to have an open scientific debate on the

classification of foods and to provide suggestions for the Food Classification and Description System for exposure assessment under development in EFSA.

Recurrent issues addressed in the discussion were the need for flexibility in the system to be able to meet future and unanticipated requests for risk assessment as well as innovation in food products, the importance for detail versus feasibility of the reporting, the need for the system to deal with composite foods, and the challenge to meet needs in the different sectors stemming from different legislative backgrounds.

Participants welcomed the first outline of EFSA's working group for a food classification system for risk assessment purposes. There was general support for the system to include a food list with the possibility of adding facets.

- **EFSA Stakeholders Consultative Platform, 22 June 2010**

The activities of the Scientific Committee, the ANS and the AHAW Panels were presented to the Platform with particular focus on areas where input was received from the stakeholders. Other issues discussed were: endocrine active substances and work done by the assessment methodology unit (AMU).

Participants were informed about the 15th EFSA Scientific Colloquium on Emerging Risks that will take place in Parma on 12-13 October 2010. The importance of developing methodologies involving Member States and stakeholders to identify signals without duplicating efforts will be discussed.

- **Visit of the delegation of the EU Parliament's Committee on the Environment, Public Health and Food Safety (ENVI), 24 June 2010**

On 24 June 2010, the Committee on the Environment, Public Health and Food Safety visited EFSA in order to learn about the latest developments affecting EFSA and, in particular, to examine and discuss the ways in which it is involved in the implementation of food and feed legislation. The delegation was chaired by Mr Jo Leinen, Chairman of the Committee on the Environment, Public Health and Food Safety. A Budget Committee MEP was also included in the delegation.

The delegation attended sessions aimed at presenting how EFSA works, the work of EFSA's Scientific Committee and Panels and EFSA's recent activities. Views were exchanged on topics such as health claims, genetically modified organisms (GMOs), Bisphenol A, and pesticides.

Mr. Leinen addressed EFSA Staff, acknowledging their hard work, and confirming the support of the ENVI Committee of the Parliament.

5. DRAFT OPINION ON HUMAN HEALTH RISK-BENEFIT ASSESSMENT OF FOOD

The report on the public consultation of the draft guidance for human health risk-benefit assessment of foods was proposed to the Scientific Committee for endorsement. This report lists the comments submitted and summarises how they were considered by the working group of the Scientific Committee before finalising the opinion. The Scientific Committee endorsed the public consultation report for publication on the EFSA website.

The guidance document for human health risk-benefit assessment of foods was submitted for possible adoption. A stepwise approach is proposed for the assessment, with an iterative dialogue between the risk-benefit assessor and the risk-benefit manager after each step of the assessment. It was clarified that this guidance document is not intended to replace any document for risk assessment currently used within EFSA. Members of the Scientific Committee recommended exploring the feasibility of expanding the scope of the guidance document to other risk-benefit assessment aspects, e.g. animal welfare considerations.

The Scientific Committee adopted the guidance document, provided that a glossary with abbreviations be included and editorial adjustments made.

6. NEW MANDATE

EFSA received a request from the European Commission for an update on the state of play of animal cloning. An EFSA statement is under preparation to answer this request, and the related roadmap was shared with the members of the Scientific Committee for information. The objective is to have the draft statement discussed at the 14-15 September 2010 Plenary meeting and send it to the European Commission latest by 1 October 2010. In view of the short timeframe, it was agreed to circulate an early draft of the Statement to the Scientific Committee already by end of July 2010 in order to gather comments and remarks as soon as possible.

7. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

Three Representatives of the European Commission attended the 50th Plenary meeting and provided positive feedback on the opinions adopted in 2009 and early 2010. The opinion on Q-fever was cited as an example.

The Panel received a mandate to provide guidance on GM-animals and derived food and feed to include animal health and welfare aspects. A working group was set up for this purpose and will be composed of experts from the AHAW and GMO Panels.

The Panel is developing a database on the spread of ticks in Europe, these insects being vectors for a number of diseases, among which African Swine Fever and Crimean-Congo Haemorrhagic Fever.

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

The Panel is continuing its work on the re-evaluation of food additives. All synthetic food colours are expected to be reviewed by end of December 2010. The Panel will then start working on food preservatives and antioxidants.

An update of the guidance document on the risk assessment of food additives is under preparation. The working group considered the SC guidance for the safety assessment of botanicals and botanical preparations used as ingredient in food supplements as background information. The update of the guidance document was considered to be of relevance for the Scientific Committee and a draft of the guidance on food additives will be shared with the Scientific Committee before it is adopted.

Panel on biological hazards (BIOHAZ)

The Panel adopted a statement on the food safety implications of H1N1 influenza virus. The preparation of the statement was supported by the report provided by a contractor.

The Panel received a request for technical assistance on the format for applications for new alternative methods for animal by-products. EFSA received a new mandate for a scientific opinion and technical assistance on the public and animal health hazards to be covered by inspection of meat. Close collaboration will be established with the AHAW, BIOHAZ and CONTAM Panels, with the Zoonoses, AMU and DATEX Units, and with the European Centre for Disease Prevention and Control (ECDC) on this issue.

The Panel received a request for an opinion on the quantitative residual BSE risk in meat and bone meal. The European Commission will consider this opinion for a possible revision of the management measures currently in place.

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

The evaluation of the Stump study on Bisphenol A (BPA) is progressing. The Panel has received three mandates from the European Commission on BPA: i) to assess the relevance of a new study on possible neurodevelopmental effects of BPA and, if necessary, to update the existing TDI accordingly, ii) to also take into account in its risk assessment any other new scientific evidence that may be available and to liaise closely with EU Member States risk assessment bodies on this issue, and iii) to review scientific arguments supplied by Denmark in support of the government's decision to ban the use of BPA in food contact materials for infants aged from 0 to 3 years .

The Panel adopted its guidance document on data needed for the evaluation of flavourings. A particular section of the guidance is dealing with undefined flavourings and flavourings coming from new sources. A workshop was organised with stakeholders in March 2010 to exchange views on this issue.

Panel on contaminants in the food chain (CONTAM)

The Panel adopted a statement on Ochratoxin A, after having been asked by the European Commission to review five recent publications.

Lead and Cadmium were addressed during the 73rd JECFA meeting. The same conclusions as from the CONTAM Panel were reached for Lead. It seems, however, that for Cadmium, JECFA arrived at a different provisional tolerable weekly intake (PTWI). EFSA is in contact with the JECFA Secretariat to clarify this difference in the assessment's outcome.

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

The Panel updated its guidance for the preparation of dossiers for technological additives. It now includes the new functional group "substances for reduction of the contamination of feed by mycotoxins".

The Panel is progressing in the process of re-evaluating all feed additives currently on the European Market, authorised under previous Directive 70/524/EEC, and in line with current EU legislation on feed additives for use in animal nutrition (Regulation (EC) N0 1831/2003). The aim of the work is to ensure that all feed additives in Europe are re-assessed following the same, up-to-date guidelines, taking into account the newest scientific developments.

Panel on genetically modified organisms (GMO)

Progress has been made in the development of guidance documents for risk assessment of GM animals and derived food and feed with respect to human/animal and environmental safety. In cooperation with the AHAW Panel guidance ìs under development for the risk assessment of GM-animals and derived food and feed which includes animal health and welfare aspects.

Two of the three interim reports on environmental risk assessment of GM animals have been received from external contractors. Feedback has been provided on the interim report on GM fish. The interim report on GM insects is under assessment by the working group. The interim report on GM mammals and birds is expected in November 2010. All reports will be made publically available through EFSA's website and will help with the preparation of draft opinions.

Panel on dietetic products, nutrition and allergies (NDA)

Experts from the Panel met over 400 participants during a technical meeting organised in Parma on 2 June 2010. The purpose of the meeting was to share information on the current status of EFSA's scientific health claim evaluations, and to exchange views with experts from

the food and beverage industry, Member States, and the European Commission. A commitment was made to pursue dialogue with stakeholders through on-line consultations and technical workshops to provide additional guidance to applicants in selected areas, such as gut and immune function, antioxidants, satiety, and mental function (see section 4).

The Panel is still allocating the majority of its resources to the assessment of claims submitted under article 13 and article 14 of Regulation 1924/2006.

Panel on plant health (PLH)

The development of a guidance document for environmental risk assessment in plant health is progressing. During its last Plenary meeting, the environmental risk assessment guidance for GMOs, as well as the example of the Mountain Pine Beetle and its environmental risks in Canada was presented to the Panel.

Three opinions on *Tilletia indica*, *Gibberella circinata and Dryocosmus kuriphilus* were adopted by the Panel and communicated to the European Member States for feedback.

Panel on plant protection products and their residues (PPR)

The Panel is working on a guidance document on how to use field persistence and soil accumulation studies; litter appears to be an important layer that needs to be included in the risk assessment when dealing with persistence of pesticides.

Eighty participants attended the stakeholder workshop on protection goals for environmental risk assessment of pesticides. Feedback received will be considered for the finalisation of the draft opinion that is expected to be adopted in September 2010.

The Panel is developing a guidance document on how to estimate emissions from protected crops (green houses and covered crops). A data collection on protected crop structures in the European Union is currently ongoing.

8. ENSURING AN INTEGRATED APPROACH IN THE DEVELOPMENT OF EFSA'S GUIDANCE DOCUMENTS

The Scientific Committee had a general discussion on guidance documents produced by EFSA: is there a need to develop or update guidance documents, how to increase their visibility and monitor their use within EFSA but also by national competent authorities or other stakeholders?

It was underlined during the discussion that guidance documents produced by EFSA can be of very different nature; definitions should therefore be clarified first.

The Scientific Committee suggested that the EFSA Mandate Review Committee informs relevant Panels when a new mandate for a new guidance is adopted. These Panels should then

be represented in the working group developing the guidance to ensure that the document answers their specific needs.

The awareness and use of EFSA guidance documents could be increased by involving Member States' Competent Authorities, e.g. via the EFSA Advisory Forum at an early stage. The format of this involvement is still to be considered by EFSA. Currently EFSA organises a workshop or a technical meeting with Member States Experts during or after the public consultation of Panel opinions.

This issue will be further discussed at the next Plenary meeting.

9. INTERNAL MANDATE ON RESEARCH PRIORITIES

The Scientific Committee and Advisory Forum Unit of EFSA received an internal mandate to coordinate the identification of research priorities to strengthen EFSA's risk assessments. A task force composed of representatives from the EFSA Risk Assessment, Scientific Cooperation and Assistance, and Communications Directorates will be created for this purpose. Research proposals will be sought from EFSA's Scientific Committee, Panels and Units, but also from the members of the Advisory Forum. The task force will then prepare a proposal for key research priorities for EFSA. This proposal will be submitted in December 2010 for consideration by DG Research and potential other research funding organisations, such as the Joint Research Centre of the European Commission.

10. REPORT BACK FROM WORKING GROUPS AND INTERNAL TASKFORCES

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

The activity is ongoing. An interim meeting for the outsourced part of the project took place with the contractor. The final report of this project is expected by the end of 2010. The finalisation of the opinion is expected for summer 2011.

Participants were informed about a joint EC/ILSI/WHO workshop on TTC that is expected to take place in May 2011 in Brussels.

- **WG Genotoxicity Testing Strategies**

Work is ongoing and is proceeding well. Several panel members are part of the working group to ensure that their Panels' views and needs are considered. The working group aims to present a draft opinion to the Scientific Committee in April next year. The opinion is expected to be finalised by summer 2011.

- **WG 90-day Feeding Trials**

The draft opinion was initially expected by the end of 2010, but finalization will request a prolongation of the timeframe. The subject being of interest to several EFSA Panels, dedicated presentations during Plenary meetings will be organised before the opinion is

finalised. A discussion will be planned for the November Plenary meeting of the Scientific Committee.

- **WG Nanotechnologies**

The activity is ongoing. A presentation of the draft opinion is planned for the September Plenary meeting. A panel consultation will be initiated after the Scientific Committee September plenary. The working group will consider the Panels' contributions before the draft opinion is submitted for endorsement for public consultation at the November Plenary meeting. After the public consultation, and considering the comments received, the opinion will be submitted for adoption in February 2011.

The difficulty to characterise a nanomaterial in a complex matrix is a main issue in the draft guidance. The Scientific Committee was informed that the Joint Research Centre is analysing various definitions used and that the European Commission will come up with a general definition for Europe; this general definition may have to be refined to be applicable in the food and feed area.

- **WG Statistical Approaches**

The working group had its first meeting in May 2010 and discussed on the issues to address. Decision was made to focus first on the issue of statistical significance and biological relevance in risk assessment. A first draft of the document is expected for October 2010, with the objective to submit the opinion for adoption in March 2011.

- **WG Risk Assessment Terminology**

A procurement reviewing the terminology used to express risk and uncertainty in concluding sections of 250 EFSA published opinions is currently ongoing. The final report is expected end of September 2010. This report will then be used as a starting point for the first meeting of the SC working group on risk assessment terminology that has recently been established.

- **WG Default Assumptions**

The working group will have its first meeting on 21 July 2010. The purpose of this activity is, starting from the DATEX overview of the default assumptions used by EFSA Panels and Units, to identify where possible harmonisation could bring further added value. This activity will run until end 2011.

- **WG Compendium on Botanicals**

The working group is in the process of updating the information contained in the compendium of botanicals reported to contain substances of concern. A review of national lists of plants or available from stakeholders organisations is currently ongoing for this purpose. The working group is also considering expanding the information contained in the compendium with information on plants having no market history in the European Union but a history of traditional use in third countries. Some contacts have been established with several countries to get a better idea of the information available.

- **WG Benchmark Dose (BMD II)**

The working group will have its first meeting on 26 July 2010. The objective of the activity is to produce a technical report illustrating with several case-studies how to use the software available for dose-response modelling to derive a BMDL. A workshop for EFSA Experts and Staff will be organised early December 2010 as an intermediate deliverable.

The Scientific Committee underlined the importance of this workshop to develop the expertise on Benchmark Dose within EFSA and suggested, in view of the limited timeframe, to limit the case-studies to continuous and quantal data. The question on how to deal with human epidemiological data could be considered as a possible activity for a future working group. The workshop and the technical report should also address the question of the interpretation of the outcome of a BMD calculation.

- **Taskforce on Environmental Risk Assessment**

The task force is looking at the potential for harmonisation of environmental risk assessment across EFSA Scientific Panels. A first draft paper will be discussed at the September SC Plenary meeting. Several annexes will address various specific aspects. The finalisation of the technical report is expected in February 2011.

- **Taskforce on Endocrine Active Substances**

The task force is developing a technical report to identify any additional needs for harmonisation or to develop new approaches to assessment and communication. It will be presented for discussion at the September SC Plenary meeting. Discussions have taken place with the European Commission to ensure that there is no overlap with ongoing activities within DG Environment.

11. THE EFSA JOURNAL

The 2nd release of the EFSA Journal Web area took place in March 2010. It now provides an improved advanced search tool, a section for editorials, and an easier access to background and supporting documents of the scientific outputs. It also allows for a single repository for all EFSA scientific outputs. Progress has been made regarding the indexation of the EFSA Journal in bibliographic databases; CABI and IFIS/FSTA confirmed their interest to index EFSA publications.

Communication and promotion material has been developed to disseminate the EFSA Journal as widely as possible, e.g. to DG Health and Consumers Protection Non-Food Committees.

12. GRANTS AND PROCUREMENT WORK PROGRAMME 2011

An estimated budget of 8.59 million Euros is available in 2011 for the grants and procurement work programme. Around 64 calls are planned in 2011 in 4 main working areas:

- Support for the examination of authorisation dossiers
- Preparatory work for risk assessment
- Data collection and analysis supporting risk assessment and risk monitoring
- Horizontal issues and scientific cooperation.

The work programme was shared via the Advisory Forum with the Member States and the European Commission who proposed some priorities. The Scientific Committee was also invited to comment on the work programme that will be presented to the Management Board in October 2010.

13. ANY OTHER BUSINESS

- **Emerging risks colloquium, 12-13 October 2010**

The Scientific Committee was informed about the 15th EFSA Colloquium on emerging risks that will take place in Parma on 12-13 October 2010. The objective is to bring together experts from different fields of the food chain to discuss various aspects of emerging risks such as data sources; how to communicate emerging risks, how to identify the drivers for emerging risks. The Organising Committee is currently working on the preliminary programme. The colloquium will be announced on the EFSA website mid-July 2010.

- **Quantitative Structure Activity Relationship (QSAR)**

A workshop on QSAR will be organised jointly by the DG Health and Consumers Protection, the DG Joint Research Centre and EFSA in Brussels in the end of September 2010. The objective is to increase awareness among EFSA and EC experts and staff of this tool for risk assessment.