Scientific Committee

Minutes of the 71st Plenary meeting
Held on 18-19 February 2015, Parma
(Agreed on 23 April 2015)

Participants

- Scientific Committee Members:

  Tony Hardy (Chair) Jan Alexander, Qasim Chaudhry, John Griffin, Michael John Jeger[1], Gijs Kleter[1], Robert Luttik, Ambroise Martin, Simon More, Alicja Mortensen, Josef Schlatter, Vittorio Silano.

- Hearing experts:

  Theo Brock[2], Kostas Koutsoumanis[3], Salomon Sand[4]

- European Commission:
  - Marina Marini (DG Sante)[5]

- EFSA:
  - **Executive Directorate**: Bernhard Url[6], Hubert Deluyker
  - **RASA Department:** Marta Hugas, Didier Verloo
  - **REPRO Department:** Juliane Kleiner
  - **SCISTRAT Department**: Tobin Robinson, Djien Liem
  - **SCER Unit**: Andrea Altieri, Bernard Bottex, Jean-Lou Dorne, Andrea Germini, Angelo Maggiore, Daniela Maurici, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans.

[1] Via conference call
[2] Day 2 only
[3] Agenda item 6.3b, via conference call
[4] Agenda item 7.1, via conference call
[5] Only day 1 p.m. and day 2
[6] Only day 1 a.m.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Diane Benford, Birgit Nørrung, Bernadette Ossendorp, Joe Perry (substituted by Gijs Kleter) and Kristen Sejrsen.

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[7] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[8], 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. For further details on the outcome of the Oral Declaration of Interests made at the beginning of the meeting, please refer to Annex I.

4. Agreement of the minutes of the 70th Plenary meeting held on 11-12 November 2014

The minutes of the 70th Plenary meeting held on 11-12 November 2014 were agreed[9].

5. Scientific outputs submitted for discussion and possible adoption or endorsement

5.1. Draft opinion on guidance lifecycle

The agenda point was chaired by Prof. Jan Alexander, vice chair of the Scientific Committee, as the Chair of the Scientific Committee was involved in the drafting of the opinion.

The content of the opinion was presented by Daniela Maurici. The document describes how EFSA's cross-cutting guidance documents should be reviewed, revised and kept up to date. A distinction is made between unconditional guidance whose implementation by the EFSA Scientific Panels and Scientific Committee is compulsory, and conditional guidance where deviation is possible, as long as it is justified and documented.

[7] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[8] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[9] http://www.efsa.europa.eu/en/events/event/141111-m.pdf

The opinion recommends reviewing the need for revision of all guidance documents every three years, with priority given to the unconditional ones. The Scientific Committee suggested that this review takes place at the end of the 3-year mandate of the Panels/Scientific Committee.
Cross-cutting guidance documents and their binding level should be clearly mentioned and all the guidance should be easily retrievable on the EFSA website in a dedicated central repository. A mechanism should be put in place so that the "valid" version of the guidance document (as compared to the version(s) it supersedes) is clearly identified.
The opinion also recommends an endorsement by the Scientific Committee of cross-cutting guidance documents that were not developed by the Scientific Committee but by EFSA, and that a dissemination plan is established for each guidance document to improve the uptake and implementation by Panels and Units.
It was suggested that, when preparing the revision plan, consultation of relevant networks and Member States' Competent Authorities on the guidance that would require an update, should also be made.

The above-mentioned comments and recommendations will be incorporated in the draft guidance document that will then be circulated again to the Scientific Committee for possible adoption by written procedure.

5.2. Guidance on dealing with divergence over scientific issues between EFSA and Member States

Tobin Robinson presented the on-going work on how to deal with divergence over scientific issues between EFSA and Member States (article 30 of Regulation 178/2002). A guidance document will be tabled for possible agreement at a future Advisory Forum meeting.

5.3. PROMETHEUS deliverable 1: Principles and process for dealing with data and evidence in scientific assessment

Elisa Aiassa presented the scientific report "Principles and process for dealing with data and evidence in EFSA assessments". This report is the first deliverable of the EFSA PROMETHEUS (PRomoting MeTHods for Evidence Use in Scientific assessments) project, which is part of a number of EFSA activities aiming at increasing the robustness, transparency and openness of its assessments.

The Scientific Committee stressed the importance of transparency and of documenting correctly what has been done during an assessment.
The Scientific Committee recommended making the document fit-for-purpose, in particular in relation to the *a priori* definition of a strategy for the assessment (i.e. the protocol). The issue of to what extent such a protocol can be anticipated and the level of detail was discussed: the same protocol cannot be applied both for a question where new data should be generated, and for a question where data already exist and should be retrieved from the literature or elsewhere. The importance of having the possibility to update the protocol in an iterative manner during the assessment was stressed.

Finally, the Scientific Committee asked to see examples at the next plenary meeting on how these principles and processes apply to EFSA's assessments. It was suggested to discuss, as a case study, the protocol that has been developed for the assessment of isoflavones by the ANS Panel.

5.4. Draft opinions on (i) coverage of endangered species as non-target organisms in single-stressor environmental risk assessments at EFSA, (ii) the temporal and spatial recovery of non-target organisms for environmental risk assessments, and (iii) accounting for biodiversity and ecosystem services to define protection goals for environmental risk assessment

Robert Luttik, Chair of the Working Group on Overarching Elements of Environmental Risk Assessment, introduced the three above-mentioned opinions, highlighting the fact that they are part of a package aimed at developing a common strategy for environmental risk assessment in the different areas within EFSA's remit and should therefore be considered together. The three draft opinions were submitted so that the Scientific Committee could endorse them for targeted consultation of the EFSA Scientific Panels and the European Commission (from March to April 2015).

The content of the three draft opinions was detailed to the Scientific Committee by Reinhilde Schoonjans, Agnes Rortais and Angelo Maggiore, respectively. The draft opinions will be presented during the Plenary meetings of the relevant Panels. The draft opinions will be published for public consultation probably during the summer and are expected to be finalised by the end of the year.

6. New mandates

None.

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

7.1. Feedback on the work-programme of the Scientific Committee Working Groups:

a. Production and consumption of insects as food and feed

A meeting will be organised with stakeholders on 20 February 2015 to collect data on this topic. It is forecast that a first draft of the opinion will be ready for discussion at the Scientific Committee plenary in June 2015 and that the opinion will then be tabled for possible adoption in September this year.

b. Compendium of botanicals (version 3.0)

The Scientific Committee was informed about the outcome of the kick-off meeting of the procurement aimed at transferring the currently MS Excel®-based Compendium of botanicals reported to contain naturally-occurring substances of possible concern for human health, into the EFSA Data Warehouse. The resulting version 3 of the compendium should be ready by summer 2015.

c. Standing WG on Emerging Risks

The Standing Working Group discussed, during its last meeting, the use of possible risks related to fish farming and resulting products as a first example of a food chain analysis. The working group is encountering difficulties in involving the EFSA Panels in identifying possible emerging issues because of their high workload. The suggestion was made to have joint meetings with Panels working on common areas. This proposal will be further discussed and probably proposed for implementation after the Panels/Scientific Committee's renewal.

d. WG on exposure

The Scientific Committee was informed that the self-task mandate for a harmonised approach to assess exposure from dietary and non-dietary sources is being drafted with the Evidence Management Unit. A consultation phase to map existing guidance and approaches in Member States and international organisations, led by the Evidence Management Unit, will start as soon as possible. The outcome of the consultation activity will be presented to the renewed Scientific Committee who will discuss the need for EFSA guidance and the establishment of a dedicated working group.

e. Update on the establishment of the WGs on Weight of Evidence, Biological Relevance and BMD approach

The compositions of the new working groups on weight of evidence, biological relevance and benchmark dose were presented. The first meeting of the working group on weight of evidence is planned on 19-20 March. The working groups on benchmark dose and biological relevance will start on 15 and 17 April, respectively.

f. Update on the WG on uncertainty

The next working group meeting will take place from 25-27 February in Brussels. Part of the meeting will be dedicated to the discussion of the draft opinion with selected risk managers and risk communicators from DG SANTE and the EFSA Advisory Forum Working Group on Communications.
The draft opinion will be presented during the next plenary meeting of the Scientific Committee for possible endorsement for public consultation until mid-June 2015. Once updated with the comments received, the guidance will be tested by all EFSA Panels (autumn 2014 - summer 2015). The feedback received during the testing phase will then be used to revise the guidance document where necessary. Finalisations of the guidance is expected by the end of 2016.

g. Update on the WG on bees

Agnes Rortais presented the EFSA activities of the newly established MUST-B (MUltiple STressors in Bees) Working Group which will develop a holistic approach for the risk assessment of multiple stressors in bees with the support of the EFSA Bee Task Force comprising members of the SCER, ALPHA, AMU, Pesticides and Risk Communication Units. This will be done after analysing

specific datasets becoming available through outsourcing and other EFSA activities. The WG will have its kick-off meeting on 12-13 March 2015.

h. Update on activities on nanotechnology

Reinhilde Schoonjans informed the Scientific Committee about the publication of the 2014 annual report of EFSA's Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed[10]. The report underlines the need for discriminating methodologies to decide what is *nano* and what is not *nano*; the current EC recommended definition (as well as the method(s) to implement it) should apply to the pristine state of the ingredient rather than to the final product. During its meeting in 2014, the Network dedicated most of its discussions to relevant research results for possible toxic effects following the oral route of exposure.
Feedback on activities on Nanotechnology in EFSA was also on the agenda of the meeting of the Executive Director of EFSA with the European Parliament Committee on the Environment, Public Health and Food Safety that took place on 3 December 2014.

7.2 Feedback from the Scientific Panels:

a. EFSA's work in the area of area of Animal Health and Animal Welfare

Simon More, Chair of the Panel on Animal Health and Animal Welfare (AHAW), gave an overview of the Panel's activities in the last few years. The first area of activity of the Panel is related to both exotic and endemic animal health threat challenges. The second area of activity for the Panel is related to animal welfare, developing good welfare practice and welfare assessment methodologies. Since 2004, the Panel has adopted a total of 85 opinions.

The Scientific Committee acknowledged the huge work done by the AHAW Panel, and noted that many issues addressed by the Panel are actually emerging issues and should be brought to the attention of the Emerging Risk Working Group. The European Commission also reported its appreciation of the work of the AHAW Panel, particularly considering the increasing complexity of the questions the Panel has to answer.

b. EFSA's work in other areas

ANS Panel
During its 55th Plenary meeting, the Panel adopted an opinion on erythritol and another one on ascorbic acid. The Panel is currently working on thickening agents used for infant formulas. As the ADI concept does not cover infants of 3-12 weeks of age, an *ad hoc* discussion on this issue was proposed for the next SC Plenary.

[10] http://www.efsa.europa.eu/en/supporting/pub/762e.htm

GMO Panel
During its January 2015 Plenary meeting, the Panel discussed the possible use of the EFSA Comprehensive European Food Consumption Database for the intake assessment of GM crops.

BIOHAZ Panel
The Panel has had two plenary meetings since the last SC meeting. An opinion on risk ranking and a statement reviewing the organism with qualified presumption of safety (QPS) status were adopted.
The Panel adopted its opinion on the public health risks related to the consumption of raw drinking milk. The opinion led to some discussion with several Member States.
The DG SANTE asked the Panel for a follow-up opinion on the risk of transmission of Ebola virus via the food chain, considering this time legal import.
Following the publication in December 2014 of a scientific article in *Nature Communications* on the zoonotic potential of scrapie, the DG SANTE asked EFSA to scientifically appraise the publication and to provide a conclusion on whether the natural exposure of consumers to ovine products represents a non-negligible risk for public health. The opinion should be finalised by July 2015.

CEF Panel
The Panel, in close contact with the DG SANTE, is currently reviewing its approach for assessing the safety of food contact materials. The Panel is also working to finalise its guidance document on methodologies for the assessment of enzymes, clarifying a number of issues related to the exposure assessment.

NDA Panel
The Panel is having a public consultation of its draft guidance on the scientific requirements for health claims related to the gastrointestinal tract, the immune system and defence against pathogenic microorganisms.
Following the public consultation on the safety of caffeine, the Panel will organise a meeting with stakeholders in Brussels on 5 March 2015 to exchange views on the content of the opinion and address some of the comments received.

The work of the NDA Panel was presented to the Management Board during its 63rd meeting (18 December 2014).

PPR Panel
The Panel discussed the mandate of the Pesticide Steering Network (formerly called Pesticide Steering Committee). The network, which is composed of Representatives of the European Member States' Competent Authorities, provides advice on prioritisation and European risk assessors needs in the development and updating of guidance documents.

The Chair of the Panel brought to the attention of the Scientific Committee the fact that in order to be implemented by the European Member States, a guidance document needs to be "taken note of" by the Standing Committee on Food Chain and Animal Health (PAFF). It was suggested to get the relevant guidances of the Scientific Committee (e.g. benchmark dose, default values) also validated by the PAFF to increase their implementation in the pesticides area.

7.3 Feedback from EFSA:

a. Outcome of the consultation of the scoping paper: Increasing Robustness, Transparency and Openness of Scientific Assessments

Jean Lou Dorne summarised the outcome of the targeted consultation on the draft EFSA Journal editorial "Increasing robustness, transparency and openness of scientific assessments". Comments were received from the European Chemicals Agency, the European Medicines Agency, the EC Joint Research Centre, the Scientific Committees of DG SANTE, the FAO/WHO, the New Zealand Food Safety Authority, the National Toxicology Program and three European Member States' Competent Authorities. This consultation is part of the initiatives in the context of the transformation to an "Open EFSA that has the goals to improve the overall quality of available information and data used for the developments of EFSA's outputs and to comply with normative and societal expectations of openness.

The Editorial will be updated considering the comments received, and a report on the targeted consultation will be prepared, summarising the comments received and how they have been/will be addressed. The Editorial and the consultation report will be published on the EFSA website by the end of March 2015.

b. Possible follow up on the procurement on risk ranking and lessons learnt by the BIOHAZ Panel from a self tasking activity

The SC was presented with the outcome of the procurement on risk ranking[11]. The objective of this outsourced research project was to critically review existing methodologies and the application of risk ranking for the prioritisation of food and feed related issues on the basis of the anticipated health impact.

The SC took note of the results, underlining the fact that each of the proposed methodologies has its pros and cons and it will be difficult for a Panel to come with a specific method; depending on the type of questions received by the Panels and on the data that are available, the methodology for prioritisation to be used will vary. The SC also underlined that very often, there is not sufficient information to perform a risk ranking. In the first instance the prioritisation is made by discussing the problem formulation and deadlines with the risk managers.

A number of possible (risk) ranking activities in EFSA were proposed for discussion:

- Prioritisation of incoming mandates: EFSA reported that work is in progress, as there is a need to integrate not only risk/public health considerations, but also urgency for the risk manager and available resources considerations.
- Risk ranking of botanicals and botanical preparations: the usefulness of some of the proposed methodologies to prioritise the assessment of

[11] http://www.efsa.europa.eu/en/supporting/pub/710e.htm

botanical preparations, should such need arise at some point, was acknowledged. The criteria for the priority setting could be identified as a preparatory step.

- Prioritisation of the EU risk assessment agenda: A priority setting of the EU risk assessment agenda items based on a structured approach was welcomed by the Scientific Committee who suggested bringing the procurement report to the attention of the Advisory Forum.
- Prioritisation of EFSA's research needs to be considered under Horizon 2020: the Scientific Committee supported the idea of a further prioritisation of the topics sent to DG Research and Innovation and DG AGRI. A suggestion was made to use expert knowledge elicitation.
- Development of an evidence database, i.e. ranking of the substances evaluated by EFSA according to a common risk matrix such as burden of disease metrics for the European population. The idea is to go further than the chemical hazard database currently being developed and complement it with additional data on exposure or burden of disease. The Scientific Committee noted that this activity would be very challenging and require a multi-annual programme, also involving other EFSA Partners.

The lessons learned by the BIOHAZ Panel on risk ranking were presented by Kostas Koutsoumanis (participating via conference call), member of the BIOHAZ Panel and WG chair. In 2012, the Panel developed a risk ranking framework for biological hazards, as well as a risk ranking toolbox in 2015. Eight tools were reviewed and their actual performance for the Panel's needs was evaluated[12]. Dr. Koutsoumanis underlined the fact that performing risk ranking to a high standard, (using quantitative methods) takes a lot of time and resources. It is subsequently has to be agreed with the risk managers when such a high standard is needed.

c. Report back on issues relevant for the Scientific Committee

The SC was update on the outcome of the 63rd Management Board meeting held on 18-19 December 2014, on the 54th Advisory Forum meeting, held on 10-11 December 2014 and on the stakeholder consultative platform meeting held in Brussels on 19-20 November 2014.

The SC was also informed about the international scientific cooperation activities of EFSA and the relative outcomes, particularly multi-lateral and bilateral meetings with international bodies that took place since last SC plenary.

8. Other scientific topics for information and/or discussion

8.1 Consultation of the Swedish National Agency on the draft report on Risk Thermometer

Salomon Sand (participating via conference call) presented the draft report "The risk thermometer" subject of a public consultation by the Swedish National Food Agency. The Risk Thermometer aims at communicating levels of risks to the

[12] http://www.efsa.europa.eu/en/efsajournal/pub/3939.htm

"customers". The systematic use of this new approach should allow for the grouping of substances used in food based on their risk level.

The outcome of the discussion will be summarised in a document to be sent to the Swedish National Food Agency as a contribution from EFSA to the consultation.

9. Any other business

New courses for panel members and EFSA staff on specific aspects of risk assessment and on expert knowledge elicitation:

Participants were updated on the dates and place of the next plenary meetings. The six non-Panel Chairs of the new Scientific Committee, whose mandate will run from July 2015 to July 2018, will have their induction day in Parma on 1-2 July.

The Scientific Committee was briefly informed about the new advanced training courses in risk assessment that will take place from 2015 to 2017. The following courses will run in 2015:

- Use of the benchmark dose approach in risk assessment
- Environmental Risk Assessment
- Computational toxicology
- Expert knowledge elicitation
- Probabilistic judgements (e-learning)
- Systematic review (both basic and advanced trainings)
- Environmental risk assessment

The list of the various courses, as well as the dates when they will take place, will be circulated to the Scientific Committee once finalised.

External review of the impact of scientific grants and procurement projects:

Kerstin Gross-Helmert presented the outcome of the external review of the impact of grants and procurement. The review considered not only the terms of reference and deliverables of the projects, but also their duration, budget, number of partners, as well as the outcome of a survey and interviews with organisations who took part between 2009 and 2012 in these calls for grants and procurement, or applied for some of them.

Grants and procurement are seen as having an important role in supporting EFSA in its task delivery but also in facilitating collaboration between Member States' organisations. A number of suggestions were made to increase incentives for applying, improve project monitoring, increase the dissemination of the calls and the impact of the projects' outputs.

Update on the EXPO 2015 scientific conference:

Andrea Germini updated the participants on the EFSA 2nd scientific conference – "Shaping the future of food safety, together", that will take place on 14-16 October 2015 on the occasion of the EXPO 2015 in Milan. The deadline for registration is 15 May 2015. All experts of the new Panels and Scientific Committee will be invited to participate. The members of the Scientific Committee were invited to advertise the poster session (deadline for the abstract: 3 April 2015), as well as the opportunity offered to young researchers who have their poster abstract selected to have their travel and accommodation costs covered by EFSA.

Annex I

Interests and actions resulting from the oral declarations of interests done

at the beginning of the meeting

a) With regard to this meeting, Dr. Gijs Kleter declared that one of his colleagues has been involved in the subcontracted work on risk ranking (see point 7.3b of these minutes). The expert himself was not involved in this work. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of Interest for the expert concerned.