

**MINUTES OF THE 42ND PLENARY MEETING OF THE EFSA SCIENTIFIC
COMMITTEE HELD ON 28-29 APRIL 2010**

agreed by written procedure on 23 June 2010

PARTICIPANTS

Scientific Committee (SC):

Susan Barlow, Albert Flynn¹, Corrado L. Galli, Anthony Hardy, Klaus-Dieter Jany, Michael Jeger, Ada Knaap, Sirpa Kärenlampi, Josef Schlatter, Vittorio Silano, Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):

Catherine Geslain-Lanéelle, Hubert Deluyker, Anne-Laure Gassin², Riitta Maijala, Didier Verloo³, Elisa Aiassa⁴, Jaume Galobart.⁵

Secretariat of the Scientific Committee:

Djien Liem, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici, Torben Nilsson⁶, Francesca Piombini and Tomas Öberg.

European Commission (EC):

Michael Walsh.⁷

Hearing Expert

Frederic Paeps.⁸

¹ Present on 29th April

² Present for agenda item 12

³ Present for agenda point 13

⁴ Present for agenda point 13

⁵ Present for agenda point 8

⁶ Present on 28th April

⁷ Present on 28th of April

⁸ Present for agenda point 12

1. OPENING

The Chair welcomed the participants. Apologies were received from John Collins, Andrew Chesson, John Christian Larsen, David Lovell and Harry Kuiper who was replaced by Sirpa Kärenlampi, vice-chair of the GMO Panel.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

Sue Barlow informed that she has recently been asked to assist WHO in relation to their consultation of Bisphenol A, agenda point 4. EFSA did not consider this to represent a conflict of interest in the framework of this meeting.

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. FEEDBACK FROM EFSA ON ISSUES RELEVANT FOR THE SCIENTIFIC COMMITTEE

- **Joint event EFSA-AESAN "Science supporting risk surveillance imports", 10 February 2010**

This workshop, organised with the Spanish Food Safety Agency (AESAN) aimed to share best practices currently in place in various areas of the world for the assessment of risks related to the import of foods, animals and plants. Experts presented scientific methods applied in this field and discussed how best to support risk management decisions regarding possible food safety, animal health and plant health concerns related to those imports.

The workshops stressed the importance of relying on harmonised data and methods for import risk assessment, and called for international dialogue in this area. The possibility of strengthening the network between EFSA, Member States and third countries in order to facilitate access to international data was also raised during the workshop. Participants looked at the scientific and technical aspects related to import risk assessment (e.g. databases and software applications to predict the possible establishment of diseases related to imports), with a particular focus on new developments in analytical and modelling approaches.

- **EFSA Advisory Forum, 11-12 February 2010**

At the 35th Advisory Forum meeting in Seville Member States expressed strong support for the EU Menu project (the multi-year, pan-European food consumption survey) and signed a supportive "Seville declaration". The AF endorsed a mandate for a nanotechnology network. The AF agreed on the priorities for the Focal Points for 2010 which include promotion of the Information Exchange Platform and stimulation of organisations on the Article 36 list to apply for projects. The chairs of the BIOHAZ and PPR Panels and the PRAPeR Head of Unit presented the work in their respective areas and the cooperation with the EU Member States which was well received by the AF members.

- **EFSA Visits**

Delegation from the Ministry of Health, Welfare and Sport of the Netherlands, 10 March 2010

At the visit EFSA provided information and update on EFSA's 2010 work program and discussion were held to foster cooperation with Member States, especially using the Article 36 network of organisations and involving Member States for midterm planning. In addition, Q fever was discussed which is currently being assessed by the Animal Health and Welfare Panel on a request from the European Commission.

Delegation from Canada Government, 11 March 2010

At the visit of a delegation from the Canadian Ministry of Agriculture, EFSA presented its work program for 2010 and its priorities. Several topics were discussed such as how EFSA work and cooperate with EU Member States, international organisations and third-country bodies. In addition, focused sessions were held to exchange views between Canadian representatives and EFSA on topics such as nutrition, health claims, genetically modified plants and risk communication, as well as on competitiveness of industry and assessment of new technologies and innovation.

John Dalli, EU Commissioner for Health and Consumers Policy, 12 March 2010

Commissioner Dalli met the Executive Director Catherine Geslain-Lanéelle, the Members of the Management Board, the Chair of EFSA's Scientific Committee, the EFSA senior management and addressed all staff in a speech. The Commissioner attended several sessions aimed at presenting the work of EFSA and recent activities. EFSA's interaction with the Commission and the Member States, and risk communication were also addressed. The discussions also covered new technologies, health claims, pesticides and novel foods. Commissioner Dalli is supportive of independent science and of the processes put in place by EFSA to ensure independence. The Commissioner also mentioned benefit assessments as becoming more important. The Commission is preparing a report of the functioning of EU agencies and will look into the issue of having fees to provide additional resources for EFSA.

José Manuel Barroso, President of the European Commission, 12 April 2010

President Barroso met with the Executive Director Catherine Geslain-Lanéelle and addressed EFSA staff where he expressed support and confidence of the work of EFSA and the role EFSA has in the "Europe 2020: A strategy for smart, sustainable and inclusive growth". Mr Barroso stressed the importance of a good communication between EFSA and the Commission's services.

EFSA Directors visit to Food Standards Agency (FSA) in the United Kingdom, 24 March 2010

The Executive Director Catherine Geslain-Lanéelle, the Director of Risk Assessment Directorate Riitta Maijala and the Director of Scientific Cooperation and Assistance Directorate Hubert Deluyker visited the FSA. Issues discussed at the visit included

cooperation with Member States, the format of the Steering Group of Cooperation strategic views and how to influence EU risk assessment research.

- **WHO – 5th Ministerial Conference on the Environment and health and WHO-EFSA side event, 10-12 March 2010**

In the context of the Fifth Ministerial Conference on Environment and Health - "Protecting children's health in a changing environment" the World Health Organisation (WHO) and EFSA hosted a side event "Seafood safety: Delivering the benefits of a healthy diet and reducing risks from environmental contamination". This meeting provided the participants an opportunity to look at seafood safety risks, such as persistent organic pollutants, methyl mercury, and algal blooms. The communication challenges in terms of weighing the food safety risks versus the nutritional benefits were also explored.

- **EFSA Management Board, 18 March 2010**

The Management Board endorsed the 2009 Annual Activity Report, which showed that EFSA issued more than 630 scientific outputs last year, and endorsed for public consultation the EFSA's communications strategy for 2010-2013. The Management Board also backed EFSA's preliminary draft Management Plan for 2011 and its preliminary draft budget for 2011. The Management Board adopted five impact assessment indicators to be used to help assess EFSA's impact over a medium term (2-3 years), and the rules of procedure for EFSA's networks.

- **Member States consultation on Bisphenol A, 26 March 2010**

Assessments of Bisphenol A (BPA) from France and Denmark has been shared with Member States and EFSA. The CEF panel is scheduling to adopt its opinion of BPA later in 2010 which combines several requests received from the European Commission into one opinion.

- **Letter of Understanding with WHO, 29 March 2010**

Letters have been shared between WHO and EFSA which confirm the mutual interest of the two organisations for increased contacts and setting in place ways of exchanging views on relevant scientific and technical data in their respective fields of the missions and remits. Under this understanding, information on lead and Bisphenol A has been shared.

5. PRELIMINARY MANAGEMENT PLAN 2011

The preliminary Management Plan for 2011, which will be used to initiate the budgetary procedure, was presented to the Scientific Committee. The increase in the number of applications observed in 2009 and beginning of 2010 is expected to continue in 2011. EFSA's role will evolve with assessments in new areas such as re-evaluation of feed additives and food enzymes, efficacy assessment of pesticides and preparatory work for the recast novel food regulation. The planned external evaluation of EFSA, as described in Article 61 of Regulation (EC) No 178/2002 will take place in 2011. The move to the final seat building will be implemented in the second half of 2011. The priorities as such are similar to the 2010 Management Plan; to boost the risk assessment capacity in EU in cooperation with Member States and increase the engagement of National Agencies to support Panels, to harmonise risk

assessment methodologies and consolidate international activities and strengthen the efficiency in processing applications.

The Scientific Committee supported the draft and provided their initial views, especially on the requirement for EFSA to assess efficiency in certain areas (e.g. pesticides). The Scientific Committee will be given time to provide input again later in the year.

6. MEDIUM TERM PLANNING

The Chair of the Scientific Committee, Vittorio Silano, gave a presentation on the interaction between EFSA and National Food Safety Agencies with a remit similar to EFSA. The aim was to stimulate a discussion to promote reflection on how to establish a better structured and more integrated risk assessment system in the EU through a more effective collaboration.

The Scientific Committee supported the approach outlined with cooperation with National Food Safety Agencies to improve the participation of Member States in EFSA assessments, to avoid duplication of work, and as a consequence, to save time and resources. Some members commented that the presence of experts from national agencies in the EFSA Panels was not perceived by the agencies as being sufficiently involved in the work of the Panels. It was proposed that the commitment may be increased if agencies were more involved in the preparatory aspects of assessing applications and to have separate consultations with Member States on draft opinions published for public consultations.

The Scientific Committee asked to come back to this point at a later meeting, after further reflection and feedback from discussions in the Advisory Forum on the same topic.

Transfer expertise to new Panels

A number of EFSA Panels' experts are currently in their third term and according to the Authority's internal rules "Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and external Experts to assist EFSA with its scientific work", an expert can only sit for three consecutive terms in the same Panel. In the renewal of Panels foreseen in 2012, and excluding the three most recent Panels (ANS, CEF and PLH), this restriction will affect about 38 % of the current Panel experts. Therefore several actions are proposed to ensure continuity by transferring knowledge from Panel experts who have been involved for a longer time to experts who are not as experienced in the Panel work. The Scientific Committee was supportive of the proposed actions.

7. EFSA WORKING DOCUMENT ON ENDOCRINE ACTIVE SUBSTANCES

Following the discussion at the last plenary Tomas Öberg, deputy head of the Scientific Committee and Advisory Forum unit, is chairing an internal EFSA task force on endocrine active substances. A draft working document was presented to the Scientific Committee which provides an overview of the trends and developments in the assessment of the health risks of endocrine active substances and proposes possible actions in relation to science and communications that could be taken in this area. The Scientific Committee welcomed the

draft and provided its comments which will be taken on board for the technical report which is to be presented to the Scientific Committee after the summer.

8. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

The Panel has adopted an opinion on African Swine Fever, related to the risk for transmission of the disease from the EU eastern borders and an opinion on Q Fever. The Chair of the Panel underlined the excellent collaboration with the European Commission on these two opinions and with the European Centre for Disease Control (ECDC) on the latter.

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

The Panel has issued an opinion which addressed data on migration of melamine from plastics, and confirms the opinion of the CONTAM Panel that the resulting exposure is well below the tolerable daily intake (TDI). The Panel works on new guidelines concerning flavourings from substances not previously used as food sources which will be discussed at its plenary in May 2010. The Panel is also finalising its opinion on Bisphenol A.

Panel on contaminants in the food chain (CONTAM)

At the plenary in March, the Panel adopted the opinions on melamine and lead. The Panel is also assessing the presence of seeds of *Ambrosia spp.* in animal feed. This opinion is prepared in cooperation with the NDA and PLH panels (see section 11 of these minutes).

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

The Panel is preparing a technical guidance for the safety assessment of *Bacillus* species in animal nutrition and is updating the guidance for the preparation of dossiers for technological additives in relation to the new functional group of feed additives “substances for the reduction of contamination of feed by mycotoxins”. A technical meeting with industry experts to present this draft update will take place on 8 June 2010. The final guidance and the proposal for guidelines will be delivered, in principle, early July. The Panel is undertaking a revision of guidance documents already adopted by the Panel in the last two years to take into account the experience gained and new scientific developments.

Panel on genetically modified organisms (GMO)

The Panel is updating its guidance document on genetically modified microorganisms in connection to applications for use in areas of feed additives, enzymes, additives and flavourings. The Panel cooperates with the NDA Panel on the nutritional aspects of soy with increased levels of omega 3 fatty acids. The Panel is also working on its guidance document for assessing genetically modified animals.

Panel on dietetic products, nutrition and allergies (NDA)

The Panel has received the final list from the European Commission of about 4500 Article 13.1 claims; 900 of these claims have been assessed to date. The Panel aims at completing the assessments by end of 2011. A meeting with stakeholders will be organised on 1 June 2010 in

Parma to discuss procedures followed by EFSA for the assessments. The European Commission and Member States' Competent Authorities will be involved in the discussion. The Panel has published opinions on dietary reference values and opinions on dietary values for water, carbohydrates and dietary fibre, and fats, as well as on methods for establishing food based dietary guidelines following a public consultation.

Panel on plant health (PLH)

The Panel adopted two opinions (*Gibberella circinata* and *Dryocosmus kuriphilus*) at its last plenary. The Panel adopted two proposals for self task mandates to develop a guidance for the evaluation of risk management options and a guidance on environmental assessment of plant pest risk.

Panel on plant protection products and their residues (PPR)

The Panel adopted an opinion which gives new guidance for assessing emissions from plant protection products from greenhouses and crops grown under cover. Recently the Panel was involved in a consultative workshop that discussed protection goals for environmental risk assessment of pesticides. This workshop provided feedback for a guidance document on environmental protection goals which is under preparation.

9. REPORT BACK FROM WORKING GROUPS AND INTERNAL TASKFORCES

• WG Threshold of Toxicological Concern

The WG is making good progress, but its final opinion may be delayed to take into account outcomes of a commissioned project which will be delivered by the end of the year.

• WG Genotoxicity Testing Strategies

The WG has had two meetings and is making good progress.

• WG 90-day Feeding Trials

The WG has had two meetings and is making good progress.

• WG Nanotechnologies

The WG is making progress and is acknowledging that the lack of information in certain areas may not allow for a very detailed guidance. The aim is to present a draft for public consultation in July.

• WG Risk Benefit Assessment

The WG is assessing the comments received from the public consultation with the aim to present an opinion for adoption in June 2010.

• WG Statistical Approaches

The WG is currently being set up, and will have its first meeting by end of May.

- **WG Risk Assessment Terminology**

The activity has not yet started and Panels have recently been asked to nominate experts. The first meeting will probably be held in September 2010.

- **WG Default Assumptions**

The activity has not yet started and Panels are asked to nominate experts.

- **WG Compendium on Botanicals**

The WG has started expanding and updating the currently published compendium of botanicals reported to contain toxic, addictive, psychotropic or other substances of concern. This revision of the Compendium should be finalised by end of 2011.

- **WG Benchmark Dose**

The WG will be asked to provide input to set up a training workshop for Panels' experts and EFSA Staff, and to produce a technical report illustrating with case studies how to use existing software

- **Taskforce on Environmental Risk Assessment**

An internal task force is currently being set up and aims to produce a first draft working document for discussion at the Scientific Committee plenary in September 2010.

10. UPCOMING CALLS FOR EXPERTS

EFSA is planning to publish calls for experts to fill needs in three areas. One call is for experts needed in the ANS and CEF Panels which are to be renewed next year. In addition a dedicated call will seek to expand the reserve list of experts for the Scientific Committee and Panels to cover for possible resignations. A call will also be launched to extend the reserve list of external evaluators for the EFSA external review process (INEX process). The external evaluation working group will be requested in 2011 to analyse scientific outputs produced in 2010.

11. UPDATE ON SCIENTIFIC OPINION PREPARED BY CONTAM, NDA AND PLH PANELS ON SEEDS OF *AMBROSIA SPP.* IN ANIMAL FEED

European Commission has asked EFSA to provide a scientific opinion on the effect on public and animal health or on the environment of the presence of seeds of *Ambrosia spp.* in animal feed. A draft opinion has been prepared by the CONTAM panel, but as some questions in the mandate are outside the competence of the CONTAM Panel the involvement of the NDA and PLH Panels would be required to address all questions. The Scientific Committee supports the proposed approach to co-adopt the opinion on *Ambrosia spp.* seeds in animal feed between the CONTAM, NDA and PLH Panels, thus replying to all questions as requested by the mandate in one single opinion.

12. TARGET AUDIENCE RESEARCH

EFSA has commissioned a qualitative research on the image that stakeholders have of EFSA. The external consultant Frederic Paeps presented the outcome of this research to the Scientific

Committee. The result indicates that EFSA has become a well-respected European body, recognised as an essential part of the European food safety network, producing independent, science-based support for policy makers. The research also highlights future opportunities, including that EFSA should provide more predictable timetables for its scientific work – taking into account increasing demand – as well as communicate its outputs more simply and continue to strengthen its Member State network. This research has helped to confirm that EFSA’s overall approach of working closely with national food safety agencies and stakeholder networks remains appropriate. The Scientific Committee appreciated the presentation and support public consultation of the Draft Communication Strategy 2010-2013.

13. SYSTEMATIC REVIEW

The Assessment Methodology Unit presented a draft guidance on the “Application of systematic review methodology to food and feed safety assessments in support of decision making” prepared by a working group as a self task activity. The Scientific Committee supports the approach presented which is a useful addition to the toolbox available for providing concise information on complex subjects where scientific peer reviewed publications are available. The Scientific Committee invites Panels and EFSA Secretariats to seek practice in applying systematic reviews in the food and feed area and to evaluate the process when more experience is gained. The value of this guidance document when outsourcing systematic reviews was underlined. The draft guidance is under peer review and it will be soon published.

14. ANY OTHER BUSINESS

- **EFSA to launch an independent review of its declaration of interest screening process**

An independent review of the screening and evaluation process in place for the declaration of interests requested to each Panel and/or WG member will be commissioned by EFSA. The review will focus on declarations of interests from Panels who deal with applications. The result is expected to be ready in the autumn 2010.

- **Biography of the members of the SC/Panels**

All EFSA Scientific Committee and Panel members will be asked to fill in a biography which will complement information available in the published declarations of interest. The biographies will be published on the EFSA website

- **Feedback from WHO meetings for the creation of new global network on chemical risk assessment and nutrition**

The Scientific Committee was informed that EFSA is involved in an international network together with WHO, ECHA, OECD, ILSI and others to discuss global capacity for the risk assessment of chemicals, and identify needs for training. EFSA is also following, as an observer, discussions of an international network in the nutrition area.

- **Tentative dates SC plenary meetings in 2011**

The meeting dates for plenary meetings in 2011 have been discussed and tentatively agreed.