Scientific Committee
Minutes of the 70th Plenary meeting
Held on 11-12 November 2014, Parma (Italy)
(Agreed on 8 January 2015)

Participants

- **Scientific Committee Members**
  - Tony Hardy (Chair), Jan Alexander, Diane Benford, Qasim Chaudry, John Griffin, Michael John Jeger, Robert Luttik, Ambroise Martin, Alicja Mortensen, Birgit Noerrung, Bernadette Ossendorp, Josef Schlatter, Kristen Sejrsen, Vittorio Silano, Joe Perry[1]

- **European Commission and/or Member States representatives:**
  - Michael Walsh (DG Health and Consumers)
- **EFSA:**
  - **Executive Directorate**: Bernhard Url, Hubert Deluyker, Roy Kirby[2]
  - **RASA Department:** Marta Hugas
  - **REPRO Department:** Per Bergman
  - **SCER Unit**: Tobin Robinson, Andrea Altieri, Bernard Bottex, Jean-Lou Dorne, Andrea Germini, Tilemachos Goumperis, Angelo Maggiore, Daniela Maurici, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans.
  - **Assessment and Methodological Support Unit**: Didier Verloo, Saghir Bashir[3]
  - **Evidence Management Unit**: Davide Arcella[4]
  - **Legal & Regulatory Affairs Unit :** Dirk Detken[5]

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Simon More, Chair of the Panel on Animal Health and Welfare.

[1] Participated via Teleconference
[2] Present for agenda item 9.1
[3] Present for agenda item 5.2
[4] Present for agenda item 6.1
[5] Present for agenda item 7.3b and 7.3d

European Food Safety Authority – Via Carlo Magno 1/a, 43126 Parma, ITALY
Tel: (+39) 0521 036 111 • Fax: (+39) 0521 036 110 • www.efsa.europa.eu

The Chair welcomed Caroline Merten, new member of the Scientific Committee and Emerging Risks Unit (SCER) Unit.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[6] and the Decision of the Executive Director on Declarations of Interest[7], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Committee Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were 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 69th Plenary meeting held on 16-17 September, Parma (Italy)

After minor editorial changes, the minutes of the 69th Plenary meeting held on 16-17 September 2014 were agreed.[8]

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

5.1 Draft SC statement on the benefits and risks of fish/seafood consumption

The SC was presented with the approach followed in the draft statement that will answer the question from the European Commission on the benefits of fish/seafood consumption compared to the risks of methylmercury in fish/seafood (EFSA-Q-2014-00665). It is based on previous opinions from CONTAM on the risk for public health related to the presence of mercury and methylmercury in food and on the NDA opinion on health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury. The fish/seafood intakes are compiled from the Member State databases and are available in the EFSA Comprehensive European Food Consumption Database. Many comments and suggestions were made in particular on the benefit part, its uncertainty, the methodology of the dietary survey, the type of fish considered, the scenario for fish consumption and the levels of mercury in the environment. The issues for which more clarity is needed have been identified and the conclusions were discussed.

The draft will be revised on the basis of the received comments and will be proposed for written adoption by the end of December 2014.

5.2 Draft EFSA guidance on statistical reporting

EFSA's Assessment and Methodological Support Unit launched an open consultation on the draft of its Guidance on Statistical Reporting on 28 May 2014. The public consultation ended on 23 July. The guidance aims to assist EFSA's Scientific Committee, its Scientific Panels, working groups, units and stakeholders on harmonisation and standardisation in the reporting of statistical methodology, analyses and results to allow independent peer review and reproducibility.

[6] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[7] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[8] http://www.efsa.europa.eu/en/events/event/140916a-m.pdf

The SC was presented with the objectives, scope and structure of the Guidance, general information on the comments received and the way they have been implemented in the updated version and, finally, with follow up actions. EFSA has assessed all comments from interested parties and taken them into consideration in the updated version, if found to be relevant. The comments were primarily suggesting improvements on the specific details of the guidance, minor changes to the structure and improvements for readability.

The SC endorsed the Guidance and took note of the Public Consultation Report. Publication of both documents is expected in December 2014.

6. New Mandates

6.1 Preliminary discussion on a possible mandate on internal dose exposure

The EFSA Scientific Opinion on "Priority topics for the development of risk assessment guidance by EFSA's Scientific Committee", published in 2013, proposed developing guidance to clarify which exposure estimate is to be compared with health based guidance values and how to assess the internal dose, in particular, how to add up estimated exposure from different routes and sources.

At the 68th Scientific Committee Plenary meeting (July 2014), the DATA Unit proposed to provide guidance on further harmonisation of screening methods and refinements related to dietary exposure assessments. The Unit also requested assistance from the SC on the selection and definition of non–dietary sources of exposure to be considered for harmonization, how to add exposure estimates from different non-dietary sources up to dietary sources (via oral route) and how to assess the internal dose.

Following these requests and recommendations, a self-task mandate (with support of both DATA and SCER units) is proposed to cover tasks initially planned (harmonisation of screening methods and refinements related to dietary exposure) and to complement the work with guidance on the assessment of exposure via oral route from non-dietary sources.

Regarding the assessment of the internal dose through aggregated exposure via all routes (oral, dermal, inhalation) it was proposed to put on hold the development of a guidance document until the end of 2016 in order to wait for the results of the on-going outsourced project on "Integrating toxicokinetics in chemical risk assessment: application to human, animal and environmental risk assessment" (OC/EFSA/SCER/2014/06).

The SC welcomed the initiative of having such a guidance, and agreed on the need of a targeted consultation towards sister agencies and international regulatory bodies before initiating the work in order to map the existing non-dietary exposure models in use.

The SC will be provided with an updated draft mandate at the next plenary meeting.

7. Feedback from the Scientific Committee/the Scientific Panel, 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

The WG held two meetings since the last SC plenary. The draft table of content for the opinion was discussed. Representatives from the European Commission also participated in the WG meetings in order to clarify some parts of the Terms of Reference. A draft of the opinion is scheduled to be discussed at the SC Plenary in June 2015. A workshop with stakeholders is planned at the beginning of next year in order to get insights on production, processing and consumption of insects and products thereof.

b. Compendium of botanicals (version 3.0)

The WG has not had any meetings since the last SC plenary. The call for tender to transform the currently published MS Excel®-based compendium of botanicals (reported to contain naturally-occurring substances of possible concern for human health) into a web-searchable database and prepare version 3 of the Compendium closed on 19 September 2014. The evaluation of the offers is underway.

A Strategic Presidency Meeting organised, under the Italian presidency of the Council of the European Union, by the Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency was held in Rome on 4-5 November to address scientific issues in evaluating safety and efficacy of herbal medicinal products and botanical food supplements. The controversial issue of whether any botanical should be treated as a food supplement or as a medicinal product was raised and discussed. Representatives of the SC and EFSA participated in this meeting.

c. Environmental Risk Assessment

The three draft ERA opinions (on Protection Goals, on Recovery and on Endangered Species) are planned to be ready for the first reading by the SC in the February 2015 plenary meeting, aiming at endorsement prior to consultation by the relative Panels (PPR, GMO, PLH and FEEDAP).

The Panels' consultation will then be followed by consultation of the other EU agencies (EMA, ECHA and EEA) and international regulatory bodies (JRC, WHO, OECD, US-EPA) involved in environmental risk assessment. All comments received will be taken into account before adoption of the opinion planned by the end of 2015.

d. Uncertainty in Risk Assessment

Work is ongoing. The WG is discussing some of the methods that will be included in the appendix of the guidance document. Further discussion on the methods will take place during the next meetings.

In February 2015 the SC will be presented with a draft opinion for a preliminary discussion.

The SC highlighted the need to consider the activities carried out on this topic by other EU Agencies (in particular the European Centre for Disease Prevention and Control, ECDC).

e. Standing WG on Emerging Risks

The SWG met at the end of September. The SWG is in the process of drafting the report on the Emerging Risks activities due by June 2015. The report will describe past and on-going activities of EFSA on emerging risks and provide recommendations for further improvement of the emerging risk identification procedure. The topics discussed at the last WG meeting included possible issues linked to the illegal importation of bush meat and the introduction of new perfluorinated alternatives in food contact materials. The WG also explored the possibility

of starting a project on food chain analysis, defining possible objectives and the needed expertise. The SC provided some inputs on areas which could be improved for further development of the EFSA emerging risk identification process, such as increasing exchange of information and engagement with Panels, a more operational and shared definition of emerging risks, a leaner procedure with fewer filtering steps, and more shared expectations with managers. It was also acknowledged that EFSA addresses the legislation on emerging risks through several activities at the Panel level, e.g. scientific opinions of the CONTAM Panel on emerging and novel brominated flame retardants in food and on emerging marine biotoxins. The mandate of the SWG will be reconsidered with the renewal of the SC in 2015, taking into account the final report and the feed-back provided by the SC.

f. Standing WG on Genotoxicity

The SWG had the kick-off meeting on 10 October. The agenda of the meeting included 4 items for which the advice of the WG was requested. The WG discussed the items on the agenda and the results of the discussion will be presented to the requestors in the form of advice. The next meeting will be called if additional requests need to be addressed to the WG in 2015.

g. Standing WG on Guidance Review

At the last WG meeting, the WG discussed the table of contents of the document addressing the guidance lifecycle. Reasons for updating the Guidance Documents (GDs), the level of obligation to follow them as well as the time for revision were discussed. The WG also discussed criteria for prioritisation of revision of existing GDs (on the basis of the category, level of obligation, number of panels involved and international dimension) and criteria for the need to have new GDs (on the basis of harmonisation needs due to inconsistencies, new available information and new regulations).

The next meeting will be held in December. A draft opinion will probably be tabled for possible adoption at the SC plenary meeting in February 2015.

The SC suggested including in the opinion an implementation plan for GDs following adoption, to improve uptake of the guidance by the different Panels.

h. Update on the establishment of the WGs on Weight of evidence, Biological relevance and BMD approach

The activity of the WGs on weight of evidence in risk assessment, biological relevance in toxicology and on the update of the guidance document of benchmark dose approach will start at the beginning of 2015. A document contextualising the background and terms of reference of these three projects and linking them with the EFSA Prometheus initiative for promoting methods for evidence use in science is now under consultation by the Member States food safety authorities via the Advisory Forum. A Workshop on these three activities (and also on how to characterise, document and explain uncertainties in risk assessment) is planned in June 2015, with the aim of collecting experience and scientific information from Member States and relevant EU agencies.

i. Update on EMRISK activities

The Head of the SCER Unit informed the SC about a crisis training course held at EFSA in October, focused on risk communication during crisis. Members of the Advisory Forum, Member States Food Safety Authorities, the RASFF team of the European Commission and EFSA staff participated in the event. Good feedback was provided by the participants. The next exercise is scheduled in autumn 2015.

The SC was informed about the activities carried out by the Stakeholder Consultative Group (StaCG-ER, bringing together representatives of consumers, food producers and food processing industry) and the Emerging Risk Exchange Network (EREN, the EFSA networks with Member States, EU and international agencies). These activities were reported in the last

meeting of the StaCG-ER, which was held on 10 October 2014 and of the EREN, which was held on 4-5 November.

It was highlighted that StaCG-ER and EREN constitute an opportunity to raise issues on newly identified emerging risks and to be kept updated regarding ongoing activities.

7.2 Feedback from the Scientific Panels:

a. EFSA work in the area of FEED – feedback from the FEEDAP Panel

The Chair of the FEEDAP Panel provided an overview on the different categories of feed additives, conditions for market authorisation and main risks to be assessed for feed additives. The Chair reported on the activities of the Panel and provided an overview on the category (coccidiostats and histomonostats, zootechnical, nutritional, sensory and technological) and number of dossiers (including re-evaluation dossiers) to be assessed, the different ongoing working groups (16), and future activities in the re-evaluation of botanicals and technological additives like binders, anticaking, emulsifying and stabilising agents.

The Chair of the Panel highlighted that the quality and content of the dossiers is extremely variable. Some applicants had access to extensive data sets (e.g. nutritional), others had to generate dossiers *de novo* (e.g. for most technological additives).

b. EFSA work in the area of GMO – feedback from the GMO Panel

The Chair of the GMO Panel gave an overview of the legal framework within which the GMO Panel operates, focusing on the new implementing regulation on GM plant applications for food and feed use (Regulation (EU) No 503/2013) and its novel elements. The Chair highlighted several guidance documents drafted by the Panel. The subsequent discussion focused on challenges like stacks and sub-combinations, interplay between herbicide tolerant GM plants and herbicide use and risk assessment of environmental impacts of the specific farm management practices. The Chair of the GMO Panel illustrated the strategy to address them.

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

<u>CONTAM</u>

The public consultation for the draft opinion on acrylamide in food (EFSA-Q-2013-00007) closed on 15 September. EFSA has received around 100 comments from interested stakeholders, national authorities and scientific committees, academia as well as individuals. To complete the public consultation process and to ensure a full understanding of the comments received during the consultation phase, EFSA is holding a public scientific meeting on 10 December to discuss the results of the online consultation phase with all the contributing stakeholders and other relevant parties. The CONTAM Panel will review the results of the entire process prior to adoption of the final output in the first half of 2015.

In the last plenary meeting of the Panel, a letter from BfR (Germany) requesting a scientific opinion on plastic micro-particles in marine animals was discussed. The BIOCONTAM Unit gave a presentation on the collected literature data on plastic micro particles. The Panel discussed whether a scientific opinion on plastic micro-particles in marine animals would be appropriate considering the currently available information. The Panel concluded that there is not sufficient information available to do a complete risk assessment but agreed to develop a scientific statement that should not be confined to the marine environment but cover the entire food chain and address also the issue of the nano-particles.

The next plenary meeting will be held on 25-27 November. The outcome of the project on extensive literature search and provision of summaries on oral toxicity of perfluoroalkylated

substances (PFASs), their precursors and potential replacements in experimental animals and humans will be presented.

BIOHAZ

The last plenary meeting was held on 22 October. The Panel discussed the Scientific opinion on the development of a risk ranking toolbox for the EFSA BIOHAZ Panel. The Panel also discussed the statement on the update of the list of Qualified Presumption of Safety (QPS) microorganisms intentionally added to food or feed as notified to EFSA.

Following a request from the European Commission, EFSA was asked to provide scientific and technical assistance on the risk of transmission of Ebola virus (EBOV) via the food chain. A Scientific report on an update on the risk of transmission of the Ebola Virus via the food chain, the risk for persons in Europe linked to the transmission of the virus via handling, preparation and consumption of bushmeat illegally imported from Africa was published. The conclusion of the report is that it can be assumed that the potential for introduction and transmission of the virus via bushmeat in Europe is currently low.

PLH

Work is ongoing to complete the pest categorization of plant pests (bacteria, fungi, insects, mites, nematodes, viruses) listed in the plant health directive (Council Directive 2000/29/EC). This activity is showing a very good coordination with the EC Standing Committee on Plant Health.

The Panel is revising the scientific opinion on the risk to plant health of the plant pathogenic bacterium *Xylella fastidiosa* detected in olive trees in the Apulia region of Italy. Diseases caused by this bacterium are quite common in tropical, subtropical and temperate areas of the Americas. However, the identification of *Xylella fastidiosa* in Italy represents the first confirmation of this pest under field conditions in the European Union.

In the last plenary meeting, held in September, there was a presentation on the international risk assessment framework for biological weed control agents. The Panel was asked by the EC to look at possible implications at European level.

NDA

The public consultation on the discussion paper on the revision of the Guidance on scientific requirements for health claims related to gut and immune function closed on 10 September. The comments will be considered for drafting the revision of the guidance that will be published for public consultation in the beginning of 2015.

At the last plenary meeting, the Panel considered the WHO draft guideline on sugars intake for adults and children published for public consultation in March 2014 and compared it with the EFSA (2010) opinion on Dietary Reference Values for carbohydrates and fibre. The mandate for the EFSA (2010) opinion was to derive Reference Ranges (lower and upper bound levels). Sugars were considered as a component of dietary carbohydrates. On the other hand, the terms of reference of the WHO guideline was to provide recommendations on the consumption of free sugars to reduce the risk of non-communicable diseases in adults and children. The Panel noted that the terms of references of the two documents are different, that slightly different methodologies were applied, and that therefore the outcomes are not directly comparable. The EFSA opinion only covered risk assessment, whereas the WHO draft guideline also included risk management.

The last plenary meeting took place at the end of October.

CEF

The last plenary meeting, open to observers, was held on 23 October 2014. The participation of observers was high, most of them coming from private companies.
The Panel developed a work plan to finalise the opinion on the assessment of the human health risks posed by exposure to bisphenol A (BPA) by the end of the year.
The Panel is working on the assessment of three food enzymes, two recycled plastic products and three food flavourings.

PPR

The last plenary was held at the beginning of October. It was a session open to observers, with a high level of participation from industry and private consultancy companies.

The Panel discussed the need for further action in response to comments received on the Scientific Opinion on the developmental neurotoxicity potential of the neonicotinoid insecticides acetamiprid and imidacloprid that was published in December 2013. In the Opinion more conservative reference values were proposed based on the analysis of existing toxicological data.

After a discussion with the Pesticide Steering Network, the chair of the Panel highlighted the need to include nanopesticides in the activities of EFSA. The SC agreed to discuss this further in the February SC meeting.

ANS

The last plenary meeting was held on 16 September. The discussion focussed on the re-evaluations of six food additives, in particular on the exposure assessment part. Another topic tabled for discussion was the protocol for risk assessment of Isoflavones in peri- and post-menopausal women. The next plenary is scheduled in December.

7.3 Feedback from EFSA:

a. Report back on issues relevant for the Scientific Committee

Per Bergman, Head of the Scientific Evaluation of Regulated Products Department will leave EFSA at the end of November to start a new career at the Swedish authority for food safety. The SC thanked Per for the support provided to the SC work during the last 6 years and wished him all the best for his new career. The SC was also informed that Olivier Ramsayer, Head of the Resources and Support Department, is leaving EFSA as of 1 January 2015 to take a new position as Director of Resources and Support at the European Aviation Safety Agency (EASA) in Cologne.

The SC was updated on the outcome of the 62nd Management Board meeting held in Parma on 23-24 October 2014, on the 53rd Advisory Forum meeting held in Venice on 24-25 September 2014 and on the international scientific cooperation activities of EFSA and the relative outcomes, particularly multilateral and bilateral meetings with international bodies that took place during September and October.

b. Outcome of the public consultation of the Discussion paper – transformation to an "Open EFSA"

The Head of the EFSA Legal and Regulatory Affairs Unit informed the SC about the outcome of the public consultation on the document "Open EFSA". The discussion paper elaborates a conceptual framework, a methodology and a plan for the transformation of the EFSA into an Open Science organisation over the next five years focusing on transparency and openness.

The paper was designed to promote discussion and to seek the input of EFSA's partners and stakeholders in particular on how to further increase openness, ensure that commercially sensitive information and data are protected, foster even further an environment of creative debate and other strategic drivers and contextual elements or policy options for the Authority to consider.

Almost 200 comments were received from more than 50 contributors, mainly industry and NGOs.

EFSA will finalise a list of possible actions that should be subject to a cost/benefit analysis. When each cost/benefit analysis is completed, EFSA will develop a plan to prioritise each action considering their added value. Finally, from 2016 onwards, EFSA will roll out the actions.

c. Feedback from the annual meeting of the Nanonetwork

The 4th yearly meeting of the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed was held on 21-22 October 2014. Besides EFSA staff from relevant units, participants were Member States representatives and the European Commission.

The discussion focused on the methodological implications of the EC recommendation for the definition of nanoparticles, on research activities covering nano-forms in food legislation and risk assessment covering oral exposure.

The inventory of nanomaterials in products on the market was addressed (through an EFSA procurement contract) and published in July 2014 (EFSA 2014 EN-621). Also Member States took initiatives on this priority. Methods for measuring the physico-chemical parameters of nanoparticles are under development by JRC and research consortia. The need for suitable, validated safety test methods *in vivo* and *in vitro* still needs to be further addressed by the responsible bodies. Given the growing body of research results and the need to streamline data generation, EFSA is encouraged to start working on an update of its SC Guidance for the risk assessment of nanomaterials used in the food chain.

EFSA attended the topical Scientific Workshop on Regulatory Challenges in Risk Assessment of Nanomaterials that was held at the European Chemicals Agency, Helsinki, on 23-24 October 2014. The workshop brought together experts representing academia, policy makers, industry and NGOs. ECHA will continue its work on the development of guidance for the assessment of nanomaterials, giving the priority on methods for the discrimination of nanoforms from non-nanoforms, the metrics for effect and exposure assessment, and modalities to use the read-across principle.

The discussion on nanomaterials will continue at the next SC meeting in February 2015, with the possibility to re-establish the WG on nanotechnologies and nanomaterials.

d. Refinement on the Implementing rules on Declaration of Interests

The Head of the EFSA Legal and Regulatory Affairs Unit presented a revised version of EFSA's implementing rules of the Policy on Independence of the Scientific decision making

process. These rules apply to all members of EFSA's Management Board, Advisory Forum, Scientific Committee, Scientific Panels, Working Groups and all other EFSA experts.

Implementing rules on declarations of interest adopted in 2012 were updated following a technical review in July 2014 and became applicable as of 30 September 2014. The changes refer mainly to an overall simplification and clarification of language, structure and definitions.

The EFSA Policy on Independence and Scientific Decision-Making Processes, adopted in 2011, will be reviewed within four years of its adoption.

8. Other scientific topics for information and/or discussion

8.1 Preliminary programme of the Scientific Conference in the context of Expo 2015

Within the EU scientific programme for EXPO 2015, EFSA is organising a scientific conference on 14-16 October 2015 in Milan (at the EXPO site). Representatives from the scientific and risk assessment community as well as risk managers from in and outside Europe are invited to contribute. Registration to attend the event as well as call for abstracts for the poster session will be launched in mid-January 2015. The conference will be focused on the challenges and opportunities that lay ahead in the domain of EFSA's activities, in particular regulatory science/risk assessment and science and innovation.

The program of the conference is under development and discussion. It aims at achieving a balance between scientific topics for a general scientific audience and more specific risk assessment science issues. The preliminary program was presented to the SC, which expressed its appreciation.

This event constitutes the second high level scientific conference organised by EFSA and follows EFSA's first successful Scientific Conference "Challenging boundaries in risk assessment – sharing experiences", organised to mark its 10th year anniversary in November 2012.

9. Any Other Business

9.1 New OpenText tool for sharing documents with panel/WG/SC members

A new tool has been available since October 2014 to share meeting documents between experts and EFSA. All the documents uploaded in the former Sciencenet have been successfully migrated to the new OpenText system.

The EFSA Executive Office Quality Management Team gave a presentation on how to access the system, how to work with the documents, add and search for documents. Technical problems encountered by the SC members were described and discussed.

9.2 New advanced trainings for Panel members

Four additional specialised courses on advanced aspects of risk assessment will be provided to EFSA Panel members and staff, starting early 2015.

End of the meeting