European Food Safety Authority

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

MINUTES OF THE 40TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 11 DECEMBER 2009 IN BRUSSELS

[adopted by written procedure on 28 January 2010]

PARTICIPANTS

Scientific Committee (SC):
Susan Barlow, John D. Collins, Corrado L. Galli, Anthony Hardy, Klaus-Dieter Jany, Michael Jeger, Ada Knaap, Harry Kuiper, John-Christian Larsen, David Lovell, Josef Schlatter, Mike Sharp[1], Vittorio Silano and Frans Smulders.

European Food Safety Authority (EFSA):
Catherine Geslain-Lanéelle, Davide Arcella, Hubert Deluyker, Dirk Detken, Pietro Ferrari, Riitta Maijala and Liisa Valsta.

Secretariat of the Scientific Committee:
Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici, Torben Nilsson and Francesca Piombini.

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

[1] Vice-Chair of the AHAW Panel

1. OPENING

The Chair opened the meeting and welcomed the participants. Apologies were received from Andrew Chesson, Albert Flynn and Philippe Vannier.

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. ADOPTION OF THE MINUTES FROM THE 39TH PLENARY MEETING

The minutes were adopted with minor amendments.

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

- **5th meeting of the Chairs and Secretariats of Commission and Agency Scientific Committees / Panels involved in risk assessment, 18-19 November 2009**

This meeting was aiming at fostering further collaboration among the different scientific committees on issues of common interest. A report describing the procedure to identify emerging risks was adopted and will be followed by a mandate for an interagency working group to make such an early detection system operational in Europe.

EFSA will take the lead of an activity aiming at harmonising terminology used in risk assessment in Europe. This activity will focus on the expression of uncertainty and confidence. A mandate will be prepared for adoption at the next plenary meeting of the EFSA Scientific Committee.

The meeting included a workshop on alternative testing methods for risk assessment. The presentations will be circulated to the members of the Scientific Committee.

- **Scientific colloquium on "What's new on Novel Foods", 19-20 November 2009**

One hundred participants coming from 24 countries participated in the colloquium organised by EFSA to discuss the scientific information needed for applications on novel foods and novel food ingredients submitted for authorisation in the European Union. The colloquium, which was very well received by the participants and the European Commission, provided valuable input for the future development of EFSA's guidance on the safety assessment of novel foods.

- **Workshop on safety assessment of botanicals and botanical preparations, 24 November 2009**

Sixty participants from the European Member States' Competent Authorities, the industry, the European Commission and the European Medicines Agency were invited by EFSA to discuss the guidance document for the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, which was published on the EFSA website in September 2009. Recommendations were made to risk assessors to use the approach for safety assessment proposed by EFSA and report back on any difficulty encountered or suggestions for improving the guidance document, and to EFSA to continue expanding the information contained in the compendium of botanicals reported to contain toxic, addictive, psychotropic or other substances of concern.

- **Advisory Forum meeting, 25-26 November 2009**

The work programme of DG Research was presented to the Representatives of the Member States who were offered the possibility to provide input on their research needs. The participants also discussed the work of EFSA in the animal feed area, and endorsed a document describing how EFSA should work with networks; this document will be presented to the EFSA Management Board.

The mandate for the creation of an EFSA Scientific Cooperation (ESCO) working group on non-plastic food contact materials was endorsed. Advisory Forum members were invited to propose experts for the working group.

The Advisory Forum members expressed their strong support to EFSA's EUMENU project (see section 7 of these minutes) and underlined the importance of the outcome for the work of EFSA and the Member States in the future. A declaration will be signed to formalise this support. The Executive Director of EFSA underlined the high trust and cooperation spirit between EFSA and the Member States' Competent Authorities, which is illustrated by this project. Competent Authorities were also invited to visit EFSA in Parma to discuss specific areas of collaboration. After the visit of AFSSA in December 2009, BfR is expected to come to Parma in January 2010.

EFSA received a new mandate from the European Commission on influenza A. Participants were invited to provide an overview of related activities in their countries.

- **Stakeholders Consultative Platform, 1-2 December 2009**

This was the first meeting of the "new" Stakeholders Consultative Platform, after its term was extended for 1 year. EFSA and the participants expressed their appreciation of the good working spirit and the new possibility to invite associated members for agenda items of specific interest, e.g. discussion on health claims.
Participants were provided with an update on current EFSA activities on nanotechnologies and the EFSA emerging risk strategy.

- **Travelling modalities for experts**

Following the concerns expressed during the last plenary meeting of the Scientific Committee, a number of new modalities were presented by the Head of the Finance Unit in order to take account of the specificity of the Parma location. Experts were invited to test these new modalities for 6 months and report back on any difficulty encountered. A questionnaire will be sent to all experts in order for EFSA to gather all issues related to travelling and consider appropriate solutions.

- **International cooperation**

In addition to the agreement on confidentiality for the exchange of data, EFSA signed in December 2009 a memorandum of cooperation with the Food Safety Commission of Japan and exchanged some letters to foster cooperation with the New Zealand Food Safety Authority. The same approach for cooperation is foreseen early 2010 with Australia and with Health Canada.

6. DRAFT TECHNICAL REPORT ON DEFAULT ASSUMPTIONS USED IN RISK ASSESSMENT BY THE EFSA SCIENTIFIC COMMITTEE AND PANELS

The EFSA DATEX Unit was requested by the Scientific Committee to prepare a state-of-the-art document describing the default assumptions presently in use within the remit of EFSA's activities to perform human health risk assessment. The document reports a high degree of similarity for many default assumptions being used by the EFSA Panels/Units and can serve as a starting point for further harmonisation within EFSA, if the need and opportunity for fine-tuning of the few identified differences arises.

The document on default assumptions was shared with the members of the Scientific Committee for comments; they underlined the high quality of the report and asked for further discussion on the possible follow-up of this completed report at the next plenary.

7. PAN-EUROPEAN FOOD CONSUMPTION SURVEY (EUMENU)

Article 33 of Regulation (EC) N°178/2002 states that EFSA shall collect data relating to food consumption and the exposure of individuals to risks related to the consumption of food. Such activity was initiated by EFSA in April 2005 with the colloquium "European food consumption database – current and medium to long-term strategies", followed-up by the creation of the EFSA concise food consumption database. In 2008, EFSA launched a collaborative project with the European Member States to establish a comprehensive European food consumption database for the adult population, and a project to generate, for food colours, selenium, chromium and lead, individual food consumption data and exposure assessment studies for children. The consumption data gathered in the EFSA projects are the best currently available in Europe, but still include crucial methodological differences, which make them hardly suitable for comparisons across countries and use at European level.

EFSA will launch and coordinate the first pan-European food consumption survey (EUMENU). With the collaboration of the European Member States, a preparatory phase would take place in 2010-2011: the guidelines on general principles in view of data collection for a pan European food intake survey have been already adopted and published, and EFSA is now working on the detailed planning of the project and budget issues. The survey as such is planned to run from January 2012 to December 2017 as a rolling programme (5-6 countries/year), and would cover 80,000 persons in total.

Like the members of the Advisory Forum and the European Commission, the Scientific Committee expressed its strong support to this project which will contribute to improve the quality of the exposure data used for the safety assessments.

8. REPORT BACK FROM SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

- **Results on the monitoring of dioxin levels in food and feed**

The EFSA DATEX Unit has received a mandate to develop a database with information on the levels of dioxins, furans, dioxin-like polychlorinated biphenyls (PCBs) and non dioxin-like PCBs in food and feed, and to evaluate the impact of changing the WHO Toxic Equivalency Factors (TEF) from the 1998 to the 2005 values on existing legal values (action levels and maximum levels). The draft report on this activity is considered of high relevance for the CONTAM Panel and will be made available to the members of the Panel for comments. The publication of this EFSA report is foreseen early 2010.

9. REGULATORY ASPECTS OF DATA COLLECTION AND SHARING

A reflection paper was developed by EFSA's Legal Services, in close cooperation with DG Health and Consumers, to ensure along with the European Member States that data are used in a transparent manner, respecting restrictions that may derive from legal framework. This paper will be presented to the Advisory Forum in February 2010.

The Scientific Committee welcomed this reflection paper, which clarifies and facilitates the exchange of data, not only with the Member States, but also with other European agencies.

10. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

An opinion on epizootic hemorrhagic disease (EHD) in North Africa has been adopted. This disease, which is vector-borne, can also affect cattle and is therefore a potential threat on the borders of the European Union.

The Panel has also adopted a guidance document on good practice for conducting scientific assessments in animal health using modelling. It was suggested that this guidance could have wider application across EFSA.

The epidemiological situation for African swine fever in Russia is being followed by the Panel; a spread of the disease over long distance was reported, with outbreaks of the disease close to the Ukraine border. This new information will be considered for the risk assessment related to the spread of the disease in the European Union.

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

A working group was formed to prepare guidance on data required for the evaluation of food additives; currently the guidance prepared by the former Scientific Committee on Food is used.

The review of new data on Quinoline yellow (E104) led to a 20-fold reduction of the Acceptable Daily Intake (ADI). The Panel estimated that at the maximum levels of use of E104, the newly established ADI would be significantly exceeded.

Panel on biological hazards (BIOHAZ)

The opinion updating the Qualified Presumption of Safety (QPS) list of microorganisms intentionally added to food and feed, as well as the opinions evaluating the risk of transmission of TSEs via semen and embryos in small ruminants, and the analytical sensitivity of approved TSE rapid tests were adopted.

The Panel is currently finalising its quantitative microbiological risk assessment on *Salmonella* in slaughter and breeding pigs, as well as its self task mandate on risk assessment of food and waterborne viruses.

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

The Panel adopted 16 opinions on chemically defined flavourings; the evaluation of chemically defined flavourings should be finalised in January 2010.

All smoke flavourings have been evaluated. Out of the 11 considered, 2 of them showed no safety concerns, 8 showed some concern due to low margins of safety, and one could not be evaluated due to insufficient data. The interpretation of the margins of safety was discussed with the European Commission.

A working group for the evaluation of dossiers on food enzymes will be established. A high workload is expected. Enzymes derived from GM microorganisms will be assessed together with the GMO and FEEDAP Panels.

Panel on contaminants in the food chain (CONTAM)

The Panel adopted opinions on the evaluation of previous cargoes and the risk assessment of Palytoxins (a marine biotoxin).

The Panel discussed the role of working group experts and the handling of diverging views. It was clarified that, when consensus cannot be reached, diverging views expressed by members of a working group shall be reported to the Scientific Panel for consideration.

Panel on genetically modified organisms (GMO)

The Panel is finalising a guidance document on the environmental risk assessment of GMOs, including guidance for the risk assessment of non-target animals exposed to GMO, and a more extended opinion on the issue of risk assessment of non-target organisms. Both the guidance document and the opinion will be published for public consultation prior to adoption. Furthermore work is in progress on a guidance document on risk assessment of food and feed derived from GM animals, including animal welfare aspects related to safety. Further consultation and cooperation with the AHAW and NDA Panels will take place.

Panel on plant health (PLH)

The Panel published for public consultation its guidance document on harmonised framework for pest risk assessment. The adoption of the opinion is foreseen in January 2010. The guidance will then be used to assess the risk to plant health of *Dryocosmus kuriphilus* Yasumatsu, the Oriental chestnut gall wasp, for the European territory.

In 2010, the whole EU Plant Health regime will be reviewed by the Commission, with consequences for the work of the Panel in view of possible effects of climate change.

Panel on plant protection products and their residues (PPR)

A working group composed of Member States' Competent Authorities, EFSA, and chaired by the European Commission finalised the guidance document for the risk assessment of birds and mammals. This guidance will be reviewed in two years time. The guidance document will be published as an EFSA opinion in December 2009.

11. REPORT BACK FROM WORKING GROUPS

- ***Risk benefit assessment***

The working group had no meeting since the last Scientific Committee plenary.

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

During its last meeting, the working group agreed on the possible content for the draft opinion. Presentations were given on a project of the PPR Panel regarding the application of the TTC approach to degradation products and metabolites of pesticides, and the possible application of the TTC approach to food contact materials. A close cooperation with the PPR Unit is in place to share common interests which may be helpful to draft the opinion.

- ***Genotoxicity testing strategies***

The kick-off meeting of this new working group will take place on 20 January 2010; the Chairs of the Panels were invited to identify relevant experts to join the working group.

- ***90-day feeding trials***

The mandate was adopted by the Scientific Committee and EFSA, and sent to DG Health and Consumers. The Scientific Committee and Advisory Forum (SCAF) Unit is now in the process of identifying experts for this new working group.

- ***Nanotechnologies***

The mandate has been adopted and the SCAF Unit is now in the process of identifying experts for this new working group.

12. FEEDBACK FROM THE SC AWAY DAY, 1 OCTOBER 2009

Participants were provided with a report summarising the discussions during the away day of the Scientific Committee. Considerations on the role of the Committee, its priorities, and the need to strengthen the dialogue with other Panels already raised a number of issues to build further on, e.g. assist the different Panels in implementing horizontal guidance and in building coherent and consistent approaches to risk assessment. Some of the recommendations have already been addressed by EFSA, e.g. getting regular feedback from the European Commission on EFSA's opinions (see section 13 of these minutes).

The Scientific Committee took note of the document and forwarded it to the Executive Director of EFSA for consideration of possible follow up. It was agreed to report back on a regular basis on the actions implemented to address these points.

13. FEEDBACK FROM THE COMMISSION ON THE USE OF EFSA'S SCIENTIFIC OUTPUTS

The Scientific Committee was provided with a copy of the exchange of letters between the Executive Director of EFSA and the Director General of DG Health and Consumers, agreeing on a systematic feedback on the use of EFSA's scientific outputs twice a year. This feedback will complement the current practice consisting in regular exchange of information between EFSA and Commission's Representatives on running activities.
This feedback from the European Commission will also be used by EFSA for the impact assessment of its work and to improve the quality / usefulness of its scientific outputs.

14. ANY OTHER BUSINESS

- ***INEX – External review***

The outcome of the review of a sample of EFSA scientific outputs by external scientists was presented to the Scientific Committee. The draft report on this review is being finalised; the overall conclusions will be shared with the Scientific Committee in February 2010, while specific remarks will be sent directly to the relevant Panels. An action plan will also be prepared by EFSA, based on the recommendations received from the external reviewers, the Scientific Committee and the Panels.

- ***EFSA Journal – latest news***

The launch of the EFSA Journal is expected on 18 December 2009.

- ***Science supporting risk surveillance of imports workshop***

The importance of this issue that was raised under the French Presidency of the European Union during the joint AFSSA/EFSA symposium on health risk assessment in the context of food, animal and plant imports in the European Union was underlined by the Advisory Forum. A follow up workshop on scientific support for risk surveillance of imports will be organised under the Spanish Presidency of the European Union on 11th February 2010 in Seville. The subject is considered to be of particular interest for the AHAW, BIOHAZ, CONTAM, GMO and PLH Panels.