

**MINUTES OF THE 45TH PLENARY MEETING OF THE EFSA SCIENTIFIC
COMMITTEE HELD ON 9-10 NOVEMBER 2010**

Agreed on 7 December 2010

PARTICIPANTS

Scientific Committee (SC):

Sue Barlow, Corrado L. Galli, Anthony Hardy, Joerg Hartung, Klaus-Dieter Jany, Michael Jeger, Ada Knaap, Harry Kuiper, David Lovell, Josef Schlatter, Vittorio Silano and Frans Smulders.

European Food Safety Authority (EFSA):

Bernhard Berger¹, Hubert Deluyker, Anne-Laure Gassin², Catherine Geslain- Laneelle³, Riitta Maijala, Carola Sondermann⁴.

Secretariat of the Scientific Committee:

Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici, Francesca Piombini and Tomas Öberg.

European Commission (EC):

Michael Walsh.

Hearing Expert:

Ville Flari⁵.

¹ Present on 10th, November for agenda item 13, 14, 15

² Present on 9th November

³ Participated via telephone

⁴ Present on 10th November for agenda item 13, 14, 15

⁵ Present on 10th November for agenda point 12

1. OPENING

The Chair welcomed the participants. Apologies were received from Andrew Chesson, John Dan Collins, Albert Flynn, John-Christian Larsen, and Philip Vannier who was replaced by Joerg Hartung (vice chair of the AHAW 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.

4. AGREEMENT OF THE MINUTES OF 44TH SC PLENARY

The minutes of the last Scientific Committee plenary meeting, held 14-15 September were agreed.

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

• Meeting with MEPs on animal cloning, 16th September

Vittorio Silano attended this meeting arranged by the Working Party of Socialist and Democrats Party and presented the latest updates from EFSA in relation to animal cloning. The Scientific Committee members were informed about the Report from the Commission to the European Parliament and the Council on Animal Cloning for Food Production which was published in October 2010. This report refers to the EFSA 2008 Scientific Opinion and to the two EFSA Statements published in 2009 and 2010. The report proposes measures in relation to animal cloning in light of the current legislative framework.

• Advisory Forum and meeting with Commissioner Dalli, 22-23 September, Malta

The Advisory Forum meeting had strategic discussions on the work of EFSA and Member States. The meeting emphasised the importance of the regular dialogue on short and medium term planning to improve the prioritisation and use of resources of EFSA and Member States. The Advisory Forum supported a document from EFSA aimed at setting out its medium-term planning to help Member States gauge their future involvement in areas of interest in EFSA's work. The workload of EFSA has over the years shifted from generic opinions to applications where 40% of EFSA resources are now allocated, compared to 20% two years ago.

Commissioner Dalli underlined also the importance of such medium-term planning and the need for further involvement from Member States, as EFSA will not be able to address properly its heavy workload without finding new ways of working and cooperating with national bodies. He also said EFSA should raise awareness of the need to maintain and develop expertise at national level to ensure that the EU system for risk assessment can be sustained. The Commissioner expressed his support for the work of EFSA and showed sympathy with additional discussions on how EFSA can be compared with other agencies.

The Advisory Forum members also discussed collection of exposure data on energy drinks and appreciated the report reviewing the current EFSA activities on endocrine active substances which has now been published. The Scientific Committee was informed that Norway and Iceland are now full members of the Advisory Board.

- **Visit of Danish delegation, 5th October**

A delegation from the Danish Veterinary and Food Administration and the National Food Institute of the Technical University of Denmark (DTU) and risk managers visited EFSA and discussed, among other issues, current and future cooperation and networking between EFSA and Denmark. This visit helped the risk managers to understand the importance of the contribution of DTU experts to the work of EFSA.

- **Management Board, 21st October**

The Management Board re-elected Professor Diána Bánáti as chair of the Management Board and elected as Vice-Chairs Sue Davies and Piergiuseppe Facelli. The Board reiterated that scientific independence is a fundamental principle and a core value of EFSA and the Board decided that in order to avoid any misperception of its role, the Chair should refrain from having a management role or other influential roles in organisations representing interests of the food chain, other than public interests.

The Board supported the continued increase in grants and contracts to fund scientific work with Member States and discussed EFSA's communication strategy for 2010-2013. The Board adopted the 2011 work programme on funds for cooperation projects, which have nearly tripled in the past five years. Most of the funds are allocated to supporting risk assessment activities, such as the examination of authorisation dossiers, data collection and analysis.

6. NEW INTERNAL MANDATES

- **Establishment and operation of the Scientific Network on Harmonisation of Risk Assessment Methodologies**

The Scientific Committee welcomed this mandate which aims to harmonise general risk assessment methodologies with regard to food and feed to accomplish an integrated approach between specific scientific fields under the umbrella of the Scientific Committee. This mandate is supported by the Advisory Forum. The Scientific Committee commented that the presence of experts with suitable scientific expertise is crucial for the success of the network. The Scientific Committee suggested that the terms of reference for the network could be slightly revised and clarified in the sense that the network is not meant to deliver scientific opinions.

- **Procedures currently carried out by the different EFSA Panels to assess dietary exposure to chemicals**

The Scientific Committee welcomed this EFSA internal mandate aimed to develop a technical report on the procedures currently applied by EFSA Panels to assess dietary exposure. With the advent of the comprehensive food consumption database this work is very timely. It will

also be of use for the ongoing work on TTCs. It is the long term objective for EFSA to harmonise, to the extent possible, exposure assessment procedures across different classes of substances through the development of a standardised procedure.

- **Inventory of Hazard Databases**

The Scientific Committee welcomed this EFSA internal mandate aimed at creating an inventory of databases currently used by EFSA to identify and characterise chemical hazards. The Scientific Committee was explained that generating an inventory is a step in an exercise to identify gaps and unmet needs of EFSA, and building a hazard characterisation database.

7. UPDATE ON THE DRAFT OPINION ON NANOTECHNOLOGIES

The Scientific Committee provided comments on the draft guidance document which after revision is scheduled to be endorsed for public consultation at the Scientific Committee plenary in December. The Scientific Committee was also informed that the EFSA Scientific Network for Nanotechnologies in Food and Feed Safety is scheduled to have its first meeting in February 2011, which will take place during the public consultation of the draft nanotechnology guidance document.

8. THE EUROBAROMETER 2010 ON FOOD-RELATED RISKS: KEY FINDINGS

The EFSA Director of Communications presented the outcome of a recent Eurobarometer 2010 commissioned by EFSA in cooperation with DG Health and Consumers which polled the European consumers' perceptions of food risks. The fieldwork was carried out in June 2010 and 26 691 EU citizens were questioned in face-to-face interviews; the outcome of the poll is quantitative rather than qualitative.

Key findings indicate that the majority of Europeans associate food and eating with enjoyment. Those who are concerned about possible food-related risks tend to worry more about chemical contamination of food rather than bacterial contamination or health and nutrition issues. The poll also showed most Europeans have confidence in national and European food safety agencies as information sources on possible risks associated with food. The previous Eurobarometer was made in 2005 and the results from the recent Eurobarometer make it possible to assess, evaluate and monitor changes over time. The Scientific Committee welcomed the presentation on the key findings from the Eurobarometer and the source the data creates for further research and analysis.

9. POSSIBLE SUBJECTS FOR FUTURE CONSIDERATION BY THE SCIENTIFIC COMMITTEE

- **Synthetic biology – for information and discussion**

The Scientific Committee was presented a briefing note on synthetic biology and possible follow up actions. The Scientific Committee considered it to be of value to monitor developments in this area for an understanding of possible applications in the food and feed sector of this technology. The Scientific Committee noted the importance of an early consideration of potential risks of new technologies to generate an understanding of potential risk assessment issues and possible needs for adaptation of risk assessment principles.

- **QSAR – Feedback on DG SANCO workshop, 30 Sept - 1 Oct 2010, Brussels**

EFSA staff and experts attended this workshop which aimed to raise awareness of the applications of quantitative structure-activity relationship (QSAR) methodologies and their use in risk assessment. The current EFSA activities in the area were presented at the workshop. The Scientific Committee notes that this is an area attracting lot of activity from various risk assessment bodies both within EU (e.g. ECHA, JRC) and internationally (US EPA and FDA) and that developments should be followed closely. The Scientific Committee welcomes the use of information derived from QSAR for risk assessment purposes but noted that the models and tools require experts' knowledge for use and interpretation of the outcome of the modelling.

10. REPORT BACK FROM WORKING GROUPS AND INTERNAL TASKFORCES

- **WG Threshold of Toxicological Concern**

The project outsourced by EFSA to explore the applicability of physico-chemical properties, QSARs and read across in TTC assessment, initially expected to be finalised in December 2010, will be slightly delayed until end of March 2011. The working group will then assess the outcome of this project before finalising the opinion, planned to be presented to the Scientific Committee in June 2011 for endorsement for public consultation.

The Chair of the working group attended a meeting of the DG Health and Consumers non-food scientific committees who are also working on in this area; the purpose was to review respective objectives and progress.

- **WG Genotoxicity Testing Strategies**

The Working Group invited during its last meeting a hearing expert to present recent data and publications that were discussed together with the working group. Another meeting is planned before the end of 2010. The working group aims at presenting the draft opinion for endorsement for public consultation to the Scientific Committee in April.

- **WG 90-day Feeding Trials**

The Working Group has had several in-depth discussions on general principles related to various issues, such as selection of suitable animal strains and statistical design and analysis. At the last working group meeting the preliminary outcome of a French report under preparation by Agence National de Sécurité Sanitaire (ANSES) regarding the performance of animal feeding trials and statistical analysis of results was presented.

Further discussion between EFSA and the ANSES working group are envisaged.

- **WG Statistical Approaches**

The Working Group is progressing and a draft of the guidance is being developed for discussion at the Scientific Committee beginning of 2011 for discussion at the Scientific Committee.

- **WG Default Values**

The Working Group is progressing and addressed during its last meeting the possibility of harmonising rules for rounding and number of significant digits for quantitative results. David Lovell explained that statistical rules exist for this and will forward information to the Working Group. The opinion is expected to be discussed at the Scientific Committee 2nd half of 2011.

- **WG Compendium on Botanicals**

The Working Group is continuing its review of the lists of plants received from the EFSA Focal Points and Stakeholders in order to complete the information contained in the EFSA compendium of botanicals reported to contain substances of possible health concern. The updated compendium will be published end of 2011.

- **WG Benchmark Dose (II)**

EFSA will organise on 1 and 2 December 2010 a training workshop on the BMD approach for EFSA Staff and Panel Experts. Participants will work on practical exercises using two software packages currently available for BMD calculation: BMDS and PROAST. A technical report summarising the outcome of the workshop will be published beginning of 2011.

11. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

The opinion on increased mortality events in Pacific oysters, as well as the opinion on the practice of harvesting feathers from live geese for down production were adopted. The Panel has received a new mandate, asking to update the 2007 opinion on blue tongue. The Panel is currently working on H1N1 influenza virus, monitoring for emergence of new pandemic influenza strains and trying to better understand the mechanisms for such emergence. The European Commission has asked for an opinion on welfare of animals during transport, looking at scientific basis for further improvement of possible weak points. The drafting of guidelines on welfare risk assessment is progressing; the purpose is to formalise the approach for assessing the welfare of animals.

The Panel has provided indicators to measure animal welfare parameters in dairy cows. The Panel contributed to the BIOHAZ opinion on meat inspection by looking at animal welfare aspects. The Panel discussed with Mr. A. Gravinelli, Head of Unit D5, the animal welfare action plan from the European Commission DG Health and Consumers. The objective of the action plan is to lay the basis for a European animal welfare legislation within 2015.

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

The Panel finalised its work on Bisphenol A and concluded that there is no need to change the existing tolerable daily intake level (TDI). The Chair appreciated the help received from the EFSA Assessment Methodology Unit on the analysis of the statistical data. The Panel discussed during its last meeting a draft opinion on chemical safety of food irradiation. The

Panel is continuing the work on the data to be supplied for assessment of flavourings under Commission Regulation (EC) No 2565/2000.

Panel on contaminants in the food chain (CONTAM)

At its last plenary in September the Panel adopted a section in the BIOHAZ Panel opinion on the use of recycled water for decontamination of carcasses and an opinion on brominated flame retardants. The Panel has recently received a request from the Commission related to the health of infants from acute dietary exposure of leafy vegetables containing nitrates. The Panel has received a number of new mandates and has an intense work program for the next two years.

Panel on genetically modified organisms (GMO)

The Panel has recently adopted several guidance documents regarding environmental risk assessment of cultivation of GMOs and risk assessment of GMOs for non-target organisms. Furthermore, an updated guidance document for the risk assessment of GM microorganisms was adopted, as well as an opinion on the choice of comparators for risk assessment of GM plants. The latter two documents are soon to be published for public consultation. The Panel Chair also reported that the GMO Panel works on an update of the EFSA guidance document on the risk assessment of GM plants and derived food/feed to be finalised in March 2010.

Panel on plant health (PLH)

A recent opinion from the Panel assessed the risk for *Anoplophora chinensis*, a pest of woody plant species to be introduced in the European Union with bonsai trees imported from Japan. The Panel has currently five working groups working with various opinions and has a self task mandate to draft a guidance document related to environmental risk assessment in the area of plant health. This guidance is discussing the ecosystem service concept earlier developed by the PPR Panel. The Panel has also received a recent internal mandate related to pest risk management options. Risk management options are provided in the evaluation performed by outside parties, and there is a need to provide additional guidance for this type of assessment.

Panel on plant protection products and their residues (PPR)

The Panel has recently adopted two comprehensive opinions. One deals with specific protection goals for environmental risk assessment and introduces the ecosystem services approach. The next step in this area is to set up a Working Group who will develop specific protection goals. The second opinion provides guidance for monitoring the fate of the pesticides in the environment, by looking at the distribution in the soil of target group organisms; the information obtained will then allow for setting better exposure scenarios.

12. RISK ASSESSMENT TERMINOLOGY

Dr Villie Flari from the Food and Environment Research Agency (FERA) in UK presented a report commissioned by EFSA to look at the terminology employed in EFSA opinions to express risk and uncertainty. The report assessed a selection of 219 scientific outputs of EFSA Scientific Committee and Panels published in 2008, 2009 and beginning of 2010. The analysis of the assessed outputs indicates a number of similarities as well as differences between EFSA Panels on how risks, benefit, efficacy and uncertainties are expressed. The great majority of terms used are qualitative in nature. Some preliminary conclusions and recommendations are indicated in the report that will be used as a starting point for the discussion in the recently established Scientific Committee Working Group on Terminology.

The Scientific Committee welcomed the presentation and the comprehensive report. A discussion followed which raised, among other issues, the difficulty in communicating qualitative terms in a quantitative way, and that the science of using tables or descriptive ranges to do this is still in its infancy. The Scientific Committee is of the view that continuing the efforts to communicate risks and uncertainties in a harmonised way is valuable, but recognises that specificities of various Panels and their scientific areas may prevent a full harmonisation.

The Scientific Committee Working Group had its kick off meeting in October. Dr Villie Flari was invited to present in details the external report. This working group aims to present its outcome by the end of 2011.

13. RESEARCH PRIORITIES TO BE PROPOSED TO DG RESEARCH FOR 2011

A proposal on research priority areas to be submitted to DG Research for consideration for the framework program 7 (FP7) has been developed by an internal task force considering proposal from Members States and EFSA Panels and Units. A total of 84 proposals were received and, based on screening criteria, four proposals are prioritised. The Scientific Committee welcomed such prioritisation and provided comments that will be considered by EFSA before the proposal is sent to DG Research by the end of the year.

14. EFSA MEDIUM TERM PLANNING

EFSA Director on Cooperation and Assistance gave a presentation on the EFSA medium term planning. The scientific cooperation with Member States is based on the Strategy and Cooperation policy which was adopted in 2006 and reviewed in 2008. Since 2007 the EFSA budget for grants and procurement has increased and is €8 million for 2011.

During discussions in the Advisory Forum, Members States have indicated the need for a document helping Member States to plan resources on the medium term. A discussion group composed of Member States' experts and EFSA staff has prepared a draft report on scientific cooperation activities. The main scientific cooperation activities are in the areas of risk assessment, regular data collection programmes and information exchange. The discussion

group has also compiled a table of specific medium-term activities. The Scientific Committee welcomed the report and is invited to submit any comments before the report is finalised.

15. ANY OTHER BUSINESS

- **Update on Panels renewal process**

ANS and CEF Panels will be renewed in 2011 and the call for experts has recently closed and is currently being evaluated according to the EFSA procedures. The number of applicants has increased since the last renewals. A separate call to extend the reserve list for the eight other Panels and the Scientific Committee experts is also under evaluation. It is scheduled that the nominated experts will be appointed by the Management Board in the spring of 2011.

- **Update on the preparation of the EFSA Science Strategy**

A discussion with the Scientific Committee on the EFSA Science Strategy is scheduled for the February 2011 plenary, ahead of the discussion in the Management Board.