

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

**Scientific Committee
Minutes of the 67th plenary meeting
Held on 03 – 04 April 2014, Parma
(Agreed on 20 June 2014)**

Participants

• **Scientific Committee Members:**

Tony Hardy (Chair), Jan Alexander, Diane Benford, Qasim Chaudhry, Arie Havelaar, Christer Hogstrand¹, Michael John Jeger¹, Robert Luttik, Ambroise Martin, Alicja Mortensen, Birgit Nørrung, Bernadette Ossendorp, Joe Perry², Josef Schlatter, Hans Hermann Thulke¹, Detlef Wölfle².

• **European Commission and/or Member States representatives:**

- Michael Walsh (DG Health and Consumers)

• **EFSA:**

- **Executive Directorate:** Bernhard Url, Hubert Deluyker
- **Communications Department:** Alessia Vecchio
- **RASA Department:** Marta Hugas, Didier Verloo, Elisa Aiassa, Fulvio Barizzone, Laura Martino
- **REPRO Department:** Karine Lheureux, Camilla Smeraldi, Andrea Terron
- **SCISTRAT Department:** Juliane Kleiner, Stef Bronzwaer, Djien Liem
- **SCER Unit:** Tobin Robinson, Andrea Altieri, Bernard Bottex, Arianna Chiusolo, Jean-Lou Dorne, Andrea Germini, Tilemachos Goumperis, Daniela Maurici, Agnès Rortais, Reinhilde Schoonjans.

¹ Present on 3rd April

² By teleconference

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from John Griffin, chair of the BIOHAZ Panel, replaced by the vice chair Arie Havelaar; Simon More, chair of the AHAW Panel, replaced by the vice chair Hans Hermann Thulke and Kristen Sejrsen, chair of the FEEDAP Panel.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁴, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest 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 at the Oral Declaration of interest at the beginning of this meeting.

4. Agreement of the minutes of the 66th Plenary meeting held on 18 – 19 February 2014.

The minutes were adopted without changes.

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

5.1 Draft Opinion on Carvone (EFSA-Q-2013-00290) - for discussion and possible adoption

The Scientific Committee (SC) reviewed the draft opinion. Comments and requests for modifications received during the discussion will be implemented in a new version of the draft opinion. The draft opinion will be presented for possible adoption at the next Plenary meeting.

5.2 Draft technical report on emerging risks identification in the domain of biological risks to animal and public health: a pilot study (EFSA-Q-2014-00077)

The Scientific Committee(SC) discussed the draft technical report. It was highlighted that this is to be seen as an interim report contributing to the development of the overall emerging risks identification process. The SC commented on the conclusions of the report pointing out that, although the concept of drivers and issues has been applied here to the identification of emerging risks of biological nature, similar concepts would apply also to chemical risks; a joint approach could therefore be possible. The SC agreed with the conclusion that some of the expertise relevant to evaluate drivers of emerging risks in the food chain lies outside the current expertise present in EFSA (e.g. consumer behaviour, economics, ...). It was agreed that EFSA should investigate ways to have access to such expertise which is crucial to be able to predict emerging risks.

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

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

⁵ [EFSA Register of questions](#)

The report was already presented for comments to the members of the AHAW, BIOHAZ and PLH Panels. The SC was invited to send any further comment to the secretariat with a view to finalising the text and publishing the report by the end of April 2014. The SC also suggested disseminating the report through the EFSA networks once published.

6. New Mandates

The Scientific Committee discussed the mandates proposed for the activity of the WGs.

6.1 Revision of the SC guidance on the use of Benchmark (BMD) dose approach

The Scientific Committee was presented with an overview of the feedback gathered by the SC Secretariat regarding the implementation of the benchmark dose approach by EFSA's Scientific Panels during the last five years. A list of issues to be considered for updating the guidance on the use of the benchmark dose approach in risk assessment adopted by the Scientific Committee in 2009 was discussed.

The SC agreed to initiate this new activity. In agreement with the Head of Unit and the SC chair, Joseph Schlatter was appointed as chair of the Working Group that will prepare the draft opinion.

6.2 Use of the weight of evidence approach in risk assessment

The Scientific Committee discussed the mandate proposed for the activities of the WG. The chair of the SC briefly presented the discussion on weight of evidence that took place at the last meeting of the WG on Uncertainty where the possible interaction between these two WGs and also with the WG on Biological Relevance for toxicology that will soon be established were investigated. The SC agreed that there are specific aspects of the work that would deserve the establishment of a stand-alone WG on weight of evidence; it was nevertheless highlighted that the WG should work in close collaboration with the WG on Uncertainty and the WG on Biological Relevance. The working group should also consider the ongoing activities of the EFSA Evidence Base for Risk Assessment programme (see item 8.2).

In agreement with the Head of Unit and the SC chair, Qasim Chaudhry was appointed as chair of the WG. Ongoing international activities in this field will be considered by the WG while developing the detailed work-programme.

The mandate will be amended to take into account the comments made by the SC prior to the submission to EFSA's Mandate Review Committee. It was also agreed to broaden the scope of the mandate to "the use of the weight of evidence in scientific assessment" in order to encompass all EFSA's activities.

6.3 Biological relevance

The Scientific Committee discussed the mandate proposed for a new activity aiming at providing EFSA's Panels with a list of criteria and generic issues to consider in order to decide whether an observed effect is biologically relevant.

The SC agreed to initiate this activity. In agreement with the Head of Unit and the SC chair, Jan Alexander was proposed as chair of the Working Group who will prepare the draft opinion. The WG will work in close collaboration with the WG on Uncertainty and the WG on Biological Relevance.

6.4 Standing WG on genotoxicity

The Scientific Committee agreed on the mandate proposed which outlined the need to establish a standing WG to provide ad hoc assistance to the Panels in the interpretation of the existing SC guidelines on assessing genotoxicity. Nominations for chairmanship of this WG will be discussed between the chair of the SC and the head of the SCER Unit. Members

of the WG will be genotoxicity experts of the different EFSA Panels. It is expected that the WG will become operational in the coming months. Ad hoc requests to the WG should be put forward by the chair of the Panel requesting the advice.

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

7.1 Feedback from the Scientific Panels:

a. Report back of Panels Chair on issues of common interest for the SC and on guidance documents under public consultation

ANS

The Panel adopted one opinion at its last plenary. The Panel is currently discussing the conceptual framework for the re-evaluation of food additives.

BIOHAZ

John Sofos resigned as Chair of the Panel. The Panel elected John Griffin as new Chair with the consequence that the vice chair position he was previously occupying became vacant. Paul Cook was elected as vice-Chair. Arie Havelaar will continue to serve as the second vice chair of the BIOHAZ Panel.

The Panel is organising a workshop on the applicability of the Numeral Unit Spread Assessment Pedigree (NUSAP) methodology to characterise uncertainty in risk ranking. The Panel has initiated a mandate on the public health risks related to the consumption of raw milk.

The opinion on the safety and efficacy of peroxyacetic acid (PAA) solutions for reduction of pathogens on poultry carcasses and meat was adopted and published.

The Panel will set up a WG on the maintenance of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA.

CEF

The public consultation on the scientific opinion on Bisphenol A (BPA) closed at the 13th of March and received over 200 comments. A stakeholder meeting to discuss the draft opinion and the received public comments will be held in Brussels on the 23rd of April.

CONTAM

The Panel held an extra plenary meeting to make progress in the opinion on Acrylamide. The opinion is expected to be endorsed in May and then published for public consultation.

The Panel is discussing whether there is a need for a self task mandate to define criteria on when to update already published opinions. The Panel considers that such a topic should not be addressed at individual panels' level, but rather be part of the discussion on guidance lifecycle currently considered by the SC WG on Guidance Review.

GMO

The Panel has further defined its strategy for dealing with GM stacked events and recently adopted by written procedure one opinion on a GM stacked cotton. Progress is now envisaged for other dossiers concerning GM stacked events.

The next meeting of the Panel will be a plenary open to public: 43 observers have registered to attend.

NDA

No Panel meeting was held since the last SC plenary. The Panel is currently working on the finalisation of several opinions including a report on food allergy, and the definition of dietary reference value (DRV) for iodine. The endorsement of the opinion on caffeine for public consultation has been postponed and it is now expected to be finalised by December 2014. Assistance was requested to the SC to support the WG on caffeine and critically help in the finalisation of the opinion. Jan Alexander, Diane Benford and Josef Schlatter were selected as members of the SC that will be invited to join the WG.

The adoption of the opinion on the benefit of fish consumption has also been postponed to allow for further consultation with the CONTAM Panel and the SC. Two opinions on DRV for zinc and folates and one on the essential composition of infant and follow-on formulas are expected to be endorsed soon and published for public consultation.

PPR

The Communications Department identified pesticides as one of the topic that they intend to promote this year; the topic will be given extra emphasis on the EFSA website.

The Pesticides Unit developed a new guidance document for non-dietary exposure assessment of operators, workers, residents and bystanders to plant protection products, which is currently published for public consultation. The consultation will close on 20th May.

b. Draft mandate of the PPR Panel on literature review on epidemiological studies linking exposure to pesticides and health effects

The SC was presented with the draft self-task mandate where the PPR Panel is requested to prepare a Scientific Opinion investigating experimental toxicology data of pesticides and their potential link to Parkinson's disease and childhood leukemia, based on the findings in the Ntanzu et al., report (2013).

The SC welcomed the presentation and asked to be kept informed on the progress. The results of this work will be considered by the SC when developing a guidance document on interpretation of human epidemiological data, probably in 2015.

c. Feedback on ANS Panel activities

Activities of the WG on isoflavone (EFSA-Q-2013-00916)

The mandate for the activity of this WG originates from a request from Germany through BfR to EFSA. While the efficacy of isoflavones has already been covered in the health claims evaluation performed by NDA Panel, the terms of reference of this activity focus on the potential adverse effects associated with intake of isolated isoflavones in food supplements in peri- and postmenopausal women. The WG will evaluate data from human and animal studies and focus on possible harmful effects on mammary gland, uterus and thyroid and the mode of action for these effects. The WG will also estimate the exposure of the target populations to the isolated isoflavones from food supplements and advice on a safe intake level.

This mandate will be used as a case study to implement the EFSA Methodological Framework for the Evidence Base for Risk Assessment currently under development by the Assessment and Methodological Unit (see section 8.2 of these minutes).

Deadline for the completion of the activities is September 2015.

The SC welcomed the presentation and highlighted that the exposure assessment will be very complex due to the variety and different composition of food supplements available on the market and containing isoflavones.

Conceptual framework for the risk assessment of certain food additives

The ANS Panel is developing a conceptual framework supporting their process of re-evaluation of food additives. Such framework is needed since open calls for scientific data on additives under re-evaluation often do not result in the receipt of the information needed for the risk assessment. This work aims primarily at defining the general principles for determining the outcome of the risk assessment of certain food additives under re-evaluation on the basis of available data, thus allowing for abbreviated outputs of risk assessments. Such an approach would increase the transparency and the consistency in the ANS Panel approach for the re-evaluation of food additives. A stakeholder workshop is expected to take place to discuss the framework and hopefully will help increasing the response rate of interested parties to the next calls for data.

The SC highlighted that, although there are food additives currently authorised in the EU at *quantum satis* use or with ADI not specified, in the case of lack of data on exposure it will be difficult to conclude on the probability of adverse effects. Therefore the specific calls for exposure data and the use of additionally uncertainty factors needs to be considered in the assessment.

7.2 Feedback on the work-programme of the SC Working groups:

a. Compendium of Botanicals (version 3.0):

No meeting of the WG has taken place since the last plenary. A call for tender is being prepared to outsource the reorganisation of the Compendium and part of data collection for its further expansion. The call is expected to be launched in June and the contract is expected to start in September 2014.

b. Standing WG on Guidance Review:

The WG on guidance review will prepare a statement describing the various types of cross cutting guidance documents developed by the Scientific Committee, the process and periodicity for reviewing/updating guidance and the criteria for prioritisation of subjects for guidance development. This document will help in getting better uptake of the SC guidance documents by the EFSA Panels.

c. Environmental Risk Assessment (ERA):

The Scientific Committee was informed about the ongoing discussions and ideas for hazard assessment in the absence of data on the endangered species itself. Such hazard assessment can be based on tests with standard test species or surrogate species with or without the use of extrapolation factors to cover for the variability in sensitivity that exists. It was reminded that as is also the case for human health hazard assessment, the use of extrapolation factors can be problematic in view of the existing variability in toxicity values between and within a species.

The WG held its first meeting fully dedicated to the topic of recovery. The representatives from the different areas (PPR, GMO, plant health) shared experiences with this concept in their respective ERA schemes. The outline of the draft opinion will be presented at the next SC plenary.

d. Uncertainty in Risk Assessment:

The timeline for the activities of the WG foresees the development of a draft guidance document by February 2015 followed by a public consultation. The revised guidance is expected to be presented for SC endorsement in May 2015 and then go through a try-out-phase in the different Panels. The guidance document and case studies are then expected to be completed by mid 2016. The WG is planning to organise its next activities in sub-WGs addressing the different approaches considered to address uncertainty in risk assessment, namely i) qualitative, ii) semi-quantitative, iii) deterministic and iv) probabilistic. In particular the WG is now gathering information from the WG members, in consultation with the Chair of their Panel, on the guidelines developed by international organisations/research papers dealing with uncertainty in the Panels' remit.

The SC highlighted the importance of the continuous consultation with the Panels as well as the case studies planned for the try-out-phase.

e. Standing WG on Emerging Risks:

The call for the procurement following up from the recommendations in the Technical report prepared by the sub-WG dealing with chemical Emerging Risks has been published on the EFSA website. The call will close in mid June.

The update of the activities of the sub-WG dealing with Emerging Risks of biological nature was provided under point 5.2.

f. Activities on Emerging Risks:

The SC was presented with a technical report covering the activities on Emerging risks (EmRisk) carried out in 2012 and 2013. The report provides an update of the activities of the EmRisk Network, the EmRisk Stakeholder Consultative Group and the SC standing WG on Emerging Risks. The report presents the results obtained in terms of issues identified and follow-up actions, an update of the developments in the EFSA's strategy for emerging risk identification, the knowledge networks established, and indication on next steps and future direction of EFSA's work in the area of emerging risks. The report also highlights the future steps which include a further engagement with Member States and Stakeholders, the appraisal of the procedure by the SC's Standing WG on Emerging Risks and the completion of the ongoing activities on the issues identified.

The SC appreciated the shift from collection of concerns to a more focused analysis of specific topics. The SC requested the Unit to update the information on the EFSA website to have the Emerging Risks identification process presented in a clearer and more accessible manner to all stakeholders.

7.3 EFSA:

a. Report back on issues relevant for the Scientific Committee

The Management Board nominated Bernhard Url as new EFSA Director during its meeting held on 20th March. As part of the appointment procedure, Dr Url is scheduled to present himself at a meeting of the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee on 14 April, 2014 and answer any questions they may have.

The Board also appointed 21 independent scientific experts to the Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) and 19 to the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel), for a three year term.

Check of the annual Declaration of Interest of selected experts is currently ongoing.

b. Update on the activities of the Applications Desk Unit (APDESK)

The SC was presented with an overview of the activities carried out by the APDESK Unit. The role of APDESK is to centralise and harmonise the workflow on applications for regulated products. In doing so, APDESK performs the administrative task and the completeness check but also performs a scientific check, in cooperation with the relevant Unit(s). Electronic submission is in the long term development plan for the unit and is expected to push applicants to provide more consolidated dossiers containing all the required information for their applications or justification for not providing the data.

The SC suggested that the information presented concerning the workflow of applications, with indication of timeline depending on the legislative framework applicable, and the overview table of the regulatory frameworks and the related existing EFSA guidance documents should be made more visible in the EFSA website. This would provide clearer guidance to applicants and more transparency for stakeholders in general.

c. Update on the activities of the Advisory Forum and Scientific Cooperation Unit (AFSCO)

The SC was presented with the ongoing and upcoming activities of the AFSCO Unit. With regard to trainings, the SC was informed about the progress of the EC programme on Better Training for Safer Food (BTSF), on the launch of a pilot programme on Guest Scientists and Staff Exchange. The EFSA expert database (EDB) has been constantly growing over the past years and now includes more than 3600 experts. A survey on EDB users was performed and the outcome will inform future directions to be taken on expert selection tools.

The Article 36 list of competent organisations has been updated and an external review of the impact of the past grants and procurement projects on EFSA's work is currently ongoing.

EFSA currently maintains 14 Scientific Networks whose members are nominated by the Advisory Forum. It is proposed to use further these networks to get feedback on work planning and possible contentious scientific issues.

The SC was also informed that a Scientific Cooperation Roadmap covering the timeframe 2015-2018 is currently under development and will be presented at the Management Board in June.

8. Other scientific topics for information and/or discussion

8.1 New structure of EFSA's scientific outputs

The Scientific Committee discussed the final draft proposal for the new structure of the EFSA opinions and statements. The SC proposed that Panels should test the new structure with an already published opinion to identify possible difficulties in the implementation of the revised format. The feedback on this testing will be collected before the format is finally adopted by the SC at its next plenary.

8.2 Evidence base for risk assessment: conceptual and methodological framework

The Scientific Committee was presented with a recap of the objectives of the Evidence Base for Risk Assessment programme and with an update of progress since the last SC plenary. The presentation addressed in particular the points previously raised by the SC and how they were addressed with a focus on the practical feasibility of the approach in EFSA's context. In this regard, a tiered approach was proposed to address the different needs of EFSA's assessments. Ongoing activities concern addressing the applicability of the programme to dossiers submitted in EFSA regulated frameworks and its implementation in case studies (see section 7.1c of these minutes). Alicja Mortensen, Ambroise Martin and Simone More were appointed as contact points to provide feedback on the document on behalf of the Scientific Committee.

The Scientific Committee reiterated its comment on the need to focus the programme on the applicability to dossier assessments and its practical implementation in EFSA's daily work. It would be important to collect the views from the Panels in relation to the relevance for their work, the difference from their current practice or the needs to be adapted for their work.

The SC proposed a reality check of what would be feasible to implement in the daily risk assessment carried out by EFSA Panels to be performed before finalisation of the document.

The SC pointed out that several parallel initiatives are currently ongoing in EFSA (i.e. uncertainty; weight of evidence; biological relevance; evidence base for risk assessment; expert knowledge elicitation). It is suggested that EFSA develops an overarching document providing experts with the overall picture of the outcomes of these activities and their impact on the Panel's work.

8.3 Update from the EFSA's Journal Editorial Board

The Editorial Board of the EFSA Journal met on 2 April. A review of Journal operations is underway to address editorial quality and efficiency. A presentation on the work ongoing will be prepared for the next SC plenary meeting.

9. Any other business

- Changes in the DoI tool

The SC was briefly presented with an update of the changes in the Declaration of Interest tool. It was highlighted that the changes affects only newly declared interests.

- EFSA Panels renewal

The call for the renewal of 8 of its 10 Panels and the SC will be published the 9th of April on the EFSA website. EFSA initiated already a promotional campaign to advertise the call. The SC suggested that the renewal of all the EFSA Panels should be synchronized

to avoid disruption in EFSA's activities. The issue has been discussed with the European Commission but synchronisation would require revising the EFSA Founding Regulation, which is not foreseen for the moment.

- **Open SC plenary meeting, 8-9 July 2014**

The SC was informed that the plenary meeting of 8-9 July will be open to observers. The draft agenda will be published at the end of May.

- **Proposal to go paperless in SC meetings**

The SC welcomed the proposal to receive only paper copies of the agenda and of the presentations tabled at its plenary meetings but not print outs of the documents presented for information and/or discussion.

- **Experts' CVs on EFSA website**

The Scientific Committee discussed the proposal to publish a short CV of the experts on the EFSA website instead of the biographies as currently available. This would align EFSA with what is being done by other agencies (e.g. EMA publishes a kind of simplified Europass CV of their experts). EFSA will come back to the SC with a proposal for harmonizing CV information to be made available on its website.