Scientific Committee

Minutes of the 64th plenary meeting

Held on 13-14 November 2013, Parma

(Agreed on 17 December 2013)

Participants

- **Scientific Committee (SC) Members:**

  Anthony Hardy (chair), Jan Alexander, Diane Benford, Qasim Chaudhry, Arie Havelaar, Susanne Hougaard Bennekou, Michael John Jeger, Robert Luttik, Ambroise Martin, Simon More, Alicja Mortensen, Birgit Nørrung, Bernadette Ossendorp[1], Joe Perry[2], Iona Pratt, Josef Schlatter, Kristen Sejrsen.

- **Hearing experts:** Andrew Chesson[3]
- **DG Health and Consumers:** Michael Walsh[4]
- **EFSA:**
  - **Executive Directorate:** Bernhard Url[5], Hubert Deluyker[6]
  - **Communications Directorate:** Anne Laure Gassin[7]
  - **RASA Directorate:** Marta Hugas
  - **REPRO Directorate:** Per Bergman[8]
  - **SCISTRAT Directorate:** Juliane Kleiner[9]
  - **AFSCO Unit:** Liem Djien
  - **SCER Unit:** Tobin Robinson**,** Bernard Bottex, Jean-Lou Dorne, Andrea Germini, Daniela Maurici, Reinhilde Schoonjans

[1] By teleconference for item 13
[2] By teleconference
[3] Present for agenda item 5
[4] Not present in the morning of 13th November
[5] Present on the morning of 13th November
[6] Present on the 13th for agenda item 1 to 8
[7] Present for agenda item 6
[8] Not present in the morning of 13th November
[9] Not present in the morning of 13th November

1. Opening and apologies for absence

The Chair welcomed the participants. Apologies were received from John Sofos, chair of the BIOHAZ Panel, who was replaced by Arie Havelaar; Bernadette Ossendorp, chair of the PPR Panel, who was replaced by Susanne Hougaard Bennekou.

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of interests

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[10] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[11], 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 63rd Plenary meeting held on 16-17 September 2013

The minutes of the 63rd plenary held on 16-17 September were agreed by written procedure on 11 November 2013 and published on the EFSA website on 11 November 2013.

5. Report back on issues relevant for the Scientific Committee

5.1 General matters arising

The Scientific Committee was informed that the Management Board has officially appointed Bernhard Url as the Authority's Acting Executive Director. Dr Url became Deputising Executive Director in September and has been carrying out the role following the resignation of Catherine Geslain-Lanéelle on 1 September 2013. Dr Url, who joined EFSA in June 2012 as Director of Risk Assessment and Scientific Assistance, now assumes the duties of EFSA Executive Director until a permanent appointment is made following a recruitment procedure launched by the European Commission.
The Scientific Committee was informed that the next Advisory Forum meeting will take place on 5-6 December in Parma and the next Management Board meeting will be held on 19 December in Parma.

5.2 European Parliament event "A cure for bias in chemicals policy", 5 November 2013

On 5 November 2013 the European Member of Parliament Corinne Lepage (Group of the Alliance of Liberals and Democrats for Europe) organised a meeting to launch the new Policy from Science Project report entitled "A cure for bias in chemicals policy". The launch meeting took place in the European Parliament in Brussels, and Hubert Deluyker participated representing EFSA. The subject of

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

the meeting was mainly on proposals for more robust and transparent approaches to use expert opinions in chemical safety review. It drew primarily from experiences with the safety review of Bisphenol A (BPA). The new report proposes a systematic review to resolve debates about chemicals safety and enhance the scientific authority of EU agencies. Hubert Deluyker was invited to represent EFSA and to briefly inform about the status of the BPA opinion in preparation.

6. Draft opinion on Qualified Presumption of Safety (QPS) approach for botanicals

Andrew Chesson, chair of the Scientific Committee working group, presented the opinion on "Qualified Presumption of Safety (QPS) approach for the safety assessment of botanicals and botanical preparations". A structured QPS approach for the assessment of botanicals was developed and tested on a number of different case studies. The exercise showed that it is possible to apply the QPS approach for the safety assessment of botanicals, even if it is slightly different compared to the approach initially developed for the assessment of microorganisms deliberately added to food. The members of the Scientific Committee made some comments on the draft that will be included in the next revision. The opinion will be tabled for final adoption at the December SC plenary.

7. Review of the EFSA's Communications Strategy

EFSA's mission in risk communications, set out in its Communications strategy, is to provide appropriate, consistent, accurate and timely communications on food safety issues to all interested parties, stakeholders and the public at large, based on the Authority's risk assessments and scientific expertise. The type of work undertaken by EFSA has changed significantly since EFSA's establishment, with the share of scientific outputs related to the safety evaluation of regulated products and substances growing to 70% in comparison with those related to more to broader public and animal health-related issues. Since 2011, EFSA has introduced a more thematic approach to communications, welcomed by Member States and stakeholders, providing much needed context to often complex, misunderstood subject areas. During 2011-2013, EFSA's outreach continued to grow and a strategic framework to guide its use of social media has been put in place.

A multi-annual plan covering the Communications strategy for 2014-2018 is in development and will be presented at the Management Board in December 2013. In the coming years, EFSA would like to be and be perceived as a leading global reference and resource in risk communications related to the food chain. In realising this vision, EFSA will reinforce confidence and trust in the Authority and the EU food safety system through effective corporate and risk communications coupled with enhanced dialogue with partners and stakeholders.

EFSA's strategic priorities will be to better understand, define and meet target audience needs; strengthen the clarity of EFSA's communications and improve information delivery through its website and other communications tools; build awareness, understanding and recognition of EFSA and its role as risk assessor in the EU and beyond; promote coherence in risk communications with EU and international partners; increase transparency, openness and stakeholder dialogue. EFSA will seek to build greater understanding of the risk assessment/scientific process and the broader context in which it operates. This not only involves enhancing transparency of the risk assessment process, access to data and scientific meetings but also "educational" initiatives to better explain risk assessment and EFSA's working procedures (e.g. independence and transparency policies and rules) and the underlying scientific process (e.g. guide to understanding scientific studies).

The Director of Communications presented also a project to create a lexicon of scientific terms frequently used in EFSA's risk assessment and the corresponding layman definition. The project is a joint initiative of EFSA with the Advisory Forum Communication Working Group (AFCWG). It is foreseen that the Scientific Committee will be consulted during the development of the project. This lexicon will enhance the coherence and accessibility of EFSA's communications and help simplify complex scientific concepts and terminology that are too complex for use in communications outputs. The lexicon, comprising the layman definitions, will be made available on the website in 2015 (in conjunction with the launch of EFSA's "new" website).

8. EFSA's work in the area of Plant Health (PLH)

The Chair of the Plant Health Panel presented the ongoing work, the Network and the outsourced and cooperation projects detailing current and forthcoming activities.
The remit of the Panel is to conduct pest risk assessment, mainly upon request from the EU Commission. These include both plant pests which threaten crop production and species which threaten biodiversity. Many risk assessment by the PLH Panel are of global relevance and regard important plant pests that are absent from the EU but that could be introduced in the future through the trade of plants and plant products. The Panel develops also guidance documents for risk assessment as well as for evaluation of risk reduction options and for the environmental risk assessment of plant pests.

The Panel has recently moved from pest risk assessment (PRA) to commodity-based risk assessment and this requires cooperation with other organisations not only at Member States (MS) and EU level, but also internationally. The Panel is also working on re-assess the risk of plant pests currently listed in the EU Directive 2000/29/EC to anticipate the updating of the legislative plant health technical annexes in the view of the entering into force of the new plant health Regulation in 2015-2016.

The Network on plant health, composed by Member States (MS) representatives, has the objective to build mutual understanding of risk assessment principles in plant health sector, to provide increased transparency process among MSs and EFSA, to facilitate harmonisation of risk assessment practices and methodologies, to enhance exchange of information and data and more in general to achieve synergies in plant risk assessment activities.
In the end, the Chair illustrated the outsourced projects and the ongoing regional cooperation with the European and Mediterranean Plant Protection Organization (EPPO).

The Scientific Committee welcomed the presentation and underlined the need to consider further EFSA's role in risk assessment methodology relating to the new plant health control regime.

9. Use of the Benchmark Dose (BMD) approach in the safety assessment of chemicals

In May 2009, the EFSA Scientific Committee adopted its guidance on the use of the benchmark dose (BMD) approach in risk assessment. The Scientific Committee concluded that the BMD approach is a scientifically more advanced method to the No-Observed-Adverse-Effect-Level (NOAEL) approach for deriving a Reference Point (RP), and therefore recommended EFSA Scientific Panels and Units to adopt the BMD approach for the risk assessment of chemicals in food. One of the recommendation of the opinion was to review the implementation experience and acceptability of the BMD approach in EFSA's work in few year time.

Recent case studies where the BMD approach was used were brought to the attention of the Scientific Committee and the possibility to update the guidance developed in 2009 was discussed by the members of the Committee. The Scientific Committee discussed in particular about the need to clarify further the criteria to judge the adequacy of the dose-response data to derive a reference point, e.g. the range of BMDL values obtained from different accepted models should not exceed one order of magnitude. Other criteria such as the range between the BMD and the BMDL (lower confidence limit), or the range between the BMDL and the BMDU (upper confidence limit) have also been considered. It was agreed that the revision of the guidance will be included in the work-programme of the Scientific Committee, but it will be given a lower priority since the concept and methods presented in the guidance are still valid and applicable.

10. Draft Multi-Annual Programme on International Scientific Cooperation

Djien Liem provided an update on the state-of-play with respect to the development of EFSA's multi-annual programme on scientific cooperation. It will focus on scientific cooperation with EU Agencies, international organisations and third countries. An attempt is made to translate the recommendations from the Management Board based on the outcomes of EFSA's external evaluation performed in 2012, the strategy outlined in EFSA's document "International Activities – A Strategic Approach" (EFSA, 2009) and EFSA's Science Strategy 2012-2016 (EFSA, 2012) into scientific activities to be conducted in the next coming years. Key objectives of the international scientific cooperation have been identified: support of the EU in its international commitments; the optimisation of the use of risk assessment capacity in the EU and internationally; the development and harmonisation of methodologies and approaches to assess risks associated with the food chain; the strengthening the scientific evidence for risk assessment and risk monitoring; the promotion of coherence in risk communication and building awareness of EFSA's activities at international level.
Mechanisms of scientific cooperation could include, among others, exchange of work-programmes and visits, development of joint projects, and exchange of staff. The Advisory Forum has been already consulted on the draft programme; other consultations are foreseen with the EU Commission and the EFSA stakeholders consultative platform whereas a wider consultation is foreseen before the multi-annual programme will be finalised.

The Scientific Committee welcomed the presentation and agreed that it is important to clarify EFSA's role on the international arena and which complementary support can be achieved with the Member States in order to export European best practices.

11. Preliminary discussion on new mandates

11.1 Use of the weight of evidence approach in risk assessment

11.2 Biological relevance for toxicology

This agenda item has been postponed to the February 2014 plenary due to time constrains.

12. Draft Scientific Report on emerging methodologies

Jean Lou Dorne presented an overview of the EFSA scientific report on the state of science of new/emerging tools and their applicability for hazard identification and characterisation of chemicals. The report in preparation reviews principles, strengths, limitations and applications of

OMICS technologies (e.g. transcriptomics, metabolomics, etc) for human hazard assessment; it also revises biologically-based models and physiologically-based models, *in silico* tools and integrated testing strategies for human risk assessment of chemicals. The report gives also recommendations for future activities at EFSA on emerging methodologies. Finalisation of the draft report is foreseen in the beginning of 2014.

13. Update on the work-programme of the SC: working groups and networks

13.1 WG on Compendium of botanicals (vers 3.0)

13.2 Standing WG on Guidance Review

13.3 WG on Environmental Risk Assessment

13.4 WG Uncertainty in Risk Assessment

13.5 Feedback on the meeting of the Network Harmonisation in Risk Assessment Methodologies, 22-23 October 2013

13.6 Standing WG on emerging risks

13.7 Report back on EmRisk activities

Due to time constrain, these agenda items have been postponed to the December SC plenary.

13.8 Colloquium on "Biodiversity as protection goal in environmental risk assessment for EU agro-ecosystems", 27-28 November 2013

The Colloquium on "*Biodiversity as Protection Goal in Environmental Risk Assessment for EU agro-ecosystems*" will take place in Parma on 27-28 November 2013. This is an opportunity both for international experts and for EFSA for an open scientific debate on the most recent scientific progress made on protection goals for environmental risks assessment, particularly assessing potential effects on biodiversity and related eco-system services in EU agro-eco systems, endangered species and recovery. Discussions will focus on challenges involved in assessing the impact of products or invasive species in EU agro-eco systems, in a harmonized manner. The colloquium will be structured to enable participants to reach conclusions and make recommendations focusing the discussions on four specific topics:

- Translating protection goals into measurable endpoints for use in ERA of regulated products and invasive species: what has been done and are current practices applicable to different types of products/species?
- Protecting biodiversity in agro-ecological landscapes: how to assess it, how to measure it and how to monitor it afterwards?
- Endangered Species: are they adequately covered as potential non-target species in current ERA schemes?
- Recovery and/or up-scaling from Fields-Farm-Landscape: where and what to protect and how long?

The outcomes of the Colloquium will be summarised in an overall report after the meeting.

14. Draft opinion on Carvone

Bernadette Ossendorp (Chair of the Working Group) presented the ongoing safety assessment of Carvone. Carvone is a substance that is naturally occuring in *Carum carvi* and *Mentha spicata*. The two isomers of carvone (d- and l-) are used in various food and feed areas, as well as non-food products such as toothpaste and mouthwash solutions. The mandate requires the Scientific Committee to derive a single ADI for Carvone to be used at EU level, regardless of the food area, and considering previous evaluations made by JECFA and the European Commission. It also asks for an estimation of the overall exposure of EU consumers to Carvone, and to characterise the contribution of the various sources of exposure to the overall exposure.

The Scientific Committee took note of the progress made by the working group on the assessment of Carvone. The draft opinion will be discussed at the December Plenary meeting before being proposed for final adoption on 18-19 February 2014.

15. New format for scientific opinions

The Scientific Committee was presented with a draft document proposing a revision of the current format of EFSA's scientific opinions. The draft proposal was circulated internally to the Units for comments. It was agreed to address the comments received and to table a revised version of the document at the February 2014 SC plenary meeting. The document will be published in the form of an EFSA opinion.

16. Feedback from the Scientific Panels and other scientific activities

16.1 Panel on Animal Health and Animal Welfare

The Panel held its last meeting on 22-23 October; the meeting was open to observers. Work is ongoing on monitoring procedures at slaughterhouses for pigs, sheep and goats, chickens and turkeys.
At the next plenary on 27 November, the draft guidance on the assessment criteria for studies evaluating the effectiveness of stunning interventions regarding animal protection at the time of killing will be proposed for adoption. The Panel is also providing support to the Commission on the evaluation of risk management options for the outbreak of African swine fever.

16.2 Panel on Food Additives and Nutrient Sources Added to Food (ANS)

The Panel will have a plenary meeting the last week of November, where the draft opinion on the re-evaluation of aspartame (E951) as food additives will be proposed for adoption.

EFSA received a request from the German BfR on isoflavone. The new mandate has been allocated to the ANS panel and a Working Group is currently being established. While the precise Terms of References are currently being finalised with the requestor, it is envisaged that the new Working Group will start its activities most likely early 2014.

16.3 Panel on Biological Hazards (BIOHAZ)

During its last plenary held on 23-24 October, the Panel discussed, among others, the opinion on the quantitative evaluation of BSE risk in bovine intestines and mesentery and the opinion on the evaluation of the safety and efficacy of peroxyacetic acid solution for reduction of pathogens on

poultry carcasses and meat. For the latter, the CEF panel is providing support for the assessment of the safety for consumers and for the environmental risk assessment, whereas BIOHAZ, as leading Panel, is working on the assessment of efficacy and antimicrobial resistance.
The Panel adopted the Scientific Opinion on the maintenance of the list of Qualified Presumption of Safety (QPS) biological agents intentionally added to food and feed (2013 update).

The Scientific Committee asked for an update on the work in progress for the evaluation of molecular typing methods for major food-borne microbiological hazards. A detailed presentation will be probably given in one of the future SC plenary meetings.

16.4 Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

The public consultation on consumer exposure to Bisphenol A closed on 15 September and received more than two hundred comments, mainly from national/international food authorities and from stakeholders associations. The working group is revising the draft opinion that will be discussed in the next plenary.

The draft revised guidance for the assessment of Food Contact Materials (FCM) has been discussed at the last plenary. EFSA has launched a call for proposals[12] to assess the possible implications triggered by the draft revised guidelines on the requirements for submission of toxicological information and restrictions of substances' to a set of chemical substances which have been already evaluated by the CEF Panel. The differences from the current guidelines will be also assessed. In addition, an extrapolation of study results to the total of about 900 substances of the Annex I of the EU Regulation 10/2011 on plastic materials and articles intended to come into contact with food will be provided. The Panel will re-discuss the draft guidance in the light of the results provided by the outsourced project.

16.5 Panel on Contaminants in the Food Chain (CONTAM)

The Panel held the last plenary on 25 September and discussed draft opinions on chromium in foodstuffs, on tropane alkaloids in food and feed and on acrylamide in food.

The opinion on chromium (chromium III and VI) in food and drinking water will be proposed for adoption at the next plenary, on 26 November. The NDA Panel is also working on chromium in the context of the revision of Dietary Reference Values (DRVs) for essential micronutrients. It is currently addressing the essentiality of chromium, as a pre-requisite for setting DRVs.

16.6 Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

The Panel will hold its 100th plenary next meeting on 3 December. Work is in progress and there are no public consultations ongoing on draft opinions in preparation.

16.7 Panel on Genetically Modified Organisms (GMO)

The Panel will have its next meeting in December. The debate is ongoing on how to better address stacked events and identify plant of origin the appropriate conventional counterpart. The Commission request is to address not only the stacked event itself but also all the possible sub-combinations. There might be not sufficient data on these so the Panel is still discussing what would be the best approach to address uncertainties in relation to data gaps.

[12] http://www.efsa.europa.eu/en/art36grants/article36/gpefsafip201301.htm

16.8 Panel on Dietetic Products, Nutrition and Allergies (NDA)

The Panel will have its next meeting on 11-13 December. The draft opinion on caffeine will be proposed for adoption together with the opinion on the population reference intake of iodine.

At the last plenary meeting, the Panel adopted the opinion on dietary requirements of infants and young children in the framework of advice to be provided on milk based-drinks and similar products. Work is ongoing on a scientific and technical guidance for the preparation and presentation of applications in the field of allergies for ingredients or additives.

A technical meeting on the reporting of human studies submitted for the scientific substantiation of health claims will be held on 20 November 2013 in Parma to discuss with scientists the information required for a full scientific evaluation of human studies submitted for the scientific substantiation of health claims.

16.9 Panel on Plant Protection Products and their Residues (PPR)

The PPR Panel will meet on 20-21 November. The draft opinion on the relevance of dissimilar mode of actions for cumulative risk assessment of pesticides in food will be proposed for adoption.

Work is in progress on the mandate for good modelling practise for pesticides. The FEEDAP and GMO Panels have been consulted on this issue. The draft opinion is expected in spring next year.

17. Any other business

Members of the Scientific Committee were reminded about the programme and deadline for applying to the EFSA specialised courses for advanced trainings in risk assessment. The Chairs of the Panels were asked to highlight these training opportunities to their Panel members.