

**MINUTES OF THE 53RD PLENARY MEETING OF THE EFSA SCIENTIFIC
COMMITTEE HELD ON 7-8 FEBRUARY 2012**

Agreed by written procedure on 21 March 2012

PARTICIPANTS

Scientific Committee (SC):

Boris Antunovic, Sue Barlow, Herbert Budka, Susanne Hougaard, Michael Jeger, Ada Knaap, Harry Kuiper, Wim Mennes, **Ivonne Rietjens**, Josef Schlatter, Vittorio Silano, Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):

Bernhard Berger¹, Per Bergman, Stef Bronzwaer², David Cairá³, Hubert Deluyker, Dirk Detken⁴, Catherine Geslain-Lanéelle, Claudia Heppner, Carola Sondermann⁵, Anne Laure Gassin.⁶

Secretariat of the Scientific Committee:

Djien Liem, Bernard Bottex, Miriam Jacobs, Daniela Maurici, Theresa Mc Fadden, Francesca Piombini, Reinhilde Schoonjans.

European Commission (EC):

Michael Walsh

Observer:

Francesca Migliavacca – Ernst and Young⁷

¹ Present for agenda item 14

² Present for agenda item 14

³ Present for agenda item 1

⁴ Present for agenda item 6, 8 & 9

⁵ Present for agenda item 14

⁶ Present for agenda items 4, 6, 8, & 9

⁷ Present on the first day only

1. OPENING, APOLOGIES FOR ABSENCE

The Chair welcomed the participants to EFSA's new seat. Apologies were received from Andrew Chesson, Albert Flynn, David Lovell, Anthony Hardy who was replaced by Susanne Hougaard-Bennekou, Vice-chair of the PPR Panel, Birgit Noerrung who was replaced by Hubert Budka, Vice-chair of the Biohaz Panel and Iona Pratt who was replaced by Wim Mennes, Vice-chair of the CEF Panel.

EFSA's internal auditor informed the Scientific Committee that, in compliance with its founding legislation (Regulation (EC) No 178/2002), EFSA is currently undergoing its second independent evaluation led by the external consultancy, Ernst & Young. The Chair welcomed Ms. Migliavacca from Ernst & Young who will participate in the framework of the evaluation to this plenary meeting as an observer. As part of the evaluation, a number of questionnaires have been sent to, amongst others, stakeholders, the European Parliament, the European Commission, EFSA Scientific Committee and Panel members, NGOs, consumers organisations etc. Scientific Committee members were informed that they may be asked to participate in interviews at a later stage. A final report will be presented to the Management Board in June 2012 from which recommendations will be drawn up.

2. ADOPTION OF THE DRAFT AGENDA

The draft 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 other conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

Ivonne Rietjens informed the participants that she would resign from the ANS Panel end of February 2012 in order to accept an appointment as member to the Supervisory Board of Royal Wessanen nv. The Chair of the Scientific Committee congratulated Ms. Rietjens with this honourable appointment, thanked her for all the work done for EFSA and wished her all the best for this new professional challenge.

4. DRAFT OPINION ON RISK ASSESSMENT TERMINOLOGY

The draft opinion on Risk Assessment Terminology was presented to the Scientific Committee for discussion and possible endorsement for public consultation.

The Scientific Committee reviewed the draft opinion and made a number of comments and suggestions on the structure and content of the document. During the discussions, the Scientific Committee noted that the document provides a very useful description of the current state-of-play as regards the approaches followed by the different Panels to express risks and uncertainties, which could be used as a starting point for further work within EFSA. As such, the present document was more considered to become a stock taking Opinion (or Scientific Report). The members suggested that, due to the different nature of the document, instead of publishing a draft for public consultation, the document could be circulated to all Panels and units to capture all different approaches, prior to its finalisation.

The Scientific Committee requested that a drafting group composed of a few members of the current Working Group on Terminology and some members of the Scientific Committee be invited to revise the draft opinion and to incorporate the suggestions made. The drafting group will be asked to consider the need to circulate the draft opinion to the EFSA Panels and Units for targeted consultation prior to final adoption.

The opinion will be submitted to the Scientific Committee for possible adoption at the April 2012 plenary meeting.

5. DRAFT STATEMENT ON THE APPLICABILITY OF THE MARGIN OF EXPOSURE (MOE) APPROACH FOR SAFETY ASSESSMENT OF GENOTOXIC AND CARCINOGENIC IMPURITIES IN SUBSTANCES DELIBERATELY ADDED TO FOOD/FEED

The draft Statement on the applicability of the Margin of Exposure (MOE) approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed was presented to the Scientific Committee for discussion and possible adoption.

The Chair of the SC working group explained the background of the document and the involvement of experts from the EFSA Scientific Committee and Panels. The draft document was also brought to the attention of risk managers of the European Commission who confirmed that the MOE approach fulfils the requirements regarding the characterisation of the safety of the product according to existing regulations, and answers the European Commission's needs for deciding on appropriate risk management actions.

The Scientific Committee welcomed the draft and adopted the statement with some minor modifications. EFSA will pre-notify the European Commission prior to publication of the final Statement.

6. DRAFT OPINION ON THRESHOLD OF TOXICOLOGICAL CONCERN

The draft opinion on the Threshold of Toxicological Concern (TTC) was presented to the Scientific Committee for discussion and possible adoption. The Scientific Committee made comments which will be considered in the next revision.

The Scientific Committee was also updated on the status of the draft opinion of the DG SANCO non-food Scientific Committees which focuses on the application of the TTC approach on ingredients in cosmetics. The Chair and the scientific coordinator of the SC working group on TTC participated in the last three meetings organised by the non-food Scientific Committees to present the work in progress and to exchange views and information about the respective developments of their draft opinions. Despite frequent communication and liaison, diverging views remain on a few issues. Due to these divergences, adoption of the draft EFSA TTC opinion was deferred in order to comply with Article 30 of EFSA's Founding Regulation (EC) No 178/2002. Should an agreement be found to conciliate both views, the EFSA draft opinion will be presented to the Scientific Committee for final adoption at the 54th plenary on 17th -18th April 2012. In case the diverging views cannot be resolved, a report will be produced, in compliance with the Article 30⁸ of EFSA's Founding

⁸ [Article 30 \(page 26\) of EFSA's Founding Regulation \(EC\) No 178/2002](#)

Regulation, explaining and justifying the differences between the opinions of the two EU bodies. This report would be published together with the opinions.

Pesticide Action Network (PAN) Europe request to access documents related to the TTC WG

The Scientific Committee was informed of the list of documents disclosed to Pesticide Action Network Europe further to their October 2011 request for access to documents in relation to the work of the Scientific Committee TTC working group.

An explanation and clarification was given to the Scientific Committee on EFSA's policy on the handling of requests for access to EFSA's documents in compliance with Regulation (EC) No 1049/2001 on the public access to documents and in line with the case-law of the Court of Justice of the European Union.

Transparency and openness are key values of EU Institutions activities. Documents related to a working group activity may also be subject to access to documents rules. Besides commercially sensitive data, the protection of personal data, privacy and integrity can be granted in application of the rules established in Regulation (EC) No 45/2001. A respective guidance was circulated.

The Scientific Committee discussed the recent media coverage triggered by press releases and web-based articles by PAN Europe, attacking individual experts, with the Director of Communications and expressed its disappointment to see repeated attacks on the integrity of EFSA Experts and misrepresentations of EFSA's work. The Director of Communications described the communications approach which consists in understanding the concerns and engaging both with stakeholders and media on these issues, aiming both to be proactive in promoting the independence of EFSA and its scientific work as well as addressing criticism appropriately. The Scientific Committee underlined the importance to protect not only EFSA and its work but also its Experts contributing to EFSA's work.

7. DRAFT GUIDANCE ON DEFAULT VALUES

The draft guidance on selected default values to be used by the EFSA Scientific Panels and Committee and the EFSA Units in the absence of actual measured data, was presented to the Scientific Committee for discussion and possible adoption. This draft takes into consideration the comments received from the Scientific Committee during the December 2011 plenary meeting.

The Scientific Committee welcomed the revised draft and adopted the guidance with some modifications. The final guidance will be published by early March 2012 together with a report on the public consultation of the draft guidance that took place from 7 July to 15 September 2011. The report lists the comments received and summarises how they were considered by the SC working group on Default Values.

8. EFSA'S APPROACH REGARDING MULTISECTORAL ISSUES

The Scientific Committee was presented with EFSA's approach and operating procedures regarding multisectoral issues, in line with EFSA's founding Regulation (EC) No 178/2002. As identified in EFSA's Science Strategy 2012-2016, it is expected that an increasing number of risk assessments which consider risks in a wider integrated manner will be required in

order to provide risk managers with comprehensive advice on which to base their decisions. When risk assessments have required a broader range of skills than may currently exist in one single Panel, EFSA has established so far joint work between Scientific Panels to ensure the full range of disciplines is available to build the risk assessment.

In cases where the required competence for a scientific opinion falls largely in the remit of one Scientific Panel, EFSA may assign the mandate to that leading Panel. A working group would be set up in order to have a representation of all the necessary expertise. Should EFSA receive a request concerning a truly multisectoral matter, the Scientific Committee will become responsible for adopting the final opinion.

The Scientific Committee provided comments and suggestions on the draft document which will be considered prior to finalising the Executive Director decision.

9. PILOT PROJECT ON THE OBSERVERS ATTENDANCE TO EFSA SCIENTIFIC PANEL SCIENTIFIC COMMITTEE MEETINGS AND GUIDELINES FOR OBSERVERS

The Director of the EFSA's Scientific Strategy and Coordination Directorate introduced the pilot project on the attendance of observers to EFSA Scientific Committee and Panel meetings and guidelines for observers. The Scientific Committee was informed that this would be a once a year event and a pilot project would be carried out with Panels volunteering to host observers during their plenary meetings. Conclusions on the outcome of this project will be drawn up at the end of the pilot phase.

The Scientific Committee welcomed this project in principle, however it posed several questions relating to the confidentiality and declaration of interests of the observers.

10. DRAFT SELF TASK MANDATES FOR THE SCIENTIFIC COMMITTEE

The Scientific Committee was informed of two follow-up activities on botanicals for which draft mandates were circulated. The first mandate aims to maintain and develop further the existing Compendium on botanicals. The second one is meant to develop a generic assessment system allowing for priority settings among the botanicals to be evaluated.

The Scientific Committee was asked to review the mandates and to submit comments in writing to the Scientific Committee secretariat prior to the finalisation of the mandates by the end of February 2012.

11. INTERNAL MANDATE ON RESEARCH PRIORITIES AND HORIZON 2020

This topic was postponed to the next SC plenary meeting.

12. DEVELOPMENT OF A CHEMICAL HAZARD DATABASE

This topic was postponed to the next SC plenary meeting.

13. REPORT BACK FROM SCIENTIFIC PANELS

This topic was postponed to the next SC plenary meeting.

14. EFSA'S SCIENTIFIC EVENTS IN 2012

EFSA's 10 Anniversary

The Scientific Committee was informed of a number of activities planned to take place to celebrate EFSA's 10th anniversary in 2012. EFSA will hold a two day scientific conference on 7-8 November 2012 in the Paganini auditorium in Parma. During this conference, EFSA will not only reflect on its achievements to date but will also look to the future and challenges ahead. Discussions on topics such as risk assessment methodologies and Science and Communications Strategies will be part of the agenda.

Invitations to all current and soon to be elected, Scientific Committee and Panel members and experts from different domains will be sent out in March.

EFSA Journal - Special issue

EFSA will publish a special issue in the EFSA Journal as part of its 10th year anniversary. It will be a synthesis of EFSA's achievements over the last 10 years with regards to risk assessment and new methodologies, and will project how this has been encompassed in the structure of EFSA's Scientific Committee and Panels. This issue will be made available both electronically and published in paper format. The Chairs of the Scientific Panels and Committee were invited to contribute to this special issue by providing articles on their respective areas.

The Scientific Committee greatly welcomed the idea and suggested that all experts who contributed to the outputs reported in these articles be appropriately acknowledged.

15. ANY OTHER BUSINESS

Minutes of the 52nd SC plenary – for adoption

The minutes of the 52nd Scientific Committee plenary meeting will be circulated for adoption via written procedure by 17 February 2012.

Update of Scientific Committee plenary meeting dates in 2012

An updated calendar revising plenary meeting dates in 2012 was presented and agreed by the Scientific Committee.