SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

# SCIENTIFIC COMMITTEE

## MINUTES OF THE 93rd PLENARY MEETING

**Held on 24 April 2019, 08.30 – 16.00h**

**Centre Albert Borschette, Brussels (Belgium)**

**(Agreed on 20 May 2019)**

## Participants

- **Scientific Committee Members:**

  Simon More (Chair), Diane Benford (Vice chair, via teleconference), Susanne Hougaard Bennekou (Vice chair), Claude Bragard, Thorhallur Halldorsson, Lieve Herman, Antonio Hernandez-Jerez, Christer Hogstrand, Kyriaki Machera, Hanspeter Naegeli, Søren Saxmose Nielsen, Josef Schlatter, Dieter Schrenk, Vittorio Silano, Dominique Turck, Maged Younes.

- **European Commission:**

  Marina Marini (DG SANTE D.D.1)

- **EFSA:**

  - **EXECUTIVE Directorate:** Marta Hugas

  - **Risk Assessment and Scientific Assistance Department (RASA):** Juliane Kleiner

  - **Scientific Committee and Emerging Risks Unit (SCER):** Tobin Robinson, Daniela Maurici, Georges Kass, Djien Liem, Reinhilde Schoonjans, Agnes Rortais.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Vasileios Bampidis, chair of the Additives and Products or Substances used in Animal Feed Panel (FEEDAP); Kostas Koutsoumanis, chair of the Biological Hazards panel (BIOHAZ) (replaced by Lieve Herman). The chair introduced Kyriaki Machera as new member of the SC. DR Machera was selected after the official resignation of Jos Boesten in the end of 2018.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Scientific Committee/Scientific Panel Members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declarations of Interest filled out by the members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Scientific topic(s) for discussion and/or possible adoption

### 4.1. Draft guidance Threshold of Toxicological Concern (TTC) approach

The revised version of the guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment was discussed. The Scientific Committee (SC) proposed final editorials changes and adopted the guidance that will be published by the end of May, together with the technical report summarising the comments received during the public consultation.

The SC furthermore discussed the timeline for implementation of the Guidance and the strategy proposed for future databases, as recommended in the Guidance.

### 4.2. Proposal for a technical guidance on the use of Whole Genome Sequencing (WGS) in risk assessment of FEED additives

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) has recently adopted a series of updates on the guidance documents to support applicants in the preparation and submission of technical dossiers for the authorisation of additives for use in animal nutrition according to Regulation (EC) No 1831/2003. Extra guidance on the characterisation of microorganisms used as feed additives or as production organisms is now being implemented since 1 September 2019.

The Guidance establishes the use of the Whole Genome Sequence Analysis to address some of the molecular characterisation requirements for microorganisms. This has raised the request from applicants to provide further technical guidance for implementation.

The SC gave its feedback on the technicality of this issue and on its broader perspective, since similar characterisations may take place also for food additives, novel foods and pesticides. There is considerable expertise also established in the areas of GMO and BIOHAZ Panels. Follow up discussion will be organised within EFSA, both on the proposed workplan as well as the possible endorsement by the SC once the work is concluded.

## 5. New Mandates

### 5.1. Draft EC mandate on technical guidance to document the presence of small particles in a material

The Scientific Committee was informed about a draft mandate from the EC DG SANTE in preparation that has been shared with EFSA for preliminary comments before finalisation of the Terms of Reference. The aim of the mandate would be to ask for the technical and scientific information that the applicant will need to include in the application to document the presence or absence of small

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

particles including in the nanoscale or a nanoparticle fraction in the material and/or in the final regulated product. Once clarified and finalised the Terms of Reference, the mandate will be published and work will be initiated, probably in autumn.

### 5.2. European Parliament mandate on risk assessment of multiple stressors in managed honey bees

The SC was informed about the progress of the mandate received by the European Parliament (EP) on the science behind the development of an integrated approach for the risk assessment of multiple stressors in managed honey bees (***Apis mellifera***). An update was provided regarding the composition of the working group (WG), the timeline for the drafting of the scientific opinion and its reporting to the EP (Apiculture WG) and ENVI committee. The Terms of reference (ToRs) and a proposed way forward to address those ToRs were presented to the SC. Regular updates of the work will be presented to the SC until the completion of the work.

## 6. Other scientific topics for information and/or discussion

### 6.1. Cumulative risk assessment: proposal for a way forward

The SC discussed a draft terms of reference for a new task to prepare a scientific statement/opinion on scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals. Valuable progress has been made on this topic in the area of pesticides and there are also examples in other EFSA panels where the grouping of chemicals for the risk assessment was considered. The statement should be based on the principles laid down in the SC Guidance on "Harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals" which was recently published on EFSA's website on the 25th of March (link here).

During the discussion, the members emphasised that it is important to focus on specific toxic effects rather than all target organs and that it would be useful to develop criteria taking into consideration knowledge about mode of action and adverse outcome pathways as well as data from monitoring programmes. It was also underlined that the usefulness (fitness-for-purpose) of an assessment will very much depend on the problem formulation, on the question(s) to be addressed in the assessment. Some members expressed caution as there may be some knowledge gaps for relevant aspects to be considered in the area of cumulative risk assessment.

The Scientific Committee agreed to be consulted on an updated draft of the terms of reference and a scoping document that will specify in more detail the anticipated work and timelines.

### 6.2. Draft strategy for chemical risk assessment 2020-2027

The SC was informed about the preparation of reflection papers on the future of risk assessment in EFSA to support the development of the new EFSA Strategy 2021-2027 that will replace the current EFSA Strategy 2020 in December 2020. The SC was informed about one of the four reflection papers in preparation, which is devoted to chemical risk assessment. Colleagues from the different units dealing with chemical risk assessment are reviewing EFSA's the achievements in the area of chemical

risk assessment and are proposing targets for EFSA to be achieved by 2027 and the kind of activities in the area of methods, models, tools and data to be given priority to achieve these targets. The SC will be consulted on a first draft of the reflection paper "Future of Chemical Risk Assessment in EFSA" at its next plenary meeting.

## 7. Any Other Business

### 7.1. Feedback on stakeholders' workshop on testing phase of the SC nanotechnologies guidance

The Stakeholders workshop took place on 1-2 April 2019 in EFSA and gathered 60 participants that are users of the "Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health", published in July 2018.

The agenda was built with the contributions of the applicants and consultants that shared their experience with using the guidance. The EFSA staff, together with the members of the cross-cutting working group NANO, collected comments and will consider them for possible amendments of the guidance before its final publication at the end of the pilot phase. The re-publication is foreseen by mid 2020.

### 7.2. Draft agenda for June Plenary

The SC was presented with an overview of the topics that will be on the agenda of the June plenary meeting, open to observers.

### 7.3. SC plenary meeting dates 2020

Meeting dates for plenary were discussed and agreed. They will be soon published on the EFSA website.

### 7.4. Update on the REFIT of the General Food Law

The SC was informed that the revision of the Regulation 178/2002 (General Food Law) was approved by the EU Parliament. This marks the last step in the legislative approval process and clears the path towards an update of EFSA's Founding Regulation. The final text will be published in the Official Journal of the European Union during the summer and enter into force 20 days after publication. With a transition period of 18 months, most measures will become applicable in early 2021.

**END OF THE MEETING**