

**MINUTES OF THE 41ST PLENARY MEETING OF THE EFSA SCIENTIFIC
COMMITTEE HELD ON 2-3 FEBRUARY 2010 IN PARIS**

adopted by written procedure on 30 March 2010

PARTICIPANTS

Scientific Committee (SC):

Susan Barlow, John D. Collins, Corrado L. Galli, Anthony Hardy, Klaus-Dieter Jany, Michael Jeger, Ada Knaap, David Lovell, Hildegard Przyrembel¹, Josef Schlatter, Vittorio Silano, Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):

Catherine Geslain-Lanéelle, Bernhard Berger², Hubert Deluyker, Anne-Laure Gassin, Riitta Maijala, Tobin Robinson³, Carola Sondermann⁴, Karen Talbot.⁵

Secretariat of the Scientific Committee:

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

European Commission (EC):

Michael Walsh.

¹ Present on 2nd February

² Present in the morning of the 2nd February

³ Present in the morning of the 2nd February

⁴ Present in the morning of the 2nd February

⁵ Present on 3rd February

1. OPENING

Apologies were received from Andrew Chesson, John-Christian Larsen, Harry Kuiper and Albert Flynn who was replaced by the vice chair of the NDA Panel: Hildegard Przyrembel.

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. FEEDBACK FROM EFSA ON ISSUES RELEVANT FOR THE SCIENTIFIC COMMITTEE

• EFSA Management Board

The Management Board adopted EFSA's 2010 Management Plan during its December meeting.

The work programme outlined in the Management Plan is guided primarily by the EFSA's strategic plan 2009-2013 which outlines key projects scheduled for 2010 including the initiation of the "EU Menu", a pan-European food consumption survey, and the first EFSA annual report on emerging risks. In 2009, EFSA issued nearly 640 scientific outputs, representing a 30 percent increase compared with 2008. The workload is expected to further increase, mostly due to applications submitted for authorisation in areas such as health claims, food and feed additives, packaging materials and pesticides.

The Management Board adopted the €73 million 2010 budget required to address the growth and increasing breadth of EFSA's scientific work, in particular applications submitted for authorisation and new opportunities in data collection. The Management Board also adopted a proposal to increase the compensation for EFSA's scientific experts.

• Visit to EFSA

EFSA is organising bilateral visits with national food agencies to strengthen cooperation in the area of food and feed safety. The French Food Agency, Agence Francaise de Securite Sanitaire des Aliments (AFSSA) visited EFSA on 9 December 2009 and the German Federal Institute for Risk Assessment, Bundesinstitut für Risikobewertung (BfR) on 11-12 January 2010. Additional visits will be organised in 2010, with among other objectives to increase cooperation on emergency questions.

5. POSSIBLE SELF TASKS MANDATES

- **Development of guidance on statistical approaches to assess adverse or biologically relevant effects**

A revised self-task mandate to develop guidance on how to integrate statistical approaches to assess adverse or biologically relevant effects was proposed for adoption. The Scientific Committee is requested to address by spring 2011 the issue of statistical significance vs. biological relevance, and then consider other statistical issues identified by the EFSA Panels and Units. The mandate was adopted after some minor changes.

- **Harmonisation of risk assessment terminology**

This activity aims at improving harmonisation and consistency of risk assessment terminology used across EFSA Scientific Committee, Panels and Units. As a self-task mandate, EFSA is requested to develop a report which will contribute to the ongoing international activities in the field of terminology.

As part of this work-programme, EFSA has awarded a contract to review 250 EFSA scientific outputs with the objective to perform a comparative review of terms of expression of risks and/or uncertainties in the outputs issued between 2008 and 2009 and to recommend possible ways to improve expression and communication of risks within the scope of published opinions by EFSA Committee and Panels. The outcome of this project is expected in October 2010 and will be considered for the finalisation of the opinion that is expected in summer 2011.

The Scientific Committee welcomed the proposal and made some minor comments to the draft mandate before it was adopted. The Scientific Committee also suggested to present the interim results of the ongoing work at the 2nd International Risk Assessment Conference that will be held in Brussels in November 2010.

- **Default assumptions used by the EFSA Panels/SC**

A draft self-task mandate was presented to develop a guidance document proposing harmonised values and procedures to be used as default by the EFSA's Scientific Committee, Panels and Units where needed. This activity will consider the working document developed by the EFSA DATEX Unit presented at the previous Scientific Committee plenary where the state of the art of default assumptions used by EFSA is described.

The Scientific Committee agreed on the mandate to be proposed to the Executive Director with minor amendments. The work is expected to be completed by summer 2011.

- **Compendium on botanicals**

EFSA published in September 2009 a guidance document for the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. A large database was established to compile the available literature data and other information

on botanicals and botanical preparations, which have been reported to contain substances that may be of health concern when used in food or food supplements. The self-task mandate proposes to carry out a bi-annual review of the compendium with the aim to include the missing relevant botanical species currently used as ingredients in the European Union, and to update where necessary, the information already included in the compendium.

The Scientific Committee welcomed the proposal and suggested to make use of the EFSA article 36 network to contract out part of the work regarding data collection in order to facilitate the work of the experts.

6. REPORT BACK FROM SCIENTIFIC COOPERATION AND ASSISTANCE DIRECTORATE

- **Training activities on food safety risk assessment**

The Head of the Scientific Cooperation Unit presented the work undertaken in the area of training activities in food and feed risk assessment. In the process of reviewing the strategy in 2008, a questionnaire was sent to Member States via the Advisory Forum. The majority of MS underlined the importance of training activities and supported the idea of courses on risk assessment. Many training opportunities are offered at national level but they are mostly intended for risk managers and controllers. The issue of training is also considered in the EFSA Strategic Plan 2009-2013 where it is stated that to build capacity EFSA will organise training and build on its existing scientific events to foster greater understanding of risk assessment practises.

An EFSA technical report has been drafted to provide an overview of the existing activities, identify possible gaps in training on food safety risk assessment, and propose future actions. The report reviews also training opportunities offered by EFSA, the European Commission, Member States, international organisations/Universities and private organisations. The Scientific Committee underlined that all existing trainings are highly specialised in specific areas. It endorsed the proposal to start developing a course “principles of risk assessment in food and feed safety” and also to explore possibilities to cooperate with the “Better training for safety food” of the European Commission.

- **Progress report on emerging risks activities**

The Head of the Emerging Risks (EmRisk) Unit presented an update on the EFSA’s strategy for the identification of emerging risks in the food and feed chain. The overall strategy relies on three steps: data collection; data analysis, including signals detection and filtering; exchange of information. A number of tools for data collection are currently being evaluated by the EmRisk Unit. A working group composed of external experts will be established with the aim to detect additional data sources.

An Emerging Risks Internal Collaborative Group (ERIC) has been established and comprises a multidisciplinary team of EFSA’s staff drawn from all scientific Units and from Communications. The objective of this group is to evaluate the relevance of signals identified

and potentially leading to emerging risks. The outcome will be a list of potential emerging risks to be submitted to the Panels for their consideration in plenary meetings.

The exchange of information with stakeholders will be assured on the one hand through a network on emerging risks comprising representatives from Member States, EU Agencies, EU Commission and international institutions, and on the other hand by the Stakeholders Consultative Group on Emerging Risks (StaCG-ER), including experts nominated by the EFSA Stakeholder Platform. Both groups will be operational in March 2010. The aim of the latter platform is sharing information, data and methodologies for emerging risks identification, in particular on potential drivers such as new technologies, industrial practices and farming practices within the food and feed area.

In addition to active monitoring and filtering of data, methodologies to carry out these tasks need to be developed and a coherent strategy evolved. Procedures and best practise for data collection, data analysis and signal identification and filtering will be developed. An ad-hoc Working Group will be established in summer 2010 for this purpose.

An annual report on emerging risks in food and feed will be produced to include a detailed account of the strategy that EFSA has developed for the identification of emerging risks, reporting on methodologies developed, data sources identified and assessed, networks established and any emerging risks that have been identified. The report should be finalised in March 2010. An EFSA Colloquium on Emerging Risks is planned for June 2010.

The Scientific Committee asked clarification on the estimated number of signals that might be identified and that would need to be assessed by the Panels. The Panels that probably would most often be concerned are CONTAM, BIOHAZ, GMO and NDA.

- **EFSA's activities on data collection (article 33)**

The Director of Scientific Cooperation & Assistance outlined the provisions for data collection in Article 33 of EFSA's Founding Regulation and described EFSA's current data collection activities.

The strategy for networking and cooperation between EFSA and Member States that was revised in 2008 emphasises the need for up-to-date data for exposure assessment and to give prioritisation to food consumption data collection activities.

The networks on data collection cover the area of zoonoses, food consumption, contaminants and pesticides. The 2008 annual report on trends and sources of zoonoses in EU has just been published in cooperation with ECDC. Regarding chemical contaminants and pesticides, data are collected to monitor and report annually occurrence of pesticides and veterinary drug residues.

Specific data such as on dioxins and dioxins-like compounds are also collected from Member States and analysed by EFSA in cooperation with DG Health and Consumers. A report on dioxins has been drafted and will be finalised in spring 2010.

Work is progressing for harmonisation of data collection on food classification, left censored data and total diet studies.

Contacts have been established with the DG Joint Research Centre to collaborate on quality assurance standards in relation to data collection.

The pan-European food consumption survey “EU Menu”, presented at the last plenary, will be launched in 2010 with a preparatory phase that will be over in 2011. The actual dietary survey is planned to run from 2012 to 2017 and it would cover 80,000 persons in total.

The Scientific Committee expressed its strong support to the initiatives presented and recommended to improve exchange of information in relation to data collected by the different Panels.

- **The EFSA Journal: update on the project and feedback from the Editorial board meeting**

The Scientific Cooperation Unit gave an update on the EFSA Journal project and provided feedback from the second Editorial Board meeting held on 1st February 2010. The new EFSA Journal was successfully launched on 18th December 2009 and a second release of the EFSA Journal, with additional search functions, and an editorial section is planned for March 2010. A policy document regarding editorials will be prepared and shared with the Scientific Committee at future plenary meetings.

In its meeting on the 1st of February, the Editorial Board discussed the application to bibliographic databases, the promotion plan of the Journal, the possibility to launch a user survey and the suggestion to publish special issues where to include colloquia reports and conference proceedings. As from February statistics on the EFSA Journal web area will be available to help in measuring the use of the EFSA Journal web area and to better understand behaviour of users. The next Editorial Board meeting is planned for June 2010.

The Scientific Committee expressed its gratitude on behalf of the Panel members who congratulated EFSA for the successful transformation of the EFSA journal.

7. DRAFT OPINION ON HUMAN HEALTH RISK BENEFIT ASSESSMENT OF FOOD

The Chair of the Working Group introduced the draft opinion intended to give guidance for performing human health risk benefit assessment of foods. It was underlined that the document does not address social, economic, environmental or animal welfare issues.

The Scientific Committee endorsed the draft guidance for public consultation with minor amendments. The 6-week public consultation will be launched on 1 March 2010. Comments received will then be considered to finalise the guidance document before it is submitted to the Scientific Committee for adoption end of June 2010.

8. REPORT BACK FROM WORKING GROUPS

• Working Group on Threshold of Toxicological Concern (TTC)

The TTC Working Group has had no meeting since last plenary. A contract has been awarded to provide a report on the applicability of physicochemical data, QSAR and read across in threshold of toxicological concern assessments. The overall aim of the project is to investigate how the applicability of TTC schemes may be improved by incorporating physicochemical data (both experimental and predicted) as well as toxicity information generated by non-testing methods such as QSARs, expert systems and read across within structurally related chemical groups. The finalisation of the report is expected in December 2010. The TTC Working group will consider the outcome of the report for inclusion in the draft opinion which is expected in spring 2011.

• Working Group on Genotoxicity Testing Strategies

The kick-off meeting of the Working Group was held in January 2010. The terms of reference were presented by the chair and the experts asked several clarifications and made suggestions on issues to be addressed in developing the opinion. The likely content of the draft opinion was discussed together with a tentative road map. The next meeting is planned for March 2010.

• Working Group 90-day feeding trials

The Working group has been established and the kick off meeting is planned for 10th February 2010.

• Working Group on nanotechnologies

The kick off meeting was held on 29th January 2010. The discussion focussed on the content that would be addressed in the guidance document. A draft outline of the opinion was discussed and the sharing of the workload was initiated. A first draft of the guidance document is scheduled for public consultation in July 2010.

9. NANOTECHNOLOGY NETWORK

The main goals of the Scientific Network for Risk Assessment of Nanotechnologies in food and feed are to facilitate harmonisation of assessment practise and methodologies; enhance exchange of information and data between EFSA and Member States; and to achieve synergies in risk assessment activities. The draft mandate with the relative Terms of Reference was endorsed by the Scientific Committee and will next be discussed to the Advisory Forum on 12 February 2010

10. INEX – EXTERNAL REVIEW

- **Outcome of the 2009 external review and planning of the 2010 external review**

The Director of Risk Assessment presented the outcome of the 2009 external review process. The overall conclusions of the draft report were shared with the Scientific Committee. Several outputs were reviewed and the majority of them were found of high quality, well constructed, transparent and easy to be understood. A report providing recommendations for further improving the quality of scientific outputs will be prepared by EFSA.

The Scientific Committee was encouraged to consider the comments of the report and propose by the end of March actions to be taken in order to further strengthen the quality of outputs.

11. ENVIRONMENTAL RISK ASSESSMENT

- **Update on Environmental Risk Assessment of GM plants**

Salvatore Arpaia from the GMO Panel presented two opinions related to environmental risk assessment (ERA) recently adopted by the GMO Panel for public consultation. The first document updates the guidance document for the environmental risk assessment of genetically modified plants published in 2006. The second document provides some guidance on how to assess the risk of the potential effects of GM plants on non-target organisms.

The Scientific Committee congratulated the Panel for the work done and suggested the creation of an EFSA internal task force with the aim of reviewing current practices of environmental risk assessment within the different Panels and identifying communalities and possible discrepancies. A short paper will be prepared and presented at a future plenary to discuss an action plan for 2010 on ERA.

The PPR Unit is organising in April a workshop on protection goal options for environmental risk assessment of pesticides (more about this in the report back from the PPR Panel below). The workshop aims at collecting feedback from EFSA's stakeholders (Member States, agrochemical industry representatives, consulting companies, growers' associations and others) during the work process. The outcome of this workshop will be a report compiling the collected stakeholders' views.

12. EFSA'S ACTIVITIES IN THE AREA OF CUMULATIVE RISK ASSESSMENT AND ENDOCRINE DISRUPTORS

The Head of the PPR Unit presented an overview of EFSA activities in the area of cumulative risk assessment and endocrine disruptors as well as ongoing activities coordinated by the EU Commission, by the OECD and by Member States. Requirements for the assessment of the endocrine properties of substances are present in the new Regulation on Plant Protection Products (EC) 1107/2009 (entering into force in May 2011) and in the REACH Regulation

(EC) 1907/2006. Testing Guidelines for the assessment of endocrine activities of chemicals are under development at the OECD.

A documents produced by the Council in the end of 2009 on Combination Effects of Chemicals suggested that when humans are exposed to multiple chemicals, the possibility of health concerns arising from exposure of substances with potential endocrine activity should be investigated. Further action to assess how and whether relevant existing Community legislations adequately addresses risk from exposure to multiple chemicals from different sources is suggested in the document and the Commission and the Member States have been encouraged to take an active role on this issue.

The PPR Panel has published two opinions on cumulative risk assessment and there are some activities foreseen for 2010 and 2011 among which the development of guidelines for the use of probabilistic methodology to perform cumulative exposure assessment.

The Scientific Committee encouraged EFSA to draft a working paper where trends and developments in the assessment of the health risks of substances with endocrine activity are identified, and make proposals for possible future activities in this area. The paper will be discussed at the next SC plenary meeting in April 2010 and will serve as a starting point to develop a common strategy on endocrine active substances activity within EFSA, taking into account already ongoing activities in Europe.

13. REVIEW ON EFSA'S COMMUNICATIONS STRATEGY

The Director of Communications presented the revised EFSA Communications strategy. The strategy was adopted by the Management Board in 2006 and it is now in the process of being revised, taking into account the EFSA Strategic Plan 2009-2013. A preliminary discussion was held at the Management Board meeting in October 2009.

A qualitative research on EFSA image among key target audience has been performed between October and December 2009. Forty-six interviews have been made towards? risk managers (EU Commission, EU Parliament and Member States), scientists, non-EU food safety authorities, stakeholders and media. The aim was to assess several key aspects in Communications among which the awareness and understanding of EFSA; how EFSA's overall image is perceived; how to better target the audience with their needs and expectations. The qualitative research was also used to assess the level of satisfaction in relation to outputs and to the way EFSA is working. The results of the qualitative research highlighted that EFSA is seen as good holistic communicator where coherence with risk managers is improving. A need for simplicity in "translation of science into human language" in communications was also emphasised.

The analysis of the 46 interviews should be finalised in February 2010 and a revised draft Communications strategy integrating key findings from this qualitative research will be presented to the Management Board in March 2010. A public consultation on EFSA's revised

Communications strategy will be launched in April 2010. The revised strategy, taking into account the comments received, will be presented for adoption at the Management Board by the end of the year.

The Scientific Committee welcomed the presentation and the proposed methodology for the review of the Communications Strategy emphasising the need to coordinate communications with the EU Commission so that stakeholders and general public get consistent messages.

14. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

At the last plenary, the guidance document on good practise in scientific assessment using modelling has been adopted. New EU Commission mandates have been received and discussed: significance of Q-fever in the animal husbandry as regards the risk it may pose to public health; a mandate on mortality of Pacific Oysters in relation to Ostreid herpesvirus 1; a mandate on harvesting feather from live geese for down production. All the three mandates have been accepted.

Panel on biological hazards (BIOHAZ)

At the last plenary, the Panel adopted a self mandate to update the QPS list. Work is in progress for the preparation of the report on food safety considerations of novel H1N1 virus infections in humans. The opinion on quantitative microbiological risk assessment (QMRA) on Salmonella in slaughter and breeding pigs is scheduled for adoption at the March plenary.

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

Work is ongoing for the preparation of the stakeholders meeting to present the guidelines for the assessment of flavouring substances that was published for public consultation in 2009. The opinion will be finalised in spring 2010.

The Bisphenol A (updated) opinion is currently being prepared and will be finalised in May 2010. EFSA has called a meeting with national experts from Member States in March to discuss its ongoing scientific work. The meeting will allow Member States to contribute with any relevant national work in support of the finalisation of the EFSA's opinion.

Panel on contaminants in the food chain (CONTAM)

At the last plenary, the Panel discussed the draft opinions on melamine in food and feed and on lead in food. The opinions will be presented for adoption in the upcoming plenary meetings.

Panel on Dietetic products, nutrition and allergies (NDA)

The opinions in relation to the authorisation procedure for health claims pursuant to article 13 of Regulation (EC) No 1924/2006 and adopted at the panel plenary in December 2009 are

ready to be published. Assessments of individual claims are combined, as appropriate, to form coherent opinions.

The draft opinion related to the safety assessment of conjugated linoleic acid in the framework of the Novel Foods Regulation will be discussed and proposed for adoption at the upcoming plenary.

The work on dietary reference values is ongoing.

Panel on plant health (PLH)

The draft guidance document on harmonised framework for pest risk assessment was adopted at the January plenary. The framework aims at implementing the fundamental principles of risk assessment as laid down in Regulation (EC) No 178/2002, most importantly, the independence and transparency of risk assessments carried out by EFSA.

Following a request from the European Commission in 2009, the PLH Panels was asked to deliver a statement on a study proposal prepared by the US to support a future derogation request from the Community import requirements for wood packaging material originating in the US and used to pack and transport military ammunition. The Panel reviewed the submitted study proposal and based its conclusions on the shortcomings identified in the study proposal. The Statement was adopted at the last plenary and published.

Work is ongoing to provide a pest risk assessment of *Gibberella circinata* Nirenberg & O'Donnell in the EU territory.

Panel on plant protection products and their residues (PPR)

The guidance document for pesticide exposure assessment for workers, operators, bystanders and resident was adopted at the last plenary. Work is ongoing for the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology.

The Panel was asked to prepare a scientific opinion on protection goal options for environmental risk assessment (ERA) of pesticides and to consult risk managers and stakeholders. A workshop will be held on 15-16 April 2010 on protection goals for environmental risk assessment of pesticides. Even if general protection goals are stated in the relevant EU legislation, these are defined with different levels of detail for different elements and some issues are not specifically described. In order to develop a risk assessment methodology, specific protection goals for the respective environmental compartments need to be identified.

A guidance document on probabilistic methodologies for modelling dietary exposure to pesticides residues was endorsed for public consultation at the January plenary.

15. ANY OTHER BUSINESS

- **Benchmark dose (BMD) workshop**

Following the recommendations of the published EFSA opinion on benchmark dose (BMD), The Scientific Committee and Advisory Forum Unit will organise a workshop in 2010. The aim is to build expertise within EFSA and in Europe on the BMD approach, and therefore facilitate its implementation. The Scientific Committee welcomed the proposal.

- **Ministerial Conference and WHO/EFSA side event, 11-12 March 2010**

The 5th Ministerial Conference on Environment and Health will be organised by WHO in Parma from 10-12 March 2010. A side event is organised in cooperation with EFSA on “Seafood safety: delivering the benefit of a healthy diet and reducing risks from environmental contaminations”. The event will be chaired by Vittorio Silano (the Scientific Committee Chair) and Hilde Kruse (WHO).

- **Evaluation of available approaches for computational toxicology**

DG Health and Consumers proposed to organise a meeting between scientists from EFSA and the Commission to have an initial discussion on computational toxicology and identify possibilities for a systematic evaluation of the various approaches.