European Food Safety Authority

SCIENTIFIC COMMITTEE UNIT

MINUTES OF THE 54TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 17-18 APRIL 2012

Publicly opened session

Agreed on 22 May 2012

PARTICIPANTS

Scientific Committee (SC):
Boris Antunovic, Sue Barlow, Andrew Chesson, Albert Flynn, David Gott, Anthony Hardy[1], Michael Jeger, Ada Knaap, Harry Kuiper[2], David Lovell, Sirpa Kärenlampi[3], Birgit Noerrung[4], Iona Pratt[5], Josef Schlatter, Mike Sharp, Vittorio Silano, and Frans Smulders.

European Food Safety Authority (EFSA):
Per Bergman[6], Hubert Deluyker[7], Catherine Geslain-Lanéelle[8], Claudia Heppner.

Present only for the agenda item presented:
Saghir Bashir, Stef Bronzwaer, Dirk Detken, Jean-Lou Dorne, Jeffrey Moon, Tobin Robinson, Claudia Roncancio Pena, Carola Sondermann, Alberto Spagnolli, Andras Szoradi, Didier Verloo.

Secretariat of the Scientific Committee:
Djien Liem, Bernard Bottex, Daniela Maurici, Theresa Mc Fadden, Francesca Piombini, Reinhilde Schoonjans.

European Commission (EC):
Michael Walsh.

Observers:
Giancarlo Belluzzi (Italian Ministry of Health), Stefanie Geiser (European Federation of Associations of Health Product Manufactures), Nergiz Ozbag (Turkish Ministry of Food, Agriculture and Livestock), Roberto Ortuño (AINIA Technological Center), Paul Parsons (Syngenta representing European Crop Protection Association).

[1] Absent on 18th April p.m.
[2] Present on 17th April
[3] Present on 18th April
[4] Present on 17th April
[5] Present on 17th April
[6] Present on 18th April
[7] Absent on 18th April p.m.
[8] Absent on 17th April a.m.

1. OPENING, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies were received from Alicja Mortensen who was replaced by David Gott and Philippe Vannier who was replaced by Mike Sharp. Harry Kuiper was replaced by Sirpa Kärenlampi on the second day of the meeting.

2. ADOPTION OF THE DRAFT AGENDA

The draft 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.

4. WELCOME AND PRESENTATION OF THE RULES FOR OBSERVERS

The Chair welcomed the Observers who were attending this Plenary meeting as part of a pilot project underpinning EFSA's commitment to openness and transparency. The aim of this pilot phase is to test the feasibility of opening up the risk assessment process to Observers from interested parties, providing them with the opportunity to raise questions in relation to EFSA's work. Observers were invited to introduce themselves before being presented the code of conduct to be followed during and after attendance.

Observers and members of the Scientific Committee were invited to fill in a feedback form at the end of the meeting. Comments and suggestions will be used to improve future open Plenary meetings organised by EFSA.

5. REPORT BACK ON ISSUES RELEVANT FOR THE SCIENTIFIC COMMITTEE

Members of the Scientific Committee were provided, prior to the meeting, with a summary of the following meetings:

- Focal Points meeting (14-15 February 2012): agreements have been concluded with all Focal Points (27 member States, Norway and Iceland) to continue supporting in 2012 the cooperation between national risk assessment organisations and EFSA.
- Information session on Implementing rules and Independence Policy (5 March 2012): the information session held in Brussels provided an opportunity to see and discuss how EFSA will assess interests and make decisions regarding the interests of experts.
- Advisory Forum meeting (7-8 March 2012): strategic discussion took place on EFSA's work with the Member States centred on EFSA's policy on independence and scientific decision-making processes, with Member States sharing examples and experience of independence from national perspectives.
- EFSA Management Board meeting (15-16 March 2012): the list of candidates nominated for appointment to EFSA's Scientific Committee and eight of its scientific Panels, which are due for renewal in July 2012, was adopted. The Management Board also adopted EFSA's Draft Annual Activity Report for 2011.

The members of the Scientific Committee did not raise any additional question.

6. COMPENDIUM ON BOTANICALS

Members of the Scientific Committee approved the publication of the new (second) version of the Compendium of Botanicals reported to contain naturally occurring substances of possible concern for human health when used in food or food supplements.
This new version will replace the Compendium currently available on the EFSA website.

The Scientific Committee underlined the fact that this Compendium is a living database and should be updated on a regular basis. Suggestion was also made to ask Member States' Competent Authorities for their safety assessments of botanicals or botanical preparations in order to complete the information in the third version of the Compendium and therefore to further increase its usefulness. The preparation of the third version should also address botanical species from third countries. Moreover, the Qualified Presumption of Safety (QPS) approach applicable to botanical preparations should be developed and tested.

7. NANOTECHNOLOGIES

After briefly summarising the content of the EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain adopted in 2011, the Chair of the Scientific Committee presented the new EC recommendation on the definition of nanomaterial, and its possible implications on EFSA's work. Various stakeholders have been invited to use this definition for their work and to provide feedback to the European Commission. The EC definition will be reviewed by December 2014 on the basis of experience accrued and technological development. Hence, the Scientific Committee discussed ways for a proactive approach by EFSA to assist the European Commission in this task, for aspects related to risk assessment of food.

The Scientific Committee discussed the need to reconsider the contents of its 2011 guidance document on the basis of this new definition. Considering the broadness of the definition, and in order to make the guidance document of direct use for the EFSA Scientific Panels and Committee, it was suggested that EFSA should seek the intentions of the food and feed industries with regards to the particular use of nanotechnologies, and look at whether there is sufficient genuine data available to warrant a revision of the existing EFSA guidance.
The second meeting of the EFSA network on nanotechnologies was held in Parma on 3-4 April 2012. The objective was to capture and discuss ongoing related activities in the European Member States and update the participants on EU-level work in this area. Presentations were given on the DG Research Framework Programme 7 funded project (NanoLyse) on methods for detecting nanoproducts in food, on the activities at the Joint Research Centre concerning Nanomaterials in EU Regulation and on the ongoing and envisaged EU Research projects. The coordinators of these EU-level activities will liaise with the partners of the network for dissemination of information and for participation of Member States for example to test the developed detection methods in various European laboratories. Moreover it was pointed out the need for getting more information on recent developments taking place at the OECD level and in specific third countries. In view of the many ongoing developments, it was agreed that the issue of nanotechnologies should be discussed again at the next Scientific Committee meeting with the view of establishing an ad hoc working group to closely follow the different issues previously highlighted and report to the next Scientific Committee as soon as possible.

8. INTERNAL MANDATE ON RESEARCH PRIORITIES AND HORIZON 2020

Members of the Scientific Committee were presented with the Horizon 2020 programme from DG Research that will replace the existing 7th Framework Programme in 2014. This new programme will focus on three main priorities: excellent science, industrial leadership and societal challenges. EFSA has been invited to submit its proposals for research topics to DG Research by August 2012. Members of the Scientific Committee were invited to send their comments and proposals by end of April 2012.

The Scientific Committee asked whether it would be possible to get a more clear feedback from DG Research on proposals submitted by EFSA in the past and to establish a mechanism to get early information on the results obtained from research programmes of EFSA's interest. The Committee members were reminded that EFSA is just one of many DG Research stakeholders; as such, EFSA's research priorities are considered together with those of other parties when defining research programmes. The European Commission representative suggested that it could be worthwhile for EFSA to consider the possibility of coordinating and submitting a joint list of research priorities together with DG Health and Consumers. The Scientific Committee took note of this proposal and also asked EFSA to explore the feasibility of having an EFSA representative in DG Research' Programme Committee deciding on the research themes.

9. UPDATE ON ENDOCRINE ACTIVE SUBSTANCES

Members of the Scientific Committee were informed about the recent publication by DG Environment of a report summarising the advances in the state of the science since 2002 and mapping out ways of dealing with endocrine disrupters in important pieces of the EU chemicals regulation. DG Health and Consumers indicated this report should be considered as work in progress for the development of the Commission's overall strategy for endocrine disruptors.

Several related ongoing activities and upcoming events were presented:

- The EU Conference on endocrine disruptors – current challenges and policy, to be held on 11 and 12 June 2012 in Brussels, where EFSA will also participate.
- The EFSA Scientific Colloquium on low-dose response in toxicology and risk assessment that will take place in Parma on 14- 15 June 2012.
- EFSA is involved in monitoring the work of various groups and institutions, such as the US National Institute of Environmental Health Sciences, the OECD Advisory Group on Endocrine Disrupter Testing and Assessment and the OECD endocrine disrupter Validation Management Group of Non-Animal Testing.

The Scientific Committee asked to have a review of the outcome of the above-mentioned various events and activities at its September 2012 Plenary meeting, to discuss possible follow-up activities for EFSA.

10. DRAFT OPINION ON THRESHOLD OF TOXICOLOGICAL CONCERN

Members of the Scientific Committee were presented with the revised opinion which incorporates the changes made following the comments received during the previous SC Plenary meeting in February 2012, and the discussion with DG SANCO non-food Scientific Committees of the European Commission (SCCS, SCHER and SCENIHR). The non-food Scientific Committees, like EFSA, are now in the process of finalising their opinion on the use of TTC approach for human safety assessment of chemical substances with focus on cosmetics and consumer products. EFSA has been in close contact with the non-food Scientific Committees to discuss the work in progress and to exchange views and information about the respective developments of their draft opinions. EFSA considers it important to reach a common understanding on the possible use of the TTC approach in the food and feed area as well as in non-food consumer products, in particularly cosmetics. Should there be any differences between these scientific opinions, EFSA and DG SANCO will prepare a report explaining the rationale for any diverging views according to Article 30 (3) of Regulation (EC) 178/2002.

The Scientific Committee, after going through all the modifications, endorsed the draft opinion. The document will be shared with EMA and ECHA for consultation and possible comments.

11. HARMONISATION OF STATISTICAL REPORTING: PROPOSAL FOR FUTURE EFSA'S ACTIVITIES

The SAS Unit presented a proposal for developing a guidance document on how best to report statistical methodology (including design and conduct), data collection, analyses and results. The guidance is not intended to prescribe what kind of study design or statistics should be done, but to explain to applicants, stakeholders, EFSA Scientific Panels and Committee how to report results in order to ensure transparency.
The Scientific Committee supported this proposal.

Following a request from a member of the Scientific Committee, the SAS Unit explained how Bayesian analysis can be conducted.
The Scientific Committee invited the SAS Unit to prepare a short technical paper for use by EFSA's Scientific Panels and Committee.

12. NOTE TO THE SCIENTIFIC COMMITTEE REGARDING AN INVITATION FROM ANSES TO PARTICIPATE IN A WORKING GROUP

Members of the Scientific Committee were informed about an invitation received from the French Food Safety Agency (ANSES) for EFSA staff to participate in a working group looking at a number of toxicological reference values and the critical toxicological studies from which they were derived. This work would be done in the context of a total diet study performed for children between 0 and 3 years old.

The Scientific Committee asked further clarification on the compounds that would be considered, as well as on the choice of the [0-3 year] age range for children, while the sub-population at highest risk is infants between 0 and 6 months. The Scientific Committee underlined the possible impact of reviewing internationally-agreed toxicological reference values and the methodologies to derive these values, and recommended such activity to be brought at a European level.

13. DRAFT OPINION ON RISK ASSESSMENT TERMINOLOGY

The draft opinion on risk assessment terminology was presented to the Scientific Committee. The opinion acknowledges the fact that the terminology used within EFSA for risk assessment is not fully harmonised and makes several recommendations to improve clarity and consistency across EFSA's scientific opinions. A number of possible follow-up actions have been identified to develop appropriate detailed guidance to the Scientific Panels.

The Scientific Committee expressed its appreciation for the work done and adopted the opinion after having reviewed its content.

14. THE DEVELOPMENT OF A PROCESS FOR THE IDENTIFICATION OF EMERGING RISKS IN THE FOOD CHAIN: LESSONS LEARNT, NEXT STEPS

The Scientific Committee was presented with the system in place for the identification of emerging risks within EFSA. The current system consists of the following:

- a data monitoring group composed of 6 Scientific Officers from EFSA Units who discuss the signals received,
- a primary filter involving stakeholders consultative groups, the emerging risks network, the Advisory Forum and EFSA Units who analyse and filter the signals received from the data monitoring group
- If deemed relevant, the signals are then presented to the secondary filter (i.e. EFSA's Panels) for further advice.

Between February 2010 and May 2011, the data monitoring group discussed approximately 2200 signals. 158 were brought to the attention of the primary filter, 12 were considered to be important and in need of follow up, and were therefore brought to the attention of the secondary filter.

Following the experience acquired during this testing phase, the EMRISK Unit identified the need to have the signals reviewed by a group of experts covering the whole remit of activity of EFSA. A proposal was therefore made to merge the above mentioned data monitoring group and primary filter. Signals deemed relevant would then be forwarded to a newly created standing working group of the Scientific Committee on emerging risks for further analysis. Resulting recommendations would then be brought to the attention of the EFSA's Mandate Review Committee[9] for decision on follow up actions.

The Scientific Committee fully supported this proposal and agreed with the creation of a standing working group of the Scientific Committee on Emerging Risks. The mandate for such a working group will be presented at the next Plenary meeting of the Scientific Committee.

15. DEVELOPMENT OF A CHEMICAL HAZARD DATABASE: STATE OF PLAY

Members of the Scientific Committee were provided with a presentation of EFSA's Chemical Hazards Database under development. The purpose of this database is to facilitate the retrieval of the information associated to a particular chemical, e.g. in the context of an urgent question. The database will compile information on risk assessment of chemicals performed

[9] The Mandate Review Committee (MRC) is entrusted with the task of advising the Executive Director on the allocation of requests of scientific opinion or of scientific or technical assistance received by the European Food Safety Authority or issued by EFSA on its own initiative (*cf.* http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf)

by EFSA and provide the main figures (e.g. health-based guidance values), the critical study and a link to the full opinion. The database will also be compatible with the OECD E-Chem and the ECHA- REACH databases.

The Scientific Committee expressed some concerns on the resources and time necessary to develop the database with the level of details described during the presentation and recommended to consider the possibility of structuring the project into various phases (e.g definition of database structure; systematic start up of data gathering and transfer for new and previous EFSA's assessments).

16. PRELIMINARY MANAGEMENT PLAN

Members of the Scientific Committee were presented with the Preliminary Management Plan 2013. The main priorities are to:

- Boost further EFSA's risk assessment capacity
- Develop further the dialogue with risk managers
- Review of planning in scientific cooperation
- Develop support for applicants
- Review the 2010-2013 communication strategy
- Further enhancement of EFSA's efficiency, e.g. by developing tele-meetings.

The Scientific Committee underlined difficulties encountered by some of the Panels due to the poor functioning of the audio-conferencing system and questioned the gain in efficiency for the work of the Scientific Committee and Panels.
The allocation of 33% of the budget to scientific cooperation was noted. Question was raised on how EFSA is measuring the quality of the outputs for outsourced projects.

Members of the Scientific Committee were invited to provide EFSA with their comments by mid-September 2012.

17. REPORT BACK FROM SCIENTIFIC PANELS

Some Panel Chairs expressed concerns that representatives from the European Commission are no longer able to attend plenary meetings in Parma on a regular basis due to budget constraints. Participation using audio-conferencing would be a suitable alternative, but is currently not efficient due to the poor audio-conferencing connections with Parma. A proper interaction between the Panel and Commission services during the preparation of the opinion is under these circumstances no longer optimal and eventually leading to delays for delivering scientific opinions.

Panel on animal health and animal welfare (AHAW)

The Panel adopted two opinions, the first one on swine vesicular disease and vesicular stomatitis, the second one on Foot and Mouth Disease.

The Panel is waiting for the conclusions of the CONTAM and BIOHAZ Panels in order to be able to adopt its opinions on meat inspection approaches. The first opinion to be adopted will address public health hazards to be covered by inspection of poultry meat.

The Panel is expecting to receive a new mandate for a scientific opinion concerning the risk of introduction and spread of Rift Valley Fever in the European neighbouring countries of the Mediterranean region. The Panel is also expecting to receive a new mandate on bee diseases.

Panel on food additives and nutrient sources added to food (ANS)
The new guidance document on submission for food additive evaluations will be presented for discussion and possible adoption at the next Plenary meeting.

The Panel adopted several opinions on carotenes and beta-carotenes.

Panel on biological hazards (BIOHAZ)
Two opinions on possible decontaminating agents for chicken and raw fish were adopted.

The work on meat inspection mandates is ongoing; the Panel will discuss the opinion on poultry meat inspection for possible adoption at the next plenary. The opinion on swine meat inspection has already been adopted.

Panel on food contact materials, enzymes, flavourings and processing aids (CEF)
The Chair informed the participants that the European Commission has decided on the grouping of enzymes for safety assessment. The timeline for the industry to gather and submit data will be extended by 24 months.

The Panel has started reviewing applications for the recycling of plastics. Similar applications are grouped for the safety assessment. The European Commission communicated to EFSA that it would like to see all opinions published at once in order to avoid any commercial advantage.

The Chair of the Panel reported on the good cooperation with the BIOHAZ Panel on an opinion on processing aid for chicken carcass disinfection.

Panel on contaminants in the food chain (CONTAM)
During its last plenary the Panel adopted an opinion on brominated phenols and their derivatives as flame retardants. The Chair reported having to increasingly deal with this type of substances for which there is no toxicity or no exposure data. A call for data was launched but no data were submitted. The Panel subsequently followed up with a literature search.

The Panel received a mandate from the European Commission for an opinion on mineral hydrocarbons in food. The opinion may raise the interest of the public as it deals with thousands of poorly defined substances present in various areas of the food chain.

Panel on additives and products of substances used in animal feed (FEEDAP)
During its next Plenary meeting the Panel will adopt a guidance document on the safety assessment of *Enterococcus faecium* in animal nutrition. The opinion is expected to trigger some discussion as some strains of *E. faecium* are associated to an increasing number of hospital infections due to antibiotic resistance, while this opinion recommends adopting the Qualified Presumption of Safety (QPS) approach for the assessment of this microorganism.

Panel on genetically modified organisms (GMO)
The EFSA environmental risk assessment guidance on genetically modified animals will be presented at the next Plenary meeting. The Chair acknowledged the huge work from the various working groups and Panel members to finalise this document.

The Panel received a mandate for the assessment of the scientific elements supporting the French prohibition to place on the market GM maize MON 810 for cultivation purposes. The opinion will be presented for possible adoption at the next plenary meeting.

Panel on dietetic products, nutrition and allergies (NDA)
The Panel will propose its opinion on dietary reference values on energy to be endorsed for public consultation during its next Plenary meeting.

The Panel continues its work on health claims, aiming to adopt ongoing applications (article 13(5) and 14) before the end of its mandate. The Commission's Standing Committee has adopted the permissive list of claims evaluated under article 13 of the Regulation EC 1924/2006; the list is expected to be published soon.
A number of claims have been sent back to EFSA for further assessment after Member States have submitted additional info. The deadline for the assessment is end of 2012.

Panel on plant health (PLH)
The European Plant Health Regulation foresees the setting up of a list of harmful organisms to be kept outside of the European borders, and a list of harmful organisms that are already present in the European Union and are subject to some regulation in terms of movement of plants. The PLH Panel was asked assess the risk associated to the organisms on the latter list and evaluate possible risk reduction options. This work will keep the panel busy for the next three years.

Panel on plant protection products and their residues (PPR)
The Panel adopted its opinion on the clustering and ranking of emissions from protected crops. The opinion helps setting up priorities and designing some scenarios for the risk assessment.

The Panel is working on an opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticides active substances for the dietary risk assessment. The Chair explained that the Panel is waiting for the finalisation of the opinion from the Scientific Committee on TTC to be able to finalise its opinion since TTC is of relevance for this opinion.

18. NEW IMPLEMENTING RULES OF INDEPENDENCE POLICY

The rules for the implementation of the new EFSA policy on independence and scientific decision making process regarding declarations of interests (DoIs) were presented to the Scientific Committee. This document lays down detailed rules for the screening and management of Declarations of Interest submitted by scientific experts and other individuals and organisations involved in EFSA's work. It provides definitions of interests to be declared,

what EFSA considers to be a conflict of interest (in line with OECD guidelines) and also a clearer and more transparent set of general principles applicable to all those engaging in EFSA's work – scientific experts, staff, members of the Management Board and third party organisations, including external contractors. In the document, a new table makes clear which interests need to be declared, as well as what is allowed or not allowed. The Executive Director of EFSA underlined the importance of these new rules to improve the transparency of the process and to protect and defend experts working for EFSA.

The Scientific Committee took note of this document and asked for a more detailed discussion on the document and its annexes at the next Plenary meeting.

19. ANY OTHER BUSINESS

WHO meeting on Global Collaboration in Chemical Risk Assessment, 28-30 March 2012
The Scientific Committee was informed about the intention of WHO to create a global network on chemical risk assessment, which EFSA is invited to join. The creation of such a network will help to have a better understanding of the existing evidence base at a global level and will give the opportunity to its members to link and share information with other organisations. A full report of the meeting will be published on WHO's website.

Network on Harmonisation in Risk Assessment Methodologies, 7-8 June 2012
EFSA created a Member States' network on harmonisation in risk assessment. A first meeting will be held on 7-8 June 2012 for Member States' Experts to exchange information on related ongoing activities, try to identify common projects and possibilities for harmonisation of risk assessment methodologies. The programme of the meeting will be presented at the next Plenary of the Scientific Committee.

Inaugural meeting of the new Scientific Committee 2012-2015, 23-24 July 2012
Participants of the meeting were informed about the dates for the inaugural meeting of the renewed Scientific Committee for the period 2012-2015.

EFSA Journal – special issue
Members of the Scientific Committee were updated on the status of the special issue of the EFSA Journal for the 10th anniversary of EFSA. The issue will focus on methodologies and contain around 15 articles covering the whole remit of activities of EFSA. This issue will also contain a foreword prepared by the Executive Director of EFSA, a welcome message from the European Commission and an Editorial written by the Chair of the Scientific Committee. All participants were reminded about the end of May 2012 deadline for submitting manuscripts. EFSA aims to publish the special issue in October; this will allow for distribution during the EFSA Scientific Colloquium to be held in November 2012 in Parma.

20. QUESTIONS AND ANSWERS SESSION FROM OBSERVERS
The Chair granted the Observers the opportunity to ask questions, after they had observed the meeting. These questions had been circulated in advance of the meeting, and were answered by the Chair.

Question from Ms. Stefanie Geiser: *What are the next steps the Scientific Committee foresees in 2012-2013 related to its activities on botanicals and the Compendium*?

The Scientific Committee has recently agreed on two mandates for follow-up activities:

- Preparation of a version 3 of the Compendium on botanicals for the end of 2014. The current compendium will be expanded with new botanicals that were not considered yet, e.g. botanicals from non-European countries that do not have any history of food use in Europe. It was reminded to the participants that the Compendium is a living document and is therefore open for corrections or consideration of additional data.
- Consideration of a generic approach for setting priorities for the safety assessment of botanicals when used in food or feed. The working group will start from the Qualified Presumption of Safety (QPS) approach developed for the assessment of microorganisms deliberately added in food and consider whether such approach could be applicable for the assessment of botanicals. The Working Group should report back on the applicability of such generic approach to the Scientific Committee by end of 2013.

Question from Mr. Roberto Ortuño: *Could the TTC approach be applied for the assessment of nanoparticles*?

The available data on oral exposure to specific nanomaterials and any consequent toxicity are very limited; the majority of available information on toxicity of nanomaterials is in the form vitro study or in vivo studies using other route of exposure. The different physicochemical properties of nanomaterials compared to conventional dissolved and micro/macroscale chemical counterparts imply that their toxicokinetic and toxicity profiles cannot be fully inferred by extrapolation from data on their equivalent non-nanoforms. Moreover, nanomaterials are not included in the database underpinning the TTC approach. For the considerations given above, the TTC approach cannot be used at present for the risk assessment of nanomaterials.