

15 September 2015
EFSA/SC/1962

Scientific Committee

Minutes of the 74th Plenary meeting Held on 23 July 2015, Parma (Agreed on 15 September 2015)

Participants

■ Scientific Committee Members:

Tony Hardy (Chair as from agenda item 5), Diane Benford, Lutz Edler, Thorhallur Halldorsson, Kostas Koutsoumanis, Michael Jeger, Simon More, Alicja Mortensen, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford, Josef Schlatter, Roland Solecki, Vittorio Silano, Dominique Turck.

■ European Commission:

none

■ EFSA:

- **Executive Directorate:** Bernhard Url, Hubert Deluyker
- **COMMS Directorate:** Alberto Spagnolli, Djien Liem, Jeff Moon (agenda item 7.3a)
- **RASA Department:** Marta Hugas, Laura Martino (agenda item 7.1)
- **REPRO Department:** Juliane Kleiner
- **RESU Department:** Dirk Detken (agenda item 4)
- **SCER Unit:** Tobin Robinson, Bernard Bottex, Jean-Lou Dorne, Andrea Germini, Tilemachos Goumperis, Angelo Maggiore, Daniela Maurici, Caroline Merten, Agnes Rortais.

1. Welcome and apologies for absence

Tobin Robinson welcomed the participants. Apologies were received from Helle Katrine Knutsen, chair of the CONTAM Panel, substituted by Lutz Edler; Antonia Ricci, chair of the BIOHAZ Panel, substituted by Konstantinos Koutsoumanis; Guido Rychen, chair of the FEEDAP Panel, and from Panagiotis Daskleros (DG Sante).

The Executive Director welcomed the new Scientific Committee (SC) members and outlined the roles and responsibility of the Scientific Committee (SC) in guaranteeing consistency and harmonisation of working methods and procedures, handling multi-sectorial issues, coordinating panels' work programs and emerging issues. The ED also focused on the SC key role in EFSA's strategic vision, in fostering innovation, cooperation within EFSA, the EU, internationally and in engaging with society and the scientific communities.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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.

4. Election of the Scientific Committee Chair and Vice Chairs

Dirk Detken explained the applicable legal framework for the election of the chair and the two vice-chairs of the SC.

Prof. Anthony Hardy was re-elected chair of the Scientific Committee for a second three-year term. The newly elected Vice-Chairs are Dr. Diane Benford and Dr. Hubert Noteborn.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

5. Scientific outputs submitted for discussion and possible adoption.

None.

6. New mandates

EFSA received a request from the Commission DG Sante to provide scientific assistance (art. 31 of the Regulation (EC) No 178/2002) on the review of the research paper recently published by Prof. Seralini in the PLoS ONE Journal³ and laboratory studies conducted by Dr. Samsel⁴. Both studies test animal feed diets used in regulatory toxicology tests.

In addition, the Commission requested EFSA to address the issue of contaminants in feed of animals used in toxicology tests.

A task force will be set up to address this request for advice. The time limit for completion of the task (agreed with the Commission) is the end of September 2015.

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

7.1 Feedback on the work-programme of the Scientific Committee (SC) Working Groups (WGs):

- SC Work programme 2015-2018: proposal of new activities to be initiated

The SC discussed the work programme for its new three year mandate. Tobin Robinson proposed a list of possible new activities to be initiated, with a brief explanation on the background, possible Terms of Reference for the Mandate and priorities. Some of them had been assessed as priority topics for the development of risk assessment guidance by the SC in 2013⁵. The Scientific Committee had an initial preliminary discussion on them and agreed to have a more thorough one in the September plenary.

In addition, Tobin Robinson mentioned the Commission DG Sante mandate to the ANS Panel to consider the safety of food additives already authorised for infants and young children in sub food category 13.1, as reported in the Annex II to Regulation (EC) No. 1333/2008⁶, when extending their use as food supplement.

³ Mesnage R, Defarge N, Rocque L-M, Spiroux de Vendômois J, Seralini G-E (2015) Laboratory Rodent Diets Contain Toxic Levels of Environmental Contaminants: Implications for Regulatory Tests. PLoS ONE 10(7): e0128429. doi: 10.1371/journal.pone.0128429

⁴ <http://farmwars.info/?p=14095>

⁵ EFSA Scientific Committee, 2013. Scientific Opinion on Priority topics for the development of risk assessment guidance by EFSA's Scientific Committee. EFSA Journal 2013;11(8):3345, 20 pp. doi:10.2903/j.efsa.2013.3345

⁶ Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on Food Additives

Considering the horizontal nature of this issue, at the 72nd SC plenary it was agreed to set up a SC WG to develop a guidance addressing specific aspects to be considered for the safety evaluation of infants less than 12 weeks of age. The SC WG will be chaired by Alicja Mortensen, chair of the ANS Panel.

▪ On-going work programme of the Scientific Committee and agreement on the appointment of WG Chairs:

The Scientific Committee, in particular its new members, were presented with the on-going activities of the different Working Groups and Networks.

➤ WG Insects as food and feed (EFSA-Q-2014-00578)

The SC was presented with a summary of the activities of the Working Group on Safety risks arising from the production and consumption of insects as food and feed, focusing in particular on the workshop with relevant stakeholders which was held on 19 February 2015 and the discussion of the draft opinion at the last Scientific Committee plenary (9 June 2015). The draft opinion will be discussed at the 75th SC plenary in September for possible adoption. Birgit Nørrung will continue as chair of the WG.

➤ WG Compendium of botanicals (vers 3.0) (EFSA-Q-2012-00486)

The SC was presented with a summary of the activities of the WG, focusing in particular on version 3 of the Compendium of botanicals reported to contain naturally-occurring substances of possible concern for human health and the results of the on-going procurement for the transformation and further development of the Compendium.

The mandate of the WG, as well as the procurement procedure, will end in December 2016.

Vittorio Silano (chair of the CEF Panel and already member of the WG) was appointed as new chair.

➤ WG on Weight of Evidence (EFSA-Q-2015-00007)

The SC was presented with a summary of the activities of the WG on "The Use of the weight of evidence approach in scientific assessments", focusing in particular on its composition (one EFSA staff member from each unit, representation from panels, external experts including those from sister agencies like ECHA and EMA), guidance development and timelines. Maged Younes (member of the ANS Panel) was appointed as new chair.

➤ WG Biological Relevance (EFSA-Q-2014-00746)

The SC was presented with a summary of the mandate of the WG that consists in providing the EFSA Panels with criteria and concepts to decide on the relevance of an effect for their assessment. The importance for all the Panels to be represented in the WG was therefore highlighted. Jan Alexander, member of the CONTAM Panel, was confirmed as Chair of the WG.

➤ WG on Benchmark Dose approach (EFSA-Q-2014-00747)

The SC was presented with a summary of the issues which are being addressed in the update of the 2009 SC guidance on the use of the benchmark dose approach in risk assessment. A targeted consultation of the relevant Panels is foreseen early in 2016 and the update of the guidance should be finalised around May 2016. The members of the Scientific Committee were also reminded about the trainings on benchmark dose that will be organised by EFSA during the second half of 2015; they were warmly invited to advertise these trainings to their panels and to attend them. Josef Schlatter, member of the Scientific Committee, was confirmed as Chair of the WG.

➤ WG on Bees (EFSA-Q-2014-00881)

The SC was presented with a summary of the activities, timelines and deliverables of the MUST-B project (Multiple STressors in Bees) coordinated by the SCER Unit and currently including three working groups: the MUST-B WG coordinated by the SCER Unit, the HEALTHY-Bees WG coordinated by the ALPHA Unit, and the BEEHAVE WG whose activity has now been completed and was coordinated by the Pesticides Unit. The MUST-B project is further supported by the EFSA staff: the Bee Task Force gathering representatives of each involved Unit. The different tools (modelling, experimental and monitoring) and their relationships (in terms of timing and data requirement) for the development of a holistic approach to the risk assessment of multiple stressors in bees were illustrated. Simon More will continue to be chair of the WG.

➤ WGs on Environmental Risk Assessment

The SC was presented with a summary of the aim, activities, deliverables and composition of the WGs on overarching elements of environmental risk assessment (ERA).

The SC was reminded that on 22 June, EFSA launched open consultations on the three draft scientific documents on ERA for potential stressors (e.g. plant protection products, genetically

modified organisms, invasive plant pests, feed additives) that fall under the remit of EFSA. These documents are:

- Draft guidance document to define protection goals for ERA in relation to biodiversity and ecosystem services (EFSA-Q-2013-00289). This draft document presents a framework which accounts for biodiversity and ecosystem services, to make policy protection goals operational for use in EFSA's ERA.
- Draft opinion on coverage of endangered species in environmental risk assessments at EFSA (EFSA-Q-2013-00901). The draft opinion reviews the characteristics that determine vulnerability of endangered species and reviews whether or not endangered species can suffer more than non-endangered species from assessed potential stressors in an agricultural context.
- Draft opinion on the temporal and spatial ecological recovery of non-target organisms for environmental risk assessments (EFSA-Q-2013-00902). This draft opinion presents an integrative approach based on well-defined specific protection goals, scientific knowledge derived by means of experimentation, modelling and monitoring, and the selection of focal taxa, communities, processes and landscapes to develop environmental scenarios to allow the assessment of recovery of organisms and ecological processes at relevant spatial and temporal scales.

Interested parties are invited to submit written comments by 10 September 2015, through the following link:

<http://www.efsa.europa.eu/it/consultations/call/150622.htm>.

Theo Brock (vice-chair of the PPR Panel) was appointed as chair of the three working groups.

➤ WG Uncertainty in RA (EFSA-Q-2013-00738)

The SC was presented with a summary of the aim, activities, deliverables and composition of the WGs on Uncertainty in Risk Assessment. The WG has developed a draft guidance document on how to characterise, document and explain all types of uncertainty arising in EFSA's scientific assessments.

The Scientific Coordinator reminded the meeting participants that EFSA has launched public consultations on this draft document. Interested parties are invited to submit written comments by 10 September 2015 (link [here](#))

After the public consultation, comments will be addressed and the final draft of the guidance will be endorsed by the SC for a trial period of about one year by each Panel. The outcome of this testing phase will be used to further revise the Guidance

Document before its finalisation foreseen end of 2016-beginning of 2017.

Tony Hardy was appointed as chair of the WG.

➤ Scientific Network on Nanotechnologies

The SC was presented with a summary of the aim, activities, composition and deliverables of the Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed, which was established in 2010 with the aim of enhancing exchange of information and data between EFSA and Member States (MS).

The Network is composed of representatives from MS. There are also observers from the European Commission (DG Sante and JRC). The Network delivers an annual report on its specific activities and achievements.

The SC was informed about the outcome of the last network meeting held on 7-8 July 2015 and about the inventory of nanotechnology applications already present in the agricultural, feed and food sector. The purpose of this inventory is to estimate possible upcoming requests for safety assessment of substances produced in nano form.

➤ Emerging risks network (EREN)

The SC was presented with a summary of the aim, composition and expected deliverables of the Emerging Risks Exchange Network, which is the principal body for exchanging information on emerging risks to food and feed safety between EFSA, Member States, Commission, EU-agencies and international organisations. EREN was established in 2010 and its meetings are held twice a year. The last meeting was held on 14-15 April 2015 in Parma and the next one is scheduled on 25- 26 November 2015 in Madrid.

➤ Stakeholder Consultative Group on Emerging Risks

The SC was presented with a summary of the aim, composition and expected deliverables of the Stakeholder Consultative Group on Emerging Risks. This group brings together representatives of consumers, food producers and processors and was established in 2010. The 2015 report on Stakeholder Group activities in the area of emerging risks will be published by the end of the year. The Stakeholder Consultative Group meets twice a year. The last meeting was held on 5 May 2015 in Brussels.

➤ Other related activities: the PROMETHEUS Project (EFSA-Q-2014-00896)

Laura Martino from the Assessment and Methodological Unit described the PROMETHEUS project (Promoting Methods for

Evidence Use in Scientific assessments) (2014-2016), which aims at defining the principles for evidence use in scientific assessments and critically evaluating the available methods to fulfil these principles (e.g. collecting data, appraising and integrating evidence, ensuring transparency, data accessibility, etc.).

The deliverables and timelines were indicated. The first deliverable consisted in the scientific report "Principles and process for dealing with data and evidence in scientific assessment" and was published in June 2015⁷. The following scientific reports are now being prepared: "Gap Analysis of methods for dealing with data and evidence" and "Impact analysis of implementing PROMETHEUS approach in EFSA". Once finalised, these documents will be presented to the SC for endorsement. The foreseen publication date is October 2016.

7.2 Feedback from the Scientific Panels

Due to time constraints, this was postponed to the September meeting.

7.3 Feedback from EFSA:

a. Report back on issues relevant for the Scientific Committee

- EU Risk Assessment Agenda "Delphi" Study

Jeffrey Moon informed the Scientific Committee that at the 54th Advisory Forum meeting, held in Parma in December 2014, it was proposed to undertake a "Delphi" study with Member States (MS) involvement to identify and gain consensus on the most important food safety topics for collaboration between EFSA and EU MS and generate an agreed list of common priorities.

The results of the study are relevant to the development of an EU risk assessment agenda, which will set out a plan of joint initiatives and activities, in partnership with MS, to strengthen risk assessment, as part of its Scientific Cooperation Roadmap 2014-2016.

The study involves a number of 'rounds', in which information is collected from experts by a questionnaire, summarised, and then fed back to participants in later 'rounds'.

The first round of the study started in June 2015 and will be finalised in December 2015. The next round questionnaire will be trialled with SC members. Their feedback will be used to amend and improve the questionnaire in order to launch the second round to experts in the coming weeks.

⁷ <http://www.efsa.europa.eu/it/efsajournal/pub/4121.htm>

8. Other scientific topics for information and/or discussion

- Update on US EPA's activities in the area of chemical safety

David Dix, Director of the Office of Science Coordination and Policy of the US EPA, paid a visit to EFSA and provided a presentation on the use of high throughput assays and predictive models by the US EPA's Endocrine Disruptor Screening Program.

He described the tools used by the US EPA to support the prioritization and screening for endocrine bioactivity/exposure of (a large number of) chemicals and successive testing of fewer chemicals for dose-response and adverse effects. Given the large number of chemicals to be screened, he stated that it is pivotal to use high throughput assays and computational models to rapidly screen chemicals for potential bioactivity and exposure also contributing to weight of evidence evaluations. These computational tools have been peer-reviewed for publication and allow resources to be focused on chemicals more likely to have endocrine effects.

More detailed information on the Endocrine Disruptor Screening Program and its use of computational tools can be found at the following web sites: <http://www.epa.gov/endo/> or <http://www.epa.gov/endo/pubs/pivot.htm>.

9. Any other business

- Update on EFSA's 2nd Scientific Conference, 14-16 October 2015, Milan

The SC was updated on the status of the organisation of the scientific conference on 14-16 October 2015 in the EXPO. The conference will be organised in plenary and breakout sessions. Thematic poster sessions will be held for scientists to showcase their work in areas of relevance for the conference.

Panel members have received the invitation to participate in this event

- SC workshop on workprogramme 2015-2018, 16 September 2015

A brainstorming with the Scientific Committee members is being organised to discuss the work programme for the next three year. It is scheduled to take place on 16 September, the day after the 75th plenary meeting.

- SC meeting dates 2015-2016

The 2015 dates of the plenary meetings have already been agreed and published on the EFSA website⁸. Possible dates for the 2016 were discussed and provisionally approved.

⁸ <http://www.efsa.europa.eu/en/scer/scmeetings.htm>

- Agreement on best practices during plenary meetings

The SC was presented with the best practices in relation to invitations, logistics, agenda and exchange of documents tabled for plenary meetings.

End of the meeting