SCIENTIFIC COMMITTEE

Minutes of the 60th plenary meeting of the Scientific Committee
Held on 27-28 February 2013, Parma

(Agreed on 7 April 2013)

Participants

- **Scientific Committee (SC) Members:**

  Jan Alexander, Diane Benford, Qasim Chaudhry, Anthony Hardy[1], Michael John Jeger, Robert Luttik, Ambroise Martin, Simon More[2], Alicja Mortensen, Bernadette Ossendorp, Iona Pratt, Josef Schlatter, Kristen Sejrsen, John Sofos.

- **EFSA:**
  - **Executive Directorate:** Catherine Geslain-Lanéelle
  - **REPRO Directorate:** Per Bergman
  - **SCISTRAT Directorate:** Hubert Deluyker
  - **EMRISK Unit:** Jean-Lou Dorne[3], Tobin Robinson[3]
  - **SCOM Unit:** Juliane Kleiner, Djien Liem, Bernard Bottex, Miriam Jacobs, Daniela Maurici, Reinhilde Schoonjans, Sarah Maria Trattnig.

- **EC :** Michael Walsh

[1] Participated via teleconference for agenda items 5 and 6
[2] Present on 28 February 2013
[3] Present for agenda items 7 and 10

1. Opening and apologies for absence

Due to the unavailability of Anthony Hardy to attend, Robert Luttik took over as Chair for this meeting.

The Chair welcomed the participants. Apologies were received from Birgit Noerrung and Joe Perry[4], Chair of the GMO Panel, who was replaced by Gijs Kleter.

2. Adoption of the agenda

The draft agenda was adopted as tabled.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[5] and the Decision of the Executive Director implementing this Policy[6], EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or in the Oral Declaration of Interest (ODoI) at the beginning of this meeting.

4. Report back on issues relevant for the Scientific Committee

- **General matters arising**

There were no general matters to report to the Scientific Committee.

5. Draft opinion on hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment

Jan Alexander, Chair of the Working Group, guided the Scientific Committee through the revised draft opinion, highlighted the elements that were addressed after the previous Scientific Committee plenary meeting.

The Scientific Committee adopted the opinion and congratulated the working group for the excellent work done. Some minor editorial changes were suggested that will be considered in a dedicated meeting after the plenary.

On 20 March 2013 EFSA will hold a meeting with a wide range of stakeholders, in order to present the opinion and to provide an overview of the various reports released by European and international bodies that have carried out work in this area.

6. Reflection on whole food long term feeding trials

Per Bergman informed the Scientific Committee about a potential upcoming mandate from the DG Health and Consumers to EFSA to provide support for the development of a protocol for a 2- year carcinogenicity study with whole food and feeds. The EFSA advice should provide input for a planned DG Research and Innovation research project focussing on a 2-

[4] Participated via teleconference for agenda item 6.
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[6] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

year carcinogenicity feeding study in rodents with genetically modified feed for which a call is expected to be launched soon.

The Scientific Committee raised some concern about the usefulness of long-term feeding trial with whole foods/feed without having a clear objective for such a trial. In addition, information that will assist in such a study design should take into account results of any in vitro or in vivo toxicity tests. An assessment of carcinogenicity/chronic toxicity should be carried out after initial information on toxicity have been obtained from repeated dose 28 and/or 90-day toxicity tests.

7. Risk assessment of chemical mixtures

- Update on the draft report on chemical mixtures

The Scientific Committee was informed about the progress of the EFSA report reviewing terminology, methodologies and frameworks developed by national and international agencies for the human risk assessment of combined exposure to multiple chemicals.

The report will be finalised in April.

- Possible activities for the Scientific Committee

The Chair of the PPR Panel informed the Scientific Committee about the progress in the ongoing work for the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile and structural similarities. The draft opinion, is due for adoption by the PPR Panel at the end of April. The Chair of the PPR Panel suggested to table an extract of the draft opinion for information and discussion at the next plenary of the Scientific Committee together with a proposal on possible future activities of the Scientific Committee in this area,.

The Commission Services informed the Scientific Committee about the possibility to task EFSA with a new mandate to develop guidance on integrated approaches for the assessment of chemical mixtures. The request would include coordination and cooperation with other EU agencies.

8. Harmonised timelines for submitting information to EFSA within the stop-the clock mechanism

The Directorate of Scientific Evaluation of Regulated Products (REPRO) coordinates the activities of 6 Panels working under 18 different stream of legislation. The mechanism of stopping the clock is foreseen in many EC food and feed sectoral legislation for regulated products. The procedure consists of freezing the timeline of a scientific risk assessment to request additional or supplementary information to applicants in cases where the responsible Scientific Panel cannot conclude its evaluation based on the information available.

As this mechanism is differently described in different legislations and its use by EFSA varies between its different sectors, EFSA has developed a draft guideline which aims, where possible, at harmonisation of the use of the stop-the-clock procedure. This document has been submitted to the Commission for comments.

In parallel, EFSA has started to analyse the types of information typically requested to applicants under this stop-the-clock mechanisms and the timelines applied for collection of this information. The draft document was presented for discussion by the Scientific Committee and it will be also presented and discussed at plenary meetings of the relevant Panels.

An updated document will be tabled for discussion at the next SC plenary.

9. EFSA's Transparency initiative on data and processes

The Executive Director informed the Scientific Committee about a major initiative designed to enhance transparency in risk assessment. The programme, to be developed in cooperation with the Authority's partners and stakeholders, will consider how best and to what extent technical data used in risk assessments can be made available to the broader scientific community and interested parties.

The project is part of EFSA's continuing commitment to openness and addresses recommendations made by an independent evaluation report of the Authority's performance to further enhance transparency in its decision-making processes. EFSA's Science Strategy also highlights the importance of the Authority playing a leading role in making relevant scientific data more accessible to all interested parties. The transparency initiative builds on a range of measures already undertaken by EFSA to increase understanding, strengthen scrutiny and build confidence in EFSA's work.

10. Update on prioritisation of research proposals for consideration in the context of Horizon 2020

Horizon 2020 is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness. Running from 2014 to 2020 with an €80 billion budget, the EU's new programme for research and innovation is part of the drive to create new growth and jobs in Europe. Horizon 2020 is managed by DG Research and Innovation (DG RI) and DG Agriculture and Rural Development (DG AGRI) and it is linked to EU 2020 strategy for smart, sustainable and inclusive growth. It is organised in three parts: excellent science, which includes food security, sustainable agriculture, marine and maritime research and bio-economy; industrial leadership and societal changes.

EFSA can contribute on this important initiative by listing priority research areas of interests for EFSA's mandate. At the next plenary meeting, the Scientific Committee will discuss possible priority research areas identified during various consultations with the Scientific Committee, the Advisory Forum and EFSA Panels and Units. The final list of priorities will be communicated to DG RI and DG AGRI for their possible consideration.

11. Framework for future scientific cooperation between EFSA and EU agencies, third countries and international organisations

Due to time constraints, this item was deferred to the April meeting.

12. Any other business

- Member States' request for EFSA's safety assessment of "botanicals" supplements

EFSA received a letter from six Heads of national food safety agencies in relation to the safety assessment of "botanicals" supplements. The letter suggests that a review of the safety of the botanicals "should be led by EFSA in order to be undertaken in a more consistent and systematic way".
EFSA will follow-up on this issue with the European Commission. An initial prioritisation of the botanicals to be considered for harmonised assessment would be necessary to take into account the limited resources available. In this context, the Scientific Committee ongoing work on a proposal for a generic assessment system for setting priorities among botanicals to be evaluated by EFSA will be very useful.

- Consideration of new data available close or after adoption of opinions

The Scientific Committee discussed how to consider new scientific data that become available close or immediately after adoption of an opinion. It was agreed to prepare a draft document to facilitate the discussion on this important issue at the next plenary.

- Away day of the Scientific Committee

The Scientific Committee will have an Away Day, probably in July, to brainstorm and reflect on strategic issues important for its future direction. A draft agenda will be tabled for discussion at the next plenary meeting in April.

- Agenda of the next Advisory Forum and Stakeholders Platform meetings

The agenda of the next Advisory Forum and Stakeholders Platform meetings were tabled for information.

- Possible mandate on Carvone

Evaluations of Carvone, a natural component in several food items, have previously been performed by different scientific bodies and by the European Commission. Different values for the acceptable daily intake (ADI) were established based on different short-term toxicity studies.
In the light of the different ADIs and considering that several food sector areas of EFSA are involved in the evaluation of Carvone, the Scientific Committee proposed to conduct a new safety assessment of Carvone based on all data available.

A self task mandate will be prepared and submitted to EFSA Mandate Review Committee for discussion and possible approval.

- Allura Red

The Chair of the ANS Panel informed the Scientific Committee about the ongoing evaluations of Allura Red when used as food and feed colorant. The ANS WG on Allura Red, which consists of experts from FEEDAP and ANS Panel as well as other experts, have met to discuss in particular the evaluation of the genotoxicity data and a summary of the outcome was given.