Scientific Committee

Minutes of the 85th Plenary meeting

Held on 13-14 September 2017, EFSA

(Agreed on 18 October 2017)

Participants

- Scientific Committee Members:

  Tony Hardy (Chair), Diane Benford, Thorhallur Halldorsson, Mike Jeger (via telecon), Helle Katrine Knutsen, Hanspeter Naegeli, Hubert Noteborn (day 2 only), Colin Ockleford, Josef Schlatter, Roland Solecki, Dominique Turck and Maged Younes.

- Hearing experts[1]:

  Alijca Mortensen (agenda item 4 only)

- European Commission: Marina Marini

- EFSA:
  - **EXECUTIVE Directorate**: Hubert Deluyker, Juliane Kleiner
  - **COMMS Department**: Stef Bronzwaer (agenda item 5.3f), Jacopo Alabiso (agenda item 5.3e)
  - **RASA Department:** Hans Verhagen
  - **REPRO Department:** Claudia Paoletti (agenda item 5.3c), Carla Martino (agenda item 5.3b)
  - **BuS Department:** Dirk Detken (agenda item 5.3d)
  - **SCER Unit**: Tobin Robinson, Ana Afonso, Bernard Bottex, Jean-Lou Dorne, Raquel Garcia Matas, Nikolaos Georgiadis, Tilemachos Goumperis, Melpo Karamitrou, Georges Kass, Angelo Maggiore, Daniela Maurici, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans.

[1] 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 Simon More (AHAW Panel), Antonia Ricci (BIOHAZ Panel), Guido Rychen (FEED Panel) and Vittorio Silano (CEF Panel).

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[2] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[3], 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 Draft guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1 on human and animal health (EFSA-Q-2016-00281): preliminary discussion

Alicja Mortensen, Chair of the SC Working Group on nanoscience and nanotechnology, presented the draft guidance for the first reading by the SC. The document covers the areas of novel foods, food additives, food contact materials, feed additives and pesticides. The draft guidance provides full physicochemical characterisation requirements and an approach for assessing the oral toxicity of nanomaterials, including (amongst others) *in vitro* digestion, ADME, *in vitro/in vivo* testing, genotoxicity, immunotoxicity and endocrine activity. The document also discusses how to assess inhalation and dermal toxicity, especially for nanopesticides and feed.

The guidance will be presented at the November SC plenary for possible endorsement for public consultation. It will then be made available for consultation by January 2018, and will be proposed for final adoption by July 2018.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

The Scientific Committee was invited to provide feedback on the general approach proposed, and to make suggestions for possible improvements.

The Scientific Committee discussed the consequences of the ambiguities still existing in the legal context of nanomaterial for the guidance. It was explained that an overarching recommendation for a definition of nanomaterial is not yet embedded in its final form in food law. A suggestion was made to clarify this by expanding the paragraph explaining that the approach proposed is for assessing all materials having properties dependent on the extremely small dimensions of their particulates.

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

5.1. Feedback from the Scientific Committee and its Working Groups

- Standing Working Group on Benchmark dose (BMD)

The Standing Working Group has now been established. It is expected that its first task will consist of reviewing the new BMD analysis made by the CONTAM Panel for the opinion on 3-MCPD.

- Working Group on Chemical Mixtures (EFSA-Q-2016-00307)

The SC was presented with a summary of the table of content and of the content of the different chapters of the document providing guidance on risk assessment of chemical mixtures. The structure includes a chapter presenting overarching principles, historical frameworks and an overarching framework for the guidance followed by chapters on problem formulation, exposure assessment, hazard assessment and risk characterisation (including uncertainty). The draft guidance will have specific focus of the food and feed safety areas related to the work of the EFSA panels. Decision trees for problem formulation and hazard assessment (component-based approaches) were also presented. A first draft of the guidance will be presented at the November Plenary meeting for the first reading.

- Working Group on Compendium of Botanicals (version 3.0) (EFSA-Q-2012-00486)

The Working Group is busy validating the data retrieved by the Contractor to further develop the EFSA Compendium of botanicals containing naturally occurring substances of possible concern for human health. Around 2,000 plant species and 1,500 substances / chemical groups of possible concern will be added to the database.

- Standing Working Group on Emerging Risks (EFSA-Q-2017-00385)

Hub Noteborn, Chair of the Standing Working Group, provided the Scientific Committee with an update on ongoing activities. The SWG provides scientific support to the work on methodological developments for emerging risk identification. These include the project AQUARIUS (use of food supply chain analysis for identification of emerging risks), REACH 2 (prioritization of possible chemical emerging risks) and DEMETER (metrics and methods for emerging risks identification). The SWG was also involved in the preparation of an EU wide web survey on emerging risks communication. The group is also developing a report reviewing EFSA activities and formulating recommendations for future work on emerging risks.

- WG Must B

The first two interim reports on GIS landscapes and literature searches for the development of the formal ApisRAM model were received by EFSA to be discussed with the contractor on 20 September.

The open call on the field data collection to calibrate and evaluate the model ApisRAM was published on 3 August 2017 and tenderers will have until end October to send their offers. The plan is to start the data collection in early 2018.

The Event report of the EFSA scientific symposium on "Collecting and sharing data on bee health: Towards a European Bee Partnership" that took place on 26 June 2017 at the European Parliament (EP) has been reviewed and will be published on the EFSA website shortly.

A call for expression of interest to participate in a stakeholders discussion group for the establishment of a partnership to collect and share data on bee health will be published on the ESFA website before the end of September 2017. The composition of the discussion group will be finalised in October and the first meeting is scheduled to be held by the end of the year. This discussion group will prepare the terms of reference of the partnership to be presented to the European Parliament in June 2018, at the occasion of the EU Bee Week Event.

- Standing Working Group on Genotoxicity (EFSA-Q-2017-00112)

The public consultation on the draft opinion on "Reflection on interpretation of some aspects related to genotoxicity assessment" resulted in 180 submitted comments by 20 different parties. The working group is currently addressing them to finalise the opinion. The opinion will be tabled for final adoption at the November plenary.

- Working Group on the Threshold of Toxicological Concern (TTC) (EFSA-Q-2017-00468)

The working group is under construction. Depending on available budget, the working group will have its first meeting in late 2017, or early 2018.

- Working Group on Uncertainty (EFSA-Q-2013-00738)

The WG uncertainty has started to implement the recommendations from the EFSA internal workshop on uncertainty held on 22-23 June 2017. A new concise and practical guidance document is in preparation. The previous "long" version of the guidance document will be revised by addressing further comments received at the workshop and will become the supporting document for the concise guidance document. Both documents will be presented at the November SC plenary for possible adoption.

In parallel EFSA is preparing an implementation plan on how to roll out the uncertainty guidance document across the different panels from July 2018 onwards.

In addition, the WG has started its activity on a guidance on how to communicate uncertainties in scientific assessments. A preliminary draft is expected to be presented to the SC in its February 2018 plenary meeting.

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

PPR Panel:

The Panel received 223 comments on the draft opinion following up the finding of the external scientific report "Literature review on the epidemiological studies linking exposure to pesticides and health effects". The document will be proposed for possible adoption at the plenary on 20-21 September 2017.

The Scientific Committee was asked whether there is a need for a follow up addressing the issue of the use of epidemiology studies in risk assessment, and to test the recommendations of the above-mentioned report for a more horizontal application across EFSA's remit of activity. The participants were reminded that the development of horizontal guidance on the use of epidemiological data in risk assessment has been on the "to-do list" of the Scientific Committee for some time and will probably be initiated in 2018. It was agreed that there would be discussion of this matter as a specific timetabled agenda item at the meeting of the Scientific Committee to be held on 13-14 February 2018.

NDA Panel:

The new working group on "Added Sugars" had its first meeting in July 2017. The working group was established following a request from the National Food Agencies of Denmark, Finland, Iceland, Norway and Sweden to derive a science-based cut-off value for daily exposure to added sugars from all sources, but not associated with adverse health effects in the population. The opinion is foreseen in 2020.

ANS Panel:

The statement on the approach for exposure assessment used in the re-evaluation of food additives has been adopted and will soon be published in the EFSA Journal. The Panel is starting the re-evaluation of the safety of phosphates and polyphosphates as food additives, which may be of interest for the NDA Panel. The re-evaluation of silicon dioxide as a food additive will be finalised by the end of the year.

GMO Panel:

The implementation of the SC guidance documents on uncertainty analysis, biological relevance and weight of evidence is ongoing. Feedback on the use of these guidance documents will be provided to the Scientific Committee in due time.

PLH Panel:

The Panel is busy with 133 pest categorisations of the harmful organisms included in the annexes of Directive 2000/29/EC.

5.3. Feedback from EFSA

5.3a General matters arising

The Scientific Committee was provided with a document summarising relevant activities that had taken place since the last Plenary meeting with focus on International Scientific Cooperation.

5.3b Cross cutting issues relevant for EFSA

Impact assessment of the ongoing reflection paper on genotoxicity (EC mandate) on the previous EFSA assessments:

A preliminary impact assessment has been done to evaluate how many substances evaluated by EFSA in the past may need to be reconsidered after the adoption of the reflection paper related to some aspects of genotoxicity assessment (EC mandate, EFSA-Q-2017-00112). One of the considerations is whether a UDS assay *in vivo* was the only test considered to follow up positive *in vitro* genotoxicity results. The Scientific Committee does not recommend a systematic re-evaluation of past opinions but the proposed approach presented in the new opinion should be followed for future evaluations.

The Scientific Committee also discussed the issue of the assessment of genotoxicity in chemical mixtures with example of smoke flavourings.

There was a consensus among the experts that genotoxic substances are of safety concern, therefore they should not be added voluntarily to food. This also applies if they are part of a chemical mixture.

In principle, a mixture can be assessed either via a 'whole mixture' testing approach or via a 'component based' approach. The appropriate approach to follow should be chosen on a case by case basis, based on the *weight of evidence* principle. In general, it was agreed that the "whole mixture" testing approach should be followed when no known genotoxic substances are present in the mixture, while the "component based approach" should be applied if the mixture contains known genotoxic substances, with no need to conduct any further *in vitro/in vivo* genotoxicity tests on the whole mixture. A statement should be prepared by the Scientific Committee with the support of the Standing WG on genotoxicity, confirming the outcome of this discussion. Work will probably start in the beginning of 2018.

5.3c Sampling approaches for the generation of reliable data supporting risk assessment: an example from GMO

A detailed presentation on the sampling recommended approaches for generating reliable data was provided. The work is the result of a procurement tailored for the GMO Panel, but the results can be extrapolated to scientific assessment in general.

Starting from the observation that the appropriateness of sampling is often overlooked in risk assessment, or wrongly addressed, relying on unverified distribution assumptions when designing sampling protocols, the external report provides an analysis of the sample needs for GM plants risk assessment, a review of possible sampling strategies, and the proposal of reliable and representative sampling methods for GM plants risk assessment.

The SC was asked whether more horizontal guidance is needed on the importance of sampling and on how it should be performed. This question will be further considered at EFSA level.

5.3d Update on the new rules on independence

The Head of the EFSA Legal and Assurance Service Unit, briefly presented the new policy on independence that was adopted by the EFSA Management Board in June 2017. EFSA is now working on the implementing decision, which will be discussed at the Management Board in October 2017. The main changes compared to the previous policy were highlighted and discussed.

The Scientific Committee asked for further discussions on this implementation rules during the next Plenary meeting in November 2017.

5.3e Revamping of the EFSA website for visibility of cross cutting guidance documents

Following the previous request to make horizontal cross-cutting guidance more visible and easier to access on the EFSA website, the SC was presented with a new feature called "Virtual Issue", included in the next upgrade of Wiley's platform, planned for the end of September 2017. Via the EFSA website, it will be possible to be redirected to the Virtual Issue on the Wiley platform that will be populated with cross cutting guidance documents. The SC recommended presenting these improvements, once implemented, to the different EFSA Scientific Panels to increase awareness and visibility of cross-cutting guidance documents in use.

5.3f Update on Advisory Forum and Scientific Cooperation activities

The SC was updated on the EU Risk Assessment Agenda (EU RAA). The objective of the EU RAA is to identify priorities for Member States and EFSA to enable collaboration, avoid duplication of efforts, and have a greater impact on the setting of research agendas to allow access to funding opportunities, whether they are international/European, regional or national.

A new grant instrument was launched this year to foster knowledge transfer between EFSA and its partners, the so-called "partnering grants" (more info here).

The European Food Risk Assessment Fellowship Programme (EU-FORA) is giving the opportunity for fellows to join a risk assessment agency for a one-year programme. A 6-week training is first provided by EFSA. The objectives are to attract early career scientists to become risk assessors, harmonise risk assessment methodologies and increase cooperation between EFSA and MS competent authorities. 15 fellows from 11 different Member States will be hosted by 7 MS Competent Authorities. A new call for applications for hosting sites and fellows will be published in October 2017. SC and Panel members are asked to disseminate this call.

5.3g Exchanging views on potential impacts of climate change for food and feed safety in the EU

As part of its mandate to identify emerging risks and the effort of reviewing and improving the process in place, EFSA is developing a methodological approach for identifying, ranking and prioritising emerging issues based on the analysis of drivers. Climate change, as a potential cause of emerging risks for food and feed safety, including plant and animal health, is proposed as a test exercise. The

establishment of an ad-hoc "knowledge network" is considered for this purpose.

The SC confirmed the importance of this initiative. The composition of the network should include the relevant areas in the food safety remit potentially impacted by climate change. The SC will be kept updated on the progress of this initiative during future meetings.

6. Any other business

- Update on the EFSA external evaluation

The SC was presented with an update on the external evaluation of EFSA that takes place every 6 years as outlined in article 61 of the EFSA Founding Regulation. The external evaluation should assess the working practice and the impact of EFSA, taking into account the views of the different stakeholders.

A survey will be sent to all EFSA Stakeholders as part of the EFSA external evaluation. The first part of the survey covers EFSA's performance and structure, while the second part of the survey is more intended for Member States' review of EFSA activities. The Survey will be open to all respondents from 29 September to 20 October 2017.

Once finalised, the evaluation will be submitted in spring 2018 to the Management Board to examine the results and conclusions; the Management Board will then issue recommendations by summer 2018.

- Update on EFSA's 3rd Scientific Conference

The 3rd EFSA Scientific Conference will take place during the week of 18-21 September 2018. The conference will be a checkpoint for EFSA's 2020 Strategy and feed EFSA's 2025 strategy. It will also be an opportunity to discuss how to communicate EFSA's work, taking account of the societal changes and evolving world. The Scientific Committee was presented with the four main pillars, as well as the various milestones to prepare the conference, and was invited to suggest ideas/topics and possible speakers for the conference by 29 September 2017.

The Scientific Committee was reminded that the Plenary meeting initially planned on 7 December 2017 has been cancelled. The next meeting will take place on 15-16 November 2017.

END OF MEETING