European Food Safety Authority

SCIENTIFIC COMMITTEE UNIT

MINUTES OF THE 50TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 13-14 SEPTEMBER 2011

Agreed on 8 November 2011

PARTICIPANTS

Scientific Committee (SC):
Boris Antonovic, Sue Barlow, Andrew Chesson, Albert Flynn[1], Anthony Hardy, Michael Jeger[2], Ada Knaap, Harry Kuiper, David Lovell, Alicja Mortensen, Birgit Noerrung, Iona Pratt, Josef Schlatter, Vittorio Silano, Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):
Stef Bronzwaer[3], Hubert Deluyker, Dirk Detken[4], Anne Laure Gassin[5], Catherine Geslain-Lanéelle, Per Bergman, Bernhard Berger[6], Andras Szoradi[7].

Secretariat of the Scientific Committee:
Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici, Theresa Mc Fadden.

European Commission (EC):
Michael Walsh, Maurice Whelan[8]

Hearing expert
Alan Boobis[9]

[1] Present on 13th September
[2] Present in the morning of 13th September
[3] Present for agenda item 10
[4] Present for agenda item 10
[5] Present on 13th September
[6] Present for agenda item 12
[7] Present for agenda item 12
[8] Present for agenda item 9
[9] Present for agenda item 9

1. OPENING, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies were received from Ivonne Rietjens who was replaced by Alicja Mortensen, Vice-Chair of the ANS Panel.

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.

Sue Barlow declared a new involvement as advisor in the recently started COSMOS project[10] which relates to agenda item 14 "Feedback from working groups". The main aim of the COSMOS project, jointly funded by the European Commission and Colipa, is to develop freely available tools to predict the effects of long-term exposure to cosmetic ingredients in humans. The draft TTC opinion does not mention COSMOS, but the project has been cited in some of the comments submitted on the draft opinion during the public consultation period. The focus of the COSMOS project is on cosmetic ingredients and TTC is considered just one of the various tools that will be explored. Her involvement in this project was not considered to constitute a conflict with her involvement in the TTC working group of the Scientific Committee.

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

The EFSA Executive Director informed the members of the Scientific Committee on the appointment of Hubert Deluyker as Director of Science Strategy and Coordination. She also informed the Committee that Karine Lheureux was appointed as head of the Application Desk Unit and Alberto Spagnolli as head of the Executive Directorate office. These new appointments are part of the re-organisation ongoing in EFSA (e3 project) which started on 1st May 2011.

5. DRAFT OPINION ON GENOTOXICITY TESTING STRATEGIES

The draft opinion on genotoxicity testing strategies was presented to the Scientific Committee for discussion and possible adoption. The final draft takes into consideration the comments received during the public consultation that was launched during the spring. The Scientific Committee, once again, congratulated the chair and the working group for the excellent work done and adopted the opinion with minor modifications. The opinion will be published by the end of September 2011 together with a report on the public consultation of the draft opinion

[10] For further information: see http://www.cosmostox.eu/

which lists the comments received and summarises how they were considered by the working group.

6. DRAFT EFSA GUIDANCE ON REPEATED-DOSE 90-DAY ORAL TOXICITY STUDY ON WHOLE FOOD/FEED IN RODENTS

This agenda point was chaired by Ada Knaap, Vice-Chair of the Scientific Committee, as Vittorio Silano was involved in the preparation of the guidance document.

The draft guidance on repeated dose 90-day toxicity study on whole food and feed in rodent has been subject to a 6 weeks public consultation, which closed on 22 August. 262 comments were received from 32 different organisations. The working group is in the process of analysing the comments received. A meeting has been scheduled to address the comments and to revise the draft guidance which will then be submitted to the Scientific Committee for possible adoption at the plenary in November 2011.

7. OVERVIEW OF THE PROCEDURES CURRENTLY USED AT EFSA FOR THE ASSESSMENT OF DIETARY EXPOSURE TO THE DIFFERENT CHEMICAL SUBSTANCES

The Dietary and Chemical Monitoring Unit presented a draft report describing the procedures currently used in the assessment of exposure to chemicals (not to biological agents) by EFSA's Panels and Units. The report contains a critical evaluation of the methodologies currently used and provides suggestions concerning possible areas of improvement in EFSA's strategies for the assessment of exposure to chemical substances.

The report has been prepared in close cooperation with the various Scientific Panels and Units. Recommendations are given on how to further harmonise the way dietary exposures are estimated within EFSA. The importance to expand probabilistic dietary exposure assessment is also considered together with the possibility to explore cumulative exposure assessment for all metabolically or structurally-related chemical substances. Importance is also given to test statistical methodologies for the estimation of usual intake from short-term dietary data.

The Scientific Committee welcomed the report which they considered to be very helpful. The Scientific Committee particularly appreciated the clear recommendations given in order to improve the validity of the chemical concentration and consumption data and to better harmonise the dietary exposure methodologies used across EFSA. In addition, the Scientific Committee requested that these recommendations be shared with the experts in exposure assessment from all Panels. The final draft report will be circulated once again to the Panels for endorsement of the "Conclusions and recommendations" section. It will be proposed for final endorsement at the Scientific Committee plenary in December 2011.

8. DRAFT SCIENCE STRATEGY

EFSA's draft Science Strategy 2012-2016 was presented to the Scientific Committee. The draft is based on the reflection paper presented to the Management Board at its meeting in June.

The Science Strategy will enable EFSA to clearly illustrate how it will meet evolving demands while being a trusted source of scientific advice on food safety and healthy diets, pursuing its work in keeping with its core values of independence, scientific excellence, responsiveness, openness and transparency.

EFSA has developed its work on the science strategy over the past year through holding surveys and workshops with its staff, and discussions with the Scientific Committee and Advisory Forum. The comments raised in these discussions have been incorporated into the development of the present draft of the strategy. In addition, EFSA commissioned an external study to identify with EFSA's stakeholders, including the Commission, scientific experts and national authorities, which aspects they would envisage EFSA addressing in developing its future strategic scientific direction. The Science Strategy is based on and complements the strategic directions given by the EFSA Strategic Plan 2009-2013, by laying down more specifically the foundations for its scientific work over the long term through a set of key strategic initiatives.

The Scientific Committee was asked to consider the document and to provide insight and guidance to the further elaboration of the Science Strategy. In particular, the Scientific Committee was asked to comment on the underlying vision and thinking in this document and to assess the direction and adequacy of the key strategic priorities identified.

The Scientific Committee comments will be considered in the next revision. The strategy will be presented and discussed at the Management Board in October 2011, and, once endorsed, it will be published for a public consultation in November.

9. NEW RISK ASSESSMENT APPROACHES

The Chair welcomed Dr. Alan Boobis from the Imperial College London, and Dr. Maurice Whelan from the European Commission's Joint Research Centre in Ispra (EC/JRC). Dr Boobis and Dr Whelan were invited to present their views on the new approaches in toxicological hazard/risk assessment.

Dr Boobis made a presentation on new approaches in toxicity testing. Recent technologies such as toxicogenomics, bioinformatics, systems biology, epigenetic and computational toxicology aimed to transform toxicity testing, from a system based on whole animal testing to one founded primarily on *in vitro* methods that evaluate changes in biological processes using cells, cell lines, or cellular components, preferably of human origin. The use of emerging methods for understanding how environmental or chemical agents affect human health will promote beneficial changes in testing chemicals and in the use of data for decision making.

The new paradigm proposed for toxicity testing includes chemical characterisation, toxicity testing, dose-response and extrapolation modelling. The goal of new toxicity testing is to identify critical pathways (e.g. cell signalling motifs, genetic circuits, cellular response networks) that when perturbed, can lead to adverse health outcomes. The evaluation of the host susceptibility to understand the effects of perturbations on human populations is then

critical. To implement the new toxicity testing approach, toxicologists have started to propose a comprehensive array of test procedures in key toxicity pathways. Epidemiologists and toxicologists are developing approaches to understand the range of host susceptibility within populations.

Dr. Maurice Whelan presented the activity ongoing at the Joint Research Centre in the Institute for Heath and Consumers Protection (JRC-IHCP). Dr Whelan shortly introduced the ToxCast programme that was developed by the US Environmental Protection Agency (EPA) in 2007. Tox Cast was launched to develop ways to predict potential toxicity and to develop a cost-effective approach for prioritizing the thousands of chemicals that need toxicity testing. The JRC-IHCP signed in 2010 a Material Transfer Agreement to test with a high-throughput systems a certain number of chemicals in the frame of the project aimed at understanding how human body processes are impacted by exposures to chemicals and helps determine which exposures are most likely to lead to adverse health effects. Data available from the high-throughput assays are available via the ToxCast Database. Toxicity signatures from ToxCast are defined and evaluated by how well they predict outcomes from mammalian toxicity tests and identify toxicity pathways relevant to human health effects. Dr. Whelan continued by presenting the activity on validation on high-throughput screening of *in vitro* methods. He presented data generated using a high-throughput system to evaluate the usefulness of the BG1Luc oestrogen receptor transcriptional activation test method as a screening test to identify substances with *in vitro* oestrogen receptor agonist and antagonist activity. He also presented activities in the field of metabolomics, toxicogenomics and computational toxicology used with the aim of exploring new modelling of *in vitro* cytotoxicity and repeated dose toxicity. Dr. Whelan concluded his presentation remarking on the importance of understanding mode of action of toxic chemicals as a prerequisite for exploiting new and emerging methods.

- **Draft internal mandate: discussion and next steps**

The Secretariat presented a draft internal mandate for an internal task force on new risk assessment methodologies to review the state-of-the-science of the modern and emerging methodologies and tools available and their applicability to the hazard identification and characterisation of chemicals. The resulting scientific report would be presented to the Scientific Committee in April 2012 for a discussion on priorities for further work. The Scientific Committee welcomed the decision of EFSA to prepare a position paper on this issue and underlined the relevance of this topic for an international colloquium as part of the EFSA 10th Anniversary celebrations next year.

The Committee was informed that EFSA's Emerging Risks unit has launched a procurement procedure on the state-of-the-art OMIC's technologies and their potential application in the food and feed safety area. The results of the outcome of this project will be considered by the before mentioned internal task force to further explore the possible application of these technologies in EFSA's work.

The Scientific Committee welcomed the decision of EFSA to prepare a position paper on this issue and supported the draft mandate, proposing minor modifications. The Scientific Committee suggested the final report, giving direction on EFSA's future work intentions in

this field, should be presented to the Scientific Committee's Member States' network on harmonisation of risk assessment. The Scientific Committee finally underlined the relevance of this topic for an international colloquium to be organised in 2012 as part of the EFSA 10th Anniversary celebrations.

10. EXPERTS SURVEY REPORT

The results of the 2011 EFSA expert satisfaction survey were presented to the Scientific Committee. The survey was carried out in order to understand how EFSA's external experts perceive the administrative, scientific and communication support given by EFSA. Out of the 1734 EFSA Scientific Committee, Panel, working groups, and Network experts invited, 912 participated in the survey. Both administrative and scientific support scored very high in the survey and 94% of experts confirmed their willingness to continue working with EFSA. The survey scored lower on the financial remuneration given to the experts for their work.

The Scientific Committee found the questionnaire to be a worthy exercise and the results interesting. The Committee suggested that for the next survey the amount of time experts spend working for EFSA be more accurately measured.

11. SCIENTIFIC ASSESSMENT SUPPORT UNIT

Mandate for the preparation of guidance on expert knowledge elicitation

EFSA currently applies the use of systematic reviews to retrieve, appraise and synthesise publicly available and accessible scientific evidence to food and feed safety risk assessment models. However, in the absence of such publicly available empirical evidence, it is necessary to elicit knowledge from external experts, such as professionals or other knowledgeable persons. The Scientific Assessment Support Unit (SAS) presented an internal mandate for an EFSA working group to prepare guidance for expert knowledge elicitation in food and feed safety risk assessment.

The working group, to be composed of EFSA staff and SC experts, will be created to produce a practical guidance on how to transparently elicit knowledge from external experts ensuring neutrality and comprehensiveness in the choice of experts, how to use a consistent and reproducible approach, ensuring reliable information the retrieval of which is correctly documented. The draft guidance will be made available for public consultation prior to finalisation.

The Scientific Committee expressed some reservations on the proposed mandate especially with regards to the efforts needed to draft a guidance that would probably have only limited added value for EFSA's risk assessment process. Concern was raised about how to ensure that information is endorsed by Member States. The Committee suggested to involve EFSA's focal points and the networks in the working group to be established and welcomed the proposal to present the draft guidance during a workshop with EFSA staff and Panel members for further discussion.

Options for launching a study on determination of natural variation observed in controls and historical controls in 90 day feeding trials

The SAS Unit also proposed to launch a call for tender to collect data on natural background variation in the repeated-dose 90-day oral toxicity study. The Scientific Committee discussed the relevance of having an in-house database of 90-day feeding trials. It expressed concerns that such a broad activity would require a considerable amount of resources without adding value to the scientific work of EFSA.

Statistical concepts and definitions: possible new topics

Following the adoption by written procedure on 8 September 2011of the Scientific Opinion on Statistical Significance and Biological Relevance, the Scientific Committee agreed with a third proposal from the SAS unit to prepare a guidance document on how to submit data to EFSA on the reporting of the results, its analysis and the interpretation of the results. The aim of such a guidance would be to enhance the quality of methodology of reporting which would be fundamental and practical for EFSA's Panels. The SAS Unit was asked to prepare a mandate for an EFSA working group to be coordinated by the Unit. A public consultation of the draft guidance shall be included in due time prior to endorsement of the guidance by the Scientific Committee.

12. PRESENTATION OF THE NEW EXPERT SUPPORT SYSTEM – DECLARATION OF INTEREST (DOI) TOOL

The Scientific Committee was presented with the new Declaration of Interest (DoI) tool. This electronic tool is used by experts when submitting their annual and/or specific DoIs.

This updated tool now allows the contents of the DOI to be linked to specific agenda items of upcoming meeting. The Committee appreciated the presentation and technical explanations.

13. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

The Panel held its last plenary in June. The opinion on hatchery waste as animal by-product was co-adopted with the BIOHAZ Panel. The opinion on meat inspection in domestic swine was endorsed by the Panel, but adoption of the complete opinion will be done by written procedures, as BIOHAZ and CONTAM were also involved in the drafting of the opinion.

The draft guidance on the risk assessment of food and feed from GM animals, including animal health and welfare aspects, was endorsed for public consultation in August. This draft guidance has been developed in close cooperation with the GMO Panel. The guidance does not cover the environmental risk assessment of GM animals which will be addressed in a stand-alone environmental risk assessment guidance document, developed by the GMO Panel.

The draft guidance for risk assessment on animal welfare, published for public consultation in the beginning of the summer, received interesting comments that will be reviewed at the upcoming plenary. The adoption of the guidance is expected by the end of the year.

A new mandate from the Commission was received upon a request from Bulgaria to issue an opinion on foot and mouth disease.

Panel on biological hazards (BIOHAZ)

Five opinions were adopted at the last plenary. The BIOHAZ Panel, like the majority of the other EFSA Panels, will be renewed in spring 2012. To ensure continuity and to ensure that the expertise developed by the former Panel is not lost, a self-task mandate has been proposed to reflect experience accrued on technical mathematical models over the last years. Each time a model will be used in the near future by a working group, it will be presented to all Panel members in order to increase awareness of the tools developed.

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

The renewed CEF Panel held its inaugural meeting in July, back to back to the last meeting of the former Panel. Dr Iona Pratt was elected as chair of the Panel. Dr Wim Mennes and Dr Catherine Leclercq were elected as Vice Chairs.

Prior to the renewal of the Panel at the July plenary, an opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET was adopted. The Panel also adopted an explanatory note on the guidance on submission of a dossier on food enzymes. The note will help the applicants to compose a technical dossier giving examples of scientific data needed.

Panel on contaminants in the food chain (CONTAM)

Four opinions were adopted at the last plenary. The opinion on meat inspection for domestic swine has been adopted by written procedure. This opinion has been produced in collaboration with the BIOHAZ and the AHAW Panels. The work on the opinion on meat inspection of poultry is ongoing and progressing well. The external report on “Comparison between 3-MCPD and its palmitic esters in a 90-day toxicological study” has been finalised and it is now published on the EFSA website.

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

During its last plenary, the Panel adopted nineteen opinions. The draft guidance on the assessment of the toxigenic potential of *Bacillus* and related genera used in animal nutrition was published for public consultation during the summer. The consultation closes 16th September 2011. The Panel is in the process of updating several guidance documents. Adoption and consequently publication is expected by the end of the year.

Panel on genetically modified organisms (GMO)

The Panel received a series of requests from the Commission for safety assessment of new breeding technologies and a mandate for the risk assessment of a GM maize cultivation.

A public consultation was launched on a draft guidance for risk assessment of food and feed derived from GM animals. The risk assessment approach compares GM animals and derived food and feed with their respective conventional counterparts integrating both food and feed safety as well as animal health and welfare aspects. The public consultation will run until 30 September 2011.

Panel on dietetic products, nutrition and allergies (NDA)

The assessment of health claims under art.13 has been completed and the opinions have been published. This very challenging task was accomplished thanks to the dedication and commitment of the experts on the NDA Panel in collaboration with EFSA staff, who have had to cope with an unprecedented workload, coupled with very tight deadlines. More than one thousand claims on "botanicals" have been placed on hold by the Commission pending further consideration on how to proceed with these.

EFSA is liaising with the European Commission and Member States regarding the re-submission of a limited number of 'general function' health claims, such as those relating to microorganisms which were considered by the Panel to be insufficiently characterised or claims for which the evidence provided during the initial submission was not sufficient to establish a cause and effect relationship. EFSA expects to receive the claims for reassessment from the European Commission before the end of 2011 and the precise timetable for the further assessment will be drawn up once the re-submission process has been completed.

Panel on plant protection products and their residues (PPR)

The Panel held its last meeting Plenary in June. The guidance on dermal absorption was thoroughly discusses together with the report on the outcome of the public consultation. Two other documents were endorsed for public consultation: the draft opinion on the science behind the guidance for scenario selection and parameterisation for predicting environmental concentration in soil, and the draft opinion on clustering and ranking of emissions of plant protection products from protected crops to relevant environmental compartments. Both consultations closed in September.

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

The Panel held its last meeting before its renewal in July. The new Panel held its inaugural meeting back to back to the last meeting of the former Panel. Ivonne Rietjens was elected Chair of the Panel. Alicja Mortensen and David Gott were elected as Vice Chairs.

EFSA has launched a public call for data on the artificial sweetener aspartame (E 951) for consideration in a full re-evaluation to be completed in 2012 as requested by the European

Commission. Among the data received so far are 112 original studies submitted to support the request for the authorisation of aspartame in Europe in the early 1980s. The public call for data, which runs until 30 September 2011, was launched to ensure that EFSA's first full risk assessment of the safety of aspartame will be the most thorough and up-to-date. To complete its evaluation, EFSA is asking for all available scientific and technical data – published, unpublished and newly generated – related to aspartame in food and drinks and as a table-top sweetener.

14. REPORT BACK FROM WORKING GROUPS

WG Compendium on Botanicals

The update of the Compendium of botanicals reported to contain compounds of possible concern for human health is ongoing. The mandate has been extended until the end of the mandate of the current Scientific Committee, the updated compendium and a list of recommendations for the new Scientific Committee will be presented in February 2012. In preparation of this document a questionnaire was distributed to Member States and focal points via the Advisory Forum. The questionnaire should provide feedback on how Member States have used the compendium so far and on what improvements could be considered by EFSA. The same feedback will also be sought from other stakeholders (e.g. professional associations dealing with botanicals). The outcome of the questionnaires will be shared with the Scientific Committee.

WG TTC

The public consultation on the draft opinion has been extended until 23rd September 2011. The comments received will be addressed in an ad-hoc meeting in the beginning of October. The revised draft will be most probably proposed for adoption at the December plenary.

WG RA Terminology

Work is in progress. The working group aims to present the first draft of the opinion at the plenary in December 2011.

WG Default Values

The draft opinion on default assumptions used by EFSA's Scientific Panels, Scientific Committee and Units in the absence of actual measured data was launched for public consultation during the summer. The consultation closed on 15th September. A working group meeting will be held to address the comments received. The final draft opinion will be presented to the Scientific Committee for possible adoption at the December plenary.

Internal task force on Environmental Risk Assessment

The technical report developed by the internal task force was published on the 22 September 2011. The draft mandate for a self task on environmental risk assessment will be presented at the December plenary.

15. ANY OTHER BUSINESS

- The Commission informed EFSA that the 7th Chairs' meeting that was to be held on 9-11 November in Helsinki, has been cancelled.

- The Head of the AFSCO unit informed the Committee that EFSA recently launched a call for tender for English proofreading and editing of draft EFSA scientific outputs. Once awarded, EFSA units will be able to make use of this service in order to improve the linguistic quality of scientific outputs. Proofreading will be available on request at any stage during the drafting of the opinion.