

# Scientific Committee

## Minutes of the 89<sup>th</sup> Plenary meeting

**Held on 28-29 May 2018, EFSA**  
**(Agreed on 15 June 2018)**

### Participants

■ Scientific Committee Members:

Tony Hardy (Chair), Diane Benford, Thorhallur Halldorsson, Mike Jeger<sup>1</sup>, Helle Katrine Knutsen, Kostas Koutsoumanis, Simon More, Hanspeter Naegeli (day 2 only), Hubert Noteborn, Colin Ockleford, Maria Saarela (not on day 2 pm), Josef Schlatter, Vittorio Silano, Roland Solecki, Dominique Turck and Maged Younes.

■ Hearing experts<sup>2</sup>: Christer Hogstrand (agenda item 4.1), Alicja Mortensen (via teleconference for agenda item 4.4)

■ European Commission: Marina Marini (DG SANTE DDG2.D.1) (via videoconference)

■ EFSA:

- **EXECUTIVE Directorate:** Bernhard Url (day 1 only), Marta Hugas (day 1 only), Juliane Kleiner
- **RASA Department:** Hans Verhagen; Elisa Aiassa and Laura Martino (agenda item 5.3c)
- **REPRO Department:** Guilhem de Seze
- **SCER Unit:** Tobin Robinson, Ana Afonso, Bernard Bottex, Jean-Lou Dorne, Andrea Gervelmeyer, Georges Kass, Djien Liem, Angelo Maggiore, Daniela Maurici, Caroline Merten, Reinhilde Schoonjans.

---

<sup>1</sup> Via webconference

<sup>2</sup> As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Guido Rychen (FEEDAP Panel) and Antonia Ricci (BIOHAZ panel). They were replaced by Maria Saarela and Kostas Koutsoumanis, respectively.

## **2. Adoption of the agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Scientific Committee Members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>4</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declarations of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting were identified during the screening process.

No additional interests were declared at the meeting.

## **4. Scientific outputs submitted for discussion and/or possible adoption**

### **4.1 Draft guidance on risk assessment of chemical mixtures: for discussion and possible endorsement for public consultation (EFSA-Q-2015-000057)**

Christer Hogstrand, Chair of the working group, presented the draft guidance, highlighting the contents that have been modified since the last plenary meeting. A harmonised framework applicable to the human health, animal health and the ecological area and stepwise approaches has been proposed for problem formulation and each step of the risk assessment process (exposure, hazard and risk). These allow for flexibility, specific needs of the various EFSA Panels and fit for purpose approaches to be applied in the different mixture risk assessment contexts (human health, animal health and the ecological area). The current plan is to publish the draft guidance for public consultation over the summer.

The Scientific Committee congratulated the working group for the improvements made to the guidance document.

The Scientific Committee endorsed the document to go to public consultation, after taking into account a number of suggestions for

---

<sup>3</sup><http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>4</sup><http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

further improvements made during the plenary meeting. The consultation will probably close in September and the guidance will be finalised by the end of 2018.

**4.2 Draft statement on genotoxicity assessment of chemical mixtures:** for discussion and possible endorsement for public consultation ([EFSA-Q-2018-00126](#))

Josef Schlatter, Chair of the working group, presented the statement highlighting the changes made since the last Plenary meeting when the document was discussed. The statement was endorsed for public consultation following suggestions for improvement which will be taken into account for finalising the document before it is published on the EFSA website. The public consultation will be launched in June and will probably run until beginning of September. Because of the interest in the topic of the statement, a technical hearing will be organised in Brussels, during the public consultation (probably in September).

**4.3 Draft technical report on the activities of the Standing Working Group on Emerging Risks:** for discussion and possible endorsement ([EFSA-Q-2017-00385](#))

Hub Noteborn, Chair of the Standing working group on Emerging Risks presented the technical report. The report reviews the emerging risks identification methodologies in place, the results obtained by EFSA so far and proposes future developments. Recommendations are given in three areas: (i) to further develop a food system based approach including the integration of social sciences to improve the understanding of interactions and dynamics between actors and drivers and the development of horizon scanning protocols; (ii) to improve data processing pipelines to prepare big data analytics, implement a data validation system and develop data sharing agreements to explore mutual benefits; (iii) to revise the EFSA procedure for emerging risk identification to increase transparency and improve communication.

The Scientific Committee acknowledged all the work done and endorsed the report for publication. The Scientific Committee recommended EFSA and the new Scientific Committee to consider the recommendations presented in the document and proposed some actions in order to increase the visibility of this activity.

**4.4 Draft guidance on risk assessment of nanotechnologies:** for discussion and possible endorsement for piloting phase ([EFSA-Q-2016-00281](#))

The Scientific Committee was presented with the latest version of the draft guidance, which was revised to take account of the comments

received during the public consultation. A pilot phase is now proposed to test the guidance with the relevant EFSA Panels and Units. A Standing Working Group will be created to support the implementation of the guidance and to be used as a consultative platform. A hearing with stakeholders will be organised in the beginning of 2019 to gather feedback on the applicability of the guidance. The guidance will be finalised, with the received feedback, by end of 2019.

The Scientific Committee agreed with the above proposal, and endorsed the guidance for the pilot phase as well as the technical report summarising the outcome of the public consultation. Both documents will be published.

#### **4.5 Scientific Committee comments on the draft EFSA-ECHA guidance for the implementation of the hazard-based criteria to identify endocrine disruptors:** document for final endorsement for publication

The comments submitted by the SC on the EFSA-ECHA draft guidance on endocrine disruptors, were reviewed and endorsed for publication in the technical report of the consultation summarising all the consultations on the GD.

### **5. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission**

#### **5.1 Feedback from the Scientific Committee and its Working Groups**

##### 5.1a Working Group on Compendium of Botanicals (version 3.0) ([EFSA-Q-2012-00486](#))

The working group is screening the articles retrieved for 2600 plant species and is validating the composition and toxicity/adverse effect information to be transferred to the EFSA data warehouse.

Following the request for assistance received from the NUTRI Standing Working Group (SWG) on Traditional Foods, the working group on Compendium contributed to the assessment of two traditional foods, fonio (*Digitaria exilis* grain) and haskap (*Lonicera caerulea* berries), notified to the European Commission under the Regulation on Novel Foods. The working group reviewed the composition and toxicity/adverse effects information in the Compendium of Botanicals to complement the information provided in the notification. The outcome of this work has been forwarded to the NUTRI SWG on Traditional Foods which is in charge of the assessment of these traditional foods. A third contribution is currently being prepared on the syrup of *Sorghum saccharatum* as an organic sweetener.

The Working Group also reviewed the composition/toxicity information available for the assessment of “tongkat ali” (roots of *Eurycoma longifolia*) as a novel food. The outcome of this work was forwarded to the NDA SWG on Novel Foods.

#### 5.1b Working Group on the Threshold of Toxicological Concern (TTC) ([EFSA-Q-2017-00468](#))

The working group is currently updating the 2012 EFSA Scientific Opinion on the TTC by preparing a guidance document on the use of the TTC approach in food safety. The guidance will consider recent developments and ongoing work at international level. The guidance document will be subject to a public consultation (probably in the beginning of 2019) before it is finalised and proposed for adoption by the Scientific Committee in Spring 2019.

#### 5.1c Standing Working Group BMD

The Scientific Committee was informed about the development of Bayesian BMD analysis (as opposed to the frequentist approach described in the current SC Guidance on the use of the BMD approach in risk assessment). In order to ensure the harmonised use of the BMD approach across EFSA and with European and international partners, the above-mentioned guidance document and EFSA BMD platform will have to be updated to allow for Bayesian BMD analysis. The timelines will be discussed with the new Scientific Committee during its first plenary meeting.

#### 5.1d Working Group MUST-B ([EFSA-Q-2016-00358](#))

The Chair of the MUST-B working group described the progress that has been made in the development of the ApisRAM mechanistic model to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors. The Chair also indicated the activities conducted in the context of the honey bee data collection project, in particular the description of the selected sites and the interactions with the modellers for the use of the GIS mapping for the sites.

The EU Bee Partnership Discussion group has finalised the terms of reference for the EU Bee Partnership, aimed at collecting and sharing data on bee health in Europe. They have been published on the EFSA website (<http://www.efsa.europa.eu/en/supporting/pub/en-1423>).

The discussion group was made up of representatives from beekeeper associations, conservation organisations, farmer associations, plant protection and veterinary medicine industries.

Members of the working group will present the terms of reference for the EU Bee Partnership at this year's [European Week of Bees and Pollination](#) on 26-28 June in Brussels.

## **5.2 Feedback from the chairs of the Scientific Panels: Exchange on cross cutting activities in the panels**

### AHAW Panel

The Panel has had no meetings since the last SC Plenary.

### ANS Panel

The Panel is currently re-evaluating the safety of phosphates and polyphosphates as food additives; a consultation with relevant scientific societies will be launched to clarify the validity and interpretation of some of the data.

The Panel was asked by the European Commission to assess four new studies on titanium dioxide. The mandate was discussed at the last Plenary meeting that was open to observers. The Panel agreed to look at these studies in conjunction with all the other available data.

### BIOHAZ Panel

No Panel Representative for this agenda point.

### CEF Panel

The protocol for the risk assessment of Bisphenol A was published at the end of 2017. The Chair of the Working Group for the re-assessment of Bisphenol A will be selected next week in order to start working on drafting the opinion.

### CONTAM Panel

The Chair had no new issues since the last SC Plenary report back.

### FEEDAP Panel

No Panel Representative for this agenda point.

### GMO Panel

The Panel is aiming at getting its guidance on the assessment of Next Generation Sequencing (NGS) data adopted by the end of its term.

The Panel received an application for a transgenic maize expressing insecticidal RNAs. The assessment will be performed with the existing guidance documents.

### NDA Panel

The Panel received a request from the European Commission to evaluate whether the safety of astaxanthin as a novel food used in food supplements at maximum levels of 8 mg/day is still in accordance with the requirements of Regulation (EU) 2015/2283, taking into account all sources of astaxanthin. A public call for data will soon be launched by EFSA.

### PLH Panel

The Panel is preparing a set of criteria for the evaluation of import derogation requests for high risk commodities. The document will go for public consultation in December 2018. The first requests for derogations are expected in March 2019.

### PPR Panel

The Chair of the Panel reported that the European Commission is currently rethinking the authorisation processes of Plant Protection Products. A meeting was organised on 23 February 2018 by the High Level Group (HLG) of Scientific Advisors of the European Commission's Scientific Advice Mechanism (SAM) to gather the views from stakeholders. SAPEA (Science Advice for Policy by European Academies) has also published its third Evidence Review Report that examines the methods and procedures for assessing potential harmful effects on human health from the use of Plant Protection Products (PPPs), and the ways in which the current authorisation processes could be improved from a scientific perspective.

## **5.3 Feedback from EFSA**

### **5.3a** General matters arising

The Scientific Committee was provided with a document summarising the relevant activities that had taken place since the last plenary meeting with focus on the activities of the EFSA Management Board, Advisory Forum (AF), interagency and international scientific cooperation and EFSA Stakeholders. Clarification was provided regarding the discussion that took place during the trilateral meeting between the European Commission, the US FDA and the Chinese General Administration of Quality Supervision, Inspection and Quarantine, that took place from 11 to 13 April 2018.

### **5.3b** The future of guidance development and the work programme of the SC 2018-2021

The Scientific Committee was provided with an overview of its achievements during its 3-year mandate, and was invited to reflect on

future activities. The priority will be to focus on implementation of existing guidance documents rather than the development of new ones. The implementation will be assured with more info sessions and trainings for EFSA staff and experts on newly developed guidance and with the establishment of standing working groups to provide support to the different panels when implementing the guidance.

The Scientific Committee was invited to provide feedback on this new approach and to identify possible burning priority tasks that should be considered by EFSA. The suggestions for new activities will be discussed with the new Scientific Committee in September.

### **5.3c ProMetheus: an update**

The Scientific Committee was provided with an overview of the achievements of the ProMetheus project and follow up actions. A number of needs are now considered that could help with the implementation of the 4-step approach (plan/do/verify/document) in EFSA assessments. Possible actions could be:

- Development of an EFSA guidance on evidence appraisal
- Development of an EFSA guidance on problem formulation and protocol development
- Testing the available methods for evidence synthesis and integration
- Development of one individual roadmap document connecting all EFSA cross-cutting methodological guidance
- Explore the use of automation, machine learning and artificial intelligence

### **5.3d Proposals for research needs as collected from the EFSA Panels**

The Scientific Committee was provided with feedback on the proposals for research needs collected from the Chairs of the Panels and Heads of Units. Most of the proposals reflect synergies between panels. These proposals will be shared with the European Commission who is developing the new European Research Programme (FP9).

## **6. Any other business**

The Scientific Committee was provided with feedback on the Colloquium on OMICS in risk assessment, which took place on 24 and 25 April 2018 in Berlin. The participants explored the opportunities for integration of datasets produced via specific OMICS tools within the remit of EFSA's risk assessment approaches.

The report on the Colloquium will be published at the end of September 2018.

Tobin Robinson, Head of the Scientific Committee and Emerging Risks Unit, closed the meeting, thanking the chair and the members of the SC for their outstanding contributions during the last 3 years.

The new Scientific Committee will have its first meeting on 17 September 2018.

**END OF MEETING**